PRODUCT OBSERVATIONAL STUDY REPORT

COMPOUND: Suliqua® - Insulin glargine/lixisenatide (iGlarLixi)

A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood sugar is not adequately controlled on basal insulin and oral antidiabetic therapy (BOT)

STUDY NUMBER: OBS16751

STUDY NAME: CHANCE

Study Initiation Date (first participant enrolled): 24-Sep-2020

Study Completion Date [last participant completed/last participant out (LPO)]: 04-Aug-2022

Study Design: Prospective, multicentre, non-interventional. Approx. 24 weeks of observation with interim visit after approx. 12 weeks

Report Date: 04-Aug-2023 (Version 1.0)

This study was performed in compliance with the guidelines for Good Pharmacoepidemiology Practices. This report has been prepared based on the publication 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) – Guidelines for reporting observational studies – Ann Intern Med. 2007'.

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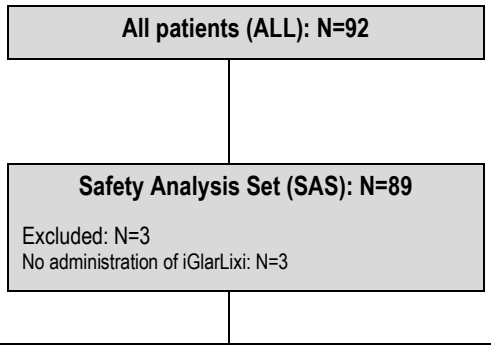
SYNOPSIS

Title of the study:	A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood sugar is not adequately controlled on basal insulin and oral antidiabetic therapy (BOT) Original title in German language: Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle durch Therapieintensivierung mit iGlarLixi im Suliqua®-(30–60)-Pen in der täglichen Praxis bei PatientInnen mit Typ-2-Diabetes, deren Blutzucker unter Basalinsulin und oraler antidiabetischer Therapie (BOT) nicht ausreichend kontrolliert ist Study number: OBS16751
Design:	Prospective, multicentre, non-interventional. Approx. 24 weeks of observation with interim visit after approx. 12 weeks.
Objectives:	**Primary objective**: Documentation of the absolute change in HbA_{1c} (%) from switching to iGlarLixi (fixed ratio combination [FRC] of insulin glargine 100 U/mL and 33 µg/mL lixisenatide) treatment from an existing BOT in everyday clinical practice until approx. 12 and approx. 24 weeks, respectively, after start of iGlarLixi treatment. **Secondary objectives**: Documentation of the changes in other glycaemic parameters, during approx. 12 and approx. 24 weeks of treatment with iGlarLixi, respectively, and documentation of the tolerability of iGlarLixi in everyday clinical practice. The following secondary endpoints were evaluated: • Relative change in HbA_{1c} (%) • Absolute and relative change in self-measured fasting blood glucose (FBG) (mg/dL)[1] • Proportion of patients achieving their individualised HbA_{1c} target (%) • Proportion of patients achieving FBG ≤110 mg/dL [≤6.1 mmol/L] (%) • Absolute and relative change in 7-point blood glucose daily profile (mg/dL)[2] • Last dose of previous basal insulin (units/day [U/d]) • Absolute and relative change in iGlarLixi dose (dose steps/day [DS/d])[2] • Absolute and relative change in body weight (kg) • Absolute change in BMI (kg/m²) • Absolute and relative change in glucose measured at median (mg/dL) • Absolute and relative change in SD of glucose profiles (mg/dL) • Incidence and rate of hypoglycaemic episodes[3] (documented hypoglycaemic episodes within the last approx. 12 weeks prior to study inclusion compared to the last 12 weeks prior to documentation 2 [after approx. 12 weeks] and the last 12 weeks prior to the final documentation [after approx. 24 weeks]) • Change in treatment satisfaction using DTSQs and DTSQc[4] *Post-hoc* the following additional endpoints were evaluated as GV parameters for Full Analysis Set (FAS; see section Methodology) patients and its subgroups: • Derived time in range from 7-point blood glucose daily profiles (%), calculated as number of glucose measurements per day between 70 and 180 mg/dL, divided by number of all glucose measurements per day, multiplied with 100 • Derived time above range from 7-point blood glucose daily profiles (%), calculated as number of glucose measurements per day >180 mg/dL, divided by number of all glucose measurements per day, multiplied with 100 • Derived time below range from 7-point blood glucose daily profiles (%), calculated as number of glucose measurements per day <70 mg/dL, divided by number of all glucose measurements per day, multiplied with 100

	Additional secondary endpoints for patients using flash glucose monitoring (FGM): • Median target blood glucose and limit value for low glucose (mg/dL)[1] • Absolute change in total time in target range in % (70-180 mg/dL) • Absolute change in total time in % above target range (>180 mg/dL) • Absolute change in total time in % below target range (<70 mg/dL) • Absolute and relative change in the number of patients with hypoglycaemic events according to level 1[2] and the number of events per patient (documented hypoglycaemic events within the 14-day FGM evaluation before inclusion in the study compared to the 14-day FGM evaluation before documentation 2 [after approx. 12 weeks] and the 14-day FGM evaluation before the final documentation [after approx. 24 weeks]) All endpoints were analysed for patients using an FGM device in addition to the endpoints for the total population. [1] These changes were documented monthly after switching to iGlarLixi in addition to documentation 1, 2 and 3. [2] self-measured blood glucose values were measured plasma calibrated, i. e. represent plasma glucose values. Values measured as mmol/L were calculated to mg/dL: mmol/L * 18.0182 = mg/dL [3] Definition and subdivision of hypoglycaemic events. Hypoglycaemic episodes were divided into three levels and recorded as symptomatic hypoglycaemic episodes as well as confirmed hypoglycaemic episodes [1]: - Level 1: Self-measured blood glucose (SMBG) <70 mg/dL (<3.9 mmol/L) and ≥54 mg/dL (≥3.0 mmol/L) - Level 2: SMBG <54 mg/dL (<3.0 mmol/L); clinically significant hypoglycaemia - Level 3: Severe hypoglycaemic event characterised by impaired mental and/or physical condition requiring outside assistance - Nocturnal hypoglycaemia: Hypoglycaemia that occurred during the patient's regular sleeping period (approx. 10 p.m. to 6 a.m.) [4] DTSQ: Diabetes Treatment Satisfaction Questionnaire: Two different forms were used: DTSQs and DTSQc questionnaire. Both include 8 questions designed to measure diabetes treatment satisfaction on a 7-point scale. DTSQs is a "status" version of the questionnaire. This was used here for baseline and final documentation, and to evaluate differences between both. DTSQc is the "change" version of the questionnaire, used to avoid ceiling effects in case of already high baseline values. It is used only at the end of a period to directly ask for perceived changes. In this study it was only used for final documentation.
Treatment:	Suliqua® 30-60 pen (FRC of insulin glargine 100 U/mL and lixisenatide 33 µg/mL, iGlarLixi)
Publications (reference):	Wiesner T et al. Effectiveness and safety of iGlarLixi in people with type 2 diabetes (Pw2D), not at target on basal insulin (BI) and oral antidiabetic therapy (BOT) - results from the observational, prospective study CHANCE. Diabetes 2023; 72 (Suppl. 1): 794-P. DOI: https://doi.org/10.2337/db23-794-P. Presented as poster 794-P at the 83rd Scientific Sessions of the American Diabetes Association (ADA) on 26.06.2023 in San Diego, CA, USA.
Introduction - Background/rationale:	Type 2 diabetes (T2D) often becomes uncontrolled over time, and inadequate or delayed escalation of treatment increases the risk for long term complications [1,2]. This so-called therapeutic inertia often already occurs during use of oral antidiabetic drug (OAD) and OAD combinations; furthermore, it is often seen in patients receiving additional basal insulin therapy [3]. Nevertheless, the international consensus report of ADA and European Association for the Study of Diabetes (EASD) as well as local German guidelines clearly advise to intensify BOT when glycemic targets are not reached [4,5]. Due to reimbursement reasons, iGlarLixi in the (30-60) pen (100 U/mL insulin glargine plus 33 µg/mL lixisenatide) is the only basal insulin and glucagon like peptide-1 receptor agonist (GLP-1 RA) FRC available in Germany since its commercial launch in January 2020. Real-world effectiveness and safety of treatment escalation from BOT regimens to iGlarLixi 30-60 have not yet been assessed in Germany. Therefore, CHANCE, a prospective, non-interventional study (NIS), provides specific insights on people with T2D (PwT2D) insufficiently controlled on at least 30 U/d of basal insulin in a BOT regimen, who are switched to 30 DS/d iGlarLixi. According to the summary of product characteristics (SmPC) of the European Medicines Agency (EMA), the iGlarLixi (30-60) pen should not be used with <30 or >60 DS/d. Times in, above and below glycaemic target range (time in range [TIR], time above range [TAR] and time below range [TBR]) as well as glycaemic variability (GV) parameters like standard deviation (SD) of glucose daily profiles are currently being recognised as key factors in addition to HbA_{1c} affecting

	quality of life of diabetes patients as well as micro- and macrovascular outcomes [6,7,8]. While use of real time continuous glucose monitoring (rtCGM) and intermittent scanning continuous glucose monitoring (iscCGM)/FGM is established in type 1 diabetes (T1D), it has been rather unusual in patients with T2D. However, also patients with T2D on BOT increasingly recognise FGM as an innovative tool helping to improve glycaemic management. Consequently, use of FGM devices becomes more and more common in patients with BOT. Visualisation of TIR/TAR/TBR as well as SD of glucose daily profiles, and with this GV, and their improvement by adaptation of the antidiabetic therapy has been shown to be a supportive tool for both physicians and patients to improve treatment adherence, patient self-motivation, and target achievement in clinical practice. The aim of this study was to collect data on glycaemic control of people with T2D intensifying treatment to iGlarLixi due to insufficient glycaemic control with a BOT regimen. While effectiveness was primarily assessed by change in HbA_{1c} and FBG, additional data were collected on TIR/TAR/TBR and resulting GV using 7-point self-measured plasma glucose (SMPG) and/or FGM profiles. For patients not sufficiently controlled with BOT who met the inclusion criteria, derived TIR/TAR/TBR (dTIR/dTAR/dTBR) was calculated from 7-point SMPG obtained at one day before Week 0 or TIR/TAR/TBR obtained from a 14-day extract of FGM measurements [9,10] before Week 0 were used to assess GV before BOT treatment was switched to iGlarLixi based on the physician's decision. Approximately 12 and 24 weeks after switch to iGlarLixi, respectively, GV was assessed again.
Methodology:	**Site and patient selection:** This NIS was conducted in accordance with Good Pharmacoepidemiology Practice (GPP) guidelines [11] and in accordance with local legal and ethical guidelines. It was distributed by employees of Sanofi (Germany) and conducted with general practitioners, diabetologists or in practices or outpatient clinics with a focus on diabetology. The participating physicians were familiar with the software of the FGM systems and already used them in their daily practice to evaluate the FGM data. Study sites were selected by Sanofi-Aventis Deutschland GmbH and supervised by a CRO (AKP GmbH). Type 2 diabetes patients were included for whom the treating physician had made the decision to switch the basal insulin to iGlarLixi based on the iGlarLixi SmPC [12] independent of the context of the NIS and independent of the patient's inclusion into the NIS. The patients had to be experienced with the use of their SMBG or FGM device and should not plan to change their device during the study. **Data and safety data collection:** There was no fixed scheme for the documentation of data. The visits were based on clinical practice with data collection at Week 0, and approx. 4, 8, 12, 16, 20, and 24 weeks after switching to iGlarLixi. No deviation longer than ± 3 weeks from the specified times was recommended. Data were collected via eCRF (electronic documentation form). The electronic data processing system could lead to additional clarifying questions that the participating physician was obligated to answer by confirming or modifying the data concerned. Data collection and validation procedures were processed in detail in appropriate operating documentation, such as the data management plan (DMP) and data validation plan (DVP). All adverse events (AEs), serious adverse events (SAEs), adverse drug reactions (ADRs), adverse drug effects (ADEs), adverse events of special interest (AESIs) and other safety-relevant events (overdose, misuse, abuse, occupational exposure, pregnancy, incidents with medical devices, medication errors, applications outside of the licensed approval, hypersensitivity reactions), regardless of their causal connection with iGlarLixi, from the time of signing the informed consent form until the end of the study (as defined for each patient in the observation plan), had to be documented on the relevant page(s) of the eCRFs. SAEs had to be documented immediately (within one working day after becoming known), non-serious AEs had to be documented within 30 calendar days. A back-up plan was to be used (i. e., using hard copies) in case the eCRF system failed. Reporting procedures for AEs and other safety-relevant events were predefined in the observational plan (Appendix 3.1) with respect to input, transmission, and additional data updates to be sent to

	AKP. This was also due for the reporting of suspected quality defects (PTC: Product Technical Complaints). **Data management, review, validation:** The processes of data collection and validation are described in detail in appropriate operational documents, such as the data management plan (DMP) and data validation plan (DVP). Data quality control (site monitoring and/or phone QC) was performed at site level, in 5% of the participating sites (which had documented at least one patient), chosen at random. The treating physician consented by signing the contract to make all information available to the sponsor for the purpose of verification. **Statistical considerations:** It was planned to document 250 patients at 100 sites in Germany. An interim analysis was planned after approx. 12 weeks or 50 patients, however, no interim analysis was performed. **1. Analysis sets**: The following analysis sets were defined for this NIS. The **All Patients Set (ALL)** included all patients who met all selection criteria for the documentation, but no selection criterion against the documentation. Evaluation of disposition of patients was done based on all patients fulfilling in- and exclusion criteria. The **Safety Analysis Set (SAS)** included all patients who had received at least one dose of iGlarLixi during the NIS. The SAS was used to analyse all safety variables including hypoglycaemia reports. The **Full Analysis Set (FAS)** was used to analyse the main evaluation variable as well as all other efficacy variables and hypoglycaemia endpoints. The FAS was defined as a subset of the SAS and included all patients for whom all the following criteria were fulfilled: • Written informed consent (date of consent reported) • All inclusion criteria fulfilled and not any exclusion criterion met • At least one dose of iGlarLixi during the NIS • Sufficient data existed for the assessment of the main criterion (primary endpoint): HbA_{1c} documented at baseline and at least once after baseline This was compliant with the mFAS defined in the observation plan. **FAS patients using an FGM device (FGM)**: All endpoints of the FAS population were analysed for the patient group using an FGM device including 7-point daily glucose profiles; in addition, the defined FGM enpoints were analysed. **FAS patients using 7-point SMBG profiles (SMBG)**: All endpoints of the FAS population were analysed for the patient group using SMBG profiles including 7-point daily glucose profiles; no FGM endpoints were analysed in this population. **2. Statistical analyses:** Statistical analyses were performed according to the Statistical Analysis Plan (Appendix III, Section 3.2.1). Additional analyses, not described in the SAP, are detailed in Appendix III, Section 3.2.2. All analyses including statistical tests are exploratory and are to be interpreted as descriptive. Appropriate 95% confidence intervals (CIs) were calculated for estimated parameters. Analyses were also performed for predefined subgroups. All descriptive and inferential statistical analyses were performed using the SAS statistical software (Version 9.4 or higher). **3. Disposition of patients and baseline characteristics** An overview was provided for duration of the study by presenting the dates of first patient who was included and the last patient who terminated the study. Demographics and baseline characteristics were to be analysed for the FAS and, in addition, for the SAS, if the difference between FAS and the respective set was ≥5%.

	Exact (Clopper-Pearson) 95% CI was provided for response rates. Comparison of subgroups was performed using Wilcoxon test and Fisher's exact test, depending of the type of variables. **4. Main evaluation variable** The main evaluation parameter was analysed for the FAS and subsets (FGM and SMBG). Based on the assumed normal distribution, the 95% CI for the estimated parameter, the absolute change in HbA_{1c} (%) with iGlarLixi from the start of treatment up to the visit after approx. 12 or approx. 24 weeks, respectively, was calculated as well as between the visit after approx. 12 weeks and the end of the documentation after approx. 24 weeks. The t-test for connected samples was used to check if the true difference was different from zero. **5. Secondary evaluation variables** Secondary parameters were analysed for the FAS and subsets (FGM and SMBG). Frequency distributions (n, %) were provided. Exact (Clopper-Pearson) 95% CI were calculated for response rates. For continuous variables the 95% CI for the mean was calculated based on an assumption of normal distribution. **6. Analysis of Safety** Safety parameters were analysed for the SAS. Data from the pharmacovigilance database were used for analyses of AEs, SAEs, ADRs, SADRs, and AESIs. **7. Subgroup analyses** Subgroup analyses comprised: • Gender • Age (divided in 3 groups of approximately the same size according to the data available: ≤60 years, >60 - <70 years, ≥70 years) • Body Mass Index (BMI) (<30 kg/m² and ≥30 kg/m²) • Renal function (eGFR ≤60 ml/min/1.73 m², >60 ml/min/1.73 m²) • Duration of diabetes (up to 5 years, 5 to 10 years, over 10 years) • Baseline HbA_{1c} (<8.5%, ≥8.5%) • Previous basal insulin therapy (Insulin detemir (IDet), Insulin glargine 100 E/mL (Gla-100), Insulin glargine 300 E/mL (Gla-300), Insulin degludec 100/200 E/mL (IDeg), NPH insulin (NPH)) • Time of iGlarLixi administration (before breakfast, before lunch, before dinner)
RESULTS	
Participants (actual):	A summary of patient numbers and disposition to the different analysis sets including numbers of patients in subgroups is depicted in Figure 1. 

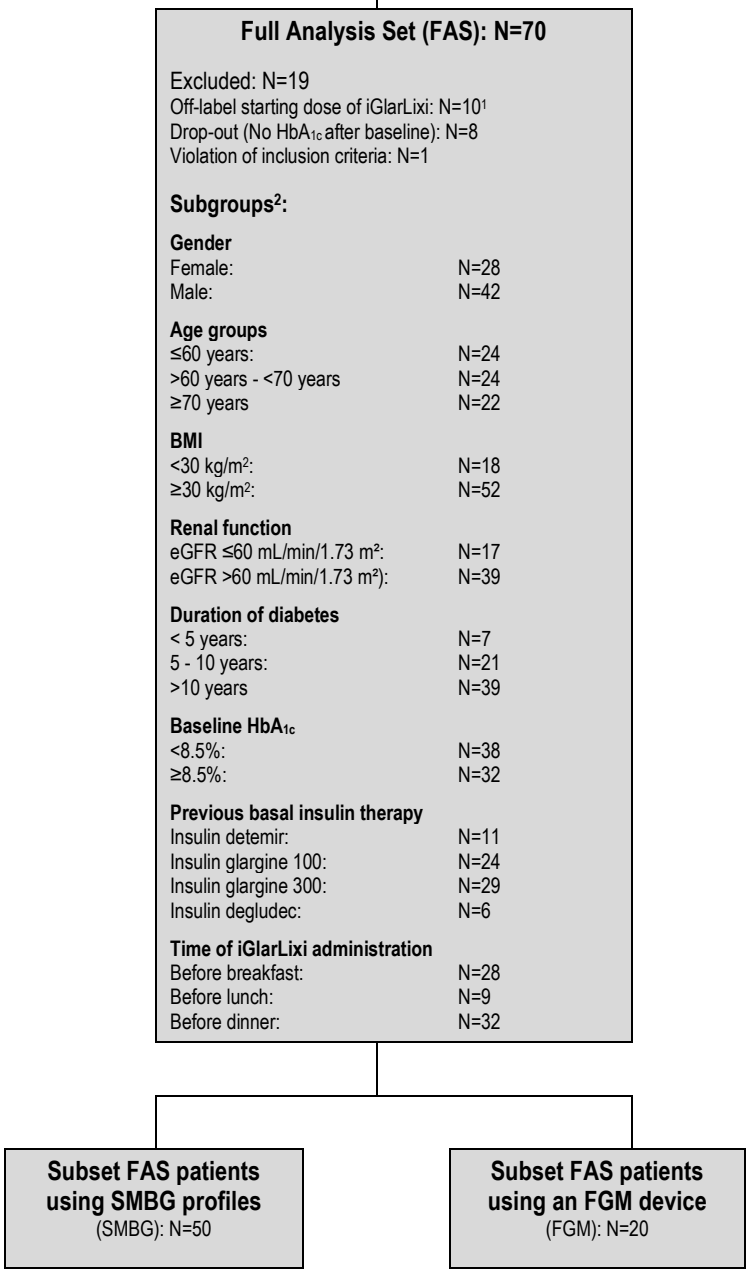


Figure 1: Flow chart for patient disposition

[1] The actual starting dose of iGlarLixi in patients with Off-label use (outside 27-33 dose steps/day) is listed in Appendix 2.1.5

[2] Difference to N=70: No data available on subgroup disposition (renal function: N=14, duration of diabetes: N=3, time of iGlarLixi administration: N=1)

ALL = all patients fulfilling all in- and exclusion criteria, BMI = body mass index, eGFR = estimated glomerular filtration rate, FAS = full analysis set, FGM = flash glucose monitoring, HbA_{1c} = glycated haemoglobin A_{1c}, SAS = safety analysis set, SMBG = self-measured blood glucose

Source: Appendix II: Tables 2.1.3, 2.1.4, 2.1.5

This prospective observational study was conducted at 33 sites in Germany. Of these, the majority were diabetologists (N=22, 66.7%) with documentation of 64 patients (69.6%), followed by general practitioners (N=8, 24.2%) with documentation of 23 patients (25%) and internists (N=3, 9.1%) with documentation of 5 patients (5.4%). The type of medical facility was predominantly established

(N=29, 87.9%]), followed by medical supply centres (N=4, 12.1%). The sites were equally distributed all over Germany to allow for geographical representativeness (Appendix II, Tables 1.1, 1.3, 1.5, 1.6).

Due to the impact of Covid 19 pandemic, the original plan to document 250 patients at 100 sites in Germany could not be realised. Currently, 111 patients at 33 sites were enrolled. Of these, 92 patients (100%) had in- and exclusion criteria reported, signed informed consent and were included in the analysis population (All). Of these, 89 patients comprised the SAS set, i. e. those patients who received at least once iGlarLixi (96.7%). From the SAS, 10 patients were excluded due to off-label starting dose of iGlarLixi, 8 patients due to missing documentation of HbA_{1c} after baseline, and 1 patient due to violation of inclusion criteria, thus leading to a sample size of 70 patients in FAS (76.1%). FGM patients including only patients using an FGM device comprised 20 patients and SMBG patients included all other patients (n = 50) (Appendix II, Tables 2.1.3, 2.1.4, 2.1.5).

Detailed information on study sites, patient disposition, reason for exclusion from an analysis set, and deviations from the observational study protocol for the main analysis and for the analysis of subgroups is presented in Appendix II, Table 1.1 to Table 2.1.6.

This report presents results of the SAS (safety data), the FAS (baseline, efficacy and hypoglycaemia data), and patients with FGM or SMBG use (baseline and efficacy data). In addition, baseline data are also presented for drop-out patients and patients with off-label starting dose of iGlarLixi to address, if any bias was introduced by excluding these groups from efficacy analyses. All results including results of subgroups are presented in detail in Appendix II.

Participant characteristics and primary analyses:

Baseline data

Comparison of baseline data of SAS patients, FAS patients, drop-out (Drop-Out) patients and patients with off-label starting dose of iGlarLixi (Off-Label), including FAS subgroup analyses (without testing on statistical significance of differences between subgroups)

Patients' demographics and baseline characteristics are tabulated in Appendix II, Table 2.2.1.1 to 2.2.4.10.2.

A summary is given in Table 1.

Table 1: Patient demographics and baseline characteristics by SAS patients, FAS patients, Drop-Out patients, and Off-Label patients

Parameter Statistics	SAS N=89	FAS N=70	Drop-Out N=8	Off-Label N=10
Gender, n (%)				
Female	36 (40.4)	28 (40.0)	5 (62.5)	2 (20.0)
Male	53 (59.6)	42 (60.0)	3 (37.5)	8 (80.0)
Age, years				
Mean (SD)	64.8 (10.2)	64.6 (9.49)	70.9 (9.30)	62.0 (14.13)
Median	64.0	64.0	68.00	61.00
Weight, kg				
Mean (SD)	102.8 (22.0)	104.3 (22.5)	91.6 (9.2)	102.9 (25.4)
Median	99.0	103.0	94.0	98.0
Height, cm				
Mean (SD)	171.5 (10.6)	172.1 (9.9)	161.6 (7.4)	178.2 (11.8)
Median	173.0	174.0	160.0	178.0
BMI, kg/m^2				
Mean (SD)	34.9 (7.0)	35.1 (7.2)	35.3 (4.7)	32.5 (8.2)
Median	34.0	34.4	35.3	31.5
HbA_{1c}, %				
Mean (SD)	-	8.5 (0.8)	8.8 (0.7)	8.9 (0.9)

Median	-	8.3	8.8	9.0
Indiv. target HbA_{1c}, %				
Mean (SD)	-	6.9 (0.4)	7.5 (0.7)	7.3 (0.5)
Median	-	7.0	7.3	7.3
FBG (SMBG), mg/dL				
Mean (SD)	-	174.3 (44.6)	196.8 (46.3)	162.4 (25.9)
Median	-			
Systolic blood pressure (mmHg), n (%)				
Mean (SD)	138.6 (16.4)	138.7 (16.2)	139.9 (22.7)	138.0 (14.8)
Median	138.0	138.0	138.0	139.0
Diastolic blood pressure (mmHg), n (%)				
Mean (SD)	81.6 (9.5)	82.0 (9.7)	79.7 (9.7)	80.3 (9.2)
Median	80.0	80.0	80.0	80.0

For missing values see tables listed below.

BMI = body mass index, Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, FBG = fasting blood glucose, HbA_{1c} = glycated haemoglobin A_{1c}, Off-Label = patients with off-label starting dose of iGlarLixi (outside 30±3 dose steps/day), SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 2.2.1.1, 2.2.2.1, 2.2.3.1, 2.2.4.1

Within the FAS population, 40.0% of patients were female and 60.0% were male with a mean age of 64.64 years, a mean BMI of 35.1 kg/m^2, and a mean blood pressure of 138.7/82.0 mmHg. With respect to the parameters shown in Table 1, the FAS population did not differ significant or clinically relevant from the Drop-Out population and the Off-Label population, respectively, in most of the baseline parameters evaluated; however, significantly less height of Drop-Out patients vs FAS population was observed (p = 0.006; Appendix II, Table 2.2.3.2.1). Furthermore, significantly higher mean HbA_{1c} target values were reported for Drop-Out (p = 0.012) and Off-label (p = 0.018) patients vs FAS patients (Appendix II, Tables 2.4.1.1 and 2.4.1.2). Within the FAS the individual HbA_{1c} target value ranged from 6.5% to 8.0% and was 6.9% in mean (Appendix II, Table 2.4.1).

Subgroup analyses revealed only small differences in mean HbA_{1c} target values between female and male patients (6.9% vs 7.0%), eGFR ≤60 mL/min/1.73 m² vs >60 mL/min/1.73 m² (7.0% vs 6.9%), duration of diabetes ≤5 years vs > 5 years (7.0% vs 6.9%) and HbA_{1c} <8.5% vs ≥8.5% (6.9% vs 7.0%). Of note, HbA_{1c} targets were higher in older age groups (≤60 years: 6.8%, >60 - <70 years: 6.9%, ≥70 years: 7.1%). Subgroups based on previous basal insulin had markedly different HbA_{1c} targets documented (IDet: 6.7%, Gla-300: 6.9%, Gla-100: 7.0%, IDeg: 7.2%). Furthermore, subgroups based on iGlarLixi injection time also differed in their HbA_{1c} targets documented (before breakfast: 7.0%, before lunch: 7.4%, before dinner: 6.8%) (Appendix II, Tables 2.4.2-2.4.10).

Within the last 3 months before study start, the mean HbA_{1c} value in FAS patients was 8.5%, ranging from 7.5% - 10.8% (Appendix II, Table 2.6.1.1), with numerical, but not significant differences between FAS, drop-out and off-label patient groups (Appendix II, Tables 2.6.1.1.1, 2.6.1.1.2). Furthermore, subgroup analyses revealed numerical differences between groups (Appendix II, Tables 2.6.2.1, 2.6.3.1, 2.6.4.1, 2.6.5.1, 2.6.6.1, 2.6.7.1, 2.6.8.1, 2.6.9.1, 2.6.10.1).

Current self-measured FBG values at study start ranged from 89 to 300 mg/dL (mean: 174.3 mg/dL) (Appendix II, Table 2.5.1), with numerical, but not significant differences between FAS, drop-out and off-label patient groups (Appendix II, Tables 2.5.1.1, 2.5.1.2). Furthermore, subgroup analyses revealed numerical differences between groups (Appendix II, Tables 2.5.2-2.5.10).

Further differences with p < 0.05 (Wilcoxon test, Kruskal Wallis test) in pre-defined subgroups of the FAS as defined in Figure 1 were identified for:

- Age: subgroups age groups (mean age increasing with increasing age group), renal function (patients with eGFR ≤60 mL/min/1.73 m² being significantly older than those with

eGFR >60 mL/min/1.73 m²), and duration of diabetes (the longer diabetes duration the higher the mean age)

- Height: subgroup gender (female significantly smaller than male)
- Weight: subgroups gender (female significantly less weight than male), age groups (patients ≤60 years significantly more weight than patients >60 - < 70 years and ≥70 years, respectively), BMI (patients with BMI ≥30 kg/m² significantly more weight than patients with BMI <30 kg/m²), renal function (patients with ≤60 mL/min/1.73 m² trending to less weight than patients with >60 mL/min/1.73 m²), and previous basal insulin (patients with IDet and IDeg trending to more weight than patients with Gla-100 and Gla-300)
- BMI: subgroup BMI (patients with BMI ≥30 kg/m² significantly higher BMI than patients with BMI <30 kg/m²)
- Diastolic blood pressure: subgroup age groups (age group ≤60 years had significantly higher diastolic blood pressure than age group >60 - <70 and ≥70 years, respectively)

Details are presented in Appendix II, Tables 2.2.1.3.2, 2.2.2.3.2, 2.2.3.3.2, 2.2.4.3.2.

Different parameters were analysed to characterize specific diabetes medical history. For reference see the respective statistical output in Appendix II, Table 2.3.1.1.1.1 to 2.3.7.10.2.

The period since initial diabetes diagnosis, basal insulin medication at baseline, number and time of basal insulin injections, and non-insulin medication at baseline are displayed in Table 2. Further parameters will be presented below the table.

Table 2: Period since initial diabetes diagnosis, basal insulin medication, and non-insulin medication at baseline (FAS patients, Drop-Out patients, and Off-Label patients)

Parameter Statistics	FAS N=70	Drop-Out N=8	Off-Label N=10
Period since initial diabetes diagnosis, years, n (%)			
Mean (SD)	12.3 (6.7)	13.3 (6.7)	11.3 (4.1)
Median	11.0	14.0	12.0
Unknown	3	1	1
Up to 5 years	7 (10.5)	1 (14.3)	0 (0.0)
5 to 10 years	21 (31.3)	0 (0.0)	3 (33.3)
Over 10 years	39 (58.2)	6 (85.7)	6 (66.7)
Basal insulin medication at baseline, n (%)			
Insulin glargine 300 U/mL	29 (41.4)	3 (42.9)	5 (50.0)
Insulin glargine 100 U/mL	24 (34.3)	3 (42.9)	3 (30.0)
Insulin detemir	11 (15.7)	1 (14.3)	1 (10.0)
Insulin degludec 100/200 U/mL	6 (8.6)	0 (0.0)	0 (0.0)
NPH Insulin	0 (0.0)	0 (0.0)	1 (10.0)
Last dose of previous basal insulin, Units/day [U/d]			
Insulin glargine 300 U/mL			
Mean (SD)	38.0 (10.0)	39.3 (9.5)	41.2 (8.8)
Median	34.0	36.0	40.0
Insulin glargine 100 U/mL			
Mean (SD)	37.9 (8.9)	35.3 (9.2)	26.7 (15.3)
Median	35.0	30.0	30.0
Insulin detemir			
Mean (SD)	42.8 (10.0)	40.0	32.0
Median	40.0	40.0	32.0
Insulin degludec 100/200 U/mL			
Mean (SD)	37.3 (9.7)	-	-

	Median	35.0	-	-
	Total			
	Mean (SD)	38.7 (9.6)	37.7 (8.0)	35.2 (11.5)
	Median	36.0	36.0	35.0
Duration of basal insulin medication, months				
	Mean (SD)	38.1 (44.8)	49.1 (39.8)	48.1 (38.5)
	Median	24.9	46.2	44.1
Number of injections per day				
	Mean (SD)	1.1 (0.2)	1.0 (0.0)	1.0 (0.0)
Time of injection, n (%)				
	Morning	18 (25.7)	3 (42.9)	0 (0.0)
	Noon	1 (1.4)	0 (0.0)	1 (10.0)
	Evening	18 (25.7)	0 (0.0)	5 (50.0)
	Before bedtime	26 (37.1)	4 (57.1)	4 (40.0)
	Morning/evening	3 (4.3)	0 (0.0)	0 (0.0)
	Morning/noon/evening	1 (1.4)	0 (0.0)	0 (0.0)
	Noon/before bedtime	1 (1.4)	0 (0.0)	0 (0.0)
	Evening/before bedtime	2 (2.9)	0 (0.0)	0 (0.0)
Non-insulin antiglycaemic medication at baseline, n (%)				
Metformin				
	Yes	51 (73.9)	5 (83.3)	6 (60.0)
	No	18 (26.1)	1 (16.7)	4 (40.0)
SGLT2 inhibitor				
	Yes	35 (50.0)	3 (50.0)	1 (10.0)
	No	35 (50.0)	3 (50.0)	9 (90.0)
DPP-4 inhibitor				
	Yes	24 (34.8)	3 (60.0)	1 (11.1)
	No	45 (65.2)	2 (40.0)	8 (88.9)
Glinide				
	Yes	3 (4.4)	0 (0.0)	1 (10.0)
	No	66 (95.7)	5 (100.0)	9 (90.0)
Sulfonylurea				
	Yes	2 (2.9)	0 (0.0)	1 (11.1)
	No	66 (97.1)	5 (100.0)	8 (88.9)
Any medication				
	Yes	67 (95.7)	6 (75.0)	7 (70.0)
	No	3 (4.3)	2 (25.0)	3 (30.0)

For missing values see tables listed below.

DPP-4 = dipeptidyl peptidase-4, Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, Off-Label = patients with off-label starting dose of iGlarLixi, SD = standard deviation, SGLT2 = Sodium-glucose cotransporter-2

Source: Appendix II: Tables 2.3.1.1.1.1, 2.3.1.1.1.2, 2.3.2.1.1.1,2.3.2.1.2.1, 2.3.2.1.3.1, 2.3.2.1.4, 2.3.2.1.5.1, 2.3.3.1

Duration of diabetes was >10 years in more than half of the patients (58.2%) without significant differences between FAS, Drop-Out and Off-Label groups. Mean duration of diabetes was 12.26 years (FAS). Considerable differences in mean duration of diabetes were observed in the following subgroups: gender (male patients: 14.4 years, female patients: 8.4 years), according to previous basal insulin therapy (IDeg: 14.7 years, Gla-100: 14.0 years, Gla-300: 11.6 years, IDet: 8.2 years), and time of iGlarLixi administration (before lunch: 16.8 years, before dinner: 11.4 years, before breakfast: 11.2 years) (Appendix II, Tables 2.3.1.1.3.2, 2.3.1.1.9.2, 2.3.1.1.10.2).

In FAS, basal insulin medication before switch was predominantly Gla-300 (41.4%) and Gla-100 (34.3%), respectively, followed by IDet (15.7%) and IDeg (8.6%). Mean last basal insulin dose was highest with IDet (42.8 U/d) and lowest with IDeg (37.3 U/d) (Appendix II, Tables 2.3.2.1.1.1,

	2.3.2.1.2.1). Mean duration of basal insulin medication was 38.1 months. Most frequent time of basal insulin injection was before bedtime (37.1%), followed by morning and evening (25.7%, each) (Appendix II, Tables 2.3.2.1.3.1, 2.3.2.1.5.1). Subgroup analyses revealed that SMBG patients received more frequently Gla-300 (48.0% vs 25.0%) and IDeg (10.0% vs 5.0%) as compared to FGM patients (Appendix II, Table 2.3.2.2.1). Mean duration of basal insulin treatment was longer in FGM patients (55 months vs 35 months) (Appendix II, Table 2.3.2.2.3). More female than male patients received IDet (21.4% vs 11.9%) (Appendix II, Table 2.3.2.3.1). In contrast to glargine-based basal insulins the last doses of IDet (40.2 U/d vs 46.0 U/d) and IDeg (30.0 U/d vs 41.0 U/d) were lower for women than men (Appendix II, Table 2.3.2.3.2). Due to the longer diabetes duration in men also the mean duration of basal insulin medication before switch was considerably higher in male patients (44.9 months) vs female patients (27.5 months) (Appendix II, Table 2.3.2.3.3). Within age groups, mean basal insulin treatment duration was lowest in the age group ≥70 years (27.7 months), followed by ≤60 years (39.5 months) and >60 - <70 years (45.7 months) (Appendix II, Table 2.3.2.4.3). Patients with BMI ≥30 kg/m² received considerably more often IDet than those with BMI <30 kg/m² (19.2% vs 5.6%) (Appendix II, Table 2.3.2.5.1); furthermore, the mean duration of basal insulin treatment was considerably longer in obese patients than in non-obese patients (41.7 vs 28.7 months) (Appendix II, Table 2.3.2.5.3). Longer duration of diabetes was accompanied by longer mean duration of basal insulin treatment (≤5 years: 14.6 months vs 5-10 years: 33.7 months vs >10 years 48.0 months) (Appendix II, Table 2.3.2.7.3). Within the subgroup according to basal insulin used, mean duration of basal insulin treatment was longest with Gla-100 (50.1 months), followed by IDet (43.6 months), Gla-300 (31.3 months) and IDeg (23.4 months) (Appendix II, Table 2.3.2.9.3). iGlarLixi was applicated before lunch in patients with longer mean duration of previous basal insulin treatment (54.1 months) vs patients with iGlarLixi application before breakfast (37.4 months) and before dinner (33.7 months), respectively (Appendix II, Table 2.3.2.10.3). Within the FAS population, non-insulin antidiabetic medication at baseline primarily consisted of metformin (73.9%), SGLT2 inhibitors (50.0%), or DPP-4 inhibitors (34.8%). Except for 3 patients (4.3%), all other patients received any kind of non-insulin antidiabetic medication; percentage of non-insulin medication was different for Drop-Out (75%; p = 0.079) and Off-Label patients (70.0%; p = 0.024). Off-label patients received significantly less SGLT2 inhibitors (10.0%) than FAS and Drop-Out patients (50.0% both; p = 0.020 vs FAS), respectively (Appendix II, Tables 2.3.3.1, 2.3.3.1.1, 2.3.3.1.2). Subgroup analyses revealed that women received less metformin (66.7% vs 78.6%) and less SGLT2 inhibitors (39.3% vs 57.1%) than men. On the other hand, only women received sulfonyl urea and glinides (7.4% both) (Appendix II, Table 2.3.3.3). Patients ≥70 years received less metformin (57.1%) and SGLT2 inhibitors (40.9%), than patients ≤60 years (70.8% and 50.0%, respectively) and patients >60 - <70 years (91.7% and 58.3%, respectively). On the other hand, patients ≥70 years received more DPP4 inhibitors (52.4%) than patients ≤60 years (16.7%) and >60 - <70 years (37.5%), respectively (Appendix II, Table 2.3.3.4). Obese patients received more metformin (78.4% vs 61.1%), but less DPP4 inhibitors (27.5% vs 55.6%) and SGLT2 inhibitors (46.2% vs 61.1%) (Appendix II, Table 2.3.3.5). Patients with eGFR ≤60 mL/min/1.73 m² received less metformin (47.1% vs 84.6%), but more DPP4 inhibitors (52.9% vs 28.2%) and SGLT2 inhibitors (58.8% vs 43.6%) (Appendix II, Table 2.3.3.6). Patients with shorter duration of diabetes (<5 years) received more DPP4 inhibitors (57.1%) than patients with 5-10 years duration of diabetes (33.3%) and >10 years duration of diabetes (29.0%), respectively. SGLT2 inhibitors were more common in patients with >10 years duration of diabetes (69.2%) than in patients with <5 years duration of diabetes (28.6%) and 5-10 years duration of diabetes (28.6%), respectively (Appendix II, Table 2.3.3.7). At baseline, in 3 patients of the FAS, 9 hypoglycaemia events with glucose level <70 mg/dL and ≥54 mg/dL (ADA level 1) were documented (0.584 events per patient year [E/PY]) including 1 patient with 4 events of nocturnal hypoglycaemia (0.259 E/PY) (Appendix II, Tables 2.3.1.2.1.1 and 2.3.1.2.1.5). These hypoglycaemia ADA level 1 occurred in older patients (in two ≥70 years, in one >60 - <70 years; Appendix II, Table 2.3.1.2.4.1) with longer duration of diabetes (in two >10 years, in one 5-10 years; Appendix II, Table 2.3.1.2.7.1). Two obese patients experienced events, one non-obese patient (Appendix II, Table 2.3.1.2.5.1). Mean HbA_{1c} <8.5% was associated with two patients

experiencing events (one nocturnal), mean HbA_{1c} ≥8.5% with one patient with events (Appendix II, Table 2.3.1.2.8.1). All baseline ADA level 1 hypoglycaemia events occurred under treatment with second generation basal insulins (Gla-300, IDeg). ADA level 2 and 3 hypoglycaemia events were not reported (Appendix II, Tables 2.3.1.3 ff and 2.3.1.5 ff).

Late complications and concomitant diseases, documented at study start, are presented in Table 3.

Table 3: Late complications and concomitant diseases (FAS patients, Drop-Out patients, and Off-Label patients)

Parameter Statistics	FAS N=70	Drop-Out N=8	Off-Label N=10
Late complications, n (%)			
Diabetic neuropathy			
Yes	29 (41.4)	3 (37.5)	3 (30.0)
No	40 (57.1)	3 (37.5)	7 (70.0)
Unknown	1 (1.4)	1 (12.5)	0 (0.0)
Duration [years, mean (SD)]	5.0 (3.5)	9.0 (5.7)	12.5 (0.7)
Diabetic nephropathy			
Yes	14 (20.0)	2 (25.0)	1 (10.0)
No	56 (80.0)	5 (62.5)	9 (90.0)
Duration [years, mean (SD)]	4.5 (4.0)	2.5 (2.1)	4.0
Diabetic foot syndrome			
Yes	6 (8.6)	3 (37.5)	2 (20.0)
No	63 (90.0)	4 (50.0)	8 (80.0)
Unknown	1 (1.4)	0 (0.0)	0 (0.0)
Duration [years, mean (SD)]	2.0 (1.7)	7.0 (2.8)	7.5 (6.4)
Diabetic retinopathy			
Yes	4 (5.7)	0 (0.0)	0 (0.0)
No	64 (91.4)	7 (87.5)	9 (90.0)
Unknown	2 (2.9)	0 (0.0)	1 (10.0)
Duration [years, mean (SD)]	4.3 (3.5)		
Limb amputation due to diabetic foot			
Yes	2 (2.9)	0 (0.0)	0 (0.0)
No	68 (97.1)	7 (87.5)	10 (100.0)
Duration [years, mean (SD)]	3.0		
Any complication			
Yes	36 (51.4)	4 (50.0)	3 (30.0)
No	34 (48.6)	4 (50.0)	7 (70.0)
Concomitant diseases, n (%)			
Arterial hypertension	61 (87.1)	5 (62.5)	10 (100.0)
Renal failure	15 (21.4)	4 (50.0)	2 (20.0)
Coronary heart disease	14 (20.0)	0 (0.0)	3 (30.0)
History of myocardial Infarction	6 (8.6)	0 (0.0)	2 (20.0)
Peripheral arterial occlusive disease	5 (7.1)	2 (25.0)	0 (0.0)
Stroke (ischemic, hemorrhagic) in the history	3 (4.3)	0 (0.0)	1 (10.0)
Any concomitant disease	63 (90.0)	6 (75.0)	10 (100.0)

For missing values see tables listed below.

Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, Off-Label = patients with off-label starting dose of iGlarLixi, SD = standard deviation

Source: Appendix II: Tables 2.3.4.1.1, 2.3.4.1.2, 2.3.5.1.1

Most frequently, diabetic neuropathy (41%) with a mean duration of 5.0 years and diabetic nephropathy (20%) with a mean duration of 4.5 years were documented as late diabetic

	complications, with no significant differences between FAS, Drop-Out and Off-Label groups (Appendix II, Tables 2.3.4.1.1, 2.3.4.1.2). However, significantly less diabetic foot syndrome was documented in FAS vs Drop-Out (8.6% vs 42.9%, p = 0.043) (Appendix II, Table 2.3.4.1.3) and significantly shorter duration of diabetic neuropathy in FAS vs Off-Label (5.0 vs 12.5 years, p = 0.038) (Appendix II, Table 2.3.4.1.6). Regarding concomitant diseases, arterial hypertension (87.1%), renal failure (21.4%), and coronary heart disease (20.0%) were prevailing at study start (Appendix II, Table 2.3.5.1.1). Documentation of renal failure trended to be lower in FAS vs Drop-Out (21.4% vs 57.1%, p = 0.058), whereas in FAS vs Off-Label peripheral arterial occlusive disease trended to be higher in FAS (7.1% vs 0.0%, p = 0.052) and a history of stroke trended to be lower in FAS (4.3% vs 10.0%, p = 0.054) (Appendix II, Tables 2.3.5.1.2, 2.3.5.1.3). Subgroup analyses revealed that patients with more late complications were older, obese, had lower eGFR and had lower baseline HbA_{1c} values (Appendix II, Tables 2.3.4 ff). Of note, 9.5% of male patients had diabetic retinopathy documented vs 0.0% of female patients (Appendix II, Table 2.3.4.3.1). Patients with more concomitant diseases were older, had lower eGFR, longer duration of diabetes and higher HbA_{1c} values (Appendix II, Tables 2.3.5 ff). Of note, more male than female patients had hypertension (92.9% vs 78.6%), peripheral arterial occlusive disease (9.5% vs 3.6%), and less history of myocardial infarction (7.1% vs 10.7%) (Appendix II, Table 2.3.5.3) Regarding lipid lowering medication, only statins (51.4%, mean duration of treatment 6.4 years) and ezetimibe (10.0%, mean duration of treatment 5.5 years) were documented for FAS patients. About half of FAS patients (52.9%) received any lipid lowering medication (Appendix II, Tables 2.3.6.1.1, 2.3.6.1.2). However, significantly more Off-Label patients received statins vs FAS patients (90.0% vs 51.4%, p = 0.037) (Appendix II, Table 2.3.6.1.4); on the other hand, ezetimibe was only documented for FAS patients. Subgroup analyses revealed more lipid lowering treatment in non-obese and patients with longer duration of diabetes. Of note, patients with eGFR ≤60 mL/min/1.73 m² had nearly double as many statins documented vs patients with eGFR >60 mL/min/1.73 m² (64.7% vs 35.9%) (Appendix II, Tables 2.3.6 ff). Different classes of antihypertensive medication were documented within the FAS with the following frequencies: beta blocking agents (50.0%), AT1R inhibitors (44.3%), ACE inhibitors (37.1%), calcium channel blockers (24.3%), and thiazides (21.4%) (Appendix II, Table 2.3.7.1.1), with no significant differences between FAS, Drop-Out and Off-Label populations, except for ACE inhibitors being significantly less often documented in Drop-Out vs FAS (14.3% vs 37.1%, p = 0.044) and calcium channel blockers being significantly more often documented in Off-Label vs FAS (50.0% vs 24.3%, p = 0.017). Furthermore, use of AT1R inhibitors was trending to be longer for Off-Label vs FAS (14.0 vs 5.9 years, p = 0.094) (Appendix II Tables 2.3.7.1.3, 2.3.7.1.4). Subgroup analyses revealed more frequent documentation of ACE inhibitors in older patients and in obese patients, of AT1R inhibitors and calcium channel blockers in patients with longer duration of diabetes, and of beta blockers in patients with baseline HbA_{1c} ≥8.5% (Appendix II, Tables 2.3.7 ff). Of note, female patients received more ACE inhibitors (42.9% vs 33.3%) and more beta blockers (60.7% vs 42.9%) than male patients. On the other hand, male patients received more AT1R inhibitors (57.1% vs 25.0%), thiazides (26.2% vs 14.3%) and calcium channel blockers (28.6% vs 17.9%) (Appendix II, Table 2.3.7.3.1). Patients with eGFR ≤60 mL/min/1.73 m² vs >60 mL/min/1.73 m² received more ACE inhibitors (41.2% vs 25.6%), beta blockers (64.7% vs 43.6%), and calcium channel blockers (23.5% vs 15.4%), as well as less thiazides (5.9% vs 28.3%) (Appendix II, Table 2.3.7.6.1). Last available laboratory values within the last 6 months are displayed in Table 4. Data available ranged from 38 to 58 out of 70 FAS patients, 4 to 6 out of 8 drop-out patients, and 4 to 9 out of 10 off-label starting dose patients.

Table 4: Last available laboratory values within the last 6 months (FAS patients, Drop-Out patients, and Off-Label patients)

Parameter Statistics	FAS N=70	Drop-Out N=8	Off-Label N=10
eGFR in ml/min/1.73m²			
Mean (SD)	73.5 (21.2)	64.0 (15.2)	80.4 (24.2)
Median	76.5	58.5	68.0
Creatinine (mg/dL)			
Mean (SD)	1.0 (0.3)	1.0 (0.2)	1.0 (0.2)
Median	1.0	1.0	1.0
AST (U/L)			
Mean (SD)	25.8 (11.9)	30.1 (11.0)	50.3 (53.5)
Median	23.0	25.3	26.5
ALT (U/L)			
Mean (SD)	33.5 (20.6)	39.2 (24.9)	35.8 (15.4)
Median	28.0	30.0	31.0
FPG (mg/dL)			
Mean (SD)	185.3 (63.7)	202.4 (44.6)	211.6 (42.2)
Median	170.0	199.0	213.5
Total cholesterol (mg/dL)			
Mean (SD)	181.7 (41.7)	183.0 (38.8)	183.3 (37.1)
Median	181.0	185.5	186.0
LDL cholesterol (mg/dL)			
Mean (SD)	107.6 (37.1)	110.1 (40.6)	109.9 (41.0)
Median	109.0	96.5	111.0
HDL cholesterol (mg/dL)			
Mean (SD)	49.9 (23.5)	43.3 (4.9)	42.5 (11.3)
Median	47.0	42.5	46.8
Triglycerides (mg/dL)			
Mean (SD)	188.9 (82.0)	218.8 (84.8)	223.6 (109.0)
Median	180.0	245.1	195.3

For missing values see table listed below.

ALT = alanine transaminase, AST = aspartate aminotransferase, Drop-Out = patients with only baseline parameters documented, eGFR = estimated glomerular filtration rate, FAS = full analysis set, FPG = fasting plasma glucose, HDL = high density lipoprotein, LDL = low density lipoprotein, Off-Label = patients with off-label starting dose of iGlarLixi, SD = standard deviation

Source: Appendix II: Table 2.6.1.2

There were no significant differences between FAS population vs Drop-Out patients and vs Off-Label patients, respectively (Appendix II, Tables 2.6.1 ff).

Baseline values of glycaemic variability parameters were obtained from FGM or were calculated from 7-point blood glucose daily profiles, using the following. The respective results are presented in Table 5.

Table 5: Assessment of GV parameters from FGM and from 7-point blood glucose daily profiles (FAS patients, Drop-Out patients, and Off-Label patients)

Parameter Statistics	FAS N=70	Drop-Out N=8	Off-Label N=10
FGM parameters			
Glucose median (mg/dL)			
n	20	0	2
Mean (SD)	149.0 (23.8)	-	169.0 (5.7)

Median	148.4	-	169.0
TIR (%)			
n	20	0	2
Mean (SD)	56.5 (18.3)	-	37.5 (31.8)
Median	57.0	-	37.5
TAR (%)			
n	20	0	2
Mean (SD)	36.5 (16.5)	-	57.5 (24.8)
Median	34.0	-	57.5
TBR (%)			
n	20	0	2
Mean (SD)	6.9 (8.1)	-	5.0 (7.1)
Median	4.5	-	5.0
Parameters from 7-point blood glucose daily profiles			
Glucose Median (mg/dL)			
n	45	8	7
Mean (SD)	195.5 (42.9)	203.3 (46.6)	181.7 (26.0)
Median	189.2	196.9	175.0
Standard deviation of mean daily glucose (mg/dL)			
n	45	8	7
Mean (SD)	39.6 (16.0)	50.8 (16.2)	43.2 (20.1)
Median	38.0	50.6	42.2

Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, GV = glycemic variability, Off-Label = patients with off-label starting dose of iGlarLixi, SD = standard deviation, TAR = time above range, TBR = time below range, TIR = time in range

Source: Appendix II: Tables 2.6.1.3, 2.6.1.4

Neither for FGM parameters significant differences were observed between FAS patients vs Off-Label patients (Appendix II, Table 2.6.1.3.1) nor for parameters from 7-point blood glucose daily profiles between FAS patients vs Drop-Out patients and vs Off-Label patients, respectively (Appendix II, Tables 2.6.1.4.1, 2.6.1.4.2).

Reasons for therapy switch from basal insulin to iGlarLixi are listed in Table 6 (multiple answers were possible).

Table 6: Reason for switch to iGlarLixi (FAS patients, Drop-Out patients, and Off-Label patients)

Reason for switch	FAS N=70	Drop-Out N=8	Off-Label N=10
Improving glycaemic control, n (%)			
Improvement of HbA_{1c}	70 (100.0)	7 (87.5)	10 (100.0)
Improvement of FBG	55 (78.6)	4 (50.0)	7 (70.0)
Improvement of postprandial blood glucose (ppBG)	52 (74.3)	4 (50.0)	7 (70.0)
Improvement of GV	22 (31.4)	2 (25.0)	0 (0.0)
Improvement of TIR	18 (25.7)	0 (0.0)	0 (0.0)
Already high dosage of basal insulin	17 (24.3)	1 (12.5)	2 (20.0)
Change in time of injection	6 (8.6)	0 (0.0)	0 (0.0)
Reduction of hypoglycaemia rate	1 (1.4)	0 (0.0)	0 (0.0)
Improving compliance, n (%)			
Easy handling of the FRC	35 (50.0)	4 (50.0)	6 (60.0)
Patient request	18 (25.7)	0 (0.0)	0 (0.0)
Preference for the iGlarLixi pen device	6 (8.6)	0 (0.0)	2 (20.0)
Other			

	Compliance	0 (0.0)	1 (12.5)	0 (0.0)
	Weight loss	1 (1.4)	0 (0.0)	0 (0.0)
	No OAD as intensification option due to elevated liver enzymes	0 (0.0)	0 (0.0)	1 (10.0)

Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, FBG = fasting blood glucose, FRC = Fixed-ratio combination, GV = glycemic variability, HbA_{1c} = glycated haemoglobin A_{1c}, Off-Label = patients with off-label starting dose of iGlarLixi, ppBG = postprandial blood glucose, SD = standard deviation, TIR = time in range

Source: Appendix II: Tables 2.7.1.1

Within the FAS population, main reasons for therapy switch from previous basal insulin treatment to treatment with iGlarLixi were related to improvement of glycaemic control: HbA_{1c} value (100%), FBG (78.6%), and postprandial blood glucose (ppBG; 74.3%). Furthermore, improvement of GV (31.4%) and of TIR (25.7%) as well as high dose of basal insulin (24.3%) were mentioned frequently. Regarding improving compliance, easy handling of the FRC (50.0%) and request of the patient (25.7 %) were mentioned most frequently (Appendix II, Table 2.7.1.1).

Subgroup analyses revealed that more male than female patients had fasting blood glucose (88.1% vs 64.3%), easy handling of the FRC (57.1% vs 39.3%) and request of the patient (31.0% vs 17.9%) documented as reason for switching treatment to iGlarLixi (Appendix II, Table 2.7.2.1). Easy handling was documented more frequently for older patients, improvement of FBG, GV and TIR was more often documented in patients with longer duration of diabetes and most of these parameters were documented in patients switching to iGlarLixi before lunch (Appendix II, Tables 2.7 ff).

As per label, for all FAS and Drop-Out patients 30 dose steps per day iGlarLixi was documented as starting dose. Patients with off-label starting dose documentation were either documented with erroneous doses of 0, 1 or 2 dose steps, or with dose steps of 34, 35, and 40 dose steps (Appendix II, Table 2.7.1.2). Within the FAS population, most frequently used injection times were before dinner (46.4%) and before breakfast (40.6%), with only few patients injecting before lunch (13.0%) (Appendix II, Table 2.7.1.3). No significantly different injection times were documented for FAS vs Drop-Out and vs Off-Label patients (Appendix II, Tables 2.7.1.3.1, 2.7.1.3.2).

Subgroup analyses revealed that more male than female patients received iGlarLixi before lunch (19.0% vs 3.7%) (Appendix II, Table 2.7.3.3). Most patients ≥70 years received iGlarLixi before breakfast (57.1%), while most patients aged ≤60 years and >60 - <70 years, respectively, received iGlarLixi before dinner (50.0% and 54.2%, respectively) (Appendix II, Table 2.7.4.3). Patients with eGFR ≤60 mL/min/1.73 m² received iGlarLixi mainly before breakfast (52.9%), those with eGFR >60 mL/min/1.73 m² mainly before dinner (53.8%) (Appendix II, Table 2.7.6.3). More patients with HbA_{1c} <8.5% vs HbA_{1c} ≥8.5% received iGlarLixi before lunch (16.2% vs 9.4%) (Appendix II, Table 2.7.8.3).

At treatment start of iGlarLixi, non-insulin concomitant glucose lowering medication was changed for 28.6% of FAS patients, while for 71.4% no change of these medications was documented (Appendix II, Table 2.7.1.4). There were no significant differences documented between FAS population vs Drop-Out and vs Off-Label, respectively (Appendix II, Tables 2.7.1.4.1, 2.7.1.4.2).

Subgroup analyses revealed that changes in non-insulin glucose lowering medication more often were documented for patients aged ≥70 years than for patients aged ≤60 and >60 - <70 years, respectively (45.5% vs 25.0% and 16.7%, respectively) (Appendix II, Table 2.7.3.4). Furthermore, non-insulin glucose lowering medication was more often changed in patients with BMI <30 kg/m² vs ≥30 kg/m² (50.0% vs 21.2%) and in patients with eGFR ≤60 mL/min/1.73 m² vs >60 mL/min/1.73 m² (52.9% vs 25.6%) (Appendix II, Tables 2.7.4.4, 2.7.5.4). In contrast, non-insulin glucose lowering medication was changed most often in patients with duration of diabetes <5 years vs 5-10 years and >10 years, respectively (71.4% vs 38.1% and 12.8%, respectively (Appendix II, Table 2.7.6.4)

Within the FAS population, non-insulin concomitant antidiabetic medication at treatment start of iGlarLixi continued to primarily consist of metformin (72.5%) and SGLT2 inhibitors (49.3%). However, DPP-4 inhibitors were markedly reduced (13.2% vs 34.8% before switch of treatment), glinides (5.8%) and sulfonyl urea (1.5%) remained at low level. (Appendix II, Table 2.7.1.5). Consistent with the

results at baseline, Off-Label patients also received significant less SGLT2 inhibitors (10.0%) at treatment start with iGlarLixi vs FAS patients (p = 0.037) (Appendix II, Table 2.7.1.5.2).

Subgroup analyses revealed that at start of iGlarLixi treatment women still received less metformin (59.3% vs 81.0%) and less SGLT2 inhibitors (35.7% vs 58.5%) than men (Appendix II, Table 2.7.3.5). Patients ≥70 years received less metformin (61.9%) and SGLT2 inhibitors (40.9%), than patients ≤60 years (70.8% and 52.2%, respectively) and patients >60 - <70 years (83.3% and 54.2%, respectively). On the other hand, patients ≤60 years received now less DPP4 inhibitors (4.3%) than patients ≥70 years (9.5%) and >60 - <70 years (25.0%), respectively (Appendix II, Table 2.7.4.5). Obese patients received less SGLT2 inhibitors (45.1% vs 61.1%) (Appendix II, Table 2.7.5.5). Patients with eGFR ≤60 mL/min/1.73 m² continued to receive less metformin (47.1% vs 82.1%) (Appendix II, Table 2.7.6.5). Patients with shorter duration of diabetes (<5 years) received no DPP4 inhibitors anymore (0.0%) vs patients with 5-10 years duration of diabetes (10.0%) and >10 years duration of diabetes (18.4%), respectively, receiving both markedly less DPP4 inhibitors than before switch to iGlarLixi. SGLT2 inhibitors were still more common in patients with >10 years duration of diabetes (66.7%) than in patients with <5 years duration of diabetes (28.6%) and 5-10 years duration of diabetes (30.0%), respectively (Appendix II, Table 2.7.7.5).

The status version of the questionnaire DTSQs is based on 8 questions. They are evaluated based on a six-point rating scale (from 0 = e. g. “very dissatisfied”, “very inconvenient”, “very seldom” to 6 = e. g. “very satisfied”, “very convenient”, “very often”). They can be evaluated one by one, resulting in a score ranging from 0 to 6. For 6 questions (Q1 + Q4-8) a lower score indicates lower treatment satisfaction and a higher score higher treatment satisfaction. They can also be evaluated as a sum score of treatment satisfaction, resulting in a score ranging from 0 to 36. Q2 and Q3 (perceived hyper- and hypoglycaemia) are evaluated separately, because a lower score indicates less hypo- or hyperglycaemia, i. e. is more favourable, and a higher score indicates more frequent hypo- or hyperglycaemia, i.e. is less favourable. Results are shown in Table 7.

Table 7: Patient questionnaires on treatment satisfaction (FAS patients, Drop-Out patients, and Off-Label patients)

Parameter Statistics	FAS N=70	Drop-Out N=8	Off-Label N=10
Q1: Satisfaction with current treatment			
Mean (SD)	4.0 (1.8)	3.7 (1.5)	4.9 (1.5)
Median	4.0	4.0	5.0
Q2: Impression how often blood glucose was unacceptably high			
Mean (SD)	3.8 (1.4)	4.8 (1.3)	4.0 (1.3)
Median	4.0	5.0	5.0
Q3: Impression how often blood glucose was unacceptably low			
Mean (SD)	0.9 (1.2)	2.0 (2.2)	0.7 (1.3)
Median	0.5	2.0	0.0
Q4: Practicability/convenience of treatment			
Mean (SD)	4.0 (1.6)	4.0 (1.4)	4.4 (1.1)
Median	4.0	4.0	5.0
Q5: Satisfaction with the flexibility of treatment			
Mean (SD)	4.0 (1.5)	4.1 (1.4)	4.6 (1.7)
Median	4.0	4.0	5.0
Q6: Satisfaction with knowledge/ understanding of diabetes			
Mean (SD)	4.1 (1.4)	4.0 (1.6)	4.3 (1.5)
Median	4.0	5.0	4.0
Q7: Recommend treatment to others			

Mean (SD)	4.3 (1.3)	4.0 (1.6)	4.7 (1.0)
Median	4.0	3.0	5.0
Q8: Satisfaction with continuing current treatment			
Mean (SD)	3.8 (1.7)	3.6 (1.9)	4.6 (1.7)
Median	4.0	3.0	5.0
Summary score of Q1 + Q4-8			
Mean (SD)	24.2 (7.7)	23.4 (8.2)	27.4 (7.8)
Median	24.5	20.0	31.0

For missing values see tables listed below.

Drop-Out = patients with only baseline parameters documented, FAS = full analysis set, Off-Label = patients with off-label starting dose of iGlarLixi, SD = standard deviation

Source: Appendix II: Tables 2.8.1

Within the FAS population the mean scores of Q1 and Q4-Q8 were ≥4.0 with exception of Q8 satisfaction with continuing current treatment [mean (SD): 3.8 (1.69) of 6]. It was highest for Q7 recommend treatment to others ([4.3 (1.34) of 6]. Mean sum score of these was 24.2 (7.74) of 36. For Q2 impression how often blood glucose was unacceptably high a rather high score of 3.8 (1.44) of 6 was documented indicating a patient need for treatment improvement by lowering blood glucose levels. In addition, for Q3 impression how often blood glucose was unacceptably low a rather low score of 0.9 (1.24) was documented (Appendix II, Table 2.8.1). No significant differences were documented for FAS vs Drop-Out and vs Off-Label patients, respectively (Appendix II, Tables 2.8.1.1, 2.8.1.2).

Subgroup analyses revealed that overall female patients were slightly more satisfied with their previous treatment than male patients, as were patients aged >60 to <70 years vs those ≤60 years and those ≥70 years, respectively, obese patients vs non-obese patients and patients with eGFR ≤60 mL/min/1.73 m² vs >60 mL/min/1.73 m², as well as patients with <5 years duration of diabetes vs ≥5 years (Appendix II, Tables 2.8.3, 2.8.4, 2.8.5, 2.8.6, 2.8.7). Patients with Gla-100 were less satisfied than patients with Gla-300, IDet and IDeg, respectively (Appendix II, Table 2.8.9)

Comparison of baseline data of FAS patients, FGM patients and SMBG patients

Parameters that were documented at baseline only are presented here. All parameters with baseline as well as follow-up documentation are presented in the Efficacy Section. Patient demographics and baseline characteristics for FAS patients, FGM patients and SMBG patients are summarised in Table 8.

Table 8: Patient demographics and baseline characteristics by FAS patients, FGM patients and SMBG patients

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Gender, n (%)			
Female	28 (40.0)	8 (40.0)	20 (40.0)
Male	42 (60.0)	12 (60.0)	30 (60.0)
Age, years			
Mean (SD)	64.6 (9.49)	60.3 (7.86)	66.4 (9.59)
Median	64.0	59.5	65.0
Weight, kg			
Mean (SD)	104.3 (22.5)	107.0 (23.1)	103.1 (22.4)
Median	103.0	103.5	98.5
Height, cm			
Mean (SD)	171.5 (10.6)	172.9 (8.8)	171.7 (10.3)
Median	173.0	175.0	173.0
BMI (kg/m^2), n (%)			
Mean (SD)	35.1 (7.2)	35.8 (7.6)	34.8 (7.0)

Median	34.4	34.2	34.4
Systolic blood pressure (mmHg), n (%)			
Mean (SD)	138.7 (16.2)	136.6 (17.6)	139.6 (15.7)
Median	138.0	132.5	140.0
Diastolic blood pressure (mmHg), n (%)			
Mean (SD)	82.0 (9.7)	82.9 (11.0)	81.6 (9.2)
Median	80.0	80.0	80.0

For missing values see tables listed below.

BMI = body mass index, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 2.2.1.1, 2.2.1.3.1, 2.2.2.1, 2.2.2.3.1, 2.2.3.1, 2.2.3.3.1, 2.2.4.1, 2.2.4.3.1

Significant differences in patient demographics and baseline characteristics between FGM patients and SMBG patients were seen in patients' age (60.3 vs 66.4 years, p=0.014). All other parameters did not significantly differ (Appendix II, Tables 2.2.1.3.2, 2.2.2.3.2, 2.2.3.3.2, 2.2.4.3.2,).

The period since initial diabetes diagnosis, basal insulin medication at baseline, number and time of basal insulin injections, and non-insulin medication at baseline for FAS patients, FGM patients and SMBG patients are shown in Table 9.

Table 9: Period since initial diabetes diagnosis, basal insulin medication, and non-insulin medication at baseline (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Period since initial diabetes diagnosis, years, n (%)			
Mean (SD)	12.3 (6.7)	14.3 (8.3)	11.6 (6.1)
Median	11.0	12.5	11.0
Unknown	3	1	2
Up to 5 years	7 (10.5)	1 (5.3)	6 (12.5)
5 to 10 years	21 (31.3)	7 (36.8)	14 (29.2)
Over 10 years	39 (58.2)	11 (57.9)	28 (58.3)
Basal insulin medication at baseline, n (%)			
Insulin glargine 300 U/mL	29 (41.4)	5 (25.0)	24 (48.0)
Insulin glargine 100 U/mL	24 (34.3)	9 (45.0)	15 (30.0)
Insulin detemir	11 (15.7)	5 (25.0)	6 (12.0)
Insulin degludec 100/200 U/mL	6 (8.6)	1 (5.0)	5 (10.0)
NPH Insulin	0 (0.0)	0 (0.0)	0 (0.0)
Last dose of previous basal insulin, U/d			
Insulin glargine 300 U/mL			
Mean (SD)	38.0 (10.0)	40.6 (13.7)	37.5 (9.3)
Median	34.0	33.0	34.5
Insulin glargine 100 U/mL			
Mean (SD)	37.9 (8.9)	40.4 (11.2)	36.3 (7.1)
Median	35.0	36.0	32.0
Insulin detemir			
Mean (SD)	42.8 (10.0)	42.0 (11.0	43.5 (10.2)
Median	40.0	40.0	42.5
Insulin degludec 100/200 U/mL			
Mean (SD)	37.3 (9.7)	38.0	37.2 (10.8)
Median	35.0	38.0	34.0

	Total			
	Mean (SD)	38.7 (9.6)	40.8 (10.9)	37.8 (8.9)
	Median	36.0	38.0	35.0
	Duration of basal insulin medication, months			
	Mean (SD)	38.1 (44.8)	55.0 (85.2)	35.0 (34.1)
	Median	24.9	32.4	24.9
	Number of injections per day			
	Mean (SD)	1.1 (0.2)	1.0 (0.00)	1.1 (0.3)
	Time of injection, n (%)			
	Morning	18 (25.7)	3 (15.0)	15 (30.0)
	Noon	1 (1.4)	1 (5.0)	0 (0.0)
	Evening	18 (25.7)	7 (35.0)	11 (22.0)
	Before bedtime	26 (37.1)	8 (40.0)	18 (36.0)
	Morning/evening	3 (4.3)	0 (0.0)	3 (6.0)
	Morning/noon/evening	1 (1.4)	0 (0.0)	1 (2.0)
	Noon/before bedtime	1 (1.4)	0 (0.0)	1 (2.0)
	Evening/before bedtime	2 (2.9)	1 (5.0)	1 (2.0)
	Non-insulin antiglycaemic medication at baseline, n (%)			
	Metformin			
	Yes	51 (73.9)	15 (75.0)	36 (73.5)
	No	18 (26.1)	5 (25.0)	13 (26.5)
	SGLT2 inhibitor			
	Yes	35 (50.0)	10 (50.0)	25 (50.0)
	No	35 (50.0)	10 (50.0)	25 (50.0)
	DPP-4 inhibitor			
	Yes	24 (34.8)	4 (20.0)	20 (40.8)
	No	45 (65.2)	16 (80.0)	29 (59.2)
	Glinide			
	Yes	3 (4.4)	3 (15.0)	0 (0.0)
	No	66 (95.7)	17 (85.0)	49 (100.0)
	Sulfonyl urea			
	Yes	2 (2.9)	1 (5.3)	1 (2.0)
	No	66 (97.1)	18 (94.7)	48 (98.0)
	Any medication			
	Yes	67 (95.7)	19 (95.0)	48 (96.0)
	No	3 (4.3)	1 (5.0)	2 (4.0)

For missing values see tables listed below.

FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose, U/d = units/day

Source: Appendix II: Tables 2.3.1.1.1.1, 2.3.1.1.1.2, 2.3.1.1.2.1, 2.3.1.1.2.2, 2.3.2.1.1.1, 2.3.2.1.2.1, 2.3.2.1.3.1, 2.3.2.1.4, 2.3.2.1.5.1, 2.3.2.2.1 to 2.3.2.2.5

Mean duration of diabetes was longer in FGM patients (14.3 years) compared to SMBG patients (11.6 years) (Appendix II, Table 2.3.1.1.2.2). Further differences between these groups were observed for basal insulin medication before switch with higher frequencies of Gla-300 use in SMBG patients (48.0%) than in FGM patients (25.0%), while the use of IDet was lower in SMBG patients (12.0% vs 25.0%) (Appendix II, Table 2.3.2.2.1). Mean last total basal insulin dose was higher in FGM patients (40.8 U/d vs 37.8 U/d) (Appendix II, Table 2.3.2.2.2). A considerable difference was documented with respect to mean duration of basal insulin medication (FGM patients: 55.0 months, SMBG patients: 35.0 months) (Appendix II, Table 2.3.2.2.3). Morning as time of injection was more frequent in SMBG patients (30.0% vs 15.0%), and evening as time of injection less frequent (22.0% vs 35.0%) vs FGM patients. (Appendix II, Table 2.3.2.2.5).

Regarding non-insulin antiglycaemic medication, considerably more SMBG patients received DPP-4 inhibitors (40.8%) vs FGM patients (20.0%) (Appendix II, Table 2.3.3.2). Only FGM patients received glinides in 15.0% of cases, none of the SMBG patients.

In one FGM patient, 4 hypoglycaemia events with glucose level <70 mg/dL and ≥54 mg/dL (ADA level 1) were documented being nocturnal hypoglycaemia events. In 2 SMBG patients 5 hypoglycaemia events without nocturnal hypoglycaemia were reported (Appendix II, Table 2.3.1.2.2.1).

Late complications and concomitant diseases in FAS patients, FGM patients and SMBG patients, documented at study start, are presented in Table 10.

Table 10: Late complications and concomitant diseases (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Late complications, n (%)			
Diabetic neuropathy			
Yes	29 (41.4)	7 (35.0)	22 (44.0)
No	40 (57.1)	13 (65.0)	27 (54.0)
Unknown	1 (1.4)	0 (0.0)	1 (2.0)
Duration [years, mean (SD)]	5.0 (3.5)	7.8 (3.0)	4.1 (3.2)
Diabetic nephropathy			
Yes	14 (20.0)	4 (20.0)	10 (20.0)
No	56 (80.0)	16 (80.0)	40 (80.0)
Duration [years, mean (SD)]	4.5 (4.0)	5.0 (4.3)	4.3 (4.2)
Diabetic foot syndrome			
Yes	6 (8.6)	0 (0.0)	6 (12.0)
No	63 (90.0)	20 (100.0)	43 (86.0)
Unknown	1 (1.4)	0 (0.0)	1 (2.0)
Duration [years, mean (SD)]	2.0 (1.7)	-	2.0 (1.7)
Diabetic retinopathy			
Yes	4 (5.7)	0 (0.0)	4 (8.0)
No	64 (91.4)	20 (100.0)	44 (88.0)
Unknown	2 (2.9)	0 (0.0)	2 (4.0)
Duration [years, mean (SD)]	4.3 (3.5)	-	4.3 (3.5)
Limb amputation due to diabetic foot			
Yes	2 (2.9)	0 (0.0)	2 (4.0)
No	68 (97.1)	20 (100.0)	48 (96.0)
Duration [years, mean (SD)]	3.0	-	3.0
Any complication			
Yes	36 (51.4)	8 (40.0)	28 (56.0)
No	34 (48.6)	12 (60.0)	22 (44.0)
Concomitant diseases, n (%)			
Arterial hypertension	61 (87.1)	14 (70.0)	47 (94.0)
Renal failure	15 (21.4)	1 (5.0)	14 (28.0)
Coronary heart disease	14 (20.0)	6 (30.0)	8 (16.0)
History of myocardial Infarction	6 (8.6)	2 (10.0)	4 (8.0)
Peripheral arterial occlusive disease	5 (7.1)	2 (10.0)	3 (6.0)
Stroke (ischemic,hemorrhagic) in the history	3 (4.3)	2 (10.0)	1 (2.0)
Any concomitant disease	63 (90.0)	16 (80.0)	47 (94.0)

For missing values see tables listed below.
FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = Self-measured blood glucose

Source: Appendix II: Tables 2.3.4.1.1, 2.3.4.1.2, 2.3.4.2.1, 2.3.4.2.2, 2.3.5.1.1, 2.3.5.2

The frequency of any late complications and concomitant diseases was higher in SMBG patients compared to FGM patients (56.0% vs 40.0% and 94.0% vs 80.0%, respectively). Most prominent differences in late complications were observed for diabetic neuropathy (44.0% vs 35%, diabetic foot syndrome (12.0% vs 0.0%), and diabetic retinopathy (8.0% vs 0.0%). The duration of diabetic neuropathy and diabetic nephropathy was shorter in SMBG patients. The higher frequency of concomitant diseases in SMBG patients was due to higher frequencies in arterial hypertension (94.0% vs 80.0%) and renal failure (28.0% vs 5.0%). On the other hand, frequencies were higher in FGM patients for coronary heart disease (30.0% vs 16.0%) and stroke (10.0% vs 2.0%) (Appendix II, Tables 2.3.4.2.1, 2.3.4.2.2, 2.3.5.2).

Any lipid lowering treatment was higher in SMBG patients (58.0) compared to FGM patients (40.0%). This was due to higher use of statins in SMBG patients (56.0% with mean duration of 6.7 years vs 40.0 % with mean duration of 4.8 years) patients (Appendix II, Tables 2.3.6.2.1, 2.3.6.2.2).

Between SMBG patients and FGM patients, differences were documented with respect to the use of antihypertensive medication. Frequencies were higher in SMBG patients for beta blocking agents (58.0% vs 30.0%), ACE inhibitors (44.0% vs 20.0%)) and lower for AT1R inhibitors (38.0% vs 60.0%) and calcium channel blockers (22.0% vs 30.0%) (Appendix II, Tables 2.3.7.2.1).

Mean individualised HbA_{1c} target values were comparable between SMBG and FGM patients (6.9% vs 7.0%) (Appendix II, Tables 2.4.2). In addition, mean HbA_{1c} baseline values within the last 3 months before study start were comparable (8.4% vs 8.5%) (Appendix II, Tables 2.6.1).

However, mean fasting SMBG values at study start markedly differed between SMBG and FGM patients (180.6 mg/dL vs 159.3 mg/dL) (Appendix II, Tables 2.5.2).

Last available laboratory values within the last 6 months for FAS patients, FGM patients and SMBG patients, are displayed in Table 11.

Table 11: Last available laboratory values within the last 6 months (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
eGFR in ml/min/1.73m²			
Mean (SD)	73.5 (21.2)	81.2 (18.5)	69.8 (21.7)
Median	76.5	84.0	70.0
Creatinine (mg/dL)			
Mean (SD)	1.0 (0.3)	0.9 (0.3)	1.1 (0.3)
Median	1.0	0.9	1.0
AST (U/L)			
Mean (SD)	25.8 (11.9)	28.5 (11.4)	24.6 (12.1)
Median	23.0	25.0	21.0
ALT (U/L)			
Mean (SD)	33.5 (20.6)	35.9 (15.4)	32.4 (22.9)
Median	28.0	32.5	26.0
FPG (mg/dL)			
Mean (SD)	185.3 (63.7)	177.2 (47.8)	189.2 (70.2
Median	170.0	166.0	171.5
Total cholesterol (mg/dL)			
Mean (SD)	181.7 (41.7)	178.6 (50.8)	183.1 (37.3)
Median	181.0	172.0	186.0
LDL cholesterol (mg/dL)			
Mean (SD)	107.6 (37.1)	113.7 (39.2)	104.4 (36.1)

Median	109.0	115.0	108.5
HDL cholesterol (mg/dL)			
Mean (SD)	49.9 (23.5)	45.4 (10.9)	52.3 (27.8)
Median	47.0	45.0	48.2
Triglyceride (mg/dL)			
Mean (SD)	188.9 (82.0)	179.0 (92.5)	194.1 (76.8)
Median	180.0	147.0	192.0

For missing values see table listed below.

ALT = alanine transaminase, AST = aspartate aminotransferase, eGFR = estimated glomerular filtration rate, FAS = full analysis set, FGM = flash glucose monitoring, FPG = fasting plasma glucose, HDL = high density lipoprotein, LDL = low density lipoprotein, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Table 2.6.1.2, 2.6.2.2

There were only small differences between SMBG patients and FGM patients concerning last available laboratory values within the last 6 months, except for FPG values (189.2 vs 177.2 mg/dL (Appendix II, Table 2.6.2.2).

All FGM and SMBG patients were started according to the European label for the iGlarLixi (30-60) pen with 30 dose steps per day (DS/d) (Appendix II, Tables 2.7.2.2). Time of injection was predominantly before breakfast (57.1%) within the SMBG group, and before dinner within the FGM group (65.0%) (Appendix II, Table 2.7.2.3).

Main reasons for therapy switch from previous basal insulin treatment to treatment with iGlarLixi in FGM and SMBG group were related to improvement of glycaemic control: HbA_{1c} value (100.0% both), FBG (80.0% vs 78.6%), and ppBG (75.0% vs 74.0%). Furthermore, easy handling of the FRC (45.0% and 52.0%, respectively) and high dose of basal insulin (25.0%vs 24.0%) was mentioned at similar rates. However, improvement of GV (50.0% vs 24.0%) and of TIR (55.0% vs. 14.0%) as well as change of injection time (20.0% vs 4.0%), preference for iGlarLixi pen (20.0% vs 4.0%) and request of the patient (55.0% vs 14.0%) were mentioned markedly more frequent in the FGM group (Appendix II, Table 2.7.2.1).

At treatment start of iGlarLixi, non-insulin concomitant glucose lowering medication was more frequently changed in SMBG patients as compared to FGM patients (36.0% vs 10.0%) (Appendix II, Table 2.7.2.4). Those changes were mainly due to removal of DPP4 inhibitors in the SMBG group (10.2% vs 40.8% before switch to iGlarLixi, none in the FGM group (Appendix II, Table 2.7.2.5).

Efficacy

Efficacy parameters were evaluated for FAS patients, FGM patients, SMBG patients and the predefined subgroups, respectively. The following report focuses on FAS patients, FGM patients and SMBG patients. Efficacy results of the predefined subgroups are given in detail in Appendix II in Section 3 *Effectiveness – Absolute change in HbA1c [%] under iGlarLixi* for the primary endpoint and in Section 4 *Effectiveness (secondary)* for all other endpoints.

Primary efficacy endpoint

Primary efficacy endpoint was absolute change in HbA_{1c} (%) under iGlarLixi treatment from start of the treatment up to the visit after approx. 12 and approx. 24 weeks, respectively.

Detailed statistical analyses of the primary efficacy endpoint including subgroup analyses can be found in Appendix II, Tables 3.1.1 to 3.3.9.

The respective results for FAS patients, FGM patients, and SMBG patients are presented in Table 12.

Table 12:: **Absolute change in HbA_{1c} (%) under iGlarLixi treatment from baseline until 12 and 24 weeks, respectively (FAS patients, FGM patients and SMBG patients)**

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.82)	8.44 (0.76)	8.55 (0.85)
95% CI	[8.32; 8.71]	[8.09; 8.80]	[8.31; 8.79]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 10.8
Median	8.30	8.25	8.45
Q1-Q3	7.80 - 9.20	7.85 - 8.90	7.80 - 9.27
After 12 weeks			
n	68	20	48
Mean (SD)	7.89 (0.81)	8.00 (0.90)	7.85 (0.78)
95% CI	[7.70; 8.09]	[7.57; 8.42]	[7.62; 8.08]
Min-Max	5.9 - 9.7	6.5 - 9.7	5.9 - 9.3
Median	7.80	7.90	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.70	7.35 - 8.40
Change from baseline			
n	68	20	48
Mean (SD)	-0.64 (0.78)	-0.45 (0.62)	-0.71 (0.83)
95% CI	[-0.83; -0.45]	[-0.74; -0.16]	[-0.96; -0.47]
Min-Max	-2.6 - 1.3	-1.6 - 1.3	-2.6 - 0.7
Median	-0.50	-0.45	-0.60
Q1-Q3	-0.90 - -0.10	-0.65 - -0.20	-1.09 - -0.10
t-test	p < 0.001	p = 0.005	p < 0.001
After 24 weeks			
n	68	20	48
Mean (SD)	7.74 (0.76)	7.75 (0.85)	7.74 (0.73)
95% CI	[7.56; 7.93]	[7.35; 8.14]	[7.53; 7.96]
Min-Max	5.8 - 9.8	6.4 - 9.8	5.8 - 9.2
Median	7.80	7.80	7.75
Q1-Q3	7.20 - 8.20	7.10 - 7.95	7.20 - 8.25
Change from baseline			
n	68	20	48
Mean (SD)	-0.74 (0.81)	-0.70 (0.74)	-0.76 (0.85)
95% CI	[-0.94; -0.55]	[-1.04; -0.35]	[-1.01; -0.52]
Min-Max	-3 - 0.5	-1.9 - 0.5	-3 - 0.3
Median	-0.50	-0.55	-0.50
Q1-Q3	-1.30 - -0.10	-1.40 - -0.10	-1.25 - -0.10
t-test	p < 0.001	p < 0.001	p < 0.001

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, Q = quartile, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 3.1.1, 3.2.1

Mean baseline HbA_{1c} values were 8.52% for FAS patients, 8.44% for FGM patients and 8.55% for SMBG patients. After 12 weeks of treatment with iGlarLixi, mean changes from baseline were -0.64% (FAS), -0.45% (FGM), and -0.71% (SMBG), respectively. The respective mean changes from baseline until 24 weeks were -0.74%, -0.70%, and -0.76%, respectively. For all patient populations changes were highly statistically significant from baseline until Week 12 and Week 24, respectively (paired t-test) (Appendix II, Tables 3.1.1, 3.2.1).

Changes in HbA_{1c} (%) from Week 12 until Week 24 are displayed in Table 13.

Table 13:: Absolute change in HbA_{1c} (%) under iGlarLixi from Week 12 until Week 24 (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
After 12 weeks			
n	68	20	48
Mean (SD)	7.89 (0.81)	8.00 (0.90)	7.85 (0.78)
95% CI	[7.7; 8.09]	[7.57; 8.42]	[7.62; 8.08]
Min-Max	5.9 - 9.7	6.5 - 9.7	5.9 - 9.3
Median	7.80	7.90	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.70	7.35 - 8.40
After 24 weeks			
n	68	20	48
Mean (SD)	7.74 (0.76)	7.75 (0.85)	7.74 (0.73)
95% CI	[7.56; 7.93]	[7.35; 8.14]	[7.53; 7.96]
Min-Max	5.8 - 9.8	6.4 - 9.8	5.8 - 9.2
Median	7.80	7.80	7.75
Q1-Q3	7.20 - 8.20	7.10 - 7.95	7.20 - 8.25
Change from Week 12			
n	66	20	46
Mean (SD)	-0.15 (0.57)	-0.25 (0.59)	-0.10 (0.56)
95% CI	[-0.29; -0.01]	[-0.53; 0.03]	[-0.27; 0.06]
Min-Max	-1.7 - 1.8	-1.7 - 0.8	-1.3 - 1.8
Median	-0.15	-0.25	-0.10
Q1-Q3	-0.50 - 0.20	-0.55 - 0.20	-0.40 - 0.20
t-test	p = 0.040	p = 0.075	p = 0.222

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, Q = quartile, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 3.3.1

Within FAS, mean change in HbA_{1c} (%) from Week 12 to Week 24 was -0.15% (p = 0.040). Mean change between Week 12 to Week 24 was -0.25% in FGM patients (p = 0.075) and -0.10% in SMBG patients (p = 0.222); therefore, both were not statistically significant (Appendix II, Table 3.3.1).

Mean changes in HbA_{1c} (%) from start of iGlarLixi treatment to Week 12 and Week 24, respectively, within FAS subgroups are presented in Table 14.

Table 14: Absolute change in HbA_{1c} (%) under iGlarLixi from baseline until 12 and 24 weeks, respectively, in FAS subgroups

Subgroup	Timepoint	N	Mean (SD)	P (t-test)
Gender				
Female	Baseline	28	8.44 (0.82)	
	Change Week 12	27	-0.51 (0.74)	p = 0.001
	Change Week 24	26	-0.74 (0.80)	p < 0.001
Male	Baseline	42	8.57 (0.83)	
	Change Week 12	41	-0.72 (0.81)	p < 0.001
	Change Week 24	42	-0.74 (0.83)	p < 0.001
Age groups				
≤60 years	Baseline	24	8.68 (1.00)	
	Change Week 12	24	-0.63 (0.88)	p = 0.002
	Change Week 24	24	-0.98 (1.06)	p < 0.001
>60 to <70 years	Baseline	24	8.48 (0.72)	
	Change Week 12	23	-0.67 (0.77)	p < 0.001

		Change Week 24	24	-0.73 (0.71)	p < 0.001
	≥70 years	Baseline	22	8.39 (0.71)	
		Change Week 12	21	-0.60 (0.71)	p = 0.001
		Change Week 24	20	-0.47 (0.45)	p < 0.001
	BMI				
	<30 kg/m^2	Baseline	18	8.75 (0.85)	
		Change Week 12	18	-0.64 (0.77)	p = 0.003
		Change Week 24	16	-0.58 (0.65)	p = 0.003
	≥30 kg/m^2	Baseline	52	8.44 (0.80)	
		Change Week 12	50	-0.63 (0.80)	p < 0.001
		Change Week 24	52	-0.79 (0.86)	p < 0.001
	Renal function				
	≤60ml/min/1.73	Baseline	17	8.64 (0.70)	
		Change Week 12	17	-0.75 (0.76)	p = 0.001
		Change Week 24	15	-0.43 (0.51)	p = 0.005
	>60ml/min/1.73	Baseline	39	8.31 (0.70)	
		Change Week 12	38	-0.44 (0.73)	p = 0.001
		Change Week 24	39	-0.65 (0.74)	p < 0.001
	Duration of diabetes				
	Up to 5 years	Baseline	7	8.37 (1.00)	
		Change Week 12	7	-0.81 (1.06)	p = 0.091
		Change Week 24	7	-0.98 (1.06)	p = 0.049
	5 to 10 years	Baseline	21	8.72 (0.88)	
		Change Week 12	21	-0.65 (0.99)	p = 0.007
		Change Week 24	19	-0.78 (1.08)	p = 0.006
	>10 years	Baseline	39	8.47 (0.78)	
		Change Week 12	37	-0.60 (0.63)	p < 0.001
		Change Week 24	39	-0.69 (0.63)	p < 0.001
	Baseline HbA_{1c}				
	<8.5%	Baseline	38	7.89 (0.30)	
		Change Week 12	36	-0.37 (0.61)	p = 0.001
		Change Week 24	38	-0.46 (0.58)	p < 0.001
	≥8.5%	Baseline	32	9.26 (0.58)	
		Change Week 12	32	-0.93 (0.86)	p < 0.001
		Change Week 24	30	-1.10 (0.92)	p < 0.001
	Previous basal insulin therapy				
	Detemir	Baseline	11	8.69 (0.87)	
		Change Week 12	11	-0.65 (0.66)	p = 0.009
		Change Week 24	11	-0.91 (0.85)	p = 0.005
	Glargine 100	Baseline	24	8.57 (0.77)	
		Change Week 12	22	-0.49 (0.85)	p = 0.013
		Change Week 24	23	-0.83 (0.90)	p < 0.001
	Glargine 300	Baseline	29	8.45 (0.88)	
		Change Week 12	29	-0.79 (0.76)	p < 0.001
		Change Week 24	29	-0.72 (0.77)	p < 0.001
	Degludec	Baseline	6	8.33 (0.75)	
		Change Week 12	6	-0.38 (0.85)	p = 0.321
		Change Week 24	5	-0.12 (0.23)	p = 0.305
	Time of iGlarLixi administration				

	Before breakfast	Baseline	28	8.53 (0.89)	
		Change Week 12	27	-0.70 (0.92)	p = 0.001
		Change Week 24	27	-0.77 (0.87)	p < 0.001
	Before lunch	Baseline	9	8.33 (0.59)	
		Change Week 12	9	-0.37 (0.37)	p = 0.018
		Change Week 24	9	-0.44 (0.34)	p = 0.004
	Before dinner	Baseline	32	8.58 (0.84)	
		Change Week 12	32	-0.66 (0.74)	p < 0.001
		Change Week 24	31	-0.82 (0.86)	p < 0.001

BMI = body mass index, FAS = full analysis set, SD = standard deviation
Source: Appendix II: Tables 3.1.2 to 3.1.9 and 3.2.2 to 3.2.98

Within the FAS subgroups analysed, mean absolute reductions in HbA_{1c} from iGlarLixi treatment start at baseline until Week 12 and Week 24, respectively, were statistically significant, except for patients with duration of diabetes up to 5 years (p = 0.091, Week 12, N = 7) and previous basal insulin therapy with degludec (p = 0.321, Week 12, N = 6; p = 0.305, Week 24, N = 6) (Appendix II, Tables 3.1.2 to 3.1.9 and 3.2.2 to 3.2.9).

Other analyses:

Secondary efficacy endpoints

Detailed statistical analysis of the secondary efficacy criteria including subgroup analyses can be found in Appendix II, Tables 4.1.1 to 4.12.9.10.

Relative change of HbA_{1c} under iGlarLixi

Relative change from baseline to Week 12 and Week 24 in HbA_{1c} (%) under iGlarLixi treatment is summarized in Table 15.

Table 15: Relative change in HbA_{1c} (%) under iGlarLixi after 12 and 24 weeks (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.82)	8.44 (0.76)	8.55 (0.85)
95% CI	[8.32; 8.71]	[8.09; 8.80]	[8.31; 8.79]
Median	8.30	8.25	8.45
Relative change from baseline after 12 weeks			
n	68	20	48
Mean (SD)	-7.11 (8.63)	-5.23 (7.43)	-7.89 (9.04)
95% CI	[-9.20; -5.02]	[-8.711; -1.75]	[-10.52; -5.27]
Median	-6.18	-5.23	-7.31
Relative change from baseline after 24 weeks			
n	66	20	46
Mean (SD)	-8.58 (8.72)	-8.06 (8.23)	-8.81 (9.01)
95% CI	[10.73; -6.44]	[-11.91; -4.21]	[-11.48; -6.13]
Median	-6.45	-7.21	-6.44

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose
Source: Appendix II: Tables 4.1.1.1, 4.1.2.1

Within the FAS population, a mean relative change from baseline of -7.11% after 12 weeks and of -8.58% after 24 weeks was documented. Excluded zeros from the 95% confidence intervals of changes indicate significance of changes (p < 0.05). Changes from baseline were slightly greater in

the SMBG group vs FGM group; however, baseline HbA_{1c} was slightly higher in the SMBG group vs FGM group (Appendix II: Tables 4.1.1.1, 4.1.2.1).

Absolute and relative change in fasting self-measured blood glucose

The absolute and relative changes in fasting self-measured blood glucose at baseline and in 4 weeks intervals of follow-up are shown in detail in Table 4.7.1.2, Appendix II. Table 16 depicts the absolute changes from baseline after 4, 8, 12, 16, 20 and 24 weeks of iGlarLixi treatment.

Table 16: Self-measured fasting glucose levels (mg/dL) at baseline and absolute changes from baseline to Week 4, 8, 12, 16, 20 and 24 (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
Baseline			
n	68	20	48
Mean (SD)	174.34 (44.59)	159.31 (27.28)	180.60 (48.96)
95% CI	[163.55; 185.13]	[146.54; 172.08]	[166.39; 194.82]
Median	162.50	159.00	167.00
Change to base-line after 4 weeks			
n	48	15	33
Mean (SD)	-20.20 (32.86)	-26.03 (24.15)	-17.55 (36.16)
95% CI	[-29.74; -10.66]	[-39.40; -12.66]	[-30.37; -4.73]
Median	-23.00	-21.00	-24.00
t-test	p < 0.001	p = 0.001	p= 0.009
Change to base-line after 8 weeks			
n	46	14	32
Mean (SD)	-19.28 (37.63)	-26.47 (29.18)	-16.14 (40.80)
95% CI	[-30.46; -8.11]	[-43.31; -9.62]	[-30.85; -1.43]
Median	-17.00	-18.00	-13.00
t-test	p = 0.001	p = 0.005	p= 0.033
Change to base-line after 12 weeks			
n	65	20	45
Mean (SD)	-27.60 (48.25)	-17.15 (36.59)	-32.25 (52.30)
95% CI	[-39.56; -15.65]	[-34.27; -0.02]	[-47.97; -16.54]
Median	-29.00	-15.00	-34.23
t-test	p < 0.001	p = 0.050	p < 0.001
Change to base-line after 16 weeks			
n	43	14	29
Mean (SD)	-26.31 (34.79)	-35.87 (36.64)	-21.69 (33.53)
95% CI	[-37.01; -15.60]	[-57.02; -14.71]	[-34.45; -8.94]
Median	-21.00	-26.61	-16.22
t-test	p < 0.001	p = 0.003	p= 0.002
Change to base-line after 20 weeks			
n	39	16	23
Mean (SD)	-28.16 (37.44)	-30.79 (39.28)	-26.33 (36.88)
95% CI	[-40.29; -16.02]	[-51.72; -9.85]	[-42.28; -10.38]
Median	-24.00	-32.00	-19.00
t-test	p < 0.001	p = 0.007	p= 0.002

Change to base-line after 24 weeks			
n	62	19	43
Mean (SD)	-32.87 (46.33)	-21.18 (31.96)	-38.04 (50.90)
95% CI	[-44.64; -21.11]	[-36.58; -5.77]	[-53.70; -22.38]
Median	-22.50	-21.00	-25.00
t-test	p < 0.001	p = 0.010	p < 0.001

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Table 4.7.1.2

Mean baseline fasting plasma glucose levels (FAS: 174.34 mg/dL, FGM patients: 159.31 mg/dL, SMBG patients: 180.60 mg/dL) were markedly different between FGM vs SMBG group, being lower at baseline in the FGM group. Both were reduced during treatment with iGlarLixi in FAS, FGM, and SMBG patients. At Week 24, mean changes were -32.87 mg/dL (FAS), -21.18 mg/dL (FGM patients), and -38.04 mg/dL (SMBG patients). For each timepoint from Week 4 to Week 24, absolute changes from baseline were statistically significant (Appendix II: Table 4.7.1.2).

Proportion of patients who achieved their individual HbA_{1c} target value and fasting plasma glucose levels ≤110 mg/dL

The proportions of patients who achieved their individual HbA_{1c} target value and fasting plasma glucose levels ≤110 mg/dL are presented in Table 17.

Table 17: Achievement of individual HbA_{1c} target values and fasting blood glucose ≤110 mg/dL (FAS patients, FGM patients and SMBG patients)

Parameter Week Statistics	FAS N=70	FGM N=20	SMBG N=50
Achievement of individual HbA_{1c} target values			
Week 0-12			
n (%)	8 (11.43)	2 (10.00)	6 (12.00)
95% CI	[5.07; 21.28]	[1.23; 31.70]	[4.53; 24.31]
Week 13-24			
n (%)	9 (12.86)	3 (15.00)	6 (12.00)
95% CI	[6.05; 23.01]	[3.21; 37.89]	[4.53; 24.31]
Week 0-24[1]			
n (%)	12 (17.14)	4 (20.00)	8 (16.00)
95% CI	[9.18; 28.03]	[5.73; 43.66]	[7.17; 29.11]
First achieved at			
Week 12			
n (%)	8 (11.43)	2 (10.00)	6 (12.00)
Week 24			
n (%)	4 (5.71)	2 (10.00)	2 (4.00)
Failed			
n (%)	58 (82.86)	16 (80.00)	42 (84.00)
Stayed below target			
n (%)	5 (7.14)	1 (5.00)	4 (8.00)
95% CI	[2.36; 15.89]	[0.13; 24.87]	[2.22; 19.23]
Achieving fasting blood glucose ≤110 mg/dL			
Week 0-12			
n (%)	15 (21.43)	5 (25.00)	10 (20.00)

95% CI	[12.52; 32.87]	[8.66; 49.10]	[10.03; 33.72]
Week 13-24			
n (%)	17 (24.29)	5 (25.00)	12 (24.00)
95% CI	[14.83; 36.01]	[8.66; 49.10]	[13.06; 38.17]
Week 0-24[1]			
n (%)	21 (30.00)	5 (25.00)	16 (32.00)
95% CI	[19.62; 42.13]	[8.66; 49.10]	[19.52; 46.70]

[1] Individual HbA_{1c} target value reached at Week 0-12 or Week 13-24

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, SMBG = self-measured plasma glucose

Source: Appendix II: Tables 4.3.1.1, 4.3.2.1, 4.3.3.1, 4.4.1

At the end of observation, individual HbA_{1c} target values were reached by 17.14% of FAS patients, by 20.0% of FGM patients, and by 16.0% of SMBG patients. In most cases, the individual HbA_{1c} target value was reached at Week 12 (11.43%, FAS) with only marginal differences between groups. In 7.14% of FAS patients, HbA_{1c} stayed below the target value. (Appendix II: Tables 4.3.1.1, 4.3.2.1, 4.3.3.1).

After 24 weeks of treatment, fasting plasma glucose ≤110 mg/dL was achieved by 30.0% of FAS patients, by 25% of FGM patients, and by 32% of SMBG patients (Appendix II: Table 4.4.1)

Absolute change in 7-point SMBG daily profiles

Values of SMBG measurements for each of the 7 measurement time points are provided in detail in Appendix II, Tables 4.5.1.1.1 to 4.5.1.1.7 (0-12 weeks) and in Appendix II, Tables 4.5.1.2.1 to 4.5.1.2.7 (0-24 weeks). For each patient median values of the 7-point SMBG measurements (at baseline, after 12 and 24 weeks, and changes of these median values after 12 and 24 weeks) were calculated. Mean values and absolute changes in the median of 7-point SMBG daily profiles from baseline to Week 12 and Week 24 are presented in Table 18 (FAS) and Table 19 (FGM and SMBG).

Table 18: Absolute changes in the median of 7-point SMBG daily profiles (mg/dL) from baseline to Week 12 and Week 24 (FAS patients)

Parameter	**FAS**	
Statistics	**N=70**	
Baseline		
n	45	
Mean (SD)	195.53 (42.89)	
95% CI	[182.65; 208.42]	
Median	189.19	
Post	Week 12	Week 24
n	41	33
Mean (SD)	161.76 (31.31)	158.00 (26.71)
95% CI	[151.88; 171.65]	[148.53; 167.47]
Median	162.00	151.00
Absolute change from baseline		
n	32	28
Mean (SD)	-24.83 (36.35)	-24.77 (39.58)
95% CI	[-37.93; -11.73]	[-40.11; -9.42]
Median	-14.50	-29.00
t-test	P = 0.001	p = 0.003

CI = confidence interval, FAS = full analysis set, SD = standard deviation

Source: Appendix II: Tables 4.5.1.1.8, 4.5.1.2.8

Table 19: Absolute changes in the median of 7-point SMBG daily profiles (mg/dL) from baseline to Week 12 and Week 24 (FGM patients and SMBG patients)

Parameter Statistics	FGM N=20		SMBG N=50	
Baseline				
n	9		36	
Mean (SD)	180.57 (24.44)		199.27 (45.87)	
95% CI	[161.78; 199.36]		[183.75; 214.79]	
Median	172.00		198.50	
Post	Week 12	Week 24	Week 12	Week 24
n	7	8	34	25
Mean (SD)	163.16 (16.88)	156.27 (22.30)	161.47 (33.71)	158.55 (28.38)
95% CI	[147.55;178.77]	[137.63;174.91]	[149.71;173.24]	[146.84;170.26]
Median	167.00	154.50	160.28	150.50
Absolute change from baseline				
n	7	7	25	21
Mean (SD)	-21.01 (28.30)	-28.29 (20.85)	-25.90 (38.74)	-23.59 (44.48)
95% CI	[-47.18; 5.16]	[-47.58; -9.01]	[-41.89; -9.91]	[-43.84; -3.34]
Median	-8.00	-27.00	-21.00	-31.00
t-test	p = 0.097	p = 0.012	p = 0.003	p = 0.025

CI = confidence interval, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose
Source: Appendix II: Tables 4.5.1.1.8, 4.5.1.2.8

Within the FAS population, relevant and statistically significant changes to the median baseline values of 7-point SMBG daily profiles (195.53 mg/dL) were documented at Week 12 and Week 24. Mean absolute change at Week 12 was -24.83 mg/dL (p = 0.001). Mean absolute change at Week 24 was -24.77 mg/dL (p = 0.003). Changes to the median baseline values in SMBG patients (Week 12: p = 0.003: Week 24: p = 0.025) were also statistically significant. In FGM patients, statistical significance was only reached for Week 24 (p = 0.012) (Appendix II: Tables 4.5.1.1.8, 4.5.1.2.8).

Derived time in range (dTIR), below range (dTBR), and above range (dTAR) based on 7-point SMBG daily measurements (at baseline, after 12 weeks, after 24 weeks) were calculated. Summary statistics are presented in Table 20.

Table 20: Derived time in/below/above range (percentage of dTIR, dTBR, dTAR of all measurements of the day) based on 7-point SMBG daily profiles (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
dTIR			
Baseline			
n	34	9	25
Mean (SD)	40.3 (31.35)	50.8 (25.86)	36.6 (32.75)
Median	42.9	57.1	28.6
After 12 weeks			
n	29	7	22
Mean (SD)	61.6 (31.74)	77.6 (29.57)	56.5 (31.32)
Median	71.4	85.7	64.3
After 24 weeks			
n	25	8	17
Mean (SD)	75.4 (23.52)	82.1 (26.18)	72.3 (22.29)
Median	85.7	92.9	71.4

dTBR			
Baseline			
n	34	9	25
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
After 12 weeks			
n	29	7	22
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
After 24 weeks			
n	25	8	17
Mean (SD)	0.6 (2.86)	0.0 (0.00)	0.8 (3.46)
dTAR			
Baseline			
n	34	9	25
Mean (SD)	59.7 (31.35)	49.2 (25.86)	63.4 (32.75)
Median	57.1	42.9	71.4
After 12 weeks			
n	29	7	22
Mean (SD)	38.4 (31.74)	22.4 (29.57)	43.5 (31.32)
Median	28.6	14.3	35.7
After 24 weeks			
n	25	8	17
Mean (SD)	24.0 (22.86)	17.9 (26.18)	26.9 (21.36)
Median	14.3	7.1	28.6

dTAR = derived time above range, dTBR = derived time below range, dTIR = derived time in range, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.5.1.3.1, 4.5.1.3.2, 4.5.1.3.3

At baseline, mean dTIR was 40.3% in FAS patients, 50.8% in FGM patients, and 36.6% in SMBG patients. During treatment with iGlarLixi, a clinically relevant increase in mean dTIR was observed at Week 12 and Week 24 in all groups. After 24 weeks, the respective values were 75.4% (FAS), 82.1% FGM patients, and 72.3% (SMBG patients).

Mean dTBR was 0.0% at baseline and Week 12 in all groups and 0.6%, (FAS), 0.0% (FGM patients), and 0.8% (SMBG patients) at Week 24.

A clinically relevant decrease in mean dTAR was documented in FAS patients, FGM patients and SMBG patients between baseline and Week 24. Mean baseline values were reduced from 59.7% to 24.0% in FAS patients, from 49.2% to 17.9% in FGM patients, and from 63.4% to 26.9% in SMBG patients (Appendix II: Tables 4.5.1.3.1, 4.5.1.3.2, 4.5.1.3.3).

FGM-derived time in range (TIR), time below range (TBR) and time above range (TAR) in FGM patients

FGM-derived TIR, TBR and TAR measurements were documented for FGM patients (at baseline, after 12 weeks, after 24 weeks). Summary statistics are presented in Table 21.

Table 21: FGM-derived time in/below/above range (percentage of TIR, TBR, TAR) (FGM patients)

Parameter Statistics	Total time in range (TIR) [%]	Total time above range (TAR) [%]	Total time below range (TBR) [%]
Baseline			
n	20	20	20
Mean (SD)	56.50 (18.30)	36.50 (16.47)	6.85 (8.14)
Median	57.00	34.00	4.50
After 12 weeks			
n	17	17	17

Mean (SD)	64.82 (24.37)	31.82 (23.76)	3.35 (6.77)
Median	75.00	25.00	0.00
Absolute change after 12 weeks			
n	17	17	17
Mean (SD)	5.06 (18.66)	-0.94 (19.35)	-4.12 (6.49)
Median	9.00	-7.00	-2.00
t-test	p= 0.280	p= 0.844	p= 0.019
After 24 weeks			
n	16	16	16
Mean (SD)	74.50 (11.18)	22.56 (10.25)	3.50 (6.07)
Median	77.50	22.00	0.00
Absolute change after 24 weeks			
n	16	16	16
Mean (SD)	15.19 (16.43)	-10.19 (13.57)	-4.44 (5.72)
Median	13.00	-11.00	-2.50
t-test	p= 0.002	p= 0.009	p= 0.007

FGM = flash glucose monitoring, SD = standard deviation, TAR = time above range, TBR = time below range, TIR = time in range

Source: Appendix II: Tables 5.1.2.1, 5.1.2.2, 5.1.2.3

At baseline, mean TIR was 56.5% in FGM patients. During treatment with iGlarLixi, a clinically relevant increase in mean TIR to 64.8% was observed at Week 12 (difference 5.06%, p = 0.280, n = 17) and to 74.5% at Week 24 (difference 15.19%, p = 0.002, n = 16), respectively.

Mean TBR was 6.9% at baseline, which was markedly reduced to 3.4% at Week 12 (difference -4.12%, p = 0.019, n = 17) and 3.5% at Week 24 (difference -4.44%, p = 0.007, n = 16), respectively.

A clinically relevant decrease in mean TAR was documented in FGM patients between baseline (36.5%) and Week 24 (22.6%, difference -10.19, p = 0.009, n = 16) (Appendix II: Tables 5.1.2.1, 5.1.2.2, 5.1.2.3).

Absolute changes in iGlarLixi dose (dose steps/day)

Absolute changes in iGlarLixi dose (dose steps/day [DS/d]) from baseline to Week 12 and Week 24 are shown in Table 22 (FAS patients) and Table 23 (FGM patients and SMBG patients).

Table 22: Absolute changes in iGlarLixi dose (DS/d) from baseline to Week 12 and Week 24 (FAS patients)

Parameter **Statistics**	**FAS N=70**	
Baseline		
n	70	
Mean (SD)	30.00 (0.00)	
Median	30.00	
Post	Week 12	Week 24
n	65	64
Mean (SD)	40.11 (9.75)	41.14 (9.52)
95% CI	[37.69; 42.52]	[38.76; 43.52]
Median	38.00	40.00
Absolute change from baseline		
n	65	64
Mean (SD)	10.11 (9.75)	11.14 (9.52)
95% CI	[7.69; 12.52]	[8.76; 13.52]

Median	8.00	10.00
t-test	p < 0.001	p < 0.001

CI = confidence interval, DS/d = dose steps/day, FAS = full analysis set, SD = standard deviation
Source: Appendix II: Tables 4.6.1.1, 4.6.1.2

Table 23: Absolute changes in iGlarLixi dose (DS/d) from baseline to Week 12 and Week 24 (FGM patients and SMBG patients)

Parameter Statistics	FGM N=20		SMBG N=50	
Baseline				
n	20		50	
Mean (SD)	30.00 (0.00)		30.00 (0.00)	
Median	30.00		30.00	
Post	Week 12	Week 24	Week 12	Week 24
n	20	20	45	44
Mean (SD)	41.65 (9.15)	43.30 (9.76)	39.42 (10.03)	40.16 (9.36)
95% CI	[37.37; 45.93]	[38.73; 47.87]	[36.41; 42.44]	[37.31; 43.00]
Median	39.00	41.00	36.00	39.00
Absolute change from baseline				
n	20	20	45	44
Mean (SD)	11.65 (9.15)	13.30 (9.76)	9.42 (10.03)	10.16 (9.36)
95% CI	[7.37; 15.93]	[8.73; 17.87]	[6.41; 12.44]	[7.31; 13.00]
Median	9.00	11.00	6.00	9.00
t-test	p < 0.001	p < 0.001	p < 0.001	p < 0.001

CI = confidence interval, DS/d = dose steps/day, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose
Source: Appendix II: Tables 4.6.1.1, 4.6.1.2

In FAS patients, mean dose of iGlarLixi increased markedly after 12 weeks (40.11 DS/d), but only little further after 24 weeks (41.14 DS/d); both increases were significant compared to baseline (30.00 DS/d).

The mean absolute change at Week 12 was 10.11 DS/d (p < 0.001). The mean absolute change at Week 24 was 11.14 DS/d (p < 0.001). The respective values for FGM patients and SMBG patients were comparable, although SMBG patients had slightly lower doses vs FGM patients after 12 and 24 weeks, respectively (Appendix II: Tables 4.6.1.1, 4.6.1.2).

The number of iGlarLixi dose changes within the last 4 weeks after 4, 8, 12, 16, 20 and 24 weeks are shown in Table 24.

Table 24: Number of iGlarLixi dose changes within the last 4 weeks after 4, 8, 12, 16, 20 and 24 weeks (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
After 4 weeks			
n	53	16	37
Mean (SD)	2.32 (3.98)	3.63 (5.81)	1.76 (2.77)
95% CI	[1.23; 3.42]	[0.53; 6.72]	[0.83; 2.68]
Median	1.00	1.00	1.00
After 8 weeks			
n	52	16	36
Mean (SD)	0.98 (1.49)	0.81 (1.56)	1.06 (1.47)

95% CI	[0.57; 1.40]	[-0.02; 1.64]	[0.56; 1.55]
Median	0.00	0.00	0.50
After 12 weeks			
n	63	20	43
Mean (SD)	1.76 (3.03)	1.60 (2.91)	1.84 (3.11)
95% CI	[1.00; 2.52]	[0.24; 2.96]	[0.88; 2.79]
Median	1.00	0.00	1.00
After 16 weeks			
n	48	16	32
Mean (SD)	0.35 (0.60)	0.25 (0.45)	0.41 (0.67)
95% CI	[0.18; 0.53]	[0.01; 0.49]	[0.17; 0.65]
Median	0.00	0.00	0.00
After 20 weeks			
n	49	16	33
Mean (SD)	0.29 (0.61)	0.19 (0.55)	0.33 (0.65)
95% CI	[0.11; 0.46]	[-0.10; 0.48]	[0.10; 0.56]
Median	0.00	0.00	0.00
After 24 weeks			
n	64	19	45
Mean (SD)	1.58 (6.79)	0.53 (1.17)	2.02 (8.05)
95% CI	[-0.12; 3.28]	[-0.04; 1.09]	[-0.40; 4.44]
Median	0.00	0.00	0.00

CI = confidence interval, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Table 4.6.1.3

Highest mean number of dose changes in FAS patients within the last 4 weeks of treatment were observed after 4 weeks (2.32), after 12 weeks (1.76), and after 24 weeks (1.58). Data documented for FGM patients and SMBG patients showed that FGM patients increased their dose more often in the first 4 weeks after iGlarLixi treatment start (3.63) and less often after 12 weeks (1.60) and 24 weeks 0.53), respectively. In contrast, SMBG patients increased their dose similarly often in the first 4 weeks (1.76) and after 12 weeks (1.84), but more often after 24 weeks (2.02). (Appendix II: Table 4.6.1.3).

Absolute and relative change in fasting blood glucose (laboratory values)

The absolute and relative change in fasting blood glucose (laboratory values) after 12 and 24 weeks with analyses of missing values as documented and last observation carried forward (LOCF) are depicted in Table 25 (FAS patients) and Table 26 (FGM patients and SMBG patients).

Table 25: Absolute and relative change in fasting blood glucose (mg/dL) after 12 weeks and 24 weeks (FAS patients)

Parameter	**FAS**	
Statistics [1]	**N=70**	
	Missing values	
	As documented	LOCF
Baseline		
n	53	
Mean (SD)	185.33 (63.68)	
95% CI	[167.78; 202.88]	
Median	170.00	
After 12 weeks		
n	48	61
Mean (SD)	150.63 (43.87)	159.18 (51.52)

	95% CI	[137.90; 163.37]	[145.982; 172.37]
	Median	141.50	149.55
	Absolute change from baseline		
	n	40	53
	Mean (SD)	-26.90 (57.63)	-20.30 (51.26)
	95% CI	**[-45.33; -8.47]**	**[-34.43; -6.17]**
	Median	-24.00	0.00
	Relative change from baseline		
	n	40	53
	Mean (SD)	-8.93 (28.14)	-6.74 (24.67)
	95% CI	[-17.93; 0.07]	[-13.54; 0.06]
	Median	-15.56	0.00
	After 24 weeks		
	n	47	63
	Mean (SD)	143.54 (41.03)	155.57 (54.90)
	95% CI	[131.49; 155.59]	[141.74; 169.40]
	Median	134.00	144.00
	Absolute change from baseline		
	n	39	53
	Mean (SD)	-18.38 (49.71)	-22.25 (53.18)
	95% CI	**[-34.49; -2.27]**	**[-36.90; -7.59]**
	Median	-21.00	-5.60
	Relative change from baseline (%)		
	n	39	53
	Mean (SD)	-6.75 (26.87)	-8.15 (26.55)
	95% CI	[-15.46; 1.95]	**[-15.47; -0.84]**
	Median	-12.28	-6.47

[1] Significance of changes due to excluded zeros from the 95% confidence intervals are marked in bold letters ($p < 0.05$)
CI = confidence interval, FAS = full analysis set, LOCF = last observation carried forward, SD = standard deviation
Source: Appendix II: Tables 4.2.1.1.1, 4.2.1.1.2

Table 26: Absolute and relative change in fasting blood glucose (mg/dL) after 12 weeks and 24 weeks (FGM patients and SMBG patients)

Parameter	**FGM**		**SMBG**	
Statistics	**N=20**		**N=50**	
	Missing values		Missing values	
	As documented	LOCF	As documented	LOCF
Baseline				
n	17		36	
Mean (SD)	177.17 (47.79)		189.19 (70.23)	
95% CI	[152.60; 201.74]		[165.42; 212.95]	
Median	166.00		171.50	
After 12 weeks				
n	13	17	35	44
Mean (SD)	144.73 (30.75)	155.73 (45.65)	152.83 (48.05)	160.51 (54.06)
95% CI	[126.15; 163.32]	[132.26; 179.20]	[136.32; 169.33]	[144.07; 176.94]
Median	145.00	149.55	137.00	147.00
Absolute change from baseline				
n	13	17	27	36

	Mean (SD)	-28.04 (49.32)	-21.44 (44.43)	-26.35 (62.12)	-19.76 (54.77)
	95% CI	[-57.84; 1.76]	[-44.29; 1.41]	**[-50.92; -1.78]**	**[-38.30; -1.23]**
	Median	-8.00	0.00	-26.00	-0.50
	Relative change from baseline				
	n	13	17	27	36
	Mean (SD)	-12.58 (24.12)	-9.62 (21.60)	-7.17 (30.15)	-5.38 (26.18)
	95% CI	[-27.16; 1.99]	[-20.73; 1.48]	[-19.10; 4.76]	[-14.23; 3.48]
	Median	-5.06	0.00	-0.34	-0.34
	After 24 weeks				
	n	14	18	33	45
	Mean (SD)	149.07 (38.63)	154.15 (52.01)	141.20 (42.37)	156.14 (56.58)
	95% CI	149.07 (38.63)	154.15 (52.01)	[126.18; 156.22]	[139.14; 173.14]
	Median	141.00	149.78	134.00	143.00
	Absolute change from baseline				
	n	13	17	26	36
	Mean (SD)	-13.82 (50.21)	-21.71 (51.73)	-20.66 (50.29)	-22.50 (54.57)
	95% CI	[-44.16; 16.53]	[-48.31; 4.88]	**[-40.97; -0.35]**	**[-40.96; -4.04]**
	Median	-21.00	-21.00	-20.00	-4.80
	Relative change from baseline (%)				
	n	13	17	26	36
	Mean (SD)	-6.00 (25.80)	-10.07 (26.55)	-7.13 (27.88)	-7.25 (26.88)
	95% CI	[-21.59; 9.59]	[-23.72; 3.58]	[-18.40; 4.13]	[-16.34; 1.85]
	Median	-12.28	-12.28	-12.24	-4.17

[1] Significance of changes due to excluded zeros from the 95% confidence intervals are marked in bold ($p < 0.05$)

CI = confidence interval, FGM = flash glucose monitoring, LOCF = last observation carried forward, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.2.1.1.1, 4.2.1.1.2

In FAS patients, mean baseline fasting blood glucose (laboratory values) was 185.33 mg/dL. At Week 12 and Week 24, clinically relevant mean absolute (-26.90 mg/dL and -18.38 mg/dL, respectively), and mean relative reductions (-8.93% and -6.75%, respectively) from baseline values were documented. Results from the LOCF analysis were comparable. This was also due for FGM patients and SMBG patients. Significance of changes due to excluded zeros from the 95% confidence intervals ($p < 0.05$) was reached for absolute changes from baseline to Week 12 and Week 24 in both analyses of FAS patients and SMBG patients (missing values as documented and LOCF). (Appendix II: Tables 4.2.1.1.1, 4.2.1.1.2).

Absolute changes in body weight and BMI

Absolute changes in body weight and BMI from baseline to Week 12 and Week 24 of treatment with iGlarLixi are presented in Table 27 (FAS patients) and Table 28 (FGM patients and SMBG patients).

Table 27: Absolute changes in body weight (kg) and BMI (kg/m^2) from baseline to Week 12 and Week 24 (FAS patients)

Parameter Statistics	FAS N=70
	Body weight (kg)
Baseline	
n	68
Mean (SD)	104.25 (22.53)
95% CI	[98.80; 109.70]
Median	103.00

	Week 12	Week 24
Absolute change from baseline		
n	59	68
Mean (SD)	-1.41 (5.38)	-2.96 (7.53)
95% CI	[-2.81; -0.01]	[-4.79; -1.14]
Median	0.00	-1.00
t-test	P = 0.048	p = 0.002
	BMI (kg/m²)	
Baseline		
n	68	
Mean (SD)	35.10 (7.17)	
95% CI	[33.37; 36.84]	
Median	34.44	
	Week 12	Week 24
Absolute change from baseline		
n	59	68
Mean (SD)	-0.48 (1.77)	-1.01 (2.50)
95% CI	[-0.94; -0.02]	[-1.61; -0.40]
Median	0.00	-0.31
t-test	p = 0.042	p = 0.001

CI = confidence interval, BMI = body mass index, FAS = full analysis set, SD = standard deviation
Source: Appendix II: Tables 4.8.1.1, 4.8.1.2, 4.9.1.1, 4.9.1.2

Table 28: Absolute changes in body weight (kg) and BMI (kg/m²) from baseline to Week 12 and Week 24 (FGM patients and SMBG patients)

Parameter Statistics	**FGM N=20**		**SMBG N=50**	
	Body weight (kg)			
Baseline				
n	20		48	
Mean (SD)	107.00 (23.11)		103.10 (22.44)	
95% CI	[96.18; 117.82]		[96.59; 109.62]	
Median	103.50		98.50	
	Week 12	Week 24	Week 12	Week 24
Absolute change from baseline				
n	16	20	43	48
Mean (SD)	-1.99 (4.10)	-4.46 (6.05)	-1.20 (5.81)	-2.34 (8.04)
95% CI	[-4.18; 0.19]	[-7.29; -1.62]	[-2.98; 0.59]	[-4.68; -0.01]
Median	-1.50	-2.50	0.00	-0.35
t-test	p = 0.070	p = 0.004	p = 0.184	p = 0.049
	BMI (kg/m²)			
Baseline				
n	20		48	
Mean (SD)	35.82 (7.64)		34.81 (7.02)	
95% CI	[32.24; 39.39]		[32.77; 36.85]	
Median	34.24		34.44	
	Week 12	Week 24	Week 12	Week 24

Absolute change from baseline				
n	16	20	43	48
Mean (SD)	-0.62 (1.32)	-1.50 (2.05)	-0.42 (1.92)	-0.80 (2.66)
95% CI	[-1.33; 0.08]	[-2.46; -0.54]	[-1.01; 0.17]	[-1.57; -0.03]
Median	-0.47	-0.90	0.00	-0.13
t-test	p = 0.077	p = 0.004	p = 0.156	p = 0.042

CI = confidence interval, BMI = body mass index, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.8.1.1, 4.8.1.2, 4.9.1.1, 4.9.1.2

In FAS patients, mean baseline body weight (104.25 kg) was reduced after 12 weeks of treatment with iGlarLixi by -1.41 kg and after 24 weeks by -2.96 kg. Mean baseline BMI (35.10 kg/m^2) was reduced by -0.48 kg/m^2 (Week 12) and -1.01 kg/m^2 (Week 24), respectively. At each timepoint, all mentioned mean changes were statistically significant ($p < 0.05$).

Absolute changes in body weight in FGM patients and SMBG patients were -1.99 kg and -1.20 kg at Week 12, respectively, and -4.46 kg and -2.34 kg at Week 24, respectively. Week 24 values for changes from baseline were statistically significant for both subsets. Absolute changes in BMI were -1.50 kg/m² (FGM) and -0.80 kg/m² (SMBG) after 24 weeks; both changes were statistically significant ($p < 0.05$) (Appendix II: Tables 4.8.1.1, 4.8.1.2, 4.9.1.1, 4.9.1.2).

Absolute changes in the median value of FGM-derived glucose measurements

Absolute changes from baseline to Week 12 and Week 24, respectively, in the median value of FGM-derived glucose measurements in FGM patients are shown in Table 29.

Table 29: Absolute changes in the median value of glucose measurements (mg/dL) in patients using FGM from baseline to Week 12 and Week 24 (FGM patients)

Parameter	**FGM**	
Statistics	**N=20**	
Baseline		
n	20	
Mean (SD)	148.95 (23.81)	
95% CI	[137.81;160.09]	
Median	148.37	
	Week 12	Week 24
Absolute change from baseline		
n	17	16
Mean (SD)	-5.19 (27.68)	-9.53 (21.99)
95% CI	[-19.42; 9.04]	[-21.24; 2.19]
Median	-3.60	-5.80
t-test	p = 0.451	p = 0.104

CI = confidence interval, FGM = flash glucose monitoring, SD = standard deviation

Source: Appendix II: Table 4.10.1.1

Median values of FGM-derived glucose measurements in FGM patients were slightly reduced from baseline (mean: 148.95 mg/dL) to Week 12 (mean: 142.87 mg/dL) and Week 24 (mean: 137.66 mg/dL). The absolute (Week 12: -5.19 mg/dL, p = 0.451; Week 24: -9.53 mg/dL, p = 0.104) and relative changes (Week 12: -2.83%, p = 0.530; Week 24: -5.02%, p = 0.170) to baseline did not reach statistical significance (Appendix II: Table 4.10.1.1).

Incidence and rate of hypoglycaemia

ADA level 1 hypoglycaemia (SMBG < 70 mg/dL and ≥ 54 mg/dL)

	At baseline, for 3 FAS patients 9 ADA level 1 hypoglycaemic events with SMBG values < 70 mg/dL and ≥ 54 mg/dL were documented for the period of 12 weeks before baseline. These 3 patients had 2, 3, and 4 events, respectively. Of those, the 4 events in one patient were nocturnal hypoglycaemia (Appendix II: Tables 4.11.1.1.2, 4.11.1.1.4). ADA level 1 hypoglycaemia incidence at baseline was 4.5% in FAS patients, 5.3% in FGM patients and 4.2% in SMBG patients, respectively. Incidence of nocturnal ADA level 1 hypoglycaemia was 1.5% (FAS), 5.3% (FGM) and 0% (SMBG), respectively (Appendix II: Tables 2.3.1.2.1.1, 2.3.1.2.2.1). Events per patient year (E/PJ) were 0.58 E/PJ (FAS), 0.92 (FGM) and 0.45 (SMBG), respectively. Nocturnal events per patient year were 0.26 E/PJ (FAS), 0.92 E/PJ (FGM) and 0 E/PJ (SMBG), respectively (Appendix II: Tables 2.3.1.2.1.5, 2.3.1.2.2.3). After 12 weeks of iGlarLixi treatment, for 3 FAS patients 4 ADA level 1 hypoglycaemic events with SMBG values < 70 mg/dL and ≥ 54 mg/dL were documented for the period of the last 12 weeks. One patient had 2 events and 2 patients had 1 event documented. One of those was a nocturnal hypoglycaemic event (Appendix II: Tables 4.11.1.1.2, 4.11.1.1.4). ADA level 1 hypoglycaemia incidence after 12 weeks was 4.8% in FAS patients, 0% in FGM patients and 6.5% in SMBG patients, respectively. Incidence of nocturnal ADA level 1 hypoglycaemia was 1.6% (FAS), 0% (FGM) and 2.2% (SMBG), respectively (Appendix II: Tables 4.11.1.1.1, 4.11.1.1.3). Events per patient year were 0.26 E/PJ (FAS), 0 E/PJ (FGM) and 0.36 E/PJ (SMBG), respectively. Nocturnal events per patient year were 0.07 E/PJ (FAS), 0 E/PJ (FGM) and 0.09 E/PJ (SMBG), respectively (Appendix II: Tables 4.11.1.1.2a, 4.11.1.1.4a). After 24 weeks of iGlarLixi treatment, for 2 FAS patients 7 hypoglycaemic events with SMBG values < 70 mg/dL and ≥ 54 mg/dL were documented for the period of the last 12 weeks. One patient had 3 events and 1 patient had 4 events. These 4 events in one patient were nocturnal hypoglycaemic events (Appendix II: Tables 4.11.1.1.2, 4.11.1.1.4). ADA level 1 hypoglycaemia incidence between Week 13 and Week 24 was 3.6% in FAS patients, 0% in FGM patients and 5.1% in SMBG patients, respectively. Incidence of nocturnal ADA level 1 hypoglycaemia was 1.8% (FAS), 0% (FGM) and 2.6% (SMBG), respectively (Appendix II: Tables 4.11.1.1.1, 4.11.1.1.3). Events per patient year were 0.52 E/PJ (FAS), 0 E/PJ (FGM) and 0.73 E/PJ (SMBG), respectively. Nocturnal events per patient year were 0.30 E/PJ (FAS), 0 E/PJ (FGM) and 0.42 E/PJ (SMBG), respectively (Appendix II: Tables 4.11.1.1.2a, 4.11.1.1.4a). **ADA level 2 hypoglycaemia (SMBG < 54 mg/dL)** At baseline, there were no FAS patients, FGM patients and SMBG patients with ADA level 2 hypoglycaemia with SMBG values < 54 mg/dL, respectively (Appendix II: Table 4.11.2.1.1). After 12 weeks of iGlarLixi treatment, for 1 FAS patient 2 ADA level 2 hypoglycaemic events with SMBG values < 54 mg/dL were documented for the period of the last 12 weeks. Nocturnal hypoglycaemia did not occur (Appendix II: Tables 4.11.2.1.1, 4.11.2.1.2, 4.11.2.1.3). ADA level 2 hypoglycaemia incidence after 12 weeks was 1.6% in FAS patients, 0% in FGM patients and 2.2% in SMBG patients, respectively (Appendix II: Table 4.11.2.1.1). Events per patient year were 0.13 E/PJ (FAS), 0 E/PJ (FGM) and 0.18 E/PJ (SMBG), respectively (Appendix II: Table 4.11.2.1.2a). After 24 weeks of iGlarLixi treatment, for 2 FAS patients 5 ADA level 2 hypoglycaemic events with SMBG values < 54 mg/dL were documented. One patient had 1 event and 1 patient had 4 events. Of those 4 events in one patient, 3 events were nocturnal hypoglycaemic events (Appendix II: Tables 4.11.2.1.2, 4.11.2.1.4). ADA level 2 hypoglycaemia incidence between Week 13 and Week 24 was 3.6% in FAS patients, 0% in FGM patients and 5.1% in SMBG patients, respectively. Incidence of nocturnal ADA level 1 hypoglycaemia was 1.8% (FAS), 0% (FGM) and 2.6% (SMBG), respectively (Appendix II: Tables 4.11.2.1.1, 4.11.2.1.3). Events per patient year were 0.37 E/PJ (FAS), 0 E/PJ (FGM) and 0.52 E/PJ (SMBG), respectively. Nocturnal events per patient year were 0.22 E/PJ (FAS), 0 E/PJ (FGM) and 0.31 E/PJ (SMBG), respectively (Appendix II: Tables 4.11.2.1.2a, 4.11.2.1.4a). **Symptomatic hypoglycaemia with unknown SMBG value**

A symptomatic hypoglycaemic event without confirming SMBG measurement occurred in 1 FAS patient (FGM subset) at baseline only (Appendix II: Table 4.11.3).

Severe hypoglycemia

No severe hypoglycaemia was documented in any patient at any timepoint.

Absolute values in treatment satisfaction (DTSQs and DTSQc)

Treatment satisfaction, practicability/comfort, and other therapy related parameters were evaluated using the 8 questions of the diabetes treatment satisfaction questionnaire status (DTSQs) at baseline and Week 24, and of the change version (DTSQc) at Week 24. An overview is given in Table 30 to Table 33. DTQSs questions range on a scale of 0 to 6. Therefore, single parameters can reach values between 0 and 6. A sum score can be calculated for questions 1, 4, 5, 6, 7 and 8, reaching values between 0 to 36, low values indicating treatment problems and high values being favourable. Question 2 (blood glucose unacceptably high) and question 3 (blood glucose unacceptably low) are always evaluated separately, because low values are favourable and high values indicate treatment problems.

Table 30: Impression of patients how often blood glucose was unacceptably low (question 3) or high (question 2) (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
	Impression how often blood glucose was unacceptably low		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	0.92 (1.24)	1.10 (1.02)	0.85 (1.33)
95% CI	[0.62; 1.23]	[0.62; 1.58]	[0.45; 1.24]
Median	0.50	1.00	0.00
Status after 24 weeks (DTSQs)[1]			
n	60	19	41
Mean (SD)	0.78 (1.22)	0.26 (0.56)	1.02 (1.37)
95% CI	[0.47; 1.10]	[-0.01; 0.53]	[0.59; 1.46]
Median	0.00	0.00	0.00
DTSQs, difference to baseline[2]			
n	59	19	40
Mean (SD)	-0.14 (1.77)	-0.79 (1.08)	0.18 (1.95)
95% CI	[-0.60; 0.33]	[-1.31; -0.27]	[-0.45; 0.80]
Median	0.00	0.00	0.00
t-test	p = 0.558	p = 0.005	p = 0.573
Change after 24 weeks (DTSQc)[2]			
n	61	20	41
Mean (SD)	-1.15 (1.61)	-1.25 (1.25)	-1.10 (1.77)
95% CI	[-1.56; -0.74]	[-1.84; -0.66]	[-1.66; -0.54]
Median	-2.00	-1.50	-2.00
	Impression how often blood glucose was unacceptably high		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	3.77 (1.44)	4.00 (1.03)	3.67 (1.59)
95% CI	[3.42; 4.13]	[3.52; 4.48]	[3.20; 4.15]
Median	4.00	4.00	4.00
Status after 24 weeks (DTSQs)[1]			
n	60	20	40

Mean (SD)	2.48 (1.57)	2.20 (1.47)	2.63 (1.61)
95% CI	[2.08; 2.89]	[1.51; 2.89]	[2.11; 3.14]
Median	2.50	2.00	3.00
DTSQs, difference to baseline[2]			
n	59	20	39
Mean (SD)	-1.25 (1.73)	-1.80 (1.47)	-0.97 (1.80)
95% CI	[-1.71; -0.80]	[-2.49; -1.11]	[-1.56; -0.39]
Median	-1.00	-2.00	-1.00
t-test	p < 0.001	p < 0.001	p = 0.002
Change after 24 weeks (DTSQc)[2]			
n	61	20	41
Mean (SD)	-0.89 (1.67)	-1.90 (0.72)	-0.39 (1.79)
95% CI	[-1.31; -0.46]	[-2.24; -1.56]	[-0.95; 0.17]
Median	-1.00	-2.00	-1.00

[1] Rating scale: 0 = at no time - 6 = the most time

[2] Rating scale: -3 = now much more rarely - 3 = now much more often

CI = confidence interval, DTSQc = diabetes treatment satisfaction questionnaire – change, DTSQs = diabetes treatment satisfaction questionnaire – Status, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.12.1.2, 4.12.1.3

Mean DTSQs differences to baseline with respect to improvements in the impression how often blood glucose was unacceptably low were small and not statistically significant in FAS patients (p = 0.558) and SMBG patients (p = 0.573), while statistical significance was reached with greater differences in FGM patients (p = 0.005). However, baseline values were already low and therefore, DTSQc evaluation is better suited to show differences. DTSQc evaluation showed further and comparable improvements of -1.15 (FAS), -1.25 (FGM) and -1.10 (SMBG), respectively (Appendix II: Table 4.12.1.3).

Mean DTSQs differences to baseline with respect to improvements in the impression how often blood glucose was unacceptably high were markedly and statistically significant in all groups (FAS: -1.25, p < 0.001; FGM patients: -1.80, p < 0.001; SMBG patients: -0.97, p = 0.002). DTSQc results showed a markedly greater improvement within FGM patients vs SMBG patients (Appendix II: Table 4.12.1.2).

Table 31: Satisfaction with current treatment (question 1) and practicability/ comfort of treatment (question 4) (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
	Satisfaction with current treatment		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	3.97 (1.75)	3.60 (1.60)	4.13 (1.81)
95% CI	[3.54; 4.40]	[2.85; 4.35]	[3.59; 4.67]
Median	4.00	3.00	5.00
Status after 24 weeks (DTSQs)[1]			
n	61	20	41
Mean (SD)	4.74 (1.44)	4.90 (0.91)	4.66 (1.64)
95% CI	[4.37; 5.11]	[4.47; 5.33]	[4.14; 5.18]
Median	5.00	5.00	5.00
DTSQs, difference to baseline[2]			
n	60	20	40
Mean (SD)	0.73 (1.94)	1.30 (1.34)	0.45 (2.14)
95% CI	[0.23; 1.23]	[0.67; 1.93]	[-0.23; 1.13]

	Median	1.00	1.00	0.00
	t-test	p = 0.005	p < 0.001	p = 0.190
	Change after 24 weeks (DTSQc)[2]			
	n	60	19	41
	Mean (SD)	1.75 (1.46)	1.58 (0.96)	1.83 (1.64)
	95% CI	[1.37; 2.13]	[1.12; 2.04]	[1.31; 2.35]
	Median	2.00	2.00	2.00
		Practicability/comfort of treatment		
	Baseline status (DTSQs)[3]			
	n	66	20	46
	Mean (SD)	3.97 (1.56)	3.70 (1.34)	4.09 (1.64)
	95% CI	[3.59; 4.35]	[3.07; 4.33]	[3.60; 4.58]
	Median	4.00	3.00	4.00
	Status after 24 weeks (DTSQs)[3]			
	n	61	20	41
	Mean (SD)	4.90 (1.19)	4.70 (1.08)	5.00 (1.25)
	95% CI	[4.60; 5.21]	[4.194; 5.206]	[4.61; 5.39]
	Median	5.00	5.00	5.00
	DTSQs, difference to baseline[2]			
	n	60	20	40
	Mean (SD)	0.93 (1.47)	1.00 (1.03)	0.90 (1.66)
	95% CI	[0.55; 1.31]	[0.52; 1.48]	[0.37; 1.43]
	Median	1.00	1.00	1.00
	t-test	p < 0.001	p < 0.001	p = 0.001
	Change after 24 weeks (DTSQc)[4]			
	n	61	20	41
	Mean (SD)	1.90 (1.23)	1.60 (1.00)	2.05 (1.32)
	95% CI	[1.59; 2.22]	[1.13; 2.07]	[1.63; 2.47]
	Median	2.00	2.00	2.00

[1] Rating scale: 0 = very dissatisfied - 6 = very satisfied

[2] Rating scale: -3 = now much less satisfied - 3 = now much more satisfied

[3] Rating scale: 0 = very impractical/uncomfortable - 6 = very practical/comfortable

[4] Rating scale: -3 = now much less practical/comfortable - 3 = now much more practical/comfortable

CI = conficence interval, DTSQc = diabetes treatment satisfaction questionnaire – change, DTSQs = diabetes treatment satisfaction questionnaire – status, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.12.1.1, 4.12.1.4

Ratings of satisfaction with current treatment and practicability/comfort of treatment both improved after start of iGlarLixi treatment at Week 24. Notably, differences to baseline in DTSQs were greater in FGM patients, while differences in DTSQc were greater in SMBG patients for both parameters.

Mean DTSQs differences to baseline with respect to satisfaction with current treatment were statistically significant in FAS (p = 0.005) and FGM patients (p < 0.001), while statistical significance was not reached in SMBG patients (p = 0.190).

Mean DTSQs differences to baseline with respect to practicability/comfort of treatment were statistically significant in all groups (FAS: p < 0.001; FGM patients: p < 0.001; SMBG patients: p = 0.001) (Appendix II: Tables 4.12.1.1, 4.12.1.4).

Table 32: Satisfaction with the flexibility of treatment (question 5) and with knowledge/understanding of diabetes (question 6) (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
	Satisfaction with the flexibility of treatment		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	4.00 (1.53)	3.85 (1.46)	4.07 (1.57)
95% CI	[3.62; 4.38]	[3.17; 4.53]	[3.60; 4.53]
Median	4.00	3.50	4.00
Status after 24 weeks (DTSQs)[1]			
n	61	20	41
Mean (SD)	4.93 (1.17)	4.85 (0.88)	4.98 (1.29)
95% CI	[4.64; 5.23]	[4.44; 5.26]	[4.57; 5.38]
Median	5.00	5.00	5.00
DTSQs, difference to baseline[2]			
n	60	20	40
Mean (SD)	0.93 (1.41)	1.00 (1.12)	0.90 (1.55)
95% CI	[0.57; 1.30]	[0.47; 1.53]	[0.41; 1.40]
Median	1.00	1.00	1.00
t-test	p < 0.001	p = 0.001	p = 0.001
Change after 24 weeks (DTSQc)[2]			
n	60	20	40
Mean (SD)	1.85 (1.18)	1.40 (1.10)	2.08 (1.16)
95% CI	[1.55; 2.15]	[0.89; 1.91]	[1.70; 2.45]
Median	2.00	2.00	2.00
	Satisfaction with knowledge/understanding of diabetes		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	4.08 (1.41)	3.95 (1.28)	4.13 (1.47)
95% CI	[3.73; 4.42]	[3.35; 4.55]	[3.69; 4.57]
Median	4.00	4.00	4.50
Status after 24 weeks (DTSQs)[1]			
n	61	20	41
Mean (SD)	4.82 (1.12)	5.00 (0.86)	4.73 (1.23)
95% CI	[4.53; 5.11]	[4.60; 5.40]	[4.35; 5.12]
Median	5.00	5.00	5.00
DTSQs, difference to baseline[2]			
n	60	20	40
Mean (SD)	0.67 (1.42)	1.05 (0.89)	0.48 (1.60)
95% CI	[0.30; 1.03]	[0.64; 1.47]	[-0.04; 0.99]
Median	0.00	1.00	0.00
t-test	p = 0.001	p < 0.001	p = 0.068
Change after 24 weeks (DTSQc)[2]			
n	61	20	41
Mean (SD)	2.05 (0.92)	1.75 (1.02)	2.20 (0.84)
95% CI	[1.81; 2.29]	[1.27; 2.23]	[1.93; 2.46]
Median	2.00	2.00	2.00

[1] Rating scale: 0 = very dissatisfied - 6 = very satisfied

[2] Rating scale: -3 now much less satisfied - 3 = now much more satisfied

CI = confidence interval, DTSQc = diabetes treatment satisfaction questionnaire – change, DTSQs = diabetes treatment satisfaction questionnaire – status, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.12.1.5, 4.12.1.6

Mean ratings of satisfaction with the flexibility of treatment and with knowledge/ understanding of diabetes both improved after start of iGlarLixi treatment at Week 24. Notably, differences to baseline in DTSQs were greater in FGM patients, while differences in DTSQc were greater in SMBG patients for both parameters.

Mean DTSQs differences to baseline with respect to satisfaction with flexibility of treatment were statistically significant in all groups (FAS: $p < 0.001$; FGM patients: $p = 0.001$; SMBG patients: $p = 0.001$).

Mean DTSQs differences to baseline with respect to satisfaction with knowledge/understanding of diabetes were statistically significant in FAS ($p = 0.001$) and in FGM patients ($p < 0.001$); but did not reach statistical significance in SMBG patients ($p = 0.068$) (Appendix II: Tables 4.12.1.5, 4.12.1.6).

Table 33: Recommendation of current treatment to others (question 7) and satisfaction with continuing current treatment (question 8) (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
	Recommendation of current treatment to others		
Baseline status (DTSQs)[1]			
n	66	20	46
Mean (SD)	4.29 (1.35)	4.15 (1.35)	4.35 (1.35)
95% CI	[3.967; 4.62]	[3.52; 4.78]	[3.95; 4.75]
Median	4.00	4.00	4.50
Status after 24 weeks (DTSQs)[1]			
n	61	20	41
Mean (SD)	5.11 (1.07)	5.25 (0.85)	5.05 (1.16)
95% CI	[4.84; 5.39]	[4.85; 5.65]	[4.68; 5.42]
Median	5.00	5.00	5.00
DTSQs, difference to baseline[2]			
n	60	20	40
Mean (SD)	0.75 (1.58)	1.10 (1.02)	0.58 (1.78)
95% CI	[0.34; 1.16]	[0.62; 1.58]	[0.01; 1.15]
Median	1.00	1.00	0.00
t-test	p = 0.001	p < 0.001	p = 0.048
Change after 24 weeks (DTSQc)[2]			
n	61	20	41
Mean (SD)	1.85 (1.30)	1.40 (1.05)	2.07 (1.37)
95% CI	[1.52; 2.19]	[0.91; 1.89]	[1.64; 2.51]
Median	2.00	1.50	3.00
	Satisfaction with continuing current treatment		
Baseline status (DTSQs)[3]			
n	66	20	46
Mean (SD)	3.85 (1.69)	3.85 (1.35)	3.85 (1.84)
95% CI	[3.43; 4.27]	[3.22; 4.48]	[3.30; 4.39]
Median	4.00	4.00	4.00
Status after 24 weeks (DTSQs)[3]			
n	61	20	41
Mean (SD)	5.05 (1.49)	5.25 (0.97)	4.95 (1.69)

95% CI	[4.67; 5.43]	[4.80; 5.70]	[4.42; 5.48]
Median	6.00	5.00	6.00
DTSQs, difference to baseline[2]			
n	60	20	40
Mean (SD)	1.18 (2.10)	1.40 (1.10)	1.08 (2.45)
95% CI	[0.64; 1.73]	[0.89; 1.91]	[0.29; 1.86]
Median	1.00	1.00	1.00
t-test	p < 0.001	p < 0.001	p = 0.009
Change after 24 weeks (DTSQc)[4]			
n	61	20	41
Mean (SD)	2.13 (1.41)	1.90 (0.79)	2.24 (1.63)
95% CI	[1.77; 2.49]	[1.53; 2.27]	[1.73; 2.76]
Median	3.00	2.00	3.00

[1] Rating scale: 0 = not recommend the treatment in any case - 6 = definitely recommend the treatment

[2] Rating scale: -3 now much less probable - 3 = now much more probable

[3] Rating scale: 0 = very dissatisfied - 6 = very satisfied

[4] Rating scale: -3 = now much less satisfied - 3 = now much more satisfied

CI = conficence interval, DTSQc = diabetes treatment satisfaction questionnaire – change, DTSQs = diabetes treatment satisfaction questionnaire – status, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.12.1.7, 4.12.1.8

Mean ratings of recommendation of current treatment to others and satisfaction with continuing current treatment both improved after start of iGlarLixi treatment at Week 24. Notably, differences to baseline in DTSQs were greater in FGM patients, while differences in DTSQc were greater in SMBG patients for both parameters.

Mean DTSQs differences to baseline with respect to recommendation of current treatment to others were statistically significant in all groups (FAS: p = 0.001; FGM patients: p < 0.001; SMBG patients: p = 0.048).Mean DTSQs differences to baseline with respect satisfaction with continuing current treatment were statistically significant in all groups (FAS: p < 0.001; FGM patients: p < 0.001; SMBG patients: p = 0.009) (Appendix II: Tables 4.12.1.7, 4.12.1.8).

Sums of scores were calculated for question 1, 4, 5, 6, 7, and 8 of DTSQs and DTSQc. The respective data are presented in Table 34.

Table 34: DTSQs and DTSQc sum of scores of questions 1, 4, 5, 6, 7 and 8 (FAS patients, FGM patients and SMBG patients)

Parameter Statistics	FAS N=70	FGM N=20	SMBG N=50
		DTSQs sum of scores	
Baseline			
n	66	20	46
Mean (SD)	24.15 (7.74)	23.10 (6.90)	24.61 (8.11)
95% CI	[22.25; 26.06]	[19.87; 26.33]	[22.20; 27.02]
Median	24.50	21.00	25.50
After 24 weeks			
n	61	20	41
Mean (SD)	29.56 (5.92)	29.95 (4.27)	29.37 (6.61)
95% CI	[28.04; 31.07]	[28.00; 32.00]	[27.28; 31.45]
Median	31.00	29.00	31.00
Difference to baseline			
n	60	20	40
Mean (SD)	5.20 (8.26)	6.85 (4.45)	4.38 (9.57)

95% CI	[3.07; 7.33]	[4.77; 8.93]	[1.32; 7.43]
Median	5.00	5.00	4.50
t-test	p < 0.001	p < 0.001	p = 0.006
	DTSQc sum of scores		
After 24 weeks (DTSQs)[3]			
n	59	19	40
Mean (SD)	11.73 (6.12)	9.47 (4.70)	12.80 (6.47)
95% CI	[10.13; 13.32]	[7.21; 11.74]	[10.73; 14.87]
Median	14.00	11.00	15.00

CI = confidence interval, DTSQc = diabetes treatment satisfaction questionnaire – change, DTSQs = diabetes treatment satisfaction questionnaire – status, FAS = full analysis set, FGM = flash glucose monitoring, SD = standard deviation, SMBG = self-measured blood glucose

Source: Appendix II: Tables 4.12.1.9, 4.12.1.10

Mean sum of scores for DTSQs and DTSQc increased from baseline about 23.1-24.6 to nearly 30 of 36 in Week 24 in all groups. Differences to baseline for DTSQs were all statistically significant (FAS: 5.20, p < 0.001; FGM patients: 6.85, p < 0.001; SMBG patients: 4.38, p = 0.006). These findings are supported by the results of DTSQc, indicating a positive awareness of treatment satisfaction change of 9.5 in FGM patients and 12.8 in SMBG patients, resulting in 11.7 in all FAS patients (Appendix II: Tables 4.12.1.9, 4.12.1.10).

Additional efficacy analyses for FGM patients

Median target blood glucose and limit value for low glucose (mg/dl) at baseline, after 12 weeks and after 24 weeks in FGM patients is summarized in Table 35.

Table 35: Median target blood glucose and limit value for low glucose (FGM)

Parameter Statistics	Median target blood glucose (mg/dL)	Limit value for low glucose (mg/dL)
Baseline		
n	20	20
Mean (SD)	139.4 (13.90)	69.3 (6.03)
Median	140.0	70.0
After 12 weeks		
n	17	17
Mean (SD)	132.3 (12.51)	72.2 (6.51)
Median	130.0	70.0
After 24 weeks		
n	16	16
Mean (SD)	137.6 (15.85)	71.0 (4.31)
Median	135.0	70.0

FGM = flash glucose monitoring, SD = standard deviation

Source: Appendix II: Tables 5.1.1.1, 5.1.1.2

The mean of the median target blood glucose in FGM patients at baseline (139.4 mg/dL) was slightly reduced to 132.3 mg/dL at Week 12 and 137.6 mg/dL at Week 24. The mean of the limit value for low glucose at baseline (69.3 mg/dL) slightly increased to 72.2 mg/dL at Week 12 and 71.0 mg/dL at Week 24. (Appendix II: Tables 5.1.1.1, 5.1.1.2).

Additional assessment parameters

The changes in non-insulin concomitant medication are presented in Table 36.

Table 36: Changes in non-insulin concomitant medication (FAS patients, FGM patients and SMBG patients)

Medication Timepoint	FAS N=70	FGM N=20	SMBG N=50
	Patients with non-insulin concomitant medication n (%)[1]		
Metformin			
Baseline	51 (73.9)	15 (75.0)	36 (73.5)
After switch	50 (72.5)	16 (80.0)	34 (69.4)
After 12 weeks	40 (64.5)	12 (75.0)	28 (60.9)
After 24 weeks	39 (66.1)	13 (76.5)	26 (61.9)
SGLT2 inhibitor			
Baseline	35 (50.0)	10 (50.0)	25 (50.0)
After switch	34 (49.3)	10 (52.6)	24 (48.0)
After 12 weeks	35 (56.5)	10 (62.5)	25 (54.3)
After 24 weeks	28 (48.3)	10 (58.8)	18 (43.9)
DPP-4 inhibitor			
Baseline	24 (34.8)	4 (20.0)	20 (40.8)
After switch	9 (13.2)	4 (21.1)	5 (10.2)
After 12 weeks	4 (6.7)	2 (12.5)	2 (4.5)
After 24 weeks	4 (6.8)	2 (11.8)	2 (4.8)
Glinide			
Baseline	3 (4.3)	3 (15.0)	0 (0.0)
After switch	4 (5.8)	3 (15.0)	1 (2.0)
After 12 weeks	1 (1.6)	1 (6.3)	0 (0.0)
After 24 weeks	1 (1.7)	1 (5.9)	0 (0.0)
Sulfonyl urea			
Baseline	2 (2.9)	1 (5.3)	1 (2.0)
After switch	1 (1.5)	1 (5.6)	0 (0.0)
After 12 weeks	1 (1.7)	1 (6.3)	0 (0.0)
After 24 weeks	2 (3.4)	1 (5.9)	1 (2.4)

For missing values see tables listed below. Percentage is related to the number of non-missing documentations.
FAS = full analysis set, FGM = flash glucose monitoring, SMBG = self-measured blood glucose
Source: Appendix II: Tables 6.1.1.1, 6.1.1.2, 6.1.1.3, 6.1.1.6, 6.1.1.7

In FAS patients, use of non-insulin concomitant medication was markedly reduced after 24 weeks of treatment with iGlarLixi. This was mainly due to termination of DPP4 inhibitor treatment, but also of metformin treatment in some patients (within the FAS population and the SMBG subgroup) (Appendix II: Tables 6.1.1.1, 6.1.1.2, 6.1.1.3, 6.1.1.6, 6.1.1.7).

The number of different non-insulin concomitant medications is presented in Table 37.

Table 37: Number of different non-insulin concomitant medications (FAS patients, FGM patients and SMBG patients)

Time Number of drugs	FAS (N=70) n (%)	FGM (N=20) n (%)	SMBG (N=50) n (%)
Baseline			
n	70 (100.0)	20 (100.0)	50 (100.0)
None	3 (4.3)	1 (5.0)	2 (4.0)
1 drug	29 (41.4)	9 (45.0)	20 (40.0)
2 drugs	28 (40.0)	6 (30.0)	22 (44.0)
3 drugs	10 (14.3)	4 (20.0)	6 (12.0)
Baseline, after switch to iGlarLixi			

n	70 (100.0)	20 (100.0)	50 (100.0%)
None	10 (14.3)	1 (5.0)	9 (18.0)
1 drug	27 (38.6)	8 (40.0)	19 (38.0)
2 drugs	28 (40.0)	7 (35.0)	21 (42.0)
3 drugs	5 (7.1)	4 (20.0)	1 (2.0)
After 12 weeks			
n	62 (100.0)	16 (100.0)	46 (100.0)
None	12 (19.4)	1 (6.3)	11 (23.9)
1 drug	23 (37.1)	7 (43.8)	16 (34.8)
2 drugs	23 (37.1)	5 (31.3)	18 (39.1)
3 drugs	4 (6.5)	3 (18.8)	1 (2.2)
After 24 weeks			
n	59 (100.0)	17 (100.0)	42 (100.0)
None	12 (20.3)	1 (5.9)	11 (26.2)
1 drug	24 (40.7)	8 (47.1)	16 (38.1)
2 drugs	19 (32.2)	5 (29.4)	14 (33.3)
3 drugs	4 (6.8)	3 (17.6)	1 (2.4)

For missing values see table listed below. Percentage is related to the number of non-missing documentations.
FAS = full analysis set, FGM = flash glucose monitoring, SMBG = self-measured blood glucose
Source: Appendix II: Table 6.1.1.8

After switch to iGlarLixi, the number of different non-insulin concomitant medications was reduced in all groups (Appendix II: Table 6.1.1.8).

In one patient, the FGM system was changed (after 12 weeks) (Appendix II: Table 6.1.2).

Safety

Safety of the study treatment was assessed by AEs and other safety-relevant events. The analysis of safety is tabulated in Appendix II: Table 7.1 to 7.7).

The frequency of AEs during the study course is given in Table 38.

Table 38: Frequency of AEs (SAS)

	SAS (N=89)
Number of patients, n (%)	
with at least one AE	39 (43.8)
with at least one ADR	12 (13.5)
with at least one SAE	1 (1.1)
Events - as reported, n	
AE	61
ADR	23
SAE	1

ADR = adverse drug reaction, AE = adverse event, SAE = serious adverse event, SAS = safety analysis set
Source: Appendix II: Table 7.1

In 39 patients (43.8%) at least one AE was reported. ADRs were documented in 12 patients (13.5%). One SAE occurred during the study (diabetic retinopathy). In total, 61 AEs, 23 ADRs, and 1 SAE were reported. Serious ADR or AESI were not documented (Appendix II: Table 7.1).

AEs by MedDRA system organ class and preferred term (MedDRA 25.0) are summarized in Table 39.

Table 39: AEs by MedDRA system organ class and preferred term (SAS)

System organ class Preferred term	SAS (N=89) n (%)
Metabolism and nutrition disorders	16 (18.0)
Hypoglycaemia	16 (18.0)
Injury, poisoning and procedural complications	14 (15.7)
Inappropriate schedule of product administration	1 (1.1)
Off-label use[1]	14 (15.7)
Investigations	6 (6.7)
Aspartate aminotransferase increased	1 (1.1)
Blood glucose decreased	3 (3.4)
Blood triglycerides increased	2 (2.2)
Gastrointestinal disorders	4 (4.5)
Diarrhoea	2 (2.2)
Nausea	2 (2.2)
Nervous system disorders	4 (4.5)
Diabetic neuropathy	4 (4.5)
Renal and urinary disorders	2 (2.2)
Diabetic nephropathy	2 (2.2)
Eye disorders	1 (1.1)
Diabetic retinopathy	1 (1.1)

[1] In 14 patients off-label use (outside 27-33 dose steps/day) was documented. No adverse events were reported in patients with off-label use (see Section off-label use below)

AE = adverse event, SAS = safety analysis set

Source: Appendix II: Table 7.3

Most frequently affected system organ classes were "metabolism and nutrition disorders" (N=16, 18.0%) and "injury, poisoning and procedural complications" (N=14, 15.7%). Most frequent AE (preferred term) was "hypoglycaemia" (N=16, 18.0%) (Appendix II: Table 7.3). AEs as reported are listed in Appendix II: Table 7.2.

Patients with off-label use of iGlarLixi

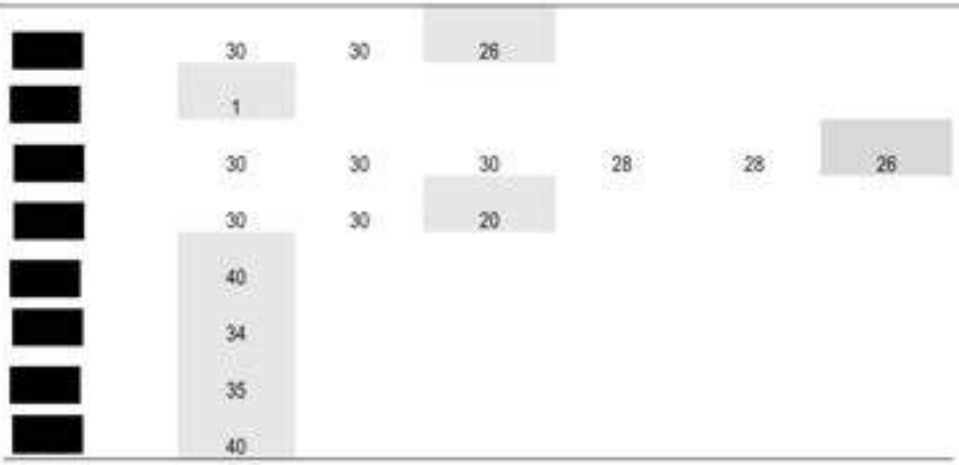
According to the observational plan, applications of iGlarLixi during the study that were not covered by approval (outside 27-33 dose steps/day) were to be documented with or without an adverse event.

During the study course, 14 patients with off-label use were documented. No adverse events were reported in these patients.

Table 40 specifies patient numbers, timepoint, and actual dose of off-label use.

Table 40: Patients with off-label use of iGlarLixi

Patient number	Week (dose step/day)					
	0	4	8	12	16	20
[redacted]	0					
[redacted]	2					
[redacted]	2					
[redacted]	30	1				
[redacted]	1					



Off-label use is marked with a gray background.

ADRs by MedDRA system organ class and preferred term are summarized in Table 41.

Table 41: ADRs by MedDRA system organ class and preferred term (SAS)

System organ class Preferred term	SAS (N=89) n (%)
Metabolism and nutrition disorders	6 (6.7)
Hypoglycaemia	6 (6.7)
Injury, poisoning and procedural complications	5 (5.6)
Off-label use	5 (5.6)
Gastrointestinal disorders	4 (4.5)
Diarrhoea	2 (2.2)
Nausea	2 (2.2)
Nervous system disorders	1 (1.1)
Diabetic neuropathy	1 (1.1)

ADR = adverse drug reaction, SAS = safety analysis set
Source: Appendix II: Table 7.5

Most frequently reported ADRs were hypoglycaemia (N=6, 6.7%), off-label use (N=5, 5.6%), diarrhoea and nausea (N=2, 2.2% each) (Appendix II: Table 7.5).

Discussion:

This was a prospective observational study, conducted at 33 sites in Germany, to generate data with respect to the assessment of glycaemic control by intensifying basal insulin supported oral therapy (BOT) based on ≥30 units of basal insulin with switching to iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes inadequately controlled on BOT.

The total patient population comprised 92 patients. Of these, 89 patients were analysed in the SAS and 70 patients were analysed in the FAS. Ten patients were identified with off-label use (i. e. not starting iGlarLixi treatment with 30 dose steps per day as per EU label for the Suliqua® (30-60) pen) and 8 patients were classified as drop-out (i. e. only baseline data available) and were excluded from the FAS population. The FAS population was divided in two subsets: one including only patients using an FGM device, which comprised 20 patients; and the other including patients with only SMBG profiles, which comprised 50 patients.

Demographic and baseline characteristics in the FAS showed that about 40% of patients were female and 60% were male with mean age of 64.64 years and a BMI of 35.1 kg/m². Further relevant baseline characteristics in the FAS included a mean period since initial diabetes diagnosis of 12.26 years, insulin glargine 300 U/mL and insulin glargine 100 U/mL as predominant current basal insulin medication before switch to iGlarLixi and mean duration of current basal insulin medication of 38.1 months. Current non-insulin antidiabetic medication primarily consisted of metformin (N=51, 73.9%), SGLT2 inhibitors (N=35, 50.0%), and DPP-4 inhibitors (N=24, 34.8%). Most frequently, diabetic

	neuropathy (N=29, 41.4%, mean pre-duration: 5.0 years) and diabetic nephropathy (N=14, 20%, mean pre-duration: 4.5 years) were documented as late diabetic complications. The individual HbA_{1c} target value ranged from 6.5% to 8.0% and was 6.9% in mean. Current self-measured FBG values at study start ranged from 89 to 300 mg/dL with a mean of 174.3 mg/dL. The most frequent reasons documented at baseline for therapy switch from previous treatment to treatment with iGlarLixi were improvements in the HbA_{1c} value (N=70, 100%), fasting blood glucose (N=55, 78.6%), postprandial blood glucose (N=52, 74.3%), and easy handling of the fixed combination (N=35, 50.0%). Current non-insulin concomitant medication at study start primarily consisted of metformin (N=50, 72.5%), followed by SGLT2 inhibitors (N=34, 49.3%). Primary efficacy endpoint was the absolute change in HbA_{1c} (%) with iGlarLixi from start of treatment up to the visit after approx. 12 weeks and approx. 24 weeks. In FAS patients, the mean baseline HbA_{1c} of 8.52% was relevantly reduced with mean changes to baseline of -0.64% (Week 12) and -0.74% (Week 24). Changes to baseline were both statistically significant with $p < 0.001$ (Week 12) and $p = 0.001$ (Week 24) (paired t-test). Mean change in HbA_{1c} (%) from Week 12 to Week 24 was -0.15% and was also statistically significant ($p = 0.040$). In all subgroups analysed, mean baseline HbA_{1c} was statistically significant reduced at Week 12 and Week 24 of treatment with iGlarLixi vs baseline. Various secondary efficacy endpoints were analysed: Statistically significant improvements ($p < 0.05$) were documented for the relative change from baseline to Week 12 and Week 24 in HbA_{1c} (%) and the absolute and relative change in self-measured fasting blood glucose after 12 and 24 weeks, respectively. At Week 24, the individual HbA_{1c} target value was reached by 12 patients (17.14%) and a FBG of ≤110 mg/dL by 21 (30.00%) of FAS patients, suggesting insufficient titration of iGlarLixi to reach glycaemic targets. In fact, iGlarLixi was only titrated to a mean of 41 DS/d after 24 weeks of treatment, having been switched from a mean of 39 U/d of the previous basal insulin and started at 30 DS/d as per EU label. In FAS patients, relevant and statistically significant changes to the mean median baseline value of the 7-point SMBG daily profile (195.53 mg/dL) could be shown at Week 12 and Week 24. The mean absolute and relative changes at Week 12 were -24.83 mg/dL ($p = 0.001$) and -11.38% ($p < 0.001$). The mean absolute and relative changes at Week 24 were -24.77 mg/dL ($p = 0.003$) and -11.17% ($p = 0.011$). Most reductions of single mean SMBG values of the 7-point daily profile reached statistical significance, leading to target dTIR of >70%, dTAR of around 25% and dTBR of < 4% [10], suggesting flattened blood glucose profiles and improvements in time in range. The TIR, TAR and TBR levels documented for a subgroup of 20 patients using a FGM system also reached target ranges after 24 weeks of iGlarLixi treatment. Median values of glucose in patients using FGM were reduced from baseline (mean: 148.95 mg/dL) to Week 12 (mean: 142.87 mg/dL) and Week 24 (mean: 137.66 mg/dL). Mean baseline body weight (103.34 kg) and mean baseline BMI (34.87 kg/m^2) were relevantly reduced after 12 weeks and 24 weeks of treatment with iGlarLixi. Hypoglycaemia in general were reported at very low numbers, probably due to underreporting, as suggested by TBR measurements in the FGM subgroup. During treatment with iGlarLixi there was a small numerical increase in ADA level 2 [1] hypoglycaemia and a small numerical decrease in ADA level 1 [1] hypoglycaemia. No ADA level 3 [1] (severe) hypoglycaemia were reported during the study. Within the FGM subgroup, TBR decreased significantly from 6.85% at baseline to 3.35% after 12 weeks of iGlarLixi treatment and to 3.50% after 24 weeks, i. e. below target range of <4% [10]. All ratings of treatment satisfaction (ascertained by DTSQs and DTSQc) statistically significant improved during treatment with iGlarLixi.

	The use of non-insulin concomitant medication was relevantly reduced after 24 weeks of treatment with iGlarLixi. This was most pronounced regarding DPP-4 inhibitors and metformin. Safety analysis: In 39 patients (43.8%) at least one AE was reported. ADRs were documented in 12 patients (13.5%). One SAE occurred during the study (diabetic retinopathy). In total, 61 AEs, 23 ADRs, and 1 SAE were reported. Serious ADR or AESI were not documented. Most frequent AE was hypoglycaemia (N=16, 18.0%) and most frequently reported ADRs were hypoglycaemia (N=6, 6.7%), off-label use (N=5, 5.6%), diarrhoea and nausea (N=2, 2.2% each).
Conclusions:	The aim of this observational study was to collect information on the efficacy and safety in the treatment of people with type 2 diabetes with iGlarLixi who could not achieve adequate glycaemic control with a previous BOT. The study design reflects the living situation of these patients under everyday conditions. Treatment with iGlarLixi was highly effective with a positive safety profile. Treatment intensification from a BOT regimen to iGlarLixi significantly improved HbA_{1c} and FPG levels, leading to recommended dTIR/TIR >70% and dTBR/TBR <4%, respectively, as well as dTAR/TAR around 25%. Hypoglycaemia were seldom reported, probably due to underreporting, because more hypoglycaemic events were seen from FGM readings. This was the first study reporting on real world use of iGlarLixi in Germany with 29% of patients with type 2 diabetes using FGM devices.
Date of report:	04-Aug-2023 (Version 1.0)

LIST OF ABBREVIATIONS

Initials	Explanation
ADE	Adverse drug effect
ADR	Adverse drug reaction
AE	Adverse event
AESI	Adverse event of special interest
ALL	All patients enrolled set
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BMI	Body mass index
BOT	Basal-supported oral therapy
CI	Confidence interval
CRF	Case Report Form
CRO	Clinical Research Organisation
DMP	Data Management Plan
DS/d	Dose steps/day
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DTSQc	Diabetes Treatment Satisfaction Questionnaire – Change
DTSQs	Diabetes Treatment Satisfaction Questionnaire – Status
DVP	Data Validation Plan
eCRF	Electronic Case Report Form
eGFR	Estimated glomerular filtration rate
EMA	European Medicines Agency
FAS	Full analysis set
FBG	Fasting blood glucose
FGM	Flash Glucose Monitoring or intermittend [sic: intermittent] continuous glucose monitoring (iCGM)

FRC	Fixed ratio combination
GLP-1	Glucagon-like peptide-1
GLP-1 RA	GLP-1 receptor agonist
GPP	Good Pharmacoepidemiology Practice
GV	Glycaemic variability
HbA_{1c}	Glycohaemoglobin A1c
iscCGM	Intermittent scanning continuous glucose monitoring
mFAS	Modified full analysis set
NIS	Non-interventional study
OAD	Oral antidiabetic drugs
PTC	Product technical complaints
PwT2D	People with T2D
QC	Quality control
rtCGM	real-time continuous glucose monitoring
SADR	Serious adverse drug reaction
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Safety analysis set
SD	Standard deviation
SmPc	Summary of product characteristics
SMBG	Self-measured blood glucose
SMPG	Self-measured plasma glucose
T2D	Type 2 diabetes
TAR	Time above range
TBR	Time below range
TIR	Time in range

APPENDICES

1 APPENDIX I – ADMINISTRATIVE AND LEGAL CONSIDERATIONS

1.1 ETHICAL CONSIDERATIONS

1.1.1 Ethical principles

This study was conducted in accordance with the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) including all subsequent amendments.

1.1.2 Laws and regulations

This study was conducted in compliance with all international guidelines, and national laws and regulations of the country(ies) in which the study was performed, as well as any applicable guidelines.

Each participating country locally ensured that all necessary regulatory submissions (eg, IRB/IEC) were performed in accordance with local regulations including local data protection regulations.

Regulatory authorities' submissions by country are presented in Section 3.7 (Appendix III).

1.2 DATA PROTECTION

The participant's personal data and physician's personal data which were to be included in the Company's databases were treated in compliance with all local applicable laws and regulations.

When archiving or processing personal data pertaining to the physician and/or to the participants, the Company took all appropriate measures to safeguard and prevent access to these data by any unauthorized third party.

1.3 RECORD RETENTION

The physician was responsible for the retention of the study documentation until the end of the study. In addition, the physician had to comply with specific local regulations and recommendations regarding participant record retention.

1.4 THE COMPANY AUDITS AND INSPECTIONS BY COMPETENT AUTHORITIES (CA)

The physician agreed to allow the Company's auditors and Competent Authorities' inspectors to have direct access to records of the study for review, it being understood that all personnel with access to participants' records are bound by professional secrecy and as such, could not disclose any personal identity or personal medical information.

The physician had to make every effort to help with the performance of the audits and inspections, giving access to all necessary facilities, data, and documents. As soon as notification from the authorities for an inspection was received by the physician, he/she had to inform the Company and authorize the Company to participate in this inspection. The confidentiality of the data to verify and the protection of the participants must be respected during these inspections. Any results or information arising from the inspections by the Competent Authorities were to be immediately communicated by the physician to the Company. The physician had to take appropriate measures required by the Company to ensure corrective actions for all problems found during audits and inspections.

1.5 CENTRAL LABORATORY

Not applicable.

1.6 OWNERSHIP OF DATA AND USE OF STUDY RESULTS

Unless otherwise specified by local laws and regulations, the Company retains ownership of data, results, reports, findings, and discoveries related to the study. Therefore, the Company reserves the right to use the data from the present study for any purpose, including to submit them to the Competent Authorities of any country.

The Study Committee, has full access to the final database allowing for appropriate academic analysis and reporting of the study results.

1.7 STUDY CONSULTANTS

1.7.1 Scientific committee and charter

A Steering Committee was involved in the preparation and approval of the protocol and its amendment(s) by giving advice to the medical advisor diabetes responsible for this study. It will also be involved in analysing and interpreting the results of the study by giving advice to the medical advisor diabetes responsible for this study in a ZOOM meeting scheduled for 23.08.2023. Further TCs and meetings are planned for Q4/2023 to further discuss the evaluation and publication of the results. The Steering Committee was given full authority for presentation and publication of the results.

Members of the Steering Committee:

[redacted]

1.7.2 National coordination

[redacted]

1.7.3 Other experts/consultants

Not applicable.

1.8 PARTICIPATING PHYSICIANS

The physicians performed the study in accordance with the protocol, applicable local regulations, and international guidelines.

The physician or a person designated by the physician, fully informed the participant, in language and terms they were able to understand, to the fullest extent possible, about the study, objectives, constraints, duration, and participant's rights.

It was the responsibility of the physician's or a person designated by the physician to obtain written and signed informed consent from participants prior to inclusion. The participant's legal representative could also sign the written informed consent form (ICF) on behalf of the participant. A copy of the signed and dated written ICF was provided to the participant and/ or his legal representative.

The following participating physicians enrolled at least on patient in the study:

Title	Last Name	First Name	Street	Postal Code	City
[redacted]					

Title	Last Name	First Name	Street	Postal Code	City
[redacted]					

1.9 STUDY PERSONNEL

1.9.1 Personnel involved in the study

The Coordinating physician's and Company responsible medical officer's signed approvals of the report are provided in Section 3.8.

This report was prepared by:

- [redacted] (Clinical Project Leader)
- [redacted] (Medical Project Manager)
- [redacted] (Medical Advisor Diabetes)
- [redacted] (Biostatistician, dsh)
- [redacted] (Biostatistician, dsh)
- [redacted] (Biometrician Winicker Norimed GmbH)
- [redacted] (Pharmacovigilanz)
- [redacted] (Medical Writer, AKP GmbH)

1.9.2 The company internal staff

The Company was responsible for providing adequate resources to ensure the proper conduct of the study.

The Company was responsible for local submission(s) complying with data protection rules and any other local submission(s) required.

1.9.3 Service provider

Data management and statistical activities were carried out by the CRO Arbeitskreis Klinische Prüfungen (AKP), Munzinger Str. 5a, 79111 Freiburg, Germany.

2 APPENDIX II – TABLES AND GRAPHS

All tables of the main analyses and subgroup analyses are summarized in the documents “OBS16751-CHANCE-2023-05-16”.

3 APPENDIX III – SUPPORTIVE DOCUMENTS

3.1 PROTOCOL

The protocol is given in “3 APPENDIX III – SUPPORTIVE DOCUMENTS, Paragraph 3.1 Protocol” at the end of this document.

3.2 STATISTICAL ANALYSIS PLAN (SAP)

3.2.1 Final statistical analysis plan

The statistical analysis plan is given in “3 APPENDIX III – SUPPORTIVE DOCUMENTS, Paragraph 3.2 Statistical Analysis Plan, Paragraph 3.2.1 Final Statistical Analysis Plan” at the end of this document.

3.2.2 Changes from the final statistical analysis plan

The following additional analyses were performed:

- Baseline analyses FAS vs FAS off label and FAS vs FAS dropout including tests (Wilcoxon rank sum statistic, Fisher's exact test or t-test), where applicable
- Additional subgroup SMBG (N=50) in all efficacy and (partly) baseline tables
- 7-point daily profiles derived time in range (dTIR), derived time above range (dTAR), and derived time below range (dTBR)
- DTSQs differences and sum scores
- Hypoglycaemia incidence and hypoglycaemia rates as events per patient-year

Patients 82-03 and 30-01 were excluded from all weight and BMI analyses due to missing post-values but remained in the subgroups for weight and BMI.

3.3 CASE REPORT FORM (CRF)/ PARTICIPANT QUESTIONNAIRE

The case report form (CFR) is given in “3 APPENDIX III – SUPPORTIVE DOCUMENTS, Paragraph 3.3 Case Report Form” at the end of this document.

3.4 PARTICIPANT INFORMED CONSENT

The Patient Informed Consent Form is included in the appendix of the protocol (section 3.1)

3.5 OTHER DOCUMENTS RELEVANT TO THE STUDY

Not applicable.

3.6 OTHER STUDY INFORMATION

3.6.1 Safety reporting

For details about safety data reporting refer to study protocol Section 13.

3.6.1.1 Adverse events (AE)

An adverse event was defined as any unfavourable medical incident that occurred in a patient treated with a medication or in a patient who participated in a clinical trial and who was administered a medicinal product, which did not necessarily have to have a causal relationship to the treatment. These included atypical healing progression, misuse or incorrect use, application outside of the licensed approval, dependency, absence of the expected efficacy or function, suspicion of infection transmission due to a medicinal product or medical device, occupational or environmentally-caused exposition, unexpected positive healing progression and suspected interactions with other products. In the case of abnormal laboratory values, the doctor had to decide on the medical relevance of the laboratory result for the patient concerned and, thereby, whether this abnormal laboratory value was to be evaluated as an adverse event for the patient or not.

3.6.1.2 Serious adverse events (SAE)

An SAE was defined as any unfavourable medical event that, at any arbitrary dose:

- Led to death, or
- Was life-threatening, or

Note: The term “life-threatening” in the definition of “severe” relates to an event in which the patient was in mortal danger at the time of the event; it does not relate to an event that could have hypothetically caused death if it had been of a more serious nature.

- Necessitated an admission to the hospital or led to a prolongation of the hospital stay, or
- Led to permanent or severe invalidity/incapacity to work, or
- Was a congenital anomaly/birth defect, or
- Was a serious medical event:
  - Suspected transmission of an infectious agent was any suspicion of transmission of an infectious agent via a medical product (e.g. product contamination).
  - Required an intervention to prevent a serious course (permanent impairment or damage, a fatal outcome or a hospital stay).

A medical and scientific assessment had to be taken into consideration for the decision if accelerated reporting was appropriate in other situations, such as in the event of important medical events that were not directly life-threatening or did not result in death or hospital admission, but put the patient at risk, or could be necessary to prevent an outcome other than those described by the definition above.

3.6.1.3 Adverse events of special interest (AESI)

An AESI was defined as an event that was product- or programme-specific from a scientific or medical point of view and required continued monitoring and a quick notification from the treating physician. As a rule,

such AEs required careful documentation and examination in order to characterise them. AESIs were immediately documented by the physician in the eCRF (i.e. within one working day). The eCRF contained a corresponding query as to whether the documented AE was an AESI. In this query, the relevant AESI had to be ticked, and the associated special input mask had to be filled in. The reporting rules described in Section 13.1.3 of the observational plan applied.

The following event had to be reported immediately and systematically as AESIs by the participating physician:

- Pregnancy of a female study participant (as well as a pregnant female partner of a male patient participating in a study with Sanofi products): As soon as a pregnancy had been documented as described in Sections 13.1.2 and 13.1.3 of the observational plan, a data collection form for the pregnancy was issued to the notifier/treating physician to ensure that additional information regarding the outcome of the pregnancy was collected. If the affected woman refuses to make information about the pregnancy and its outcome available, this information was gathered by Sanofi using the (Pregnancy/Drug Exposure via Parent Data Collection Form; Version 6.0; Effective Date: 25 May 2020).

3.7 REGULATORY AUTHORITIES' SUBMISSIONS BY COUNTRY

At finalization, the ethics' committee approval will be inserted.

3.8 REPORT APPROVAL

3.8.1 Coordinating physician's approval or chairman of steering committee

A copy of the coordinating physician's approval of the study report is at the end of this document.

3.8.2 The company's approval

This report has been electronically approved by the Company's responsible medical officer.

4 APPENDIX IV - PUBLICATIONS

4.1 REFERENCES

No results of this study have been published in a peer reviewed journal so far.

4.2 PUBLICATIONS/ABSTRACTS OF THE STUDY RESULTS

Wiesner T, Pfohl M, Pegelow K, Müller J, Seufert J. Effectiveness and safety of iGlarLixi in people with type 2 diabetes (Pw2D), not at target on basal insulin (BI) and oral antidiabetic therapy (BOT) - results from the observational, prospective study CHANCE. Diabetes 2023; 72 (Suppl. 1): 794-P. DOI: https://doi.org/10.2337/db23-794-P. Presented as poster 794-P at the 83rd Scientific Sessions of the American Diabetes Association (ADA) on 26.06.2023 in San Diego, CA, USA.

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12. Suliqua® Summary of Product Characteristics; as of May 2023.

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1 Physician Questionnaire
1.1 Speciality of the physician

Speciality of the physician	All physicians (N = 33) N (%)
General practitioner	8 (24.2%)
Internist	3 (9.1%)
Diabetologist	11 (33.3%)
General practitioner/Diabetologist	4 (12.1%)
Internist/Diabetologist	6 (18.2%)
Internist/Diabetologist/Other	1 (3.0%)
Total	33 (100.0%)

1 Physician Questionnaire
1.2 Number of patients (certificates) per quarter
1.2.1 Categorical

Number of patients per quarter	All physicians (N = 33) N (%)
not documented	3 (9.1%)
< 1000 per quarter	4 (12.1%)
1000 - < 2000 per quarter	17 (51.5%)
2000 - < 3000 per quarter	5 (15.2%)
3000 - 5000 per quarter	4 (12.1%)
Total	33 (100.0%)

1 Physician Questionnaire
1.2 Number of patients (certificates) per quarter
1.2.2 Continuous

	All physicians (N = 33)
Number of patients per quarter	
n	30
Mean (SD)	1882 (1208.8)
Min-Max	800 - 5000
Median	1450
Q1-Q3	1200 - 2100

1 Physician Questionnaire
1.3 Type of institution

Type of institution	All physicians (N = 33) N (%)
Established	29 (87.9%)
Supply center	4 (12.1%)
Total	33 (100.0%)

1 Physician Questionnaire
1.4 Location of the institution

Location of the institution	All physicians (N = 33) N (%)
Rural (<= 5.000 inhabitants)	2 (6.1%)
Small town (5.001-20.000 inhabitants)	14 (42.4%)
Medium sized city (20.001-100.000 inhabitants)	5 (15.2%)
City (> 100.000 inhabitants)	12 (36.4%)
Total	33 (100.0%)

1 Physician Questionnaire
1.5 KV area of the institution

KV area of the institution	All physicians (N = 33) N (%)
Baden-Württemberg	3 (9.1%)
Bavaria	5 (15.2%)
Brandenburg	1 (3.0%)
Hamburg	2 (6.1%)
Hesse	1 (3.0%)
Mecklenburg-Western Pomerania	2 (6.1%)
Lower Saxony	4 (12.1%)
Northrhine	5 (15.2%)
Rhineland Palatinate	2 (6.1%)
Saxony	5 (15.2%)
Saxony-Anhalt	1 (3.0%)
Schleswig Holstein	1 (3.0%)
Westphalia-Lippe	1 (3.0%)
Total	33 (100.0%)

1 Physician Questionnaire
1.6 Number of patients per speciality

Number of patients per speciality	All documented patients (N = 92) N (%)
General practitioner	23 (25.0%)
Internist	5 (5.4%)
Diabetologist	29 (31.5%)
General practitioner/Diabetologist	8 (8.7%)
Internist/Diabetologist	23 (25.0%)
Internist/Diabetologist/Other	4 (4.3%)
Total	92 (100.0%)

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.1 First patient entering study and last patient leaving the study
All patients

Consent date of the first patient	24/09/2020
Screening date of the first patient	24/09/2020
Last follow-up date of the last patient	04/08/2022

Note: A total of 111 patients have been enrolled.
From them 92 patients have been documented into the study database
According to SAP, these 92 patients form the group 'All patients'

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.2 Patient selection
2.1.2.1 Criteria for the documentation of a patient
All patients

Criteria for the documentation of a patient	All documented patients (N = 92) N (%)
Adult patients with type 2 diabetes mellitus	
yes	92 (100.0%)
In treatment with OADs and a basal insulin without prandial insulin and without GLP-1 RA for at least 6 months	
no	1 (1.1%)
yes	91 (98.9%)
HbA1c 7,5% to 10,0% - findings from the last 3 months	
yes	92 (100.0%)
Age >= 18 years at the time of signing the informed consent form	
yes	92 (100.0%)
Presence of prior basal insulin therapy that is stable between 30-60 units per day	
yes	92 (100.0%)
Switching to iGlarLixi takes place between 14 days before the initial documentation and 7 days after the initial documentation	
yes	92 (100.0%)
Decision of the treating physician to replace the previous basal insulin with iGlarLixi regardless of the enrolment in the study	
yes	92 (100.0%)
Ability and willingness to perform 7-point glucose daily profile measurements using a glucometer	
yes	92 (100.0%)
At least 70% of recorded sensor data from the FGM daily profiles of the last approx. 14 days are available before switching to iGlarLixi	
yes	23 (25.0%)
not applicable	69 (75.0%)
Informed consent signed by the patient and the physician	
yes	92 (100.0%)

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.2 Patient selection
2.1.2.2 Criteria against the documentation of a patient
All patients

Criteria against the documentation of a patient	All documented patients (N = 92) N (%)
Participation in a clinical research	
no	92 (100.0%)
Type 1 diabetes mellitus	
no	92 (100.0%)
Contraindications to treatment with iGlarLixi according to the Summary of Product Characteristics	
no	92 (100.0%)
Daily basal insulin dose <30 units or >60 units	
no	92 (100.0%)
Planned or existing pregnancy, cancer, drug or alcohol abuse, dementia, or general inability to understand the content of the observational study	
no	92 (100.0%)

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.3 Analysis populations
All patients

Analysis Population	All documented patients (N = 92) N (%)
Safety Analysis Set	
no	3 (3.3%)
yes	89 (96.7%)
Full Analysis Set °	
no	22 (23.9%)
yes	70 (76.1%)
Full Analysis Set - Patients using an FGM device	
no	72 (78.3%)
yes	20 (21.7%)

° Reason for exclusion
No treatment: 3 patients
Off-label use: 10 patients
Dropout (no HBA1C after baseline): 8 patients
Inclusion criteria violation: 1 patient

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.4 Patients excluded from analysis - categorical
All patients

Reason for exclusion	All documented patients (N = 92) N (%)
Did not receive iGlarLixi at any time	3 (3.3%)
Inclusion criteria violation	1 (1.1%)
No HbA1c value documented after baseline	8 (8.7%)
Off-label use at week 0	10 (10.9%)
Total	22 (23.9%)

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.5 Listing of patients excluded from analysis

Patient	ALL	SAS	FAS	FGM	SMBG	Category	Reason
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						NO HBA1C BL	No HbA1c baseline value documented
[redacted]	Y	N	N	N	N	NO CONSENT DATE	No informed consent date reported
						NO HBA1C AFTER BL	No HbA1c value documented after baseline
						NO HBA1C BL	No HbA1c baseline value documented
						NO TREATMENT	Did not receive iGlarLixi at any time
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 0 dose steps/day
[redacted]	Y	N	N	N	N	NO CONSENT DATE	No informed consent date reported
						NO HBA1C AFTER BL	No HbA1c value documented after baseline
						NO HBA1C BL	No HbA1c baseline value documented
						NO TREATMENT	Did not receive iGlarLixi at any time
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 2 dose steps/day
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 2 dose steps/day
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline

ALL = All documented patients, SAF = Safety Analysis Set
FAS = Full Analysis Set, FGM = Full Analysis Set - Patients using an FGM device
SMBG = Full Analysis Set - subgroup self-measured blood glucose
Y=Yes, N=No

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.5 Listing of patients excluded from analysis

Patient	ALL	SAS	FAS	FGM	SMBG	Category	Reason
[redacted]	Y	Y	N	N	N	OFF-LABEL USE	Off-label use at week 4, iGlarLixi dose steps/day not between 20 and 60: 1 dose steps/day
[redacted]	Y	N	N	N	N	NO CONSENT DATE	No informed consent date reported
						NO HBA1C AFTER BL	No HbA1c value documented after baseline
						NO HBA1C BL	No HbA1c baseline value documented
						NO TREATMENT	Did not receive iGlarLixi at any time
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 1 dose steps/day
[redacted]	Y	Y	N	Y	N	INCLUSION CRITERIA VIOLATION	In treatment with OAD and a basal insulin without prandial insulin and without GLP-1 receptor agonists for at least 6 months = NO
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
						OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 1 dose steps/day
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline
[redacted]	Y	Y	N	N	N	NO HBA1C AFTER BL	No HbA1c value documented after baseline

ALL = All documented patients, SAF = Safety Analysis Set
FAS = Full Analysis Set, FGM = Full Analysis Set - Patients using an FGM device
SMBG = Full Analysis Set - subgroup self-measured blood glucose
Y=Yes, N=No

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.5 Listing of patients excluded from analysis

Patient	ALL	SAS	FAS	FGM	SMBG	Category	Reason
[redacted]	Y	Y	N	Y	N	OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 40 dose steps/day
[redacted]	Y	Y	N	Y	N	OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 34 dose steps/day Off-label use at week 24, iGlarLixi dose steps/day not between 10 and 60: 1 dose steps/day Off-label use at week 4, iGlarLixi dose steps/day not between 20 and 60: 1 dose steps/day
[redacted]	Y	Y	N	N	N	OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 35 dose steps/day
[redacted]	Y	Y	N	N	N	OFF-LABEL USE	Off-label use at week 0, iGlarLixi dose steps/day not between 27 and 33: 40 dose steps/day

ALL = All documented patients, SAF = Safety Analysis Set
FAS = Full Analysis Set, FGM = Full Analysis Set - Patients using an FGM device
SMBG = Full Analysis Set - subgroup self-measured blood glucose
Y=Yes, N=No

2 Disposition and Baseline Characteristics
2.1 Analysis populations and patient disposition
2.1.6 Number of patients available at each visit

Number of patients available at each visit	SAS (N = 89) N (%)
Baseline	89 (100.0%)
After 4 weeks	63 (70.8%)
After 8 weeks	59 (66.3%)
After 12 weeks	77 (86.5%)
After 16 weeks	58 (65.2%)
After 20 weeks	56 (62.9%)
After 24 weeks	74 (83.1%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.1 All patients

	SAS (N = 89)	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Age in years				
n	89	70	8	10
Mean (SD)	64.76 (10.197)	64.64 (9.485)	70.88 (9.296)	62.00 (14.134)
Min-Max	41 - 87	41 - 87	61 - 84	42 - 85
Median	64.00	64.00	68.00	61.00
Q1-Q3	58.00 - 71.00	58.00 - 71.00	63.00 - 80.00	53.00 - 66.00

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.2 Full Analysis Set
2.2.1.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	70	8	
	Mean	64.64	70.88	0.103
	SE	1.134	3.287	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.2 Full Analysis Set
2.2.1.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	70	10	
	Mean	64.64	62.00	0.369
	SE	1.134	4.470	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.1.3.1 Summary

	FGM (N = 20)	SMBG (N = 50)
Age in years		
n	20	50
Mean (SD)	60.30 (7.855)	66.38 (9.591)
Min-Max	48 - 80	41 - 87
Median	59.50	65.00
Q1-Q3	53.50 - 65.00	60.00 - 74.00

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.1.3.2 Comparison of groups

Variable	Statistic	FGM (G1)	SMBG (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	20	50	
	Mean	60.300	66.380	0.014
	SE	1.7563	1.3564	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.4 Full Analysis Set - Subgroups - Gender
2.2.1.4.1 Summary

	Female (N = 28)	Male (N = 42)
Age in years		
n	28	42
Mean (SD)	64.25 (8.742)	64.90 (10.046)
Min-Max	51 - 83	41 - 87
Median	63.00	64.50
Q1-Q3	58.50 - 70.00	58.00 - 72.00

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.4 Full Analysis Set - Subgroups - Gender
2.2.1.4.2 Comparison of groups

Variable	Statistic	female (G1)	male (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	28	42	
	Mean	64.250	64.905	0.702
	SE	1.6520	1.5501	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.5 Full Analysis Set - Subgroups - Age groups
2.2.1.5.1 Summary

	<=60 years (N = 24)	61 - 69 years (N = 24)	>=70 years (N = 22)
Age in years			
n	24	24	22
Mean (SD)	54.58 (4.481)	64.54 (2.467)	75.73 (4.753)
Min-Max	41 - 60	61 - 69	70 - 87
Median	54.00	64.00	75.00
Q1-Q3	52.00 - 58.50	63.00 - 65.50	71.00 - 80.00

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.5 Full Analysis Set - Subgroups - Age groups
2.2.1.5.2 Comparison of groups

Variable	Statistic	<= 60 years (G1)	>60 - <70 years (G2)	>=70 years (G3)	P-value
Age in years*	N non-miss	24	24	22	
	Mean	54.583	64.542	75.727	<.001
	SE	0.9147	0.5035	1.0133	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.1.6.1 Summary

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Age in years		
n	18	52
Mean (SD)	68.33 (10.488)	63.37 (8.865)
Min-Max	53 - 87	41 - 81
Median	66.00	63.50
Q1-Q3	60.00 - 75.00	56.50 - 70.00

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.1.6.2 Comparison of groups

Variable	Statistic	<30 kg/m² (G1)	>=30 kg/m² (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	18	52	
	Mean	68.333	63.365	0.133
	SE	2.4721	1.2294	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Age in years at date of consent

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.7 Full Analysis Set - Subgroups - Renal function
2.2.1.7.1 Summary

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Age in years		
n	17	39
Mean (SD)	71.94 (7.830)	61.97 (8.595)
Min-Max	60 - 87	41 - 81
Median	73.00	62.00
Q1-Q3	64.00 - 76.00	55.00 - 66.00

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.7 Full Analysis Set - Subgroups - Renal function
2.2.1.7.2 Comparison of groups

Variable	Statistic	<=60 ml (G1)	>60 ml (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	17	39	
	Mean	71.941	61.974	<.001
	SE	1.8991	1.3762	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.1.8.1 Summary

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Age in years			
n	7	21	39
Mean (SD)	57.43 (7.976)	62.71 (11.632)	66.85 (7.717)
Min-Max	41 - 65	48 - 87	52 - 81
Median	60.00	60.00	68.00
Q1-Q3	54.00 - 62.00	53.00 - 71.00	63.00 - 72.00

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.1.8.2 Comparison of groups

Variable	Statistic	up to 5 years (G1)	5 to 10 years (G2)	over 10 years (G3)	P-value
Age in years*	N non-miss	7	21	39	
	Mean	57.429	62.714	66.846	0.018
	SE	3.0147	2.5384	1.2357	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.1.9.1 Summary

	<8.5% (N = 38)	>=8.5% (N = 32)
Age in years		
n	38	32
Mean (SD)	65.18 (9.535)	64.00 (9.538)
Min-Max	41 - 81	48 - 87
Median	64.50	63.00
Q1-Q3	58.00 - 72.00	57.00 - 69.50

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.1.9.2 Comparison of groups

Variable	Statistic	<8.5% (G1)	>=8.5% (G2)	P-Val G1 vs. G2
Age in years*	N non-miss	38	32	
	Mean	65.184	64.000	0.453
	SE	1.5467	1.6860	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.1.10.1 Summary

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Age in years				
n	11	24	29	6
Mean (SD)	62.45 (6.440)	63.71 (8.549)	65.62 (9.314)	67.67 (17.478)
Min-Max	52 - 71	48 - 78	52 - 81	41 - 87
Median	63.00	64.00	63.00	70.50
Q1-Q3	58.00 - 68.00	57.50 - 70.50	60.00 - 73.00	54.00 - 83.00

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.1.10.2 Comparison of groups

Variable	Statistic	Detemir (G1)	Glargin 100 (G2)	Glargin 300 (G3)	Degludec (G4)	P-value
Age in years*	N non-miss	11	24	29	6	
	Mean	62.455	63.708	65.621	67.667	0.657
	SE	1.9417	1.7451	1.7295	7.1352	

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* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.1.11.1 Summary

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Age in years			
n	28	9	32
Mean (SD)	65.96 (10.661)	65.67 (7.762)	62.78 (8.631)
Min-Max	41 - 87	54 - 80	48 - 81
Median	66.50	66.00	63.00
Q1-Q3	60.00 - 74.00	60.00 - 69.00	56.00 - 67.00

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.1 Age - continuous
2.2.1.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.1.11.2 Comparison of groups

Variable	Statistic	before breakfast (G1)	before lunch (G2)	before dinner (G3)	P-value
Age in years*	N non-miss	28	9	32	
	Mean	65.964	65.667	62.781	0.338
	SE	2.0148	2.5874	1.5258	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.1 All patients

	SAS (N = 89) N (%)	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Gender				
female	36 (40.4%)	28 (40.0%)	5 (62.5%)	2 (20.0%)
male	53 (59.6%)	42 (60.0%)	3 (37.5%)	8 (80.0%)
Total	89 (100.0%)	70 (100.0%)	8 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.2 Full Analysis Set
2.2.2.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Gender*	N non-miss	70	8	
	% female	40.00	62.50	0.272
	% male	60.00	37.50	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.2 Full Analysis Set
2.2.2.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Gender*	N non-miss	70	10	
	% female	40.00	20.00	0.306
	% male	60.00	80.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.2.3.1 Summary

	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Gender		
female	8 (40.0%)	20 (40.0%)
male	12 (60.0%)	30 (60.0%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.2.3.2 Comparison of groups

Variable	Statistic	FGM (G1)	SMBG (G2)	P-value
Gender*	N non-miss	20	50	
	% female	40.00	40.00	1.000
	% male	60.00	60.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.4 Full Analysis Set - Subgroups - Gender

NOTE

Not applicable

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.5 Full Analysis Set - Subgroups - Age groups
2.2.2.5.1 Summary

	<=60 years (N = 24) N (%)	61 - 69 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Gender			
female	9 (37.5%)	11 (45.8%)	8 (36.4%)
male	15 (62.5%)	13 (54.2%)	14 (63.6%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.5 Full Analysis Set - Subgroups - Age groups
2.2.2.5.2 Comparison of groups

Variable	Statistic	<= 60 years (G1)	>60 - <70 years (G2)	>=70 years (G3)	P-value
Gender*	N non-miss	24	24	22	
	% female	37.50	45.83	36.36	0.825
	% male	62.50	54.17	63.64	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.2.6.1 Summary

	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Gender		
female	7 (38.9%)	21 (40.4%)
male	11 (61.1%)	31 (59.6%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.2.6.2 Comparison of groups

Variable	Statistic	<30 kg/m² (G1)	>=30 kg/m² (G2)	P-Val G1 vs. G2
Gender*	N non-miss	18	52	
	% female	38.89	40.38	1.000
	% male	61.11	59.62	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.7 Full Analysis Set - Subgroups - Renal function
2.2.2.7.1 Summary

	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Gender		
female	10 (58.8%)	15 (38.5%)
male	7 (41.2%)	24 (61.5%)
Total	17 (100.0%)	39 (100.0%)

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.7 Full Analysis Set - Subgroups - Renal function
2.2.2.7.2 Comparison of groups

Variable	Statistic	<=60 ml (G1)	>60 ml (G2)	P-Val G1 vs. G2
Gender*	N non-miss	17	39	
	% female	58.82	38.46	0.242
	% male	41.18	61.54	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.2.8.1 Summary

	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Gender			
female	5 (71.4%)	10 (47.6%)	12 (30.8%)
male	2 (28.6%)	11 (52.4%)	27 (69.2%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.2.8.2 Comparison of groups

Variable	Statistic	up to 5 years (G1)	5 to 10 years (G2)	over 10 years (G3)	P-value
Gender*	N non-miss	7	21	39	
	% female	71.43	47.62	30.77	0.094
	% male	28.57	52.38	69.23	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.2.9.1 Summary

	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Gender		
female	15 (39.5%)	13 (40.6%)
male	23 (60.5%)	19 (59.4%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.2.9.2 Comparison of groups

Variable	Statistic	<8.5% (G1)	>=8.5% (G2)	P-Val G1 vs. G2
Gender*	N non-miss	38	32	
	% female	39.47	40.63	1.000
	% male	60.53	59.38	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.2.10.1 Summary

	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Gender				
female	6 (54.5%)	9 (37.5%)	11 (37.9%)	2 (33.3%)
male	5 (45.5%)	15 (62.5%)	18 (62.1%)	4 (66.7%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.2.10.2 Comparison of groups

Variable	Statistic	Detemir (G1)	Glargin 100 (G2)	Glargin 300 (G3)	Degludec (G4)	P-value
Gender*	N non-miss	11	24	29	6	
	% female	54.55	37.50	37.93	33.33	0.761
	% male	45.45	62.50	62.07	66.67	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.2.11.1 Summary

	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Gender			
female	13 (46.4%)	1 (11.1%)	13 (40.6%)
male	15 (53.6%)	8 (88.9%)	19 (59.4%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.2 Gender - categorical
2.2.2.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.2.11.2 Comparison of groups

Variable	Statistic	before breakfast (G1)	before lunch (G2)	before dinner (G3)	P-value
Gender*	N non-miss	28	9	32	
	% female	46.43	11.11	40.63	0.175
	% male	53.57	88.89	59.38	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.1 All patients

	SAS (N = 89)	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Height in cm				
n	88	70	8	9
Mean (SD)	171.5 (10.59)	172.1 (9.87)	161.6 (7.37)	178.2 (11.79)
Min-Max	143 - 202	143 - 189	152 - 173	159 - 202
Median	173.0	174.0	160.0	178.0
Q1-Q3	163.0 - 180.0	166.0 - 180.0	157.0 - 167.0	174.0 - 182.0
Weight in kg				
n	86	68	8	9
Mean (SD)	102.8 (21.99)	104.3 (22.53)	91.6 (9.15)	102.9 (25.37)
Min-Max	56 - 158	56 - 158	78 - 104	76 - 158
Median	99.0	103.0	94.0	98.0
Q1-Q3	84.0 - 119.0	84.5 - 122.0	83.5 - 98.0	84.0 - 112.0
BMI in kg/m²				
n	86	68	8	9
Mean (SD)	34.9 (7.02)	35.1 (7.16)	35.3 (4.73)	32.5 (8.16)
Min-Max	21.6 - 51.59	21.6 - 51.59	29.07 - 41.14	23.46 - 51.59
Median	34.0	34.4	35.3	31.5
Q1-Q3	30.1 - 39.0	30.1 - 39.2	31.3 - 39.4	27.5 - 32.8

Patient [redacted] (off-label): height, weight and BMI not documented
Patient [redacted] and [redacted] excluded from calculation
because weight was not documented after 24 weeks

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.2 Full Analysis Set
2.2.3.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	70	8	
	Mean	172.06	161.63	0.006
	SE	1.179	2.605	
Weight in kg*	N non-miss	68	8	
	Mean	104.25	91.63	0.108
	SE	2.733	3.235	
BMI in kg/m²*	N non-miss	68	8	
	Mean	35.10	35.26	0.673
	SE	0.869	1.672	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.2 Full Analysis Set
2.2.3.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	70	9	
	Mean	172.06	178.22	0.171
	SE	1.179	3.929	
Weight in kg*	N non-miss	68	9	
	Mean	104.25	102.89	0.693
	SE	2.733	8.458	
BMI in kg/m²*	N non-miss	68	9	
	Mean	35.10	32.52	0.203
	SE	0.869	2.721	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted] (off-label): height, weight and BMI not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.3.3.1 Summary

	FGM (N = 20)	SMBG (N = 50)
Height in cm		
n	20	50
Mean (SD)	172.90 (8.831)	171.72 (10.317)
Min-Max	153 - 184	143 - 189
Median	175.00	173.00
Q1-Q3	166.50 -180.00	166.00 -178.00
Weight in kg		
n	20	48
Mean (SD)	107.00 (23.108)	103.10 (22.438)
Min-Max	68 - 158	56 - 154
Median	103.50	98.50
Q1-Q3	92.00 -120.00	84.00 -122.00
BMI in kg/m²		
n	20	48
Mean (SD)	35.82 (7.640)	34.81 (7.020)
Min-Max	25.59 - 51.59	21.6 - 51.27
Median	34.24	34.44
Q1-Q3	30.62 - 40.01	29.86 - 38.75

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.3.3.2 Comparison of groups

Variable	Statistic	FGM (G1)	SMBG (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	20	50	
	Mean	172.900	171.720	0.609
	SE	1.9747	1.4591	
Weight in kg*	N non-miss	20	48	
	Mean	107.000	103.104	0.569
	SE	5.1672	3.2386	
BMI in kg/m²*	N non-miss	20	48	
	Mean	35.817	34.808	0.688
	SE	1.7084	1.0132	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.4 Full Analysis Set - Subgroups - Gender
2.2.3.4.1 Summary

	Female (N = 28)	Male (N = 42)
Height in cm		
n	28	42
Mean (SD)	163.96 (7.937)	177.45 (6.915)
Min-Max	143 - 176	157 - 189
Median	164.00	176.50
Q1-Q3	159.00 -168.00	173.00 -183.00
Weight in kg		
n	26	42
Mean (SD)	97.42 (23.418)	108.48 (21.156)
Min-Max	56 - 143	72 - 158
Median	98.00	104.50
Q1-Q3	75.00 -118.00	90.00 -123.00
BMI in kg/m²		
n	26	42
Mean (SD)	36.13 (7.880)	34.47 (6.704)
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.72	34.03
Q1-Q3	30.67 - 40.01	29.07 - 37.92

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.4 Full Analysis Set - Subgroups - Gender
2.2.3.4.2 Comparison of groups

Variable	Statistic	female (G1)	male (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	28	42	
	Mean	163.964	177.452	<.001
	SE	1.5000	1.0670	
Weight in kg*	N non-miss	26	42	
	Mean	97.423	108.476	0.083
	SE	4.5927	3.2644	
BMI in kg/m²*	N non-miss	26	42	
	Mean	36.132	34.469	0.394
	SE	1.5454	1.0344	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.5 Full Analysis Set - Subgroups - Age groups
2.2.3.5.1 Summary

	<=60 years (N = 24)	61 - 69 years (N = 24)	>=70 years (N = 22)
Height in cm			
n	24	24	22
Mean (SD)	172.96 (10.556)	171.25 (10.645)	171.95 (8.488)
Min-Max	154 - 189	143 - 187	157 - 187
Median	174.50	172.50	173.50
Q1-Q3	164.00 -182.50	167.50 -177.00	165.00 -180.00
Weight in kg			
n	24	24	20
Mean (SD)	113.21 (23.609)	99.25 (20.638)	99.50 (21.063)
Min-Max	68 - 158	65 - 138	56 - 130
Median	112.00	96.50	98.00
Q1-Q3	99.00 -128.50	83.00 -118.00	83.50 -118.00
BMI in kg/m²			
n	24	24	20
Mean (SD)	38.06 (8.451)	33.54 (4.341)	33.44 (7.397)
Min-Max	25.59 - 51.59	26.57 - 40.12	21.6 - 49.15
Median	37.66	33.69	33.82
Q1-Q3	30.88 - 46.49	30.10 - 37.58	28.57 - 36.36

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.5 Full Analysis Set - Subgroups - Age groups
2.2.3.5.2 Comparison of groups

Variable	Statistic	<= 60 years (G1)	>60 - <70 years (G2)	>=70 years (G3)	P-value
Height in cm*	N non-miss	24	24	22	
	Mean	172.958	171.250	171.955	0.837
	SE	2.1548	2.1730	1.8096	
Weight in kg*	N non-miss	24	24	20	
	Mean	113.208	99.250	99.500	0.068
	SE	4.8192	4.2128	4.7097	
BMI in kg/m²*	N non-miss	24	24	20	
	Mean	38.059	33.538	33.441	0.119
	SE	1.7250	0.8860	1.6541	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.3.6.1 Summary

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Height in cm		
n	18	52
Mean (SD)	172.56 (8.813)	171.88 (10.282)
Min-Max	158 - 187	143 - 189
Median	173.00	174.00
Q1-Q3	168.00 -177.00	165.50 -180.00
Weight in kg		
n	16	52
Mean (SD)	80.94 (11.096)	111.42 (20.197)
Min-Max	56 - 99	65 - 158
Median	82.50	114.00
Q1-Q3	74.50 - 87.00	98.00 -125.00
BMI in kg/m²		
n	16	52
Mean (SD)	26.78 (2.270)	37.67 (6.121)
Min-Max	21.6 - 29.64	30.08 - 51.59
Median	27.29	36.06
Q1-Q3	25.33 - 28.67	33.60 - 39.95

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.6 Full Analysis Set - Subgroups - Body Mass Index
2.2.3.6.2 Comparison of groups

Variable	Statistic	<30 kg/m² (G1)	>=30 kg/m² (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	18	52	
	Mean	172.556	171.885	0.995
	SE	2.0773	1.4258	
Weight in kg*	N non-miss	16	52	
	Mean	80.938	111.423	<.001
	SE	2.7741	2.8009	
BMI in kg/m²*	N non-miss	16	52	
	Mean	26.777	37.667	<.001
	SE	0.5676	0.8489	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.7 Full Analysis Set - Subgroups - Renal function
2.2.3.7.1 Summary

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Height in cm		
n	17	39
Mean (SD)	168.24 (9.176)	173.13 (10.815)
Min-Max	143 - 183	153 - 189
Median	168.00	175.00
Q1-Q3	165.00 -174.00	163.00 -183.00
Weight in kg		
n	15	39
Mean (SD)	95.47 (17.940)	105.05 (22.428)
Min-Max	65 - 129	56 - 143
Median	98.00	105.00
Q1-Q3	83.00 -107.00	84.00 -122.00
BMI in kg/m²		
n	15	39
Mean (SD)	33.73 (7.161)	35.00 (6.957)
Min-Max	24.78 - 49.15	21.6 - 51.27
Median	33.75	34.85
Q1-Q3	28.41 - 36.00	30.12 - 39.46

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.7 Full Analysis Set - Subgroups - Renal function
2.2.3.7.2 Comparison of groups

Variable	Statistic	<=60 ml (G1)	>60 ml (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	17	39	
	Mean	168.235	173.128	0.107
	SE	2.2254	1.7317	
Weight in kg*	N non-miss	15	39	
	Mean	95.467	105.051	0.133
	SE	4.6320	3.5913	
BMI in kg/m²*	N non-miss	15	39	
	Mean	33.735	34.997	0.410
	SE	1.8489	1.1140	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.3.8.1 Summary

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Height in cm			
n	7	21	39
Mean (SD)	168.57 (9.519)	170.62 (9.222)	173.54 (10.463)
Min-Max	154 - 183	154 - 186	143 - 189
Median	168.00	171.00	174.00
Q1-Q3	162.00 -176.00	163.00 -176.00	168.00 -182.00
Weight in kg			
n	7	19	39
Mean (SD)	108.29 (14.092)	102.74 (27.763)	103.13 (21.801)
Min-Max	89 - 129	56 - 154	65 - 158
Median	105.00	105.00	98.00
Q1-Q3	98.00 -122.00	79.00 -123.00	84.00 -122.00
BMI in kg/m²			
n	7	19	39
Mean (SD)	38.27 (5.499)	34.94 (9.026)	34.17 (6.378)
Min-Max	30.08 - 48.07	21.6 - 51.27	23.24 - 51.59
Median	38.52	33.90	33.63
Q1-Q3	34.72 - 40.01	28.41 - 42.94	30.12 - 37.24

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.8 Full Analysis Set - Subgroups - Duration of diabetes
2.2.3.8.2 Comparison of groups

Variable	Statistic	up to 5 years (G1)	5 to 10 years (G2)	over 10 years (G3)	P-value
Height in cm*	N non-miss	7	21	39	
	Mean	168.571	170.619	173.539	0.272
	SE	3.5980	2.0124	1.6754	
Weight in kg*	N non-miss	7	19	39	
	Mean	108.286	102.737	103.128	0.747
	SE	5.3261	6.3692	3.4909	
BMI in kg/m²*	N non-miss	7	19	39	
	Mean	38.270	34.944	34.171	0.226
	SE	2.0784	2.0708	1.0213	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.3.9.1 Summary

	<8.5% (N = 38)	>=8.5% (N = 32)
Height in cm		
n	38	32
Mean (SD)	172.76 (9.862)	171.22 (9.964)
Min-Max	143 - 187	153 - 189
Median	174.00	173.50
Q1-Q3	167.00 -180.00	163.50 -176.00
Weight in kg		
n	38	30
Mean (SD)	104.82 (21.847)	103.53 (23.734)
Min-Max	56 - 143	72 - 158
Median	103.50	98.00
Q1-Q3	85.00 -122.00	83.00 -118.00
BMI in kg/m²		
n	38	30
Mean (SD)	35.02 (6.611)	35.22 (7.926)
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.79	34.03
Q1-Q3	30.41 - 38.97	29.06 - 39.46

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.9 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.3.9.2 Comparison of groups

Variable	Statistic	<8.5% (G1)	>=8.5% (G2)	P-Val G1 vs. G2
Height in cm*	N non-miss	38	32	
	Mean	172.763	171.219	0.522
	SE	1.5999	1.7613	
Weight in kg*	N non-miss	38	30	
	Mean	104.816	103.533	0.507
	SE	3.5440	4.3332	
BMI in kg/m²*	N non-miss	38	30	
	Mean	35.017	35.216	0.787
	SE	1.0724	1.4470	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.3.10.1 Summary

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Height in cm				
n	11	24	29	6
Mean (SD)	174.55 (8.153)	172.75 (10.246)	170.10 (10.655)	174.17 (6.969)
Min-Max	162 - 187	153 - 189	143 - 187	167 - 183
Median	176.00	174.00	170.00	173.50
Q1-Q3	168.00 -183.00	168.00 -180.00	163.00 -176.00	168.00 -180.00
Weight in kg				
n	11	23	29	5
Mean (SD)	117.64 (19.679)	103.04 (20.901)	97.76 (22.674)	118.00 (22.204)
Min-Max	82 - 154	74 - 140	56 - 158	83 - 143
Median	122.00	103.00	98.00	118.00
Q1-Q3	98.00 -128.00	84.00 -122.00	84.00 -114.00	117.00 -129.00
BMI in kg/m²				
n	11	23	29	5
Mean (SD)	38.78 (7.156)	34.30 (6.306)	33.77 (7.375)	38.44 (8.054)
Min-Max	27.4 - 49.72	24.78 - 47.88	21.6 - 51.59	29.06 - 51.27
Median	38.22	33.90	31.79	37.24
Q1-Q3	34.72 - 45.92	28.93 - 38.97	29.64 - 37.10	36.11 - 38.52

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.10 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.3.10.2 Comparison of groups

Variable	Statistic	Detemir (G1)	Glargin 100 (G2)	Glargin 300 (G3)	Degludec (G4)	P-value
Height in cm*	N non-miss	11	24	29	6	
	Mean	174.546	172.750	170.103	174.167	0.548
	SE	2.4582	2.0914	1.9785	2.8451	
Weight in kg*	N non-miss	11	23	29	5	
	Mean	117.636	103.044	97.759	118.000	0.044
	SE	5.9334	4.3582	4.2105	9.9298	
BMI in kg/m²*	N non-miss	11	23	29	5	
	Mean	38.775	34.303	33.773	38.440	0.126
	SE	2.1576	1.3150	1.3695	3.6019	

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* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.3.11.1 Summary

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Height in cm			
n	28	9	32
Mean (SD)	170.11 (10.192)	176.67 (7.297)	172.94 (9.735)
Min-Max	143 - 187	158 - 182	153 - 189
Median	170.00	180.00	174.00
Q1-Q3	163.50 -176.00	177.00 -180.00	166.50 -181.50
Weight in kg			
n	27	9	31
Mean (SD)	105.00 (25.701)	104.11 (16.556)	104.29 (21.779)
Min-Max	56 - 154	74 - 130	68 - 158
Median	105.00	103.00	101.00
Q1-Q3	83.00 -128.00	99.00 -117.00	85.00 -119.00
BMI in kg/m²			
n	27	9	31
Mean (SD)	36.13 (7.987)	33.21 (3.884)	34.79 (7.292)
Min-Max	21.6 - 51.27	28.41 - 40.12	23.24 - 51.59
Median	36.00	31.79	34.15
Q1-Q3	30.41 - 40.01	30.56 - 36.11	29.07 - 38.22

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.3 Height, weight and BMI - continuous
2.2.3.11 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.3.11.2 Comparison of groups

Variable	Statistic	before breakfast (G1)	before lunch (G2)	before dinner (G3)	P-value
Height in cm*	N non-miss	28	9	32	
	Mean	170.107	176.667	172.938	0.120
	SE	1.9261	2.4324	1.7209	
Weight in kg*	N non-miss	27	9	31	
	Mean	105.000	104.111	104.290	0.968
	SE	4.9461	5.5188	3.9117	
BMI in kg/m²*	N non-miss	27	9	31	
	Mean	36.133	33.211	34.793	0.593
	SE	1.5371	1.2946	1.3097	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.1 All patients

Blood pressure in mmHg	SAS (N = 89)	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Systolic				
n	84	67	7	9
Mean (SD)	138.6 (16.39)	138.7 (16.23)	139.9 (22.72)	138.0 (14.75)
Min-Max	100 - 188	100 - 186	120 - 188	120 - 165
Median	138.0	138.0	138.0	139.0
Q1-Q3	130.0 - 145.0	130.0 - 145.0	123.0 - 140.0	130.0 - 145.0
Diastolic				
n	84	67	7	9
Mean (SD)	81.6 (9.50)	82.0 (9.70)	79.7 (9.74)	80.3 (9.17)
Min-Max	55 - 108	55 - 108	61 - 93	66 - 96
Median	80.0	80.0	80.0	80.0
Q1-Q3	80.0 - 86.0	80.0 - 86.0	78.0 - 86.0	80.0 - 80.0

Patient [redacted], [redacted], [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.2 Full Analysis Set
2.2.4.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	67	7	
	Mean	138.67	139.86	0.745
	SE	1.983	8.587	
Diastolic in mmHg*	N non-miss	67	7	
	Mean	81.96	79.71	0.618
	SE	1.185	3.682	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.2 Full Analysis Set
2.2.4.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	67	9	
	Mean	138.67	138.00	0.987
	SE	1.983	4.916	
Diastolic in mmHg*	N non-miss	67	9	
	Mean	81.96	80.33	0.599
	SE	1.185	3.055	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.4.3.1 Summary

	FGM (N = 20)	SMBG (N = 50)
Systolic in mmHg		
n	20	47
Mean (SD)	136.60 (17.602)	139.55 (15.723)
Min-Max	110 - 180	100 - 186
Median	132.50	140.00
Q1-Q3	120.50 -144.50	130.00 -145.00
Diastolic in mmHg		
n	20	47
Mean (SD)	82.85 (10.999)	81.57 (9.191)
Min-Max	60 - 108	55 - 99
Median	80.00	80.00
Q1-Q3	79.50 - 87.50	80.00 - 86.00

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.3 Full Analysis Set - Subgroups - FGM - SMBG
2.2.4.3.2 Comparison of groups

Variable	Statistic	FGM (G1)	SMBG (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	20	47	
	Mean	136.600	139.553	0.406
	SE	3.9359	2.2934	
Diastolic in mmHg*	N non-miss	20	47	
	Mean	82.850	81.574	0.748
	SE	2.4594	1.3406	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.4 Full Analysis Set - Subgroups - Age groups
2.2.4.4.1 Summary

	<=60 years (N = 24)	61 - 69 years (N = 24)	>=70 years (N = 22)
Systolic in mmHg			
n	23	23	21
Mean (SD)	140.87 (18.003)	133.48 (14.378)	141.95 (15.403)
Min-Max	100 - 180	110 - 173	130 - 186
Median	140.00	130.00	140.00
Q1-Q3	130.00 -150.00	122.00 -140.00	130.00 -149.00
Diastolic in mmHg			
n	23	23	21
Mean (SD)	86.61 (10.465)	79.30 (7.900)	79.76 (9.121)
Min-Max	60 - 108	60 - 97	55 - 95
Median	85.00	80.00	80.00
Q1-Q3	80.00 - 95.00	75.00 - 84.00	78.00 - 85.00

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.4 Full Analysis Set - Subgroups - Age groups
2.2.4.4.2 Comparison of groups

Variable	Statistic	<= 60 years (G1)	>60 - <70 years (G2)	>=70 years (G3)	P-value
Systolic in mmHg*	N non-miss	23	23	21	
	Mean	140.870	133.478	141.952	0.084
	SE	3.7539	2.9979	3.3612	
Diastolic in mmHg*	N non-miss	23	23	21	
	Mean	86.609	79.304	79.762	0.019
	SE	2.1822	1.6472	1.9903	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.2.4.5.1 Summary

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Systolic in mmHg		
n	17	50
Mean (SD)	134.82 (12.238)	139.98 (17.289)
Min-Max	120 - 167	100 - 186
Median	130.00	140.00
Q1-Q3	130.00 -140.00	130.00 -149.00
Diastolic in mmHg		
n	17	50
Mean (SD)	79.53 (8.966)	82.78 (9.884)
Min-Max	55 - 97	60 - 108
Median	80.00	80.00
Q1-Q3	80.00 - 80.00	79.00 - 90.00

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.2.4.5.2 Comparison of groups

Variable	Statistic	<30 kg/m² (G1)	>=30 kg/m² (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	17	50	
	Mean	134.824	139.980	0.195
	SE	2.9683	2.4451	
Diastolic in mmHg*	N non-miss	17	50	
	Mean	79.529	82.780	0.306
	SE	2.1746	1.3978	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted], [redacted] and [redacted]: not documented

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.6 Full Analysis Set - Subgroups - Renal function
2.2.4.6.1 Summary

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Systolic in mmHg		
n	17	36
Mean (SD)	141.94 (18.593)	136.28 (16.794)
Min-Max	120 - 186	100 - 180
Median	140.00	131.00
Q1-Q3	130.00 -150.00	128.50 -142.50
Diastolic in mmHg		
n	17	36
Mean (SD)	79.41 (8.725)	82.44 (10.584)
Min-Max	55 - 95	60 - 108
Median	80.00	80.00
Q1-Q3	78.00 - 84.00	79.50 - 90.00

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.6 Full Analysis Set - Subgroups - Renal function
2.2.4.6.2 Comparison of groups

Variable	Statistic	<=60 ml (G1)	>60 ml (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	17	36	
	Mean	141.941	136.278	0.462
	SE	4.5094	2.7990	
Diastolic in mmHg*	N non-miss	17	36	
	Mean	79.412	82.444	0.353
	SE	2.1162	1.7640	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of renal function

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.2.4.7.1 Summary

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Systolic in mmHg			
n	7	19	38
Mean (SD)	130.71 (16.938)	141.21 (15.204)	138.50 (16.765)
Min-Max	100 - 150	120 - 180	110 - 186
Median	130.00	140.00	136.00
Q1-Q3	120.00 -145.00	130.00 -145.00	127.00 -144.00
Diastolic in mmHg			
n	7	19	38
Mean (SD)	79.29 (11.701)	84.11 (10.306)	80.87 (9.230)
Min-Max	60 - 95	55 - 108	60 - 106
Median	80.00	85.00	80.00
Q1-Q3	70.00 - 90.00	80.00 - 90.00	78.00 - 84.00

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.2.4.7.2 Comparison of groups

Variable	Statistic	up to 5 years (G1)	5 to 10 years (G2)	over 10 years (G3)	P-value
Systolic in mmHg*	N non-miss	7	19	38	
	Mean	130.714	141.211	138.500	0.408
	SE	6.4021	3.4881	2.7197	
Diastolic in mmHg*	N non-miss	7	19	38	
	Mean	79.286	84.105	80.868	0.271
	SE	4.4224	2.3643	1.4974	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of duration of diabetes

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.4.8.1 Summary

	<8.5% (N = 38)	>=8.5% (N = 32)
Systolic in mmHg		
n	37	30
Mean (SD)	137.54 (14.809)	140.07 (17.985)
Min-Max	120 - 180	100 - 186
Median	132.00	140.00
Q1-Q3	130.00 -144.00	130.00 -145.00
Diastolic in mmHg		
n	37	30
Mean (SD)	81.41 (8.552)	82.63 (11.062)
Min-Max	60 - 106	55 - 108
Median	80.00	80.00
Q1-Q3	80.00 - 86.00	80.00 - 91.00

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.2.4.8.2 Comparison of groups

Variable	Statistic	<8.5% (G1)	>=8.5% (G2)	P-Val G1 vs. G2
Systolic in mmHg*	N non-miss	37	30	
	Mean	137.541	140.067	0.313
	SE	2.4346	3.2835	
Diastolic in mmHg*	N non-miss	37	30	
	Mean	81.405	82.633	0.715
	SE	1.4059	2.0197	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.4.9.1 Summary

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Systolic in mmHg				
n	10	23	28	6
Mean (SD)	134.90 (9.195)	144.91 (20.376)	135.96 (14.869)	133.67 (4.967)
Min-Max	120 - 154	110 - 186	100 - 170	130 - 140
Median	132.50	140.00	135.50	131.00
Q1-Q3	130.00 -140.00	130.00 -159.00	125.50 -144.50	130.00 -140.00
Diastolic in mmHg				
n	10	23	28	6
Mean (SD)	83.70 (7.088)	81.57 (12.383)	81.32 (9.096)	83.50 (4.183)
Min-Max	75 - 97	55 - 108	60 - 106	80 - 90
Median	80.00	80.00	80.00	82.50
Q1-Q3	80.00 - 85.00	78.00 - 90.00	79.00 - 85.50	80.00 - 86.00

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.2.4.9.2 Comparison of groups

Variable	Statistic	Detemir (G1)	Glargin 100 (G2)	Glargin 300 (G3)	Degludec (G4)	P-value
Systolic in mmHg*	N non-miss	10	23	28	6	
	Mean	134.900	144.913	135.964	133.667	0.297
	SE	2.9077	4.2487	2.8099	2.0276	
Diastolic in mmHg*	N non-miss	10	23	28	6	
	Mean	83.700	81.565	81.321	83.500	0.805
	SE	2.2413	2.5821	1.7191	1.7078	

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* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.4.10.1 Summary

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Systolic in mmHg			
n	26	8	32
Mean (SD)	136.38 (12.630)	142.63 (15.638)	138.94 (18.875)
Min-Max	100 - 170	121 - 167	110 - 186
Median	138.00	142.00	134.50
Q1-Q3	130.00 -140.00	130.00 -154.50	126.00 -145.00
Diastolic in mmHg			
n	26	8	32
Mean (SD)	82.65 (8.419)	80.38 (13.522)	81.78 (10.035)
Min-Max	60 - 97	60 - 106	55 - 108
Median	80.00	79.50	80.00
Q1-Q3	80.00 - 90.00	74.00 - 85.00	80.00 - 85.50

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.2 Demographic data and baseline characteristics
2.2.4 Blood pressure - continuous
2.2.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.2.4.10.2 Comparison of groups

Variable	Statistic	before breakfast (G1)	before lunch (G2)	before dinner (G3)	P-value
Systolic in mmHg*	N non-miss	26	8	32	
	Mean	136.385	142.625	138.938	0.645
	SE	2.4770	5.5289	3.3366	
Diastolic in mmHg*	N non-miss	26	8	32	
	Mean	82.654	80.375	81.781	0.511
	SE	1.6511	4.7807	1.7739	

* :p-values are based on the Kruskal Wallis test statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Only patients with documentation of Time of iGlarLixi administration

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.1 Full Analysis Set - Dropout - Off-Label
2.3.1.1.1.1 Categorical

Period of initial diagnosis	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
unknown	3	1	1
up to 5 years	7 (10.45%)	1 (14.29%)	0 (0.00%)
5 to 10 years	21 (31.34%)	0 (0.00%)	3 (33.33%)
over 10 years	39 (58.21%)	6 (85.71%)	6 (66.67%)
Total	67 (100.00%)	7 (100.00%)	9 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.1 Full Analysis Set - Dropout - Off-Label
2.3.1.1.1.2 Continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Period in years			
n	50	6	8
Mean (SD)	12.26 (6.679)	13.33 (6.713)	11.25 (4.062)
Min-Max	2 - 30	2 - 22	5 - 17
Median	11.00	14.00	12.00
Q1-Q3	9.00 - 16.00	11.00 - 17.00	8.50 - 13.50

Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.1 Full Analysis Set - Dropout - Off-Label
2.3.1.1.1.3 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Period of initial diagnosis*	N non-miss	67	7	
	% up to 5 year	10.45	14.29	0.173
	% 5 to 10 year	31.34	0.00	
	% over 10 year	58.21	85.71	
Years**	N non-miss	50	6	
	Mean	12.3	13.3	0.501
	SE	0.94	2.74	

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* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing
Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.1 Full Analysis Set - Dropout - Off-Label
2.3.1.1.1.4 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Period of initial diagnosis*	N non-miss	67	9	
	% up to 5 year	10.45	0.00	0.878
	% 5 to 10 year	31.34	33.33	
	% over 10 year	58.21	66.67	
Years**	N non-miss	50	8	
	Mean	12.3	11.3	0.991
	SE	0.94	1.44	

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* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing
Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.1.2.1 Categorical

Period of initial diagnosis	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
unknown	1	2
up to 5 years	1 (5.26%)	6 (12.50%)
5 to 10 years	7 (36.84%)	14 (29.17%)
over 10 years	11 (57.89%)	28 (58.33%)
Total	19 (100.00%)	48 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.1.2.2 Continuous

	FGM (N = 20)	SMBG (N = 50)
Period in years		
n	12	38
Mean (SD)	14.25 (8.324)	11.63 (6.065)
Min-Max	2 - 30	2 - 25
Median	12.50	11.00
Q1-Q3	9.50 - 19.00	7.00 - 15.00

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.3 Full Analysis Set - Subgroups - Gender
2.3.1.1.3.1 Categorical

Period of initial diagnosis	Female (N = 28) N (%)	Male (N = 42) N (%)
unknown	1	2
up to 5 years	5 (18.52%)	2 (5.00%)
5 to 10 years	10 (37.04%)	11 (27.50%)
over 10 years	12 (44.44%)	27 (67.50%)
Total	27 (100.00%)	40 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.3 Full Analysis Set - Subgroups - Gender
2.3.1.1.3.2 Continuous

	Female (N = 28)	Male (N = 42)
Period in years		
n	18	32
Mean (SD)	8.44 (4.902)	14.41 (6.642)
Min-Max	2 - 20	3 - 30
Median	9.00	13.50
Q1-Q3	3.00 - 11.00	10.00 - 19.50

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.4 Full Analysis Set - Subgroups - Age groups
2.3.1.1.4.1 Categorical

Period of initial diagnosis	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
unknown	1	1	1
up to 5 years	4 (17.39%)	3 (13.04%)	0 (0.00%)
5 to 10 years	12 (52.17%)	3 (13.04%)	6 (28.57%)
over 10 years	7 (30.43%)	17 (73.91%)	15 (71.43%)
Total	23 (100.00%)	23 (100.00%)	21 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.4 Full Analysis Set - Subgroups - Age groups
2.3.1.1.4.2 Continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Period in years			
n	18	18	14
Mean (SD)	10.22 (6.274)	13.56 (7.957)	13.21 (4.980)
Min-Max	2 - 22	2 - 30	5 - 21
Median	10.00	13.00	12.00
Q1-Q3	5.00 - 14.00	9.00 - 15.00	10.00 - 17.00

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.1.5.1 Categorical

Period of initial diagnosis	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
unknown	0	3
up to 5 years	0 (0.00%)	7 (14.29%)
5 to 10 years	9 (50.00%)	12 (24.49%)
over 10 years	9 (50.00%)	30 (61.22%)
Total	18 (100.00%)	49 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.1.5.2 Continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Period in years		
n	10	40
Mean (SD)	12.20 (5.653)	12.28 (6.976)
Min-Max	5 - 21	2 - 30
Median	11.50	11.00
Q1-Q3	7.00 - 15.00	9.00 - 16.00

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.6 Full Analysis Set - Subgroups - Renal function
2.3.1.1.6.1 Categorical

Period of initial diagnosis	<=60 ml (N = 17) N (%)	>60 ml (N = 39) N (%)
unknown	1	2
up to 5 years	1 (6.25%)	6 (16.22%)
5 to 10 years	5 (31.25%)	11 (29.73%)
over 10 years	10 (62.50%)	20 (54.05%)
Total	16 (100.00%)	37 (100.00%)

Only patients with documentation of renal function
Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.6 Full Analysis Set - Subgroups - Renal function
2.3.1.1.6.2 Continuous

	<=60 ml (N = 17)	>60 ml (N = 39)
Period in years		
n	11	27
Mean (SD)	11.00 (4.561)	12.52 (7.925)
Min-Max	3 - 20	2 - 30
Median	11.00	11.00
Q1-Q3	9.00 - 14.00	7.00 - 17.00

Only patients with documentation of renal function
Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.1.7.1 Categorical

Period of initial diagnosis	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
up to 5 years	7 (100.00%)	0 (0.00%)	0 (0.00%)
5 to 10 years	0 (0.00%)	21 (100.00%)	0 (0.00%)
over 10 years	0 (0.00%)	0 (0.00%)	39 (100.00%)
Total	7 (100.00%)	21 (100.00%)	39 (100.00%)

Only patients with documentation of duration of diabetes
Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.1.7.2 Continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Period in years			
n	7	15	28
Mean (SD)	2.86 (0.690)	8.33 (1.988)	16.71 (5.170)
Min-Max	2 - 4	5 - 10	11 - 30
Median	3.00	9.00	15.00
Q1-Q3	2.00 - 3.00	7.00 - 10.00	13.00 - 20.50

Only patients with documentation of duration of diabetes
Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.1.8.1 Categorical

Period of initial diagnosis	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
unknown	3	0
up to 5 years	4 (11.43%)	3 (9.38%)
5 to 10 years	10 (28.57%)	11 (34.38%)
over 10 years	21 (60.00%)	18 (56.25%)
Total	35 (100.00%)	32 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.1.8.2 Continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Period in years		
n	27	23
Mean (SD)	12.74 (7.304)	11.70 (5.973)
Min-Max	2 - 30	3 - 25
Median	11.00	11.00
Q1-Q3	9.00 - 17.00	7.00 - 15.00

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.1.9.1 Categorical

Period of initial diagnosis	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
unknown	1	0	2	0
up to 5 years	2 (20.00%)	0 (0.00%)	4 (14.81%)	1 (16.67%)
5 to 10 years	2 (20.00%)	12 (50.00%)	4 (14.81%)	3 (50.00%)
over 10 years	6 (60.00%)	12 (50.00%)	19 (70.37%)	2 (33.33%)
Total	10 (100.00%)	24 (100.00%)	27 (100.00%)	6 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.1.9.2 Continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Period in years				
n	6	19	22	3
Mean (SD)	8.17 (5.707)	14.00 (7.203)	11.55 (5.595)	14.67 (11.060)
Min-Max	2 - 16	5 - 30	2 - 22	3 - 25
Median	7.50	10.00	11.50	16.00
Q1-Q3	3.00 - 13.00	9.00 - 20.00	7.00 - 14.00	3.00 - 25.00

Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.1.10.1 Categorical

Period of initial diagnosis	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
unknown	1	0	2
up to 5 years	3 (11.11%)	0 (0.00%)	4 (13.33%)
5 to 10 years	10 (37.04%)	3 (33.33%)	8 (26.67%)
over 10 years	14 (51.85%)	6 (66.67%)	18 (60.00%)
Total	27 (100.00%)	9 (100.00%)	30 (100.00%)

Only patients with documentation of Time of iGlarLixi administration
Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.1 Period of initial diagnosis
2.3.1.1.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.1.10.2 Continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Period in years			
n	20	9	20
Mean (SD)	11.15 (6.150)	16.78 (9.244)	11.35 (5.422)
Min-Max	2 - 23	5 - 30	2 - 21
Median	10.50	16.00	11.50
Q1-Q3	6.00 - 14.00	9.00 - 25.00	9.00 - 15.00

Only patients with documentation of Time of iGlarLixi administration
Years: Only patients with known date of initial Diagnosis

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.1 Full Analysis Set - All patients
2.3.1.2.1.1 Events total/nocturnal - categorical

	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl			
Missing	3	1	0
no	64 (95.52%)	7 (100.00%)	10 (100.00%)
yes	3 (4.48%)	0 (0.00%)	0 (0.00%)
Total	67 (100.00%)	7 (100.00%)	10 (100.00%)
If yes, nocturnal?			
Missing	3	1	0
no	66 (98.51%)	7 (100.00%)	10 (100.00%)
yes	1 (1.49%)	0 (0.00%)	0 (0.00%)
Total	67 (100.00%)	7 (100.00%)	10 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.1 Full Analysis Set - All patients
2.3.1.2.1.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg	N non-miss	67	7	
	% no	95.52	100.00	1.000
	% yes	4.48	0.00	
If yes nocturnal?*	N non-miss	67	7	
	% no	98.51	100.00	1.000
	% yes	1.49	0.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.1 Full Analysis Set - All patients
2.3.1.2.1.3 FAS compared to Off-label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg	N non-miss	67	10	
	% no	95.52	100.00	1.000
	% yes	4.48	0.00	
If yes nocturnal?*	N non-miss	67	10	
	% no	98.51	100.00	1.000
	% yes	1.49	0.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.1 Full Analysis Set - All patients
2.3.1.2.1.4 Number of events - continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Number of events			
n	67	7	10
Mean (SD)	0.1 (0.65)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 4	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal			
n	67	7	10
Mean (SD)	0.1 (0.49)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 4	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.1 Full Analysis Set - All patients
2.3.1.2.1.5 Events per patient year

	Number of events	Patient years	Events per patient year
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	9	15.42	0.584
nocturnal	4	15.42	0.259

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.2.2.1 Events total/nocturnal - categorical

	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl		
Missing	1	2
no	18 (94.7%)	46 (95.8%)
yes	1 (5.3%)	2 (4.2%)
Total	19 (100.0%)	48 (100.0%)
If yes, nocturnal?		
Missing	1	2
no	18 (94.7%)	48 (100.0%)
yes	1 (5.3%)	0 (0.0%)
Total	19 (100.0%)	48 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.2.2.2 Number of events - continuous

	FGM (N = 20)	SMBG (N = 50)
Number of events		
n	19	48
Mean (SD)	0.2 (0.92)	0.1 (0.52)
Min-Max	0 - 4	0 - 3
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal		
n	19	48
Mean (SD)	0.2 (0.92)	0.0 (0.00)
Min-Max	0 - 4	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.2.2.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
FGM	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	4	4.373	0.915
	nocturnal	4	4.373	0.915
SMBG	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	5	11.05	0.453
	nocturnal	0	11.05	0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.3 Full Analysis Set - Subgroups - Gender
2.3.1.2.3.1 Events total/nocturnal - categorical

	Female (N = 28) N (%)	Male (N = 42) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl		
Missing	1	2
no	26 (96.3%)	38 (95.0%)
yes	1 (3.7%)	2 (5.0%)
Total	27 (100.0%)	40 (100.0%)
If yes, nocturnal?		
Missing	1	2
no	27 (100.0%)	39 (97.5%)
yes	0 (0.0%)	1 (2.5%)
Total	27 (100.0%)	40 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.3 Full Analysis Set - Subgroups - Gender
2.3.1.2.3.2 Number of events - continuous

	Female (N = 28)	Male (N = 42)
Number of events		
n	27	40
Mean (SD)	0.1 (0.58)	0.2 (0.70)
Min-Max	0 - 3	0 - 4
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal		
n	27	40
Mean (SD)	0.0 (0.00)	0.1 (0.63)
Min-Max	0 - 0	0 - 4
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.3 Full Analysis Set - Subgroups - Gender
2.3.1.2.3.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
Female	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	6.214	0.483
	nocturnal	0	6.214	0
Male	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	6	9.205	0.652
	nocturnal	4	9.205	0.435

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.4 Full Analysis Set - Subgroups - Age groups
2.3.1.2.4.1 Events total/nocturnal - categorical

	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl			
Missing	0	2	1
no	24 (100.0%)	21 (95.5%)	19 (90.5%)
yes	0 (0.0%)	1 (4.5%)	2 (9.5%)
Total	24 (100.0%)	22 (100.0%)	21 (100.0%)
If yes, nocturnal?			
Missing	0	2	1
no	24 (100.0%)	22 (100.0%)	20 (95.2%)
yes	0 (0.0%)	0 (0.0%)	1 (4.8%)
Total	24 (100.0%)	22 (100.0%)	21 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.4 Full Analysis Set - Subgroups - Age groups
2.3.1.2.4.2 Number of events - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Number of events			
n	24	22	21
Mean (SD)	0.0 (0.00)	0.1 (0.43)	0.3 (1.06)
Min-Max	0 - 0	0 - 2	0 - 4
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal			
n	24	22	21
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.87)
Min-Max	0 - 0	0 - 0	0 - 4
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.4 Full Analysis Set - Subgroups - Age groups
2.3.1.2.4.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
<= 60 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	0	5.523	0
	nocturnal	0	5.523	0
>60 - <70 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	2	5.063	0.395
	nocturnal	0	5.063	0
>=70 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	7	4.833	1.448
	nocturnal	4	4.833	0.828

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.2.5.1 Events total/nocturnal - categorical

	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl		
Missing	2	1
no	15 (93.8%)	49 (96.1%)
yes	1 (6.3%)	2 (3.9%)
Total	16 (100.0%)	51 (100.0%)
If yes, nocturnal?		
Missing	2	1
no	16 (100.0%)	50 (98.0%)
yes	0 (0.0%)	1 (2.0%)
Total	16 (100.0%)	51 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.2.5.2 Number of events - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Number of events		
n	16	51
Mean (SD)	0.2 (0.75)	0.1 (0.62)
Min-Max	0 - 3	0 - 4
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal		
n	16	51
Mean (SD)	0.0 (0.00)	0.1 (0.56)
Min-Max	0 - 0	0 - 4
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.2.5.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
<30 kg/m²	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	3.682	0.815
	nocturnal	0	3.682	0
>=30 kg/m²	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	6	11.74	0.511
	nocturnal	4	11.74	0.341

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.6 Full Analysis Set - Subgroups - Renal function
2.3.1.2.6.1 Events total/nocturnal - categorical

	<=60 ml (N = 17) N (%)	>60 ml (N = 39) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl		
Missing	0	2
no	15 (88.2%)	36 (97.3%)
yes	2 (11.8%)	1 (2.7%)
Total	17 (100.0%)	37 (100.0%)
If yes, nocturnal?		
Missing	0	2
no	16 (94.1%)	37 (100.0%)
yes	1 (5.9%)	0 (0.0%)
Total	17 (100.0%)	37 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.6 Full Analysis Set - Subgroups - Renal function
2.3.1.2.6.2 Number of events - continuous

	<=60 ml (N = 17)	>60 ml (N = 39)
Number of events		
n	17	37
Mean (SD)	0.4 (1.18)	0.1 (0.33)
Min-Max	0 - 4	0 - 2
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal		
n	17	37
Mean (SD)	0.2 (0.97)	0.0 (0.00)
Min-Max	0 - 4	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.6 Full Analysis Set - Subgroups - Renal function
2.3.1.2.6.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
<=60 ml	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	7	3.912	1.789
	nocturnal	4	3.912	1.022
>60 ml	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	2	8.515	0.235
	nocturnal	0	8.515	0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.2.7.1 Events total/nocturnal - categorical

	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl			
Missing	0	1	2
no	7 (100.0%)	19 (95.0%)	35 (94.6%)
yes	0 (0.0%)	1 (5.0%)	2 (5.4%)
Total	7 (100.0%)	20 (100.0%)	37 (100.0%)
If yes, nocturnal?			
Missing	0	1	2
no	7 (100.0%)	20 (100.0%)	36 (97.3%)
yes	0 (0.0%)	0 (0.0%)	1 (2.7%)
Total	7 (100.0%)	20 (100.0%)	37 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.2.7.2 Number of events - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Number of events			
n	7	20	37
Mean (SD)	0.0 (0.00)	0.2 (0.67)	0.2 (0.73)
Min-Max	0 - 0	0 - 3	0 - 4
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal			
n	7	20	37
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.66)
Min-Max	0 - 0	0 - 0	0 - 4
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.2.7.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
5 to 10 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	4.603	0.652
	nocturnal	0	4.603	0
over 10 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	6	8.515	0.705
	nocturnal	4	8.515	0.47
up to 5 years	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	0	1.611	0
	nocturnal	0	1.611	0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.2.8.1 Events total/nocturnal - categorical

	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl		
Missing	2	1
no	34 (94.4%)	30 (96.8%)
yes	2 (5.6%)	1 (3.2%)
Total	36 (100.0%)	31 (100.0%)
If yes, nocturnal?		
Missing	2	1
no	35 (97.2%)	31 (100.0%)
yes	1 (2.8%)	0 (0.0%)
Total	36 (100.0%)	31 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.2.8.2 Number of events - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Number of events		
n	36	31
Mean (SD)	0.2 (0.74)	0.1 (0.54)
Min-Max	0 - 4	0 - 3
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal		
n	36	31
Mean (SD)	0.1 (0.67)	0.0 (0.00)
Min-Max	0 - 4	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.2.8.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
<8.5%	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	6	8.285	0.724
	nocturnal	4	8.285	0.483
>=8.5%	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	7.134	0.421
	nocturnal	0	7.134	0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.2.9.1 Events total/nocturnal - categorical

	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl				
Missing	1	1	1	0
no	10 (100.0%)	23 (100.0%)	26 (92.9%)	5 (83.3%)
yes	0 (0.0%)	0 (0.0%)	2 (7.1%)	1 (16.7%)
Total	10 (100.0%)	23 (100.0%)	28 (100.0%)	6 (100.0%)
If yes, nocturnal?				
Missing	1	1	1	0
no	10 (100.0%)	23 (100.0%)	27 (96.4%)	6 (100.0%)
yes	0 (0.0%)	0 (0.0%)	1 (3.6%)	0 (0.0%)
Total	10 (100.0%)	23 (100.0%)	28 (100.0%)	6 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.2.9.2 Number of events - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Number of events				
n	10	23	28	6
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.83)	0.5 (1.22)
Min-Max	0 - 0	0 - 0	0 - 4	0 - 3
Median	0.0	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal				
n	10	23	28	6
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.76)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 4	0 - 0
Median	0.0	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.2.9.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
Degludec	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	1.381	2.173
	nocturnal	0	1.381	0
Detemir	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	0	2.301	0
	nocturnal	0	2.301	0
Glargin 100	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	0	5.293	0
	nocturnal	0	5.293	0
Glargin 300	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	6	6.444	0.931
	nocturnal	4	6.444	0.621

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.2.10.1 Events total/nocturnal - categorical

	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl			
Missing	2	1	0
no	25 (96.2%)	7 (87.5%)	31 (96.9%)
yes	1 (3.8%)	1 (12.5%)	1 (3.1%)
Total	26 (100.0%)	8 (100.0%)	32 (100.0%)
If yes, nocturnal?			
Missing	2	1	0
no	26 (100.0%)	7 (87.5%)	32 (100.0%)
yes	0 (0.0%)	1 (12.5%)	0 (0.0%)
Total	26 (100.0%)	8 (100.0%)	32 (100.0%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.2.10.2 Number of events - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Number of events			
n	26	8	32
Mean (SD)	0.1 (0.59)	0.5 (1.41)	0.1 (0.35)
Min-Max	0 - 3	0 - 4	0 - 2
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Number of events nocturnal			
n	26	8	32
Mean (SD)	0.0 (0.00)	0.5 (1.41)	0.0 (0.00)
Min-Max	0 - 0	0 - 4	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.2 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
2.3.1.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.2.10.3 Events per patient year

Group		Number of events	Patient years	Events per patient year
before breakfast	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	3	5.984	0.501
	nocturnal	0	5.984	0
before dinner	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	2	7.364	0.272
	nocturnal	0	7.364	0
before lunch	Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl	4	1.841	2.173
	nocturnal	4	1.841	2.173

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.3 Hypoglycaemia with glucose < 54 mg/dl
2.3.1.3.1 Full Analysis Set (FAS)
2.3.1.3.1.1 Events total/nocturnal - categorical

	Total (N = 70) N (%)
Hypoglycaemia with glucose < 54 mg/dl	
Missing	1 (1.4%)
no	69 (98.6%)
Total	70 (100.0%)

No nocturnal events are documented
No events were documented from Dropout patients
No events were documented from Off-label patients

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.3 Hypoglycaemia with glucose < 54 mg/dl
2.3.1.3.1 Full Analysis Set (FAS)
2.3.1.3.1.2 Number of events - continuous

NOTE

Not applicable
No events were documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.3 Hypoglycaemia with glucose < 54 mg/dl
2.3.1.3.2 Full Analysis Set - Subgroups

NOTE

Not applicable
No events were documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.1 Full Analysis Set - All patients
2.3.1.4.1.1 Events total/nocturnal - categorical

	Total (N = 70) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known	
Missing	1 (1.4%)
no	68 (97.1%)
yes	1 (1.4%)
Total	70 (100.0%)

No nocturnal events are documented
No events were documented from Dropout patients
No events were documented from Off-label patients

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.1 Full Analysis Set - All patients
2.3.1.4.1.2 Number of events - continuous

	Total (N = 70)
Number of events	
n	1
Mean (SD)	1.0
Min-Max	1 - 1
Median	1.0
Q1-Q3	1.0 - 1.0

No nocturnal events are documented
No events were documented from Dropout patients
No events were documented from Off-label patients

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.1 Full Analysis Set - All patients
2.3.1.4.1.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
Total	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.4.2.1 Events total/nocturnal - categorical

	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known		
Missing	1 (5.0%)	0 (0.0%)
no	18 (90.0%)	50 (100.0%)
yes	1 (5.0%)	0 (0.0%)
Total	20 (100.0%)	50 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.4.2.2 Number of events - continuous

	FGM (N = 20)	SMBG (N = 50)
Number of events		
n	1	0
Mean (SD)	1.0	
Min-Max	1 - 1	
Median	1.0	
Q1-Q3	1.0 - 1.0	

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.1.4.2.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
FGM	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	
SMBG	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.3 Full Analysis Set - Subgroups - Gender
2.3.1.4.3.1 Events total/nocturnal - categorical

	Female (N = 28) N (%)	Male (N = 42) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known		
Missing	0 (0.0%)	1 (2.4%)
no	28 (100.0%)	40 (95.2%)
yes	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.3 Full Analysis Set - Subgroups - Gender
2.3.1.4.3.2 Number of events - continuous

	Female (N = 28)	Male (N = 42)
Number of events		
n	0	1
Mean (SD)		1.0
Min-Max		1 - 1
Median		1.0
Q1-Q3		1.0 - 1.0

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.3 Full Analysis Set - Subgroups - Gender
2.3.1.4.3.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
Female	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
Male	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.4 Full Analysis Set - Subgroups - Age groups
2.3.1.4.4.1 Events total/nocturnal - categorical

	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known			
Missing	0 (0.0%)	1 (4.2%)	0 (0.0%)
no	23 (95.8%)	23 (95.8%)	22 (100.0%)
yes	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.4 Full Analysis Set - Subgroups - Age groups
2.3.1.4.4.2 Number of events - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Number of events			
n	1	0	0
Mean (SD)	1.0		
Min-Max	1 - 1		
Median	1.0		
Q1-Q3	1.0 - 1.0		

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.4 Full Analysis Set - Subgroups - Age groups
2.3.1.4.4.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
<= 60 years	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	
>60 - <70 years	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
>=70 years	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.4.5.1 Events total/nocturnal - categorical

	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known		
Missing	0 (0.0%)	1 (1.9%)
no	18 (100.0%)	50 (96.2%)
yes	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.4.5.2 Number of events - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Number of events		
n	0	1
Mean (SD)		1.0
Min-Max		1 - 1
Median		1.0
Q1-Q3		1.0 - 1.0

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.1.4.5.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
<30 kg/m²	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
>=30 kg/m²	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.6 Full Analysis Set - Subgroups - Renal function
2.3.1.4.6.1 Events total/nocturnal - categorical

	<=60 ml (N = 17) N (%)	>60 ml (N = 39) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known		
Missing	0 (0.0%)	1 (2.6%)
no	17 (100.0%)	38 (97.4%)
Total	17 (100.0%)	39 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.6 Full Analysis Set - Subgroups - Renal function
2.3.1.4.6.2 Number of events - continuous

	<=60 ml (N = 17)	>60 ml (N = 39)
Number of events		
n	0	0
Mean (SD)		
Min-Max		
Median		
Q1-Q3		

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.6 Full Analysis Set - Subgroups - Renal function
2.3.1.4.6.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
<=60 ml	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
>60 ml	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.4.7.1 Events total/nocturnal - categorical

	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known			
Missing	0 (0.0%)	0 (0.0%)	1 (2.6%)
no	7 (100.0%)	21 (100.0%)	37 (94.9%)
yes	0 (0.0%)	0 (0.0%)	1 (2.6%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.4.7.2 Number of events - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Number of events			
n	0	0	1
Mean (SD)			1.0
Min-Max			1 - 1
Median			1.0
Q1-Q3			1.0 - 1.0

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.1.4.7.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
5 to 10 years	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
over 10 years	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	
up to 5 years	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.4.8.1 Events total/nocturnal - categorical

	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known		
Missing	1 (2.6%)	0 (0.0%)
no	37 (97.4%)	31 (96.9%)
yes	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.4.8.2 Number of events - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Number of events		
n	0	1
Mean (SD)		1.0
Min-Max		1 - 1
Median		1.0
Q1-Q3		1.0 - 1.0

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.1.4.8.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
<8.5%	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
>=8.5%	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.4.9.1 Events total/nocturnal - categorical

	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known				
Missing	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
no	10 (90.9%)	23 (95.8%)	29 (100.0%)	6 (100.0%)
yes	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.4.9.2 Number of events - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Number of events				
n	1	0	0	0
Mean (SD)	1.0			
Min-Max	1 - 1			
Median	1.0			
Q1-Q3	1.0 - 1.0			

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.1.4.9.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
Degludec	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
Detemir	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	
Glargin 100	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
Glargin 300	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.4.10.1 Events total/nocturnal - categorical

	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Hypoglycaemia with symptomatology and the Glucose value is not known			
Missing	0 (0.0%)	1 (11.1%)	0 (0.0%)
no	28 (100.0%)	8 (88.9%)	31 (96.9%)
yes	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.4.10.2 Number of events - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Number of events			
n	0	0	1
Mean (SD)			1.0
Min-Max			1 - 1
Median			1.0
Q1-Q3			1.0 - 1.0

No nocturnal events are documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.4 Hypoglycaemia with symptomatology and the Glucose value is not known
2.3.1.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.1.4.10.4 Events per patient year

Group		Number of events	Patient years	Events per patient year
before breakfast	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	
before dinner	Hypoglycaemia symptomatology not known	1	0.23	4.345
	nocturnal		0	
before lunch	Hypoglycaemia symptomatology not known		0	
	nocturnal		0	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.5 Severe hypoglycaemia
2.3.1.5.1 Full Analysis Set - All patients
2.3.1.5.1.1 Events total/nocturnal - categorical

	Total (N = 70) N (%)
Severe hypoglycaemia	
Missing	2 (2.9%)
no	68 (97.1%)
Total	70 (100.0%)

No nocturnal events are documented
No events were documented from Dropout patients
No events were documented from Off-label patients

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.5 Severe hypoglycaemia
2.3.1.5.1 Full Analysis Set - All patients
2.3.1.5.1.2 Number of events - continuous

NOTE

Not applicable
No events were documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.1 History of diabetes mellitus
2.3.1.5 Severe hypoglycaemia
2.3.1.5.2 Full Analysis Set - Subgroups

NOTE

Not applicable
No events were documented

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.1 Medication - categorical
2.3.2.1.1.1 Summary

Current basal insulin medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Missing	0	1	0
1 - Insulin detemir	11 (15.71%)	1 (14.29%)	1 (10.00%)
2 - Insulin glargin 100 U/ml	24 (34.29%)	3 (42.86%)	3 (30.00%)
3 - Insulin glargin 300 U/ml	29 (41.43%)	3 (42.86%)	5 (50.00%)
4 - Insulin degludec 100/200 U/ml	6 (8.57%)	0 (0.00%)	0 (0.00%)
5 - NPH Insulin	0 (0.00%)	0 (0.00%)	1 (10.00%)
Total	70 (100.00%)	7 (100.00%)	10 (100.00%)

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.1 Medication - categorical
2.3.2.1.1.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Current basal insulin medication*	N non-miss	70	7	
	% Detemir	15.71	14.29	1.000
	% Glargin 100	34.29	42.86	
	% Glargin 300	41.43	42.86	
	% Degludec 100	8.57	0.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.1 Medication - categorical
2.3.2.1.1.3 FAS compared to Off-label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Current basal insulin medication*	N non-miss	70	10	
	% Detemir	15.71	10.00	0.275
	% Glargin 100	34.29	30.00	
	% Glargin 300	41.43	50.00	
	% Degludec 100	8.57	0.00	
	% NPH Insulin	0.00	10.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.2 Last dose of previous basal insulin in Units/day - continuous
2.3.2.1.2.1 Summary

Last dose of previous basal insulin in Units/day	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Insulin detemir			
n	11	1	1
Mean (SD)	42.8 (10.02)	40.0	32.0
Min-Max	30 - 60	40 - 40	32 - 32
Median	40.0	40.0	32.0
Q1-Q3	36.0 - 55.0	40.0 - 40.0	32.0 - 32.0
Insulin glargin 100 U/ml			
n	24	3	3
Mean (SD)	37.9 (8.86)	35.3 (9.24)	26.7 (15.28)
Min-Max	30 - 60	30 - 46	10 - 40
Median	35.0	30.0	30.0
Q1-Q3	30.0 - 43.5	30.0 - 46.0	10.0 - 40.0
Insulin glargin 300 U/ml			
n	29	3	5
Mean (SD)	38.0 (9.97)	39.3 (9.45)	41.2 (8.79)
Min-Max	30 - 60	32 - 50	30 - 50
Median	34.0	36.0	40.0
Q1-Q3	30.0 - 44.0	32.0 - 50.0	36.0 - 50.0
Insulin degludec 100/200 U/ml			
n	6	0	0
Mean (SD)	37.3 (9.69)		
Min-Max	30 - 56		
Median	35.0		
Q1-Q3	30.0 - 38.0		
Total			
n	70	7	10
Mean (SD)	38.7 (9.55)	37.7 (7.95)	35.2 (11.48)
Min-Max	30 - 60	30 - 50	10 - 50
Median	36.0	36.0	35.0
Q1-Q3	30.0 - 44.0	30.0 - 46.0	30.0 - 40.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.2 Last dose of previous basal insulin in Units/day - continuous
2.3.2.1.2.2 FAS compared to Dropout

Variable	Stratum	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Last dose of previous basal insulin in Units/day*	Detemir	N non-miss	11	1	
		Mean	42.8	40.0	1.000
		SE	3.02	.	
	Glargin 100	N non-miss	24	3	
		Mean	37.9	35.3	0.506
		SE	1.81	5.33	
	Glargin 300	N non-miss	29	3	
		Mean	38.0	39.3	0.467
		SE	1.85	5.46	
	Degludec 100	N non-miss	6	0	
		Mean	37.3	.	not done
		SE	3.96	.	
	ALL	N non-miss	70	7	
		Mean	38.7	37.7	0.993
		SE	1.14	3.01	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.2 Last dose of previous basal insulin in Units/day - continuous
2.3.2.1.2.3 FAS compared to Off-label

Variable	Stratum	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Current basal insulin medication*	Detemir	N non-miss	11	1	
		Mean	42.8	32.0	0.394
		SE	3.02	.	
	Glargin 100	N non-miss	24	3	
		Mean	37.9	26.7	0.219
		SE	1.81	8.82	
	Glargin 300	N non-miss	29	5	
		Mean	38.0	41.2	0.332
		SE	1.85	3.93	
	Degludec 100	N non-miss	6	0	
		Mean	37.3	.	not done
		SE	3.96	.	
	NPH Insulin	N non-miss	0	1	
		Mean	.	34.0	not done
		SE	.	.	
	ALL	N non-miss	70	10	
		Mean	38.7	35.2	0.717
		SE	1.14	3.63	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the numner patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.3 Duration of current basal insulin therapy in months - continuous
2.3.2.1.3.1 Summary

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Duration of current basal insulin therapy in months			
n	46	7	4
Mean (SD)	38.1 (44.76)	49.1 (39.76)	48.1 (38.54)
Min-Max	0.03 - 244.59	7.08 - 123.77	8.39 - 95.74
Median	24.9	46.2	44.1
Q1-Q3	8.5 - 49.8	10.2 - 68.4	17.7 - 78.4

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5
Only patients with start of current basal insulin therapy prior to the date of inclusion
(Patient [redacted] excluded)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.3 Duration of current basal insulin therapy in months - continuous
2.3.2.1.3.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Duration*	N non-miss	46	7	
	Mean	38.1	49.1	0.292
	SE	6.60	15.03	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5
Only patients with start of current basal insulin therapy prior to the date of inclusion
(Patient [redacted] excluded)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.3 Duration of current basal insulin therapy in months - continuous
2.3.2.1.3.3 FAS compared to Off-label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Duration*	N non-miss	46	4	
	Mean	38.1	48.1	0.405
	SE	6.60	19.27	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5
Only patients with start of current basal insulin therapy prior to the date of inclusion
(Patient [redacted] excluded)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.4 Number of insulin injections per day - continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Number of insulin injections per day			
n	70	7	10
Mean (SD)	1.1 (0.23)	1.0 (0.00)	1.0 (0.00)
Min-Max	1 - 2	1 - 1	1 - 1
Median	1.0	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.5 Time of injection - categorical
2.3.2.1.5.1 Summary

Time of injection	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Missing	0	1	0
1 morning	18 (25.7%)	3 (42.9%)	0 (0.0%)
2 noon	1 (1.4%)	0 (0.0%)	1 (10.0%)
3 evening	18 (25.7%)	0 (0.0%)	5 (50.0%)
4 before bedtime	26 (37.1%)	4 (57.1%)	4 (40.0%)
5 morning/evening	3 (4.3%)	0 (0.0%)	0 (0.0%)
6 morning/noon/evening	1 (1.4%)	0 (0.0%)	0 (0.0%)
7 noon/before bedtime	1 (1.4%)	0 (0.0%)	0 (0.0%)
8 evening/before bedtime	2 (2.9%)	0 (0.0%)	0 (0.0%)
Total	70 (100.0%)	7 (100.0%)	10 (100.0%)

Percentage related to the number of patients with documentation

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.5 Time of injection - categorical
2.3.2.1.5.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Time*	N non-miss	70	7	
	% 1 morning	25.71	42.86	0.634
	% 2 noon	1.43	0.00	
	% 3 evening	25.71	0.00	
	% 4 before bed	37.14	57.14	
	% 5 morning/ev	4.29	0.00	
	% 6 morning/no	1.43	0.00	
	% 7 noon/befor	1.43	0.00	
	% 8 evening/be	2.86	0.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the number of patients with documentation
1 = morning 2 = noon 3 = evening 4 = before bedtime 5 = morning/evening
6 = morning/noon/evening 7 = noon/before bedtime 8 = evening/before bedtime

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.1 Full Analysis Set - Dropout - Off-Label
2.3.2.1.5 Time of injection - categorical
2.3.2.1.5.3 FAS compared to Off-label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Time*	N non-miss	70	10	
	% 1 morning	25.71	0.00	0.251
	% 2 noon	1.43	10.00	
	% 3 evening	25.71	50.00	
	% 4 before bed	37.14	40.00	
	% 5 morning/ev	4.29	0.00	
	% 6 morning/no	1.43	0.00	
	% 7 noon/befor	1.43	0.00	
	% 8 evening/be	2.86	0.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to the number of patients with documentation
1 = morning 2 = noon 3 = evening 4 = before bedtime 5 = morning/evening
6 = morning/noon/evening 7 = noon/before bedtime 8 = evening/before bedtime

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.2.2.1 Medication - categorical

Current basal insulin medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Insulin detemir	5 (25.0%)	6 (12.0%)
Insulin glargin 100 U/ml	9 (45.0%)	15 (30.0%)
Insulin glargin 300 U/ml	5 (25.0%)	24 (48.0%)
Insulin degludec 100/200 U/ml	1 (5.0%)	5 (10.0%)
Total	20 (100.0%)	50 (100.0%)

Percentage related to the number of patients with documentation
1 = morning 2 = noon 3 = evening 4 = before bedtime 5 = morning/evening
6 = morning/noon/evening 7 = noon/before bedtime 8 = evening/before bedtime

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.2.2.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	FGM (N = 20)	SMBG (N = 50)
Insulin detemir		
n	5	6
Mean (SD)	42.0 (10.95)	43.5 (10.17)
Min-Max	30 - 60	30 - 55
Median	40.0	42.5
Q1-Q3	40.0 - 40.0	36.0 - 55.0
Insulin glargin 100 U/ml		
n	9	15
Mean (SD)	40.4 (11.22)	36.3 (7.09)
Min-Max	30 - 60	30 - 48
Median	36.0	32.0
Q1-Q3	32.0 - 52.0	30.0 - 42.0
Insulin glargin 300 U/ml		
n	5	24
Mean (SD)	40.6 (13.67)	37.5 (9.32)
Min-Max	30 - 60	30 - 60
Median	33.0	34.5
Q1-Q3	30.0 - 50.0	30.0 - 43.0
Insulin degludec 100/200 U/ml		
n	1	5
Mean (SD)	38.0	37.2 (10.83)
Min-Max	38 - 38	30 - 56
Median	38.0	34.0
Q1-Q3	38.0 - 38.0	30.0 - 36.0
Total		
n	20	50
Mean (SD)	40.8 (10.88)	37.8 (8.94)
Min-Max	30 - 60	30 - 60
Median	38.0	35.0
Q1-Q3	31.0 - 51.0	30.0 - 44.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.2.2.3 Duration of current basal insulin therapy in months - continuous

	FGM (N = 20)	SMBG (N = 50)
Duration of current basal insulin therapy in months		
n	7	39
Mean (SD)	55.0 (85.17)	35.0 (34.13)
Min-Max	1.08 - 244.59	0.03 - 132.16
Median	32.4	24.9
Q1-Q3	3.7 - 44.3	8.5 - 53.6

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.2.2.4 Number of insulin injections per day - continuous

	FGM (N = 20)	SMBG (N = 50)
Number of insulin injections per day		
n	20	50
Mean (SD)	1.0 (0.00)	1.1 (0.27)
Min-Max	1 - 1	1 - 2
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.2.2.5 Time of injection - categorical

Time of injection	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
1 morning	3 (15.0%)	15 (30.0%)
2 noon	1 (5.0%)	0 (0.0%)
3 evening	7 (35.0%)	11 (22.0%)
4 before bedtime	8 (40.0%)	18 (36.0%)
5 morning/evening	0 (0.0%)	3 (6.0%)
6 morning/noon/evening	0 (0.0%)	1 (2.0%)
7 noon/before bedtime	0 (0.0%)	1 (2.0%)
8 evening/before bedtime	1 (5.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.3 Full Analysis Set - Subgroups - Gender
2.3.2.3.1 Medication - categorical

Current basal insulin medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Insulin detemir	6 (21.4%)	5 (11.9%)
Insulin glargin 100 U/ml	9 (32.1%)	15 (35.7%)
Insulin glargin 300 U/ml	11 (39.3%)	18 (42.9%)
Insulin degludec 100/200 U/ml	2 (7.1%)	4 (9.5%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.3 Full Analysis Set - Subgroups - Gender
2.3.2.3.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	Female (N = 28)	Male (N = 42)
Insulin detemir		
n	6	5
Mean (SD)	40.2 (8.26)	46.0 (11.94)
Min-Max	30 - 55	30 - 60
Median	40.0	45.0
Q1-Q3	36.0 - 40.0	40.0 - 55.0
Insulin glargin 100 U/ml		
n	9	15
Mean (SD)	37.0 (8.00)	38.4 (9.57)
Min-Max	30 - 52	30 - 60
Median	36.0	34.0
Q1-Q3	30.0 - 42.0	30.0 - 48.0
Insulin glargin 300 U/ml		
n	11	18
Mean (SD)	36.5 (10.29)	38.9 (9.96)
Min-Max	30 - 60	30 - 60
Median	30.0	36.5
Q1-Q3	30.0 - 44.0	30.0 - 44.0
Insulin degludec 100/200 U/ml		
n	2	4
Mean (SD)	30.0 (0.00)	41.0 (10.13)
Min-Max	30 - 30	34 - 56
Median	30.0	37.0
Q1-Q3	30.0 - 30.0	35.0 - 47.0
Total		
n	28	42
Mean (SD)	37.0 (8.76)	39.8 (9.99)
Min-Max	30 - 60	30 - 60
Median	34.0	37.0
Q1-Q3	30.0 - 41.0	30.0 - 48.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.3 Full Analysis Set - Subgroups - Gender
2.3.2.3.3 Duration of current basal insulin therapy in months - continuous

	Female (N = 28)	Male (N = 42)
Duration of current basal insulin therapy in months		
n	18	28
Mean (SD)	27.5 (19.58)	44.9 (54.55)
Min-Max	2.66 - 70.56	0.03 - 244.59
Median	25.2	23.9
Q1-Q3	10.5 - 35.5	8.0 - 56.9

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.3 Full Analysis Set - Subgroups - Gender
2.3.2.3.4 Number of insulin injections per day - continuous

	Female (N = 28)	Male (N = 42)
Number of insulin injections per day		
n	28	42
Mean (SD)	1.1 (0.26)	1.0 (0.22)
Min-Max	1 - 2	1 - 2
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.3 Full Analysis Set - Subgroups - Gender
2.3.2.3.5 Time of injection - categorical

Time of injection	Female (N = 28) N (%)	Male (N = 42) N (%)
1 morning	7 (25.0%)	11 (26.2%)
2 noon	0 (0.0%)	1 (2.4%)
3 evening	7 (25.0%)	11 (26.2%)
4 before bedtime	11 (39.3%)	15 (35.7%)
5 morning/evening	1 (3.6%)	2 (4.8%)
6 morning/noon/evening	0 (0.0%)	1 (2.4%)
7 noon/before bedtime	1 (3.6%)	0 (0.0%)
8 evening/before bedtime	1 (3.6%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.4 Full Analysis Set - Subgroups - Age groups
2.3.2.4.1 Medication - categorical

Current basal insulin medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Insulin detemir	3 (12.5%)	6 (25.0%)	2 (9.1%)
Insulin glargin 100 U/ml	10 (41.7%)	7 (29.2%)	7 (31.8%)
Insulin glargin 300 U/ml	9 (37.5%)	10 (41.7%)	10 (45.5%)
Insulin degludec 100/200 U/ml	2 (8.3%)	1 (4.2%)	3 (13.6%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.4 Full Analysis Set - Subgroups - Age groups
2.3.2.4.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Insulin detemir			
n	3	6	2
Mean (SD)	48.3 (10.41)	36.0 (4.90)	55.0 (0.00)
Min-Max	40 - 60	30 - 40	55 - 55
Median	45.0	38.0	55.0
Q1-Q3	40.0 - 60.0	30.0 - 40.0	55.0 - 55.0
Insulin glargin 100 U/ml			
n	10	7	7
Mean (SD)	39.3 (11.10)	38.3 (7.43)	35.4 (7.09)
Min-Max	30 - 60	30 - 52	30 - 48
Median	34.0	38.0	32.0
Q1-Q3	30.0 - 48.0	32.0 - 42.0	30.0 - 42.0
Insulin glargin 300 U/ml			
n	9	10	10
Mean (SD)	43.6 (13.68)	36.8 (7.13)	34.2 (6.61)
Min-Max	30 - 60	30 - 50	30 - 48
Median	40.0	36.0	30.0
Q1-Q3	30.0 - 59.0	30.0 - 42.0	30.0 - 35.0
Insulin degludec 100/200 U/ml			
n	2	1	3
Mean (SD)	33.0 (4.24)	34.0	41.3 (13.32)
Min-Max	30 - 36	34 - 34	30 - 56
Median	33.0	34.0	38.0
Q1-Q3	30.0 - 36.0	34.0 - 34.0	30.0 - 56.0
Total			
n	24	24	22
Mean (SD)	41.5 (11.81)	36.9 (6.38)	37.5 (9.37)
Min-Max	30 - 60	30 - 52	30 - 56
Median	38.0	37.0	33.5
Q1-Q3	30.0 - 51.0	30.0 - 40.0	30.0 - 44.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.4 Full Analysis Set - Subgroups - Age groups
2.3.2.4.3 Duration of current basal insulin therapy in months - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Duration of current basal insulin therapy in months			
n	16	16	14
Mean (SD)	39.5 (38.47)	45.7 (59.53)	27.7 (30.78)
Min-Max	1.08 - 132.16	6.07 - 244.59	0.03 - 102.43
Median	28.6	25.2	14.6
Q1-Q3	14.9 - 46.1	10.9 - 56.9	4.8 - 49.8

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.4 Full Analysis Set - Subgroups - Age groups
2.3.2.4.4 Number of insulin injections per day - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Number of insulin injections per day			
n	24	24	22
Mean (SD)	1.0 (0.00)	1.0 (0.00)	1.2 (0.39)
Min-Max	1 - 1	1 - 1	1 - 2
Median	1.0	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.4 Full Analysis Set - Subgroups - Age groups
2.3.2.4.5 Time of injection - categorical

Time of injection	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
1 morning	3 (12.5%)	7 (29.2%)	8 (36.4%)
2 noon	0 (0.0%)	1 (4.2%)	0 (0.0%)
3 evening	7 (29.2%)	6 (25.0%)	5 (22.7%)
4 before bedtime	12 (50.0%)	9 (37.5%)	5 (22.7%)
5 morning/evening	0 (0.0%)	0 (0.0%)	3 (13.6%)
6 morning/noon/evening	0 (0.0%)	1 (4.2%)	0 (0.0%)
7 noon/before bedtime	0 (0.0%)	0 (0.0%)	1 (4.5%)
8 evening/before bedtime	2 (8.3%)	0 (0.0%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.2.5.1 Medication - categorical

Current basal insulin medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Insulin detemir	1 (5.6%)	10 (19.2%)
Insulin glargin 100 U/ml	7 (38.9%)	17 (32.7%)
Insulin glargin 300 U/ml	8 (44.4%)	21 (40.4%)
Insulin degludec 100/200 U/ml	2 (11.1%)	4 (7.7%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.2.5.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Insulin detemir		
n	1	10
Mean (SD)	30.0	44.1 (9.56)
Min-Max	30 - 30	30 - 60
Median	30.0	40.0
Q1-Q3	30.0 - 30.0	40.0 - 55.0
Insulin glargin 100 U/ml		
n	7	17
Mean (SD)	37.7 (8.83)	37.9 (9.14)
Min-Max	30 - 52	30 - 60
Median	36.0	34.0
Q1-Q3	30.0 - 48.0	30.0 - 42.0
Insulin glargin 300 U/ml		
n	8	21
Mean (SD)	37.4 (4.84)	38.2 (11.44)
Min-Max	30 - 44	30 - 60
Median	37.5	30.0
Q1-Q3	34.0 - 41.0	30.0 - 48.0
Insulin degludec 100/200 U/ml		
n	2	4
Mean (SD)	43.0 (18.38)	34.5 (3.42)
Min-Max	30 - 56	30 - 38
Median	43.0	35.0
Q1-Q3	30.0 - 56.0	32.0 - 37.0
Total		
n	18	52
Mean (SD)	37.7 (7.99)	39.0 (10.08)
Min-Max	30 - 56	30 - 60
Median	35.5	36.0
Q1-Q3	30.0 - 42.0	30.0 - 45.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.2.5.3 Duration of current basal insulin therapy in months - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Duration of current basal insulin therapy in months		
n	13	33
Mean (SD)	28.7 (28.89)	41.7 (49.55)
Min-Max	1.08 - 102.43	0.03 - 244.59
Median	24.9	24.9
Q1-Q3	6.5 - 39.1	10.5 - 53.6

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.2.5.4 Number of insulin injections per day - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Number of insulin injections per day		
n	18	52
Mean (SD)	1.2 (0.38)	1.0 (0.14)
Min-Max	1 - 2	1 - 2
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.2.5.5 Time of injection - categorical

Time of injection	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
1 morning	3 (16.7%)	15 (28.8%)
2 noon	0 (0.0%)	1 (1.9%)
3 evening	6 (33.3%)	12 (23.1%)
4 before bedtime	4 (22.2%)	22 (42.3%)
5 morning/evening	3 (16.7%)	0 (0.0%)
6 morning/noon/evening	1 (5.6%)	0 (0.0%)
7 noon/before bedtime	0 (0.0%)	1 (1.9%)
8 evening/before bedtime	1 (5.6%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.6 Full Analysis Set - Subgroups - Renal function
2.3.2.6.1 Medication - categorical

Current basal insulin medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Insulin detemir	2 (11.8%)	6 (15.4%)
Insulin glargin 100 U/ml	5 (29.4%)	12 (30.8%)
Insulin glargin 300 U/ml	8 (47.1%)	17 (43.6%)
Insulin degludec 100/200 U/ml	2 (11.8%)	4 (10.3%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.6 Full Analysis Set - Subgroups - Renal function
2.3.2.6.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Insulin detemir		
n	2	6
Mean (SD)	45.5 (13.44)	40.8 (8.01)
Min-Max	36 - 55	30 - 55
Median	45.5	40.0
Q1-Q3	36.0 - 55.0	40.0 - 40.0
Insulin glargin 100 U/ml		
n	5	12
Mean (SD)	42.8 (7.16)	36.5 (9.84)
Min-Max	36 - 52	30 - 60
Median	42.0	32.0
Q1-Q3	36.0 - 48.0	30.0 - 39.0
Insulin glargin 300 U/ml		
n	8	17
Mean (SD)	34.9 (7.85)	37.8 (10.03)
Min-Max	30 - 50	30 - 60
Median	30.0	34.0
Q1-Q3	30.0 - 39.5	30.0 - 40.0
Insulin degludec 100/200 U/ml		
n	2	4
Mean (SD)	43.0 (18.38)	34.5 (3.42)
Min-Max	30 - 56	30 - 38
Median	43.0	35.0
Q1-Q3	30.0 - 56.0	32.0 - 37.0
Total		
n	17	39
Mean (SD)	39.4 (9.61)	37.5 (9.10)
Min-Max	30 - 56	30 - 60
Median	36.0	34.0
Q1-Q3	30.0 - 48.0	30.0 - 40.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.6 Full Analysis Set - Subgroups - Renal function
2.3.2.6.3 Duration of current basal insulin therapy in months - continuous

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Duration of current basal insulin therapy in months		
n	9	27
Mean (SD)	28.5 (28.26)	34.6 (50.25)
Min-Max	1.08 - 70.56	2.66 - 244.59
Median	24.9	21.9
Q1-Q3	4.8 - 49.8	8.5 - 32.4

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.6 Full Analysis Set - Subgroups - Renal function
2.3.2.6.4 Number of insulin injections per day - continuous

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Number of insulin injections per day		
n	17	39
Mean (SD)	1.2 (0.44)	1.0 (0.00)
Min-Max	1 - 2	1 - 1
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.6 Full Analysis Set - Subgroups - Renal function
2.3.2.6.5 Time of injection - categorical

Time of injection	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
1 morning	6 (35.3%)	11 (28.2%)
2 noon	0 (0.0%)	1 (2.6%)
3 evening	4 (23.5%)	11 (28.2%)
4 before bedtime	2 (11.8%)	15 (38.5%)
5 morning/evening	3 (17.6%)	0 (0.0%)
7 noon/before bedtime	1 (5.9%)	0 (0.0%)
8 evening/before bedtime	1 (5.9%)	1 (2.6%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.2.7.1 Medication - categorical

Current basal insulin medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Insulin detemir	2 (28.6%)	2 (9.5%)	6 (15.4%)
Insulin glargin 100 U/ml	0 (0.0%)	12 (57.1%)	12 (30.8%)
Insulin glargin 300 U/ml	4 (57.1%)	4 (19.0%)	19 (48.7%)
Insulin degludec 100/200 U/ml	1 (14.3%)	3 (14.3%)	2 (5.1%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.2.7.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Insulin detemir			
n	2	2	6
Mean (SD)	38.0 (2.83)	42.5 (3.54)	45.0 (13.42)
Min-Max	36 - 40	40 - 45	30 - 60
Median	38.0	42.5	47.5
Q1-Q3	36.0 - 40.0	40.0 - 45.0	30.0 - 55.0
Insulin glargin 100 U/ml			
n	0	12	12
Mean (SD)		40.8 (9.96)	35.0 (6.85)
Min-Max		30 - 60	30 - 52
Median		39.0	32.0
Q1-Q3		31.0 - 48.0	30.0 - 39.0
Insulin glargin 300 U/ml			
n	4	4	19
Mean (SD)	38.5 (14.46)	32.0 (2.45)	39.6 (10.23)
Min-Max	30 - 60	30 - 35	30 - 60
Median	32.0	31.5	40.0
Q1-Q3	30.0 - 47.0	30.0 - 34.0	30.0 - 48.0
Insulin degludec 100/200 U/ml			
n	1	3	2
Mean (SD)	36.0	38.7 (15.01)	36.0 (2.83)
Min-Max	36 - 36	30 - 56	34 - 38
Median	36.0	30.0	36.0
Q1-Q3	36.0 - 36.0	30.0 - 56.0	34.0 - 38.0
Total			
n	7	21	39
Mean (SD)	38.0 (10.33)	39.0 (9.56)	38.8 (9.92)
Min-Max	30 - 60	30 - 60	30 - 60
Median	36.0	36.0	35.0
Q1-Q3	30.0 - 40.0	30.0 - 45.0	30.0 - 44.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.2.7.3 Duration of current basal insulin therapy in months - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Duration of current basal insulin therapy in months			
n	5	13	25
Mean (SD)	14.6 (8.19)	33.7 (33.42)	48.0 (53.53)
Min-Max	6.1 - 25.97	1.08 - 119.61	0.03 - 244.59
Median	12.6	30.4	25.5
Q1-Q3	8.5 - 19.7	6.5 - 44.3	11.3 - 59.5

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.2.7.4 Number of insulin injections per day - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Number of insulin injections per day			
n	7	21	39
Mean (SD)	1.0 (0.00)	1.1 (0.36)	1.0 (0.16)
Min-Max	1 - 1	1 - 2	1 - 2
Median	1.0	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.2.7.5 Time of injection - categorical

Time of injection	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
1 morning	3 (42.9%)	2 (9.5%)	12 (30.8%)
2 noon	0 (0.0%)	0 (0.0%)	1 (2.6%)
3 evening	1 (14.3%)	5 (23.8%)	10 (25.6%)
4 before bedtime	3 (42.9%)	9 (42.9%)	14 (35.9%)
5 morning/evening	0 (0.0%)	3 (14.3%)	0 (0.0%)
6 morning/noon/evening	0 (0.0%)	0 (0.0%)	1 (2.6%)
7 noon/before bedtime	0 (0.0%)	0 (0.0%)	1 (2.6%)
8 evening/before bedtime	0 (0.0%)	2 (9.5%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.2.8.1 Medication - categorical

Current basal insulin medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Insulin detemir	6 (15.8%)	5 (15.6%)
Insulin glargin 100 U/ml	13 (34.2%)	11 (34.4%)
Insulin glargin 300 U/ml	16 (42.1%)	13 (40.6%)
Insulin degludec 100/200 U/ml	3 (7.9%)	3 (9.4%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.2.8.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	<8.5% (N = 38)	>=8.5% (N = 32)
Total		
n	38	32
Mean (SD)	36.9 (9.14)	40.7 (9.77)
Min-Max	30 - 60	30 - 60
Median	32.5	40.0
Q1-Q3	30.0 - 40.0	31.0 - 46.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.2.8.3 Duration of current basal insulin therapy in months - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Duration of current basal insulin therapy in months		
n	24	22
Mean (SD)	36.6 (53.43)	39.7 (34.08)
Min-Max	0.03 - 244.59	1.08 - 132.16
Median	22.3	30.8
Q1-Q3	8.0 - 36.3	12.5 - 59.5

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.2.8.4 Number of insulin injections per day - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Number of insulin injections per day		
n	38	32
Mean (SD)	1.0 (0.16)	1.1 (0.30)
Min-Max	1 - 2	1 - 2
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.2.8.5 Time of injection - categorical

Time of injection	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
1 morning	12 (31.6%)	6 (18.8%)
2 noon	1 (2.6%)	0 (0.0%)
3 evening	13 (34.2%)	5 (15.6%)
4 before bedtime	11 (28.9%)	15 (46.9%)
5 morning/evening	1 (2.6%)	2 (6.3%)
6 morning/noon/evening	0 (0.0%)	1 (3.1%)
7 noon/before bedtime	0 (0.0%)	1 (3.1%)
8 evening/before bedtime	0 (0.0%)	2 (6.3%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.2.9.1 Medication - categorical

Current basal insulin medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Insulin detemir	11 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Insulin glargin 100 U/ml	0 (0.0%)	24 (100.0%)	0 (0.0%)	0 (0.0%)
Insulin glargin 300 U/ml	0 (0.0%)	0 (0.0%)	29 (100.0%)	0 (0.0%)
Insulin degludec 100/200 U/ml	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.2.9.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Insulin detemir				
n	11	0	0	0
Mean (SD)	42.8 (10.02)			
Min-Max	30 - 60			
Median	40.0			
Q1-Q3	36.0 - 55.0			
Insulin glargin 100 U/ml				
n	0	24	0	0
Mean (SD)		37.9 (8.86)		
Min-Max		30 - 60		
Median		35.0		
Q1-Q3		30.0 - 43.5		
Insulin glargin 300 U/ml				
n	0	0	29	0
Mean (SD)			38.0 (9.97)	
Min-Max			30 - 60	
Median			34.0	
Q1-Q3			30.0 - 44.0	
Insulin degludec 100/200 U/ml				
n	0	0	0	6
Mean (SD)				37.3 (9.69)
Min-Max				30 - 56
Median				35.0
Q1-Q3				30.0 - 38.0
Total				
n	11	24	29	6
Mean (SD)	42.8 (10.02)	37.9 (8.86)	38.0 (9.97)	37.3 (9.69)
Min-Max	30 - 60	30 - 60	30 - 60	30 - 56
Median	40.0	35.0	34.0	35.0
Q1-Q3	36.0 - 55.0	30.0 - 43.5	30.0 - 44.0	30.0 - 38.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.2.9.3 Duration of current basal insulin therapy in months - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Duration of current basal insulin therapy in months				
n	5	15	22	4
Mean (SD)	43.6 (24.06)	50.1 (63.69)	31.3 (35.76)	23.4 (1.78)
Min-Max	8.52 - 69.84	0.03 - 244.59	2.66 - 132.16	21.93 - 25.97
Median	47.8	31.3	16.2	22.8
Q1-Q3	32.4 - 59.5	6.5 - 73.7	8.0 - 39.1	22.3 - 24.5

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.2.9.4 Number of insulin injections per day - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Number of insulin injections per day				
n	11	24	29	6
Mean (SD)	1.0 (0.00)	1.1 (0.28)	1.0 (0.00)	1.3 (0.52)
Min-Max	1 - 1	1 - 2	1 - 1	1 - 2
Median	1.0	1.0	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0	1.0 - 1.0	1.0 - 2.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.2.9.5 Time of injection - categorical

Time of injection	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
1 morning	3 (27.3%)	1 (4.2%)	12 (41.4%)	2 (33.3%)
2 noon	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
3 evening	4 (36.4%)	5 (20.8%)	9 (31.0%)	0 (0.0%)
4 before bedtime	4 (36.4%)	13 (54.2%)	7 (24.1%)	2 (33.3%)
5 morning/evening	0 (0.0%)	1 (4.2%)	0 (0.0%)	2 (33.3%)
6 morning/noon/evening	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)
7 noon/before bedtime	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
8 evening/before bedtime	0 (0.0%)	2 (8.3%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.2.10.1 Medication - categorical

Current basal insulin medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Insulin detemir	5 (17.9%)	0 (0.0%)	6 (18.8%)
Insulin glargin 100 U/ml	7 (25.0%)	4 (44.4%)	12 (37.5%)
Insulin glargin 300 U/ml	12 (42.9%)	3 (33.3%)	14 (43.8%)
Insulin degludec 100/200 U/ml	4 (14.3%)	2 (22.2%)	0 (0.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.2.10.2 Last dose of previous basal insulin in Units/day - continuous

Last dose of previous basal insulin in Units/day	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Insulin detemir			
n	5	0	6
Mean (SD)	45.0 (10.61)		41.0 (10.10)
Min-Max	30 - 55		30 - 60
Median	45.0		40.0
Q1-Q3	40.0 - 55.0		36.0 - 40.0
Insulin glargin 100 U/ml			
n	7	4	12
Mean (SD)	37.6 (8.90)	38.0 (9.66)	38.7 (9.43)
Min-Max	30 - 48	30 - 52	30 - 60
Median	32.0	35.0	37.0
Q1-Q3	30.0 - 48.0	32.0 - 44.0	31.0 - 42.0
Insulin glargin 300 U/ml			
n	12	3	14
Mean (SD)	38.4 (10.87)	40.0 (17.32)	37.2 (8.14)
Min-Max	30 - 60	30 - 60	30 - 50
Median	35.0	30.0	33.5
Q1-Q3	30.0 - 42.0	30.0 - 60.0	30.0 - 44.0
Insulin degludec 100/200 U/ml			
n	4	2	0
Mean (SD)	38.0 (12.33)	36.0 (2.83)	
Min-Max	30 - 56	34 - 38	
Median	33.0	36.0	
Q1-Q3	30.0 - 46.0	34.0 - 38.0	
Total			
n	28	9	32
Mean (SD)	39.3 (10.33)	38.2 (10.65)	38.5 (8.82)
Min-Max	30 - 60	30 - 60	30 - 60
Median	35.5	34.0	37.0
Q1-Q3	30.0 - 46.5	30.0 - 38.0	30.0 - 42.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.2.10.3 Duration of current basal insulin therapy in months - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Duration of current basal insulin therapy in months			
n	21	6	18
Mean (SD)	37.4 (32.59)	54.1 (94.03)	33.7 (36.62)
Min-Max	0.03 - 132.16	1.08 - 244.59	3.28 - 119.61
Median	26.0	22.4	18.8
Q1-Q3	10.5 - 54.2	3.7 - 30.4	8.1 - 39.1

Duration in months calculated:([date of switch to iGlarLixi] - [date of start of basal insulin]+1)/30.5

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.2.10.4 Number of insulin injections per day - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Number of insulin injections per day			
n	28	9	32
Mean (SD)	1.1 (0.31)	1.0 (0.00)	1.0 (0.18)
Min-Max	1 - 2	1 - 1	1 - 2
Median	1.0	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0	1.0 - 1.0

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.2 Current basal insulin therapy (including duration and last dose before switch)
2.3.2.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.2.10.5 Time of injection - categorical

Time of injection	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
1 morning	13 (46.4%)	2 (22.2%)	3 (9.4%)
2 noon	0 (0.0%)	1 (11.1%)	0 (0.0%)
3 evening	5 (17.9%)	1 (11.1%)	12 (37.5%)
4 before bedtime	6 (21.4%)	4 (44.4%)	15 (46.9%)
5 morning/evening	3 (10.7%)	0 (0.0%)	0 (0.0%)
6 morning/noon/evening	0 (0.0%)	0 (0.0%)	1 (3.1%)
7 noon/before bedtime	0 (0.0%)	0 (0.0%)	1 (3.1%)
8 evening/before bedtime	1 (3.6%)	1 (11.1%)	0 (0.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.1 Full Analysis Set - Dropout - Off-Label

Current non-insulin concomitant medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Metformin			
Missing	1	2	0
yes	51 (73.91%)	5 (83.33%)	6 (60.00%)
no	18 (26.09%)	1 (16.67%)	4 (40.00%)
Total	69 (100.00%)	6 (100.00%)	10 (100.00%)
Sulfonyl urea			
Missing	2	3	1
yes	2 (2.94%)	0 (0.00%)	1 (11.11%)
no	66 (97.06%)	5 (100.00%)	8 (88.89%)
Total	68 (100.00%)	5 (100.00%)	9 (100.00%)
Glinide			
Missing	1	3	0
yes	3 (4.35%)	0 (0.00%)	1 (10.00%)
no	66 (95.65%)	5 (100.00%)	9 (90.00%)
Total	69 (100.00%)	5 (100.00%)	10 (100.00%)
Alpha glucosidase inhibitor			
Missing	1	3	0
no	69 (100.00%)	5 (100.00%)	10 (100.00%)
Total	69 (100.00%)	5 (100.00%)	10 (100.00%)
Glitazone			
Missing	1	3	0
no	69 (100.00%)	5 (100.00%)	10 (100.00%)
Total	69 (100.00%)	5 (100.00%)	10 (100.00%)
DPP-4 inhibitor			
Missing	1	3	1
yes	24 (34.78%)	3 (60.00%)	1 (11.11%)
no	45 (65.22%)	2 (40.00%)	8 (88.89%)
Total	69 (100.00%)	5 (100.00%)	9 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.1 Full Analysis Set - Dropout - Off-Label

Current non-insulin concomitant medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
SGLT2 inhibitor			
Missing	0	2	0
yes	35 (50.00%)	3 (50.00%)	1 (10.00%)
no	35 (50.00%)	3 (50.00%)	9 (90.00%)
Total	70 (100.00%)	6 (100.00%)	10 (100.00%)
Any medication			
yes	67 (95.71%)	6 (75.00%)	7 (70.00%)
no	3 (4.29%)	2 (25.00%)	3 (30.00%)
Total	70 (100.00%)	8 (100.00%)	10 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.1 Full Analysis Set - Dropout - Off-Label
2.3.3.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Metformin*	N non-miss	69	6	
	% yes	73.91	83.33	1.000
	% no	26.09	16.67	
Sulfonyl urea*	N non-miss	68	5	
	% yes	2.94	0.00	1.000
	% no	97.06	100.00	
Glinide*	N non-miss	69	5	
	% yes	4.35	0.00	1.000
	% no	95.65	100.00	
Alpha glucosidase inhibitor*	N non-miss	69	5	
	% no	100.00	100.00	not done
Glitazone*	N non-miss	69	5	
	% no	100.00	100.00	not done
DPP-4 inhibitor*	N non-miss	69	5	
	% yes	34.78	60.00	0.348
	% no	65.22	40.00	
SGLT2 inhibitor*	N non-miss	70	6	
	% yes	50.00	50.00	1.000
	% no	50.00	50.00	
Any medication*	N non-miss	70	8	
	% JA	95.71	75.00	0.079
	% NEIN	4.29	25.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.1 Full Analysis Set - Dropout - Off-Label
2.3.3.1.2 FAS compared to Off-label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Metformin*	N non-miss	69	10	
	% yes	73.91	60.00	0.452
	% no	26.09	40.00	
Sulfonyl urea*	N non-miss	68	9	
	% yes	2.94	11.11	0.315
	% no	97.06	88.89	
Glinide*	N non-miss	69	10	
	% yes	4.35	10.00	0.425
	% no	95.65	90.00	
Alpha glucosidase inhibitor*	N non-miss	69	10	
	% no	100.00	100.00	not done
Glitazone*	N non-miss	69	10	
	% no	100.00	100.00	not done
DPP-4 inhibitor*	N non-miss	69	9	
	% yes	34.78	11.11	0.258
	% no	65.22	88.89	
SGLT2 inhibitor*	N non-miss	70	10	
	% yes	50.00	10.00	0.020
	% no	50.00	90.00	
Any medication*	N non-miss	70	10	
	% yes	95.71	70.00	0.024
	% no	4.29	30.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.2 Full Analysis Set - Subgroups - FGM - SMBG

Current non-insulin concomitant medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Metformin		
Missing	0	1
yes	15 (75.00%)	36 (73.47%)
no	5 (25.00%)	13 (26.53%)
Total	20 (100.00%)	49 (100.00%)
Sulfonyl urea		
Missing	1	1
yes	1 (5.26%)	1 (2.04%)
no	18 (94.74%)	48 (97.96%)
Total	19 (100.00%)	49 (100.00%)
Glinide		
Missing	0	1
yes	3 (15.00%)	0 (0.00%)
no	17 (85.00%)	49 (100.00%)
Total	20 (100.00%)	49 (100.00%)
Alpha glucosidase inhibitor		
Missing	0	1
no	20 (100.00%)	49 (100.00%)
Total	20 (100.00%)	49 (100.00%)
Glitazone		
Missing	0	1
no	20 (100.00%)	49 (100.00%)
Total	20 (100.00%)	49 (100.00%)
DPP-4 inhibitor		
Missing	0	1
yes	4 (20.00%)	20 (40.82%)
no	16 (80.00%)	29 (59.18%)
Total	20 (100.00%)	49 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.2 Full Analysis Set - Subgroups - FGM - SMBG

Current non-insulin concomitant medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
SGLT2 inhibitor		
yes	10 (50.00%)	25 (50.00%)
no	10 (50.00%)	25 (50.00%)
Total	20 (100.00%)	50 (100.00%)
Any medication		
yes	19 (95.00%)	48 (96.00%)
no	1 (5.00%)	2 (4.00%)
Total	20 (100.00%)	50 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.3 Full Analysis Set - Subgroups - Gender

Current non-insulin concomitant medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Metformin		
Missing	1	0
yes	18 (66.67%)	33 (78.57%)
no	9 (33.33%)	9 (21.43%)
Total	27 (100.00%)	42 (100.00%)
Sulfonyl urea		
Missing	1	1
yes	2 (7.41%)	0 (0.00%)
no	25 (92.59%)	41 (100.00%)
Total	27 (100.00%)	41 (100.00%)
Glinide		
Missing	1	0
yes	2 (7.41%)	1 (2.38%)
no	25 (92.59%)	41 (97.62%)
Total	27 (100.00%)	42 (100.00%)
Alpha glucosidase inhibitor		
Missing	1	0
no	27 (100.00%)	42 (100.00%)
Total	27 (100.00%)	42 (100.00%)
Glitazone		
Missing	1	0
no	27 (100.00%)	42 (100.00%)
Total	27 (100.00%)	42 (100.00%)
DPP-4 inhibitor		
Missing	1	0
yes	10 (37.04%)	14 (33.33%)
no	17 (62.96%)	28 (66.67%)
Total	27 (100.00%)	42 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.3 Full Analysis Set - Subgroups - Gender

Current non-insulin concomitant medication	Female (N = 28) N (%)	Male (N = 42) N (%)
SGLT2 inhibitor		
yes	11 (39.29%)	24 (57.14%)
no	17 (60.71%)	18 (42.86%)
Total	28 (100.00%)	42 (100.00%)
Any medication		
yes	26 (92.86%)	41 (97.62%)
no	2 (7.14%)	1 (2.38%)
Total	28 (100.00%)	42 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.4 Full Analysis Set - Subgroups - Age groups

Current non-insulin concomitant medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Metformin			
Missing	0	0	1
yes	17 (70.83%)	22 (91.67%)	12 (57.14%)
no	7 (29.17%)	2 (8.33%)	9 (42.86%)
Total	24 (100.00%)	24 (100.00%)	21 (100.00%)
Sulfonyl urea			
Missing	0	1	1
yes	1 (4.17%)	1 (4.35%)	0 (0.00%)
no	23 (95.83%)	22 (95.65%)	21 (100.00%)
Total	24 (100.00%)	23 (100.00%)	21 (100.00%)
Glinide			
Missing	0	0	1
yes	2 (8.33%)	1 (4.17%)	0 (0.00%)
no	22 (91.67%)	23 (95.83%)	21 (100.00%)
Total	24 (100.00%)	24 (100.00%)	21 (100.00%)
Alpha glucosidase inhibitor			
Missing	0	0	1
no	24 (100.00%)	24 (100.00%)	21 (100.00%)
Total	24 (100.00%)	24 (100.00%)	21 (100.00%)
Glitazone			
Missing	0	0	1
no	24 (100.00%)	24 (100.00%)	21 (100.00%)
Total	24 (100.00%)	24 (100.00%)	21 (100.00%)
DPP-4 inhibitor			
Missing	0	0	1
yes	4 (16.67%)	9 (37.50%)	11 (52.38%)
no	20 (83.33%)	15 (62.50%)	10 (47.62%)
Total	24 (100.00%)	24 (100.00%)	21 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.4 Full Analysis Set - Subgroups - Age groups

Current non-insulin concomitant medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
SGLT2 inhibitor			
yes	12 (50.00%)	14 (58.33%)	9 (40.91%)
no	12 (50.00%)	10 (41.67%)	13 (59.09%)
Total	24 (100.00%)	24 (100.00%)	22 (100.00%)
Any medication			
yes	23 (95.83%)	24 (100.00%)	20 (90.91%)
no	1 (4.17%)	0 (0.00%)	2 (9.09%)
Total	24 (100.00%)	24 (100.00%)	22 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.5 Full Analysis Set - Subgroups - Body Mass Index

Current non-insulin concomitant medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Metformin		
Missing	0	1
yes	11 (61.11%)	40 (78.43%)
no	7 (38.89%)	11 (21.57%)
Total	18 (100.00%)	51 (100.00%)
Sulfonyl urea		
Missing	0	2
yes	0 (0.00%)	2 (4.00%)
no	18 (100.00%)	48 (96.00%)
Total	18 (100.00%)	50 (100.00%)
Glinide		
Missing	0	1
yes	0 (0.00%)	3 (5.88%)
no	18 (100.00%)	48 (94.12%)
Total	18 (100.00%)	51 (100.00%)
Alpha glucosidase inhibitor		
Missing	0	1
no	18 (100.00%)	51 (100.00%)
Total	18 (100.00%)	51 (100.00%)
Glitazone		
Missing	0	1
no	18 (100.00%)	51 (100.00%)
Total	18 (100.00%)	51 (100.00%)
DPP-4 inhibitor		
Missing	0	1
yes	10 (55.56%)	14 (27.45%)
no	8 (44.44%)	37 (72.55%)
Total	18 (100.00%)	51 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.5 Full Analysis Set - Subgroups - Body Mass Index

Current non-insulin concomitant medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
SGLT2 inhibitor		
yes	11 (61.11%)	24 (46.15%)
no	7 (38.89%)	28 (53.85%)
Total	18 (100.00%)	52 (100.00%)
Any medication		
yes	18 (100.00%)	49 (94.23%)
no	0 (0.00%)	3 (5.77%)
Total	18 (100.00%)	52 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.6 Full Analysis Set - Subgroups - Renal function

Current non-insulin concomitant medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Metformin		
yes	8 (47.06%)	33 (84.62%)
no	9 (52.94%)	6 (15.38%)
Total	17 (100.00%)	39 (100.00%)
Sulfonyl urea		
Missing	0	1
yes	0 (0.00%)	2 (5.26%)
no	17 (100.00%)	36 (94.74%)
Total	17 (100.00%)	38 (100.00%)
Glinide		
yes	0 (0.00%)	3 (7.69%)
no	17 (100.00%)	36 (92.31%)
Total	17 (100.00%)	39 (100.00%)
Alpha glucosidase inhibitor		
no	17 (100.00%)	39 (100.00%)
Total	17 (100.00%)	39 (100.00%)
Glitazone		
no	17 (100.00%)	39 (100.00%)
Total	17 (100.00%)	39 (100.00%)
DPP-4 inhibitor		
yes	9 (52.94%)	11 (28.21%)
no	8 (47.06%)	28 (71.79%)
Total	17 (100.00%)	39 (100.00%)
SGLT2 inhibitor		
yes	10 (58.82%)	17 (43.59%)
no	7 (41.18%)	22 (56.41%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.6 Full Analysis Set - Subgroups - Renal function

Current non-insulin concomitant medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Total	17 (100.00%)	39 (100.00%)
Any medication		
yes	15 (88.24%)	39 (100.00%)
no	2 (11.76%)	0 (0.00%)
Total	17 (100.00%)	39 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.7 Full Analysis Set - Subgroups - Duration of diabetes

Current non-insulin concomitant medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Metformin			
Missing	0	0	1
yes	5 (71.43%)	14 (66.67%)	30 (78.95%)
no	2 (28.57%)	7 (33.33%)	8 (21.05%)
Total	7 (100.00%)	21 (100.00%)	38 (100.00%)
Sulfonyl urea			
Missing	0	0	2
yes	0 (0.00%)	1 (4.76%)	1 (2.70%)
no	7 (100.00%)	20 (95.24%)	36 (97.30%)
Total	7 (100.00%)	21 (100.00%)	37 (100.00%)
Glinide			
Missing	0	0	1
yes	0 (0.00%)	1 (4.76%)	1 (2.63%)
no	7 (100.00%)	20 (95.24%)	37 (97.37%)
Total	7 (100.00%)	21 (100.00%)	38 (100.00%)
Alpha glucosidase inhibitor			
Missing	0	0	1
no	7 (100.00%)	21 (100.00%)	38 (100.00%)
Total	7 (100.00%)	21 (100.00%)	38 (100.00%)
Glitazone			
Missing	0	0	1
no	7 (100.00%)	21 (100.00%)	38 (100.00%)
Total	7 (100.00%)	21 (100.00%)	38 (100.00%)
DPP-4 inhibitor			
Missing	0	0	1
yes	4 (57.14%)	7 (33.33%)	11 (28.95%)
no	3 (42.86%)	14 (66.67%)	27 (71.05%)
Total	7 (100.00%)	21 (100.00%)	38 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.7 Full Analysis Set - Subgroups - Duration of diabetes

Current non-insulin concomitant medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
SGLT2 inhibitor			
yes	2 (28.57%)	6 (28.57%)	27 (69.23%)
no	5 (71.43%)	15 (71.43%)	12 (30.77%)
Total	7 (100.00%)	21 (100.00%)	39 (100.00%)
Any medication			
yes	7 (100.00%)	20 (95.24%)	37 (94.87%)
no	0 (0.00%)	1 (4.76%)	2 (5.13%)
Total	7 (100.00%)	21 (100.00%)	39 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.8 Full Analysis Set - Subgroups - Baseline HbA1c

Current non-insulin concomitant medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Metformin		
Missing	1	0
yes	29 (78.38%)	22 (68.75%)
no	8 (21.62%)	10 (31.25%)
Total	37 (100.00%)	32 (100.00%)
Sulfonyl urea		
Missing	2	0
yes	1 (2.78%)	1 (3.13%)
no	35 (97.22%)	31 (96.88%)
Total	36 (100.00%)	32 (100.00%)
Glinide		
Missing	1	0
yes	1 (2.70%)	2 (6.25%)
no	36 (97.30%)	30 (93.75%)
Total	37 (100.00%)	32 (100.00%)
Alpha glucosidase inhibitor		
Missing	1	0
no	37 (100.00%)	32 (100.00%)
Total	37 (100.00%)	32 (100.00%)
Glitazone		
Missing	1	0
no	37 (100.00%)	32 (100.00%)
Total	37 (100.00%)	32 (100.00%)
DPP-4 inhibitor		
Missing	1	0
yes	12 (32.43%)	12 (37.50%)
no	25 (67.57%)	20 (62.50%)
Total	37 (100.00%)	32 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.8 Full Analysis Set - Subgroups - Baseline HbA1c

Current non-insulin concomitant medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
SGLT2 inhibitor		
yes	19 (50.00%)	16 (50.00%)
no	19 (50.00%)	16 (50.00%)
Total	38 (100.00%)	32 (100.00%)
Any medication		
yes	36 (94.74%)	31 (96.88%)
no	2 (5.26%)	1 (3.13%)
Total	38 (100.00%)	32 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

Current non-insulin concomitant medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Metformin				
Missing	0	1	0	0
yes	10 (90.91%)	16 (69.57%)	20 (68.97%)	5 (83.33%)
no	1 (9.09%)	7 (30.43%)	9 (31.03%)	1 (16.67%)
Total	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
Sulfonyl urea				
Missing	0	2	0	0
yes	1 (9.09%)	1 (4.55%)	0 (0.00%)	0 (0.00%)
no	10 (90.91%)	21 (95.45%)	29 (100.00%)	6 (100.00%)
Total	11 (100.00%)	22 (100.00%)	29 (100.00%)	6 (100.00%)
Glinide				
Missing	0	1	0	0
yes	2 (18.18%)	1 (4.35%)	0 (0.00%)	0 (0.00%)
no	9 (81.82%)	22 (95.65%)	29 (100.00%)	6 (100.00%)
Total	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
Alpha glucosidase inhibitor				
Missing	0	1	0	0
no	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
Total	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
Glitazone				
Missing	0	1	0	0
no	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
Total	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)
DPP-4 inhibitor				
Missing	0	1	0	0
yes	3 (27.27%)	6 (26.09%)	12 (41.38%)	3 (50.00%)
no	8 (72.73%)	17 (73.91%)	17 (58.62%)	3 (50.00%)
Total	11 (100.00%)	23 (100.00%)	29 (100.00%)	6 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

Current non-insulin concomitant medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
SGLT2 inhibitor				
yes	4 (36.36%)	11 (45.83%)	16 (55.17%)	4 (66.67%)
no	7 (63.64%)	13 (54.17%)	13 (44.83%)	2 (33.33%)
Total	11 (100.00%)	24 (100.00%)	29 (100.00%)	6 (100.00%)
Any medication				
yes	10 (90.91%)	23 (95.83%)	28 (96.55%)	6 (100.00%)
no	1 (9.09%)	1 (4.17%)	1 (3.45%)	0 (0.00%)
Total	11 (100.00%)	24 (100.00%)	29 (100.00%)	6 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Current non-insulin concomitant medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Metformin			
yes	19 (67.86%)	6 (66.67%)	26 (81.25%)
no	9 (32.14%)	3 (33.33%)	6 (18.75%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
Sulfonyl urea			
Missing	0	1	0
yes	1 (3.57%)	0 (0.00%)	1 (3.13%)
no	27 (96.43%)	8 (100.00%)	31 (96.88%)
Total	28 (100.00%)	8 (100.00%)	32 (100.00%)
Glinide			
yes	0 (0.00%)	0 (0.00%)	3 (9.38%)
no	28 (100.00%)	9 (100.00%)	29 (90.63%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
Alpha glucosidase inhibitor			
no	28 (100.00%)	9 (100.00%)	32 (100.00%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
Glitazone			
no	28 (100.00%)	9 (100.00%)	32 (100.00%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
DPP-4 inhibitor			
yes	9 (32.14%)	0 (0.00%)	15 (46.88%)
no	19 (67.86%)	9 (100.00%)	17 (53.13%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
SGLT2 inhibitor			
yes	13 (46.43%)	5 (55.56%)	16 (50.00%)
no	15 (53.57%)	4 (44.44%)	16 (50.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.3 Current non-insulin concomitant medication - Type of medication - categorical
2.3.3.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Current non-insulin concomitant medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)
Any medication			
yes	26 (92.86%)	8 (88.89%)	32 (100.00%)
no	2 (7.14%)	1 (11.11%)	0 (0.00%)
Total	28 (100.00%)	9 (100.00%)	32 (100.00%)

Percentages related to the number of patients with results non-missing

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.1 Events - categorical

Late complications	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Diabetic retinopathy			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	4 (5.7%)	0 (0.0%)	0 (0.0%)
no	64 (91.4%)	7 (87.5%)	9 (90.0%)
unknown	2 (2.9%)	0 (0.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Diabetic neuropathy			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	29 (41.4%)	3 (37.5%)	3 (30.0%)
no	40 (57.1%)	3 (37.5%)	7 (70.0%)
unknown	1 (1.4%)	1 (12.5%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Diabetic nephropathy			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	14 (20.0%)	2 (25.0%)	1 (10.0%)
no	56 (80.0%)	5 (62.5%)	9 (90.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Diabetic foot syndrome			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	6 (8.6%)	3 (37.5%)	2 (20.0%)
no	63 (90.0%)	4 (50.0%)	8 (80.0%)
unknown	1 (1.4%)	0 (0.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Limb amputation due to diabetic foot			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	2 (2.9%)	0 (0.0%)	0 (0.0%)
no	68 (97.1%)	7 (87.5%)	10 (100.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.1 Events - categorical

Late complications	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Any complication			
yes	36 (51.4%)	4 (50.0%)	3 (30.0%)
no	34 (48.6%)	4 (50.0%)	7 (70.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.2 Since years - continuous

Since in years*	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Diabetic retinopathy			
n	3	0	0
Mean (SD)	4.3 (3.51)		
Min-Max	1 - 8		
Median	4.0		
Q1-Q3	1.0 - 8.0		
Diabetic neuropathy			
n	22	2	2
Mean (SD)	5.0 (3.47)	9.0 (5.66)	12.5 (0.71)
Min-Max	0 - 12	5 - 13	12 - 13
Median	4.5	9.0	12.5
Q1-Q3	3.0 - 6.0	5.0 - 13.0	12.0 - 13.0
Diabetic nephropathy			
n	11	2	1
Mean (SD)	4.5 (4.01)	2.5 (2.12)	4.0
Min-Max	0 - 11	1 - 4	4 - 4
Median	3.0	2.5	4.0
Q1-Q3	1.0 - 8.0	1.0 - 4.0	4.0 - 4.0
Diabetic foot syndrome			
n	3	2	2
Mean (SD)	2.0 (1.73)	7.0 (2.83)	7.5 (6.36)
Min-Max	0 - 3	5 - 9	3 - 12
Median	3.0	7.0	7.5
Q1-Q3	0.0 - 3.0	5.0 - 9.0	3.0 - 12.0
Limb amputation due to diabetic foot			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.3 Events - FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Diabetic retinopathy*	N non-miss	70	7	
	% yes	5.71	0.00	1.000
	% no	91.43	100.00	
	% unknown	2.86	0.00	
Diabetic neuropathy*	N non-miss	70	7	
	% yes	41.43	42.86	0.206
	% no	57.14	42.86	
	% unknown	1.43	14.29	
Diabetic nephropathy*	N non-miss	70	7	
	% yes	20.00	28.57	0.631
	% no	80.00	71.43	
Diabetic foot syndrome*	N non-miss	70	7	
	% yes	8.57	42.86	0.043
	% no	90.00	57.14	
	% unknown	1.43	0.00	
Limb amputation due to diabetic foot*	N non-miss	70	7	
	% yes	2.86	0.00	1.000
	% no	97.14	100.00	
Any complication*	N non-miss	70	8	
	% yes	51.43	50.00	1.000
	% no	48.57	50.00	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.4 Since years - FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Diabetic neuropathy*	N non-miss	22	2	
	Mean	5.0	9.0	0.239
	SE	0.74	4.00	
Diabetic nephropathy*	N non-miss	11	2	
	Mean	4.5	2.5	0.695
	SE	1.21	1.50	
Diabetic foot syndrome*	N non-miss	3	2	
	Mean	2.0	7.0	0.213
	SE	1.00	2.00	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.5 Events - FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Diabetic retinopathy*	N non-miss	70	10	
	% yes	5.71	0.00	0.387
	% no	91.43	90.00	
	% unknown	2.86	10.00	
Diabetic neuropathy*	N non-miss	70	10	
	% yes	41.43	30.00	0.765
	% no	57.14	70.00	
	% unknown	1.43	0.00	
Diabetic nephropathy*	N non-miss	70	10	
	% yes	20.00	10.00	0.678
	% no	80.00	90.00	
Diabetic foot syndrome*	N non-miss	70	10	
	% yes	8.57	20.00	0.358
	% no	90.00	80.00	
	% unknown	1.43	0.00	
Limb amputation due to diabetic foot*	N non-miss	70	10	
	% yes	2.86	0.00	1.000
	% no	97.14	100.00	
Any complication*	N non-miss	70	10	
	% yes	51.43	30.00	0.313
	% no	48.57	70.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.1 Full Analysis Set - Dropout - Off-Label
2.3.4.1.6 Since years - FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Diabetic neuropathy*	N non-miss	22	2	
	Mean	5.0	12.5	0.038
	SE	0.74	0.50	
Diabetic nephropathy*	N non-miss	11	1	
	Mean	4.5	4.0	1.000
	SE	1.21	.	
Diabetic foot syndrome*	N non-miss	3	2	
	Mean	2.0	7.5	0.388
	SE	1.00	4.50	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.4.2.1 Events - categorical

Late complications	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Diabetic retinopathy		
yes	0 (0.0%)	4 (8.0%)
no	20 (100.0%)	44 (88.0%)
unknown	0 (0.0%)	2 (4.0%)
Total	20 (100.0%)	50 (100.0%)
Diabetic neuropathy		
yes	7 (35.0%)	22 (44.0%)
no	13 (65.0%)	27 (54.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Diabetic nephropathy		
yes	4 (20.0%)	10 (20.0%)
no	16 (80.0%)	40 (80.0%)
Total	20 (100.0%)	50 (100.0%)
Diabetic foot syndrome		
yes	0 (0.0%)	6 (12.0%)
no	20 (100.0%)	43 (86.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Limb amputation due to diabetic foot		
yes	0 (0.0%)	2 (4.0%)
no	20 (100.0%)	48 (96.0%)
Total	20 (100.0%)	50 (100.0%)
Any complication		
yes	8 (40.0%)	28 (56.0%)
no	12 (60.0%)	22 (44.0%)
Total	20 (100.0%)	50 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.4.2.2 Since years - continuous

Since in years*	FGM (N = 20)	SMBG (N = 50)
Diabetic retinopathy		
n	0	3
Mean (SD)		4.3 (3.51)
Min-Max		1 - 8
Median		4.0
Q1-Q3		1.0 - 8.0
Diabetic neuropathy		
n	5	17
Mean (SD)	7.8 (2.95)	4.1 (3.22)
Min-Max	5 - 11	0 - 12
Median	6.0	4.0
Q1-Q3	6.0 - 11.0	2.0 - 6.0
Diabetic nephropathy		
n	4	7
Mean (SD)	5.0 (4.32)	4.3 (4.15)
Min-Max	1 - 11	0 - 11
Median	4.0	3.0
Q1-Q3	2.0 - 8.0	1.0 - 8.0
Diabetic foot syndrome		
n	0	3
Mean (SD)		2.0 (1.73)
Min-Max		0 - 3
Median		3.0
Q1-Q3		0.0 - 3.0
Limb amputation due to diabetic foot		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.3 Full Analysis Set - Subgroups - Gender
2.3.4.3.1 Events - categorical

Late complications	Female (N = 28) N (%)	Male (N = 42) N (%)
Diabetic retinopathy		
yes	0 (0.0%)	4 (9.5%)
no	28 (100.0%)	36 (85.7%)
unknown	0 (0.0%)	2 (4.8%)
Total	28 (100.0%)	42 (100.0%)
Diabetic neuropathy		
yes	11 (39.3%)	18 (42.9%)
no	17 (60.7%)	23 (54.8%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
Diabetic nephropathy		
yes	6 (21.4%)	8 (19.0%)
no	22 (78.6%)	34 (81.0%)
Total	28 (100.0%)	42 (100.0%)
Diabetic foot syndrome		
yes	3 (10.7%)	3 (7.1%)
no	24 (85.7%)	39 (92.9%)
unknown	1 (3.6%)	0 (0.0%)
Total	28 (100.0%)	42 (100.0%)
Limb amputation due to diabetic foot		
yes	1 (3.6%)	1 (2.4%)
no	27 (96.4%)	41 (97.6%)
Total	28 (100.0%)	42 (100.0%)
Any complication		
yes	15 (53.6%)	21 (50.0%)
no	13 (46.4%)	21 (50.0%)
Total	28 (100.0%)	42 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.3 Full Analysis Set - Subgroups - Gender
2.3.4.3.2 Since years - continuous

Since in years*	Female (N = 28)	Male (N = 42)
Diabetic retinopathy		
n	0	3
Mean (SD)		4.3 (3.51)
Min-Max		1 - 8
Median		4.0
Q1-Q3		1.0 - 8.0
Diabetic neuropathy		
n	7	15
Mean (SD)	2.6 (2.94)	6.1 (3.20)
Min-Max	0 - 7	2 - 12
Median	2.0	5.0
Q1-Q3	0.0 - 6.0	4.0 - 9.0
Diabetic nephropathy		
n	5	6
Mean (SD)	3.2 (4.49)	5.7 (3.56)
Min-Max	0 - 11	1 - 11
Median	1.0	5.5
Q1-Q3	1.0 - 3.0	3.0 - 8.0
Diabetic foot syndrome		
n	1	2
Mean (SD)	3.0	1.5 (2.12)
Min-Max	3 - 3	0 - 3
Median	3.0	1.5
Q1-Q3	3.0 - 3.0	0.0 - 3.0
Limb amputation due to diabetic foot		
n	1	0
Mean (SD)	3.0	
Min-Max	3 - 3	
Median	3.0	
Q1-Q3	3.0 - 3.0	

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.4 Full Analysis Set - Subgroups - Age groups
2.3.4.4.1 Events - categorical

Late complications	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Diabetic retinopathy			
yes	1 (4.2%)	2 (8.3%)	1 (4.5%)
no	23 (95.8%)	21 (87.5%)	20 (90.9%)
unknown	0 (0.0%)	1 (4.2%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Diabetic neuropathy			
yes	9 (37.5%)	8 (33.3%)	12 (54.5%)
no	15 (62.5%)	16 (66.7%)	9 (40.9%)
unknown	0 (0.0%)	0 (0.0%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Diabetic nephropathy			
yes	2 (8.3%)	3 (12.5%)	9 (40.9%)
no	22 (91.7%)	21 (87.5%)	13 (59.1%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Diabetic foot syndrome			
yes	2 (8.3%)	0 (0.0%)	4 (18.2%)
no	22 (91.7%)	24 (100.0%)	17 (77.3%)
unknown	0 (0.0%)	0 (0.0%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Limb amputation due to diabetic foot			
yes	1 (4.2%)	0 (0.0%)	1 (4.5%)
no	23 (95.8%)	24 (100.0%)	21 (95.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Any complication			
yes	9 (37.5%)	10 (41.7%)	17 (77.3%)
no	15 (62.5%)	14 (58.3%)	5 (22.7%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.4 Full Analysis Set - Subgroups - Age groups
2.3.4.4.2 Since years - continuous

Since in years*	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Diabetic retinopathy			
n	1	1	1
Mean (SD)	4.0	1.0	8.0
Min-Max	4 - 4	1 - 1	8 - 8
Median	4.0	1.0	8.0
Q1-Q3	4.0 - 4.0	1.0 - 1.0	8.0 - 8.0
Diabetic neuropathy			
n	6	6	10
Mean (SD)	3.7 (2.07)	3.3 (3.56)	6.7 (3.53)
Min-Max	0 - 6	0 - 9	2 - 12
Median	4.0	2.5	6.0
Q1-Q3	3.0 - 5.0	0.0 - 6.0	4.0 - 11.0
Diabetic nephropathy			
n	1	2	8
Mean (SD)	5.0	2.0 (1.41)	5.1 (4.52)
Min-Max	5 - 5	1 - 3	0 - 11
Median	5.0	2.0	4.5
Q1-Q3	5.0 - 5.0	1.0 - 3.0	1.0 - 9.5
Diabetic foot syndrome			
n	1	0	2
Mean (SD)	3.0		1.5 (2.12)
Min-Max	3 - 3		0 - 3
Median	3.0		1.5
Q1-Q3	3.0 - 3.0		0.0 - 3.0
Limb amputation due to diabetic foot			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.4.5.1 Events - categorical

Late complications	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Diabetic retinopathy		
yes	0 (0.0%)	4 (7.7%)
no	17 (94.4%)	47 (90.4%)
unknown	1 (5.6%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Diabetic neuropathy		
yes	6 (33.3%)	23 (44.2%)
no	12 (66.7%)	28 (53.8%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Diabetic nephropathy		
yes	5 (27.8%)	9 (17.3%)
no	13 (72.2%)	43 (82.7%)
Total	18 (100.0%)	52 (100.0%)
Diabetic foot syndrome		
yes	1 (5.6%)	5 (9.6%)
no	16 (88.9%)	47 (90.4%)
unknown	1 (5.6%)	0 (0.0%)
Total	18 (100.0%)	52 (100.0%)
Limb amputation due to diabetic foot		
yes	0 (0.0%)	2 (3.8%)
no	18 (100.0%)	50 (96.2%)
Total	18 (100.0%)	52 (100.0%)
Any complication		
yes	9 (50.0%)	27 (51.9%)
no	9 (50.0%)	25 (48.1%)
Total	18 (100.0%)	52 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.4.5.2 Since years - continuous

Since in years*	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Diabetic retinopathy		
n	0	3
Mean (SD)		4.3 (3.51)
Min-Max		1 - 8
Median		4.0
Q1-Q3		1.0 - 8.0
Diabetic neuropathy		
n	6	16
Mean (SD)	4.2 (1.94)	5.3 (3.91)
Min-Max	2 - 7	0 - 12
Median	3.5	5.0
Q1-Q3	3.0 - 6.0	2.5 - 7.5
Diabetic nephropathy		
n	5	6
Mean (SD)	2.4 (2.19)	6.3 (4.46)
Min-Max	1 - 6	0 - 11
Median	1.0	6.5
Q1-Q3	1.0 - 3.0	3.0 - 11.0
Diabetic foot syndrome		
n	1	2
Mean (SD)	0.0	3.0 (0.00)
Min-Max	0 - 0	3 - 3
Median	0.0	3.0
Q1-Q3	0.0 - 0.0	3.0 - 3.0
Limb amputation due to diabetic foot		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.6 Full Analysis Set - Subgroups - Renal function
2.3.4.6.1 Events - categorical

Late complications	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Diabetic retinopathy		
yes	0 (0.0%)	3 (7.7%)
no	16 (94.1%)	36 (92.3%)
unknown	1 (5.9%)	0 (0.0%)
Total	17 (100.0%)	39 (100.0%)
Diabetic neuropathy		
yes	5 (29.4%)	17 (43.6%)
no	11 (64.7%)	22 (56.4%)
unknown	1 (5.9%)	0 (0.0%)
Total	17 (100.0%)	39 (100.0%)
Diabetic nephropathy		
yes	7 (41.2%)	5 (12.8%)
no	10 (58.8%)	34 (87.2%)
Total	17 (100.0%)	39 (100.0%)
Diabetic foot syndrome		
yes	1 (5.9%)	3 (7.7%)
no	16 (94.1%)	35 (89.7%)
unknown	0 (0.0%)	1 (2.6%)
Total	17 (100.0%)	39 (100.0%)
Limb amputation due to diabetic foot		
yes	1 (5.9%)	1 (2.6%)
no	16 (94.1%)	38 (97.4%)
Total	17 (100.0%)	39 (100.0%)
Any complication		
yes	10 (58.8%)	18 (46.2%)
no	7 (41.2%)	21 (53.8%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.6 Full Analysis Set - Subgroups - Renal function
2.3.4.6.1 Events - categorical

Late complications	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Total	17 (100.0%)	39 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.6 Full Analysis Set - Subgroups - Renal function
2.3.4.6.2 Since years - continuous

Since in years*	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Diabetic retinopathy		
n	0	2
Mean (SD)		4.5 (4.95)
Min-Max		1 - 8
Median		4.5
Q1-Q3		1.0 - 8.0
Diabetic neuropathy		
n	4	13
Mean (SD)	3.8 (4.92)	5.4 (3.71)
Min-Max	0 - 11	0 - 12
Median	2.0	5.0
Q1-Q3	1.0 - 6.5	3.0 - 7.0
Diabetic nephropathy		
n	6	3
Mean (SD)	5.2 (4.92)	4.7 (2.89)
Min-Max	1 - 11	3 - 8
Median	3.5	3.0
Q1-Q3	1.0 - 11.0	3.0 - 8.0
Diabetic foot syndrome		
n	0	2
Mean (SD)		3.0 (0.00)
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0
Limb amputation due to diabetic foot		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.4.7.1 Events - categorical

Late complications	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Diabetic retinopathy			
yes	0 (0.0%)	0 (0.0%)	4 (10.3%)
no	7 (100.0%)	21 (100.0%)	34 (87.2%)
unknown	0 (0.0%)	0 (0.0%)	1 (2.6%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Diabetic neuropathy			
yes	4 (57.1%)	5 (23.8%)	20 (51.3%)
no	3 (42.9%)	16 (76.2%)	19 (48.7%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Diabetic nephropathy			
yes	0 (0.0%)	4 (19.0%)	9 (23.1%)
no	7 (100.0%)	17 (81.0%)	30 (76.9%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Diabetic foot syndrome			
yes	1 (14.3%)	1 (4.8%)	4 (10.3%)
no	6 (85.7%)	19 (90.5%)	35 (89.7%)
unknown	0 (0.0%)	1 (4.8%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Limb amputation due to diabetic foot			
yes	1 (14.3%)	0 (0.0%)	0 (0.0%)
no	6 (85.7%)	21 (100.0%)	39 (100.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Any complication			
yes	4 (57.1%)	7 (33.3%)	24 (61.5%)
no	3 (42.9%)	14 (66.7%)	15 (38.5%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.4.7.2 Since years - continuous

Since in years*	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Diabetic retinopathy			
n	0	0	3
Mean (SD)			4.3 (3.51)
Min-Max			1 - 8
Median			4.0
Q1-Q3			1.0 - 8.0
Diabetic neuropathy			
n	4	3	15
Mean (SD)	1.3 (1.50)	4.7 (2.52)	6.0 (3.40)
Min-Max	0 - 3	2 - 7	0 - 12
Median	1.0	5.0	6.0
Q1-Q3	0.0 - 2.5	2.0 - 7.0	4.0 - 9.0
Diabetic nephropathy			
n	0	3	8
Mean (SD)		0.7 (0.58)	6.0 (3.74)
Min-Max		0 - 1	1 - 11
Median		1.0	5.5
Q1-Q3		0.0 - 1.0	3.0 - 9.5
Diabetic foot syndrome			
n	1	0	2
Mean (SD)	3.0		1.5 (2.12)
Min-Max	3 - 3		0 - 3
Median	3.0		1.5
Q1-Q3	3.0 - 3.0		0.0 - 3.0
Limb amputation due to diabetic foot			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.4.8.1 Events - categorical

Late complications	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Diabetic retinopathy		
yes	3 (7.9%)	1 (3.1%)
no	34 (89.5%)	30 (93.8%)
unknown	1 (2.6%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Diabetic neuropathy		
yes	17 (44.7%)	12 (37.5%)
no	20 (52.6%)	20 (62.5%)
unknown	1 (2.6%)	0 (0.0%)
Total	38 (100.0%)	32 (100.0%)
Diabetic nephropathy		
yes	7 (18.4%)	7 (21.9%)
no	31 (81.6%)	25 (78.1%)
Total	38 (100.0%)	32 (100.0%)
Diabetic foot syndrome		
yes	4 (10.5%)	2 (6.3%)
no	33 (86.8%)	30 (93.8%)
unknown	1 (2.6%)	0 (0.0%)
Total	38 (100.0%)	32 (100.0%)
Limb amputation due to diabetic foot		
yes	1 (2.6%)	1 (3.1%)
no	37 (97.4%)	31 (96.9%)
Total	38 (100.0%)	32 (100.0%)
Any complication		
yes	21 (55.3%)	15 (46.9%)
no	17 (44.7%)	17 (53.1%)
Total	38 (100.0%)	32 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.4.8.2 Since years - continuous

Since in years*	<8.5% (N = 38)	>=8.5% (N = 32)
Diabetic retinopathy		
n	2	1
Mean (SD)	4.5 (4.95)	4.0
Min-Max	1 - 8	4 - 4
Median	4.5	4.0
Q1-Q3	1.0 - 8.0	4.0 - 4.0
Diabetic neuropathy		
n	13	9
Mean (SD)	5.9 (3.66)	3.6 (2.79)
Min-Max	0 - 12	0 - 9
Median	6.0	3.0
Q1-Q3	4.0 - 7.0	3.0 - 4.0
Diabetic nephropathy		
n	6	5
Mean (SD)	4.0 (4.47)	5.2 (3.77)
Min-Max	0 - 11	1 - 11
Median	2.0	5.0
Q1-Q3	1.0 - 8.0	3.0 - 6.0
Diabetic foot syndrome		
n	2	1
Mean (SD)	1.5 (2.12)	3.0
Min-Max	0 - 3	3 - 3
Median	1.5	3.0
Q1-Q3	0.0 - 3.0	3.0 - 3.0
Limb amputation due to diabetic foot		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.4.9.1 Events - categorical

Late complications	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Diabetic retinopathy				
yes	0 (0.0%)	1 (4.2%)	3 (10.3%)	0 (0.0%)
no	11 (100.0%)	23 (95.8%)	24 (82.8%)	6 (100.0%)
unknown	0 (0.0%)	0 (0.0%)	2 (6.9%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Diabetic neuropathy				
yes	6 (54.5%)	7 (29.2%)	14 (48.3%)	2 (33.3%)
no	5 (45.5%)	17 (70.8%)	14 (48.3%)	4 (66.7%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Diabetic nephropathy				
yes	3 (27.3%)	5 (20.8%)	5 (17.2%)	1 (16.7%)
no	8 (72.7%)	19 (79.2%)	24 (82.8%)	5 (83.3%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Diabetic foot syndrome				
yes	0 (0.0%)	2 (8.3%)	4 (13.8%)	0 (0.0%)
no	11 (100.0%)	22 (91.7%)	24 (82.8%)	6 (100.0%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Limb amputation due to diabetic foot				
yes	0 (0.0%)	0 (0.0%)	2 (6.9%)	0 (0.0%)
no	11 (100.0%)	24 (100.0%)	27 (93.1%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Any complication				
yes	7 (63.6%)	9 (37.5%)	17 (58.6%)	3 (50.0%)
no	4 (36.4%)	15 (62.5%)	12 (41.4%)	3 (50.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.4.9.2 Since years - continuous

Since in years*	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Diabetic retinopathy				
n	0	0	3	0
Mean (SD)			4.3 (3.51)	
Min-Max			1 - 8	
Median			4.0	
Q1-Q3			1.0 - 8.0	
Diabetic neuropathy				
n	5	5	11	1
Mean (SD)	3.6 (2.61)	5.4 (2.51)	4.8 (3.92)	11.0
Min-Max	0 - 6	2 - 9	0 - 12	11 - 11
Median	4.0	5.0	4.0	11.0
Q1-Q3	2.0 - 6.0	5.0 - 6.0	3.0 - 7.0	11.0 - 11.0
Diabetic nephropathy				
n	3	3	4	1
Mean (SD)	6.3 (4.16)	0.7 (0.58)	7.0 (3.37)	1.0
Min-Max	3 - 11	0 - 1	3 - 11	1 - 1
Median	5.0	1.0	7.0	1.0
Q1-Q3	3.0 - 11.0	0.0 - 1.0	4.5 - 9.5	1.0 - 1.0
Diabetic foot syndrome				
n	0	1	2	0
Mean (SD)		0.0	3.0 (0.00)	
Min-Max		0 - 0	3 - 3	
Median		0.0	3.0	
Q1-Q3		0.0 - 0.0	3.0 - 3.0	
Limb amputation due to diabetic foot				
n	0	0	1	0
Mean (SD)			3.0	
Min-Max			3 - 3	
Median			3.0	
Q1-Q3			3.0 - 3.0	

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.4.10.1 Events - categorical

Late complications	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Diabetic retinopathy			
yes	2 (7.1%)	0 (0.0%)	2 (6.3%)
no	26 (92.9%)	9 (100.0%)	28 (87.5%)
unknown	0 (0.0%)	0 (0.0%)	2 (6.3%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Diabetic neuropathy			
yes	14 (50.0%)	2 (22.2%)	13 (40.6%)
no	14 (50.0%)	7 (77.8%)	18 (56.3%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Diabetic nephropathy			
yes	6 (21.4%)	1 (11.1%)	7 (21.9%)
no	22 (78.6%)	8 (88.9%)	25 (78.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Diabetic foot syndrome			
yes	4 (14.3%)	0 (0.0%)	2 (6.3%)
no	23 (82.1%)	9 (100.0%)	30 (93.8%)
unknown	1 (3.6%)	0 (0.0%)	0 (0.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Limb amputation due to diabetic foot			
yes	1 (3.6%)	0 (0.0%)	1 (3.1%)
no	27 (96.4%)	9 (100.0%)	31 (96.9%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Any complication			
yes	18 (64.3%)	2 (22.2%)	16 (50.0%)
no	10 (35.7%)	7 (77.8%)	16 (50.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.4.10.1 Events - categorical

Late complications	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.4 Late complications
2.3.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.4.10.2 Since years - continuous

Since in years*	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Diabetic retinopathy			
n	1	0	2
Mean (SD)	4.0		4.5 (4.95)
Min-Max	4 - 4		1 - 8
Median	4.0		4.5
Q1-Q3	4.0 - 4.0		1.0 - 8.0
Diabetic neuropathy			
n	9	2	11
Mean (SD)	3.2 (2.28)	11.0 (0.00)	5.3 (3.32)
Min-Max	0 - 7	11 - 11	0 - 12
Median	4.0	11.0	6.0
Q1-Q3	2.0 - 4.0	11.0 - 11.0	3.0 - 6.0
Diabetic nephropathy			
n	5	1	5
Mean (SD)	3.8 (4.66)	11.0	4.0 (2.65)
Min-Max	0 - 11	11 - 11	1 - 8
Median	1.0	11.0	3.0
Q1-Q3	1.0 - 6.0	11.0 - 11.0	3.0 - 5.0
Diabetic foot syndrome			
n	1	0	2
Mean (SD)	3.0		1.5 (2.12)
Min-Max	3 - 3		0 - 3
Median	3.0		1.5
Q1-Q3	3.0 - 3.0		0.0 - 3.0
Limb amputation due to diabetic foot			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		

* Calculated in years prior to the year of entry into the study
Patient [redacted]: Diabetic foot syndrome = no, but limb amputation due to diabetic foot = yes

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.1 Summary

Concomitant diseases	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Arterial hypertension			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	61 (87.1%)	5 (62.5%)	10 (100.0%)
no	9 (12.9%)	2 (25.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Coronary heart disease			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	14 (20.0%)	0 (0.0%)	3 (30.0%)
no	55 (78.6%)	7 (87.5%)	6 (60.0%)
unknown	1 (1.4%)	0 (0.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Peripheral arterial occlusive disease			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	5 (7.1%)	2 (25.0%)	0 (0.0%)
no	64 (91.4%)	5 (62.5%)	8 (80.0%)
unknown	1 (1.4%)	0 (0.0%)	2 (20.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Renal failure			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	15 (21.4%)	4 (50.0%)	2 (20.0%)
no	55 (78.6%)	3 (37.5%)	8 (80.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
History of myocardial infarction			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	6 (8.6%)	0 (0.0%)	2 (20.0%)
no	63 (90.0%)	7 (87.5%)	7 (70.0%)
unknown	1 (1.4%)	0 (0.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.1 Summary

Concomitant diseases	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Stroke (ischemic, hemorrhagic) in the history			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	3 (4.3%)	0 (0.0%)	1 (10.0%)
no	67 (95.7%)	7 (87.5%)	8 (80.0%)
unknown	0 (0.0%)	0 (0.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Any concomitant disease			
yes	63 (90.0%)	6 (75.0%)	10 (100.0%)
no	7 (10.0%)	2 (25.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Arterial hypertension*	N non-miss	70	7	
	% yes	87.14	71.43	0.261
	% no	12.86	28.57	
Coronary heart disease*	N non-miss	70	7	
	% yes	20.00	0.00	0.397
	% no	78.57	100.00	
	% unknown	1.43	0.00	
Peripheral arterial occlusive disease*	N non-miss	70	7	
	% yes	7.14	28.57	0.202
	% no	91.43	71.43	
	% unknown	1.43	0.00	
Renal failure*	N non-miss	70	7	
	% yes	21.43	57.14	0.058
	% no	78.57	42.86	
History of myocardial infarction*	N non-miss	70	7	
	% yes	8.57	0.00	1.000
	% no	90.00	100.00	
	% unknown	1.43	0.00	
Stroke (ischemic, hemorrhagic) in the history*	N non-miss	70	7	
	% yes	4.29	0.00	1.000
	% no	95.71	100.00	
Any concomitant disease*	N non-miss	70	8	
	% yes	90.00	75.00	0.229
	% no	10.00	25.00	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.2 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.3 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Arterial hypertension*	N non-miss	70	10	
	% yes	87.14	100.00	0.593
	% no	12.86	0.00	
Coronary heart disease*	N non-miss	70	10	
	% yes	20.00	30.00	0.130
	% no	78.57	60.00	
	% unknown	1.43	10.00	
Peripheral arterial occlusive disease*	N non-miss	70	10	
	% yes	7.14	0.00	0.052
	% no	91.43	80.00	
	% unknown	1.43	20.00	
Renal failure*	N non-miss	70	10	
	% yes	21.43	20.00	1.000
	% no	78.57	80.00	
History of myocardial infarction*	N non-miss	70	10	
	% yes	8.57	20.00	0.112
	% no	90.00	70.00	
	% unknown	1.43	10.00	
Stroke (ischemic, hemorrhagic) in the history*	N non-miss	70	10	
	% yes	4.29	10.00	0.054
	% no	95.71	80.00	
	% unknown	0.00	10.00	
Any concomitant disease*	N non-miss	70	10	
	% yes	90.00	100.00	0.587
	% no	10.00	0.00	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.1 Full Analysis Set - Dropout - Off-Label
2.3.5.1.3 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.2 Full Analysis Set - Subgroups - FGM - SMBG

Concomitant diseases	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Arterial hypertension		
yes	14 (70.0%)	47 (94.0%)
no	6 (30.0%)	3 (6.0%)
Total	20 (100.0%)	50 (100.0%)
Coronary heart disease		
yes	6 (30.0%)	8 (16.0%)
no	14 (70.0%)	41 (82.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Peripheral arterial occlusive disease		
yes	2 (10.0%)	3 (6.0%)
no	18 (90.0%)	46 (92.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Renal failure		
yes	1 (5.0%)	14 (28.0%)
no	19 (95.0%)	36 (72.0%)
Total	20 (100.0%)	50 (100.0%)
History of myocardial infarction		
yes	2 (10.0%)	4 (8.0%)
no	18 (90.0%)	45 (90.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Stroke (ischemic, hemorrhagic) in the history		
yes	2 (10.0%)	1 (2.0%)
no	18 (90.0%)	49 (98.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.2 Full Analysis Set - Subgroups - FGM - SMBG

Concomitant diseases	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Total	20 (100.0%)	50 (100.0%)
Any concomitant disease		
yes	16 (80.0%)	47 (94.0%)
no	4 (20.0%)	3 (6.0%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.3 Full Analysis Set - Subgroups - Gender

Concomitant diseases	Female (N = 28) N (%)	Male (N = 42) N (%)
Arterial hypertension		
yes	22 (78.6%)	39 (92.9%)
no	6 (21.4%)	3 (7.1%)
Total	28 (100.0%)	42 (100.0%)
Coronary heart disease		
yes	5 (17.9%)	9 (21.4%)
no	22 (78.6%)	33 (78.6%)
unknown	1 (3.6%)	0 (0.0%)
Total	28 (100.0%)	42 (100.0%)
Peripheral arterial occlusive disease		
yes	1 (3.6%)	4 (9.5%)
no	27 (96.4%)	37 (88.1%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
Renal failure		
yes	6 (21.4%)	9 (21.4%)
no	22 (78.6%)	33 (78.6%)
Total	28 (100.0%)	42 (100.0%)
History of myocardial infarction		
yes	3 (10.7%)	3 (7.1%)
no	25 (89.3%)	38 (90.5%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
Stroke (ischemic, hemorrhagic) in the history		
yes	1 (3.6%)	2 (4.8%)
no	27 (96.4%)	40 (95.2%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.3 Full Analysis Set - Subgroups - Gender

Concomitant diseases	Female (N = 28) N (%)	Male (N = 42) N (%)
Total	28 (100.0%)	42 (100.0%)
Any concomitant disease		
yes	24 (85.7%)	39 (92.9%)
no	4 (14.3%)	3 (7.1%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.4 Full Analysis Set - Subgroups - Age groups

Concomitant diseases	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Arterial hypertension			
yes	20 (83.3%)	20 (83.3%)	21 (95.5%)
no	4 (16.7%)	4 (16.7%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Coronary heart disease			
yes	3 (12.5%)	5 (20.8%)	6 (27.3%)
no	20 (83.3%)	19 (79.2%)	16 (72.7%)
unknown	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Peripheral arterial occlusive disease			
yes	2 (8.3%)	0 (0.0%)	3 (13.6%)
no	21 (87.5%)	24 (100.0%)	19 (86.4%)
unknown	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Renal failure			
yes	3 (12.5%)	1 (4.2%)	11 (50.0%)
no	21 (87.5%)	23 (95.8%)	11 (50.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
History of myocardial infarction			
yes	1 (4.2%)	2 (8.3%)	3 (13.6%)
no	23 (95.8%)	21 (87.5%)	19 (86.4%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Stroke (ischemic, hemorrhagic) in the history			
yes	1 (4.2%)	1 (4.2%)	1 (4.5%)
no	23 (95.8%)	23 (95.8%)	21 (95.5%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.4 Full Analysis Set - Subgroups - Age groups

Concomitant diseases	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Any concomitant disease			
yes	21 (87.5%)	21 (87.5%)	21 (95.5%)
no	3 (12.5%)	3 (12.5%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.5 Full Analysis Set - Subgroups - Body Mass Index

Concomitant diseases	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Arterial hypertension		
yes	13 (72.2%)	48 (92.3%)
no	5 (27.8%)	4 (7.7%)
Total	18 (100.0%)	52 (100.0%)
Coronary heart disease		
yes	6 (33.3%)	8 (15.4%)
no	12 (66.7%)	43 (82.7%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Peripheral arterial occlusive disease		
yes	1 (5.6%)	4 (7.7%)
no	16 (88.9%)	48 (92.3%)
unknown	1 (5.6%)	0 (0.0%)
Total	18 (100.0%)	52 (100.0%)
Renal failure		
yes	7 (38.9%)	8 (15.4%)
no	11 (61.1%)	44 (84.6%)
Total	18 (100.0%)	52 (100.0%)
History of myocardial infarction		
yes	2 (11.1%)	4 (7.7%)
no	16 (88.9%)	47 (90.4%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Stroke (ischemic, hemorrhagic) in the history		
yes	1 (5.6%)	2 (3.8%)
no	17 (94.4%)	50 (96.2%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.5 Full Analysis Set - Subgroups - Body Mass Index

Concomitant diseases	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Total	18 (100.0%)	52 (100.0%)
Any concomitant disease		
yes	15 (83.3%)	48 (92.3%)
no	3 (16.7%)	4 (7.7%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.6 Full Analysis Set - Subgroups - Renal function

Concomitant diseases	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Arterial hypertension		
yes	16 (94.1%)	32 (82.1%)
no	1 (5.9%)	7 (17.9%)
Total	17 (100.0%)	39 (100.0%)
Coronary heart disease		
yes	5 (29.4%)	5 (12.8%)
no	12 (70.6%)	33 (84.6%)
unknown	0 (0.0%)	1 (2.6%)
Total	17 (100.0%)	39 (100.0%)
Peripheral arterial occlusive disease		
yes	0 (0.0%)	3 (7.7%)
no	17 (100.0%)	35 (89.7%)
unknown	0 (0.0%)	1 (2.6%)
Total	17 (100.0%)	39 (100.0%)
Renal failure		
yes	9 (52.9%)	4 (10.3%)
no	8 (47.1%)	35 (89.7%)
Total	17 (100.0%)	39 (100.0%)
History of myocardial infarction		
yes	3 (17.6%)	3 (7.7%)
no	14 (82.4%)	36 (92.3%)
Total	17 (100.0%)	39 (100.0%)
Stroke (ischemic, hemorrhagic) in the history		
yes	1 (5.9%)	2 (5.1%)
no	16 (94.1%)	37 (94.9%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.6 Full Analysis Set - Subgroups - Renal function

Concomitant diseases	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Total	17 (100.0%)	39 (100.0%)
Any concomitant disease		
yes	17 (100.0%)	33 (84.6%)
no	0 (0.0%)	6 (15.4%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.7 Full Analysis Set - Subgroups - Duration of diabetes

Concomitant diseases	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Arterial hypertension			
yes	6 (85.7%)	17 (81.0%)	35 (89.7%)
no	1 (14.3%)	4 (19.0%)	4 (10.3%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Coronary heart disease			
yes	0 (0.0%)	4 (19.0%)	9 (23.1%)
no	6 (85.7%)	17 (81.0%)	30 (76.9%)
unknown	1 (14.3%)	0 (0.0%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Peripheral arterial occlusive disease			
yes	1 (14.3%)	0 (0.0%)	4 (10.3%)
no	6 (85.7%)	21 (100.0%)	34 (87.2%)
unknown	0 (0.0%)	0 (0.0%)	1 (2.6%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Renal failure			
yes	1 (14.3%)	6 (28.6%)	7 (17.9%)
no	6 (85.7%)	15 (71.4%)	32 (82.1%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
History of myocardial infarction			
yes	0 (0.0%)	1 (4.8%)	3 (7.7%)
no	7 (100.0%)	19 (90.5%)	36 (92.3%)
unknown	0 (0.0%)	1 (4.8%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Stroke (ischemic, hemorrhagic) in the history			
yes	0 (0.0%)	1 (4.8%)	2 (5.1%)
no	7 (100.0%)	20 (95.2%)	37 (94.9%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.7 Full Analysis Set - Subgroups - Duration of diabetes

Concomitant diseases	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Any concomitant disease			
yes	6 (85.7%)	18 (85.7%)	36 (92.3%)
no	1 (14.3%)	3 (14.3%)	3 (7.7%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.8 Full Analysis Set - Subgroups - Baseline HbA1c

Concomitant diseases	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Arterial hypertension		
yes	30 (78.9%)	31 (96.9%)
no	8 (21.1%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Coronary heart disease		
yes	6 (15.8%)	8 (25.0%)
no	32 (84.2%)	23 (71.9%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Peripheral arterial occlusive disease		
yes	3 (7.9%)	2 (6.3%)
no	35 (92.1%)	29 (90.6%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Renal failure		
yes	7 (18.4%)	8 (25.0%)
no	31 (81.6%)	24 (75.0%)
Total	38 (100.0%)	32 (100.0%)
History of myocardial infarction		
yes	3 (7.9%)	3 (9.4%)
no	35 (92.1%)	28 (87.5%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Stroke (ischemic, hemorrhagic) in the history		
yes	2 (5.3%)	1 (3.1%)
no	36 (94.7%)	31 (96.9%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.8 Full Analysis Set - Subgroups - Baseline HbA1c

Concomitant diseases	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Total	38 (100.0%)	32 (100.0%)
Any concomitant disease		
yes	32 (84.2%)	31 (96.9%)
no	6 (15.8%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

Concomitant diseases	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Arterial hypertension				
yes	11 (100.0%)	19 (79.2%)	25 (86.2%)	6 (100.0%)
no	0 (0.0%)	5 (20.8%)	4 (13.8%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Coronary heart disease				
yes	3 (27.3%)	4 (16.7%)	4 (13.8%)	3 (50.0%)
no	8 (72.7%)	20 (83.3%)	24 (82.8%)	3 (50.0%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Peripheral arterial occlusive disease				
yes	1 (9.1%)	1 (4.2%)	2 (6.9%)	1 (16.7%)
no	10 (90.9%)	23 (95.8%)	26 (89.7%)	5 (83.3%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Renal failure				
yes	2 (18.2%)	5 (20.8%)	6 (20.7%)	2 (33.3%)
no	9 (81.8%)	19 (79.2%)	23 (79.3%)	4 (66.7%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
History of myocardial infarction				
yes	2 (18.2%)	0 (0.0%)	3 (10.3%)	1 (16.7%)
no	9 (81.8%)	23 (95.8%)	26 (89.7%)	5 (83.3%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Stroke (ischemic, hemorrhagic) in the history				
yes	0 (0.0%)	0 (0.0%)	2 (6.9%)	1 (16.7%)
no	11 (100.0%)	24 (100.0%)	27 (93.1%)	5 (83.3%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

Concomitant diseases	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Any concomitant disease				
yes	11 (100.0%)	20 (83.3%)	26 (89.7%)	6 (100.0%)
no	0 (0.0%)	4 (16.7%)	3 (10.3%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Concomitant diseases	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Arterial hypertension			
yes	26 (92.9%)	7 (77.8%)	27 (84.4%)
no	2 (7.1%)	2 (22.2%)	5 (15.6%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Coronary heart disease			
yes	5 (17.9%)	2 (22.2%)	7 (21.9%)
no	22 (78.6%)	7 (77.8%)	25 (78.1%)
unknown	1 (3.6%)	0 (0.0%)	0 (0.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Peripheral arterial occlusive disease			
yes	1 (3.6%)	1 (11.1%)	3 (9.4%)
no	26 (92.9%)	8 (88.9%)	29 (90.6%)
unknown	1 (3.6%)	0 (0.0%)	0 (0.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Renal failure			
yes	8 (28.6%)	1 (11.1%)	6 (18.8%)
no	20 (71.4%)	8 (88.9%)	26 (81.3%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
History of myocardial infarction			
yes	3 (10.7%)	0 (0.0%)	3 (9.4%)
no	25 (89.3%)	9 (100.0%)	28 (87.5%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Stroke (ischemic, hemorrhagic) in the history			
yes	0 (0.0%)	2 (22.2%)	1 (3.1%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.5 Concomitant diseases - categorical
2.3.5.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Concomitant diseases	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
no	28 (100.0%)	7 (77.8%)	31 (96.9%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Any concomitant disease			
yes	26 (92.9%)	7 (77.8%)	29 (90.6%)
no	2 (7.1%)	2 (22.2%)	3 (9.4%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.1 Full Analysis Set - Dropout - Off-Label
2.3.6.1.1 Medication - categorical

Lipid lowering medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Statins			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	36 (51.4%)	3 (37.5%)	9 (90.0%)
no	34 (48.6%)	4 (50.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Fibrates			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	1 (1.4%)	0 (0.0%)	0 (0.0%)
no	69 (98.6%)	7 (87.5%)	10 (100.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Colestyramine			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
no	70 (100.0%)	7 (87.5%)	10 (100.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Ezetimibe			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	7 (10.0%)	0 (0.0%)	0 (0.0%)
no	62 (88.6%)	7 (87.5%)	10 (100.0%)
unknown	1 (1.4%)	0 (0.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
PCSK9 inhibitors			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
no	69 (98.6%)	7 (87.5%)	10 (100.0%)
unknown	1 (1.4%)	0 (0.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Omega-3 fatty acids			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
no	70 (100.0%)	7 (87.5%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.1 Full Analysis Set - Dropout - Off-Label
2.3.6.1.1 Medication - categorical

Lipid lowering medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Any lipid lowering medication			
yes	37 (52.9%)	3 (37.5%)	9 (90.0%)
no	33 (47.1%)	5 (62.5%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.1 Full Analysis Set - Dropout - Off-Label
2.3.6.1.2 Start of treatment - continuous

Start - years before entry	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Statins			
n	30	2	7
Mean (SD)	6.4 (4.92)	8.5 (9.19)	6.1 (6.26)
Min-Max	0 - 19	2 - 15	0 - 15
Median	4.0	8.5	2.0
Q1-Q3	3.0 - 11.0	2.0 - 15.0	1.0 - 12.0
Fibrates			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		
Ezetimibe			
n	6	0	0
Mean (SD)	5.5 (3.83)		
Min-Max	2 - 11		
Median	4.5		
Q1-Q3	2.0 - 9.0		

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.1 Full Analysis Set - Dropout - Off-Label
2.3.6.1.3 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Statins*	N non-miss	70	7	
	% yes	51.43	42.86	0.711
	% no	48.57	57.14	
Since years**	N non-miss	30	2	
	Mean	6.4	8.5	0.876
	SE	0.90	6.50	

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* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.1 Full Analysis Set - Dropout - Off-Label
2.3.6.1.4 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Statins*	N non-miss	70	10	
	% yes	51.43	90.00	0.037
	% no	48.57	10.00	
Since years**	N non-miss	30	7	
	Mean	6.4	6.1	0.615
	SE	0.90	2.36	

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* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.6.2.1 Medication - categorical

Lipid lowering medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Statins		
yes	8 (40.0%)	28 (56.0%)
no	12 (60.0%)	22 (44.0%)
Total	20 (100.0%)	50 (100.0%)
Fibrates		
yes	0 (0.0%)	1 (2.0%)
no	20 (100.0%)	49 (98.0%)
Total	20 (100.0%)	50 (100.0%)
Colestyramine		
no	20 (100.0%)	50 (100.0%)
Total	20 (100.0%)	50 (100.0%)
Ezetimibe		
yes	2 (10.0%)	5 (10.0%)
no	18 (90.0%)	44 (88.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
PCSK9 inhibitors		
no	20 (100.0%)	49 (98.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Omega-3 fatty acids		
no	20 (100.0%)	50 (100.0%)
Total	20 (100.0%)	50 (100.0%)
Any lipid lowering medication		
yes	8 (40.0%)	29 (58.0%)
no	12 (60.0%)	21 (42.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.6.2.1 Medication - categorical

Lipid lowering medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.6.2.2 Start of treatment - continuous

Start - years before entry	FGM (N = 20)	SMBG (N = 50)
Statins		
n	5	25
Mean (SD)	4.8 (3.77)	6.7 (5.12)
Min-Max	1 - 11	0 - 19
Median	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 11.0
Fibrates		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0
Ezetimibe		
n	1	5
Mean (SD)	2.0	6.2 (3.83)
Min-Max	2 - 2	2 - 11
Median	2.0	6.0
Q1-Q3	2.0 - 2.0	3.0 - 9.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.3 Full Analysis Set - Subgroups - Gender
2.3.6.3.1 Medication - categorical

Lipid lowering medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Statins		
yes	12 (42.9%)	24 (57.1%)
no	16 (57.1%)	18 (42.9%)
Total	28 (100.0%)	42 (100.0%)
Fibrates		
yes	0 (0.0%)	1 (2.4%)
no	28 (100.0%)	41 (97.6%)
Total	28 (100.0%)	42 (100.0%)
Colestyramine		
no	28 (100.0%)	42 (100.0%)
Total	28 (100.0%)	42 (100.0%)
Ezetimibe		
yes	3 (10.7%)	4 (9.5%)
no	25 (89.3%)	37 (88.1%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
PCSK9 inhibitors		
no	28 (100.0%)	41 (97.6%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
Omega-3 fatty acids		
no	28 (100.0%)	42 (100.0%)
Total	28 (100.0%)	42 (100.0%)
Any lipid lowering medication		
yes	12 (42.9%)	25 (59.5%)
no	16 (57.1%)	17 (40.5%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.3 Full Analysis Set - Subgroups - Gender
2.3.6.3.1 Medication - categorical

Lipid lowering medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.3 Full Analysis Set - Subgroups - Gender
2.3.6.3.2 Start of treatment - continuous

Start - years before entry	Female (N = 28)	Male (N = 42)
Statins		
n	11	19
Mean (SD)	6.9 (5.28)	6.1 (4.81)
Min-Max	1 - 15	0 - 19
Median	4.0	4.0
Q1-Q3	3.0 - 11.0	3.0 - 10.0
Fibrates		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0
Ezetimibe		
n	2	4
Mean (SD)	5.5 (4.95)	5.5 (4.04)
Min-Max	2 - 9	2 - 11
Median	5.5	4.5
Q1-Q3	2.0 - 9.0	2.5 - 8.5

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.4 Full Analysis Set - Subgroups - Age groups
2.3.6.4.1 Medication - categorical

Lipid lowering medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Statins			
yes	11 (45.8%)	14 (58.3%)	11 (50.0%)
no	13 (54.2%)	10 (41.7%)	11 (50.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Fibrates			
yes	0 (0.0%)	0 (0.0%)	1 (4.5%)
no	24 (100.0%)	24 (100.0%)	21 (95.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Colestyramine			
no	24 (100.0%)	24 (100.0%)	22 (100.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Ezetimibe			
yes	2 (8.3%)	1 (4.2%)	4 (18.2%)
no	22 (91.7%)	22 (91.7%)	18 (81.8%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
PCSK9 inhibitors			
no	24 (100.0%)	23 (95.8%)	22 (100.0%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Omega-3 fatty acids			
no	24 (100.0%)	24 (100.0%)	22 (100.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Any lipid lowering medication			
yes	11 (45.8%)	14 (58.3%)	12 (54.5%)
no	13 (54.2%)	10 (41.7%)	10 (45.5%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.4 Full Analysis Set - Subgroups - Age groups
2.3.6.4.1 Medication - categorical

Lipid lowering medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.4 Full Analysis Set - Subgroups - Age groups
2.3.6.4.2 Start of treatment - continuous

Start - years before entry	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Statins			
n	8	12	10
Mean (SD)	5.4 (3.25)	5.8 (5.41)	7.8 (5.51)
Min-Max	3 - 11	0 - 15	1 - 19
Median	4.0	4.0	7.0
Q1-Q3	3.0 - 7.5	1.5 - 9.5	3.0 - 11.0
Fibrates			
n	0	0	1
Mean (SD)			3.0
Min-Max			3 - 3
Median			3.0
Q1-Q3			3.0 - 3.0
Ezetimibe			
n	2	0	4
Mean (SD)	2.0 (0.00)		7.3 (3.50)
Min-Max	2 - 2		3 - 11
Median	2.0		7.5
Q1-Q3	2.0 - 2.0		4.5 - 10.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.6.5.1 Medication - categorical

Lipid lowering medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Statins		
yes	12 (66.7%)	24 (46.2%)
no	6 (33.3%)	28 (53.8%)
Total	18 (100.0%)	52 (100.0%)
Fibrates		
yes	0 (0.0%)	1 (1.9%)
no	18 (100.0%)	51 (98.1%)
Total	18 (100.0%)	52 (100.0%)
Colestyramine		
no	18 (100.0%)	52 (100.0%)
Total	18 (100.0%)	52 (100.0%)
Ezetimibe		
yes	3 (16.7%)	4 (7.7%)
no	15 (83.3%)	47 (90.4%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
PCSK9 inhibitors		
no	18 (100.0%)	51 (98.1%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Omega-3 fatty acids		
no	18 (100.0%)	52 (100.0%)
Total	18 (100.0%)	52 (100.0%)
Any lipid lowering medication		
yes	12 (66.7%)	25 (48.1%)
no	6 (33.3%)	27 (51.9%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.6.5.1 Medication - categorical

Lipid lowering medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.6.5.2 Start of treatment - continuous

Start - years before entry	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Statins		
n	10	20
Mean (SD)	7.6 (6.31)	5.8 (4.10)
Min-Max	0 - 19	0 - 15
Median	6.5	4.0
Q1-Q3	3.0 - 11.0	3.0 - 9.0
Fibrates		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0
Ezetimibe		
n	3	3
Mean (SD)	7.3 (4.73)	3.7 (2.08)
Min-Max	2 - 11	2 - 6
Median	9.0	3.0
Q1-Q3	2.0 - 11.0	2.0 - 6.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.6 Full Analysis Set - Subgroups - Renal function
2.3.6.6.1 Medication - categorical

Lipid lowering medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Statins		
yes	11 (64.7%)	14 (35.9%)
no	6 (35.3%)	25 (64.1%)
Total	17 (100.0%)	39 (100.0%)
Fibrates		
yes	0 (0.0%)	1 (2.6%)
no	17 (100.0%)	38 (97.4%)
Total	17 (100.0%)	39 (100.0%)
Colestyramine		
no	17 (100.0%)	39 (100.0%)
Total	17 (100.0%)	39 (100.0%)
Ezetimibe		
yes	1 (5.9%)	3 (7.7%)
no	16 (94.1%)	36 (92.3%)
Total	17 (100.0%)	39 (100.0%)
PCSK9 inhibitors		
no	17 (100.0%)	39 (100.0%)
Total	17 (100.0%)	39 (100.0%)
Omega-3 fatty acids		
no	17 (100.0%)	39 (100.0%)
Total	17 (100.0%)	39 (100.0%)
Any lipid lowering medication		
yes	11 (64.7%)	15 (38.5%)
no	6 (35.3%)	24 (61.5%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.6 Full Analysis Set - Subgroups - Renal function
2.3.6.6.2 Start of treatment - continuous

Start - years before entry	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Statins		
n	10	10
Mean (SD)	8.8 (5.83)	4.5 (4.09)
Min-Max	1 - 19	0 - 15
Median	9.5	3.5
Q1-Q3	3.0 - 12.0	3.0 - 4.0
Fibrates		
n	0	1
Mean (SD)		3.0
Min-Max		3 - 3
Median		3.0
Q1-Q3		3.0 - 3.0
Ezetimibe		
n	1	2
Mean (SD)	9.0	2.5 (0.71)
Min-Max	9 - 9	2 - 3
Median	9.0	2.5
Q1-Q3	9.0 - 9.0	2.0 - 3.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.6.7.1 Medication - categorical

Lipid lowering medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Statins			
yes	2 (28.6%)	11 (52.4%)	21 (53.8%)
no	5 (71.4%)	10 (47.6%)	18 (46.2%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Fibrates			
yes	0 (0.0%)	0 (0.0%)	1 (2.6%)
no	7 (100.0%)	21 (100.0%)	38 (97.4%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Colestyramine			
no	7 (100.0%)	21 (100.0%)	39 (100.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Ezetimibe			
yes	0 (0.0%)	3 (14.3%)	4 (10.3%)
no	7 (100.0%)	17 (81.0%)	35 (89.7%)
unknown	0 (0.0%)	1 (4.8%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
PCSK9 inhibitors			
no	7 (100.0%)	20 (95.2%)	39 (100.0%)
unknown	0 (0.0%)	1 (4.8%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Omega-3 fatty acids			
no	7 (100.0%)	21 (100.0%)	39 (100.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Any lipid lowering medication			
yes	2 (28.6%)	11 (52.4%)	22 (56.4%)
no	5 (71.4%)	10 (47.6%)	17 (43.6%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.6.7.1 Medication - categorical

Lipid lowering medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.6.7.2 Start of treatment - continuous

Start - years before entry	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Statins			
n	2	10	17
Mean (SD)	3.5 (0.71)	7.6 (5.83)	5.9 (4.74)
Min-Max	3 - 4	3 - 19	0 - 15
Median	3.5	4.5	4.0
Q1-Q3	3.0 - 4.0	3.0 - 11.0	2.0 - 11.0
Fibrates			
n	0	0	1
Mean (SD)			3.0
Min-Max			3 - 3
Median			3.0
Q1-Q3			3.0 - 3.0
Ezetimibe			
n	0	3	3
Mean (SD)		4.3 (4.04)	6.7 (4.04)
Min-Max		2 - 9	3 - 11
Median		2.0	6.0
Q1-Q3		2.0 - 9.0	3.0 - 11.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.6.8.1 Medication - categorical

Lipid lowering medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Statins		
yes	19 (50.0%)	17 (53.1%)
no	19 (50.0%)	15 (46.9%)
Total	38 (100.0%)	32 (100.0%)
Fibrates		
yes	1 (2.6%)	0 (0.0%)
no	37 (97.4%)	32 (100.0%)
Total	38 (100.0%)	32 (100.0%)
Colestyramine		
no	38 (100.0%)	32 (100.0%)
Total	38 (100.0%)	32 (100.0%)
Ezetimibe		
yes	4 (10.5%)	3 (9.4%)
no	34 (89.5%)	28 (87.5%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
PCSK9 inhibitors		
no	38 (100.0%)	31 (96.9%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Omega-3 fatty acids		
no	38 (100.0%)	32 (100.0%)
Total	38 (100.0%)	32 (100.0%)
Any lipid lowering medication		
yes	20 (52.6%)	17 (53.1%)
no	18 (47.4%)	15 (46.9%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.6.8.1 Medication - categorical

Lipid lowering medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.6.8.2 Start of treatment - continuous

Start - years before entry	<8.5% (N = 38)	>=8.5% (N = 32)
Statins		
n	16	14
Mean (SD)	4.6 (3.96)	8.4 (5.27)
Min-Max	0 - 15	0 - 19
Median	3.0	9.0
Q1-Q3	2.5 - 6.5	4.0 - 11.0
Fibrates		
n	1	0
Mean (SD)	3.0	
Min-Max	3 - 3	
Median	3.0	
Q1-Q3	3.0 - 3.0	
Ezetimibe		
n	4	2
Mean (SD)	5.5 (4.04)	5.5 (4.95)
Min-Max	2 - 11	2 - 9
Median	4.5	5.5
Q1-Q3	2.5 - 8.5	2.0 - 9.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.6.9.1 Medication - categorical

Lipid lowering medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Statins				
yes	5 (45.5%)	10 (41.7%)	17 (58.6%)	4 (66.7%)
no	6 (54.5%)	14 (58.3%)	12 (41.4%)	2 (33.3%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Fibrates				
yes	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
no	10 (90.9%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Colestyramine				
no	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Ezetimibe				
yes	3 (27.3%)	2 (8.3%)	1 (3.4%)	1 (16.7%)
no	8 (72.7%)	21 (87.5%)	28 (96.6%)	5 (83.3%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
PCSK9 inhibitors				
no	11 (100.0%)	23 (95.8%)	29 (100.0%)	6 (100.0%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Omega-3 fatty acids				
no	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Any lipid lowering medication				
yes	6 (54.5%)	10 (41.7%)	17 (58.6%)	4 (66.7%)
no	5 (45.5%)	14 (58.3%)	12 (41.4%)	2 (33.3%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.6.9.1 Medication - categorical

Lipid lowering medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.6.9.2 Start of treatment - continuous

Start - years before entry	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Statins				
n	4	9	13	4
Mean (SD)	6.3 (3.95)	4.9 (3.69)	6.5 (5.22)	9.3 (7.41)
Min-Max	3 - 11	0 - 11	0 - 15	3 - 19
Median	5.5	4.0	4.0	7.5
Q1-Q3	3.0 - 9.5	3.0 - 6.0	3.0 - 11.0	3.5 - 15.0
Fibrates				
n	1	0	0	0
Mean (SD)	3.0			
Min-Max	3 - 3			
Median	3.0			
Q1-Q3	3.0 - 3.0			
Ezetimibe				
n	2	2	1	1
Mean (SD)	2.5 (0.71)	8.5 (3.54)	2.0	9.0
Min-Max	2 - 3	6 - 11	2 - 2	9 - 9
Median	2.5	8.5	2.0	9.0
Q1-Q3	2.0 - 3.0	6.0 - 11.0	2.0 - 2.0	9.0 - 9.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.6.10.1 Medication - categorical

Lipid lowering medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Statins			
yes	17 (60.7%)	4 (44.4%)	14 (43.8%)
no	11 (39.3%)	5 (55.6%)	18 (56.3%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Fibrates			
yes	1 (3.6%)	0 (0.0%)	0 (0.0%)
no	27 (96.4%)	9 (100.0%)	32 (100.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Colestyramine			
no	28 (100.0%)	9 (100.0%)	32 (100.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Ezetimibe			
yes	4 (14.3%)	0 (0.0%)	3 (9.4%)
no	24 (85.7%)	9 (100.0%)	28 (87.5%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
PCSK9 inhibitors			
no	28 (100.0%)	9 (100.0%)	31 (96.9%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Omega-3 fatty acids			
no	28 (100.0%)	9 (100.0%)	32 (100.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Any lipid lowering medication			
yes	18 (64.3%)	4 (44.4%)	14 (43.8%)
no	10 (35.7%)	5 (55.6%)	18 (56.3%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.6.10.1 Medication - categorical

Lipid lowering medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.6 Lipid lowering medication
2.3.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.6.10.2 Start of treatment - continuous

Start - years before entry	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Statins			
n	16	3	10
Mean (SD)	7.0 (5.34)	8.0 (6.08)	5.1 (4.25)
Min-Max	0 - 19	4 - 15	0 - 11
Median	6.5	5.0	3.5
Q1-Q3	3.0 - 10.5	4.0 - 15.0	3.0 - 11.0
Fibrates			
n	1	0	0
Mean (SD)	3.0		
Min-Max	3 - 3		
Median	3.0		
Q1-Q3	3.0 - 3.0		
Ezetimibe			
n	4	0	2
Mean (SD)	5.0 (3.16)		6.5 (6.36)
Min-Max	2 - 9		2 - 11
Median	4.5		6.5
Q1-Q3	2.5 - 7.5		2.0 - 11.0

No medication with Colestyramine, PCSK9 inhibitors and Omega-3 fatty acids documented
Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.1 Medication - categorical

Antihypertensive medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
ACE inhibitors			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	26 (37.1%)	1 (12.5%)	5 (50.0%)
no	44 (62.9%)	5 (62.5%)	5 (50.0%)
unknown	0 (0.0%)	1 (12.5%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
AT1R inhibitors			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	31 (44.3%)	3 (37.5%)	4 (40.0%)
no	39 (55.7%)	4 (50.0%)	6 (60.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Thiazides			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	15 (21.4%)	1 (12.5%)	1 (10.0%)
no	54 (77.1%)	6 (75.0%)	9 (90.0%)
unknown	1 (1.4%)	0 (0.0%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Beta blocking agents			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	35 (50.0%)	2 (25.0%)	6 (60.0%)
no	35 (50.0%)	5 (62.5%)	4 (40.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Calcium channel blockers			
Missing	0 (0.0%)	1 (12.5%)	0 (0.0%)
yes	17 (24.3%)	1 (12.5%)	5 (50.0%)
no	53 (75.7%)	6 (75.0%)	4 (40.0%)
unknown	0 (0.0%)	0 (0.0%)	1 (10.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)
Any antihypertensive			

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.1 Medication - categorical

Antihypertensive medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
medication			
yes	63 (90.0%)	5 (62.5%)	10 (100.0%)
no	7 (10.0%)	3 (37.5%)	0 (0.0%)
Total	70 (100.0%)	8 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.2 Start of treatment - continuous

Start - years before entry	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
ACE inhibitors			
n	19	1	3
Mean (SD)	8.3 (6.19)	11.0	6.3 (8.50)
Min-Max	0 - 21	11 - 11	0 - 16
Median	8.0	11.0	3.0
Q1-Q3	3.0 - 11.0	11.0 - 11.0	0.0 - 16.0
AT1R inhibitors			
n	24	3	2
Mean (SD)	5.9 (5.19)	4.7 (1.53)	14.0 (4.24)
Min-Max	0 - 19	3 - 6	11 - 17
Median	5.0	5.0	14.0
Q1-Q3	2.5 - 7.0	3.0 - 6.0	11.0 - 17.0
Thiazides			
n	12	1	1
Mean (SD)	6.3 (3.98)	3.0	17.0
Min-Max	1 - 15	3 - 3	17 - 17
Median	5.0	3.0	17.0
Q1-Q3	3.5 - 9.0	3.0 - 3.0	17.0 - 17.0
Beta blocking agents			
n	29	2	3
Mean (SD)	9.0 (6.11)	3.5 (2.12)	12.7 (11.37)
Min-Max	1 - 21	2 - 5	0 - 22
Median	10.0	3.5	16.0
Q1-Q3	3.0 - 12.0	2.0 - 5.0	0.0 - 22.0
Calcium channel blockers			
n	15	1	3
Mean (SD)	5.5 (5.32)	3.0	7.0 (5.29)
Min-Max	1 - 21	3 - 3	1 - 11
Median	4.0	3.0	9.0
Q1-Q3	2.0 - 6.0	3.0 - 3.0	1.0 - 11.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.3 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
ACE inhibitors*	N non-miss	70	7	
	% yes	37.14	14.29	0.044
	% no	62.86	71.43	
	% unknown	0.00	14.29	
Since years**	N non-miss	19	1	
	Mean	8.3	11.0	0.495
	SE	1.42	.	
AT1R inhibitors*	N non-miss	70	7	
	% yes	44.29	42.86	1.000
	% no	55.71	57.14	
Since years**	N non-miss	24	3	
	Mean	5.9	4.7	0.908
	SE	1.06	0.88	
Thiazides*	N non-miss	70	7	
	% yes	21.43	14.29	1.000
	% no	77.14	85.71	
	% unknown	1.43	0.00	
Since years**	N non-miss	12	1	
	Mean	6.3	3.0	0.363
	SE	1.15	.	
Beta blocking agents*	N non-miss	70	7	
	% yes	50.00	28.57	0.433
	% no	50.00	71.43	
Since years**	N non-miss	29	2	
	Mean	9.0	3.5	0.235
	SE	1.14	1.50	
Calcium channel blockers*	N non-miss	70	7	
	% yes	24.29	14.29	1.000
	% no	75.71	85.71	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.3 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Since years**	N non-miss	15	1	
	Mean	5.5	3.0	0.746
	SE	1.37	.	

* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.4 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
ACE inhibitors*	N non-miss	70	10	
	% yes	37.14	50.00	0.498
	% no	62.86	50.00	
Since years**	N non-miss	19	3	
	Mean	8.3	6.3	0.540
	SE	1.42	4.91	
AT1R inhibitors*	N non-miss	70	10	
	% yes	44.29	40.00	1.000
	% no	55.71	60.00	
Since years**	N non-miss	24	2	
	Mean	5.9	14.0	0.094
	SE	1.06	3.00	
Thiazides*	N non-miss	70	10	
	% yes	21.43	10.00	0.718
	% no	77.14	90.00	
	% unknown	1.43	0.00	
Since years**	N non-miss	12	1	
	Mean	6.3	17.0	0.165
	SE	1.15	.	
Beta blocking agents*	N non-miss	70	10	
	% yes	50.00	60.00	0.738
	% no	50.00	40.00	
Since years**	N non-miss	29	3	
	Mean	9.0	12.7	0.564
	SE	1.14	6.57	
Calcium channel blockers*	N non-miss	70	10	
	% yes	24.29	50.00	0.017
	% no	75.71	40.00	
	% unknown	0.00	10.00	

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.1 Full Analysis Set - Dropout - Off-Label
2.3.7.1.4 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Since years**	N non-miss	15	3	
	Mean	5.5	7.0	0.680
	SE	1.37	3.06	

* :p-values are based on the Fisher's exact test
** :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.7.2.1 Medication - categorical

Antihypertensive medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
ACE inhibitors		
yes	4 (20.0%)	22 (44.0%)
no	16 (80.0%)	28 (56.0%)
Total	20 (100.0%)	50 (100.0%)
AT1R inhibitors		
yes	12 (60.0%)	19 (38.0%)
no	8 (40.0%)	31 (62.0%)
Total	20 (100.0%)	50 (100.0%)
Thiazides		
yes	4 (20.0%)	11 (22.0%)
no	16 (80.0%)	38 (76.0%)
unknown	0 (0.0%)	1 (2.0%)
Total	20 (100.0%)	50 (100.0%)
Beta blocking agents		
yes	6 (30.0%)	29 (58.0%)
no	14 (70.0%)	21 (42.0%)
Total	20 (100.0%)	50 (100.0%)
Calcium channel blockers		
yes	6 (30.0%)	11 (22.0%)
no	14 (70.0%)	39 (78.0%)
Total	20 (100.0%)	50 (100.0%)
Any antihypertensive medication		
yes	18 (90.0%)	45 (90.0%)
no	2 (10.0%)	5 (10.0%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.3.7.2.2 Start of treatment - continuous

Start - years before entry	FGM (N = 20)	SMBG (N = 50)
ACE inhibitors		
n	1	18
Mean (SD)	3.0	8.6 (6.23)
Min-Max	3 - 3	0 - 21
Median	3.0	8.0
Q1-Q3	3.0 - 3.0	4.0 - 11.0
AT1R inhibitors		
n	8	16
Mean (SD)	4.6 (3.25)	6.5 (5.92)
Min-Max	0 - 11	0 - 19
Median	5.0	4.5
Q1-Q3	2.5 - 5.5	2.5 - 9.5
Thiazides		
n	2	10
Mean (SD)	4.0 (1.41)	6.8 (4.21)
Min-Max	3 - 5	1 - 15
Median	4.0	5.5
Q1-Q3	3.0 - 5.0	4.0 - 10.0
Beta blocking agents		
n	5	24
Mean (SD)	3.2 (2.77)	10.3 (5.94)
Min-Max	1 - 8	2 - 21
Median	2.0	10.5
Q1-Q3	2.0 - 3.0	4.5 - 14.5
Calcium channel blockers		
n	5	10
Mean (SD)	3.6 (1.34)	6.5 (6.33)
Min-Max	2 - 5	1 - 21
Median	3.0	5.0
Q1-Q3	3.0 - 5.0	1.0 - 11.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.3 Full Analysis Set - Subgroups - Gender
2.3.7.3.1 Medication - categorical

Antihypertensive medication	Female (N = 28) N (%)	Male (N = 42) N (%)
ACE inhibitors		
yes	12 (42.9%)	14 (33.3%)
no	16 (57.1%)	28 (66.7%)
Total	28 (100.0%)	42 (100.0%)
AT1R inhibitors		
yes	7 (25.0%)	24 (57.1%)
no	21 (75.0%)	18 (42.9%)
Total	28 (100.0%)	42 (100.0%)
Thiazides		
yes	4 (14.3%)	11 (26.2%)
no	24 (85.7%)	30 (71.4%)
unknown	0 (0.0%)	1 (2.4%)
Total	28 (100.0%)	42 (100.0%)
Beta blocking agents		
yes	17 (60.7%)	18 (42.9%)
no	11 (39.3%)	24 (57.1%)
Total	28 (100.0%)	42 (100.0%)
Calcium channel blockers		
yes	5 (17.9%)	12 (28.6%)
no	23 (82.1%)	30 (71.4%)
Total	28 (100.0%)	42 (100.0%)
Any antihypertensive medication		
yes	24 (85.7%)	39 (92.9%)
no	4 (14.3%)	3 (7.1%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.3 Full Analysis Set - Subgroups - Gender
2.3.7.3.2 Start of treatment - continuous

Start - years before entry	Female (N = 28)	Male (N = 42)
ACE inhibitors		
n	7	12
Mean (SD)	10.3 (3.68)	7.2 (7.17)
Min-Max	4 - 16	0 - 21
Median	11.0	6.0
Q1-Q3	8.0 - 12.0	1.5 - 9.0
AT1R inhibitors		
n	6	18
Mean (SD)	6.5 (5.61)	5.7 (5.19)
Min-Max	0 - 15	0 - 19
Median	5.5	4.5
Q1-Q3	2.0 - 11.0	3.0 - 6.0
Thiazides		
n	3	9
Mean (SD)	12.0 (2.65)	4.4 (2.01)
Min-Max	10 - 15	1 - 8
Median	11.0	5.0
Q1-Q3	10.0 - 15.0	3.0 - 5.0
Beta blocking agents		
n	13	16
Mean (SD)	9.5 (4.89)	8.7 (7.10)
Min-Max	1 - 18	2 - 21
Median	10.0	5.0
Q1-Q3	7.0 - 11.0	3.0 - 14.5
Calcium channel blockers		
n	4	11
Mean (SD)	7.8 (3.95)	4.7 (5.68)
Min-Max	3 - 11	1 - 21
Median	8.5	3.0
Q1-Q3	4.5 - 11.0	1.0 - 5.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.4 Full Analysis Set - Subgroups - Age groups
2.3.7.4.1 Medication - categorical

Antihypertensive medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
ACE inhibitors			
yes	6 (25.0%)	10 (41.7%)	10 (45.5%)
no	18 (75.0%)	14 (58.3%)	12 (54.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
AT1R inhibitors			
yes	11 (45.8%)	9 (37.5%)	11 (50.0%)
no	13 (54.2%)	15 (62.5%)	11 (50.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Thiazides			
yes	4 (16.7%)	7 (29.2%)	4 (18.2%)
no	20 (83.3%)	16 (66.7%)	18 (81.8%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Beta blocking agents			
yes	11 (45.8%)	11 (45.8%)	13 (59.1%)
no	13 (54.2%)	13 (54.2%)	9 (40.9%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Calcium channel blockers			
yes	4 (16.7%)	6 (25.0%)	7 (31.8%)
no	20 (83.3%)	18 (75.0%)	15 (68.2%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)
Any antihypertensive medication			
yes	21 (87.5%)	21 (87.5%)	21 (95.5%)
no	3 (12.5%)	3 (12.5%)	1 (4.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.4 Full Analysis Set - Subgroups - Age groups
2.3.7.4.2 Start of treatment - continuous

Start - years before entry	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
ACE inhibitors			
n	4	9	6
Mean (SD)	10.3 (7.93)	7.7 (3.91)	8.0 (8.49)
Min-Max	2 - 21	0 - 12	1 - 21
Median	9.0	8.0	4.5
Q1-Q3	5.0 - 15.5	6.0 - 11.0	1.0 - 16.0
AT1R inhibitors			
n	7	8	9
Mean (SD)	5.9 (5.40)	4.6 (4.37)	7.0 (5.98)
Min-Max	0 - 17	1 - 15	0 - 19
Median	5.0	3.5	5.0
Q1-Q3	2.0 - 6.0	2.5 - 4.5	3.0 - 11.0
Thiazides			
n	2	7	3
Mean (SD)	8.0 (4.24)	5.9 (4.91)	6.3 (1.53)
Min-Max	5 - 11	1 - 15	5 - 8
Median	8.0	4.0	6.0
Q1-Q3	5.0 - 11.0	3.0 - 10.0	5.0 - 8.0
Beta blocking agents			
n	10	10	9
Mean (SD)	8.1 (4.79)	7.4 (5.17)	11.9 (7.83)
Min-Max	2 - 17	1 - 15	2 - 21
Median	9.0	7.0	12.0
Q1-Q3	3.0 - 11.0	3.0 - 11.0	6.0 - 19.0
Calcium channel blockers			
n	3	6	6
Mean (SD)	4.0 (1.73)	5.2 (3.43)	6.7 (7.94)
Min-Max	2 - 5	1 - 11	1 - 21
Median	5.0	5.0	3.0
Q1-Q3	2.0 - 5.0	3.0 - 6.0	1.0 - 11.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.7.5.1 Medication - categorical

Antihypertensive medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
ACE inhibitors		
yes	5 (27.8%)	21 (40.4%)
no	13 (72.2%)	31 (59.6%)
Total	18 (100.0%)	52 (100.0%)
AT1R inhibitors		
yes	9 (50.0%)	22 (42.3%)
no	9 (50.0%)	30 (57.7%)
Total	18 (100.0%)	52 (100.0%)
Thiazides		
yes	4 (22.2%)	11 (21.2%)
no	14 (77.8%)	40 (76.9%)
unknown	0 (0.0%)	1 (1.9%)
Total	18 (100.0%)	52 (100.0%)
Beta blocking agents		
yes	9 (50.0%)	26 (50.0%)
no	9 (50.0%)	26 (50.0%)
Total	18 (100.0%)	52 (100.0%)
Calcium channel blockers		
yes	5 (27.8%)	12 (23.1%)
no	13 (72.2%)	40 (76.9%)
Total	18 (100.0%)	52 (100.0%)
Any antihypertensive medication		
yes	15 (83.3%)	48 (92.3%)
no	3 (16.7%)	4 (7.7%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.3.7.5.2 Start of treatment - continuous

Start - years before entry	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
ACE inhibitors		
n	3	16
Mean (SD)	16.7 (7.51)	6.8 (4.68)
Min-Max	8 - 21	0 - 16
Median	21.0	6.5
Q1-Q3	8.0 - 21.0	2.5 - 10.5
AT1R inhibitors		
n	8	16
Mean (SD)	7.9 (6.49)	4.9 (4.29)
Min-Max	0 - 19	0 - 17
Median	5.0	4.0
Q1-Q3	4.0 - 13.0	2.0 - 6.0
Thiazides		
n	4	8
Mean (SD)	6.0 (6.22)	6.5 (2.88)
Min-Max	1 - 15	3 - 11
Median	4.0	5.5
Q1-Q3	2.0 - 10.0	4.5 - 9.0
Beta blocking agents		
n	7	22
Mean (SD)	12.9 (8.17)	7.8 (4.93)
Min-Max	1 - 21	2 - 18
Median	15.0	7.5
Q1-Q3	3.0 - 20.0	3.0 - 11.0
Calcium channel blockers		
n	5	10
Mean (SD)	8.2 (8.07)	4.2 (3.01)
Min-Max	1 - 21	1 - 11
Median	5.0	3.5
Q1-Q3	3.0 - 11.0	2.0 - 6.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.6 Full Analysis Set - Subgroups - Renal function
2.3.7.6.1 Medication - categorical

Antihypertensive medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
ACE inhibitors		
yes	7 (41.2%)	10 (25.6%)
no	10 (58.8%)	29 (74.4%)
Total	17 (100.0%)	39 (100.0%)
AT1R inhibitors		
yes	8 (47.1%)	20 (51.3%)
no	9 (52.9%)	19 (48.7%)
Total	17 (100.0%)	39 (100.0%)
Thiazides		
yes	1 (5.9%)	11 (28.2%)
no	16 (94.1%)	28 (71.8%)
Total	17 (100.0%)	39 (100.0%)
Beta blocking agents		
yes	11 (64.7%)	17 (43.6%)
no	6 (35.3%)	22 (56.4%)
Total	17 (100.0%)	39 (100.0%)
Calcium channel blockers		
yes	4 (23.5%)	6 (15.4%)
no	13 (76.5%)	33 (84.6%)
Total	17 (100.0%)	39 (100.0%)
Any antihypertensive medication		
yes	16 (94.1%)	35 (89.7%)
no	1 (5.9%)	4 (10.3%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.6 Full Analysis Set - Subgroups - Renal function
2.3.7.6.2 Start of treatment - continuous

Start - years before entry	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
ACE inhibitors		
n	5	7
Mean (SD)	8.8 (6.14)	8.6 (6.70)
Min-Max	1 - 16	0 - 21
Median	11.0	8.0
Q1-Q3	4.0 - 12.0	3.0 - 11.0
AT1R inhibitors		
n	6	16
Mean (SD)	8.5 (6.63)	5.1 (4.76)
Min-Max	0 - 19	0 - 17
Median	8.0	4.0
Q1-Q3	5.0 - 11.0	2.0 - 6.0
Thiazides		
n	0	10
Mean (SD)		7.2 (3.77)
Min-Max		3 - 15
Median		5.5
Q1-Q3		5.0 - 10.0
Beta blocking agents		
n	8	15
Mean (SD)	12.3 (6.54)	7.9 (5.15)
Min-Max	1 - 20	2 - 17
Median	11.5	8.0
Q1-Q3	8.5 - 18.5	3.0 - 11.0
Calcium channel blockers		
n	4	6
Mean (SD)	6.3 (3.40)	4.5 (3.45)
Min-Max	3 - 11	1 - 11
Median	5.5	3.5
Q1-Q3	4.0 - 8.5	3.0 - 5.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.7.7.1 Medication - categorical

Antihypertensive medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
ACE inhibitors			
yes	3 (42.9%)	6 (28.6%)	17 (43.6%)
no	4 (57.1%)	15 (71.4%)	22 (56.4%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
AT1R inhibitors			
yes	1 (14.3%)	12 (57.1%)	16 (41.0%)
no	6 (85.7%)	9 (42.9%)	23 (59.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Thiazides			
yes	2 (28.6%)	4 (19.0%)	7 (17.9%)
no	5 (71.4%)	16 (76.2%)	32 (82.1%)
unknown	0 (0.0%)	1 (4.8%)	0 (0.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Beta blocking agents			
yes	4 (57.1%)	8 (38.1%)	21 (53.8%)
no	3 (42.9%)	13 (61.9%)	18 (46.2%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Calcium channel blockers			
yes	0 (0.0%)	6 (28.6%)	11 (28.2%)
no	7 (100.0%)	15 (71.4%)	28 (71.8%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)
Any antihypertensive medication			
yes	7 (100.0%)	18 (85.7%)	35 (89.7%)
no	0 (0.0%)	3 (14.3%)	4 (10.3%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.3.7.7.2 Start of treatment - continuous

Start - years before entry	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
ACE inhibitors			
n	2	4	13
Mean (SD)	7.0 (4.24)	6.5 (3.42)	9.1 (7.15)
Min-Max	4 - 10	2 - 10	0 - 21
Median	7.0	7.0	8.0
Q1-Q3	4.0 - 10.0	4.0 - 9.0	3.0 - 12.0
AT1R inhibitors			
n	1	10	12
Mean (SD)	2.0	8.7 (6.41)	4.0 (3.13)
Min-Max	2 - 2	0 - 19	0 - 11
Median	2.0	6.0	3.5
Q1-Q3	2.0 - 2.0	5.0 - 15.0	1.5 - 5.0
Thiazides			
n	1	4	6
Mean (SD)	10.0	8.5 (5.51)	4.5 (2.43)
Min-Max	10 - 10	3 - 15	1 - 8
Median	10.0	8.0	4.5
Q1-Q3	10.0 - 10.0	4.0 - 13.0	3.0 - 6.0
Beta blocking agents			
n	4	6	18
Mean (SD)	7.5 (3.51)	12.3 (6.12)	8.3 (6.59)
Min-Max	4 - 11	2 - 19	1 - 21
Median	7.5	13.0	6.5
Q1-Q3	4.5 - 10.5	10.0 - 17.0	3.0 - 12.0
Calcium channel blockers			
n	0	5	10
Mean (SD)		6.0 (3.00)	5.3 (6.31)
Min-Max		3 - 11	1 - 21
Median		5.0	3.0
Q1-Q3		5.0 - 6.0	1.0 - 6.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.7.8.1 Medication - categorical

Antihypertensive medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
ACE inhibitors		
yes	14 (36.8%)	12 (37.5%)
no	24 (63.2%)	20 (62.5%)
Total	38 (100.0%)	32 (100.0%)
AT1R inhibitors		
yes	17 (44.7%)	14 (43.8%)
no	21 (55.3%)	18 (56.3%)
Total	38 (100.0%)	32 (100.0%)
Thiazides		
yes	9 (23.7%)	6 (18.8%)
no	29 (76.3%)	25 (78.1%)
unknown	0 (0.0%)	1 (3.1%)
Total	38 (100.0%)	32 (100.0%)
Beta blocking agents		
yes	15 (39.5%)	20 (62.5%)
no	23 (60.5%)	12 (37.5%)
Total	38 (100.0%)	32 (100.0%)
Calcium channel blockers		
yes	9 (23.7%)	8 (25.0%)
no	29 (76.3%)	24 (75.0%)
Total	38 (100.0%)	32 (100.0%)
Any antihypertensive medication		
yes	34 (89.5%)	29 (90.6%)
no	4 (10.5%)	3 (9.4%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.3.7.8.2 Start of treatment - continuous

Start - years before entry	<8.5% (N = 38)	>=8.5% (N = 32)
ACE inhibitors		
n	10	9
Mean (SD)	7.5 (6.28)	9.2 (6.34)
Min-Max	0 - 21	1 - 21
Median	6.5	8.0
Q1-Q3	3.0 - 11.0	6.0 - 11.0
AT1R inhibitors		
n	13	11
Mean (SD)	5.5 (4.54)	6.4 (6.05)
Min-Max	0 - 17	0 - 19
Median	5.0	5.0
Q1-Q3	3.0 - 6.0	2.0 - 11.0
Thiazides		
n	7	5
Mean (SD)	6.9 (2.91)	5.6 (5.46)
Min-Max	3 - 11	1 - 15
Median	6.0	4.0
Q1-Q3	5.0 - 10.0	3.0 - 5.0
Beta blocking agents		
n	12	17
Mean (SD)	9.1 (6.14)	9.0 (6.28)
Min-Max	1 - 21	2 - 20
Median	9.0	10.0
Q1-Q3	4.0 - 12.5	3.0 - 12.0
Calcium channel blockers		
n	8	7
Mean (SD)	6.0 (6.85)	5.0 (3.27)
Min-Max	1 - 21	1 - 11
Median	3.0	5.0
Q1-Q3	2.0 - 8.0	2.0 - 6.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.7.9.1 Medication - categorical

Antihypertensive medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
ACE inhibitors				
yes	6 (54.5%)	9 (37.5%)	10 (34.5%)	1 (16.7%)
no	5 (45.5%)	15 (62.5%)	19 (65.5%)	5 (83.3%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
AT1R inhibitors				
yes	4 (36.4%)	10 (41.7%)	12 (41.4%)	5 (83.3%)
no	7 (63.6%)	14 (58.3%)	17 (58.6%)	1 (16.7%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Thiazides				
yes	4 (36.4%)	1 (4.2%)	8 (27.6%)	2 (33.3%)
no	7 (63.6%)	22 (91.7%)	21 (72.4%)	4 (66.7%)
unknown	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Beta blocking agents				
yes	6 (54.5%)	10 (41.7%)	15 (51.7%)	4 (66.7%)
no	5 (45.5%)	14 (58.3%)	14 (48.3%)	2 (33.3%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Calcium channel blockers				
yes	3 (27.3%)	6 (25.0%)	5 (17.2%)	3 (50.0%)
no	8 (72.7%)	18 (75.0%)	24 (82.8%)	3 (50.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Any antihypertensive medication				
yes	11 (100.0%)	21 (87.5%)	25 (86.2%)	6 (100.0%)
no	0 (0.0%)	3 (12.5%)	4 (13.8%)	0 (0.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.3.7.9.2 Start of treatment - continuous

Start - years before entry	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
ACE inhibitors				
n	5	6	7	1
Mean (SD)	8.0 (5.48)	8.5 (6.98)	9.1 (6.99)	3.0
Min-Max	2 - 16	0 - 21	1 - 21	3 - 3
Median	8.0	7.0	11.0	3.0
Q1-Q3	4.0 - 10.0	6.0 - 10.0	1.0 - 12.0	3.0 - 3.0
AT1R inhibitors				
n	4	5	10	5
Mean (SD)	4.0 (1.15)	3.8 (2.17)	6.4 (6.15)	8.4 (6.80)
Min-Max	3 - 5	1 - 6	0 - 17	2 - 19
Median	4.0	5.0	4.5	6.0
Q1-Q3	3.0 - 5.0	2.0 - 5.0	1.0 - 11.0	4.0 - 11.0
Thiazides				
n	4	1	5	2
Mean (SD)	5.0 (3.92)	5.0	7.2 (4.71)	7.5 (4.95)
Min-Max	1 - 10	5 - 5	3 - 15	4 - 11
Median	4.5	5.0	5.0	7.5
Q1-Q3	2.0 - 8.0	5.0 - 5.0	5.0 - 8.0	4.0 - 11.0
Beta blocking agents				
n	5	6	14	4
Mean (SD)	8.2 (6.42)	7.2 (7.52)	10.1 (5.40)	9.0 (7.70)
Min-Max	2 - 18	1 - 21	2 - 20	2 - 19
Median	8.0	4.5	11.0	7.5
Q1-Q3	3.0 - 10.0	2.0 - 10.0	5.0 - 14.0	3.0 - 15.0
Calcium channel blockers				
n	3	5	4	3
Mean (SD)	2.0 (1.00)	8.0 (7.35)	4.8 (4.79)	6.0 (4.36)
Min-Max	1 - 3	3 - 21	1 - 11	3 - 11
Median	2.0	5.0	3.5	4.0
Q1-Q3	1.0 - 3.0	5.0 - 6.0	1.0 - 8.5	3.0 - 11.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.7.10.1 Medication - categorical

Antihypertensive medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
ACE inhibitors			
yes	15 (53.6%)	2 (22.2%)	8 (25.0%)
no	13 (46.4%)	7 (77.8%)	24 (75.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
AT1R inhibitors			
yes	8 (28.6%)	6 (66.7%)	17 (53.1%)
no	20 (71.4%)	3 (33.3%)	15 (46.9%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Thiazides			
yes	5 (17.9%)	2 (22.2%)	8 (25.0%)
no	23 (82.1%)	7 (77.8%)	23 (71.9%)
unknown	0 (0.0%)	0 (0.0%)	1 (3.1%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Beta blocking agents			
yes	15 (53.6%)	3 (33.3%)	17 (53.1%)
no	13 (46.4%)	6 (66.7%)	15 (46.9%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Calcium channel blockers			
yes	6 (21.4%)	3 (33.3%)	8 (25.0%)
no	22 (78.6%)	6 (66.7%)	24 (75.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Any antihypertensive medication			
yes	24 (85.7%)	8 (88.9%)	30 (93.8%)
no	4 (14.3%)	1 (11.1%)	2 (6.3%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.3 Medical history
2.3.7 Antihypertensive medication
2.3.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.3.7.10.2 Start of treatment - continuous

Start - years before entry	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
ACE inhibitors			
n	13	1	5
Mean (SD)	8.2 (6.24)	3.0	9.8 (6.76)
Min-Max	0 - 21	3 - 3	4 - 21
Median	8.0	3.0	7.0
Q1-Q3	2.0 - 11.0	3.0 - 3.0	6.0 - 11.0
AT1R inhibitors			
n	8	4	12
Mean (SD)	6.3 (6.09)	8.8 (5.19)	4.7 (4.54)
Min-Max	0 - 19	4 - 15	0 - 17
Median	4.5	8.0	4.0
Q1-Q3	2.5 - 8.5	4.5 - 13.0	1.5 - 5.5
Thiazides			
n	5	2	5
Mean (SD)	6.6 (4.04)	9.5 (7.78)	4.8 (2.05)
Min-Max	1 - 11	4 - 15	3 - 8
Median	6.0	9.5	5.0
Q1-Q3	5.0 - 10.0	4.0 - 15.0	3.0 - 5.0
Beta blocking agents			
n	14	3	12
Mean (SD)	11.1 (5.30)	7.0 (7.00)	7.2 (6.55)
Min-Max	2 - 20	2 - 15	1 - 21
Median	10.5	4.0	3.5
Q1-Q3	7.0 - 14.0	2.0 - 15.0	2.5 - 11.0
Calcium channel blockers			
n	5	3	7
Mean (SD)	5.4 (5.18)	4.0 (1.00)	6.3 (6.78)
Min-Max	1 - 11	3 - 5	1 - 21
Median	3.0	4.0	5.0
Q1-Q3	1.0 - 11.0	3.0 - 5.0	2.0 - 6.0

Start calculated in years prior to the year of entry into the study

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.1 Full Analysis Set - Dropout - Off-Label

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Individual HbA1c target value in %			
n	70	8	10
Mean (SD)	6.9 (0.37)	7.5 (0.71)	7.3 (0.48)
Min-Max	6.5 - 8	7 - 9.1	6.5 - 8
Median	7.0	7.3	7.3
Q1-Q3	6.5 - 7.0	7.0 - 7.5	7.0 - 7.5

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.1 Full Analysis Set - Dropout - Off-Label
2.4.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Individual HbA1c target value in %*	N non-miss	70	8	
	Mean	6.9	7.5	0.012
	SE	0.04	0.25	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.1 Full Analysis Set - Dropout - Off-Label
2.4.1.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Individual HbA1c target value in %*	N non-miss	70	10	
	Mean	6.9	7.3	0.018
	SE	0.04	0.15	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.2 Full Analysis Set - Subgroups - FGM - SMBG

	FGM (N = 20)	SMBG (N = 50)
Individual HbA1c target value in %		
n	20	50
Mean (SD)	6.9 (0.45)	7.0 (0.33)
Min-Max	6.5 - 8	6.5 - 7.9
Median	6.7	7.0
Q1-Q3	6.5 - 7.0	6.8 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.3 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
Individual HbA1c target value in %		
n	28	42
Mean (SD)	6.9 (0.35)	7.0 (0.38)
Min-Max	6.5 - 7.5	6.5 - 8
Median	7.0	7.0
Q1-Q3	6.5 - 7.0	6.8 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.4 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Individual HbA1c target value in %			
n	24	24	22
Mean (SD)	6.8 (0.35)	6.9 (0.41)	7.1 (0.32)
Min-Max	6.5 - 7.6	6.5 - 7.9	6.5 - 8
Median	6.9	7.0	7.0
Q1-Q3	6.5 - 7.0	6.5 - 7.0	7.0 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.5 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Individual HbA1c target value in %		
n	18	52
Mean (SD)	6.9 (0.38)	6.9 (0.37)
Min-Max	6.5 - 7.5	6.5 - 8
Median	7.0	7.0
Q1-Q3	6.5 - 7.0	6.5 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.6 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Individual HbA1c target value in %		
n	17	39
Mean (SD)	7.0 (0.36)	6.9 (0.40)
Min-Max	6.5 - 8	6.5 - 7.9
Median	7.0	7.0
Q1-Q3	7.0 - 7.0	6.5 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.7 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Individual HbA1c target value in %			
n	7	21	39
Mean (SD)	7.0 (0.41)	6.9 (0.33)	6.9 (0.40)
Min-Max	6.5 - 7.5	6.5 - 7.6	6.5 - 8
Median	7.0	7.0	7.0
Q1-Q3	6.5 - 7.5	6.8 - 7.0	6.5 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.8 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
Individual HbA1c target value in %		
n	38	32
Mean (SD)	6.9 (0.37)	7.0 (0.35)
Min-Max	6.5 - 8	6.5 - 7.9
Median	6.9	7.0
Q1-Q3	6.5 - 7.0	7.0 - 7.0

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Individual HbA1c target value in %				
n	11	24	29	6
Mean (SD)	6.7 (0.26)	7.0 (0.25)	6.9 (0.43)	7.2 (0.52)
Min-Max	6.5 - 7	6.5 - 7.6	6.5 - 8	6.5 - 7.9
Median	6.5	7.0	7.0	7.0
Q1-Q3	6.5 - 7.0	6.8 - 7.0	6.5 - 7.0	7.0 - 7.7

2 Disposition and Baseline Characteristics
2.4 Individual HbA1c target value - continuous
2.4.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Individual HbA1c target value in %			
n	28	9	32
Mean (SD)	7.0 (0.30)	7.4 (0.44)	6.8 (0.31)
Min-Max	6.5 - 7.6	6.8 - 8	6.5 - 7.5
Median	7.0	7.5	6.8
Q1-Q3	6.8 - 7.0	7.0 - 7.7	6.5 - 7.0

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.1 Full Analysis Set - Dropout - Off-Label

Current self-measured FBG	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Self-measured FBG in mg/dL			
n	68	7	8
Mean (SD)	174.3 (44.59)	196.8 (46.26)	162.4 (25.85)
Min-Max	89 - 300	138.74 - 276	113 - 201
Median	162.5	193.0	164.0
Q1-Q3	146.5 - 192.5	149.0 - 225.0	152.0 - 176.6

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.1 Full Analysis Set - Dropout - Off-Label
2.5.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Self-measured FBG in mg/dL*	N non-miss	68	7	
	Mean	174.3	196.8	0.230
	SE	5.41	17.48	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.1 Full Analysis Set - Dropout - Off-Label
2.5.1.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Self-measured FBG in mg/dL*	N non-miss	68	8	
	Mean	174.3	162.4	0.899
	SE	5.41	9.14	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.2 Full Analysis Set - Subgroups - FGM - SMBG

Current self-measured FBG	FGM (N = 20)	SMBG (N = 50)
Self-measured FBG in mg/dL		
n	20	48
Mean (SD)	159.3 (27.28)	180.6 (48.96)
Min-Max	113 - 232.43	89 - 300
Median	159.0	167.0
Q1-Q3	144.5 - 174.3	147.0 - 214.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.3 Full Analysis Set - Subgroups - Gender

Current self-measured FBG	Female (N = 28)	Male (N = 42)
Self-measured FBG in mg/dL		
n	28	40
Mean (SD)	167.9 (43.34)	178.9 (45.44)
Min-Max	89 - 256	113 - 300
Median	158.6	168.5
Q1-Q3	139.5 - 187.0	149.0 - 198.5

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.4 Full Analysis Set - Subgroups - Age groups

Current self-measured FBG	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Self-measured FBG in mg/dL			
n	23	24	21
Mean (SD)	171.4 (37.40)	175.7 (41.22)	176.1 (56.15)
Min-Max	113 - 252.25	122 - 279	89 - 300
Median	160.0	164.5	162.0
Q1-Q3	142.0 - 187.0	147.5 - 200.0	145.9 - 214.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.5 Full Analysis Set - Subgroups - Body Mass Index

Current self-measured FBG	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Self-measured FBG in mg/dL		
n	17	51
Mean (SD)	172.2 (49.12)	175.1 (43.48)
Min-Max	98 - 277	89 - 300
Median	151.0	166.0
Q1-Q3	140.0 - 194.0	150.0 - 191.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.6 Full Analysis Set - Subgroups - Renal function

Current self-measured FBG	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Self-measured FBG in mg/dL		
n	16	38
Mean (SD)	166.3 (44.26)	174.1 (44.97)
Min-Max	89 - 256	98 - 300
Median	160.3	164.5
Q1-Q3	143.0 - 179.0	148.0 - 180.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.7 Full Analysis Set - Subgroups - Duration of diabetes

Current self-measured FBG	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Self-measured FBG in mg/dL			
n	7	20	38
Mean (SD)	184.5 (28.94)	177.0 (44.62)	169.5 (45.51)
Min-Max	157 - 236	98 - 256	89 - 300
Median	173.0	170.0	158.8
Q1-Q3	163.0 - 212.6	141.0 - 210.0	143.0 - 174.8

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.8 Full Analysis Set - Subgroups - Baseline HbA1c

Current self-measured FBG	<8.5% (N = 38)	>=8.5% (N = 32)
Self-measured FBG in mg/dL		
n	37	31
Mean (SD)	166.1 (42.49)	184.1 (45.74)
Min-Max	98 - 300	89 - 277
Median	157.0	171.0
Q1-Q3	142.0 - 174.8	156.0 - 232.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

Current self-measured FBG	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Self-measured FBG in mg/dL				
n	11	22	29	6
Mean (SD)	164.7 (32.14)	178.3 (45.12)	176.3 (50.47)	168.1 (37.68)
Min-Max	122 - 232	89 - 256	98 - 300	128 - 236
Median	157.0	165.5	168.0	167.0
Q1-Q3	143.0 - 176.6	147.0 - 214.0	148.0 - 191.0	138.7 - 172.0

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.5 Current self-measured FBG in mg/dL - continuous
2.5.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Current self-measured FBG	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Self-measured FBG in mg/dL			
n	27	9	31
Mean (SD)	182.1 (48.39)	167.1 (22.56)	170.2 (46.69)
Min-Max	98 - 279	116 - 194	89 - 300
Median	171.0	171.0	157.0
Q1-Q3	139.0 - 232.0	160.0 - 180.0	147.0 - 176.6

FBG = Fasting Blood Glucose

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.1 HbA1c (value within the last 3 months) - continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
HbA1c in %			
n	70	7	10
Mean (SD)	8.5 (0.82)	8.8 (0.73)	8.9 (0.90)
Min-Max	7.5 - 10.8	7.97 - 9.8	7.5 - 10.4
Median	8.3	8.8	9.0
Q1-Q3	7.8 - 9.2	8.0 - 9.5	8.1 - 9.4

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.1 HbA1c (value within the last 3 months) - continuous
2.6.1.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
HbA1c in %*	N non-miss	70	7	
	Mean	8.52	8.80	0.341
	SE	0.098	0.277	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.1 HbA1c (value within the last 3 months) - continuous
2.6.1.1.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
HbA1c in %*	N non-miss	70	10	
	Mean	8.52	8.85	0.284
	SE	0.098	0.285	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
eGFR in ml/min/1.73m²			
n	56	6	9
Mean (SD)	73.5 (21.22)	64.0 (15.21)	80.4 (24.20)
Min-Max	31.9 - 123	53.9 - 93.81	52 - 109
Median	76.5	58.5	68.0
Q1-Q3	59.2 - 90.0	55.0 - 64.0	61.0 - 103.0
Creatinine in mg/dL			
n	58	6	9
Mean (SD)	1.0 (0.30)	1.0 (0.20)	1.0 (0.22)
Min-Max	0.64 - 2	0.7 - 1.25	0.69 - 1.29
Median	1.0	1.0	1.0
Q1-Q3	0.8 - 1.1	0.9 - 1.2	0.8 - 1.1
AST in U/L			
n	38	6	4
Mean (SD)	25.8 (11.85)	30.1 (11.00)	50.3 (53.46)
Min-Max	12 - 70	21 - 48	18 - 130.2
Median	23.0	25.3	26.5
Q1-Q3	19.0 - 29.0	22.0 - 39.0	21.0 - 79.6
ALT in U/L			
n	42	5	5
Mean (SD)	33.5 (20.55)	39.2 (24.91)	35.8 (15.35)
Min-Max	10 - 113	24 - 83	20 - 57
Median	28.0	30.0	31.0
Q1-Q3	19.0 - 39.6	24.0 - 35.0	25.0 - 46.0
Fasting plasma glucose in mg/dL			
n	53	6	6
Mean (SD)	185.3 (63.68)	202.4 (44.58)	211.6 (42.17)
Min-Max	86 - 401.81	149 - 254	159 - 264
Median	170.0	199.0	213.5
Q1-Q3	145.0 - 218.0	160.4 - 253.0	178.4 - 241.0
Total cholesterol in mg/dL			
n	52	6	8
Mean (SD)	181.7 (41.74)	183.0 (38.77)	183.3 (37.13)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Min-Max	83 - 273	127 - 235.86	119 - 226.19
Median	181.0	185.5	186.0
Q1-Q3	157.0 - 212.5	158.0 - 206.0	158.5 - 216.0
LDL cholesterol in mg/dL			
n	55	6	9
Mean (SD)	107.6 (37.12)	110.1 (40.64)	109.9 (40.99)
Min-Max	27 - 185	62 - 162.39	50 - 162.39
Median	109.0	96.5	111.0
Q1-Q3	86.0 - 133.0	86.0 - 157.0	71.0 - 137.0
HDL cholesterol in mg/dL			
n	55	6	7
Mean (SD)	49.9 (23.46)	43.3 (4.86)	42.5 (11.34)
Min-Max	25 - 178	36 - 50.651	22 - 53
Median	47.0	42.5	46.8
Q1-Q3	38.0 - 53.0	42.0 - 46.0	33.0 - 52.6
Triglyceride in mg/dL			
n	52	4	6
Mean (SD)	188.9 (81.98)	218.8 (84.84)	223.6 (109.02)
Min-Max	71 - 420	99 - 286	114 - 400
Median	180.0	245.1	195.3
Q1-Q3	125.0 - 247.8	159.1 - 278.5	141.0 - 296.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous
2.6.1.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
eGFR in ml/min/1.73m²*	N non-miss	56	6	
	Mean	73.46	63.95	0.183
	SE	2.836	6.209	
Creatinine in mg/dL*	N non-miss	58	6	
	Mean	1.01	1.03	0.521
	SE	0.039	0.083	
AST in U/L*	N non-miss	38	6	
	Mean	25.81	30.10	0.265
	SE	1.922	4.490	
ALT in U/L*	N non-miss	42	5	
	Mean	33.53	39.20	0.572
	SE	3.170	11.142	
Fasting plasma glucose in mg/dL*	N non-miss	53	6	
	Mean	185.33	202.39	0.345
	SE	8.747	18.200	
Total cholesterol in mg/dL*	N non-miss	52	6	
	Mean	181.67	182.98	0.939
	SE	5.788	15.829	
LDL cholesterol in mg/dL*	N non-miss	55	6	
	Mean	107.61	110.07	0.933
	SE	5.006	16.592	
HDL cholesterol in mg/dL*	N non-miss	55	6	
	Mean	49.94	43.28	0.448
	SE	3.164	1.984	
Triglyceride in mg/dL*	N non-miss	52	4	

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous
2.6.1.2.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Triglyceride in mg/dL*	Mean	188.89	218.82	0.385
	SE	11.368	42.420	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous
2.6.1.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
eGFR in ml/min/1.73m²*	N non-miss	56	9	
	Mean	73.46	80.44	0.365
	SE	2.836	8.068	
Creatinine in mg/dL*	N non-miss	58	9	
	Mean	1.01	0.98	0.927
	SE	0.039	0.073	
AST in U/L*	N non-miss	38	4	
	Mean	25.81	50.30	0.396
	SE	1.922	26.728	
ALT in U/L*	N non-miss	42	5	
	Mean	33.53	35.80	0.619
	SE	3.170	6.866	
Fasting plasma glucose in mg/dL*	N non-miss	53	6	
	Mean	185.33	211.56	0.122
	SE	8.747	17.216	
Total cholesterol in mg/dL*	N non-miss	52	8	
	Mean	181.67	183.27	0.845
	SE	5.788	13.129	
LDL cholesterol in mg/dL*	N non-miss	55	9	
	Mean	107.61	109.95	0.817
	SE	5.006	13.664	
HDL cholesterol in mg/dL*	N non-miss	55	7	
	Mean	49.94	42.48	0.507
	SE	3.164	4.285	
Triglyceride in mg/dL*	N non-miss	52	6	

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.2 Last available laboratory values within the last 6 months - continuous
2.6.1.2.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Triglyceride in mg/dL*	Mean	188.89	223.60	0.447
	SE	11.368	44.509	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.3 Acquisition of the glycaemic variability from FGM

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Glucose median in mg/dL			
n	20	0	2
Mean (SD)	149.0 (23.81)		169.0 (5.66)
Min-Max	120 - 199		165 - 173
Median	148.4		169.0
Q1-Q3	126.1 - 162.0		165.0 - 173.0
Time in range in %			
n	20	0	2
Mean (SD)	56.5 (18.30)		37.5 (31.82)
Min-Max	20 - 87		15 - 60
Median	57.0		37.5
Q1-Q3	42.5 - 70.0		15.0 - 60.0
Time above range in %			
n	20	0	2
Mean (SD)	36.5 (16.47)		57.5 (24.75)
Min-Max	9 - 75		40 - 75
Median	34.0		57.5
Q1-Q3	26.0 - 45.0		40.0 - 75.0
Time below range in %			
n	20	0	2
Mean (SD)	6.9 (8.14)		5.0 (7.07)
Min-Max	0 - 25		0 - 10
Median	4.5		5.0
Q1-Q3	0.0 - 11.0		0.0 - 10.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.3 Acquisition of the glycaemic variability from FGM
2.6.1.3.1 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Glucose median in mg/dL*	N non-miss	20	2	
	Mean	148.95	169.00	0.203
	SE	5.324	4.000	
Time in range in %*	N non-miss	20	2	
	Mean	56.50	37.50	0.371
	SE	4.091	22.500	
Time above range in %*	N non-miss	20	2	
	Mean	36.50	57.50	0.168
	SE	3.683	17.500	
Time below range in %*	N non-miss	20	2	
	Mean	6.85	5.00	0.818
	SE	1.820	5.000	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
Median			
n	45	8	7
Mean (SD)	195.5 (42.89)	203.3 (46.63)	181.7 (25.96)
Min-Max	133.33 - 311	151 - 295	145 - 217
Median	189.2	196.9	175.0
Q1-Q3	167.0 - 220.0	169.0 - 224.5	164.0 - 214.0
Standard deviation			
n	45	8	7
Mean (SD)	39.6 (15.99)	50.8 (16.19)	43.2 (20.11)
Min-Max	1.0403 - 74.986	29.558 - 79.622	20.959 - 84.724
Median	38.0	50.6	42.2
Q1-Q3	27.7 - 50.2	39.6 - 58.5	32.8 - 44.6

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile
2.6.1.4.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Glucose median*	N non-miss	45	8	
	Mean	195.53	203.34	0.630
	SE	6.393	16.485	
Standard deviation*	N non-miss	45	8	
	Mean	39.63	50.80	0.127
	SE	2.384	5.725	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.1 Full Analysis Set - Dropout - Off-Label
2.6.1.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile
2.6.1.4.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Glucose median*	N non-miss	45	7	
	Mean	195.53	181.68	0.558
	SE	6.393	9.811	
Standard deviation*	N non-miss	45	7	
	Mean	39.63	43.19	0.957
	SE	2.384	7.601	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.6.2.1 HbA1c (value within the last 3 months) - continuous

	FGM (N = 20)	SMBG (N = 50)
HbA1c in %		
n	20	50
Mean (SD)	8.4 (0.76)	8.5 (0.85)
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.3	8.5
Q1-Q3	7.9 - 8.9	7.8 - 9.3

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.6.2.2 Last available laboratory values within the last 6 months - continuous

	FGM (N = 20)	SMBG (N = 50)
eGFR in ml/min/1.73m²		
n	18	38
Mean (SD)	81.2 (18.49)	69.8 (21.68)
Min-Max	36 - 102	31.9 - 123
Median	84.0	70.0
Q1-Q3	66.0 - 96.0	55.0 - 87.5
Creatinine in mg/dL		
n	19	39
Mean (SD)	0.9 (0.27)	1.1 (0.30)
Min-Max	0.64 - 1.84	0.68 - 2
Median	0.9	1.0
Q1-Q3	0.8 - 1.0	0.9 - 1.1
AST in U/L		
n	12	26
Mean (SD)	28.5 (11.36)	24.6 (12.08)
Min-Max	13 - 51.6	12 - 70
Median	25.0	21.0
Q1-Q3	21.0 - 36.0	17.3 - 27.0
ALT in U/L		
n	14	28
Mean (SD)	35.9 (15.39)	32.4 (22.86)
Min-Max	13 - 62	10 - 113
Median	32.5	26.0
Q1-Q3	24.0 - 49.8	16.5 - 35.0
Fasting plasma glucose in mg/dL		
n	17	36
Mean (SD)	177.2 (47.78)	189.2 (70.23)
Min-Max	116 - 297.3	86 - 401.81
Median	166.0	171.5
Q1-Q3	144.0 - 182.0	145.0 - 222.5
Total cholesterol in mg/dL		
n	17	35
Mean (SD)	178.6 (50.76)	183.1 (37.33)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.6.2.2 Last available laboratory values within the last 6 months - continuous

	FGM (N = 20)	SMBG (N = 50)
Min-Max	83 - 273	101 - 268
Median	172.0	186.0
Q1-Q3	155.0 - 215.0	161.0 - 210.0
LDL cholesterol in mg/dL		
n	19	36
Mean (SD)	113.7 (39.22)	104.4 (36.12)
Min-Max	29 - 174	27 - 185
Median	115.0	108.5
Q1-Q3	89.0 - 150.0	84.5 - 122.0
HDL cholesterol in mg/dL		
n	19	36
Mean (SD)	45.4 (10.88)	52.3 (27.77)
Min-Max	32 - 74.4	25 - 178
Median	45.0	48.2
Q1-Q3	36.0 - 49.5	40.0 - 55.6
Triglyceride in mg/dL		
n	18	34
Mean (SD)	179.0 (92.52)	194.1 (76.78)
Min-Max	80 - 420	71 - 414
Median	147.0	192.0
Q1-Q3	119.0 - 210.0	134.0 - 256.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.6.2.3 Acquisition of the glycaemic variability from FGM

	FGM (N = 20)	SMBG (N = 50)
Glucose median in mg/dL		
n	20	0
Mean (SD)	149.0 (23.81)	
Min-Max	120 - 199	
Median	148.4	
Q1-Q3	126.1 - 162.0	
Time in range in %		
n	20	0
Mean (SD)	56.5 (18.30)	
Min-Max	20 - 87	
Median	57.0	
Q1-Q3	42.5 - 70.0	
Time above range in %		
n	20	0
Mean (SD)	36.5 (16.47)	
Min-Max	9 - 75	
Median	34.0	
Q1-Q3	26.0 - 45.0	
Time below range in %		
n	20	0
Mean (SD)	6.9 (8.14)	
Min-Max	0 - 25	
Median	4.5	
Q1-Q3	0.0 - 11.0	

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.2 Full Analysis Set - Subgroups - FGM - SMBG
2.6.2.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	FGM (N = 20)	SMBG (N = 50)
Median		
n	9	36
Mean (SD)	180.6 (24.44)	199.3 (45.87)
Min-Max	136.94 - 220	133.33 - 311
Median	172.0	198.5
Q1-Q3	168.0 - 199.0	161.5 - 223.9
Standard deviation		
n	9	36
Mean (SD)	35.6 (14.01)	40.6 (16.47)
Min-Max	7.2394 - 51.761	1.0403 - 74.986
Median	36.8	39.7
Q1-Q3	26.9 - 45.7	28.5 - 52.3

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.3 Full Analysis Set - Subgroups - Gender
2.6.3.1 HbA1c (value within the last 3 months) - continuous

	Female (N = 28)	Male (N = 42)
HbA1c in %		
n	28	42
Mean (SD)	8.4 (0.82)	8.6 (0.83)
Min-Max	7.5 - 10	7.5 - 10.8
Median	8.3	8.4
Q1-Q3	7.7 - 9.0	8.0 - 9.2

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.3 Full Analysis Set - Subgroups - Gender
2.6.3.2 Last available laboratory values within the last 6 months - continuous

	Female (N = 28)	Male (N = 42)
eGFR in ml/min/1.73m²		
n	25	31
Mean (SD)	68.7 (18.70)	77.3 (22.63)
Min-Max	33 - 102	31.9 - 123
Median	65.0	80.0
Q1-Q3	55.6 - 83.0	64.0 - 94.0
Creatinine in mg/dL		
n	25	33
Mean (SD)	0.9 (0.23)	1.1 (0.33)
Min-Max	0.64 - 1.59	0.68 - 2
Median	0.9	1.0
Q1-Q3	0.8 - 1.0	0.9 - 1.2
AST in U/L		
n	13	25
Mean (SD)	26.3 (18.19)	25.6 (7.12)
Min-Max	12 - 70	17.3 - 46
Median	16.0	24.0
Q1-Q3	15.0 - 36.0	21.0 - 28.0
ALT in U/L		
n	16	26
Mean (SD)	34.0 (29.18)	33.3 (13.47)
Min-Max	10 - 113	15 - 69
Median	22.5	32.0
Q1-Q3	13.5 - 53.4	24.0 - 36.0
Fasting plasma glucose in mg/dL		
n	23	30
Mean (SD)	187.4 (72.35)	183.8 (57.39)
Min-Max	86 - 401.81	86.6 - 330
Median	173.0	165.0
Q1-Q3	149.0 - 218.0	144.0 - 222.0
Total cholesterol in mg/dL		
n	23	29
Mean (SD)	179.1 (49.27)	183.7 (35.44)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.3 Full Analysis Set - Subgroups - Gender
2.6.3.2 Last available laboratory values within the last 6 months - continuous

	Female (N = 28)	Male (N = 42)
Min-Max	83 - 268	130 - 273
Median	192.0	176.0
Q1-Q3	131.5 - 216.5	161.0 - 192.0
LDL cholesterol in mg/dL		
n	24	31
Mean (SD)	106.9 (41.80)	108.1 (33.77)
Min-Max	27 - 185	36 - 174
Median	115.0	106.0
Q1-Q3	85.5 - 133.7	86.0 - 133.0
HDL cholesterol in mg/dL		
n	24	31
Mean (SD)	45.2 (11.91)	53.6 (29.16)
Min-Max	25 - 70	28.9 - 178
Median	44.2	48.0
Q1-Q3	37.0 - 52.8	38.7 - 54.1
Triglyceride in mg/dL		
n	22	30
Mean (SD)	177.6 (71.37)	197.2 (89.23)
Min-Max	75 - 291	71 - 420
Median	178.5	180.0
Q1-Q3	119.0 - 236.8	134.0 - 256.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.3 Full Analysis Set - Subgroups - Gender
2.6.3.3 Acquisition of the glycaemic variability from FGM

	Female (N = 28)	Male (N = 42)
Glucose median in mg/dL		
n	8	12
Mean (SD)	143.4 (19.64)	152.7 (26.38)
Min-Max	120 - 178	124 - 199
Median	148.4	148.0
Q1-Q3	124.1 - 152.0	129.6 - 169.5
Time in range in %		
n	8	12
Mean (SD)	48.5 (18.33)	61.8 (16.94)
Min-Max	20 - 71	35 - 87
Median	48.5	63.0
Q1-Q3	35.0 - 65.0	48.5 - 74.5
Time above range in %		
n	8	12
Mean (SD)	40.0 (16.20)	34.2 (16.93)
Min-Max	25 - 75	9 - 60
Median	37.5	32.5
Q1-Q3	27.5 - 45.0	22.0 - 47.0
Time below range in %		
n	8	12
Mean (SD)	11.5 (8.83)	3.8 (6.21)
Min-Max	2 - 25	0 - 20
Median	7.5	1.0
Q1-Q3	5.0 - 20.0	0.0 - 4.5

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.3 Full Analysis Set - Subgroups - Gender
2.6.3.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	Female (N = 28)	Male (N = 42)
Median		
n	21	24
Mean (SD)	204.0 (44.79)	188.1 (40.63)
Min-Max	135 - 311	133.33 - 275
Median	198.0	186.0
Q1-Q3	172.0 - 226.1	153.0 - 211.5
Standard deviation		
n	21	24
Mean (SD)	43.7 (14.13)	36.1 (16.96)
Min-Max	18.951 - 74.986	1.0403 - 66.647
Median	43.5	36.3
Q1-Q3	35.0 - 51.9	23.8 - 48.7

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.4 Full Analysis Set - Subgroups - Age groups
2.6.4.1 HbA1c (value within the last 3 months) - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
HbA1c in %			
n	24	24	22
Mean (SD)	8.7 (1.00)	8.5 (0.72)	8.4 (0.71)
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 9.8
Median	8.6	8.4	8.2
Q1-Q3	7.8 - 9.6	7.9 - 8.8	7.7 - 8.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.4 Full Analysis Set - Subgroups - Age groups
2.6.4.2 Last available laboratory values within the last 6 months - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
eGFR in ml/min/1.73m²			
n	18	21	17
Mean (SD)	85.9 (13.98)	76.1 (14.93)	57.1 (24.37)
Min-Max	60 - 103	51.5 - 97	31.9 - 123
Median	90.0	77.0	55.0
Q1-Q3	80.0 - 96.0	61.9 - 87.5	36.0 - 64.0
Creatinine in mg/dL			
n	19	22	17
Mean (SD)	0.9 (0.16)	0.9 (0.13)	1.3 (0.39)
Min-Max	0.64 - 1.23	0.6447 - 1.15	0.68 - 2
Median	0.9	1.0	1.2
Q1-Q3	0.7 - 1.0	0.8 - 1.0	1.0 - 1.5
AST in U/L			
n	10	16	12
Mean (SD)	28.6 (12.34)	27.9 (13.99)	20.8 (6.31)
Min-Max	13 - 51.6	16 - 70	12 - 33
Median	25.0	23.0	20.5
Q1-Q3	23.0 - 34.0	19.0 - 32.0	16.2 - 23.5
ALT in U/L			
n	12	16	14
Mean (SD)	41.3 (19.33)	38.4 (24.64)	21.3 (8.24)
Min-Max	13 - 69	12 - 113	10 - 36
Median	39.5	32.5	20.5
Q1-Q3	25.0 - 59.5	24.5 - 43.8	15.0 - 27.0
Fasting plasma glucose in mg/dL			
n	17	18	18
Mean (SD)	192.2 (69.88)	176.7 (49.42)	187.4 (72.35)
Min-Max	121 - 401.81	101 - 297.3	86 - 337
Median	180.0	164.0	183.0
Q1-Q3	143.0 - 215.0	149.0 - 182.0	144.0 - 223.0
Total cholesterol in mg/dL			
n	17	18	17
Mean (SD)	185.6 (46.61)	175.6 (34.26)	184.1 (45.50)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.4 Full Analysis Set - Subgroups - Age groups
2.6.4.2 Last available laboratory values within the last 6 months - continuous

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Min-Max	83 - 264	101 - 234.7	116 - 273
Median	176.0	172.5	187.0
Q1-Q3	155.0 - 221.0	161.0 - 200.0	150.0 - 194.0
LDL cholesterol in mg/dL			
n	17	21	17
Mean (SD)	108.1 (44.47)	108.0 (33.14)	106.7 (36.06)
Min-Max	29 - 173	27 - 162.39	50 - 185
Median	96.0	115.0	109.0
Q1-Q3	85.1 - 150.0	92.0 - 124.0	86.0 - 120.0
HDL cholesterol in mg/dL			
n	17	21	17
Mean (SD)	48.8 (22.59)	46.2 (11.85)	55.7 (33.42)
Min-Max	27.452 - 128	28.9 - 74.4	25 - 178
Median	48.0	42.7	48.3
Q1-Q3	35.4 - 53.0	39.0 - 51.0	44.0 - 60.0
Triglyceride in mg/dL			
n	16	20	16
Mean (SD)	192.0 (96.78)	198.1 (80.44)	174.3 (70.24)
Min-Max	80 - 420	71 - 414	75 - 300
Median	178.0	192.0	144.7
Q1-Q3	114.5 - 260.3	134.0 - 243.4	124.0 - 235.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.4 Full Analysis Set - Subgroups - Age groups
2.6.4.3 Acquisition of the glycaemic variability from FGM

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Glucose median in mg/dL			
n	11	7	2
Mean (SD)	152.3 (26.35)	141.8 (19.74)	155.5 (30.41)
Min-Max	120 - 199	122 - 178	134 - 177
Median	152.0	141.0	155.5
Q1-Q3	126.1 - 162.0	126.0 - 152.0	134.0 - 177.0
Time in range in %			
n	11	7	2
Mean (SD)	52.6 (17.69)	58.3 (19.51)	71.5 (17.68)
Min-Max	20 - 71	30 - 87	59 - 84
Median	53.0	55.0	71.5
Q1-Q3	40.0 - 70.0	45.0 - 79.0	59.0 - 84.0
Time above range in %			
n	11	7	2
Mean (SD)	42.9 (16.68)	29.4 (13.31)	26.0 (16.97)
Min-Max	25 - 75	9 - 45	14 - 38
Median	35.0	28.0	26.0
Q1-Q3	30.0 - 59.0	19.0 - 45.0	14.0 - 38.0
Time below range in %			
n	11	7	2
Mean (SD)	4.5 (6.36)	12.3 (9.25)	1.0 (1.41)
Min-Max	0 - 20	2 - 25	0 - 2
Median	2.0	10.0	1.0
Q1-Q3	0.0 - 5.0	4.0 - 20.0	0.0 - 2.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.4 Full Analysis Set - Subgroups - Age groups
2.6.4.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Median			
n	14	17	14
Mean (SD)	188.8 (44.50)	191.8 (38.57)	206.8 (47.03)
Min-Max	135 - 275	133.33 - 260	143 - 311
Median	172.0	189.2	200.0
Q1-Q3	157.0 - 210.0	167.0 - 220.0	172.1 - 226.1
Standard deviation			
n	14	17	14
Mean (SD)	40.6 (12.61)	34.4 (19.97)	45.1 (12.09)
Min-Max	23.472 - 66.647	1.0403 - 74.986	22.297 - 64.974
Median	35.8	34.2	46.0
Q1-Q3	33.7 - 50.2	19.0 - 48.4	36.8 - 54.6

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.6.5.1 HbA1c (value within the last 3 months) - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
HbA1c in %		
n	18	52
Mean (SD)	8.8 (0.85)	8.4 (0.80)
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.9	8.3
Q1-Q3	8.1 - 9.4	7.8 - 8.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.6.5.2 Last available laboratory values within the last 6 months - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
eGFR in ml/min/1.73m²		
n	15	41
Mean (SD)	66.6 (23.20)	76.0 (20.18)
Min-Max	31.9 - 103	33 - 123
Median	64.0	80.7
Q1-Q3	45.0 - 83.0	61.9 - 90.0
Creatinine in mg/dL		
n	16	42
Mean (SD)	1.1 (0.36)	1.0 (0.27)
Min-Max	0.64 - 2	0.6447 - 1.9
Median	1.0	1.0
Q1-Q3	0.8 - 1.3	0.8 - 1.0
AST in U/L		
n	9	29
Mean (SD)	19.9 (4.65)	27.6 (12.83)
Min-Max	13 - 28	12 - 70
Median	19.0	24.0
Q1-Q3	17.3 - 23.0	20.0 - 33.0
ALT in U/L		
n	11	31
Mean (SD)	28.7 (16.09)	35.2 (21.89)
Min-Max	10 - 62	12 - 113
Median	24.0	29.0
Q1-Q3	15.0 - 36.0	22.0 - 45.0
Fasting plasma glucose in mg/dL		
n	14	39
Mean (SD)	203.0 (74.96)	179.0 (58.91)
Min-Max	86.6 - 337	86 - 401.81
Median	200.5	165.8
Q1-Q3	149.0 - 240.0	143.0 - 214.0
Total cholesterol in mg/dL		
n	14	38
Mean (SD)	184.3 (46.81)	180.7 (40.35)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.6.5.2 Last available laboratory values within the last 6 months - continuous

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Min-Max	116 - 268	83 - 273
Median	177.5	181.0
Q1-Q3	150.0 - 215.0	159.0 - 210.0
LDL cholesterol in mg/dL		
n	15	40
Mean (SD)	116.7 (35.69)	104.2 (37.52)
Min-Max	57.5 - 185	27 - 174
Median	118.0	107.0
Q1-Q3	86.0 - 150.0	84.5 - 129.0
HDL cholesterol in mg/dL		
n	15	40
Mean (SD)	46.2 (10.22)	51.3 (26.78)
Min-Max	25 - 64	27.452 - 178
Median	49.0	45.5
Q1-Q3	37.0 - 53.0	38.3 - 55.6
Triglyceride in mg/dL		
n	14	38
Mean (SD)	172.0 (90.04)	195.1 (79.16)
Min-Max	75 - 420	71 - 414
Median	146.0	184.0
Q1-Q3	113.0 - 210.0	134.0 - 256.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.6.5.3 Acquisition of the glycaemic variability from FGM

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Glucose median in mg/dL		
n	4	16
Mean (SD)	162.3 (34.10)	145.6 (20.65)
Min-Max	120 - 199	122 - 193
Median	165.0	144.4
Q1-Q3	136.0 - 188.5	126.1 - 158.5
Time in range in %		
n	4	16
Mean (SD)	40.3 (21.61)	60.6 (15.58)
Min-Max	20 - 70	35 - 87
Median	35.5	59.5
Q1-Q3	25.0 - 55.5	48.5 - 70.5
Time above range in %		
n	4	16
Mean (SD)	51.0 (21.23)	32.9 (13.54)
Min-Max	25 - 75	9 - 60
Median	52.0	32.5
Q1-Q3	35.0 - 67.0	26.0 - 39.0
Time below range in %		
n	4	16
Mean (SD)	8.8 (11.09)	6.4 (7.62)
Min-Max	0 - 25	0 - 20
Median	5.0	3.0
Q1-Q3	2.5 - 15.0	0.0 - 11.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.5 Full Analysis Set - Subgroups - Body Mass Index
2.6.5.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Median		
n	10	35
Mean (SD)	215.9 (57.72)	189.7 (36.63)
Min-Max	143 - 311	133.33 - 275
Median	220.5	189.0
Q1-Q3	157.0 - 260.0	167.0 - 212.6
Standard deviation		
n	10	35
Mean (SD)	43.9 (15.09)	38.4 (16.24)
Min-Max	17.814 - 64.974	1.0403 - 74.986
Median	39.4	38.0
Q1-Q3	35.4 - 55.3	26.9 - 50.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.6 Full Analysis Set - Subgroups - Renal function
2.6.6.1 HbA1c (value within the last 3 months) - continuous

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
HbA1c in %		
n	17	39
Mean (SD)	8.6 (0.70)	8.3 (0.70)
Min-Max	7.5 - 9.8	7.5 - 10
Median	8.7	8.2
Q1-Q3	8.1 - 9.2	7.7 - 8.7

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.6 Full Analysis Set - Subgroups - Renal function
2.6.6.2 Last available laboratory values within the last 6 months - continuous

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
eGFR in ml/min/1.73m²		
n	17	39
Mean (SD)	48.0 (10.69)	84.6 (13.68)
Min-Max	31.9 - 60	61.9 - 123
Median	51.5	83.0
Q1-Q3	36.0 - 56.0	76.0 - 95.0
Creatinine in mg/dL		
n	17	39
Mean (SD)	1.3 (0.34)	0.9 (0.16)
Min-Max	1 - 2	0.64 - 1.3
Median	1.2	0.9
Q1-Q3	1.0 - 1.5	0.8 - 1.0
AST in U/L		
n	13	24
Mean (SD)	20.1 (6.09)	29.2 (13.19)
Min-Max	12 - 36	13 - 70
Median	20.0	25.5
Q1-Q3	16.0 - 23.0	21.0 - 33.5
ALT in U/L		
n	15	26
Mean (SD)	24.8 (15.56)	38.5 (22.03)
Min-Max	10 - 73	13 - 113
Median	22.0	33.5
Q1-Q3	15.0 - 31.0	24.0 - 49.8
Fasting plasma glucose in mg/dL		
n	16	32
Mean (SD)	172.3 (62.83)	187.3 (65.22)
Min-Max	86 - 337	98 - 401.81
Median	172.0	165.0
Q1-Q3	130.5 - 205.0	144.5 - 220.0
Total cholesterol in mg/dL		
n	17	34

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.6 Full Analysis Set - Subgroups - Renal function
2.6.6.2 Last available laboratory values within the last 6 months - continuous

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Mean (SD)	173.7 (43.30)	186.4 (41.30)
Min-Max	101 - 264	83 - 273
Median	180.0	187.5
Q1-Q3	139.0 - 207.0	161.0 - 216.5
LDL cholesterol in mg/dL		
n	17	36
Mean (SD)	100.5 (31.23)	110.9 (39.80)
Min-Max	27 - 150	29 - 185
Median	105.0	110.0
Q1-Q3	86.0 - 120.0	88.0 - 143.5
HDL cholesterol in mg/dL		
n	17	36
Mean (SD)	45.3 (12.32)	52.4 (27.59)
Min-Max	25 - 70	27.452 - 178
Median	46.0	48.0
Q1-Q3	34.2 - 52.0	38.8 - 55.1
Triglyceride in mg/dL		
n	16	34
Mean (SD)	197.9 (86.46)	186.9 (82.77)
Min-Max	75 - 420	71 - 414
Median	184.5	184.0
Q1-Q3	138.0 - 245.5	116.0 - 250.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.6 Full Analysis Set - Subgroups - Renal function
2.6.6.3 Acquisition of the glycaemic variability from FGM

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Glucose median in mg/dL		
n	3	15
Mean (SD)	170.3 (33.17)	145.9 (21.38)
Min-Max	134 - 199	120 - 193
Median	178.0	147.7
Q1-Q3	134.0 - 199.0	126.1 - 162.0
Time in range in %		
n	3	15
Mean (SD)	51.7 (28.54)	56.9 (17.96)
Min-Max	30 - 84	20 - 87
Median	41.0	59.0
Q1-Q3	30.0 - 84.0	44.0 - 70.0
Time above range in %		
n	3	15
Mean (SD)	39.3 (23.03)	36.3 (17.00)
Min-Max	14 - 59	9 - 75
Median	45.0	33.0
Q1-Q3	14.0 - 59.0	25.0 - 45.0
Time below range in %		
n	3	15
Mean (SD)	9.0 (13.89)	6.5 (7.48)
Min-Max	0 - 25	0 - 20
Median	2.0	5.0
Q1-Q3	0.0 - 25.0	0.0 - 10.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.6 Full Analysis Set - Subgroups - Renal function
2.6.6.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Median		
n	10	23
Mean (SD)	211.9 (44.93)	187.2 (40.30)
Min-Max	168 - 311	133.33 - 260
Median	198.5	183.0
Q1-Q3	179.0 - 221.6	154.0 - 212.6
Standard deviation		
n	10	23
Mean (SD)	48.7 (12.84)	32.0 (15.80)
Min-Max	27.666 - 74.986	1.0403 - 64.974
Median	46.8	33.7
Q1-Q3	43.0 - 55.3	22.2 - 37.6

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.6.7.1 HbA1c (value within the last 3 months) - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
HbA1c in %			
n	7	21	39
Mean (SD)	8.4 (1.00)	8.7 (0.88)	8.5 (0.78)
Min-Max	7.5 - 10	7.6 - 9.9	7.5 - 10.8
Median	7.9	8.6	8.4
Q1-Q3	7.5 - 9.3	8.0 - 9.5	7.8 - 8.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.6.7.2 Last available laboratory values within the last 6 months - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
eGFR in ml/min/1.73m²			
n	7	16	30
Mean (SD)	76.5 (13.96)	75.7 (22.92)	72.0 (21.59)
Min-Max	51.5 - 90	36 - 102	31.9 - 123
Median	80.7	79.5	73.0
Q1-Q3	65.0 - 90.0	59.9 - 96.0	56.0 - 87.5
Creatinine in mg/dL			
n	7	16	32
Mean (SD)	0.9 (0.16)	1.0 (0.26)	1.0 (0.30)
Min-Max	0.7 - 1.15	0.64 - 1.5	0.6447 - 2
Median	0.8	0.9	1.0
Q1-Q3	0.8 - 1.0	0.7 - 1.2	0.9 - 1.1
AST in U/L			
n	5	9	22
Mean (SD)	31.8 (23.23)	24.4 (9.25)	24.0 (8.18)
Min-Max	13 - 70	13 - 42	12 - 46
Median	25.0	23.0	21.5
Q1-Q3	15.0 - 36.0	19.0 - 29.0	19.0 - 27.0
ALT in U/L			
n	5	12	23
Mean (SD)	50.0 (42.46)	34.6 (19.46)	29.2 (12.11)
Min-Max	13 - 113	10 - 69	12 - 63
Median	34.0	31.0	27.0
Q1-Q3	17.0 - 73.0	18.5 - 49.0	22.0 - 34.0
Fasting plasma glucose in mg/dL			
n	7	17	26
Mean (SD)	156.0 (39.60)	213.6 (82.90)	175.3 (49.24)
Min-Max	101 - 218	86.6 - 401.81	86 - 330
Median	163.0	214.0	165.4
Q1-Q3	121.0 - 180.0	160.0 - 263.0	145.0 - 196.0
Total cholesterol in mg/dL			
n	6	15	28
Mean (SD)	192.2 (36.98)	193.6 (44.67)	178.8 (38.03)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.6.7.2 Last available laboratory values within the last 6 months - continuous

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Min-Max	147 - 240	116 - 268	101 - 273
Median	193.0	189.0	181.0
Q1-Q3	159.0 - 221.0	162.0 - 231.0	155.0 - 197.0
LDL cholesterol in mg/dL			
n	6	16	30
Mean (SD)	106.5 (47.63)	118.4 (37.08)	106.3 (33.84)
Min-Max	36 - 173	57.5 - 185	27 - 174
Median	98.6	104.5	114.5
Q1-Q3	89.0 - 144.0	89.9 - 154.0	86.0 - 126.0
HDL cholesterol in mg/dL			
n	6	16	30
Mean (SD)	52.8 (37.76)	45.5 (11.56)	52.7 (25.98)
Min-Max	28 - 128	25 - 64	32 - 178
Median	41.1	48.0	46.7
Q1-Q3	28.9 - 49.5	34.9 - 54.5	42.0 - 54.1
Triglyceride in mg/dL			
n	6	13	30
Mean (SD)	240.3 (123.44)	184.3 (100.95)	188.2 (61.34)
Min-Max	85 - 414	75 - 420	71 - 300
Median	275.5	173.0	184.0
Q1-Q3	108.0 - 284.0	114.0 - 213.0	139.0 - 236.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.6.7.3 Acquisition of the glycaemic variability from FGM

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Glucose median in mg/dL			
n	1	7	11
Mean (SD)	149.0	155.0 (31.57)	147.2 (19.94)
Min-Max	149 - 149	120 - 199	122 - 178
Median	149.0	152.0	147.7
Q1-Q3	149.0 - 149.0	126.1 - 193.0	126.0 - 162.0
Time in range in %			
n	1	7	11
Mean (SD)	71.0	47.9 (18.42)	62.2 (17.22)
Min-Max	71 - 71	20 - 70	30 - 87
Median	71.0	44.0	60.0
Q1-Q3	71.0 - 71.0	35.0 - 70.0	52.0 - 79.0
Time above range in %			
n	1	7	11
Mean (SD)	27.0	47.1 (20.14)	30.3 (11.82)
Min-Max	27 - 27	25 - 75	9 - 45
Median	27.0	56.0	33.0
Q1-Q3	27.0 - 27.0	25.0 - 60.0	19.0 - 38.0
Time below range in %			
n	1	7	11
Mean (SD)	2.0	5.0 (7.07)	7.3 (8.58)
Min-Max	2 - 2	0 - 20	0 - 25
Median	2.0	5.0	4.0
Q1-Q3	2.0 - 2.0	0.0 - 5.0	0.0 - 12.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.7 Full Analysis Set - Subgroups - Duration of diabetes
2.6.7.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Median			
n	5	12	27
Mean (SD)	200.9 (34.05)	213.2 (63.27)	186.6 (31.74)
Min-Max	166 - 254	135 - 311	133.33 - 263
Median	189.0	230.2	187.0
Q1-Q3	183.0 - 212.6	145.5 - 260.0	167.0 - 213.0
Standard deviation			
n	5	12	27
Mean (SD)	28.7 (14.63)	43.5 (17.16)	39.2 (15.23)
Min-Max	15.617 - 51.874	7.2394 - 66.647	1.0403 - 74.986
Median	23.5	42.4	41.4
Q1-Q3	19.0 - 33.7	34.6 - 57.2	27.4 - 48.5

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.6.8.1 HbA1c (value within the last 3 months) - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
HbA1c in %		
n	38	32
Mean (SD)	7.9 (0.30)	9.3 (0.58)
Min-Max	7.5 - 8.4	8.5 - 10.8
Median	7.9	9.3
Q1-Q3	7.6 - 8.2	8.8 - 9.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.6.8.2 Last available laboratory values within the last 6 months - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
eGFR in ml/min/1.73m²		
n	32	24
Mean (SD)	76.8 (19.60)	69.0 (22.88)
Min-Max	33 - 123	31.9 - 103
Median	80.5	65.5
Q1-Q3	63.0 - 90.0	52.3 - 88.8
Creatinine in mg/dL		
n	32	26
Mean (SD)	1.0 (0.28)	1.1 (0.32)
Min-Max	0.68 - 1.9	0.64 - 2
Median	1.0	1.0
Q1-Q3	0.8 - 1.1	0.9 - 1.2
AST in U/L		
n	21	17
Mean (SD)	28.1 (13.46)	23.0 (9.07)
Min-Max	13 - 70	12 - 46
Median	24.0	21.0
Q1-Q3	19.0 - 33.0	17.3 - 25.0
ALT in U/L		
n	22	20
Mean (SD)	35.3 (24.50)	31.6 (15.49)
Min-Max	12 - 113	10 - 63
Median	26.5	32.0
Q1-Q3	19.0 - 45.0	19.5 - 36.0
Fasting plasma glucose in mg/dL		
n	29	24
Mean (SD)	166.6 (50.77)	207.9 (71.12)
Min-Max	86.6 - 297.3	86 - 401.81
Median	158.0	191.5
Q1-Q3	136.0 - 182.0	163.5 - 229.5
Total cholesterol in mg/dL		
n	29	23
Mean (SD)	184.9 (42.13)	177.5 (41.80)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.6.8.2 Last available laboratory values within the last 6 months - continuous

	<8.5% (N = 38)	>=8.5% (N = 32)
Min-Max	83 - 273	101 - 264
Median	176.0	182.0
Q1-Q3	161.0 - 210.0	150.0 - 215.0
LDL cholesterol in mg/dL		
n	30	25
Mean (SD)	109.9 (38.71)	104.8 (35.71)
Min-Max	29 - 185	27 - 173
Median	108.5	111.0
Q1-Q3	87.0 - 133.0	86.0 - 126.0
HDL cholesterol in mg/dL		
n	30	25
Mean (SD)	55.3 (29.46)	43.5 (10.55)
Min-Max	32 - 178	25 - 65
Median	48.7	45.0
Q1-Q3	39.0 - 57.2	36.0 - 49.0
Triglyceride in mg/dL		
n	29	23
Mean (SD)	173.2 (73.71)	208.7 (89.02)
Min-Max	71 - 335	75 - 420
Median	149.0	198.0
Q1-Q3	116.0 - 232.5	139.0 - 275.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.6.8.3 Acquisition of the glycaemic variability from FGM

	<8.5% (N = 38)	>=8.5% (N = 32)
Glucose median in mg/dL		
n	13	7
Mean (SD)	142.8 (20.72)	160.4 (26.48)
Min-Max	120 - 178	124 - 199
Median	134.0	152.0
Q1-Q3	126.1 - 162.0	147.7 - 193.0
Time in range in %		
n	13	7
Mean (SD)	62.1 (18.10)	46.1 (14.58)
Min-Max	30 - 87	20 - 68
Median	67.0	45.0
Q1-Q3	55.0 - 71.0	41.0 - 53.0
Time above range in %		
n	13	7
Mean (SD)	30.8 (13.52)	47.1 (17.04)
Min-Max	9 - 60	28 - 75
Median	30.0	45.0
Q1-Q3	25.0 - 38.0	32.0 - 59.0
Time below range in %		
n	13	7
Mean (SD)	6.9 (8.68)	6.7 (7.67)
Min-Max	0 - 25	0 - 20
Median	4.0	5.0
Q1-Q3	2.0 - 5.0	0.0 - 12.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.6.8.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	<8.5% (N = 38)	>=8.5% (N = 32)
Median		
n	23	22
Mean (SD)	178.9 (36.06)	213.0 (43.23)
Min-Max	133.33 - 260	157 - 311
Median	183.0	204.5
Q1-Q3	143.0 - 212.6	172.0 - 254.0
Standard deviation		
n	23	22
Mean (SD)	35.5 (15.95)	43.9 (15.20)
Min-Max	1.0403 - 64.974	15.617 - 74.986
Median	35.8	44.6
Q1-Q3	22.3 - 48.5	34.2 - 52.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.6.9.1 HbA1c (value within the last 3 months) - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
HbA1c in %				
n	11	24	29	6
Mean (SD)	8.7 (0.87)	8.6 (0.77)	8.5 (0.88)	8.3 (0.74)
Min-Max	7.6 - 9.9	7.5 - 9.9	7.5 - 10.8	7.5 - 9.4
Median	8.4	8.4	8.2	8.3
Q1-Q3	7.9 - 9.7	8.1 - 9.1	7.7 - 8.8	7.6 - 8.9

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.6.9.2 Last available laboratory values within the last 6 months - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
eGFR in ml/min/1.73m²				
n	8	17	25	6
Mean (SD)	72.2 (21.11)	78.6 (20.09)	70.5 (21.99)	72.9 (24.13)
Min-Max	33 - 97	36 - 102	31.9 - 123	40.6 - 95
Median	82.0	81.0	66.0	83.5
Q1-Q3	57.8 - 84.0	60.0 - 96.0	59.0 - 83.0	45.0 - 90.0
Creatinine in mg/dL				
n	8	17	27	6
Mean (SD)	1.0 (0.29)	1.0 (0.20)	1.1 (0.35)	1.0 (0.28)
Min-Max	0.75 - 1.59	0.64 - 1.42	0.68 - 2	0.7238 - 1.5
Median	0.9	1.0	1.0	1.0
Q1-Q3	0.8 - 1.1	0.9 - 1.0	0.8 - 1.1	0.8 - 1.1
AST in U/L				
n	5	10	19	4
Mean (SD)	46.5 (14.92)	25.9 (10.73)	21.1 (5.20)	22.3 (7.18)
Min-Max	33 - 70	12 - 46	13 - 34	13 - 30
Median	42.0	23.5	21.0	23.0
Q1-Q3	36.0 - 51.6	19.0 - 29.0	16.0 - 24.0	17.0 - 27.5
ALT in U/L				
n	6	13	19	4
Mean (SD)	55.1 (34.23)	34.0 (18.51)	27.7 (13.96)	27.3 (8.96)
Min-Max	22 - 113	10 - 63	12 - 69	15 - 36
Median	48.3	26.0	26.0	29.0
Q1-Q3	26.0 - 73.0	22.0 - 49.8	16.0 - 34.0	21.0 - 33.5
Fasting plasma glucose in mg/dL				
n	9	14	24	6
Mean (SD)	178.9 (58.19)	200.6 (88.98)	181.0 (54.24)	176.6 (41.58)
Min-Max	101 - 297.3	86 - 401.81	98 - 330	121 - 223
Median	166.0	181.5	165.4	174.4
Q1-Q3	140.5 - 215.0	158.0 - 236.0	145.0 - 216.0	144.0 - 223.0
Total cholesterol in mg/dL				
n	6	14	26	6
Mean (SD)	164.2 (57.12)	185.9 (37.69)	182.2 (40.14)	186.8 (48.02)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.6.9.2 Last available laboratory values within the last 6 months - continuous

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Min-Max	83 - 229	116 - 264	101 - 268	125 - 273
Median	177.0	181.0	185.5	181.0
Q1-Q3	109.0 - 210.0	162.0 - 215.0	150.0 - 217.0	174.0 - 187.0
LDL cholesterol in mg/dL				
n	7	15	27	6
Mean (SD)	87.9 (48.00)	110.2 (27.69)	114.3 (35.68)	93.9 (48.21)
Min-Max	29 - 162.39	62 - 157.37	27 - 185	36 - 174
Median	91.1	104.0	115.0	90.5
Q1-Q3	48.0 - 120.0	92.0 - 135.3	86.0 - 140.0	57.5 - 115.0
HDL cholesterol in mg/dL				
n	7	15	27	6
Mean (SD)	62.0 (51.93)	45.1 (14.01)	46.8 (10.58)	62.1 (32.78)
Min-Max	36 - 178	25 - 74.4	28 - 70	40 - 128
Median	39.0	46.4	48.0	50.3
Q1-Q3	38.0 - 62.0	34.2 - 54.1	40.0 - 53.0	47.0 - 57.2
Triglyceride in mg/dL				
n	6	13	27	6
Mean (SD)	182.0 (81.19)	197.4 (93.90)	184.2 (79.11)	198.6 (88.12)
Min-Max	80 - 284	88 - 420	71 - 414	75 - 300
Median	173.5	177.0	171.0	229.3
Q1-Q3	125.0 - 256.0	135.0 - 232.5	125.0 - 257.0	108.0 - 250.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.6.9.3 Acquisition of the glycaemic variability from FGM

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Glucose median in mg/dL				
n	5	9	5	1
Mean (SD)	136.3 (15.87)	159.1 (25.96)	137.8 (17.56)	177.0
Min-Max	122 - 155	126 - 199	120 - 162	177 - 177
Median	126.1	152.0	134.0	177.0
Q1-Q3	126.1 - 152.0	141.0 - 178.0	124.0 - 149.0	177.0 - 177.0
Time in range in %				
n	5	9	5	1
Mean (SD)	52.0 (7.38)	50.1 (23.12)	72.0 (6.89)	59.0
Min-Max	40 - 60	20 - 87	67 - 84	59 - 59
Median	53.0	44.0	70.0	59.0
Q1-Q3	52.0 - 55.0	35.0 - 70.0	68.0 - 71.0	59.0 - 59.0
Time above range in %				
n	5	9	5	1
Mean (SD)	32.6 (6.02)	44.2 (21.31)	26.2 (7.60)	38.0
Min-Max	25 - 40	9 - 75	14 - 33	38 - 38
Median	35.0	45.0	27.0	38.0
Q1-Q3	28.0 - 35.0	30.0 - 59.0	25.0 - 32.0	38.0 - 38.0
Time below range in %				
n	5	9	5	1
Mean (SD)	15.4 (6.77)	5.7 (7.95)	1.8 (2.05)	0.0
Min-Max	5 - 20	0 - 25	0 - 5	0 - 0
Median	20.0	4.0	2.0	0.0
Q1-Q3	12.0 - 20.0	0.0 - 5.0	0.0 - 2.0	0.0 - 0.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.6.9.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Median				
n	8	12	21	4
Mean (SD)	188.6 (27.42)	210.1 (57.86)	192.8 (40.08)	180.0 (29.81)
Min-Max	136.94 - 213.5	133.33 - 311	137 - 263	136.94 - 201
Median	198.5	216.5	183.0	191.0
Q1-Q3	169.5 - 211.3	155.5 - 253.7	166.0 - 221.0	160.0 - 200.0
Standard deviation				
n	8	12	21	4
Mean (SD)	35.4 (19.46)	41.4 (15.72)	40.9 (16.73)	35.8 (1.72)
Min-Max	7.2394 - 66.647	1.0403 - 58.976	15.617 - 74.986	33.748 - 37.594
Median	32.7	43.2	41.4	35.9
Q1-Q3	22.1 - 50.1	35.9 - 52.4	27.7 - 51.9	34.4 - 37.2

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.6.10.1 HbA1c (value within the last 3 months) - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
HbA1c in %			
n	28	9	32
Mean (SD)	8.5 (0.89)	8.3 (0.59)	8.6 (0.84)
Min-Max	7.5 - 10.8	7.6 - 9.3	7.5 - 10
Median	8.4	8.3	8.4
Q1-Q3	7.8 - 9.3	7.9 - 8.5	7.9 - 9.3

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.6.10.2 Last available laboratory values within the last 6 months - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
eGFR in ml/min/1.73m²			
n	20	9	27
Mean (SD)	65.9 (20.69)	72.2 (18.31)	79.5 (21.32)
Min-Max	31.9 - 103	36 - 94	33 - 123
Median	63.0	72.0	83.0
Q1-Q3	52.0 - 81.5	65.0 - 90.0	64.0 - 96.0
Creatinine in mg/dL			
n	20	9	29
Mean (SD)	1.1 (0.33)	1.1 (0.31)	1.0 (0.26)
Min-Max	0.69 - 2	0.82 - 1.84	0.64 - 1.9
Median	1.0	1.0	0.9
Q1-Q3	0.8 - 1.2	0.9 - 1.2	0.8 - 1.0
AST in U/L			
n	13	8	17
Mean (SD)	23.5 (14.87)	24.3 (4.27)	28.3 (11.76)
Min-Max	13 - 70	18 - 30	12 - 51.6
Median	20.0	24.5	25.0
Q1-Q3	16.0 - 21.0	21.0 - 27.5	21.0 - 36.0
ALT in U/L			
n	14	8	20
Mean (SD)	29.1 (25.30)	29.1 (8.34)	38.4 (19.99)
Min-Max	12 - 113	17 - 45	10 - 73
Median	22.5	29.0	35.0
Q1-Q3	16.0 - 33.0	24.0 - 32.5	22.5 - 55.0
Fasting plasma glucose in mg/dL			
n	22	9	22
Mean (SD)	190.7 (67.71)	157.1 (21.93)	191.5 (69.72)
Min-Max	86.6 - 401.81	116 - 187	86 - 337
Median	178.9	158.0	165.5
Q1-Q3	150.0 - 222.0	144.0 - 171.0	145.0 - 238.0
Total cholesterol in mg/dL			
n	19	9	24
Mean (SD)	188.9 (38.85)	197.0 (48.11)	170.2 (40.06)

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.6.10.2 Last available laboratory values within the last 6 months - continuous

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Min-Max	125 - 268	130 - 273	83 - 231
Median	182.0	192.0	172.5
Q1-Q3	161.0 - 217.0	161.0 - 220.0	151.0 - 193.0
LDL cholesterol in mg/dL			
n	19	9	27
Mean (SD)	102.5 (40.79)	123.6 (28.94)	105.9 (36.64)
Min-Max	36 - 185	87 - 174	27 - 162.39
Median	96.0	118.0	109.0
Q1-Q3	65.7 - 126.0	100.0 - 143.0	86.0 - 135.3
HDL cholesterol in mg/dL			
n	19	9	27
Mean (SD)	58.9 (36.01)	48.3 (13.07)	44.2 (9.96)
Min-Max	27.452 - 178	34.7 - 74.4	25 - 65
Median	49.0	47.0	44.0
Q1-Q3	42.0 - 62.0	40.0 - 49.0	36.0 - 52.0
Triglyceride in mg/dL			
n	18	9	25
Mean (SD)	188.4 (69.15)	211.6 (99.75)	181.1 (85.56)
Min-Max	75 - 291	88 - 420	71 - 414
Median	209.5	186.0	155.0
Q1-Q3	125.0 - 245.6	149.0 - 250.0	119.0 - 236.8

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.6.10.3 Acquisition of the glycaemic variability from FGM

		before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Glucose median in mg/dL				
n		0	7	13
Mean (SD)			157.3 (25.69)	144.5 (22.48)
Min-Max			126 - 199	120 - 193
Median			162.0	147.7
Q1-Q3			134.0 - 177.0	126.1 - 152.0
Time in range in %				
n		0	7	13
Mean (SD)			69.6 (16.00)	49.5 (15.77)
Min-Max			41 - 87	20 - 71
Median			70.0	52.0
Q1-Q3			59.0 - 84.0	40.0 - 60.0
Time above range in %				
n		0	7	13
Mean (SD)			28.9 (16.95)	40.6 (15.28)
Min-Max			9 - 59	25 - 75
Median			30.0	35.0
Q1-Q3			14.0 - 38.0	28.0 - 45.0
Time below range in %				
n		0	7	13
Mean (SD)			1.1 (1.57)	9.9 (8.63)
Min-Max			0 - 4	0 - 25
Median			0.0	5.0
Q1-Q3			0.0 - 2.0	5.0 - 20.0

2 Disposition and Baseline Characteristics
2.6 Laboratory values and Acquisition of the glycaemic variability
2.6.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.6.10.4 Acquisition of the glycaemic variability from the 7-point glucose daily profile

Glucose 7-point glucose daily profile in mg/dL	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Median			
n	20	3	21
Mean (SD)	201.5 (45.10)	220.0 (34.66)	184.9 (41.28)
Min-Max	133.33 - 275	199 - 260	136.94 - 311
Median	210.0	201.0	172.0
Q1-Q3	164.5 - 236.0	199.0 - 260.0	166.0 - 199.0
Standard deviation			
n	20	3	21
Mean (SD)	41.3 (15.63)	36.2 (1.77)	37.9 (17.64)
Min-Max	1.0403 - 66.647	34.195 - 37.594	7.2394 - 74.986
Median	42.1	36.8	35.8
Q1-Q3	34.4 - 51.0	34.2 - 37.6	23.5 - 48.9

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.1 Reason for switch - categorical

Reason for switch	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Improving glycemic control,especially			
of the HbA1c value	70 (100.0%)	7 (87.5%)	10 (100.0%)
of fasting blood glucose	55 (78.6%)	4 (50.0%)	7 (70.0%)
of the postprandial blood glucose	52 (74.3%)	4 (50.0%)	7 (70.0%)
Reduction of the hypoglycemia rate	1 (1.4%)	0 (0.0%)	0 (0.0%)
Improvement of glucose variability	22 (31.4%)	2 (25.0%)	0 (0.0%)
Improvement of TIR (time in range)	18 (25.7%)	0 (0.0%)	0 (0.0%)
High dosage of basal insulin so far	17 (24.3%)	1 (12.5%)	2 (20.0%)
Change of the injection time	6 (8.6%)	0 (0.0%)	0 (0.0%)
Preference for iGlarLixi pen	6 (8.6%)	0 (0.0%)	2 (20.0%)
Easy handling of the fixed combination	35 (50.0%)	4 (50.0%)	6 (60.0%)
Request of the patient	18 (25.7%)	0 (0.0%)	0 (0.0%)
Other	1 (1.4%)	1 (12.5%)	1 (10.0%)
Other - detailed			
Compliance	0 (0.0%)	1 (12.5%)	0 (0.0%)
The concomitant disease multiple sclerosis can benefit from an optimization of the metabolism. No OAD as an option for elevated liver enzymes.	0 (0.0%)	0 (0.0%)	1 (10.0%)
Weight loss	1 (1.4%)	0 (0.0%)	0 (0.0%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Missing	0	1	0
0 dose steps	0 (0.0%)	0 (0.0%)	1 (10.0%)
1 dose step	0 (0.0%)	0 (0.0%)	2 (20.0%)
2 dose steps	0 (0.0%)	0 (0.0%)	2 (20.0%)
30 dose steps	70 (100.0%)	7 (100.0%)	1 (10.0%)
34 dose steps	0 (0.0%)	0 (0.0%)	1 (10.0%)
35 dose steps	0 (0.0%)	0 (0.0%)	1 (10.0%)
40 dose steps	0 (0.0%)	0 (0.0%)	2 (20.0%)
Total	70 (100.0%)	7 (100.0%)	10 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.3 Time of injection - categorical

Time of injection	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Missing	1	1	0
Before breakfast	28 (40.6%)	4 (57.1%)	1 (10.0%)
Before lunch	9 (13.0%)	0 (0.0%)	2 (20.0%)
Before dinner	32 (46.4%)	3 (42.9%)	7 (70.0%)
Total	69 (100.0%)	7 (100.0%)	10 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.3 Time of injection - categorical
2.7.1.3.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Time of injection*	N non-miss	69	7	
	% Before break	40.58	57.14	0.748
	% Before lunch	13.04	0.00	
	% Before dinne	46.38	42.86	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.3 Time of injection - categorical
2.7.1.3.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Time of injection*	N non-miss	69	10	
	% Before break	40.58	10.00	0.131
	% Before lunch	13.04	20.00	
	% Before dinne	46.38	70.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.4 Change of the non-insulin concomitant medication - categorical

	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Change of the non-insulin concomitant medication			
Missing	0	1	0
yes	20 (28.6%)	2 (28.6%)	1 (10.0%)
no	50 (71.4%)	5 (71.4%)	9 (90.0%)
Total	70 (100.0%)	7 (100.0%)	10 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.4 Change of the non-insulin concomitant medication - categorical
2.7.1.4.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Change of the non-insulin concomitant medication*	N non-miss	70	7	
	% yes	28.57	28.57	1.000
	% no	71.43	71.43	

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* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.4 Change of the non-insulin concomitant medication - categorical
2.7.1.4.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Change of the non-insulin concomitant medication*	N non-miss	70	10	
	% yes	28.57	10.00	0.278
	% no	71.43	90.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Metformin			
Missing	1	2	0
yes	50 (72.5%)	5 (83.3%)	6 (60.0%)
no	19 (27.5%)	1 (16.7%)	4 (40.0%)
Total	69 (100.0%)	6 (100.0%)	10 (100.0%)
Sulfonyl urea			
Missing	3	3	1
yes	1 (1.5%)	0 (0.0%)	0 (0.0%)
no	66 (98.5%)	5 (100.0%)	9 (100.0%)
Total	67 (100.0%)	5 (100.0%)	9 (100.0%)
Glinide			
Missing	1	3	1
yes	4 (5.8%)	0 (0.0%)	1 (11.1%)
no	65 (94.2%)	5 (100.0%)	8 (88.9%)
Total	69 (100.0%)	5 (100.0%)	9 (100.0%)
Alpha glucosidase inhibitor			
Missing	2	3	0
no	68 (100.0%)	5 (100.0%)	10 (100.0%)
Total	68 (100.0%)	5 (100.0%)	10 (100.0%)
Glitazone			
Missing	2	3	0
no	68 (100.0%)	5 (100.0%)	10 (100.0%)
Total	68 (100.0%)	5 (100.0%)	10 (100.0%)
DPP-4 inhibitor			
Missing	2	3	0
yes	9 (13.2%)	1 (20.0%)	1 (10.0%)
no	59 (86.8%)	4 (80.0%)	9 (90.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	FAS (N = 70) N (%)	Dropout (N = 8) N (%)	Off-Label (N = 10) N (%)
Total	68 (100.0%)	5 (100.0%)	10 (100.0%)
SGLT2 inhibitor			
Missing	1	2	0
yes	34 (49.3%)	3 (50.0%)	1 (10.0%)
no	35 (50.7%)	3 (50.0%)	9 (90.0%)
Total	69 (100.0%)	6 (100.0%)	10 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.5 Change of the non-insulin concomitant medication - current medication - categorical
2.7.1.5.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
Metformin*	N non-miss	69	6	
	% yes	72.46	83.33	1.000
	% no	27.54	16.67	
Sulfonyl urea*	N non-miss	67	5	
	% yes	1.49	0.00	1.000
	% no	98.51	100.00	
Glinide*	N non-miss	69	5	
	% yes	5.80	0.00	1.000
	% no	94.20	100.00	
Alpha glucosidase inhibitor*	N non-miss	68	5	
	% no	100.00	100.00	not done
Glitazone*	N non-miss	68	5	
	% no	100.00	100.00	not done
DPP-4 inhibitor*	N non-miss	68	5	
	% yes	13.24	20.00	0.532
	% no	86.76	80.00	
SGLT2 inhibitor*	N non-miss	69	6	
	% yes	49.28	50.00	1.000
	% no	50.72	50.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.1 Full Analysis Set - Dropout - Off-Label
2.7.1.5 Change of the non-insulin concomitant medication - current medication - categorical
2.7.1.5.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
Metformin*	N non-miss	69	10	
	% yes	72.46	60.00	0.465
	% no	27.54	40.00	
Sulfonyl urea*	N non-miss	67	9	
	% yes	1.49	0.00	1.000
	% no	98.51	100.00	
Alpha glucosidase inhibitor*	N non-miss	68	10	
	% no	100.00	100.00	not done
Glitazone*	N non-miss	68	10	
	% no	100.00	100.00	not done
DPP-4 inhibitor*	N non-miss	68	10	
	% yes	13.24	10.00	1.000
	% no	86.76	90.00	
SGLT2 inhibitor*	N non-miss	69	10	
	% yes	49.28	10.00	0.037
	% no	50.72	90.00	

* :p-values are based on the Fisher's exact test
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.1 Reason for switch - categorical

Reason for switch	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Improving glycemic control,especially		
of the HbA1c value	20 (100.0%)	50 (100.0%)
of fasting blood glucose	16 (80.0%)	39 (78.0%)
of the postprandial blood glucose	15 (75.0%)	37 (74.0%)
Reduction of the hypoglycemia rate	0 (0.0%)	1 (2.0%)
Improvement of glucose variability	10 (50.0%)	12 (24.0%)
Improvement of TIR (time in range)	11 (55.0%)	7 (14.0%)
High dosage of basal insulin so far	5 (25.0%)	12 (24.0%)
Change of the injection time	4 (20.0%)	2 (4.0%)
Preference for iGlarLixi pen	4 (20.0%)	2 (4.0%)
Easy handling of the fixed combination	9 (45.0%)	26 (52.0%)
Request of the patient	11 (55.0%)	7 (14.0%)
Other	0 (0.0%)	1 (2.0%)
Other - detailed		
Weight loss	0 (0.0%)	1 (2.0%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
30 dose steps	20 (100.0%)	50 (100.0%)
Total	20 (100.0%)	50 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.3 Time of injection - categorical

Time of injection	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Missing	0	1
Before breakfast	0 (0.0%)	28 (57.1%)
Before lunch	7 (35.0%)	2 (4.1%)
Before dinner	13 (65.0%)	19 (38.8%)
Total	20 (100.0%)	49 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.4 Change of the non-insulin concomitant medication - categorical

	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Change of the non-insulin concomitant medication		
yes	2 (10.0%)	18 (36.0%)
no	18 (90.0%)	32 (64.0%)
Total	20 (100.0%)	50 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Metformin		
Missing	0	1
yes	16 (80.0%)	34 (69.4%)
no	4 (20.0%)	15 (30.6%)
Total	20 (100.0%)	49 (100.0%)
Sulfonyl urea		
Missing	2	1
yes	1 (5.6%)	0 (0.0%)
no	17 (94.4%)	49 (100.0%)
Total	18 (100.0%)	49 (100.0%)
Glinide		
Missing	0	1
yes	3 (15.0%)	1 (2.0%)
no	17 (85.0%)	48 (98.0%)
Total	20 (100.0%)	49 (100.0%)
Alpha glucosidase inhibitor		
Missing	1	1
no	19 (100.0%)	49 (100.0%)
Total	19 (100.0%)	49 (100.0%)
Glitazone		
Missing	1	1
no	19 (100.0%)	49 (100.0%)
Total	19 (100.0%)	49 (100.0%)
DPP-4 inhibitor		
Missing	1	1
yes	4 (21.1%)	5 (10.2%)
no	15 (78.9%)	44 (89.8%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.2 Full Analysis Set - Subgroups - FGM - SMBG
2.7.2.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Total	19 (100.0%)	49 (100.0%)
SGLT2 inhibitor		
Missing	1	0
yes	10 (52.6%)	24 (48.0%)
no	9 (47.4%)	26 (52.0%)
Total	19 (100.0%)	50 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.1 Reason for switch - categorical

Reason for switch	Female (N = 28) N (%)	Male (N = 42) N (%)
Improving glycemic control,especially		
of the HbA1c value	28 (100.0%)	42 (100.0%)
of fasting blood glucose	18 (64.3%)	37 (88.1%)
of the postprandial blood glucose	20 (71.4%)	32 (76.2%)
Reduction of the hypoglycemia rate	1 (3.6%)	0 (0.0%)
Improvement of glucose variability	11 (39.3%)	11 (26.2%)
Improvement of TIR (time in range)	6 (21.4%)	12 (28.6%)
High dosage of basal insulin so far	8 (28.6%)	9 (21.4%)
Change of the injection time	0 (0.0%)	6 (14.3%)
Preference for iGlarLixi pen	2 (7.1%)	4 (9.5%)
Easy handling of the fixed combination	11 (39.3%)	24 (57.1%)
Request of the patient	5 (17.9%)	13 (31.0%)
Other	0 (0.0%)	1 (2.4%)
Other - detailed		
Weight loss	0 (0.0%)	1 (2.4%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	Female (N = 28) N (%)	Male (N = 42) N (%)
30 dose steps	28 (100.0%)	42 (100.0%)
Total	28 (100.0%)	42 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.3 Time of injection - categorical

Time of injection	Female (N = 28) N (%)	Male (N = 42) N (%)
Missing	1	0
Before breakfast	13 (48.1%)	15 (35.7%)
Before lunch	1 (3.7%)	8 (19.0%)
Before dinner	13 (48.1%)	19 (45.2%)
Total	27 (100.0%)	42 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.4 Change of the non-insulin concomitant medication - categorical

	Female (N = 28) N (%)	Male (N = 42) N (%)
Change of the non-insulin concomitant medication		
yes	9 (32.1%)	11 (26.2%)
no	19 (67.9%)	31 (73.8%)
Total	28 (100.0%)	42 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Metformin		
Missing	1	0
yes	16 (59.3%)	34 (81.0%)
no	11 (40.7%)	8 (19.0%)
Total	27 (100.0%)	42 (100.0%)
Sulfonyl urea		
Missing	1	2
yes	1 (3.7%)	0 (0.0%)
no	26 (96.3%)	40 (100.0%)
Total	27 (100.0%)	40 (100.0%)
Glinide		
Missing	1	0
yes	2 (7.4%)	2 (4.8%)
no	25 (92.6%)	40 (95.2%)
Total	27 (100.0%)	42 (100.0%)
Alpha glucosidase inhibitor		
Missing	1	1
no	27 (100.0%)	41 (100.0%)
Total	27 (100.0%)	41 (100.0%)
Glitazone		
Missing	1	1
no	27 (100.0%)	41 (100.0%)
Total	27 (100.0%)	41 (100.0%)
DPP-4 inhibitor		
Missing	1	1
yes	3 (11.1%)	6 (14.6%)
no	24 (88.9%)	35 (85.4%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.3 Full Analysis Set - Subgroups - Gender
2.7.3.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	Female (N = 28) N (%)	Male (N = 42) N (%)
Total	27 (100.0%)	41 (100.0%)
SGLT2 inhibitor		
Missing	0	1
yes	10 (35.7%)	24 (58.5%)
no	18 (64.3%)	17 (41.5%)
Total	28 (100.0%)	41 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.1 Reason for switch - categorical

Reason for switch	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Improving glycemic control,especially			
of the HbA1c value	24 (100.0%)	24 (100.0%)	22 (100.0%)
of fasting blood glucose	19 (79.2%)	22 (91.7%)	14 (63.6%)
of the postprandial blood glucose	18 (75.0%)	18 (75.0%)	16 (72.7%)
Reduction of the hypoglycemia rate	0 (0.0%)	0 (0.0%)	1 (4.5%)
Improvement of glucose variability	5 (20.8%)	9 (37.5%)	8 (36.4%)
Improvement of TIR (time in range)	7 (29.2%)	5 (20.8%)	6 (27.3%)
High dosage of basal insulin so far	6 (25.0%)	5 (20.8%)	6 (27.3%)
Change of the injection time	2 (8.3%)	2 (8.3%)	2 (9.1%)
Preference for iGlarLixi pen	2 (8.3%)	2 (8.3%)	2 (9.1%)
Easy handling of the fixed combination	9 (37.5%)	12 (50.0%)	14 (63.6%)
Request of the patient	5 (20.8%)	8 (33.3%)	5 (22.7%)
Other	0 (0.0%)	1 (4.2%)	0 (0.0%)
Other - detailed			
Weight loss	0 (0.0%)	1 (4.2%)	0 (0.0%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
30 dose steps	24 (100.0%)	24 (100.0%)	22 (100.0%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.3 Time of injection - categorical

Time of injection	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Missing	0	0	1
Before breakfast	9 (37.5%)	7 (29.2%)	12 (57.1%)
Before lunch	3 (12.5%)	4 (16.7%)	2 (9.5%)
Before dinner	12 (50.0%)	13 (54.2%)	7 (33.3%)
Total	24 (100.0%)	24 (100.0%)	21 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.4 Change of the non-insulin concomitant medication - categorical

	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Change of the non-insulin concomitant medication			
yes	6 (25.0%)	4 (16.7%)	10 (45.5%)
no	18 (75.0%)	20 (83.3%)	12 (54.5%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Metformin			
Missing	0	0	1
yes	17 (70.8%)	20 (83.3%)	13 (61.9%)
no	7 (29.2%)	4 (16.7%)	8 (38.1%)
Total	24 (100.0%)	24 (100.0%)	21 (100.0%)
Sulfonyl urea			
Missing	1	1	1
yes	0 (0.0%)	1 (4.3%)	0 (0.0%)
no	23 (100.0%)	22 (95.7%)	21 (100.0%)
Total	23 (100.0%)	23 (100.0%)	21 (100.0%)
Glinide			
Missing	0	0	1
yes	2 (8.3%)	1 (4.2%)	1 (4.8%)
no	22 (91.7%)	23 (95.8%)	20 (95.2%)
Total	24 (100.0%)	24 (100.0%)	21 (100.0%)
Alpha glucosidase inhibitor			
Missing	1	0	1
no	23 (100.0%)	24 (100.0%)	21 (100.0%)
Total	23 (100.0%)	24 (100.0%)	21 (100.0%)
Glitazone			
Missing	1	0	1
no	23 (100.0%)	24 (100.0%)	21 (100.0%)
Total	23 (100.0%)	24 (100.0%)	21 (100.0%)
DPP-4 inhibitor			
Missing	1	0	1
yes	1 (4.3%)	6 (25.0%)	2 (9.5%)
no	22 (95.7%)	18 (75.0%)	19 (90.5%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.4 Full Analysis Set - Subgroups - Age groups
2.7.4.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Total	23 (100.0%)	24 (100.0%)	21 (100.0%)
SGLT2 inhibitor			
Missing	1	0	0
yes	12 (52.2%)	13 (54.2%)	9 (40.9%)
no	11 (47.8%)	11 (45.8%)	13 (59.1%)
Total	23 (100.0%)	24 (100.0%)	22 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.1 Reason for switch - categorical

Reason for switch	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Improving glycemic control,especially		
of the HbA1c value	18 (100.0%)	52 (100.0%)
of fasting blood glucose	13 (72.2%)	42 (80.8%)
of the postprandial blood glucose	10 (55.6%)	42 (80.8%)
Reduction of the hypoglycemia rate	1 (5.6%)	0 (0.0%)
Improvement of glucose variability	7 (38.9%)	15 (28.8%)
Improvement of TIR (time in range)	4 (22.2%)	14 (26.9%)
High dosage of basal insulin so far	4 (22.2%)	13 (25.0%)
Change of the injection time	1 (5.6%)	5 (9.6%)
Preference for iGlarLixi pen	0 (0.0%)	6 (11.5%)
Easy handling of the fixed combination	8 (44.4%)	27 (51.9%)
Request of the patient	5 (27.8%)	13 (25.0%)
Other	0 (0.0%)	1 (1.9%)
Other - detailed		
Weight loss	0 (0.0%)	1 (1.9%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
30 dose steps	18 (100.0%)	52 (100.0%)
Total	18 (100.0%)	52 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.3 Time of injection - categorical

Time of injection	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Missing	0	1
Before breakfast	7 (38.9%)	21 (41.2%)
Before lunch	2 (11.1%)	7 (13.7%)
Before dinner	9 (50.0%)	23 (45.1%)
Total	18 (100.0%)	51 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.4 Change of the non-insulin concomitant medication - categorical

	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Change of the non-insulin concomitant medication		
yes	9 (50.0%)	11 (21.2%)
no	9 (50.0%)	41 (78.8%)
Total	18 (100.0%)	52 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Metformin		
Missing	0	1
yes	12 (66.7%)	38 (74.5%)
no	6 (33.3%)	13 (25.5%)
Total	18 (100.0%)	51 (100.0%)
Sulfonyl urea		
Missing	0	3
yes	0 (0.0%)	1 (2.0%)
no	18 (100.0%)	48 (98.0%)
Total	18 (100.0%)	49 (100.0%)
Glinide		
Missing	0	1
yes	0 (0.0%)	4 (7.8%)
no	18 (100.0%)	47 (92.2%)
Total	18 (100.0%)	51 (100.0%)
Alpha glucosidase inhibitor		
Missing	0	2
no	18 (100.0%)	50 (100.0%)
Total	18 (100.0%)	50 (100.0%)
Glitazone		
Missing	0	2
no	18 (100.0%)	50 (100.0%)
Total	18 (100.0%)	50 (100.0%)
DPP-4 inhibitor		
Missing	0	2
yes	3 (16.7%)	6 (12.0%)
no	15 (83.3%)	44 (88.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.5 Full Analysis Set - Subgroups - Body Mass Index
2.7.5.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Total	18 (100.0%)	50 (100.0%)
SGLT2 inhibitor		
Missing	0	1
yes	11 (61.1%)	23 (45.1%)
no	7 (38.9%)	28 (54.9%)
Total	18 (100.0%)	51 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.1 Reason for switch - categorical

Reason for switch	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Improving glycemic control,especially		
of the HbA1c value	17 (100.0%)	39 (100.0%)
of fasting blood glucose	8 (47.1%)	34 (87.2%)
of the postprandial blood glucose	10 (58.8%)	29 (74.4%)
Reduction of the hypoglycemia rate	1 (5.9%)	0 (0.0%)
Improvement of glucose variability	11 (64.7%)	7 (17.9%)
Improvement of TIR (time in range)	4 (23.5%)	10 (25.6%)
High dosage of basal insulin so far	5 (29.4%)	10 (25.6%)
Change of the injection time	2 (11.8%)	3 (7.7%)
Preference for iGlarLixi pen	1 (5.9%)	3 (7.7%)
Easy handling of the fixed combination	10 (58.8%)	17 (43.6%)
Request of the patient	4 (23.5%)	12 (30.8%)
Other - detailed	0	0

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
30 dose steps	17 (100.0%)	39 (100.0%)
Total	17 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.3 Time of injection - categorical

Time of injection	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Before breakfast	9 (52.9%)	11 (28.2%)
Before lunch	2 (11.8%)	7 (17.9%)
Before dinner	6 (35.3%)	21 (53.8%)
Total	17 (100.0%)	39 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.4 Change of the non-insulin concomitant medication - categorical

	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Change of the non-insulin concomitant medication		
yes	9 (52.9%)	10 (25.6%)
no	8 (47.1%)	29 (74.4%)
Total	17 (100.0%)	39 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Metformin		
yes	8 (47.1%)	32 (82.1%)
no	9 (52.9%)	7 (17.9%)
Total	17 (100.0%)	39 (100.0%)
Sulfonyl urea		
Missing	0	2
yes	0 (0.0%)	1 (2.7%)
no	17 (100.0%)	36 (97.3%)
Total	17 (100.0%)	37 (100.0%)
Glinide		
yes	1 (5.9%)	3 (7.7%)
no	16 (94.1%)	36 (92.3%)
Total	17 (100.0%)	39 (100.0%)
Alpha glucosidase inhibitor		
Missing	0	1
no	17 (100.0%)	38 (100.0%)
Total	17 (100.0%)	38 (100.0%)
Glitazone		
Missing	0	1
no	17 (100.0%)	38 (100.0%)
Total	17 (100.0%)	38 (100.0%)
DPP-4 inhibitor		
Missing	0	1
yes	1 (5.9%)	5 (13.2%)
no	16 (94.1%)	33 (86.8%)
Total	17 (100.0%)	38 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.6 Full Analysis Set - Subgroups - Renal function
2.7.6.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
SGLT2 inhibitor		
Missing	0	1
yes	9 (52.9%)	17 (44.7%)
no	8 (47.1%)	21 (55.3%)
Total	17 (100.0%)	38 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.1 Reason for switch - categorical

Reason for switch	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Improving glycemic control,especially			
of the HbA1c value	7 (100.0%)	21 (100.0%)	39 (100.0%)
of fasting blood glucose	4 (57.1%)	14 (66.7%)	34 (87.2%)
of the postprandial blood glucose	5 (71.4%)	15 (71.4%)	30 (76.9%)
Reduction of the hypoglycemia rate	0 (0.0%)	1 (4.8%)	0 (0.0%)
Improvement of glucose variability	1 (14.3%)	9 (42.9%)	12 (30.8%)
Improvement of TIR (time in range)	0 (0.0%)	8 (38.1%)	10 (25.6%)
High dosage of basal insulin so far	3 (42.9%)	7 (33.3%)	7 (17.9%)
Change of the injection time	0 (0.0%)	3 (14.3%)	3 (7.7%)
Preference for iGlarLixi pen	0 (0.0%)	3 (14.3%)	2 (5.1%)
Easy handling of the fixed combination	4 (57.1%)	10 (47.6%)	19 (48.7%)
Request of the patient	0 (0.0%)	6 (28.6%)	11 (28.2%)
Other	0 (0.0%)	1 (4.8%)	0 (0.0%)
Other - detailed			
Weight loss	0 (0.0%)	1 (4.8%)	0 (0.0%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
30 dose steps	7 (100.0%)	21 (100.0%)	39 (100.0%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.3 Time of injection - categorical

Time of injection	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Missing	0	0	1
Before breakfast	3 (42.9%)	10 (47.6%)	14 (36.8%)
Before lunch	0 (0.0%)	3 (14.3%)	6 (15.8%)
Before dinner	4 (57.1%)	8 (38.1%)	18 (47.4%)
Total	7 (100.0%)	21 (100.0%)	38 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.4 Change of the non-insulin concomitant medication - categorical

	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Change of the non-insulin concomitant medication			
yes	5 (71.4%)	8 (38.1%)	5 (12.8%)
no	2 (28.6%)	13 (61.9%)	34 (87.2%)
Total	7 (100.0%)	21 (100.0%)	39 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Metformin			
Missing	0	0	1
yes	2 (28.6%)	16 (76.2%)	30 (78.9%)
no	5 (71.4%)	5 (23.8%)	8 (21.1%)
Total	7 (100.0%)	21 (100.0%)	38 (100.0%)
Sulfonyl urea			
Missing	0	1	2
yes	0 (0.0%)	0 (0.0%)	1 (2.7%)
no	7 (100.0%)	20 (100.0%)	36 (97.3%)
Total	7 (100.0%)	20 (100.0%)	37 (100.0%)
Glinide			
Missing	0	0	1
yes	0 (0.0%)	1 (4.8%)	1 (2.6%)
no	7 (100.0%)	20 (95.2%)	37 (97.4%)
Total	7 (100.0%)	21 (100.0%)	38 (100.0%)
Alpha glucosidase inhibitor			
Missing	0	1	1
no	7 (100.0%)	20 (100.0%)	38 (100.0%)
Total	7 (100.0%)	20 (100.0%)	38 (100.0%)
Glitazone			
Missing	0	1	1
no	7 (100.0%)	20 (100.0%)	38 (100.0%)
Total	7 (100.0%)	20 (100.0%)	38 (100.0%)
DPP-4 inhibitor			
Missing	0	1	1
yes	0 (0.0%)	2 (10.0%)	7 (18.4%)
no	7 (100.0%)	18 (90.0%)	31 (81.6%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.7 Full Analysis Set - Subgroups - Duration of diabetes
2.7.7.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Total	7 (100.0%)	20 (100.0%)	38 (100.0%)
SGLT2 inhibitor			
Missing	0	1	0
yes	2 (28.6%)	6 (30.0%)	26 (66.7%)
no	5 (71.4%)	14 (70.0%)	13 (33.3%)
Total	7 (100.0%)	20 (100.0%)	39 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.1 Reason for switch - categorical

Reason for switch	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Improving glycemic control,especially		
of the HbA1c value	38 (100.0%)	32 (100.0%)
of fasting blood glucose	30 (78.9%)	25 (78.1%)
of the postprandial blood glucose	29 (76.3%)	23 (71.9%)
Reduction of the hypoglycemia rate	0 (0.0%)	1 (3.1%)
Improvement of glucose variability	8 (21.1%)	14 (43.8%)
Improvement of TIR (time in range)	9 (23.7%)	9 (28.1%)
High dosage of basal insulin so far	11 (28.9%)	6 (18.8%)
Change of the injection time	3 (7.9%)	3 (9.4%)
Preference for iGlarLixi pen	4 (10.5%)	2 (6.3%)
Easy handling of the fixed combination	16 (42.1%)	19 (59.4%)
Request of the patient	11 (28.9%)	7 (21.9%)
Other	0 (0.0%)	1 (3.1%)
Other - detailed		
Weight loss	0 (0.0%)	1 (3.1%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
30 dose steps	38 (100.0%)	32 (100.0%)
Total	38 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.3 Time of injection - categorical

Time of injection	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Missing	1	0
Before breakfast	15 (40.5%)	13 (40.6%)
Before lunch	6 (16.2%)	3 (9.4%)
Before dinner	16 (43.2%)	16 (50.0%)
Total	37 (100.0%)	32 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.4 Change of the non-insulin concomitant medication - categorical

	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Change of the non-insulin concomitant medication		
yes	10 (26.3%)	10 (31.3%)
no	28 (73.7%)	22 (68.8%)
Total	38 (100.0%)	32 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Metformin		
Missing	1	0
yes	27 (73.0%)	23 (71.9%)
no	10 (27.0%)	9 (28.1%)
Total	37 (100.0%)	32 (100.0%)
Sulfonyl urea		
Missing	2	1
yes	1 (2.8%)	0 (0.0%)
no	35 (97.2%)	31 (100.0%)
Total	36 (100.0%)	31 (100.0%)
Glinide		
Missing	1	0
yes	2 (5.4%)	2 (6.3%)
no	35 (94.6%)	30 (93.8%)
Total	37 (100.0%)	32 (100.0%)
Alpha glucosidase inhibitor		
Missing	1	1
no	37 (100.0%)	31 (100.0%)
Total	37 (100.0%)	31 (100.0%)
Glitazone		
Missing	1	1
no	37 (100.0%)	31 (100.0%)
Total	37 (100.0%)	31 (100.0%)
DPP-4 inhibitor		
Missing	1	1
yes	3 (8.1%)	6 (19.4%)
no	34 (91.9%)	25 (80.6%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.8 Full Analysis Set - Subgroups - Baseline HbA1c
2.7.8.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Total	37 (100.0%)	31 (100.0%)
SGLT2 inhibitor		
Missing	0	1
yes	18 (47.4%)	16 (51.6%)
no	20 (52.6%)	15 (48.4%)
Total	38 (100.0%)	31 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.1 Reason for switch - categorical

Reason for switch	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Improving glycemic control,especially				
of the HbA1c value	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
of fasting blood glucose	9 (81.8%)	18 (75.0%)	23 (79.3%)	5 (83.3%)
of the postprandial blood glucose	9 (81.8%)	14 (58.3%)	26 (89.7%)	3 (50.0%)
Reduction of the hypoglycemia rate	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
Improvement of glucose variability	5 (45.5%)	8 (33.3%)	6 (20.7%)	3 (50.0%)
Improvement of TIR (time in range)	3 (27.3%)	7 (29.2%)	6 (20.7%)	2 (33.3%)
High dosage of basal insulin so far	3 (27.3%)	6 (25.0%)	7 (24.1%)	1 (16.7%)
Change of the injection time	1 (9.1%)	4 (16.7%)	1 (3.4%)	0 (0.0%)
Preference for iGlarLixi pen	1 (9.1%)	4 (16.7%)	1 (3.4%)	0 (0.0%)
Easy handling of the fixed combination	6 (54.5%)	11 (45.8%)	13 (44.8%)	5 (83.3%)
Request of the patient	3 (27.3%)	6 (25.0%)	7 (24.1%)	2 (33.3%)
Other	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)
Other - detailed				
Weight loss	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
30 dose steps	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.3 Time of injection - categorical

Time of injection	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Missing	0	1	0	0
Before breakfast	5 (45.5%)	7 (30.4%)	12 (41.4%)	4 (66.7%)
Before lunch	0 (0.0%)	4 (17.4%)	3 (10.3%)	2 (33.3%)
Before dinner	6 (54.5%)	12 (52.2%)	14 (48.3%)	0 (0.0%)
Total	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.4 Change of the non-insulin concomitant medication - categorical

	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Change of the non-insulin concomitant medication				
yes	2 (18.2%)	6 (25.0%)	9 (31.0%)	3 (50.0%)
no	9 (81.8%)	18 (75.0%)	20 (69.0%)	3 (50.0%)
Total	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Metformin				
Missing	0	1	0	0
yes	8 (72.7%)	18 (78.3%)	20 (69.0%)	4 (66.7%)
no	3 (27.3%)	5 (21.7%)	9 (31.0%)	2 (33.3%)
Total	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Sulfonyl urea				
Missing	0	3	0	0
yes	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
no	10 (90.9%)	21 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	21 (100.0%)	29 (100.0%)	6 (100.0%)
Glinide				
Missing	0	1	0	0
yes	2 (18.2%)	1 (4.3%)	1 (3.4%)	0 (0.0%)
no	9 (81.8%)	22 (95.7%)	28 (96.6%)	6 (100.0%)
Total	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Alpha glucosidase inhibitor				
Missing	0	2	0	0
no	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Glitazone				
Missing	0	2	0	0
no	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Total	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
DPP-4 inhibitor				
Missing	0	2	0	0
yes	2 (18.2%)	3 (13.6%)	4 (13.8%)	0 (0.0%)
no	9 (81.8%)	19 (86.4%)	25 (86.2%)	6 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.9 Full Analysis Set - Subgroups - Previous basal insulin therapy
2.7.9.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Total	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
SGLT2 inhibitor				
Missing	0	1	0	0
yes	4 (36.4%)	11 (47.8%)	15 (51.7%)	4 (66.7%)
no	7 (63.6%)	12 (52.2%)	14 (48.3%)	2 (33.3%)
Total	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.1 Reason for switch - categorical

Reason for switch	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Improving glycemic control,especially			
of the HbA1c value	28 (100.0%)	9 (100.0%)	32 (100.0%)
of fasting blood glucose	20 (71.4%)	8 (88.9%)	26 (81.3%)
of the postprandial blood glucose	20 (71.4%)	8 (88.9%)	23 (71.9%)
Reduction of the hypoglycemia rate	1 (3.6%)	0 (0.0%)	0 (0.0%)
Improvement of glucose variability	7 (25.0%)	5 (55.6%)	10 (31.3%)
Improvement of TIR (time in range)	2 (7.1%)	7 (77.8%)	9 (28.1%)
High dosage of basal insulin so far	8 (28.6%)	4 (44.4%)	5 (15.6%)
Change of the injection time	1 (3.6%)	3 (33.3%)	2 (6.3%)
Preference for iGlarLixi pen	1 (3.6%)	2 (22.2%)	3 (9.4%)
Easy handling of the fixed combination	15 (53.6%)	6 (66.7%)	14 (43.8%)
Request of the patient	2 (7.1%)	7 (77.8%)	9 (28.1%)
Other	0 (0.0%)	0 (0.0%)	1 (3.1%)
Other - detailed			
Weight loss	0 (0.0%)	0 (0.0%)	1 (3.1%)

Multiple answers possible

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.2 Number of iGlarLixi dose steps per day
Full Analysis Set (FAS)

Number of iGlarLixi dose steps per day	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
30 dose steps	28 (100.0%)	9 (100.0%)	32 (100.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.3 Time of injection - categorical

Time of injection	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Before breakfast	28 (100.0%)	0 (0.0%)	0 (0.0%)
Before lunch	0 (0.0%)	9 (100.0%)	0 (0.0%)
Before dinner	0 (0.0%)	0 (0.0%)	32 (100.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.4 Change of the non-insulin concomitant medication - categorical

	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Change of the non-insulin concomitant medication			
yes	11 (39.3%)	1 (11.1%)	8 (25.0%)
no	17 (60.7%)	8 (88.9%)	24 (75.0%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Metformin			
yes	18 (64.3%)	6 (66.7%)	26 (81.3%)
no	10 (35.7%)	3 (33.3%)	6 (18.8%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Sulfonyl urea			
Missing	0	1	1
yes	0 (0.0%)	0 (0.0%)	1 (3.2%)
no	28 (100.0%)	8 (100.0%)	30 (96.8%)
Total	28 (100.0%)	8 (100.0%)	31 (100.0%)
Glinide			
yes	0 (0.0%)	0 (0.0%)	4 (12.5%)
no	28 (100.0%)	9 (100.0%)	28 (87.5%)
Total	28 (100.0%)	9 (100.0%)	32 (100.0%)
Alpha glucosidase inhibitor			
Missing	0	0	1
no	28 (100.0%)	9 (100.0%)	31 (100.0%)
Total	28 (100.0%)	9 (100.0%)	31 (100.0%)
Glitazone			
Missing	0	0	1
no	28 (100.0%)	9 (100.0%)	31 (100.0%)
Total	28 (100.0%)	9 (100.0%)	31 (100.0%)
DPP-4 inhibitor			
Missing	0	0	1
yes	0 (0.0%)	0 (0.0%)	9 (29.0%)
no	28 (100.0%)	9 (100.0%)	22 (71.0%)
Total	28 (100.0%)	9 (100.0%)	31 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.7 Start therapy with iGlarLixi
2.7.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration
2.7.10.5 Change of the non-insulin concomitant medication - current medication - categorical

Current medication	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
SGLT2 inhibitor			
Missing	0	0	1
yes	12 (42.9%)	5 (55.6%)	16 (51.6%)
no	16 (57.1%)	4 (44.4%)	15 (48.4%)
Total	28 (100.0%)	9 (100.0%)	31 (100.0%)

Percentage related to patients with documentation of results

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
1. Satisfaction with current treatment			
n	66	7	7
Mean (SD)	4.0 (1.75)	3.7 (1.50)	4.9 (1.46)
Min-Max	0 - 6	1 - 5	2 - 6
Median	4.0	4.0	5.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0	4.0 - 6.0
2. Impression how often blood glucose was unacceptably high			
n	66	6	7
Mean (SD)	3.8 (1.44)	4.8 (1.33)	4.0 (1.29)
Min-Max	0 - 6	3 - 6	2 - 5
Median	4.0	5.0	5.0
Q1-Q3	3.0 - 5.0	4.0 - 6.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low			
n	66	7	7
Mean (SD)	0.9 (1.24)	2.0 (2.24)	0.7 (1.25)
Min-Max	0 - 6	0 - 6	0 - 3
Median	0.5	2.0	0.0
Q1-Q3	0.0 - 1.0	0.0 - 3.0	0.0 - 2.0
4. Practicability/convenience of treatment			
n	66	7	7
Mean (SD)	4.0 (1.56)	4.0 (1.41)	4.4 (1.13)
Min-Max	0 - 6	2 - 6	3 - 6
Median	4.0	4.0	5.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0
5. Satisfaction with the flexibility of treatment			
n	66	7	7
Mean (SD)	4.0 (1.53)	4.1 (1.35)	4.6 (1.72)
Min-Max	0 - 6	3 - 6	1 - 6
Median	4.0	4.0	5.0
Q1-Q3	3.0 - 5.0	3.0 - 6.0	4.0 - 6.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label

	FAS (N = 70)	Dropout (N = 8)	Off-Label (N = 10)
6. Satisfaction with knowledge/understanding of diabetes			
n	66	7	7
Mean (SD)	4.1 (1.41)	4.0 (1.63)	4.3 (1.50)
Min-Max	0 - 6	2 - 6	2 - 6
Median	4.0	5.0	4.0
Q1-Q3	3.0 - 5.0	2.0 - 5.0	3.0 - 6.0
7. Recommend treatment to others			
n	66	7	7
Mean (SD)	4.3 (1.34)	4.0 (1.63)	4.7 (0.95)
Min-Max	2 - 6	2 - 6	3 - 6
Median	4.0	3.0	5.0
Q1-Q3	3.0 - 5.0	3.0 - 6.0	4.0 - 5.0
8. Satisfaction with continuing current treatment			
n	66	7	7
Mean (SD)	3.8 (1.69)	3.6 (1.90)	4.6 (1.72)
Min-Max	0 - 6	1 - 6	1 - 6
Median	4.0	3.0	5.0
Q1-Q3	2.0 - 5.0	2.0 - 6.0	4.0 - 6.0
9. Sum of scores °			
n	66	7	7
Mean (SD)	24.2 (7.74)	23.4 (8.18)	27.4 (7.76)
Min-Max	6 - 36	15 - 34	12 - 35
Median	24.5	20.0	31.0
Q1-Q3	18.0 - 31.0	17.0 - 34.0	23.0 - 32.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label
2.8.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
1. Satisfaction with current treatment*	N non-miss	66	7	
	Mean	4.0	3.7	0.608
	SE	0.22	0.57	
2. Impression how often blood glucose was unaccept	N non-miss	66	6	
	Mean	3.8	4.8	0.110
	SE	0.18	0.54	
3. Impression how often blood glucose was unaccept	N non-miss	66	7	
	Mean	0.9	2.0	0.231
	SE	0.15	0.85	
4. Practicability/convenience of treatment*	N non-miss	66	7	
	Mean	4.0	4.0	0.985
	SE	0.19	0.53	
5. Satisfaction with the flexibility of treatment*	N non-miss	66	7	
	Mean	4.0	4.1	0.856
	SE	0.19	0.51	
6. Satisfaction with knowledge/understanding of di	N non-miss	66	7	
	Mean	4.1	4.0	0.977
	SE	0.17	0.62	

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label
2.8.1.1 FAS compared to Dropout

Variable	Statistic	FAS (G1)	Dropout (G2)	P-Val G1 vs. G2
7. Recommend treatment to others*	N non-miss	66	7	
	Mean	4.3	4.0	0.626
	SE	0.17	0.62	
8. Satisfaction with continuing current treatment*	N non-miss	66	7	
	Mean	3.8	3.6	0.690
	SE	0.21	0.72	
9. Sum of scores*	N non-miss	66	7	
	Mean	24.2	23.4	0.758
	SE	0.95	3.09	

* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label
2.8.1.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
1. Satisfaction with current treatment*	N non-miss	66	7	
	Mean	4.0	4.9	0.221
	SE	0.22	0.55	
2. Impression how often blood glucose was unaccept	N non-miss	66	7	
	Mean	3.8	4.0	0.701
	SE	0.18	0.49	
3. Impression how often blood glucose was unaccept	N non-miss	66	7	
	Mean	0.9	0.7	0.509
	SE	0.15	0.47	
4. Practicability/convenience of treatment*	N non-miss	66	7	
	Mean	4.0	4.4	0.506
	SE	0.19	0.43	
5. Satisfaction with the flexibility of treatment*	N non-miss	66	7	
	Mean	4.0	4.6	0.287
	SE	0.19	0.65	
6. Satisfaction with knowledge/understanding of di	N non-miss	66	7	
	Mean	4.1	4.3	0.767
	SE	0.17	0.57	

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.1 Full Analysis Set - Dropout - Off-Label
2.8.1.2 FAS compared to Off-Label

Variable	Statistic	FAS (G1)	Off-Label (G2)	P-Val G1 vs. G2
7. Recommend treatment to others*	N non-miss	66	7	
	Mean	4.3	4.7	0.479
	SE	0.17	0.36	
8. Satisfaction with continuing current treatment*	N non-miss	66	7	
	Mean	3.8	4.6	0.264
	SE	0.21	0.65	
9. Sum od scores*	N non-miss	66	7	
	Mean	24.2	27.4	0.297
	SE	0.95	2.93	

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* :p-values are based on the Wilcoxon rank sum statistic
[G. Koch et al, Categorical Data Analysis, in Statistical Methodology in the Pharmaceutical Sciences, edited by D. Berry, Dekker 1990]

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.2 Full Analysis Set - Subgroups - FGM - SMBG

	FGM (N = 20)	SMBG (N = 50)
1. Satisfaction with current treatment		
n	20	46
Mean (SD)	3.6 (1.60)	4.1 (1.81)
Min-Max	1 - 6	0 - 6
Median	3.0	5.0
Q1-Q3	2.5 - 5.0	3.0 - 6.0
2. Impression how often blood glucose was unacceptably high		
n	20	46
Mean (SD)	4.0 (1.03)	3.7 (1.59)
Min-Max	1 - 5	0 - 6
Median	4.0	4.0
Q1-Q3	4.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low		
n	20	46
Mean (SD)	1.1 (1.02)	0.8 (1.33)
Min-Max	0 - 3	0 - 6
Median	1.0	0.0
Q1-Q3	0.0 - 2.0	0.0 - 1.0
4. Practicability/convenience of treatment		
n	20	46
Mean (SD)	3.7 (1.34)	4.1 (1.64)
Min-Max	2 - 6	0 - 6
Median	3.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 6.0
5. Satisfaction with the flexibility of treatment		
n	20	46
Mean (SD)	3.9 (1.46)	4.1 (1.57)
Min-Max	2 - 6	0 - 6
Median	3.5	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.2 Full Analysis Set - Subgroups - FGM - SMBG

	FGM (N = 20)	SMBG (N = 50)
6. Satisfaction with knowledge/understanding of diabetes		
n	20	46
Mean (SD)	4.0 (1.28)	4.1 (1.47)
Min-Max	1 - 6	0 - 6
Median	4.0	4.5
Q1-Q3	3.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others		
n	20	46
Mean (SD)	4.2 (1.35)	4.3 (1.35)
Min-Max	2 - 6	2 - 6
Median	4.0	4.5
Q1-Q3	3.0 - 5.0	3.0 - 6.0
8. Satisfaction with continuing current treatment		
n	20	46
Mean (SD)	3.9 (1.35)	3.8 (1.84)
Min-Max	2 - 6	0 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 5.0	2.0 - 6.0
9. Sum of scores °		
n	20	46
Mean (SD)	23.1 (6.90)	24.6 (8.11)
Min-Max	13 - 32	6 - 36
Median	21.0	25.5
Q1-Q3	18.0 - 31.0	19.0 - 32.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.3 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
1. Satisfaction with current treatment		
n	25	41
Mean (SD)	4.1 (1.87)	3.9 (1.70)
Min-Max	0 - 6	0 - 6
Median	5.0	4.0
Q1-Q3	2.0 - 6.0	3.0 - 5.0
2. Impression how often blood glucose was unacceptably high		
n	25	41
Mean (SD)	4.0 (1.37)	3.6 (1.48)
Min-Max	0 - 6	0 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low		
n	25	41
Mean (SD)	0.7 (1.06)	1.0 (1.34)
Min-Max	0 - 3	0 - 6
Median	0.0	1.0
Q1-Q3	0.0 - 1.0	0.0 - 2.0
4. Practicability/convenience of treatment		
n	25	41
Mean (SD)	4.3 (1.41)	3.8 (1.62)
Min-Max	2 - 6	0 - 6
Median	5.0	4.0
Q1-Q3	3.0 - 6.0	2.0 - 5.0
5. Satisfaction with the flexibility of treatment		
n	25	41
Mean (SD)	4.2 (1.27)	3.9 (1.67)
Min-Max	2 - 6	0 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.3 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
6. Satisfaction with knowledge/understanding of diabetes		
n	25	41
Mean (SD)	4.3 (1.28)	3.9 (1.47)
Min-Max	1 - 6	0 - 6
Median	5.0	4.0
Q1-Q3	4.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others		
n	25	41
Mean (SD)	4.4 (1.29)	4.2 (1.38)
Min-Max	2 - 6	2 - 6
Median	5.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0
8. Satisfaction with continuing current treatment		
n	25	41
Mean (SD)	4.1 (1.64)	3.7 (1.72)
Min-Max	0 - 6	0 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 6.0	2.0 - 5.0
9. Sum of scores °		
n	25	41
Mean (SD)	25.5 (7.45)	23.3 (7.89)
Min-Max	10 - 36	6 - 36
Median	27.0	24.0
Q1-Q3	19.0 - 32.0	18.0 - 29.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.4 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
1. Satisfaction with current treatment			
n	23	24	19
Mean (SD)	4.0 (1.46)	4.0 (1.81)	4.0 (2.08)
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.0	4.5	5.0
Q1-Q3	3.0 - 5.0	2.0 - 6.0	2.0 - 6.0
2. Impression how often blood glucose was unacceptably high			
n	23	24	19
Mean (SD)	4.0 (1.19)	3.9 (1.35)	3.3 (1.76)
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.0	4.0	3.0
Q1-Q3	4.0 - 5.0	3.0 - 5.0	2.0 - 5.0
3. Impression how often blood glucose was unacceptably low			
n	23	24	19
Mean (SD)	0.8 (1.03)	0.8 (1.06)	1.2 (1.65)
Min-Max	0 - 4	0 - 3	0 - 6
Median	1.0	0.0	1.0
Q1-Q3	0.0 - 1.0	0.0 - 1.0	0.0 - 2.0
4. Practicability/convenience of treatment			
n	23	24	19
Mean (SD)	3.7 (1.40)	4.3 (1.45)	3.9 (1.87)
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.0	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.5	2.0 - 6.0
5. Satisfaction with the flexibility of treatment			
n	23	24	19
Mean (SD)	3.9 (1.59)	4.1 (1.42)	3.9 (1.65)
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.0	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.5	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.4 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
6. Satisfaction with knowledge/understanding of diabetes			
n	23	24	19
Mean (SD)	4.0 (1.40)	4.3 (1.19)	3.9 (1.70)
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.0	4.5	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others			
n	23	24	19
Mean (SD)	4.3 (1.40)	4.2 (1.31)	4.4 (1.38)
Min-Max	2 - 6	2 - 6	2 - 6
Median	5.0	4.0	5.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0	3.0 - 6.0
8. Satisfaction with continuing current treatment			
n	23	24	19
Mean (SD)	3.7 (1.46)	4.3 (1.52)	3.5 (2.09)
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.0	5.0	4.0
Q1-Q3	2.0 - 5.0	3.0 - 5.5	2.0 - 6.0
9. Sum of scores °			
n	23	24	19
Mean (SD)	23.7 (6.99)	25.0 (7.47)	23.6 (9.16)
Min-Max	11 - 36	10 - 36	6 - 36
Median	23.0	26.0	24.0
Q1-Q3	18.0 - 31.0	19.0 - 31.5	17.0 - 32.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.5 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
1. Satisfaction with current treatment		
n	16	50
Mean (SD)	3.6 (2.10)	4.1 (1.63)
Min-Max	0 - 6	1 - 6
Median	4.5	4.0
Q1-Q3	2.0 - 5.0	3.0 - 6.0
2. Impression how often blood glucose was unacceptably high		
n	16	50
Mean (SD)	4.0 (1.67)	3.7 (1.37)
Min-Max	0 - 6	0 - 6
Median	4.5	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low		
n	16	50
Mean (SD)	1.1 (1.26)	0.9 (1.25)
Min-Max	0 - 4	0 - 6
Median	1.0	0.0
Q1-Q3	0.0 - 2.0	0.0 - 1.0
4. Practicability/convenience of treatment		
n	16	50
Mean (SD)	3.8 (1.77)	4.0 (1.50)
Min-Max	0 - 6	1 - 6
Median	4.0	4.0
Q1-Q3	2.5 - 5.0	3.0 - 5.0
5. Satisfaction with the flexibility of treatment		
n	16	50
Mean (SD)	3.8 (1.76)	4.1 (1.46)
Min-Max	0 - 6	1 - 6
Median	4.0	4.0
Q1-Q3	2.5 - 5.0	3.0 - 6.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.5 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
6. Satisfaction with knowledge/understanding of diabetes		
n	16	50
Mean (SD)	3.8 (1.84)	4.2 (1.24)
Min-Max	0 - 6	1 - 6
Median	4.5	4.0
Q1-Q3	2.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others		
n	16	50
Mean (SD)	4.2 (1.42)	4.3 (1.33)
Min-Max	2 - 6	2 - 6
Median	4.5	4.0
Q1-Q3	3.0 - 5.0	3.0 - 6.0
8. Satisfaction with continuing current treatment		
n	16	50
Mean (SD)	3.1 (1.96)	4.1 (1.55)
Min-Max	0 - 6	1 - 6
Median	2.5	4.0
Q1-Q3	2.0 - 4.5	3.0 - 5.0
9. Sum of scores °		
n	16	50
Mean (SD)	22.2 (9.40)	24.8 (7.13)
Min-Max	6 - 36	10 - 36
Median	25.5	24.0
Q1-Q3	13.0 - 30.0	19.0 - 31.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.6 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
1. Satisfaction with current treatment		
n	15	37
Mean (SD)	4.9 (1.71)	4.0 (1.63)
Min-Max	0 - 6	1 - 6
Median	5.0	4.0
Q1-Q3	5.0 - 6.0	3.0 - 5.0
2. Impression how often blood glucose was unacceptably high		
n	15	37
Mean (SD)	3.3 (1.91)	3.9 (1.32)
Min-Max	0 - 6	1 - 6
Median	4.0	4.0
Q1-Q3	2.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low		
n	15	37
Mean (SD)	1.3 (1.75)	0.9 (1.16)
Min-Max	0 - 6	0 - 4
Median	1.0	0.0
Q1-Q3	0.0 - 2.0	0.0 - 1.0
4. Practicability/convenience of treatment		
n	15	37
Mean (SD)	4.9 (1.33)	3.9 (1.49)
Min-Max	2 - 6	1 - 6
Median	5.0	4.0
Q1-Q3	4.0 - 6.0	3.0 - 5.0
5. Satisfaction with the flexibility of treatment		
n	15	37
Mean (SD)	4.7 (1.23)	3.9 (1.53)
Min-Max	2 - 6	1 - 6
Median	5.0	4.0
Q1-Q3	4.0 - 6.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.6 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
6. Satisfaction with knowledge/understanding of diabetes		
n	15	37
Mean (SD)	4.5 (1.41)	4.0 (1.29)
Min-Max	1 - 6	1 - 6
Median	5.0	4.0
Q1-Q3	4.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others		
n	15	37
Mean (SD)	4.7 (1.23)	4.3 (1.36)
Min-Max	3 - 6	2 - 6
Median	5.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0
8. Satisfaction with continuing current treatment		
n	15	37
Mean (SD)	4.5 (1.88)	4.0 (1.51)
Min-Max	0 - 6	1 - 6
Median	5.0	4.0
Q1-Q3	4.0 - 6.0	3.0 - 5.0
9. Sum of scores °		
n	15	37
Mean (SD)	28.3 (7.62)	24.1 (7.14)
Min-Max	10 - 36	10 - 36
Median	31.0	24.0
Q1-Q3	25.0 - 33.0	19.0 - 30.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.7 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
1. Satisfaction with current treatment			
n	6	20	37
Mean (SD)	5.5 (0.84)	3.5 (1.85)	4.0 (1.66)
Min-Max	4 - 6	0 - 6	0 - 6
Median	6.0	3.0	4.0
Q1-Q3	5.0 - 6.0	2.0 - 5.0	3.0 - 5.0
2. Impression how often blood glucose was unacceptably high			
n	6	20	37
Mean (SD)	4.0 (1.41)	4.1 (1.57)	3.6 (1.36)
Min-Max	2 - 6	0 - 6	0 - 6
Median	4.0	4.5	4.0
Q1-Q3	3.0 - 5.0	3.5 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low			
n	6	20	37
Mean (SD)	0.2 (0.41)	1.0 (1.26)	0.9 (1.05)
Min-Max	0 - 1	0 - 4	0 - 3
Median	0.0	1.0	1.0
Q1-Q3	0.0 - 0.0	0.0 - 1.5	0.0 - 2.0
4. Practicability/convenience of treatment			
n	6	20	37
Mean (SD)	4.5 (1.52)	4.0 (1.30)	3.9 (1.65)
Min-Max	2 - 6	2 - 6	0 - 6
Median	4.5	4.0	4.0
Q1-Q3	4.0 - 6.0	3.0 - 5.0	3.0 - 5.0
5. Satisfaction with the flexibility of treatment			
n	6	20	37
Mean (SD)	4.5 (1.64)	4.0 (1.34)	3.9 (1.62)
Min-Max	2 - 6	1 - 6	0 - 6
Median	5.0	4.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.7 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
6. Satisfaction with knowledge/understanding of diabetes			
n	6	20	37
Mean (SD)	4.0 (1.26)	4.1 (1.55)	4.0 (1.38)
Min-Max	2 - 5	1 - 6	0 - 6
Median	4.5	5.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others			
n	6	20	37
Mean (SD)	5.0 (1.26)	4.5 (1.32)	4.1 (1.32)
Min-Max	3 - 6	2 - 6	2 - 6
Median	5.5	5.0	4.0
Q1-Q3	4.0 - 6.0	3.5 - 5.5	3.0 - 5.0
8. Satisfaction with continuing current treatment			
n	6	20	37
Mean (SD)	4.7 (1.51)	3.6 (1.82)	3.9 (1.61)
Min-Max	2 - 6	0 - 6	0 - 6
Median	5.0	3.5	4.0
Q1-Q3	4.0 - 6.0	2.0 - 5.0	3.0 - 5.0
9. Sum of scores °			
n	6	20	37
Mean (SD)	28.2 (5.78)	23.6 (7.47)	23.8 (7.84)
Min-Max	20 - 34	10 - 36	6 - 36
Median	29.5	22.0	24.0
Q1-Q3	23.0 - 33.0	18.5 - 31.0	18.0 - 31.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.8 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
1. Satisfaction with current treatment		
n	36	30
Mean (SD)	4.0 (1.76)	3.9 (1.77)
Min-Max	0 - 6	0 - 6
Median	4.0	4.5
Q1-Q3	3.0 - 6.0	2.0 - 5.0
2. Impression how often blood glucose was unacceptably high		
n	36	30
Mean (SD)	3.5 (1.28)	4.1 (1.60)
Min-Max	1 - 5	0 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low		
n	36	30
Mean (SD)	1.1 (1.34)	0.7 (1.11)
Min-Max	0 - 6	0 - 4
Median	1.0	0.0
Q1-Q3	0.0 - 2.0	0.0 - 1.0
4. Practicability/convenience of treatment		
n	36	30
Mean (SD)	3.9 (1.69)	4.0 (1.41)
Min-Max	0 - 6	2 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 5.5	3.0 - 5.0
5. Satisfaction with the flexibility of treatment		
n	36	30
Mean (SD)	3.9 (1.66)	4.1 (1.37)
Min-Max	0 - 6	1 - 6
Median	4.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.8 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
6. Satisfaction with knowledge/understanding of diabetes		
n	36	30
Mean (SD)	4.2 (1.40)	3.9 (1.42)
Min-Max	0 - 6	1 - 6
Median	4.5	4.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0
7. Recommend treatment to others		
n	36	30
Mean (SD)	4.4 (1.40)	4.1 (1.28)
Min-Max	2 - 6	2 - 6
Median	5.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0
8. Satisfaction with continuing current treatment		
n	36	30
Mean (SD)	3.7 (1.74)	4.0 (1.65)
Min-Max	0 - 6	0 - 6
Median	4.0	4.0
Q1-Q3	2.0 - 5.0	3.0 - 5.0
9. Sum of scores °		
n	36	30
Mean (SD)	24.2 (8.20)	24.1 (7.30)
Min-Max	6 - 36	10 - 36
Median	25.0	23.5
Q1-Q3	18.0 - 31.5	18.0 - 31.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
1. Satisfaction with current treatment				
n	11	24	25	6
Mean (SD)	4.0 (1.48)	3.4 (1.98)	4.3 (1.65)	4.8 (1.33)
Min-Max	2 - 6	0 - 6	1 - 6	3 - 6
Median	3.0	3.5	5.0	5.0
Q1-Q3	3.0 - 6.0	2.0 - 5.0	3.0 - 6.0	4.0 - 6.0
2. Impression how often blood glucose was unacceptably high				
n	11	24	25	6
Mean (SD)	4.1 (1.04)	3.8 (1.40)	3.7 (1.57)	3.2 (1.83)
Min-Max	2 - 5	1 - 6	0 - 6	0 - 5
Median	4.0	4.0	4.0	3.0
Q1-Q3	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low				
n	11	24	25	6
Mean (SD)	0.7 (1.19)	0.7 (0.76)	1.2 (1.55)	1.3 (1.51)
Min-Max	0 - 3	0 - 2	0 - 6	0 - 4
Median	0.0	0.5	1.0	1.0
Q1-Q3	0.0 - 1.0	0.0 - 1.0	0.0 - 2.0	0.0 - 2.0
4. Practicability/convenience of treatment				
n	11	24	25	6
Mean (SD)	4.6 (1.29)	3.5 (1.59)	4.2 (1.49)	4.0 (1.90)
Min-Max	3 - 6	0 - 6	1 - 6	2 - 6
Median	5.0	3.0	4.0	4.0
Q1-Q3	3.0 - 6.0	2.0 - 5.0	3.0 - 5.0	2.0 - 6.0
5. Satisfaction with the flexibility of treatment				
n	11	24	25	6
Mean (SD)	4.5 (1.13)	3.6 (1.74)	4.2 (1.40)	3.8 (1.72)
Min-Max	3 - 6	0 - 6	2 - 6	2 - 6
Median	4.0	3.5	4.0	4.0
Q1-Q3	4.0 - 6.0	2.5 - 5.0	3.0 - 6.0	2.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.9 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
6. Satisfaction with knowledge/understanding of diabetes				
n	11	24	25	6
Mean (SD)	3.9 (0.94)	3.9 (1.75)	4.2 (1.30)	4.5 (1.05)
Min-Max	3 - 5	0 - 6	2 - 6	3 - 6
Median	4.0	4.0	4.0	4.5
Q1-Q3	3.0 - 5.0	2.5 - 5.0	4.0 - 5.0	4.0 - 5.0
7. Recommend treatment to others				
n	11	24	25	6
Mean (SD)	4.5 (1.37)	4.2 (1.47)	4.1 (1.32)	5.0 (0.63)
Min-Max	3 - 6	2 - 6	2 - 6	4 - 6
Median	5.0	4.5	4.0	5.0
Q1-Q3	3.0 - 6.0	3.0 - 5.5	3.0 - 5.0	5.0 - 5.0
8. Satisfaction with continuing current treatment				
n	11	24	25	6
Mean (SD)	4.4 (1.50)	3.4 (1.81)	4.0 (1.65)	4.3 (1.63)
Min-Max	2 - 6	0 - 6	1 - 6	2 - 6
Median	4.0	3.5	4.0	4.5
Q1-Q3	3.0 - 6.0	2.0 - 5.0	2.0 - 5.0	3.0 - 6.0
9. Sum of scores °				
n	11	24	25	6
Mean (SD)	26.0 (6.16)	22.0 (8.48)	24.9 (7.60)	26.5 (7.45)
Min-Max	19 - 34	6 - 36	10 - 36	17 - 36
Median	26.0	20.5	26.0	26.5
Q1-Q3	19.0 - 33.0	16.0 - 30.5	18.0 - 31.0	20.0 - 33.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
1. Satisfaction with current treatment			
n	24	9	32
Mean (SD)	4.2 (1.74)	4.1 (1.76)	3.7 (1.78)
Min-Max	1 - 6	1 - 6	0 - 6
Median	5.0	5.0	4.0
Q1-Q3	2.5 - 6.0	3.0 - 5.0	2.5 - 5.0
2. Impression how often blood glucose was unacceptably high			
n	24	9	32
Mean (SD)	3.5 (1.64)	3.4 (1.33)	4.1 (1.29)
Min-Max	0 - 6	1 - 5	1 - 6
Median	4.0	4.0	4.0
Q1-Q3	2.5 - 5.0	3.0 - 4.0	3.0 - 5.0
3. Impression how often blood glucose was unacceptably low			
n	24	9	32
Mean (SD)	0.9 (1.08)	1.0 (0.87)	1.0 (1.47)
Min-Max	0 - 4	0 - 2	0 - 6
Median	1.0	1.0	0.0
Q1-Q3	0.0 - 1.0	0.0 - 2.0	0.0 - 1.5
4. Practicability/convenience of treatment			
n	24	9	32
Mean (SD)	4.3 (1.71)	3.9 (1.45)	3.7 (1.49)
Min-Max	1 - 6	2 - 6	0 - 6
Median	5.0	4.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0	3.0 - 5.0
5. Satisfaction with the flexibility of treatment			
n	24	9	32
Mean (SD)	4.3 (1.54)	4.0 (1.58)	3.8 (1.54)
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.5	4.0	4.0
Q1-Q3	3.0 - 6.0	3.0 - 5.0	3.0 - 5.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

2 Disposition and Baseline Characteristics
2.8 Patient questionnaires on therapy satisfaction DTSQs - continuous
2.8.10 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
6. Satisfaction with knowledge/understanding of diabetes			
n	24	9	32
Mean (SD)	4.3 (1.20)	4.4 (0.88)	3.8 (1.61)
Min-Max	2 - 6	3 - 6	0 - 6
Median	4.0	4.0	4.0
Q1-Q3	3.5 - 5.0	4.0 - 5.0	2.5 - 5.0
7. Recommend treatment to others			
n	24	9	32
Mean (SD)	4.5 (1.44)	4.4 (1.13)	4.0 (1.33)
Min-Max	2 - 6	2 - 6	2 - 6
Median	5.0	5.0	4.0
Q1-Q3	3.0 - 6.0	4.0 - 5.0	3.0 - 5.0
8. Satisfaction with continuing current treatment			
n	24	9	32
Mean (SD)	3.9 (1.86)	3.8 (1.48)	3.8 (1.69)
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.0	3.0	4.0
Q1-Q3	2.0 - 6.0	3.0 - 5.0	2.5 - 5.0
9. Sum of scores °			
n	24	9	32
Mean (SD)	25.5 (8.03)	24.7 (6.84)	22.8 (7.81)
Min-Max	10 - 36	13 - 32	6 - 36
Median	26.0	24.0	23.0
Q1-Q3	19.5 - 33.0	21.0 - 31.0	18.0 - 29.0

1./5./6./8.: Rating scale 6 = very satisfied - 0 = very dissatisfied
2./3.: Rating scale 6 = the most time - 0 = at no time
4.: Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
7.: Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
° Sum of scores from 1, 4, 5, 6, 7 and 8

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.1 Full Analysis Set - FGM - SMBG

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.820)	8.44 (0.761)	8.55 (0.848)
95% CL	[8.32; 8.71]	[8.08; 8.80]	[8.31; 8.79]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 10.8
Median	8.30	8.25	8.45
Q1-Q3	7.80 - 9.20	7.85 - 8.90	7.80 - 9.27
After 12 weeks			
n	68	20	48
Mean (SD)	7.89 (0.814)	8.00 (0.903)	7.85 (0.780)
95% CL	[7.70; 8.09]	[7.57; 8.42]	[7.62; 8.08]
Min-Max	5.9 - 9.7	6.5 - 9.7	5.9 - 9.3
Median	7.80	7.90	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.70	7.35 - 8.40
Change from baseline			
n	68	20	48
Mean (SD)	-0.64 (0.782)	-0.45 (0.621)	-0.71 (0.834)
95% CL	[-0.82; -0.45]	[-0.74; -0.16]	[-0.96; -0.47]
Min-Max	-2.6 - 1.3	-1.6 - 1.3	-2.6 - 0.7
Median	-0.50	-0.45	-0.60
Q1-Q3	-0.90 - -0.10	-0.65 - -0.20	-1.09 - -0.10
T-Test	t= -6.69 P= 0.000	t= -3.21 P= 0.005	t= -5.93 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.2 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	8.44 (0.815)	8.57 (0.829)
95% CL	[8.12; 8.76]	[8.31; 8.83]
Min-Max	7.5 - 10	7.5 - 10.8
Median	8.25	8.35
Q1-Q3	7.70 - 9.04	8.00 - 9.20
After 12 weeks		
n	27	41
Mean (SD)	7.94 (0.889)	7.86 (0.770)
95% CL	[7.59; 8.30]	[7.62; 8.10]
Min-Max	5.9 - 9.7	6.4 - 9.5
Median	7.80	7.70
Q1-Q3	7.40 - 8.40	7.40 - 8.50
Change from baseline		
n	27	41
Mean (SD)	-0.51 (0.739)	-0.72 (0.809)
95% CL	[-0.81; -0.22]	[-0.97; -0.46]
Min-Max	-2.1 - 0.7	-2.6 - 1.3
Median	-0.40	-0.60
Q1-Q3	-0.90 - -0.10	-1.10 - -0.20
T-Test	t= -3.61 P= 0.001	t= -5.67 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.3 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	8.68 (0.998)	8.48 (0.717)	8.39 (0.712)
95% CL	[8.26; 9.10]	[8.18; 8.78]	[8.07; 8.70]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 9.8
Median	8.55	8.35	8.20
Q1-Q3	7.75 - 9.62	7.90 - 8.75	7.70 - 8.80
After 12 weeks			
n	24	23	21
Mean (SD)	8.05 (0.838)	7.81 (0.898)	7.80 (0.690)
95% CL	[7.70; 8.41]	[7.42; 8.20]	[7.49; 8.11]
Min-Max	6.9 - 9.7	5.9 - 9.3	6.6 - 9.3
Median	7.85	7.80	7.50
Q1-Q3	7.35 - 8.70	7.40 - 8.40	7.40 - 8.40
Change from baseline			
n	24	23	21
Mean (SD)	-0.63 (0.879)	-0.67 (0.770)	-0.60 (0.712)
95% CL	[-1.00; -0.25]	[-1.01; -0.34]	[-0.93; -0.28]
Min-Max	-2.6 - 1.3	-2.4 - 0.7	-2.2 - 0.7
Median	-0.50	-0.60	-0.50
Q1-Q3	-1.16 - -0.15	-0.90 - -0.10	-0.80 - -0.20
T-Test	t= -3.49 P= 0.002	t= -4.19 P= 0.000	t= -3.89 P= 0.001

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.4 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	8.75 (0.854)	8.44 (0.801)
95% CL	[8.33; 9.17]	[8.22; 8.66]
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.85	8.25
Q1-Q3	8.10 - 9.40	7.80 - 8.80
After 12 weeks		
n	18	50
Mean (SD)	8.11 (0.874)	7.81 (0.785)
95% CL	[7.68; 8.55]	[7.59; 8.04]
Min-Max	6.5 - 9.7	5.9 - 9.5
Median	8.35	7.80
Q1-Q3	7.30 - 8.80	7.40 - 8.40
Change from baseline		
n	18	50
Mean (SD)	-0.64 (0.768)	-0.63 (0.795)
95% CL	[-1.02; -0.26]	[-0.86; -0.41]
Min-Max	-2.2 - 0.7	-2.6 - 1.3
Median	-0.45	-0.50
Q1-Q3	-0.90 - -0.20	-0.90 - -0.10
T-Test	t= -3.53 P= 0.003	t= -5.64 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.5 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	8.64 (0.700)	8.31 (0.703)
95% CL	[8.28; 9.00]	[8.09; 8.54]
Min-Max	7.5 - 9.8	7.5 - 10
Median	8.70	8.20
Q1-Q3	8.10 - 9.20	7.70 - 8.70
After 12 weeks		
n	17	38
Mean (SD)	7.89 (0.800)	7.87 (0.854)
95% CL	[7.48; 8.30]	[7.59; 8.15]
Min-Max	6.5 - 9.3	5.9 - 9.7
Median	7.80	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.40
Change from baseline		
n	17	38
Mean (SD)	-0.75 (0.762)	-0.44 (0.732)
95% CL	[-1.14; -0.36]	[-0.68; -0.20]
Min-Max	-2.2 - 0.7	-2.4 - 1.3
Median	-0.60	-0.35
Q1-Q3	-0.90 - -0.30	-0.80 - -0.10
T-Test	t= -4.04 P= 0.001	t= -3.69 P= 0.001

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.6 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	8.37 (0.998)	8.72 (0.879)	8.47 (0.778)
95% CL	[7.44; 9.29]	[8.32; 9.12]	[8.22; 8.72]
Min-Max	7.5 - 10	7.6 - 9.9	7.5 - 10.8
Median	7.90	8.60	8.40
Q1-Q3	7.50 - 9.27	8.00 - 9.50	7.80 - 8.80
After 12 weeks			
n	7	21	37
Mean (SD)	7.56 (0.574)	8.07 (0.955)	7.89 (0.780)
95% CL	[7.03; 8.09]	[7.64; 8.51]	[7.63; 8.15]
Min-Max	6.4 - 8.2	6.6 - 9.7	5.9 - 9.3
Median	7.70	8.00	7.80
Q1-Q3	7.40 - 7.90	7.30 - 8.90	7.40 - 8.40
Change from baseline			
n	7	21	37
Mean (SD)	-0.81 (1.064)	-0.65 (0.994)	-0.60 (0.627)
95% CL	[-1.79; 0.17]	[-1.10; -0.20]	[-0.80; -0.39]
Min-Max	-2.4 - 0.2	-2.6 - 1.3	-2.2 - 0.7
Median	-0.10	-0.50	-0.50
Q1-Q3	-2.10 - -0.10	-0.90 - -0.20	-0.90 - -0.20
T-Test	t= -2.01 P= 0.091	t= -3.01 P= 0.007	t= -5.77 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.7 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	7.89 (0.303)	9.26 (0.579)
95% CL	[7.79; 7.99]	[9.05; 9.47]
Min-Max	7.5 - 8.4	8.5 - 10.8
Median	7.85	9.29
Q1-Q3	7.60 - 8.20	8.75 - 9.77
After 12 weeks		
n	36	32
Mean (SD)	7.50 (0.671)	8.33 (0.740)
95% CL	[7.28; 7.73]	[8.06; 8.60]
Min-Max	5.9 - 9.5	6.4 - 9.7
Median	7.40	8.40
Q1-Q3	7.10 - 7.80	7.85 - 8.90
Change from baseline		
n	36	32
Mean (SD)	-0.37 (0.607)	-0.93 (0.858)
95% CL	[-0.58; -0.17]	[-1.24; -0.62]
Min-Max	-1.6 - 1.3	-2.6 - 0.7
Median	-0.35	-0.70
Q1-Q3	-0.80 - 0.00	-1.60 - -0.35
T-Test	t= -3.68 P= 0.001	t= -6.14 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	8.69 (0.865)	8.57 (0.770)	8.45 (0.883)	8.33 (0.745)
95% CL	[8.10; 9.27]	[8.24; 8.89]	[8.12; 8.79]	[7.55; 9.11]
Min-Max	7.6 - 9.9	7.5 - 9.9	7.5 - 10.8	7.5 - 9.4
Median	8.40	8.35	8.20	8.30
Q1-Q3	7.90 - 9.70	8.05 - 9.10	7.70 - 8.80	7.60 - 8.90
After 12 weeks				
n	11	22	29	6
Mean (SD)	8.04 (0.706)	8.11 (0.913)	7.66 (0.794)	7.95 (0.524)
95% CL	[7.56; 8.51]	[7.70; 8.51]	[7.36; 7.96]	[7.40; 8.50]
Min-Max	6.6 - 8.9	6.5 - 9.7	5.9 - 9.3	7.3 - 8.7
Median	8.00	8.20	7.50	7.85
Q1-Q3	7.50 - 8.70	7.40 - 8.90	7.20 - 8.20	7.60 - 8.40
Change from baseline				
n	11	22	29	6
Mean (SD)	-0.65 (0.662)	-0.49 (0.848)	-0.79 (0.764)	-0.38 (0.852)
95% CL	[-1.09; -0.20]	[-0.87; -0.11]	[-1.08; -0.50]	[-1.28; 0.51]
Min-Max	-1.9 - 0.3	-2.6 - 1.3	-2.4 - 0.7	-2.1 - 0.2
Median	-0.50	-0.50	-0.80	-0.10
Q1-Q3	-1.24 - -0.10	-0.80 - 0.00	-1.10 - -0.40	-0.20 - 0.00
T-Test	t= -3.26 P= 0.009	t= -2.71 P= 0.013	t= -5.58 P= 0.000	t= -1.10 P= 0.321

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
3.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	8.53 (0.886)	8.33 (0.589)	8.58 (0.837)
95% CL	[8.18; 8.87]	[7.88; 8.79]	[8.28; 8.88]
Min-Max	7.5 - 10.8	7.6 - 9.3	7.5 - 10
Median	8.40	8.30	8.44
Q1-Q3	7.75 - 9.34	7.90 - 8.50	7.85 - 9.25
After 12 weeks			
n	27	9	32
Mean (SD)	7.83 (0.834)	7.97 (0.618)	7.92 (0.862)
95% CL	[7.50; 8.16]	[7.49; 8.44]	[7.61; 8.23]
Min-Max	5.9 - 9.3	7.1 - 8.9	6.4 - 9.7
Median	7.80	8.00	7.80
Q1-Q3	7.20 - 8.40	7.40 - 8.40	7.40 - 8.45
Change from baseline			
n	27	9	32
Mean (SD)	-0.70 (0.924)	-0.37 (0.371)	-0.66 (0.740)
95% CL	[-1.06; -0.33]	[-0.65; -0.08]	[-0.92; -0.39]
Min-Max	-2.6 - 0.7	-0.9 - 0.2	-2.4 - 1.3
Median	-0.60	-0.30	-0.50
Q1-Q3	-1.60 - 0.00	-0.50 - -0.10	-0.90 - -0.24
T-Test	t= -3.93 P= 0.001	t= -2.97 P= 0.018	t= -5.02 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.1 Full Analysis Set - FGM - SMBG

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.820)	8.44 (0.761)	8.55 (0.848)
95% CL	[8.32; 8.71]	[8.08; 8.80]	[8.31; 8.79]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 10.8
Median	8.30	8.25	8.45
Q1-Q3	7.80 - 9.20	7.85 - 8.90	7.80 - 9.27
After 24 weeks			
n	68	20	48
Mean (SD)	7.74 (0.759)	7.75 (0.851)	7.74 (0.728)
95% CL	[7.56; 7.93]	[7.35; 8.14]	[7.53; 7.96]
Min-Max	5.8 - 9.8	6.4 - 9.8	5.8 - 9.2
Median	7.80	7.80	7.75
Q1-Q3	7.20 - 8.20	7.10 - 7.95	7.20 - 8.25
Change from baseline			
n	68	20	48
Mean (SD)	-0.74 (0.811)	-0.70 (0.739)	-0.76 (0.846)
95% CL	[-0.94; -0.55]	[-1.04; -0.35]	[-1.01; -0.52]
Min-Max	-3 - 0.5	-1.9 - 0.5	-3 - 0.3
Median	-0.50	-0.55	-0.50
Q1-Q3	-1.30 - -0.10	-1.40 - -0.10	-1.25 - -0.10
T-Test	t= -7.55 P= 0.000	t= -4.21 P= 0.000	t= -6.24 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.2 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	8.44 (0.815)	8.57 (0.829)
95% CL	[8.12; 8.76]	[8.31; 8.83]
Min-Max	7.5 - 10	7.5 - 10.8
Median	8.25	8.35
Q1-Q3	7.70 - 9.04	8.00 - 9.20
After 24 weeks		
n	26	42
Mean (SD)	7.61 (0.706)	7.83 (0.788)
95% CL	[7.33; 7.90]	[7.58; 8.07]
Min-Max	5.8 - 8.9	6.4 - 9.8
Median	7.70	7.90
Q1-Q3	7.20 - 8.00	7.20 - 8.30
Change from baseline		
n	26	42
Mean (SD)	-0.74 (0.795)	-0.74 (0.831)
95% CL	[-1.06; -0.42]	[-1.00; -0.48]
Min-Max	-2.8 - 0.3	-3 - 0.5
Median	-0.55	-0.50
Q1-Q3	-1.30 - -0.10	-1.20 - -0.10
T-Test	t= -4.75 P= 0.000	t= -5.80 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.3 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	8.68 (0.998)	8.48 (0.717)	8.39 (0.712)
95% CL	[8.26; 9.10]	[8.18; 8.78]	[8.07; 8.70]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 9.8
Median	8.55	8.35	8.20
Q1-Q3	7.75 - 9.62	7.90 - 8.75	7.70 - 8.80
After 24 weeks			
n	24	24	20
Mean (SD)	7.70 (0.850)	7.75 (0.756)	7.80 (0.680)
95% CL	[7.34; 8.06]	[7.43; 8.06]	[7.48; 8.11]
Min-Max	5.8 - 9.8	6.2 - 8.9	6.5 - 9.2
Median	7.65	7.85	7.85
Q1-Q3	7.15 - 8.10	7.35 - 8.30	7.30 - 8.25
Change from baseline			
n	24	24	20
Mean (SD)	-0.98 (1.061)	-0.73 (0.707)	-0.47 (0.452)
95% CL	[-1.43; -0.53]	[-1.03; -0.43]	[-0.68; -0.26]
Min-Max	-3 - 0.5	-2.3 - 0.3	-1.3 - 0.2
Median	-0.65	-0.45	-0.40
Q1-Q3	-1.77 - 0.00	-1.20 - -0.20	-0.70 - -0.15
T-Test	t= -4.52 P= 0.000	t= -5.08 P= 0.000	t= -4.65 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.4 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	8.75 (0.854)	8.44 (0.801)
95% CL	[8.33; 9.17]	[8.22; 8.66]
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.85	8.25
Q1-Q3	8.10 - 9.40	7.80 - 8.80
After 24 weeks		
n	16	52
Mean (SD)	8.07 (0.815)	7.64 (0.721)
95% CL	[7.63; 8.50]	[7.44; 7.84]
Min-Max	6.6 - 9.4	5.8 - 9.8
Median	8.10	7.70
Q1-Q3	7.55 - 8.75	7.20 - 8.10
Change from baseline		
n	16	52
Mean (SD)	-0.58 (0.647)	-0.79 (0.855)
95% CL	[-0.92; -0.23]	[-1.03; -0.56]
Min-Max	-1.9 - 0.2	-3 - 0.5
Median	-0.60	-0.50
Q1-Q3	-0.95 - 0.00	-1.30 - -0.15
T-Test	t= -3.56 P= 0.003	t= -6.70 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.5 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	8.64 (0.700)	8.31 (0.703)
95% CL	[8.28; 9.00]	[8.09; 8.54]
Min-Max	7.5 - 9.8	7.5 - 10
Median	8.70	8.20
Q1-Q3	8.10 - 9.20	7.70 - 8.70
After 24 weeks		
n	15	39
Mean (SD)	8.07 (0.801)	7.67 (0.706)
95% CL	[7.63; 8.52]	[7.44; 7.90]
Min-Max	6.6 - 9.4	6.2 - 9.8
Median	8.10	7.80
Q1-Q3	7.50 - 8.70	7.20 - 8.20
Change from baseline		
n	15	39
Mean (SD)	-0.43 (0.507)	-0.65 (0.739)
95% CL	[-0.71; -0.15]	[-0.89; -0.41]
Min-Max	-1.5 - 0.3	-2.8 - 0.5
Median	-0.30	-0.50
Q1-Q3	-0.70 - -0.10	-1.20 - -0.10
T-Test	t= -3.31 P= 0.005	t= -5.47 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.6 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	8.37 (0.998)	8.72 (0.879)	8.47 (0.778)
95% CL	[7.44; 9.29]	[8.32; 9.12]	[8.22; 8.72]
Min-Max	7.5 - 10	7.6 - 9.9	7.5 - 10.8
Median	7.90	8.60	8.40
Q1-Q3	7.50 - 9.27	8.00 - 9.50	7.80 - 8.80
After 24 weeks			
n	7	19	39
Mean (SD)	7.39 (0.474)	7.85 (0.956)	7.78 (0.702)
95% CL	[6.95; 7.82]	[7.39; 8.31]	[7.55; 8.01]
Min-Max	6.8 - 8.2	5.8 - 9.8	6.2 - 9.2
Median	7.50	7.80	7.90
Q1-Q3	6.90 - 7.60	7.40 - 8.50	7.20 - 8.30
Change from baseline			
n	7	19	39
Mean (SD)	-0.98 (1.057)	-0.78 (1.080)	-0.69 (0.630)
95% CL	[-1.96; -0.00]	[-1.30; -0.26]	[-0.89; -0.49]
Min-Max	-2.8 - 0	-3 - 0.5	-2.7 - 0.3
Median	-0.60	-0.50	-0.50
Q1-Q3	-2.00 - -0.10	-1.90 - 0.20	-1.20 - -0.20
T-Test	t= -2.46 P= 0.049	t= -3.14 P= 0.006	t= -6.84 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.7 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	7.89 (0.303)	9.26 (0.579)
95% CL	[7.79; 7.99]	[9.05; 9.47]
Min-Max	7.5 - 8.4	8.5 - 10.8
Median	7.85	9.29
Q1-Q3	7.60 - 8.20	8.75 - 9.77
After 24 weeks		
n	38	30
Mean (SD)	7.43 (0.646)	8.14 (0.715)
95% CL	[7.22; 7.64]	[7.87; 8.41]
Min-Max	5.8 - 8.7	6.8 - 9.8
Median	7.50	8.10
Q1-Q3	6.90 - 7.90	7.60 - 8.60
Change from baseline		
n	38	30
Mean (SD)	-0.46 (0.582)	-1.10 (0.923)
95% CL	[-0.65; -0.27]	[-1.44; -0.76]
Min-Max	-2 - 0.5	-3 - 0.3
Median	-0.35	-0.90
Q1-Q3	-0.70 - -0.10	-1.80 - -0.40
T-Test	t= -4.87 P= 0.000	t= -6.53 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	8.69 (0.865)	8.57 (0.770)	8.45 (0.883)	8.33 (0.745)
95% CL	[8.10; 9.27]	[8.24; 8.89]	[8.12; 8.79]	[7.55; 9.11]
Min-Max	7.6 - 9.9	7.5 - 9.9	7.5 - 10.8	7.5 - 9.4
Median	8.40	8.35	8.20	8.30
Q1-Q3	7.90 - 9.70	8.05 - 9.10	7.70 - 8.80	7.60 - 8.90
After 24 weeks				
n	11	23	29	5
Mean (SD)	7.77 (0.690)	7.68 (0.885)	7.74 (0.742)	8.00 (0.447)
95% CL	[7.31; 8.24]	[7.30; 8.07]	[7.46; 8.02]	[7.44; 8.56]
Min-Max	6.4 - 8.8	5.8 - 9.8	6.2 - 9.2	7.5 - 8.7
Median	7.70	7.70	7.90	7.90
Q1-Q3	7.50 - 8.30	6.90 - 8.00	7.20 - 8.20	7.80 - 8.10
Change from baseline				
n	11	23	29	5
Mean (SD)	-0.91 (0.846)	-0.83 (0.896)	-0.72 (0.771)	-0.12 (0.228)
95% CL	[-1.48; -0.34]	[-1.22; -0.44]	[-1.01; -0.42]	[-0.40; 0.16]
Min-Max	-2.3 - 0	-3 - 0.5	-2.8 - 0.3	-0.4 - 0.2
Median	-0.60	-0.60	-0.50	-0.20
Q1-Q3	-1.70 - -0.10	-1.40 - -0.10	-1.07 - -0.30	-0.20 - 0.00
T-Test	t= -3.58 P= 0.005	t= -4.44 P= 0.000	t= -5.00 P= 0.000	t= -1.18 P= 0.305

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
3.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	8.53 (0.886)	8.33 (0.589)	8.58 (0.837)
95% CL	[8.18; 8.87]	[7.88; 8.79]	[8.28; 8.88]
Min-Max	7.5 - 10.8	7.6 - 9.3	7.5 - 10
Median	8.40	8.30	8.44
Q1-Q3	7.75 - 9.34	7.90 - 8.50	7.85 - 9.25
After 24 weeks			
n	27	9	31
Mean (SD)	7.72 (0.823)	7.89 (0.751)	7.72 (0.736)
95% CL	[7.40; 8.05]	[7.31; 8.47]	[7.45; 7.99]
Min-Max	5.8 - 9.2	6.9 - 9.4	6.4 - 9.8
Median	7.70	7.90	7.70
Q1-Q3	7.20 - 8.30	7.30 - 8.10	7.20 - 8.20
Change from baseline			
n	27	9	31
Mean (SD)	-0.77 (0.873)	-0.44 (0.340)	-0.82 (0.855)
95% CL	[-1.12; -0.43]	[-0.71; -0.18]	[-1.14; -0.51]
Min-Max	-3 - 0.3	-1 - 0.2	-2.8 - 0.5
Median	-0.50	-0.40	-0.60
Q1-Q3	-1.30 - -0.20	-0.50 - -0.40	-1.50 - -0.10
T-Test	t= -4.60 P= 0.000	t= -3.93 P= 0.004	t= -5.36 P= 0.000

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.1 Full Analysis Set - FGM - SMBG

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
12 weeks			
n	68	20	48
Mean (SD)	7.89 (0.814)	8.00 (0.903)	7.85 (0.780)
95% CL	[7.70; 8.09]	[7.57; 8.42]	[7.62; 8.08]
Min-Max	5.9 - 9.7	6.5 - 9.7	5.9 - 9.3
Median	7.80	7.90	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.70	7.35 - 8.40
After 24 weeks			
n	68	20	48
Mean (SD)	7.74 (0.759)	7.75 (0.851)	7.74 (0.728)
95% CL	[7.56; 7.93]	[7.35; 8.14]	[7.53; 7.96]
Min-Max	5.8 - 9.8	6.4 - 9.8	5.8 - 9.2
Median	7.80	7.80	7.75
Q1-Q3	7.20 - 8.20	7.10 - 7.95	7.20 - 8.25
Change from 12 weeks			
n	66	20	46
Mean (SD)	-0.15 (0.570)	-0.25 (0.593)	-0.10 (0.560)
95% CL	[-0.29; -0.01]	[-0.53; 0.03]	[-0.27; 0.06]
Min-Max	-1.7 - 1.8	-1.7 - 0.8	-1.3 - 1.8
Median	-0.15	-0.25	-0.10
Q1-Q3	-0.50 - 0.20	-0.55 - 0.20	-0.40 - 0.20
T-Test	t= -2.10 P= 0.040	t= -1.88 P= 0.075	t= -1.24 P= 0.222

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.2 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
12 weeks		
n	27	41
Mean (SD)	7.94 (0.889)	7.86 (0.770)
95% CL	[7.59; 8.30]	[7.62; 8.10]
Min-Max	5.9 - 9.7	6.4 - 9.5
Median	7.80	7.70
Q1-Q3	7.40 - 8.40	7.40 - 8.50
After 24 weeks		
n	26	42
Mean (SD)	7.61 (0.706)	7.83 (0.788)
95% CL	[7.33; 7.90]	[7.58; 8.07]
Min-Max	5.8 - 8.9	6.4 - 9.8
Median	7.70	7.90
Q1-Q3	7.20 - 8.00	7.20 - 8.30
Change from 12 weeks		
n	25	41
Mean (SD)	-0.32 (0.575)	-0.04 (0.548)
95% CL	[-0.55; -0.08]	[-0.22; 0.13]
Min-Max	-1.7 - 0.5	-1.1 - 1.8
Median	-0.30	-0.10
Q1-Q3	-0.70 - 0.20	-0.40 - 0.10
T-Test	t= -2.75 P= 0.011	t= -0.51 P= 0.611

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.3 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
12 weeks			
n	24	23	21
Mean (SD)	8.05 (0.838)	7.81 (0.898)	7.80 (0.690)
95% CL	[7.70; 8.41]	[7.42; 8.20]	[7.49; 8.11]
Min-Max	6.9 - 9.7	5.9 - 9.3	6.6 - 9.3
Median	7.85	7.80	7.50
Q1-Q3	7.35 - 8.70	7.40 - 8.40	7.40 - 8.40
After 24 weeks			
n	24	24	20
Mean (SD)	7.70 (0.850)	7.75 (0.756)	7.80 (0.680)
95% CL	[7.34; 8.06]	[7.43; 8.06]	[7.48; 8.11]
Min-Max	5.8 - 9.8	6.2 - 8.9	6.5 - 9.2
Median	7.65	7.85	7.85
Q1-Q3	7.15 - 8.10	7.35 - 8.30	7.30 - 8.25
Change from 12 weeks			
n	24	23	19
Mean (SD)	-0.35 (0.669)	-0.09 (0.386)	0.04 (0.564)
95% CL	[-0.64; -0.07]	[-0.25; 0.08]	[-0.23; 0.31]
Min-Max	-1.7 - 1.1	-1 - 0.7	-0.7 - 1.8
Median	-0.40	-0.10	-0.10
Q1-Q3	-0.80 - 0.05	-0.30 - 0.10	-0.40 - 0.20
T-Test	t= -2.60 P= 0.016	t= -1.08 P= 0.292	t= 0.33 P= 0.749

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.4 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
12 weeks		
n	18	50
Mean (SD)	8.11 (0.874)	7.81 (0.785)
95% CL	[7.68; 8.55]	[7.59; 8.04]
Min-Max	6.5 - 9.7	5.9 - 9.5
Median	8.35	7.80
Q1-Q3	7.30 - 8.80	7.40 - 8.40
After 24 weeks		
n	16	52
Mean (SD)	8.07 (0.815)	7.64 (0.721)
95% CL	[7.63; 8.50]	[7.44; 7.84]
Min-Max	6.6 - 9.4	5.8 - 9.8
Median	8.10	7.70
Q1-Q3	7.55 - 8.75	7.20 - 8.10
Change from 12 weeks		
n	16	50
Mean (SD)	-0.02 (0.704)	-0.19 (0.521)
95% CL	[-0.39; 0.36]	[-0.34; -0.04]
Min-Max	-1.7 - 1.8	-1.3 - 1.1
Median	0.00	-0.20
Q1-Q3	-0.20 - 0.15	-0.50 - 0.20
T-Test	t= -0.11 P= 0.917	t= -2.55 P= 0.014

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.5 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
12 weeks		
n	17	38
Mean (SD)	7.89 (0.800)	7.87 (0.854)
95% CL	[7.48; 8.30]	[7.59; 8.15]
Min-Max	6.5 - 9.3	5.9 - 9.7
Median	7.80	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.40
After 24 weeks		
n	15	39
Mean (SD)	8.07 (0.801)	7.67 (0.706)
95% CL	[7.63; 8.52]	[7.44; 7.90]
Min-Max	6.6 - 9.4	6.2 - 9.8
Median	8.10	7.80
Q1-Q3	7.50 - 8.70	7.20 - 8.20
Change from 12 weeks		
n	15	38
Mean (SD)	0.24 (0.573)	-0.22 (0.560)
95% CL	[-0.08; 0.56]	[-0.41; -0.04]
Min-Max	-0.7 - 1.8	-1.7 - 1.1
Median	0.20	-0.20
Q1-Q3	0.00 - 0.50	-0.50 - 0.10
T-Test	t= 1.62 P= 0.127	t= -2.46 P= 0.019

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.6 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
12 weeks			
n	7	21	37
Mean (SD)	7.56 (0.574)	8.07 (0.955)	7.89 (0.780)
95% CL	[7.03; 8.09]	[7.64; 8.51]	[7.63; 8.15]
Min-Max	6.4 - 8.2	6.6 - 9.7	5.9 - 9.3
Median	7.70	8.00	7.80
Q1-Q3	7.40 - 7.90	7.30 - 8.90	7.40 - 8.40
After 24 weeks			
n	7	19	39
Mean (SD)	7.39 (0.474)	7.85 (0.956)	7.78 (0.702)
95% CL	[6.95; 7.82]	[7.39; 8.31]	[7.55; 8.01]
Min-Max	6.8 - 8.2	5.8 - 9.8	6.2 - 9.2
Median	7.50	7.80	7.90
Q1-Q3	6.90 - 7.60	7.40 - 8.50	7.20 - 8.30
Change from 12 weeks			
n	7	19	37
Mean (SD)	-0.17 (0.359)	-0.19 (0.704)	-0.13 (0.535)
95% CL	[-0.50; 0.16]	[-0.53; 0.14]	[-0.31; 0.05]
Min-Max	-0.7 - 0.4	-1.7 - 1.1	-1.1 - 1.8
Median	-0.20	-0.10	-0.20
Q1-Q3	-0.50 - 0.00	-0.50 - 0.20	-0.40 - 0.20
T-Test	t= -1.26 P= 0.254	t= -1.21 P= 0.243	t= -1.45 P= 0.157

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.7 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
12 weeks		
n	36	32
Mean (SD)	7.50 (0.671)	8.33 (0.740)
95% CL	[7.28; 7.73]	[8.06; 8.60]
Min-Max	5.9 - 9.5	6.4 - 9.7
Median	7.40	8.40
Q1-Q3	7.10 - 7.80	7.85 - 8.90
After 24 weeks		
n	38	30
Mean (SD)	7.43 (0.646)	8.14 (0.715)
95% CL	[7.22; 7.64]	[7.87; 8.41]
Min-Max	5.8 - 8.7	6.8 - 9.8
Median	7.50	8.10
Q1-Q3	6.90 - 7.90	7.60 - 8.60
Change from 12 weeks		
n	36	30
Mean (SD)	-0.11 (0.461)	-0.19 (0.683)
95% CL	[-0.26; 0.05]	[-0.45; 0.06]
Min-Max	-1.1 - 1.1	-1.7 - 1.8
Median	-0.10	-0.20
Q1-Q3	-0.50 - 0.20	-0.50 - 0.10
T-Test	t= -1.41 P= 0.167	t= -1.55 P= 0.132

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
12 weeks				
n	11	22	29	6
Mean (SD)	8.04 (0.706)	8.11 (0.913)	7.66 (0.794)	7.95 (0.524)
95% CL	[7.56; 8.51]	[7.70; 8.51]	[7.36; 7.96]	[7.40; 8.50]
Min-Max	6.6 - 8.9	6.5 - 9.7	5.9 - 9.3	7.3 - 8.7
Median	8.00	8.20	7.50	7.85
Q1-Q3	7.50 - 8.70	7.40 - 8.90	7.20 - 8.20	7.60 - 8.40
After 24 weeks				
n	11	23	29	5
Mean (SD)	7.77 (0.690)	7.68 (0.885)	7.74 (0.742)	8.00 (0.447)
95% CL	[7.31; 8.24]	[7.30; 8.07]	[7.46; 8.02]	[7.44; 8.56]
Min-Max	6.4 - 8.8	5.8 - 9.8	6.2 - 9.2	7.5 - 8.7
Median	7.70	7.70	7.90	7.90
Q1-Q3	7.50 - 8.30	6.90 - 8.00	7.20 - 8.20	7.80 - 8.10
Change from 12 weeks				
n	11	21	29	5
Mean (SD)	-0.26 (0.396)	-0.41 (0.600)	0.08 (0.570)	-0.08 (0.192)
95% CL	[-0.53; 0.00]	[-0.68; -0.14]	[-0.14; 0.29]	[-0.32; 0.16]
Min-Max	-1 - 0.3	-1.7 - 0.8	-1.1 - 1.8	-0.3 - 0.2
Median	-0.20	-0.50	-0.10	-0.10
Q1-Q3	-0.40 - 0.00	-0.70 - 0.10	-0.20 - 0.40	-0.20 - 0.00
T-Test	t= -2.21 P= 0.052	t= -3.13 P= 0.005	t= 0.72 P= 0.480	t= -0.93 P= 0.405

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

3 Effectiveness - Absolute change in HbA1c [%] under iGlarLixi
3.3 Change in HbA1c (%) under iGlarLixi from 12 weeks to the visit after approx. 24 weeks
3.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
12 weeks			
n	27	9	32
Mean (SD)	7.83 (0.834)	7.97 (0.618)	7.92 (0.862)
95% CL	[7.50; 8.16]	[7.49; 8.44]	[7.61; 8.23]
Min-Max	5.9 - 9.3	7.1 - 8.9	6.4 - 9.7
Median	7.80	8.00	7.80
Q1-Q3	7.20 - 8.40	7.40 - 8.40	7.40 - 8.45
After 24 weeks			
n	27	9	31
Mean (SD)	7.72 (0.823)	7.89 (0.751)	7.72 (0.736)
95% CL	[7.40; 8.05]	[7.31; 8.47]	[7.45; 7.99]
Min-Max	5.8 - 9.2	6.9 - 9.4	6.4 - 9.8
Median	7.70	7.90	7.70
Q1-Q3	7.20 - 8.30	7.30 - 8.10	7.20 - 8.20
Change from 12 weeks			
n	26	9	31
Mean (SD)	-0.15 (0.597)	-0.08 (0.383)	-0.16 (0.604)
95% CL	[-0.39; 0.09]	[-0.37; 0.22]	[-0.38; 0.06]
Min-Max	-1.3 - 1.8	-0.6 - 0.5	-1.7 - 1.1
Median	-0.15	-0.10	-0.20
Q1-Q3	-0.40 - 0.10	-0.30 - 0.10	-0.70 - 0.30
T-Test	t= -1.31 P= 0.201	t= -0.61 P= 0.560	t= -1.49 P= 0.148

HbA1c in % = HbA1c in mmol/mol * 0.0915 + 2.15

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.1 Full Analysis Set - FGM - SMBG

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.820)	8.44 (0.761)	8.55 (0.848)
95% CL	[8.323; 8.714]	[8.085; 8.798]	[8.308; 8.790]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 10.8
Median	8.30	8.25	8.45
Q1-Q3	7.80 - 9.20	7.85 - 8.90	7.80 - 9.27
After 12 weeks			
n	68	20	48
Mean (SD)	7.89 (0.814)	8.00 (0.903)	7.85 (0.780)
95% CL	[7.696; 8.090]	[7.572; 8.418]	[7.624; 8.076]
Min-Max	5.9 - 9.7	6.5 - 9.7	5.9 - 9.3
Median	7.80	7.90	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.70	7.35 - 8.40
Relative change from baseline			
n	68	20	48
Mean (SD)	-7.11 (8.634)	-5.23 (7.434)	-7.89 (9.044)
95% CL	[-9.201; -5.022]	[-8.711; -1.753]	[-10.520; -5.268]
Min-Max	-27.273 - 15.8537	-19.753 - 15.8537	-27.273 - 9.09091
Median	-6.18	-5.23	-7.31
Q1-Q3	-11.39 - -1.32	-7.41 - -2.29	-12.91 - -1.22

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.2 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	8.44 (0.815)	8.57 (0.829)
95% CL	[8.125; 8.757]	[8.312; 8.829]
Min-Max	7.5 - 10	7.5 - 10.8
Median	8.25	8.35
Q1-Q3	7.70 - 9.04	8.00 - 9.20
After 12 weeks		
n	27	41
Mean (SD)	7.94 (0.889)	7.86 (0.770)
95% CL	[7.593; 8.296]	[7.615; 8.102]
Min-Max	5.9 - 9.7	6.4 - 9.5
Median	7.80	7.70
Q1-Q3	7.40 - 8.40	7.40 - 8.50
Relative change from baseline		
n	27	41
Mean (SD)	-5.85 (8.432)	-7.94 (8.767)
95% CL	[-9.182; -2.511]	[-10.712; -5.177]
Min-Max	-22.34 - 9.09091	-27.273 - 15.8537
Median	-5.10	-6.58
Q1-Q3	-10.34 - -1.27	-12.77 - -2.56

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.3 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	8.68 (0.998)	8.48 (0.717)	8.39 (0.712)
95% CL	[8.258; 9.101]	[8.175; 8.781]	[8.071; 8.702]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 9.8
Median	8.55	8.35	8.20
Q1-Q3	7.75 - 9.62	7.90 - 8.75	7.70 - 8.80
After 12 weeks			
n	24	23	21
Mean (SD)	8.05 (0.838)	7.81 (0.898)	7.80 (0.690)
95% CL	[7.700; 8.408]	[7.420; 8.197]	[7.486; 8.114]
Min-Max	6.9 - 9.7	5.9 - 9.3	6.6 - 9.3
Median	7.85	7.80	7.50
Q1-Q3	7.35 - 8.70	7.40 - 8.40	7.40 - 8.40
Relative change from baseline			
n	24	23	21
Mean (SD)	-6.65 (9.349)	-7.80 (8.872)	-6.89 (7.859)
95% CL	[-10.596; -2.700]	[-11.633; -3.960]	[-10.468; -3.313]
Min-Max	-26.531 - 15.8537	-27.273 - 8.13953	-22.917 - 9.09091
Median	-5.68	-6.38	-6.67
Q1-Q3	-12.16 - -1.68	-10.34 - -1.27	-9.88 - -2.25

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.4 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	8.75 (0.854)	8.44 (0.801)
95% CL	[8.326; 9.174]	[8.215; 8.661]
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.85	8.25
Q1-Q3	8.10 - 9.40	7.80 - 8.80
After 12 weeks		
n	18	50
Mean (SD)	8.11 (0.874)	7.81 (0.785)
95% CL	[7.676; 8.546]	[7.591; 8.037]
Min-Max	6.5 - 9.7	5.9 - 9.5
Median	8.35	7.80
Q1-Q3	7.30 - 8.80	7.40 - 8.40
Relative change from baseline		
n	18	50
Mean (SD)	-7.00 (8.607)	-7.15 (8.730)
95% CL	[-11.284; -2.723]	[-9.631; -4.669]
Min-Max	-22.917 - 9.09091	-27.273 - 15.8537
Median	-5.15	-6.45
Q1-Q3	-9.88 - -2.02	-11.54 - -1.32

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.5 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	8.64 (0.700)	8.31 (0.703)
95% CL	[8.275; 8.995]	[8.086; 8.542]
Min-Max	7.5 - 9.8	7.5 - 10
Median	8.70	8.20
Q1-Q3	8.10 - 9.20	7.70 - 8.70
After 12 weeks		
n	17	38
Mean (SD)	7.89 (0.800)	7.87 (0.854)
95% CL	[7.477; 8.300]	[7.593; 8.154]
Min-Max	6.5 - 9.3	5.9 - 9.7
Median	7.80	7.80
Q1-Q3	7.40 - 8.40	7.40 - 8.40
Relative change from baseline		
n	17	38
Mean (SD)	-8.44 (8.329)	-5.11 (8.581)
95% CL	[-12.721; -4.156]	[-7.926; -2.285]
Min-Max	-22.917 - 8.13953	-27.273 - 15.8537
Median	-6.82	-4.22
Q1-Q3	-10.84 - -3.26	-9.68 - -1.18

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.6 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	8.37 (0.998)	8.72 (0.879)	8.47 (0.778)
95% CL	[7.444; 9.290]	[8.324; 9.124]	[8.218; 8.722]
Min-Max	7.5 - 10	7.6 - 9.9	7.5 - 10.8
Median	7.90	8.60	8.40
Q1-Q3	7.50 - 9.27	8.00 - 9.50	7.80 - 8.80
After 12 weeks			
n	7	21	37
Mean (SD)	7.56 (0.574)	8.07 (0.955)	7.89 (0.780)
95% CL	[7.026; 8.088]	[7.637; 8.506]	[7.629; 8.149]
Min-Max	6.4 - 8.2	6.6 - 9.7	5.9 - 9.3
Median	7.70	8.00	7.80
Q1-Q3	7.40 - 7.90	7.30 - 8.90	7.40 - 8.40
Relative change from baseline			
n	7	21	37
Mean (SD)	-8.72 (11.529)	-7.03 (10.871)	-6.82 (7.087)
95% CL	[-19.386; 1.940]	[-11.983; -2.086]	[-9.185; -4.459]
Min-Max	-27.273 - 2.66667	-26.531 - 15.8537	-22.917 - 8.13953
Median	-1.33	-5.26	-6.33
Q1-Q3	-21.00 - -1.27	-11.54 - -2.02	-10.34 - -2.56

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.7 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	7.89 (0.303)	9.26 (0.579)
95% CL	[7.792; 7.992]	[9.053; 9.471]
Min-Max	7.5 - 8.4	8.5 - 10.8
Median	7.85	9.29
Q1-Q3	7.60 - 8.20	8.75 - 9.77
After 12 weeks		
n	36	32
Mean (SD)	7.50 (0.671)	8.33 (0.740)
95% CL	[7.276; 7.730]	[8.064; 8.598]
Min-Max	5.9 - 9.5	6.4 - 9.7
Median	7.40	8.40
Q1-Q3	7.10 - 7.80	7.85 - 8.90
Relative change from baseline		
n	36	32
Mean (SD)	-4.73 (7.635)	-9.80 (9.014)
95% CL	[-7.309; -2.142]	[-13.045; -6.545]
Min-Max	-21.333 - 15.8537	-27.273 - 8.13953
Median	-4.55	-7.53
Q1-Q3	-9.76 - 0.00	-16.16 - -4.00

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	8.69 (0.865)	8.57 (0.770)	8.45 (0.883)	8.33 (0.745)
95% CL	[8.104; 9.267]	[8.241; 8.891]	[8.118; 8.790]	[7.552; 9.115]
Min-Max	7.6 - 9.9	7.5 - 9.9	7.5 - 10.8	7.5 - 9.4
Median	8.40	8.35	8.20	8.30
Q1-Q3	7.90 - 9.70	8.05 - 9.10	7.70 - 8.80	7.60 - 8.90
After 12 weeks				
n	11	22	29	6
Mean (SD)	8.04 (0.706)	8.11 (0.913)	7.66 (0.794)	7.95 (0.524)
95% CL	[7.562; 8.511]	[7.704; 8.514]	[7.360; 7.964]	[7.400; 8.500]
Min-Max	6.6 - 8.9	6.5 - 9.7	5.9 - 9.3	7.3 - 8.7
Median	8.00	8.20	7.50	7.85
Q1-Q3	7.50 - 8.70	7.40 - 8.90	7.20 - 8.20	7.60 - 8.40
Relative change from baseline				
n	11	22	29	6
Mean (SD)	-7.14 (7.141)	-5.44 (9.362)	-9.00 (8.466)	-4.06 (9.116)
95% CL	[-11.942; -2.347]	[-9.586; -1.285]	[-12.223; -5.782]	[-13.622; 5.511]
Min-Max	-19.192 - 3.57143	-26.531 - 15.8537	-27.273 - 9.09091	-22.34 - 2.66667
Median	-6.02	-5.18	-9.09	-1.21
Q1-Q3	-12.77 - -1.32	-9.76 - 0.00	-14.29 - -4.55	-2.25 - 0.00

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.1 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 12 weeks
4.1.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	8.53 (0.886)	8.33 (0.589)	8.58 (0.837)
95% CL	[8.184; 8.871]	[7.880; 8.786]	[8.277; 8.881]
Min-Max	7.5 - 10.8	7.6 - 9.3	7.5 - 10
Median	8.40	8.30	8.44
Q1-Q3	7.75 - 9.34	7.90 - 8.50	7.85 - 9.25
After 12 weeks			
n	27	9	32
Mean (SD)	7.83 (0.834)	7.97 (0.618)	7.92 (0.862)
95% CL	[7.503; 8.163]	[7.491; 8.442]	[7.611; 8.233]
Min-Max	5.9 - 9.3	7.1 - 8.9	6.4 - 9.7
Median	7.80	8.00	7.80
Q1-Q3	7.20 - 8.40	7.40 - 8.40	7.40 - 8.45
Relative change from baseline			
n	27	9	32
Mean (SD)	-7.68 (10.062)	-4.36 (4.320)	-7.40 (8.296)
95% CL	[-11.664; -3.703]	[-7.682; -1.041]	[-10.393; -4.411]
Min-Max	-26.531 - 9.09091	-10.843 - 2.40964	-27.273 - 15.8537
Median	-7.79	-3.26	-5.68
Q1-Q3	-15.29 - 0.00	-6.58 - -1.23	-10.80 - -2.95

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.1 Full Analysis Set - FGM - SMBG

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	8.52 (0.820)	8.44 (0.761)	8.55 (0.848)
95% CL	[8.323; 8.714]	[8.085; 8.798]	[8.308; 8.790]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 10.8
Median	8.30	8.25	8.45
Q1-Q3	7.80 - 9.20	7.85 - 8.90	7.80 - 9.27
After 24 weeks			
n	68	20	48
Mean (SD)	7.74 (0.759)	7.75 (0.851)	7.74 (0.728)
95% CL	[7.560; 7.928]	[7.347; 8.143]	[7.532; 7.955]
Min-Max	5.8 - 9.8	6.4 - 9.8	5.8 - 9.2
Median	7.80	7.80	7.75
Q1-Q3	7.20 - 8.20	7.10 - 7.95	7.20 - 8.25
Relative change from baseline			
n	66	20	46
Mean (SD)	-8.58 (8.722)	-8.06 (8.226)	-8.81 (9.008)
95% CL	[-10.727; -6.438]	[-11.912; -4.212]	[-11.484; -6.134]
Min-Max	-30.612 - 6.09756	-20.988 - 6.09756	-30.612 - 3.48837
Median	-6.45	-7.21	-6.44
Q1-Q3	-15.58 - -2.25	-16.27 - -1.23	-15.56 - -2.25

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.2 Full Analysis Set - Subgroups - Gender

	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	8.44 (0.815)	8.57 (0.829)
95% CL	[8.125; 8.757]	[8.312; 8.829]
Min-Max	7.5 - 10	7.5 - 10.8
Median	8.25	8.35
Q1-Q3	7.70 - 9.04	8.00 - 9.20
After 24 weeks		
n	26	42
Mean (SD)	7.61 (0.706)	7.83 (0.788)
95% CL	[7.327; 7.897]	[7.581; 8.072]
Min-Max	5.8 - 8.9	6.4 - 9.8
Median	7.70	7.90
Q1-Q3	7.20 - 8.00	7.20 - 8.30
Relative change from baseline		
n	26	42
Mean (SD)	-8.47 (8.795)	-8.30 (8.717)
95% CL	[-12.028; -4.922]	[-11.015; -5.582]
Min-Max	-28 - 3.48837	-30.612 - 6.09756
Median	-6.54	-6.40
Q1-Q3	-15.66 - -1.32	-15.56 - -1.22

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.3 Full Analysis Set - Subgroups - Age groups

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	8.68 (0.998)	8.48 (0.717)	8.39 (0.712)
95% CL	[8.258; 9.101]	[8.175; 8.781]	[8.071; 8.702]
Min-Max	7.5 - 10.8	7.5 - 9.9	7.5 - 9.8
Median	8.55	8.35	8.20
Q1-Q3	7.75 - 9.62	7.90 - 8.75	7.70 - 8.80
After 24 weeks			
n	24	24	20
Mean (SD)	7.70 (0.850)	7.75 (0.756)	7.80 (0.680)
95% CL	[7.341; 8.059]	[7.427; 8.065]	[7.477; 8.113]
Min-Max	5.8 - 9.8	6.2 - 8.9	6.5 - 9.2
Median	7.65	7.85	7.85
Q1-Q3	7.15 - 8.10	7.35 - 8.30	7.30 - 8.25
Relative change from baseline			
n	24	24	20
Mean (SD)	-10.58 (10.987)	-8.43 (7.902)	-5.63 (5.474)
95% CL	[-15.223; -5.944]	[-11.766; -5.092]	[-8.191; -3.067]
Min-Max	-30.612 - 6.09756	-23.232 - 3.48837	-15.854 - 2.66667
Median	-8.07	-5.60	-4.71
Q1-Q3	-18.03 - 0.00	-15.00 - -2.56	-8.99 - -1.75

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.4 Full Analysis Set - Subgroups - Body Mass Index

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	8.75 (0.854)	8.44 (0.801)
95% CL	[8.326; 9.174]	[8.215; 8.661]
Min-Max	7.5 - 9.9	7.5 - 10.8
Median	8.85	8.25
Q1-Q3	8.10 - 9.40	7.80 - 8.80
After 24 weeks		
n	16	52
Mean (SD)	8.07 (0.815)	7.64 (0.721)
95% CL	[7.635; 8.503]	[7.444; 7.845]
Min-Max	6.6 - 9.4	5.8 - 9.8
Median	8.10	7.70
Q1-Q3	7.55 - 8.75	7.20 - 8.10
Relative change from baseline		
n	16	52
Mean (SD)	-6.42 (7.246)	-8.96 (9.057)
95% CL	[-10.281; -2.559]	[-11.486; -6.443]
Min-Max	-19.192 - 2.66667	-30.612 - 6.09756
Median	-6.60	-6.25
Q1-Q3	-9.88 - 0.00	-15.62 - -1.79

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.5 Full Analysis Set - Subgroups - Renal function

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	8.64 (0.700)	8.31 (0.703)
95% CL	[8.275; 8.995]	[8.086; 8.542]
Min-Max	7.5 - 9.8	7.5 - 10
Median	8.70	8.20
Q1-Q3	8.10 - 9.20	7.70 - 8.70
After 24 weeks		
n	15	39
Mean (SD)	8.07 (0.801)	7.67 (0.706)
95% CL	[7.630; 8.517]	[7.438; 7.896]
Min-Max	6.6 - 9.4	6.2 - 9.8
Median	8.10	7.80
Q1-Q3	7.50 - 8.70	7.20 - 8.20
Relative change from baseline		
n	15	39
Mean (SD)	-5.11 (5.939)	-7.49 (8.170)
95% CL	[-8.395; -1.818]	[-10.141; -4.844]
Min-Max	-18.519 - 3.48837	-28 - 6.09756
Median	-4.00	-6.41
Q1-Q3	-8.64 - -1.32	-15.56 - -1.19

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.6 Full Analysis Set - Subgroups - Duration of diabetes

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	8.37 (0.998)	8.72 (0.879)	8.47 (0.778)
95% CL	[7.444; 9.290]	[8.324; 9.124]	[8.218; 8.722]
Min-Max	7.5 - 10	7.6 - 9.9	7.5 - 10.8
Median	7.90	8.60	8.40
Q1-Q3	7.50 - 9.27	8.00 - 9.50	7.80 - 8.80
After 24 weeks			
n	7	19	39
Mean (SD)	7.39 (0.474)	7.85 (0.956)	7.78 (0.702)
95% CL	[6.947; 7.824]	[7.392; 8.313]	[7.552; 8.007]
Min-Max	6.8 - 8.2	5.8 - 9.8	6.2 - 9.2
Median	7.50	7.80	7.90
Q1-Q3	6.90 - 7.60	7.40 - 8.50	7.20 - 8.30
Relative change from baseline			
n	7	19	39
Mean (SD)	-10.77 (10.818)	-8.50 (11.662)	-7.91 (6.773)
95% CL	[-20.774; -0.764]	[-14.124; -2.883]	[-10.108; -5.716]
Min-Max	-28 - 0	-30.612 - 6.09756	-25 - 3.48837
Median	-8.00	-6.10	-6.38
Q1-Q3	-22.73 - -1.32	-20.99 - 2.50	-14.77 - -2.47

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.7 Full Analysis Set - Subgroups - Baseline HbA1c

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	7.89 (0.303)	9.26 (0.579)
95% CL	[7.792; 7.992]	[9.053; 9.471]
Min-Max	7.5 - 8.4	8.5 - 10.8
Median	7.85	9.29
Q1-Q3	7.60 - 8.20	8.75 - 9.77
After 24 weeks		
n	38	30
Mean (SD)	7.43 (0.646)	8.14 (0.715)
95% CL	[7.219; 7.644]	[7.873; 8.407]
Min-Max	5.8 - 8.7	6.8 - 9.8
Median	7.50	8.10
Q1-Q3	6.90 - 7.90	7.60 - 8.60
Relative change from baseline		
n	38	30
Mean (SD)	-5.83 (7.350)	-11.58 (9.281)
95% CL	[-8.247; -3.416]	[-15.042; -8.111]
Min-Max	-25.641 - 6.09756	-30.612 - 3.48837
Median	-4.41	-9.86
Q1-Q3	-8.64 - -1.19	-18.56 - -4.60

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	8.69 (0.865)	8.57 (0.770)	8.45 (0.883)	8.33 (0.745)
95% CL	[8.104; 9.267]	[8.241; 8.891]	[8.118; 8.790]	[7.552; 9.115]
Min-Max	7.6 - 9.9	7.5 - 9.9	7.5 - 10.8	7.5 - 9.4
Median	8.40	8.35	8.20	8.30
Q1-Q3	7.90 - 9.70	8.05 - 9.10	7.70 - 8.80	7.60 - 8.90
After 24 weeks				
n	11	23	29	5
Mean (SD)	7.77 (0.690)	7.68 (0.885)	7.74 (0.742)	8.00 (0.447)
95% CL	[7.309; 8.236]	[7.300; 8.065]	[7.456; 8.020]	[7.445; 8.555]
Min-Max	6.4 - 8.8	5.8 - 9.8	6.2 - 9.2	7.5 - 8.7
Median	7.70	7.70	7.90	7.90
Q1-Q3	7.50 - 8.30	6.90 - 8.00	7.20 - 8.20	7.80 - 8.10
Relative change from baseline				
n	11	23	29	5
Mean (SD)	-10.02 (9.015)	-9.47 (9.758)	-8.07 (8.029)	-1.36 (2.784)
95% CL	[-16.081; -3.969]	[-13.692; -5.253]	[-11.122; -5.013]	[-4.814; 2.098]
Min-Max	-23.232 - 0	-30.612 - 6.09756	-28 - 3.48837	-4.7059 - 2.63158
Median	-6.38	-8.00	-6.49	-2.25
Q1-Q3	-18.56 - -1.32	-15.85 - -1.25	-11.11 - -3.85	-2.47 - 0.00

4 Effectiveness (secondary)
4.1 Relative change in HbA1c in %
4.1.2 Change in HbA1c (%) under iGlarLixi from baseline to the visit after approx. 24 weeks
4.1.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	8.53 (0.886)	8.33 (0.589)	8.58 (0.837)
95% CL	[8.184; 8.871]	[7.880; 8.786]	[8.277; 8.881]
Min-Max	7.5 - 10.8	7.6 - 9.3	7.5 - 10
Median	8.40	8.30	8.44
Q1-Q3	7.75 - 9.34	7.90 - 8.50	7.85 - 9.25
After 24 weeks			
n	27	9	31
Mean (SD)	7.72 (0.823)	7.89 (0.751)	7.72 (0.736)
95% CL	[7.397; 8.048]	[7.312; 8.466]	[7.446; 7.986]
Min-Max	5.8 - 9.2	6.9 - 9.4	6.4 - 9.8
Median	7.70	7.90	7.70
Q1-Q3	7.20 - 8.30	7.30 - 8.10	7.20 - 8.20
Relative change from baseline			
n	27	9	31
Mean (SD)	-8.68 (9.258)	-5.42 (4.049)	-9.18 (9.199)
95% CL	[-12.338; -5.013]	[-8.532; -2.308]	[-12.555; -5.807]
Min-Max	-30.612 - 3.48837	-12.658 - 2.17391	-28 - 6.09756
Median	-6.38	-5.26	-8.00
Q1-Q3	-15.85 - -2.25	-6.41 - -4.71	-16.88 - -1.22

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.1 Full Analysis Set - FGM - SMBG
4.2.1.1.1 Missing values as documented

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	53	17	36
Mean (SD)	185.33 (63.677)	177.17 (47.785)	189.19 (70.233)
95% CL	[167.780;202.883]	[152.601;201.738]	[165.422;212.949]
Min-Max	86 - 401.806	116 - 297.3	86 - 401.806
Median	170.00	166.00	171.50
Q1-Q3	145.00 - 218.00	144.00 - 182.00	145.00 - 222.50
After 12 weeks			
n	48	13	35
Mean (SD)	150.63 (43.873)	144.73 (30.749)	152.83 (48.051)
95% CL	[137.895;163.374]	[126.153;163.316]	[136.319;169.331]
Min-Max	75 - 291.895	79 - 200	75 - 291.895
Median	141.50	145.00	137.00
Q1-Q3	124.00 - 171.00	134.00 - 152.00	116.00 - 175.00
Absolute change from baseline			
n	40	13	27
Mean (SD)	-26.90 (57.630)	-28.04 (49.316)	-26.35 (62.115)
95% CL	[-45.329; -8.468]	[-57.839; 1.764]	[-50.922; -1.778]
Min-Max	-168 - 90	-118 - 33	-168 - 90
Median	-24.00	-8.00	-26.00
Q1-Q3	-58.50 - 9.00	-53.00 - 9.00	-60.00 - 7.00
Relative change from baseline			
n	40	13	27
Mean (SD)	-8.93 (28.137)	-12.58 (24.119)	-7.17 (30.152)
95% CL	[-17.927; 0.070]	[-27.159; 1.991]	[-19.096; 4.760]
Min-Max	-60.432 - 60.4027	-56.593 - 20.625	-60.432 - 60.4027
Median	-15.56	-5.06	-15.95
Q1-Q3	-28.31 - 7.05	-29.44 - 6.95	-27.35 - 7.14

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.1 Full Analysis Set - FGM - SMBG
4.2.1.1.2 Missing values missing according to LOCF

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	53	17	36
Mean (SD)	185.33 (63.677)	177.17 (47.785)	189.19 (70.233)
95% CL	[167.780;202.883]	[152.601;201.738]	[165.422;212.949]
Min-Max	86 - 401.806	116 - 297.3	86 - 401.806
Median	170.00	166.00	171.50
Q1-Q3	145.00 - 218.00	144.00 - 182.00	145.00 - 222.50
After 12 weeks			
n	61	17	44
Mean (SD)	159.18 (51.522)	155.73 (45.645)	160.51 (54.058)
95% CL	[145.982;172.372]	[132.261;179.197]	[144.074;176.944]
Min-Max	75 - 337	79 - 297.3	75 - 337
Median	149.55	149.55	147.00
Q1-Q3	128.00 - 180.00	138.00 - 162.00	124.00 - 182.39
Absolute change from baseline			
n	53	17	36
Mean (SD)	-20.30 (51.258)	-21.44 (44.433)	-19.76 (54.773)
95% CL	[-34.429; -6.172]	[-44.286; 1.405]	[-38.295; -1.230]
Min-Max	-168 - 90	-118 - 33	-168 - 90
Median	0.00	0.00	-0.50
Q1-Q3	-48.00 - 0.00	-43.00 - 9.00	-50.50 - 0.00
Relative change from baseline			
n	53	17	36
Mean (SD)	-6.74 (24.674)	-9.62 (21.600)	-5.38 (26.178)
95% CL	[-13.539; 0.063]	[-20.729; 1.483]	[-14.233; 3.481]
Min-Max	-60.432 - 60.4027	-56.593 - 20.625	-60.432 - 60.4027
Median	0.00	0.00	-0.34
Q1-Q3	-24.24 - 0.00	-23.76 - 6.29	-24.62 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.2 Full Analysis Set - Subgroups - Gender
4.2.1.2.1 Missing values as documented

	Female (N = 28)	Male (N = 42)
Baseline		
n	23	30
Mean (SD)	187.39 (72.347)	183.75 (57.393)
95% CL	[156.103;218.674]	[162.324;205.185]
Min-Max	86 - 401.806	86.6 - 330
Median	173.00	165.00
Q1-Q3	149.00 - 218.00	144.00 - 222.00
After 12 weeks		
n	16	32
Mean (SD)	166.10 (62.633)	142.90 (28.894)
95% CL	[132.730;199.479]	[132.481;153.316]
Min-Max	79 - 291.895	75 - 200
Median	147.28	138.50
Q1-Q3	118.50 - 222.61	124.00 - 165.08
Absolute change from baseline		
n	14	26
Mean (SD)	-10.50 (71.646)	-35.73 (47.749)
95% CL	[-51.863; 30.872]	[-55.017;-16.445]
Min-Max	-118 - 90	-168 - 33
Median	3.50	-29.50
Q1-Q3	-86.49 - 47.00	-57.00 - 0.00
Relative change from baseline		
n	14	26
Mean (SD)	3.06 (37.981)	-15.38 (19.004)
95% CL	[-18.874; 24.986]	[-23.057; -7.706]
Min-Max	-56.593 - 60.4027	-60.432 - 20.625
Median	3.57	-18.77
Q1-Q3	-29.44 - 35.87	-26.64 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.2 Full Analysis Set - Subgroups - Gender
4.2.1.2.2 Missing values missing according to LOCF

	Female (N = 28)	Male (N = 42)
Baseline		
n	23	30
Mean (SD)	187.39 (72.347)	183.75 (57.393)
95% CL	[156.103;218.674]	[162.324;205.185]
Min-Max	86 - 401.806	86.6 - 330
Median	173.00	165.00
Q1-Q3	149.00 - 218.00	144.00 - 222.00
After 12 weeks		
n	25	36
Mean (SD)	174.96 (62.639)	148.22 (39.480)
95% CL	[149.104;200.816]	[134.858;161.575]
Min-Max	79 - 337	75 - 297.3
Median	150.00	138.50
Q1-Q3	134.00 - 220.00	124.00 - 168.50
Absolute change from baseline		
n	23	30
Mean (SD)	-6.39 (55.324)	-30.97 (46.023)
95% CL	[-30.312; 17.535]	[-48.152;-13.781]
Min-Max	-118 - 90	-168 - 33
Median	0.00	-24.00
Q1-Q3	-20.00 - 33.00	-53.00 - 0.00
Relative change from baseline		
n	23	30
Mean (SD)	1.86 (29.236)	-13.33 (18.428)
95% CL	[-10.783; 14.503]	[-20.212; -6.449]
Min-Max	-56.593 - 60.4027	-60.432 - 20.625
Median	0.00	-15.56
Q1-Q3	-11.76 - 27.17	-25.00 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.3 Full Analysis Set - Subgroups - Age groups
4.2.1.3.1 Missing values as documented

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	17	18	18
Mean (SD)	192.24 (69.879)	176.73 (49.415)	187.41 (72.348)
95% CL	[156.315;228.172]	[152.152;201.300]	[151.431;223.387]
Min-Max	121 - 401.806	101 - 297.3	86 - 337
Median	180.00	164.00	183.00
Q1-Q3	143.00 - 215.00	149.00 - 182.00	144.00 - 223.00
After 12 weeks			
n	12	17	19
Mean (SD)	161.16 (55.146)	145.21 (45.155)	148.84 (35.357)
95% CL	[126.120;196.196]	[121.993;168.425]	[131.800;165.883]
Min-Max	107 - 291.895	75 - 239	92.6 - 225.228
Median	141.50	139.00	150.00
Q1-Q3	121.50 - 196.50	132.00 - 150.00	123.00 - 169.00
Absolute change from baseline			
n	12	12	16
Mean (SD)	-37.99 (66.214)	-18.87 (60.081)	-24.60 (51.158)
95% CL	[-80.063; 4.078]	[-57.048; 19.300]	[-51.856; 2.664]
Min-Max	-168 - 47	-103 - 90	-155 - 59.4601
Median	-35.00	-20.50	-21.00
Q1-Q3	-81.46 - 11.00	-71.50 - 16.00	-55.00 - 6.50
Relative change from baseline			
n	12	12	16
Mean (SD)	-13.92 (27.112)	-5.81 (33.900)	-7.52 (25.432)
95% CL	[-31.145; 3.307]	[-27.350; 15.728]	[-21.074; 6.029]
Min-Max	-60.432 - 27.1676	-56.593 - 60.4027	-46.97 - 48.8372
Median	-21.95	-12.52	-13.47
Q1-Q3	-29.36 - 7.08	-28.71 - 15.99	-25.44 - 7.04

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.3 Full Analysis Set - Subgroups - Age groups
4.2.1.3.2 Missing values missing according to LOCF

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	17	18	18
Mean (SD)	192.24 (69.879)	176.73 (49.415)	187.41 (72.348)
95% CL	[156.315;228.172]	[152.152;201.300]	[151.431;223.387]
Min-Max	121 - 401.806	101 - 297.3	86 - 337
Median	180.00	164.00	183.00
Q1-Q3	143.00 - 215.00	149.00 - 182.00	144.00 - 223.00
After 12 weeks			
n	17	23	21
Mean (SD)	165.42 (51.126)	152.59 (50.255)	161.33 (54.831)
95% CL	[139.138;191.712]	[130.859;174.323]	[136.374;186.292]
Min-Max	107 - 291.895	75 - 297.3	92.6 - 337
Median	145.00	144.00	157.00
Q1-Q3	127.00 - 200.00	132.00 - 166.00	125.00 - 175.00
Absolute change from baseline			
n	17	18	18
Mean (SD)	-26.82 (57.729)	-12.58 (49.189)	-21.86 (48.708)
95% CL	[-56.500; 2.863]	[-37.044; 11.878]	[-46.085; 2.359]
Min-Max	-168 - 47	-103 - 90	-155 - 59.4601
Median	0.00	-0.50	-10.00
Q1-Q3	-48.00 - 9.00	-32.00 - 0.00	-53.00 - 6.00
Relative change from baseline			
n	17	18	18
Mean (SD)	-9.83 (23.411)	-3.87 (27.414)	-6.69 (24.013)
95% CL	[-21.862; 2.211]	[-17.507; 9.759]	[-18.628; 5.254]
Min-Max	-60.432 - 27.1676	-56.593 - 60.4027	-46.97 - 48.8372
Median	0.00	-0.34	-5.88
Q1-Q3	-27.35 - 6.29	-18.71 - 0.00	-24.24 - 6.93

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.2.1.4.1 Missing values as documented

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	14	39
Mean (SD)	202.97 (74.960)	179.00 (58.911)
95% CL	[159.691;246.252]	[159.903;198.096]
Min-Max	86.6 - 337	86 - 401.806
Median	200.50	165.77
Q1-Q3	149.00 - 240.00	143.00 - 214.00
After 12 weeks		
n	13	35
Mean (SD)	149.58 (45.545)	151.02 (43.910)
95% CL	[122.062;177.107]	[135.940;166.108]
Min-Max	79 - 239	75 - 291.895
Median	145.00	138.00
Q1-Q3	116.00 - 180.00	125.00 - 168.00
Absolute change from baseline		
n	12	28
Mean (SD)	-39.00 (67.135)	-21.71 (53.554)
95% CL	[-81.655; 3.655]	[-42.478; -0.946]
Min-Max	-155 - 90	-168 - 65
Median	-45.00	-21.00
Q1-Q3	-81.50 - 6.50	-53.00 - 12.00
Relative change from baseline		
n	12	28
Mean (SD)	-13.95 (32.232)	-6.77 (26.538)
95% CL	[-34.432; 6.527]	[-17.065; 3.515]
Min-Max	-56.593 - 60.4027	-60.432 - 48.8372
Median	-21.92	-13.47
Q1-Q3	-37.07 - 6.94	-25.80 - 8.81

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.2.1.4.2 Missing values missing according to LOCF

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	14	39
Mean (SD)	202.97 (74.960)	179.00 (58.911)
95% CL	[159.691;246.252]	[159.903;198.096]
Min-Max	86.6 - 337	86 - 401.806
Median	200.50	165.77
Q1-Q3	149.00 - 240.00	143.00 - 214.00
After 12 weeks		
n	15	46
Mean (SD)	166.97 (65.939)	156.63 (46.474)
95% CL	[130.458;203.489]	[142.834;170.436]
Min-Max	79 - 337	75 - 297.3
Median	157.00	145.05
Q1-Q3	116.00 - 200.00	128.00 - 169.00
Absolute change from baseline		
n	14	39
Mean (SD)	-33.43 (63.358)	-15.59 (46.215)
95% CL	[-70.011; 3.153]	[-30.569; -0.607]
Min-Max	-155 - 90	-168 - 65
Median	-21.50	0.00
Q1-Q3	-60.00 - 6.00	-40.00 - 0.00
Relative change from baseline		
n	14	39
Mean (SD)	-11.96 (30.079)	-4.86 (22.582)
95% CL	[-29.327; 5.408]	[-12.184; 2.456]
Min-Max	-56.593 - 60.4027	-60.432 - 48.8372
Median	-9.76	0.00
Q1-Q3	-29.27 - 6.93	-23.76 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.5 Full Analysis Set - Subgroups - Renal function
4.2.1.5.1 Missing values as documented

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	32
Mean (SD)	172.27 (62.831)	187.32 (65.218)
95% CL	[138.792;205.753]	[163.805;210.833]
Min-Max	86 - 337	98 - 401.806
Median	172.00	165.00
Q1-Q3	130.50 - 205.00	144.50 - 220.00
After 12 weeks		
n	14	26
Mean (SD)	147.63 (47.955)	153.29 (45.309)
95% CL	[119.942;175.319]	[134.986;171.587]
Min-Max	79 - 239	75 - 291.895
Median	133.00	147.28
Q1-Q3	116.00 - 181.00	127.00 - 169.00
Absolute change from baseline		
n	13	23
Mean (SD)	-6.89 (50.665)	-33.37 (56.221)
95% CL	[-37.504; 23.729]	[-57.677; -9.053]
Min-Max	-103 - 65	-155 - 90
Median	0.00	-32.00
Q1-Q3	-42.00 - 33.00	-70.00 - 7.00
Relative change from baseline		
n	13	23
Mean (SD)	0.54 (31.529)	-12.43 (25.450)
95% CL	[-18.517; 19.589]	[-23.434; -1.423]
Min-Max	-56.593 - 48.8372	-46.97 - 60.4027
Median	0.00	-20.15
Q1-Q3	-18.83 - 32.67	-29.41 - 6.29

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.5 Full Analysis Set - Subgroups - Renal function
4.2.1.5.2 Missing values missing according to LOCF

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	32
Mean (SD)	172.27 (62.831)	187.32 (65.218)
95% CL	[138.792;205.753]	[163.805;210.833]
Min-Max	86 - 337	98 - 401.806
Median	172.00	165.00
Q1-Q3	130.50 - 205.00	144.50 - 220.00
After 12 weeks		
n	17	35
Mean (SD)	163.34 (64.830)	158.28 (48.082)
95% CL	[130.010;196.675]	[141.764;174.797]
Min-Max	79 - 337	75 - 297.3
Median	150.00	149.55
Q1-Q3	123.00 - 200.00	129.73 - 173.00
Absolute change from baseline		
n	16	32
Mean (SD)	-5.60 (45.401)	-23.98 (49.754)
95% CL	[-29.789; 18.596]	[-41.919; -6.043]
Min-Max	-103 - 65	-155 - 90
Median	0.00	-4.50
Q1-Q3	-32.00 - 23.00	-50.50 - 0.00
Relative change from baseline		
n	16	32
Mean (SD)	0.44 (28.201)	-8.93 (22.179)
95% CL	[-14.592; 15.463]	[-16.929; -0.937]
Min-Max	-56.593 - 48.8372	-46.97 - 60.4027
Median	0.00	-2.88
Q1-Q3	-17.00 - 19.81	-25.80 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.2.1.6.1 Missing values as documented

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	17	26
Mean (SD)	156.00 (39.598)	213.62 (82.899)	175.29 (49.239)
95% CL	[119.378;192.622]	[170.995;256.240]	[155.402;195.178]
Min-Max	101 - 218	86.6 - 401.806	86 - 330
Median	163.00	214.00	165.38
Q1-Q3	121.00 - 180.00	160.00 - 263.00	145.00 - 196.00
After 12 weeks			
n	4	13	29
Mean (SD)	154.50 (43.867)	165.27 (60.341)	143.72 (35.612)
95% CL	[84.697;224.303]	[128.805;201.732]	[130.176;157.268]
Min-Max	127 - 220	92.6 - 291.895	75 - 239
Median	135.50	145.00	144.00
Q1-Q3	130.50 - 178.50	110.00 - 200.00	125.00 - 159.00
Absolute change from baseline			
n	4	12	22
Mean (SD)	0.25 (47.549)	-29.91 (72.161)	-27.86 (53.102)
95% CL	[-75.411; 75.911]	[-75.758; 15.939]	[-51.409; -4.321]
Min-Max	-53 - 47	-168 - 90	-155 - 65
Median	3.50	-13.50	-26.00
Q1-Q3	-39.50 - 40.00	-76.46 - 10.00	-60.00 - 9.00
Relative change from baseline			
n	4	12	22
Mean (SD)	3.61 (30.956)	-7.78 (31.957)	-10.48 (27.149)
95% CL	[-45.647; 52.870]	[-28.083; 12.526]	[-22.521; 1.554]
Min-Max	-29.444 - 32.6733	-60.432 - 60.4027	-56.593 - 48.8372
Median	5.61	-9.42	-15.24
Q1-Q3	-22.70 - 29.92	-25.56 - 7.05	-29.27 - 6.29

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.2.1.6.2 Missing values missing according to LOCF

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	17	26
Mean (SD)	156.00 (39.598)	213.62 (82.899)	175.29 (49.239)
95% CL	[119.378;192.622]	[170.995;256.240]	[155.402;195.178]
Min-Max	101 - 218	86.6 - 401.806	86 - 330
Median	163.00	214.00	165.38
Q1-Q3	121.00 - 180.00	160.00 - 263.00	145.00 - 196.00
After 12 weeks			
n	7	18	33
Mean (SD)	156.14 (43.303)	189.14 (71.334)	144.72 (33.793)
95% CL	[116.094;196.191]	[153.670;224.617]	[132.735;156.700]
Min-Max	121 - 220	92.6 - 337	75 - 239
Median	136.00	188.39	149.55
Q1-Q3	127.00 - 218.00	132.00 - 223.00	128.00 - 162.00
Absolute change from baseline			
n	7	17	26
Mean (SD)	0.14 (33.623)	-21.11 (61.459)	-23.58 (49.737)
95% CL	[-30.953; 31.239]	[-52.712; 10.487]	[-43.667; -3.489]
Min-Max	-53 - 47	-168 - 90	-155 - 65
Median	0.00	0.00	-11.50
Q1-Q3	-26.00 - 33.00	-42.00 - 6.00	-57.00 - 0.00
Relative change from baseline			
n	7	17	26
Mean (SD)	2.06 (21.974)	-5.49 (26.748)	-8.87 (25.179)
95% CL	[-18.259; 22.386]	[-19.243; 8.262]	[-19.041; 1.300]
Min-Max	-29.444 - 32.6733	-60.432 - 60.4027	-56.593 - 48.8372
Median	0.00	0.00	-7.08
Q1-Q3	-15.95 - 27.17	-20.15 - 6.93	-26.64 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.2.1.7.1 Missing values as documented

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	29	24
Mean (SD)	166.65 (50.766)	207.91 (71.117)
95% CL	[147.335;185.956]	[177.880;237.940]
Min-Max	86.6 - 297.3	86 - 401.806
Median	158.00	191.50
Q1-Q3	136.00 - 182.00	163.50 - 229.52
After 12 weeks		
n	26	22
Mean (SD)	137.27 (36.017)	166.43 (47.761)
95% CL	[122.721;151.817]	[145.253;187.606]
Min-Max	75 - 225.228	110 - 291.895
Median	136.00	150.00
Q1-Q3	115.00 - 159.00	132.00 - 193.00
Absolute change from baseline		
n	21	19
Mean (SD)	-24.93 (44.528)	-29.07 (70.593)
95% CL	[-45.199; -4.662]	[-63.098; 4.951]
Min-Max	-118 - 59.4601	-168 - 90
Median	-22.00	-26.00
Q1-Q3	-53.00 - 6.00	-64.00 - 33.00
Relative change from baseline		
n	21	19
Mean (SD)	-10.72 (23.369)	-6.95 (33.176)
95% CL	[-21.355; -0.080]	[-22.940; 9.040]
Min-Max	-56.593 - 35.8696	-60.432 - 60.4027
Median	-15.17	-15.95
Q1-Q3	-24.24 - 6.29	-29.27 - 20.63

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.2.1.7.2 Missing values missing according to LOCF

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	29	24
Mean (SD)	166.65 (50.766)	207.91 (71.117)
95% CL	[147.335;185.956]	[177.880;237.940]
Min-Max	86.6 - 297.3	86 - 401.806
Median	158.00	191.50
Q1-Q3	136.00 - 182.00	163.50 - 229.52
After 12 weeks		
n	34	27
Mean (SD)	143.92 (42.648)	178.39 (55.945)
95% CL	[129.042;158.803]	[156.256;200.518]
Min-Max	75 - 297.3	110 - 337
Median	138.50	162.00
Q1-Q3	121.00 - 162.16	134.00 - 218.00
Absolute change from baseline		
n	29	24
Mean (SD)	-18.05 (39.304)	-23.02 (63.604)
95% CL	[-33.004; -3.103]	[-49.874; 3.841]
Min-Max	-118 - 59.4601	-168 - 90
Median	0.00	-7.50
Q1-Q3	-40.00 - 0.00	-58.50 - 11.00
Relative change from baseline		
n	29	24
Mean (SD)	-7.76 (20.344)	-5.50 (29.490)
95% CL	[-15.499; -0.023]	[-17.955; 6.950]
Min-Max	-56.593 - 35.8696	-60.432 - 60.4027
Median	0.00	-4.55
Q1-Q3	-23.76 - 0.00	-26.99 - 7.08

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.2.1.8.1 Missing values as documented

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	9	14	24	6
Mean (SD)	178.87 (58.192)	200.58 (88.977)	181.03 (54.237)	176.63 (41.584)
95% CL	[134.141;223.602]	[149.210;251.958]	[158.130;203.934]	[132.991;220.271]
Min-Max	101 - 297.3	86 - 401.806	98 - 330	121 - 223
Median	166.00	181.50	165.38	174.39
Q1-Q3	140.54 - 215.00	158.00 - 236.04	145.00 - 216.00	144.00 - 223.00
After 12 weeks				
n	3	16	26	3
Mean (SD)	151.00 (17.521)	150.00 (52.500)	149.52 (43.579)	163.33 (15.948)
95% CL	[107.474;194.526]	[122.028;177.978]	[131.913;167.117]	[123.717;202.950]
Min-Max	134 - 169	79 - 291.895	75 - 239	150 - 181
Median	150.00	137.50	140.50	159.00
Q1-Q3	134.00 - 169.00	121.50 - 171.50	116.00 - 173.00	150.00 - 181.00
Absolute change from baseline				
n	3	12	22	3
Mean (SD)	-13.33 (43.386)	-38.03 (65.387)	-24.43 (59.535)	-14.00 (28.513)
95% CL	[-121.11; 94.443]	[-79.578; 3.512]	[-50.830; 1.963]	[-84.831; 56.831]
Min-Max	-53 - 33	-168 - 42	-155 - 90	-42 - 15
Median	-20.00	-20.00	-26.50	-15.00
Q1-Q3	-53.00 - 33.00	-94.74 - 9.50	-60.00 - 9.00	-42.00 - 15.00
Relative change from baseline				
n	3	12	22	3
Mean (SD)	-0.99 (29.774)	-12.10 (31.674)	-8.70 (28.689)	-5.84 (14.895)
95% CL	[-74.951; 72.974]	[-32.225; 8.024]	[-21.422; 4.018]	[-42.836; 31.164]
Min-Max	-23.874 - 32.6733	-60.432 - 48.8372	-46.97 - 60.4027	-18.834 - 10.4167
Median	-11.76	-11.89	-18.05	-9.09
Q1-Q3	-23.87 - 32.67	-32.00 - 6.94	-29.41 - 7.14	-18.83 - 10.42

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.2.1.8.2 Missing values missing according to LOCF

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	9	14	24	6
Mean (SD)	178.87 (58.192)	200.58 (88.977)	181.03 (54.237)	176.63 (41.584)
95% CL	[134.141;223.602]	[149.210;251.958]	[158.130;203.934]	[132.991;220.271]
Min-Max	101 - 297.3	86 - 401.806	98 - 330	121 - 223
Median	166.00	181.50	165.38	174.39
Q1-Q3	140.54 - 215.00	158.00 - 236.04	145.00 - 216.00	144.00 - 223.00
After 12 weeks				
n	9	18	28	6
Mean (SD)	174.43 (52.267)	159.27 (66.500)	151.98 (43.885)	169.63 (34.760)
95% CL	[134.251;214.603]	[126.196;192.335]	[134.961;168.995]	[133.153;206.109]
Min-Max	134 - 297.3	79 - 337	75 - 239	121 - 223
Median	162.00	137.50	144.50	170.00
Q1-Q3	140.54 - 169.00	128.00 - 193.00	119.50 - 174.00	150.00 - 183.79
Absolute change from baseline				
n	9	14	24	6
Mean (SD)	-4.44 (22.694)	-32.60 (61.713)	-22.40 (57.304)	-7.00 (19.596)
95% CL	[-21.889; 13.000]	[-68.232; 3.032]	[-46.595; 1.800]	[-27.565; 13.565]
Min-Max	-53 - 33	-168 - 42	-155 - 90	-42 - 15
Median	0.00	-4.00	-24.00	0.00
Q1-Q3	0.00 - 0.00	-86.49 - 6.00	-58.50 - 8.00	-15.00 - 0.00
Relative change from baseline				
n	9	14	24	6
Mean (SD)	-0.33 (14.895)	-10.37 (29.465)	-7.98 (27.523)	-2.92 (9.948)
95% CL	[-11.779; 11.120]	[-27.385; 6.640]	[-19.599; 3.645]	[-13.358; 7.521]
Min-Max	-23.874 - 32.6733	-60.432 - 48.8372	-46.97 - 60.4027	-18.834 - 10.4167
Median	0.00	-2.53	-15.56	0.00
Q1-Q3	0.00 - 0.00	-27.35 - 6.93	-29.34 - 6.72	-9.09 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.2.1.9.1 Missing values as documented

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	22	9	22
Mean (SD)	190.67 (67.710)	157.11 (21.929)	191.54 (69.720)
95% CL	[160.647;220.689]	[140.255;173.967]	[160.628;222.452]
Min-Max	86.6 - 401.806	116 - 187	86 - 337
Median	178.89	158.00	165.50
Q1-Q3	150.00 - 222.00	144.00 - 171.00	145.00 - 238.00
After 12 weeks			
n	18	9	21
Mean (SD)	164.10 (55.943)	160.33 (37.024)	134.93 (29.161)
95% CL	[136.285;191.924]	[131.874;188.792]	[121.657;148.205]
Min-Max	92.6 - 291.895	116 - 239	75 - 193
Median	159.58	150.00	134.00
Q1-Q3	115.00 - 214.00	139.00 - 159.00	125.00 - 145.00
Absolute change from baseline			
n	15	9	16
Mean (SD)	-30.70 (64.218)	3.22 (38.150)	-40.28 (57.096)
95% CL	[-66.260; 4.866]	[-26.103; 32.547]	[-70.705; -9.856]
Min-Max	-168 - 65	-43 - 90	-155 - 42
Median	-42.00	0.00	-33.50
Q1-Q3	-64.00 - 7.00	-15.00 - 13.00	-78.24 - 4.00
Relative change from baseline			
n	15	9	16
Mean (SD)	-9.92 (28.272)	3.05 (24.454)	-14.74 (29.502)
95% CL	[-25.575; 5.738]	[-15.748; 21.846]	[-30.458; 0.983]
Min-Max	-60.432 - 37.3563	-23.757 - 60.4027	-56.593 - 48.8372
Median	-18.83	0.00	-22.20
Q1-Q3	-29.27 - 7.14	-9.09 - 6.95	-33.04 - 3.26

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.1 Change from baseline to the visit after approx. 12 weeks
4.2.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.2.1.9.2 Missing values missing according to LOCF

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	22	9	22
Mean (SD)	190.67 (67.710)	157.11 (21.929)	191.54 (69.720)
95% CL	[160.647;220.689]	[140.255;173.967]	[160.628;222.452]
Min-Max	86.6 - 401.806	116 - 187	86 - 337
Median	178.89	158.00	165.50
Q1-Q3	150.00 - 222.00	144.00 - 171.00	145.00 - 238.00
After 12 weeks			
n	25	9	27
Mean (SD)	164.50 (51.508)	160.33 (37.024)	153.87 (56.552)
95% CL	[143.235;185.758]	[131.874;188.792]	[131.495;176.238]
Min-Max	92.6 - 291.895	116 - 239	75 - 337
Median	157.00	150.00	137.00
Q1-Q3	121.00 - 214.00	139.00 - 159.00	127.00 - 168.00
Absolute change from baseline			
n	22	9	22
Mean (SD)	-20.93 (54.438)	3.22 (38.150)	-29.29 (51.631)
95% CL	[-45.066; 3.207]	[-26.103; 32.547]	[-52.187; -6.403]
Min-Max	-168 - 65	-43 - 90	-155 - 42
Median	0.00	0.00	-11.50
Q1-Q3	-53.00 - 0.00	-15.00 - 13.00	-60.00 - 0.00
Relative change from baseline			
n	22	9	22
Mean (SD)	-6.76 (23.563)	3.05 (24.454)	-10.72 (25.823)
95% CL	[-17.210; 3.685]	[-15.748; 21.846]	[-22.167; 0.731]
Min-Max	-60.432 - 37.3563	-23.757 - 60.4027	-56.593 - 48.8372
Median	0.00	0.00	-7.93
Q1-Q3	-26.64 - 0.00	-9.09 - 6.95	-29.41 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 12 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.1 Full Analysis Set - FGM - SMBG
4.2.2.1.1 Missing values as documented

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	53	17	36
Mean (SD)	185.33 (63.677)	177.17 (47.785)	189.19 (70.233)
95% CL	[167.780;202.883]	[152.601;201.738]	[165.422;212.949]
Min-Max	86 - 401.806	116 - 297.3	86 - 401.806
Median	170.00	166.00	171.50
Q1-Q3	145.00 - 218.00	144.00 - 182.00	145.00 - 222.50
After 24 weeks			
n	47	14	33
Mean (SD)	143.54 (41.030)	149.07 (38.628)	141.20 (42.365)
95% CL	[131.495;155.588]	[126.762;171.368]	[126.176;156.220]
Min-Max	81 - 263	99 - 213	81 - 263
Median	134.00	141.00	134.00
Q1-Q3	110.00 - 169.00	120.00 - 186.00	110.00 - 169.00
Absolute change from baseline			
n	39	13	26
Mean (SD)	-18.38 (49.705)	-13.82 (50.214)	-20.66 (50.287)
95% CL	[-34.490; -2.265]	[-44.162; 16.526]	[-40.968; -0.346]
Min-Max	-136 - 81.0819	-134 - 52	-136 - 81.0819
Median	-21.00	-21.00	-20.00
Q1-Q3	-47.00 - 14.00	-30.63 - 26.00	-48.00 - 12.00
Relative change from baseline			
n	39	13	26
Mean (SD)	-6.75 (26.866)	-6.00 (25.798)	-7.13 (27.878)
95% CL	[-15.464; 1.954]	[-21.586; 9.593]	[-18.395; 4.126]
Min-Max	-53.125 - 62.5	-50.951 - 36.3636	-53.125 - 62.5
Median	-12.28	-12.28	-12.24
Q1-Q3	-23.87 - 13.90	-21.79 - 13.90	-23.87 - 12.24

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.1 Full Analysis Set - FGM - SMBG
4.2.2.1.2 Missing values missing according to LOCF

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	53	17	36
Mean (SD)	185.33 (63.677)	177.17 (47.785)	189.19 (70.233)
95% CL	[167.780;202.883]	[152.601;201.738]	[165.422;212.949]
Min-Max	86 - 401.806	116 - 297.3	86 - 401.806
Median	170.00	166.00	171.50
Q1-Q3	145.00 - 218.00	144.00 - 182.00	145.00 - 222.50
After 24 weeks			
n	63	18	45
Mean (SD)	155.57 (54.901)	154.15 (52.008)	156.14 (56.577)
95% CL	[141.745;169.398]	[128.290;180.016]	[139.141;173.136]
Min-Max	79 - 337	79 - 297.3	81 - 337
Median	144.00	149.78	143.00
Q1-Q3	113.00 - 186.00	120.00 - 186.00	113.00 - 183.79
Absolute change from baseline			
n	53	17	36
Mean (SD)	-22.25 (53.176)	-21.71 (51.729)	-22.50 (54.568)
95% CL	[-36.904; -7.590]	[-48.309; 4.884]	[-40.963; -4.037]
Min-Max	-168 - 81.0819	-134 - 52	-168 - 81.0819
Median	-5.60	-21.00	-4.80
Q1-Q3	-48.00 - 10.00	-47.00 - 11.00	-50.50 - 7.00
Relative change from baseline			
n	53	17	36
Mean (SD)	-8.15 (26.548)	-10.07 (26.547)	-7.25 (26.877)
95% CL	[-15.471; -0.835]	[-23.719; 3.579]	[-16.342; 1.846]
Min-Max	-60.432 - 62.5	-56.593 - 36.3636	-60.432 - 62.5
Median	-6.47	-12.28	-4.17
Q1-Q3	-25.00 - 7.35	-29.75 - 7.64	-24.44 - 4.89

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.2 Full Analysis Set - Subgroups - Gender
4.2.2.2.1 Missing values as documented

	Female (N = 28)	Male (N = 42)
Baseline		
n	23	30
Mean (SD)	187.39 (72.347)	183.75 (57.393)
95% CL	[156.103;218.674]	[162.324;205.185]
Min-Max	86 - 401.806	86.6 - 330
Median	173.00	165.00
Q1-Q3	149.00 - 218.00	144.00 - 222.00
After 24 weeks		
n	16	31
Mean (SD)	137.88 (39.803)	146.46 (41.991)
95% CL	[116.673;159.092]	[131.060;161.865]
Min-Max	100 - 212	81 - 263
Median	125.00	143.00
Q1-Q3	105.96 - 161.50	120.00 - 169.00
Absolute change from baseline		
n	14	25
Mean (SD)	-13.73 (57.499)	-20.98 (45.839)
95% CL	[-46.927; 19.471]	[-39.902; -2.059]
Min-Max	-134 - 49	-136 - 81.0819
Median	11.00	-22.00
Q1-Q3	-48.00 - 27.00	-42.00 - 4.00
Relative change from baseline		
n	14	25
Mean (SD)	-2.82 (31.231)	-8.96 (24.503)
95% CL	[-20.848; 15.216]	[-19.075; 1.153]
Min-Max	-50.951 - 48.5149	-53.125 - 62.5
Median	9.80	-13.50
Q1-Q3	-32.00 - 16.28	-20.80 - 2.42

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.2 Full Analysis Set - Subgroups - Gender
4.2.2.2.2 Missing values missing according to LOCF

	Female (N = 28)	Male (N = 42)
Baseline		
n	23	30
Mean (SD)	187.39 (72.347)	183.75 (57.393)
95% CL	[156.103;218.674]	[162.324;205.185]
Min-Max	86 - 401.806	86.6 - 330
Median	173.00	165.00
Q1-Q3	149.00 - 218.00	144.00 - 222.00
After 24 weeks		
n	25	38
Mean (SD)	163.41 (64.676)	150.41 (47.630)
95% CL	[136.717;190.111]	[134.756;166.067]
Min-Max	79 - 337	81 - 297.3
Median	149.55	142.00
Q1-Q3	110.00 - 207.21	120.00 - 180.00
Absolute change from baseline		
n	23	30
Mean (SD)	-18.55 (57.248)	-25.08 (50.645)
95% CL	[-43.303; 6.209]	[-43.995; -6.173]
Min-Max	-134 - 65	-168 - 81.0819
Median	0.00	-21.50
Q1-Q3	-59.00 - 24.00	-47.00 - 0.00
Relative change from baseline		
n	23	30
Mean (SD)	-5.33 (29.253)	-10.32 (24.566)
95% CL	[-17.983; 7.317]	[-19.488; -1.142]
Min-Max	-56.593 - 48.5149	-60.432 - 62.5
Median	0.00	-12.89
Q1-Q3	-32.00 - 16.11	-23.87 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.3 Full Analysis Set - Subgroups - Age groups
4.2.2.3.1 Missing values as documented

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	17	18	18
Mean (SD)	192.24 (69.879)	176.73 (49.415)	187.41 (72.348)
95% CL	[156.315;228.172]	[152.152;201.300]	[151.431;223.387]
Min-Max	121 - 401.806	101 - 297.3	86 - 337
Median	180.00	164.00	183.00
Q1-Q3	143.00 - 215.00	149.00 - 182.00	144.00 - 223.00
After 24 weeks			
n	14	16	17
Mean (SD)	142.85 (40.434)	138.86 (38.392)	148.51 (45.620)
95% CL	[119.505;166.197]	[118.406;159.321]	[125.058;171.969]
Min-Max	92 - 213	90 - 212	81 - 263
Median	130.50	142.50	134.00
Q1-Q3	110.00 - 186.00	101.50 - 159.50	122.52 - 169.00
Absolute change from baseline			
n	12	12	15
Mean (SD)	-26.14 (55.694)	-5.08 (56.736)	-22.81 (38.925)
95% CL	[-61.522; 9.250]	[-41.125; 30.972]	[-44.366; -1.255]
Min-Max	-134 - 52	-136 - 81.0819	-110 - 41.4419
Median	-26.50	1.50	-22.00
Q1-Q3	-50.50 - 26.00	-34.50 - 35.00	-53.00 - 11.00
Relative change from baseline			
n	12	12	15
Mean (SD)	-12.58 (27.768)	1.94 (33.530)	-9.05 (19.247)
95% CL	[-30.224; 5.061]	[-19.365; 23.243]	[-19.708; 1.609]
Min-Max	-50.951 - 36.3636	-53.125 - 62.5	-46.218 - 25
Median	-17.86	0.87	-15.17
Q1-Q3	-32.06 - 14.76	-21.62 - 21.91	-21.18 - 7.64

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.3 Full Analysis Set - Subgroups - Age groups
4.2.2.3.2 Missing values missing according to LOCF

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	17	18	18
Mean (SD)	192.24 (69.879)	176.73 (49.415)	187.41 (72.348)
95% CL	[156.315;228.172]	[152.152;201.300]	[151.431;223.387]
Min-Max	121 - 401.806	101 - 297.3	86 - 337
Median	180.00	164.00	183.00
Q1-Q3	143.00 - 215.00	149.00 - 182.00	144.00 - 223.00
After 24 weeks			
n	19	23	21
Mean (SD)	153.77 (52.515)	150.68 (52.204)	162.56 (61.499)
95% CL	[128.457;179.079]	[128.106;173.256]	[134.564;190.553]
Min-Max	92 - 291.895	79 - 297.3	81 - 337
Median	132.00	146.00	143.00
Q1-Q3	110.00 - 195.00	102.00 - 173.00	122.52 - 207.21
Absolute change from baseline			
n	17	18	18
Mean (SD)	-34.80 (62.269)	-13.63 (58.554)	-19.01 (36.391)
95% CL	[-66.812; -2.781]	[-42.752; 15.485]	[-37.105; -0.912]
Min-Max	-168 - 52	-136 - 81.0819	-110 - 41.4419
Median	-26.00	-0.50	-4.80
Q1-Q3	-59.00 - 0.00	-48.00 - 24.00	-42.00 - 4.00
Relative change from baseline			
n	17	18	18
Mean (SD)	-14.04 (26.725)	-3.20 (33.249)	-7.54 (17.808)
95% CL	[-27.786; -0.304]	[-19.735; 13.334]	[-16.397; 1.315]
Min-Max	-60.432 - 36.3636	-56.593 - 62.5	-46.218 - 25
Median	-14.92	-0.34	-4.17
Q1-Q3	-31.34 - 0.00	-29.75 - 16.11	-20.30 - 3.45

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.2.2.4.1 Missing values as documented

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	14	39
Mean (SD)	202.97 (74.960)	179.00 (58.911)
95% CL	[159.691;246.252]	[159.903;198.096]
Min-Max	86.6 - 337	86 - 401.806
Median	200.50	165.77
Q1-Q3	149.00 - 240.00	143.00 - 214.00
After 24 weeks		
n	11	36
Mean (SD)	163.18 (51.765)	137.54 (35.898)
95% CL	[128.406;197.958]	[125.394;149.687]
Min-Max	81 - 263	90 - 212
Median	146.00	130.00
Q1-Q3	129.00 - 210.00	109.96 - 154.50
Absolute change from baseline		
n	10	29
Mean (SD)	-20.96 (48.972)	-17.49 (50.782)
95% CL	[-55.992; 14.072]	[-36.803; 1.830]
Min-Max	-134 - 26	-136 - 81.0819
Median	-4.80	-22.00
Q1-Q3	-42.00 - 12.00	-47.00 - 14.00
Relative change from baseline		
n	10	29
Mean (SD)	-6.78 (20.198)	-6.75 (29.128)
95% CL	[-21.232; 7.666]	[-17.825; 4.334]
Min-Max	-50.951 - 16.1074	-53.125 - 62.5
Median	-4.17	-14.92
Q1-Q3	-18.83 - 12.24	-27.04 - 15.61

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.2.2.4.2 Missing values missing according to LOCF

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	14	39
Mean (SD)	202.97 (74.960)	179.00 (58.911)
95% CL	[159.691;246.252]	[159.903;198.096]
Min-Max	86.6 - 337	86 - 401.806
Median	200.50	165.77
Q1-Q3	149.00 - 240.00	143.00 - 214.00
After 24 weeks		
n	15	48
Mean (SD)	174.27 (68.719)	149.73 (49.224)
95% CL	[136.211;212.322]	[135.436;164.022]
Min-Max	79 - 337	90 - 297.3
Median	173.00	135.50
Q1-Q3	129.00 - 213.00	112.00 - 176.39
Absolute change from baseline		
n	14	39
Mean (SD)	-26.61 (48.254)	-20.68 (55.347)
95% CL	[-54.475; 1.247]	[-38.621; -2.738]
Min-Max	-134 - 26	-168 - 81.0819
Median	-4.80	-21.00
Q1-Q3	-60.00 - 0.00	-48.00 - 11.00
Relative change from baseline		
n	14	39
Mean (SD)	-10.67 (22.127)	-7.25 (28.175)
95% CL	[-23.449; 2.102]	[-16.381; 1.885]
Min-Max	-56.593 - 16.1074	-60.432 - 62.5
Median	-4.17	-12.28
Q1-Q3	-20.30 - 0.00	-27.35 - 7.64

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.5 Full Analysis Set - Subgroups - Renal function
4.2.2.5.1 Missing values as documented

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	32
Mean (SD)	172.27 (62.831)	187.32 (65.218)
95% CL	[138.792;205.753]	[163.805;210.833]
Min-Max	86 - 337	98 - 401.806
Median	172.00	165.00
Q1-Q3	130.50 - 205.00	144.50 - 220.00
After 24 weeks		
n	13	30
Mean (SD)	143.48 (45.780)	147.12 (40.542)
95% CL	[115.813;171.142]	[131.985;162.263]
Min-Max	81 - 213	90 - 263
Median	134.00	142.50
Q1-Q3	102.00 - 181.00	113.00 - 169.00
Absolute change from baseline		
n	12	26
Mean (SD)	-6.35 (34.677)	-23.64 (55.907)
95% CL	[-28.379; 15.686]	[-46.218; -1.055]
Min-Max	-53 - 49	-136 - 81.0819
Median	-4.80	-21.50
Q1-Q3	-39.00 - 20.00	-53.00 - 12.00
Relative change from baseline		
n	12	26
Mean (SD)	-1.28 (23.861)	-8.74 (28.640)
95% CL	[-16.445; 13.876]	[-20.307; 2.828]
Min-Max	-32 - 48.5149	-53.125 - 62.5
Median	-4.17	-12.89
Q1-Q3	-20.01 - 15.09	-29.75 - 12.24

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.5 Full Analysis Set - Subgroups - Renal function
4.2.2.5.2 Missing values missing according to LOCF

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	32
Mean (SD)	172.27 (62.831)	187.32 (65.218)
95% CL	[138.792;205.753]	[163.805;210.833]
Min-Max	86 - 337	98 - 401.806
Median	172.00	165.00
Q1-Q3	130.50 - 205.00	144.50 - 220.00
After 24 weeks		
n	17	37
Mean (SD)	161.37 (69.267)	155.57 (50.247)
95% CL	[125.751;196.979]	[138.821;172.328]
Min-Max	79 - 337	90 - 297.3
Median	143.00	146.00
Q1-Q3	102.00 - 210.00	121.00 - 173.00
Absolute change from baseline		
n	16	32
Mean (SD)	-7.13 (42.996)	-25.34 (54.381)
95% CL	[-30.046; 15.776]	[-44.948; -5.736]
Min-Max	-103 - 65	-136 - 81.0819
Median	-2.00	-19.50
Q1-Q3	-39.00 - 20.00	-56.00 - 10.50
Relative change from baseline		
n	16	32
Mean (SD)	-2.17 (26.840)	-9.10 (26.599)
95% CL	[-16.468; 12.137]	[-18.691; 0.489]
Min-Max	-56.593 - 48.5149	-53.125 - 62.5
Median	-0.93	-11.63
Q1-Q3	-20.01 - 15.09	-28.55 - 7.50

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.2.2.6.1 Missing values as documented

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	17	26
Mean (SD)	156.00 (39.598)	213.62 (82.899)	175.29 (49.239)
95% CL	[119.378;192.622]	[170.995;256.240]	[155.402;195.178]
Min-Max	101 - 218	86.6 - 401.806	86 - 330
Median	163.00	214.00	165.38
Q1-Q3	121.00 - 180.00	160.00 - 263.00	145.00 - 196.00
After 24 weeks			
n	6	11	27
Mean (SD)	144.67 (31.200)	141.09 (43.346)	147.17 (44.396)
95% CL	[111.924;177.410]	[111.971;170.211]	[129.606;164.731]
Min-Max	110 - 200	81 - 213	90 - 263
Median	143.50	132.00	143.00
Q1-Q3	121.00 - 150.00	101.00 - 181.00	111.00 - 169.00
Absolute change from baseline			
n	6	9	21
Mean (SD)	-17.17 (58.465)	-18.07 (51.695)	-12.50 (45.099)
95% CL	[-78.522; 44.189]	[-57.803; 21.669]	[-33.028; 8.030]
Min-Max	-108 - 49	-134 - 26	-110 - 81.0819
Median	-6.00	-5.60	-18.00
Q1-Q3	-59.00 - 27.00	-42.00 - 24.00	-47.00 - 11.00
Relative change from baseline			
n	6	9	21
Mean (SD)	-4.06 (35.393)	-7.11 (24.003)	-4.05 (26.372)
95% CL	[-41.200; 33.086]	[-25.562; 11.338]	[-16.052; 7.956]
Min-Max	-49.541 - 48.5149	-50.951 - 16.25	-46.218 - 62.5
Median	-3.07	-6.47	-10.98
Q1-Q3	-32.78 - 15.61	-18.83 - 13.90	-21.18 - 7.64

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.2.2.6.2 Missing values missing according to LOCF

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	17	26
Mean (SD)	156.00 (39.598)	213.62 (82.899)	175.29 (49.239)
95% CL	[119.378;192.622]	[170.995;256.240]	[155.402;195.178]
Min-Max	101 - 218	86.6 - 401.806	86 - 330
Median	163.00	214.00	165.38
Q1-Q3	121.00 - 180.00	160.00 - 263.00	145.00 - 196.00
After 24 weeks			
n	7	19	34
Mean (SD)	141.29 (29.854)	180.21 (72.845)	148.09 (44.971)
95% CL	[113.676;168.896]	[145.099;215.320]	[132.400;163.782]
Min-Max	110 - 200	81 - 337	79 - 263
Median	141.00	181.00	143.50
Q1-Q3	121.00 - 150.00	110.00 - 215.00	113.00 - 169.00
Absolute change from baseline			
n	7	17	26
Mean (SD)	-14.71 (53.764)	-25.91 (57.666)	-17.19 (49.875)
95% CL	[-64.438; 35.009]	[-55.562; 3.737]	[-37.336; 2.954]
Min-Max	-108 - 49	-168 - 26	-110 - 81.0819
Median	0.00	0.00	-19.50
Q1-Q3	-59.00 - 27.00	-42.00 - 0.00	-53.00 - 11.00
Relative change from baseline			
n	7	17	26
Mean (SD)	-3.48 (32.346)	-8.93 (22.513)	-6.38 (28.115)
95% CL	[-33.392; 26.438]	[-20.504; 2.646]	[-17.736; 4.976]
Min-Max	-49.541 - 48.5149	-60.432 - 16.25	-56.593 - 62.5
Median	0.00	0.00	-11.63
Q1-Q3	-32.78 - 15.61	-18.83 - 0.00	-25.00 - 7.64

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.2.2.7.1 Missing values as documented

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	29	24
Mean (SD)	166.65 (50.766)	207.91 (71.117)
95% CL	[147.335;185.956]	[177.880;237.940]
Min-Max	86.6 - 297.3	86 - 401.806
Median	158.00	191.50
Q1-Q3	136.00 - 182.00	163.50 - 229.52
After 24 weeks		
n	29	18
Mean (SD)	136.67 (35.349)	154.61 (47.821)
95% CL	[123.225;150.117]	[130.830;178.392]
Min-Max	81 - 212	99 - 263
Median	129.00	144.50
Q1-Q3	111.00 - 150.00	110.00 - 186.00
Absolute change from baseline		
n	24	15
Mean (SD)	-19.24 (55.864)	-17.00 (39.692)
95% CL	[-42.827; 4.352]	[-38.981; 4.981]
Min-Max	-136 - 81.0819	-108 - 27
Median	-21.50	-18.00
Q1-Q3	-47.50 - 11.50	-42.00 - 24.00
Relative change from baseline		
n	24	15
Mean (SD)	-6.67 (30.766)	-6.90 (20.102)
95% CL	[-19.657; 6.325]	[-18.030; 4.234]
Min-Max	-53.125 - 62.5	-49.541 - 16.2791
Median	-13.60	-10.98
Q1-Q3	-30.55 - 9.94	-20.80 - 15.61

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.2.2.7.2 Missing values missing according to LOCF

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	29	24
Mean (SD)	166.65 (50.766)	207.91 (71.117)
95% CL	[147.335;185.956]	[177.880;237.940]
Min-Max	86.6 - 297.3	86 - 401.806
Median	158.00	191.50
Q1-Q3	136.00 - 182.00	163.50 - 229.52
After 24 weeks		
n	35	28
Mean (SD)	142.10 (46.017)	172.41 (61.037)
95% CL	[126.294;157.909]	[148.741;196.077]
Min-Max	79 - 297.3	99 - 337
Median	129.00	165.50
Q1-Q3	111.00 - 155.00	123.50 - 211.50
Absolute change from baseline		
n	29	24
Mean (SD)	-19.47 (53.544)	-25.60 (53.679)
95% CL	[-39.840; 0.894]	[-48.266; -2.933]
Min-Max	-136 - 81.0819	-168 - 65
Median	-5.60	-11.00
Q1-Q3	-47.00 - 10.00	-56.50 - 9.00
Relative change from baseline		
n	29	24
Mean (SD)	-7.47 (29.533)	-8.98 (23.030)
95% CL	[-18.702; 3.766]	[-18.705; 0.744]
Min-Max	-56.593 - 62.5	-60.432 - 37.3563
Median	-6.47	-6.42
Q1-Q3	-29.75 - 7.35	-23.09 - 8.16

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.2.2.8.1 Missing values as documented

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	9	14	24	6
Mean (SD)	178.87 (58.192)	200.58 (88.977)	181.03 (54.237)	176.63 (41.584)
95% CL	[134.141;223.602]	[149.210;251.958]	[158.130;203.934]	[132.991;220.271]
Min-Max	101 - 297.3	86 - 401.806	98 - 330	121 - 223
Median	166.00	181.50	165.38	174.39
Q1-Q3	140.54 - 215.00	158.00 - 236.04	145.00 - 216.00	144.00 - 223.00
After 24 weeks				
n	6	12	26	3
Mean (SD)	153.49 (34.673)	141.40 (43.686)	139.37 (43.429)	168.33 (13.013)
95% CL	[117.098;189.873]	[113.644;169.158]	[121.833;156.916]	[136.008;200.659]
Min-Max	109.911 - 212	81 - 213	90 - 263	155 - 181
Median	148.00	138.50	125.50	169.00
Q1-Q3	134.00 - 169.00	106.00 - 170.00	110.00 - 146.00	155.00 - 181.00
Absolute change from baseline				
n	6	8	22	3
Mean (SD)	-2.44 (43.874)	5.81 (40.112)	-32.80 (53.582)	-9.00 (28.792)
95% CL	[-48.481; 43.604]	[-27.724; 39.344]	[-56.555; -9.041]	[-80.524; 62.524]
Min-Max	-53 - 49	-47 - 81.0819	-136 - 52	-42 - 11
Median	-10.32	4.20	-24.00	4.00
Q1-Q3	-36.00 - 46.00	-24.00 - 26.00	-59.00 - 4.00	-42.00 - 11.00
Relative change from baseline				
n	6	8	22	3
Mean (SD)	2.79 (30.405)	5.69 (28.460)	-14.41 (25.472)	-2.92 (14.023)
95% CL	[-29.119; 34.697]	[-18.103; 29.483]	[-25.699; -3.112]	[-37.760; 31.912]
Min-Max	-23.874 - 48.5149	-29.747 - 62.5	-53.125 - 36.3636	-18.834 - 7.63889
Median	-6.91	3.72	-17.28	2.42
Q1-Q3	-21.79 - 27.71	-13.60 - 16.26	-32.00 - 3.45	-18.83 - 7.64

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.2.2.8.2 Missing values missing according to LOCF

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	9	14	24	6
Mean (SD)	178.87 (58.192)	200.58 (88.977)	181.03 (54.237)	176.63 (41.584)
95% CL	[134.141;223.602]	[149.210;251.958]	[158.130;203.934]	[132.991;220.271]
Min-Max	101 - 297.3	86 - 401.806	98 - 330	121 - 223
Median	166.00	181.50	165.38	174.39
Q1-Q3	140.54 - 215.00	158.00 - 236.04	145.00 - 216.00	144.00 - 223.00
After 24 weeks				
n	9	20	28	6
Mean (SD)	177.25 (56.424)	156.51 (68.159)	144.38 (46.358)	172.13 (33.822)
95% CL	[133.874;220.617]	[124.614;188.412]	[126.407;162.359]	[136.636;207.625]
Min-Max	109.911 - 297.3	79 - 337	90 - 263	121 - 223
Median	162.00	141.00	128.50	175.00
Q1-Q3	146.00 - 212.00	110.50 - 198.41	110.00 - 176.50	155.00 - 183.79
Absolute change from baseline				
n	9	14	24	6
Mean (SD)	-1.63 (34.707)	-30.07 (66.374)	-29.86 (55.321)	-4.50 (18.865)
95% CL	[-28.304; 25.052]	[-68.388; 8.258]	[-53.217; -6.497]	[-24.298; 15.298]
Min-Max	-53 - 49	-168 - 81.0819	-136 - 65	-42 - 11
Median	0.00	-13.30	-24.00	0.00
Q1-Q3	-30.63 - 10.00	-86.49 - 14.00	-59.50 - 8.00	0.00 - 4.00
Relative change from baseline				
n	9	14	24	6
Mean (SD)	1.86 (24.078)	-9.68 (32.300)	-12.69 (26.659)	-1.46 (9.013)
95% CL	[-16.649; 20.367]	[-28.328; 8.971]	[-23.947; -1.433]	[-10.920; 7.996]
Min-Max	-23.874 - 48.5149	-60.432 - 62.5	-53.125 - 37.3563	-18.834 - 7.63889
Median	0.00	-9.37	-17.28	0.00
Q1-Q3	-21.18 - 7.35	-29.75 - 13.90	-31.67 - 7.85	0.00 - 2.42

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.2.2.9.1 Missing values as documented

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	22	9	22
Mean (SD)	190.67 (67.710)	157.11 (21.929)	191.54 (69.720)
95% CL	[160.647;220.689]	[140.255;173.967]	[160.628;222.452]
Min-Max	86.6 - 401.806	116 - 187	86 - 337
Median	178.89	158.00	165.50
Q1-Q3	150.00 - 222.00	144.00 - 171.00	145.00 - 238.00
After 24 weeks			
n	16	9	22
Mean (SD)	148.97 (42.766)	160.00 (32.492)	132.86 (41.484)
95% CL	[126.183;171.760]	[135.024;184.976]	[114.467;151.252]
Min-Max	81 - 210.813	111 - 213	90 - 263
Median	144.50	155.00	125.50
Q1-Q3	115.00 - 190.50	150.00 - 173.00	101.00 - 144.00
Absolute change from baseline			
n	14	9	16
Mean (SD)	-16.01 (52.277)	2.89 (30.440)	-32.41 (53.938)
95% CL	[-46.189; 14.178]	[-20.510; 26.287]	[-61.156; -3.673]
Min-Max	-136 - 81.0819	-47 - 52	-134 - 49
Median	-11.80	4.00	-28.32
Q1-Q3	-48.00 - 12.00	-21.00 - 24.00	-63.00 - 6.50
Relative change from baseline			
n	14	9	16
Mean (SD)	-5.19 (28.714)	2.55 (19.529)	-13.36 (28.458)
95% CL	[-21.769; 11.389]	[-12.462; 17.560]	[-28.522; 1.806]
Min-Max	-53.125 - 62.5	-29.747 - 36.3636	-50.951 - 48.5149
Median	-8.72	3.45	-19.85
Q1-Q3	-23.87 - 12.24	-12.28 - 13.90	-32.06 - 7.78

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits

4 Effectiveness (secondary)
4.2 Absolute and relative change in fasting blood glucose in mg/dL
4.2.2 Change from baseline to the visit after approx. 24 weeks
4.2.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.2.2.9.2 Missing values missing according to LOCF

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	22	9	22
Mean (SD)	190.67 (67.710)	157.11 (21.929)	191.54 (69.720)
95% CL	[160.647;220.689]	[140.255;173.967]	[160.628;222.452]
Min-Max	86.6 - 401.806	116 - 187	86 - 337
Median	178.89	158.00	165.50
Q1-Q3	150.00 - 222.00	144.00 - 171.00	145.00 - 238.00
After 24 weeks			
n	25	9	29
Mean (SD)	163.85 (53.685)	160.00 (32.492)	147.06 (61.317)
95% CL	[141.689;186.009]	[135.024;184.976]	[123.737;170.384]
Min-Max	81 - 291.895	111 - 213	79 - 337
Median	146.00	155.00	132.00
Q1-Q3	120.00 - 210.00	150.00 - 173.00	109.91 - 150.00
Absolute change from baseline			
n	22	9	22
Mean (SD)	-19.86 (59.747)	2.89 (30.440)	-34.91 (51.326)
95% CL	[-46.353; 6.627]	[-20.510; 26.287]	[-57.671;-12.158]
Min-Max	-168 - 81.0819	-47 - 52	-134 - 49
Median	-2.00	4.00	-28.32
Q1-Q3	-48.00 - 10.00	-21.00 - 24.00	-67.00 - 0.00
Relative change from baseline			
n	22	9	22
Mean (SD)	-5.59 (27.777)	2.55 (19.529)	-15.09 (26.872)
95% CL	[-17.910; 6.721]	[-12.462; 17.560]	[-27.004; -3.175]
Min-Max	-60.432 - 62.5	-29.747 - 36.3636	-56.593 - 48.5149
Median	-0.93	3.45	-19.85
Q1-Q3	-23.87 - 7.35	-12.28 - 13.90	-32.78 - 0.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes were calculated only for patients with data documented at both visits
If baseline was documented, missing values at week 24 were replaced according to the LOCF principle

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.1 Full Analysis Set - FGM - SMBG

Percentage of reaching Individual HbA1c target value	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Week 0 - 12	8 (11.43%)	2 (10.00%)	6 (12.00%)
	[5.07; 21.28]	[1.23; 31.70]	[4.53; 24.31]
Week 13 - 24	9 (12.86%)	3 (15.00%)	6 (12.00%)
	[6.05; 23.01]	[3.21; 37.89]	[4.53; 24.31]
Week 0 - 24[1]	12 (17.14%)	4 (20.00%)	8 (16.00%)
	[9.18; 28.03]	[5.73; 43.66]	[7.17; 29.11]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.2 Full Analysis Set - Subgroups - Gender

Percentage of reaching Individual HbA1c target value	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Week 0 - 12	3 (10.71%)	5 (11.90%)
	[2.27; 28.23]	[3.98; 25.63]
Week 13 - 24	3 (10.71%)	6 (14.29%)
	[2.27; 28.23]	[5.43; 28.54]
Week 0 - 24[1]	5 (17.86%)	7 (16.67%)
	[6.06; 36.89]	[6.97; 31.36]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.3 Full Analysis Set - Subgroups - Age groups

Percentage of reaching Individual HbA1c target value	<= 60 years (N = 24) N (%) [95% CI]°	>60 - <70 years (N = 24) N (%) [95% CI]°	>=70 years (N = 22) N (%) [95% CI]°
Week 0 - 12	1 (4.17%)	3 (12.50%)	4 (18.18%)
	[0.11; 21.12]	[2.66; 32.36]	[5.19; 40.28]
Week 13 - 24	3 (12.50%)	4 (16.67%)	2 (9.09%)
	[2.66; 32.36]	[4.74; 37.38]	[1.12; 29.16]
Week 0 - 24[1]	3 (12.50%)	5 (20.83%)	4 (18.18%)
	[2.66; 32.36]	[7.13; 42.15]	[5.19; 40.28]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.4 Full Analysis Set - Subgroups - Body Mass Index

Percentage of reaching Individual HbA1c target value	<30 kg/m² (N = 18) N (%) [95% CI]°	>=30 kg/m² (N = 52) N (%) [95% CI]°
Week 0 - 12	2 (11.11%)	6 (11.54%)
	[1.38; 34.71]	[4.35; 23.44]
Week 13 - 24	none	9 (17.31%)
		[8.23; 30.33]
Week 0 - 24[1]	2 (11.11%)	10 (19.23%)
	[1.38; 34.71]	[9.63; 32.53]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.5 Full Analysis Set - Subgroups - Renal function

Percentage of reaching Individual HbA1c target value	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]°	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]°
Week 0 - 12	4 (23.53%)	3 (7.69%)
	[6.81; 49.90]	[1.62; 20.87]
Week 13 - 24	1 (5.88%)	6 (15.38%)
	[0.15; 28.69]	[5.86; 30.53]
Week 0 - 24[1]	4 (23.53%)	6 (15.38%)
	[6.81; 49.90]	[5.86; 30.53]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.6 Full Analysis Set - Subgroups - Duration of diabetes

Percentage of reaching Individual HbA1c target value	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
Week 0 - 12	1 (14.29%)	1 (4.76%)	6 (15.38%)
	[0.36; 57.87]	[0.12; 23.82]	[5.86; 30.53]
Week 13 - 24	2 (28.57%)	3 (14.29%)	4 (10.26%)
	[3.67; 70.96]	[3.05; 36.34]	[2.87; 24.22]
Week 0 - 24[1]	2 (28.57%)	3 (14.29%)	7 (17.95%)
	[3.67; 70.96]	[3.05; 36.34]	[7.54; 33.53]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.7 Full Analysis Set - Subgroups - Baseline HbA1c

Percentage of reaching Individual HbA1c target value	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Week 0 - 12	5 (13.16%)	3 (9.38%)
	[4.41; 28.09]	[1.98; 25.02]
Week 13 - 24	6 (15.79%)	3 (9.38%)
	[6.02; 31.25]	[1.98; 25.02]
Week 0 - 24[1]	8 (21.05%)	4 (12.50%)
	[9.55; 37.32]	[3.51; 28.99]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

Percentage of reaching Individual HbA1c target value	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
Week 0 - 12	none	2 (8.33%) [1.03; 27.00]	6 (20.69%) [7.99; 39.72]	none
Week 13 - 24	1 (9.09%) [0.23; 41.28]	3 (12.50%) [2.66; 32.36]	5 (17.24%) [5.85; 35.77]	none
Week 0 - 24[1]	1 (9.09%) [0.23; 41.28]	4 (16.67%) [4.74; 37.38]	7 (24.14%) [10.30; 43.54]	none

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.1 Percentage of reaching Individual HbA1c target value within week 0-12, 13-24 and 0-24
4.3.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Percentage of reaching Individual HbA1c target value	before breakfast (N = 28) N (%) [95% CI]°	before lunch (N = 9) N (%) [95% CI]°	before dinner (N = 32) N (%) [95% CI]°
Week 0 - 12	4 (14.29%)	1 (11.11%)	3 (9.38%)
	[4.03; 32.67]	[0.28; 48.25]	[1.98; 25.02]
Week 13 - 24	3 (10.71%)	2 (22.22%)	4 (12.50%)
	[2.27; 28.23]	[2.81; 60.01]	[3.51; 28.99]
Week 0 - 24[1]	5 (17.86%)	2 (22.22%)	5 (15.63%)
	[6.06; 36.89]	[2.81; 60.01]	[5.28; 32.79]

° 95% CI according to Clopper-Pearson
[1] Individual HbA1c target value reached week 0-12 or week 13-24

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.1 Full Analysis Set - FGM - SMBG

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
FAS	70	8 (11.43%)	4 (5.71%)	58 (82.86%)
FGM	20	2 (10.00%)	2 (10.00%)	16 (80.00%)
SMBG	50	6 (12.00%)	2 (4.00%)	42 (84.00%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.2 Full Analysis Set - Subgroups - Gender

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
female	28	3 (10.71%)	2 (7.14%)	23 (82.14%)
male	42	5 (11.90%)	2 (4.76%)	35 (83.33%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.3 Full Analysis Set - Subgroups - Age groups

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
<= 60 years	24	1 (4.17%)	2 (8.33%)	21 (87.50%)
>60 - <70 years	24	3 (12.50%)	2 (8.33%)	19 (79.17%)
>=70 years	22	4 (18.18%)		18 (81.82%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.4 Full Analysis Set - Subgroups - Body Mass Index

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
<30 kg/m²	18	2 (11.11%)		16 (88.89%)
>=30 kg/m²	52	6 (11.54%)	4 (7.69%)	42 (80.77%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.5 Full Analysis Set - Subgroups - Renal function

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
<=60 ml	17	4 (23.53%)		13 (76.47%)
>60 ml	39	3 (7.69%)	3 (7.69%)	33 (84.62%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.6 Full Analysis Set - Subgroups - Duration of diabetes

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
up to 5 years	7	1 (14.29%)	1 (14.29%)	5 (71.43%)
5 to 10 years	21	1 (4.76%)	2 (9.52%)	18 (85.71%)
over 10 years	39	6 (15.38%)	1 (2.56%)	32 (82.05%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.7 Full Analysis Set - Subgroups - Baseline HbA1c

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
<8.5%	38	5 (13.16%)	3 (7.89%)	30 (78.95%)
>=8.5%	32	3 (9.38%)	1 (3.13%)	28 (87.50%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
Detemir	11		1 (9.09%)	10 (90.91%)
Glargin 100	24	2 (8.33%)	2 (8.33%)	20 (83.33%)
Glargin 300	29	6 (20.69%)	1 (3.45%)	22 (75.86%)
Degludec	6			6 (100.00%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.2 Time until achievement of the individual HbA1c target value
4.3.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Group	Total	First achieved at Week 12	First achieved at Week 24	Failed
before breakfast	28	4 (14.29%)	1 (3.57%)	23 (82.14%)
before lunch	9	1 (11.11%)	1 (11.11%)	7 (77.78%)
before dinner	32	3 (9.38%)	2 (6.25%)	27 (84.38%)

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.1 Full Analysis Set - FGM - SMBG

Staying below the individual HbA1c target value	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
stayed below	5 (7.14%)	1 (5.00%)	4 (8.00%)
	[2.36; 15.89]	[0.13; 24.87]	[2.22; 19.23]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.2 Full Analysis Set - Subgroups - Gender

Staying below the individual HbA1c target value	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
stayed below	1 (3.57%)	4 (9.52%)
	[0.09; 18.35]	[2.66; 22.62]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.3 Full Analysis Set - Subgroups - Age groups

Staying below the individual HbA1c target value	<= 60 years (N = 24) N (%) [95% CI]°	>60 - <70 years (N = 24) N (%) [95% CI]°	>=70 years (N = 22) N (%) [95% CI]°
stayed below	1 (4.17%)	2 (8.33%)	2 (9.09%)
	[0.11; 21.12]	[1.03; 27.00]	[1.12; 29.16]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.4 Full Analysis Set - Subgroups - Body Mass Index

Staying below the individual HbA1c target value	<30 kg/m² (N = 18) N (%) [95% CI]°	>=30 kg/m² (N = 52) N (%) [95% CI]°
stayed below	none	5 (9.62%)
		[3.20; 21.03]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.5 Full Analysis Set - Subgroups - Renal function

Staying below the individual HbA1c target value	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]°	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]°
stayed below	1 (5.88%)	3 (7.69%)
	[0.15; 28.69]	[1.62; 20.87]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.6 Full Analysis Set - Subgroups - Duration of diabetes

Staying below the individual HbA1c target value	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
stayed below	1 (14.29%)	1 (4.76%)	3 (7.69%)
	[0.36; 57.87]	[0.12; 23.82]	[1.62; 20.87]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.7 Full Analysis Set - Subgroups - Baseline HbA1c

Staying below the individual HbA1c target value	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
stayed below	3 (7.89%)	2 (6.25%)
	[1.66; 21.38]	[0.77; 20.81]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

Staying below the individual HbA1c target value	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
stayed below	none	1 (4.17%) [0.11; 21.12]	4 (13.79%) [3.89; 31.66]	none

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.3 Proportion of patients who achieve the individual HbA1c target value
4.3.3 Staying below the individual HbA1c target value between week 12 and week 24
4.3.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Staying below the individual HbA1c target value	before breakfast (N = 28) N (%) [95% CI]°	before lunch (N = 9) N (%) [95% CI]°	before dinner (N = 32) N (%) [95% CI]°
stayed below	2 (7.14%)	1 (11.11%)	2 (6.25%)
	[0.88; 23.50]	[0.28; 48.25]	[0.77; 20.81]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.1 Full Analysis Set - FGM - SMBG

Achieving a fasting blood glucose <=110 mg/dl at	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Week 0 - 12	15 (21.43%)	5 (25.00%)	10 (20.00%)
	[12.52; 32.87]	[8.66; 49.10]	[10.03; 33.72]
Week 12 - 24	17 (24.29%)	5 (25.00%)	12 (24.00%)
	[14.83; 36.01]	[8.66; 49.10]	[13.06; 38.17]
Week 0 - 24	21 (30.00%)	5 (25.00%)	16 (32.00%)
	[19.62; 42.13]	[8.66; 49.10]	[19.52; 46.70]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.2 Full Analysis Set - Subgroups - Gender

Achieving a fasting blood glucose <=110 mg/dl at	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Week 0 - 12	6 (21.43%)	9 (21.43%)
	[8.30; 40.95]	[10.30; 36.81]
Week 12 - 24	8 (28.57%)	9 (21.43%)
	[13.22; 48.67]	[10.30; 36.81]
Week 0 - 24	8 (28.57%)	13 (30.95%)
	[13.22; 48.67]	[17.62; 47.09]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.3 Full Analysis Set - Subgroups - Age groups

Achieving a fasting blood glucose <=110 mg/dl at	<= 60 years (N = 24) N (%) [95% CI]°	>60 - <70 years (N = 24) N (%) [95% CI]°	>=70 years (N = 22) N (%) [95% CI]°
Week 0 - 12	4 (16.67%)	6 (25.00%)	5 (22.73%)
	[4.74; 37.38]	[9.77; 46.71]	[7.82; 45.37]
Week 12 - 24	4 (16.67%)	9 (37.50%)	4 (18.18%)
	[4.74; 37.38]	[18.80; 59.41]	[5.19; 40.28]
Week 0 - 24	5 (20.83%)	9 (37.50%)	7 (31.82%)
	[7.13; 42.15]	[18.80; 59.41]	[13.86; 54.87]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.4 Full Analysis Set - Subgroups - Body Mass Index

Achieving a fasting blood glucose <=110 mg/dl at	<30 kg/m² (N = 18) N (%) [95% CI]°	>=30 kg/m² (N = 52) N (%) [95% CI]°
Week 0 - 12	4 (22.22%)	11 (21.15%)
	[6.41; 47.64]	[11.06; 34.70]
Week 12 - 24	3 (16.67%)	14 (26.92%)
	[3.58; 41.42]	[15.57; 41.02]
Week 0 - 24	5 (27.78%)	16 (30.77%)
	[9.69; 53.48]	[18.72; 45.10]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.5 Full Analysis Set - Subgroups - Renal function

Achieving a fasting blood glucose <=110 mg/dl at	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]°	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]°
Week 0 - 12	6 (35.29%)	6 (15.38%)
	[14.21; 61.67]	[5.86; 30.53]
Week 12 - 24	5 (29.41%)	8 (20.51%)
	[10.31; 55.96]	[9.30; 36.46]
Week 0 - 24	8 (47.06%)	8 (20.51%)
	[22.98; 72.19]	[9.30; 36.46]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.6 Full Analysis Set - Subgroups - Duration of diabetes

Achieving a fasting blood glucose <=110 mg/dl at	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
Week 0 - 12	1 (14.29%)	5 (23.81%)	8 (20.51%)
	[0.36; 57.87]	[8.22; 47.17]	[9.30; 36.46]
Week 12 - 24	1 (14.29%)	4 (19.05%)	12 (30.77%)
	[0.36; 57.87]	[5.45; 41.91]	[17.02; 47.57]
Week 0 - 24	1 (14.29%)	6 (28.57%)	13 (33.33%)
	[0.36; 57.87]	[11.28; 52.18]	[19.09; 50.22]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.7 Full Analysis Set - Subgroups - Baseline HbA1c

Achieving a fasting blood glucose <=110 mg/dl at	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Week 0 - 12	11 (28.95%)	4 (12.50%)
	[15.42; 45.90]	[3.51; 28.99]
Week 12 - 24	12 (31.58%)	5 (15.63%)
	[17.50; 48.65]	[5.28; 32.79]
Week 0 - 24	14 (36.84%)	7 (21.88%)
	[21.81; 54.01]	[9.28; 39.97]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.8 Full Analysis Set - Subgroups - Previous basal insulin therapy

Achieving a fasting blood glucose <=110 mg/dl at	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
Week 0 - 12	1 (9.09%)	6 (25.00%)	8 (27.59%)	
	[0.23; 41.28]	[9.77; 46.71]	[12.73; 47.24]	
Week 12 - 24		9 (37.50%)	8 (27.59%)	
		[18.80; 59.41]	[12.73; 47.24]	
Week 0 - 24	1 (9.09%)	10 (41.67%)	10 (34.48%)	
	[0.23; 41.28]	[22.11; 63.36]	[17.94; 54.33]	

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.4 Proportion of patients who achieve a fasting blood glucose <=110 mg/dl
4.4.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration

Achieving a fasting blood glucose <=110 mg/dl at	before breakfast (N = 28) N (%) [95% CI]°	before lunch (N = 9) N (%) [95% CI]°	before dinner (N = 32) N (%) [95% CI]°
Week 0 - 12	7 (25.00%) [10.69; 44.87]	3 (33.33%) [7.49; 70.07]	5 (15.63%) [5.28; 32.79]
Week 12 - 24	6 (21.43%) [8.30; 40.95]	3 (33.33%) [7.49; 70.07]	8 (25.00%) [11.46; 43.40]
Week 0 - 24	9 (32.14%) [15.88; 52.35]	3 (33.33%) [7.49; 70.07]	9 (28.13%) [13.75; 46.75]

° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	44	9	35
Mean (SD)	171.24 (47.578)	151.77 (29.582)	176.25 (50.307)
95% CL	[156.78; 185.71]	[129.04; 174.51]	[158.97; 193.53]
Min-Max	84 - 298	122 - 218.02	84 - 298
Median	163.00	144.00	167.00
Q1-Q3	136.94 -204.50	135.00 -154.00	138.74 -212.61
After 12 weeks			
n	41	7	34
Mean (SD)	138.74 (38.538)	121.74 (22.737)	142.25 (40.401)
95% CL	[126.58; 150.91]	[100.71; 142.76]	[128.15; 156.34]
Min-Max	77 - 242	90 - 158	77 - 242
Median	133.00	115.00	136.00
Q1-Q3	113.00 -154.96	111.00 -144.15	115.00 -159.00
Change from baseline			
n	31	7	24
Mean (SD)	-24.56 (47.414)	-31.98 (25.921)	-22.39 (52.301)
95% CL	[-41.95; -7.17]	[-55.96; -8.01]	[-44.48; -0.31]
Min-Max	-168 - 57	-73.87 - -7	-168 - 57
Median	-18.00	-20.00	-11.60
Q1-Q3	-56.00 - 7.00	-64.00 --17.00	-50.50 - 11.50
T-Test	t= -2.88 P= 0.007	t= -3.26 P= 0.017	t= -2.10 P= 0.047
Change from baseline [%]			
n	31	7	24
Mean (SD)	-10.78 (26.947)	-19.47 (13.159)	-8.24 (29.534)
95% CL	[-20.66; -0.89]	[-31.64; -7.30]	[-20.71; 4.23]
Min-Max	-62.69 - 58.763	-41.56 - -5.738	-62.69 - 58.763
Median	-12.14	-13.95	-6.61
Q1-Q3	-33.88 - 4.00	-33.88 --11.24	-30.59 - 9.26
T-Test	t= -2.23 P= 0.034	t= -3.91 P= 0.008	t= -1.37 P= 0.185

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	43	9	34
Mean (SD)	210.97 (52.549)	190.30 (28.966)	216.44 (56.248)
95% CL	[194.79; 227.14]	[168.04; 212.57]	[196.81; 236.06]
Min-Max	90.091 - 346	131.53 - 220	90.091 - 346
Median	210.00	199.00	212.00
Q1-Q3	179.00 -228.83	172.00 -212.00	180.00 -240.00
After 12 weeks			
n	35	7	28
Mean (SD)	185.75 (56.010)	170.36 (20.301)	189.60 (61.498)
95% CL	[166.51; 204.99]	[151.59; 189.14]	[165.75; 213.45]
Min-Max	107 - 440	140.54 - 193	107 - 440
Median	179.00	178.00	180.00
Q1-Q3	146.00 -200.00	145.00 -188.00	157.69 -209.50
Change from baseline			
n	27	7	20
Mean (SD)	-21.50 (51.765)	-27.09 (29.714)	-19.54 (58.073)
95% CL	[-41.98; -1.02]	[-54.57; 0.39]	[-46.72; 7.64]
Min-Max	-179 - 86	-75 - 6	-179 - 86
Median	-18.00	-24.00	-17.00
Q1-Q3	-57.66 - 6.00	-48.65 - 2.00	-59.33 - 29.00
T-Test	t= -2.16 P= 0.040	t= -2.41 P= 0.052	t= -1.50 P= 0.149
Change from baseline [%]			
n	27	7	20
Mean (SD)	-8.28 (23.553)	-12.79 (14.146)	-6.70 (26.188)
95% CL	[-17.59; 1.04]	[-25.87; 0.29]	[-18.95; 5.56]
Min-Max	-57.74 - 51.807	-34.09 - 3.4884	-57.74 - 51.807
Median	-9.09	-11.32	-8.49
Q1-Q3	-25.71 - 3.49	-25.71 - 1.19	-26.72 - 17.81
T-Test	t= -1.83 P= 0.079	t= -2.39 P= 0.054	t= -1.14 P= 0.267

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.3 7-point glucose daily profile (mg/dl) - before lunch

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	44	9	35
Mean (SD)	175.44 (45.358)	155.50 (23.400)	180.57 (48.382)
95% CL	[161.65; 189.23]	[137.51; 173.49]	[163.95; 197.19]
Min-Max	119 - 324	119 - 186	124 - 324
Median	170.50	159.00	174.78
Q1-Q3	140.50 -198.00	136.94 -176.58	141.00 -204.00
After 12 weeks			
n	39	7	32
Mean (SD)	145.03 (34.017)	129.39 (36.264)	148.45 (33.116)
95% CL	[134.00; 156.06]	[95.85; 162.93]	[136.51; 160.39]
Min-Max	89 - 218.02	95 - 202	89 - 218.02
Median	138.00	112.00	149.00
Q1-Q3	118.92 -171.17	108.00 -147.75	125.50 -174.59
Change from baseline			
n	31	7	24
Mean (SD)	-28.93 (44.840)	-32.12 (34.751)	-28.00 (47.995)
95% CL	[-45.38; -12.48]	[-64.26; 0.02]	[-48.26; -7.73]
Min-Max	-138 - 43.244	-91 - 21	-138 - 43.244
Median	-23.42	-32.00	-19.00
Q1-Q3	-53.00 - -3.00	-51.00 - -8.00	-56.23 - 4.00
T-Test	t= -3.59 P= 0.001	t= -2.45 P= 0.050	t= -2.86 P= 0.009
Change from baseline [%]			
n	31	7	24
Mean (SD)	-14.11 (22.324)	-19.43 (19.075)	-12.56 (23.324)
95% CL	[-22.30; -5.92]	[-37.07; -1.79]	[-22.41; -2.71]
Min-Max	-51.11 - 30.882	-48.92 - 11.602	-51.11 - 30.882
Median	-16.33	-19.75	-11.63
Q1-Q3	-32.08 - -1.97	-32.08 - -6.72	-31.13 - 2.07
T-Test	t= -3.52 P= 0.001	t= -2.69 P= 0.036	t= -2.64 P= 0.015

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.4 7-point glucose daily profile (mg/dl) - after lunch

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	41	9	32
Mean (SD)	223.26 (57.109)	211.70 (37.404)	226.51 (61.625)
95% CL	[205.23; 241.28]	[182.95; 240.45]	[204.29; 248.73]
Min-Max	120.72 - 361	140.54 - 258	120.72 - 361
Median	221.00	212.00	222.21
Q1-Q3	186.00 -258.00	185.00 -232.00	187.50 -272.50
After 12 weeks			
n	34	7	27
Mean (SD)	190.17 (43.321)	179.45 (34.365)	192.95 (45.503)
95% CL	[175.05; 205.29]	[147.67; 211.23]	[174.95; 210.95]
Min-Max	103 - 293.7	135.14 - 245	103 - 293.7
Median	185.50	181.00	198.00
Q1-Q3	165.77 -208.00	156.00 -190.00	165.77 -220.00
Change from baseline			
n	27	7	20
Mean (SD)	-15.01 (45.788)	-36.52 (28.405)	-7.48 (48.826)
95% CL	[-33.12; 3.11]	[-62.79; -10.25]	[-30.33; 15.38]
Min-Max	-79 - 97.298	-76 - 5	-79 - 97.298
Median	-8.00	-31.00	-3.00
Q1-Q3	-57.66 - 19.00	-64.00 --13.00	-57.33 - 30.00
T-Test	t= -1.70 P= 0.101	t= -3.40 P= 0.014	t= -0.68 P= 0.502
Change from baseline [%]			
n	27	7	20
Mean (SD)	-4.55 (21.797)	-16.75 (12.926)	-0.28 (22.878)
95% CL	[-13.17; 4.07]	[-28.70; -4.79]	[-10.99; 10.42]
Min-Max	-32.76 - 49.541	-32.76 - 2.7027	-30.16 - 49.541
Median	-3.76	-14.62	-1.46
Q1-Q3	-25.82 - 13.40	-27.71 - -5.04	-23.76 - 17.79
T-Test	t= -1.09 P= 0.288	t= -3.43 P= 0.014	t= -0.06 P= 0.956

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.5 7-point glucose daily profile (mg/dl) - before dinner

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	45	9	36
Mean (SD)	191.22 (66.103)	161.13 (45.220)	198.74 (68.811)
95% CL	[171.36; 211.08]	[126.37; 195.89]	[175.46; 222.02]
Min-Max	93 - 396	112 - 246.85	93 - 396
Median	178.00	156.00	183.00
Q1-Q3	148.00 -230.63	124.33 -172.00	153.28 -236.72
After 12 weeks			
n	39	7	32
Mean (SD)	155.70 (44.052)	128.91 (31.922)	161.56 (44.542)
95% CL	[141.42; 169.98]	[99.38; 158.43]	[145.50; 177.62]
Min-Max	79 - 261	88 - 189	79 - 261
Median	145.00	130.00	161.00
Q1-Q3	118.00 -189.00	110.00 -142.34	129.00 -195.80
Change from baseline			
n	31	7	24
Mean (SD)	-38.09 (61.287)	-38.22 (43.676)	-38.06 (66.344)
95% CL	[-60.57; -15.61]	[-78.61; 2.18]	[-66.07; -10.04]
Min-Max	-190 - 86.487	-104.5 - 11	-190 - 86.487
Median	-26.00	-26.00	-25.50
Q1-Q3	-65.00 - -2.00	-84.00 - -2.00	-58.50 - -3.50
T-Test	t= -3.46 P= 0.002	t= -2.31 P= 0.060	t= -2.81 P= 0.010
Change from baseline [%]			
n	31	7	24
Mean (SD)	-13.45 (29.075)	-19.21 (21.988)	-11.76 (31.039)
95% CL	[-24.11; -2.78]	[-39.55; 1.12]	[-24.87; 1.34]
Min-Max	-60.73 - 88.889	-48.84 - 9.1667	-60.73 - 88.889
Median	-16.13	-12.09	-16.14
Q1-Q3	-32.12 - -1.79	-42.34 - -1.79	-24.05 - -1.96
T-Test	t= -2.57 P= 0.015	t= -2.31 P= 0.060	t= -1.86 P= 0.076

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.6 7-point glucose daily profile (mg/dl) - after dinner

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	40	9	31
Mean (SD)	232.78 (63.133)	218.75 (40.674)	236.86 (68.294)
95% CL	[212.59; 252.97]	[187.48; 250.02]	[211.81; 261.91]
Min-Max	135.14 - 403	135.14 - 272	144.15 - 403
Median	218.50	231.00	217.00
Q1-Q3	186.00 -273.00	211.00 -243.00	182.00 -290.00
After 12 weeks			
n	36	7	29
Mean (SD)	199.75 (59.440)	183.22 (34.592)	203.74 (63.837)
95% CL	[179.63; 219.86]	[151.23; 215.21]	[179.45; 228.02]
Min-Max	106.31 - 390	149.55 - 258	106.31 - 390
Median	187.00	178.00	195.00
Q1-Q3	166.50 -222.31	167.00 -180.00	166.00 -232.00
Change from baseline			
n	27	7	20
Mean (SD)	-33.60 (56.861)	-44.01 (28.759)	-29.96 (64.104)
95% CL	[-56.10; -11.11]	[-70.61; -17.41]	[-59.96; 0.04]
Min-Max	-206 - 81	-82 - -3	-206 - 81
Median	-30.00	-53.00	-24.91
Q1-Q3	-55.00 - -3.00	-63.06 --14.00	-42.92 - 2.00
T-Test	t= -3.07 P= 0.005	t= -4.05 P= 0.007	t= -2.09 P= 0.050
Change from baseline [%]			
n	27	7	20
Mean (SD)	-12.57 (21.641)	-19.08 (12.184)	-10.29 (23.937)
95% CL	[-21.13; -4.01]	[-30.34; -7.81]	[-21.50; 0.91]
Min-Max	-62.24 - 44.505	-32.93 - -1.657	-62.24 - 44.505
Median	-15.31	-22.94	-13.38
Q1-Q3	-26.25 - -1.44	-29.66 - -5.15	-24.09 - 1.16
T-Test	t= -3.02 P= 0.006	t= -4.14 P= 0.006	t= -1.92 P= 0.070

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.7 7-point glucose daily profile (mg/dl) - bedtime

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	37	9	28
Mean (SD)	202.84 (45.943)	191.15 (40.571)	206.60 (47.606)
95% CL	[187.52; 218.16]	[159.96; 222.33]	[188.14; 225.06]
Min-Max	104 - 274	142.34 - 267	104 - 274
Median	201.80	172.97	211.50
Q1-Q3	169.00 -243.00	167.00 -198.00	170.50 -251.00
After 12 weeks			
n	33	7	26
Mean (SD)	167.17 (44.998)	169.97 (12.345)	166.42 (50.521)
95% CL	[151.21; 183.13]	[158.55; 181.38]	[146.01; 186.82]
Min-Max	79 - 310	156 - 190	79 - 310
Median	167.00	167.00	166.00
Q1-Q3	139.00 -190.00	156.76 -181.00	132.00 -198.00
Change from baseline			
n	23	7	16
Mean (SD)	-27.53 (56.376)	-20.75 (33.723)	-30.50 (64.619)
95% CL	[-51.91; -3.15]	[-51.93; 10.44]	[-64.93; 3.93]
Min-Max	-140 - 110	-95 - 7	-140 - 110
Median	-12.00	-11.00	-26.00
Q1-Q3	-67.00 - 7.00	-17.00 - -5.00	-75.00 - 8.00
T-Test	t= -2.34 P= 0.029	t= -1.63 P= 0.155	t= -1.89 P= 0.079
Change from baseline [%]			
n	23	7	16
Mean (SD)	-10.05 (32.517)	-8.96 (12.605)	-10.53 (38.554)
95% CL	[-24.11; 4.01]	[-20.61; 2.70]	[-31.08; 10.01]
Min-Max	-53.85 - 105.77	-35.58 - 4.375	-53.85 - 105.77
Median	-7.10	-6.59	-15.18
Q1-Q3	-33.47 - 3.93	-9.38 - -2.91	-36.09 - 4.20
T-Test	t= -1.48 P= 0.152	t= -1.88 P= 0.109	t= -1.09 P= 0.292

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.1 Change up to approx. 12 weeks after the start of treatment
4.5.1.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	45	9	36
Mean (SD)	195.53 (42.888)	180.57 (24.441)	199.27 (45.868)
95% CL	[182.65; 208.42]	[161.78; 199.36]	[183.75; 214.79]
Min-Max	133.33 - 311	136.94 - 220	133.33 - 311
Median	189.19	172.00	198.50
Q1-Q3	167.00 -220.00	168.00 -199.00	161.50 -223.88
After 12 weeks			
n	41	7	34
Mean (SD)	161.76 (31.313)	163.16 (16.878)	161.47 (33.708)
95% CL	[151.88; 171.65]	[147.55; 178.77]	[149.71; 173.24]
Min-Max	106.5 - 242	144.15 - 193	106.5 - 242
Median	162.00	167.00	160.28
Q1-Q3	144.15 -180.00	145.00 -170.00	135.00 -180.00
Change from baseline			
n	32	7	25
Mean (SD)	-24.83 (36.345)	-21.01 (28.297)	-25.90 (38.737)
95% CL	[-37.93; -11.73]	[-47.18; 5.16]	[-41.89; -9.91]
Min-Max	-155 - 25.225	-75 - 2	-155 - 25.225
Median	-14.50	-8.00	-21.00
Q1-Q3	-40.99 - -5.00	-45.05 - -5.00	-36.94 - -5.00
T-Test	t= -3.86 P= 0.001	t= -1.96 P= 0.097	t= -3.34 P= 0.003
Change from baseline [%]			
n	32	7	25
Mean (SD)	-11.38 (16.008)	-10.44 (13.187)	-11.64 (16.947)
95% CL	[-17.15; -5.61]	[-22.64; 1.75]	[-18.64; -4.65]
Min-Max	-56.36 - 18.421	-34.09 - 1.1905	-56.36 - 18.421
Median	-7.84	-3.98	-9.50
Q1-Q3	-22.94 - -2.82	-23.81 - -2.91	-22.86 - -2.73
T-Test	t= -4.02 P= 0.000	t= -2.09 P= 0.081	t= -3.43 P= 0.002

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	44	9	35
Mean (SD)	171.24 (47.578)	151.77 (29.582)	176.25 (50.307)
95% CL	[156.78; 185.71]	[129.04; 174.51]	[158.97; 193.53]
Min-Max	84 - 298	122 - 218.02	84 - 298
Median	163.00	144.00	167.00
Q1-Q3	136.94 -204.50	135.00 -154.00	138.74 -212.61
After 24 weeks			
n	33	8	25
Mean (SD)	139.99 (25.071)	124.82 (17.206)	144.84 (25.504)
95% CL	[131.10; 148.88]	[110.43; 139.20]	[134.31; 155.37]
Min-Max	98 - 191	108 - 159	98 - 191
Median	136.00	119.50	141.00
Q1-Q3	120.00 -157.00	113.00 -133.27	132.00 -158.56
Change from baseline			
n	27	7	20
Mean (SD)	-18.36 (40.001)	-26.93 (24.245)	-15.36 (44.356)
95% CL	[-34.18; -2.54]	[-49.35; -4.50]	[-36.12; 5.40]
Min-Max	-106 - 94	-77.48 - -3	-106 - 94
Median	-18.00	-19.00	-17.50
Q1-Q3	-34.00 - -4.00	-35.00 --14.00	-29.00 - 1.60
T-Test	t= -2.38 P= 0.025	t= -2.94 P= 0.026	t= -1.55 P= 0.138
Change from baseline [%]			
n	27	7	20
Mean (SD)	-8.09 (26.834)	-16.20 (10.750)	-5.26 (30.268)
95% CL	[-18.71; 2.52]	[-26.14; -6.25]	[-19.42; 8.91]
Min-Max	-46.9 - 96.907	-35.54 - -2.326	-46.9 - 96.907
Median	-11.80	-13.33	-10.54
Q1-Q3	-20.36 - -2.33	-24.31 --10.67	-20.02 - 1.45
T-Test	t= -1.57 P= 0.129	t= -3.99 P= 0.007	t= -0.78 P= 0.447

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	43	9	34
Mean (SD)	210.97 (52.549)	190.30 (28.966)	216.44 (56.248)
95% CL	[194.79; 227.14]	[168.04; 212.57]	[196.81; 236.06]
Min-Max	90.091 - 346	131.53 - 220	90.091 - 346
Median	210.00	199.00	212.00
Q1-Q3	179.00 -228.83	172.00 -212.00	180.00 -240.00
After 24 weeks			
n	27	8	19
Mean (SD)	179.10 (49.448)	173.02 (19.624)	181.67 (57.955)
95% CL	[159.54; 198.67]	[156.61; 189.42]	[153.73; 209.60]
Min-Max	97 - 368	144.15 - 205	97 - 368
Median	174.78	167.50	178.00
Q1-Q3	145.00 -195.00	162.50 -187.50	145.00 -201.00
Change from baseline			
n	24	7	17
Mean (SD)	-25.51 (56.101)	-24.58 (26.456)	-25.90 (65.278)
95% CL	[-49.20; -1.82]	[-49.05; -0.11]	[-59.46; 7.66]
Min-Max	-100.9 - 152	-55 - 8	-100.9 - 152
Median	-42.00	-39.00	-46.85
Q1-Q3	-54.00 - 6.00	-45.05 - 4.00	-61.26 - 10.00
T-Test	t= -2.23 P= 0.036	t= -2.46 P= 0.049	t= -1.64 P= 0.121
Change from baseline [%]			
n	24	7	17
Mean (SD)	-11.30 (27.023)	-11.91 (12.939)	-11.05 (31.413)
95% CL	[-22.71; 0.11]	[-23.88; 0.06]	[-27.20; 5.10]
Min-Max	-48.4 - 70.37	-25 - 4.6512	-48.4 - 70.37
Median	-19.70	-19.60	-21.31
Q1-Q3	-26.36 - 3.26	-23.81 - 1.99	-27.86 - 4.52
T-Test	t= -2.05 P= 0.052	t= -2.44 P= 0.051	t= -1.45 P= 0.166

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.3 7-point glucose daily profile (mg/dl) - before lunch

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	44	9	35
Mean (SD)	175.44 (45.358)	155.50 (23.400)	180.57 (48.382)
95% CL	[161.65; 189.23]	[137.51; 173.49]	[163.95; 197.19]
Min-Max	119 - 324	119 - 186	124 - 324
Median	170.50	159.00	174.78
Q1-Q3	140.50 -198.00	136.94 -176.58	141.00 -204.00
After 24 weeks			
n	32	8	24
Mean (SD)	145.23 (34.249)	133.62 (24.429)	149.10 (36.563)
95% CL	[132.88; 157.58]	[113.19; 154.04]	[133.66; 164.54]
Min-Max	96 - 274	110 - 179	96 - 274
Median	143.47	130.50	154.50
Q1-Q3	115.00 -164.50	112.00 -147.47	121.16 -165.00
Change from baseline			
n	27	7	20
Mean (SD)	-18.66 (44.416)	-23.66 (20.313)	-16.91 (50.566)
95% CL	[-36.23; -1.09]	[-42.45; -4.88]	[-40.57; 6.76]
Min-Max	-118.9 - 124	-52 - -1	-118.9 - 124
Median	-24.00	-29.00	-23.71
Q1-Q3	-41.00 - -2.00	-39.64 - -2.00	-41.50 - 1.00
T-Test	t= -2.18 P= 0.038	t= -3.08 P= 0.022	t= -1.50 P= 0.151
Change from baseline [%]			
n	27	7	20
Mean (SD)	-8.79 (26.024)	-14.91 (12.349)	-6.65 (29.326)
95% CL	[-19.09; 1.50]	[-26.33; -3.49]	[-20.38; 7.07]
Min-Max	-48.89 - 82.667	-32.1 - -0.758	-48.89 - 82.667
Median	-17.48	-18.24	-16.78
Q1-Q3	-27.15 - -1.10	-23.81 - -1.10	-27.39 - 0.81
T-Test	t= -1.76 P= 0.091	t= -3.19 P= 0.019	t= -1.01 P= 0.323

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.4 7-point glucose daily profile (mg/dl) - after lunch

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	41	9	32
Mean (SD)	223.26 (57.109)	211.70 (37.404)	226.51 (61.625)
95% CL	[205.23; 241.28]	[182.95; 240.45]	[204.29; 248.73]
Min-Max	120.72 - 361	140.54 - 258	120.72 - 361
Median	221.00	212.00	222.21
Q1-Q3	186.00 -258.00	185.00 -232.00	187.50 -272.50
After 24 weeks			
n	30	8	22
Mean (SD)	170.61 (43.762)	182.54 (28.052)	166.27 (48.045)
95% CL	[154.27; 186.95]	[159.09; 205.99]	[144.97; 187.57]
Min-Max	50.451 - 275	142.34 - 229	50.451 - 275
Median	170.50	175.50	158.78
Q1-Q3	140.00 -202.00	165.00 -204.00	134.00 -202.00
Change from baseline			
n	26	7	19
Mean (SD)	-38.90 (57.381)	-39.78 (30.118)	-38.58 (65.347)
95% CL	[-62.08; -15.73]	[-67.63; -11.92]	[-70.08; -7.08]
Min-Max	-198.2 - 121	-83 - 17	-198.2 - 121
Median	-43.22	-41.44	-45.00
Q1-Q3	-68.00 - -9.00	-51.00 --29.00	-81.00 - -7.00
T-Test	t= -3.46 P= 0.002	t= -3.49 P= 0.013	t= -2.57 P= 0.019
Change from baseline [%]			
n	26	7	19
Mean (SD)	-15.64 (27.443)	-17.52 (13.388)	-14.95 (31.374)
95% CL	[-26.73; -4.56]	[-29.90; -5.14]	[-30.07; 0.17]
Min-Max	-79.71 - 78.571	-32.81 - 9.1892	-79.71 - 78.571
Median	-20.71	-22.08	-17.04
Q1-Q3	-27.44 - -5.43	-23.81 --11.24	-28.62 - -3.61
T-Test	t= -2.91 P= 0.008	t= -3.46 P= 0.013	t= -2.08 P= 0.052

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.5 7-point glucose daily profile (mg/dl) - before dinner

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	45	9	36
Mean (SD)	191.22 (66.103)	161.13 (45.220)	198.74 (68.811)
95% CL	[171.36; 211.08]	[126.37; 195.89]	[175.46; 222.02]
Min-Max	93 - 396	112 - 246.85	93 - 396
Median	178.00	156.00	183.00
Q1-Q3	148.00 -230.63	124.33 -172.00	153.28 -236.72
After 24 weeks			
n	30	8	22
Mean (SD)	164.23 (40.545)	146.17 (31.276)	170.80 (42.127)
95% CL	[149.09; 179.37]	[120.03; 172.32]	[152.12; 189.47]
Min-Max	98 - 272.07	98 - 185	111 - 272.07
Median	174.00	142.50	177.50
Q1-Q3	127.00 -187.39	123.50 -177.19	132.00 -197.00
Change from baseline			
n	26	7	19
Mean (SD)	-25.60 (52.994)	-23.92 (28.921)	-26.22 (60.168)
95% CL	[-47.01; -4.20]	[-50.67; 2.82]	[-55.22; 2.78]
Min-Max	-164 - 78	-68.47 - 28	-164 - 78
Median	-26.50	-27.00	-26.00
Q1-Q3	-54.00 - 9.01	-36.00 --12.00	-65.00 - 15.00
T-Test	t= -2.46 P= 0.021	t= -2.19 P= 0.071	t= -1.90 P= 0.074
Change from baseline [%]			
n	26	7	19
Mean (SD)	-8.43 (25.943)	-11.78 (17.359)	-7.19 (28.781)
95% CL	[-18.91; 2.05]	[-27.83; 4.28]	[-21.07; 6.68]
Min-Max	-55.41 - 55.319	-27.74 - 25	-55.41 - 55.319
Median	-14.83	-15.70	-11.40
Q1-Q3	-24.81 - 7.69	-23.08 - -8.63	-25.62 - 9.55
T-Test	t= -1.66 P= 0.110	t= -1.79 P= 0.123	t= -1.09 P= 0.290

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.6 7-point glucose daily profile (mg/dl) - after dinner

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	40	9	31
Mean (SD)	232.78 (63.133)	218.75 (40.674)	236.86 (68.294)
95% CL	[212.59; 252.97]	[187.48; 250.02]	[211.81; 261.91]
Min-Max	135.14 - 403	135.14 - 272	144.15 - 403
Median	218.50	231.00	217.00
Q1-Q3	186.00 -273.00	211.00 -243.00	182.00 -290.00
After 24 weeks			
n	27	8	19
Mean (SD)	184.97 (49.517)	173.52 (36.735)	189.79 (54.167)
95% CL	[165.38; 204.56]	[142.81; 204.23]	[163.68; 215.90]
Min-Max	102 - 318	111 - 235	102 - 318
Median	172.00	169.00	185.00
Q1-Q3	151.00 -205.00	156.58 -195.50	146.00 -218.00
Change from baseline			
n	22	7	15
Mean (SD)	-28.06 (68.976)	-57.06 (31.064)	-14.52 (78.140)
95% CL	[-58.64; 2.53]	[-85.79; -28.33]	[-57.79; 28.75]
Min-Max	-211 - 140	-100 - -11	-211 - 140
Median	-15.50	-50.45	-5.00
Q1-Q3	-63.00 - 7.21	-92.00 --37.00	-28.00 - 23.00
T-Test	t= -1.91 P= 0.070	t= -4.86 P= 0.003	t= -0.72 P= 0.484
Change from baseline [%]			
n	22	7	15
Mean (SD)	-9.28 (29.043)	-25.08 (14.084)	-1.91 (31.577)
95% CL	[-22.16; 3.59]	[-38.11; -12.06]	[-19.40; 15.58]
Min-Max	-59.6 - 78.652	-47.39 - -6.077	-59.6 - 78.652
Median	-8.62	-23.73	-2.63
Q1-Q3	-27.27 - 4.58	-37.86 --13.60	-11.38 - 13.14
T-Test	t= -1.50 P= 0.149	t= -4.71 P= 0.003	t= -0.23 P= 0.818

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.7 7-point glucose daily profile (mg/dl) - bedtime

	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	37	9	28
Mean (SD)	202.84 (45.943)	191.15 (40.571)	206.60 (47.606)
95% CL	[187.52; 218.16]	[159.96; 222.33]	[188.14; 225.06]
Min-Max	104 - 274	142.34 - 267	104 - 274
Median	201.80	172.97	211.50
Q1-Q3	169.00 -243.00	167.00 -198.00	170.50 -251.00
After 24 weeks			
n	30	8	22
Mean (SD)	153.53 (30.743)	160.34 (23.929)	151.05 (33.019)
95% CL	[142.05; 165.01]	[140.34; 180.35]	[136.41; 165.69]
Min-Max	90.091 - 215	110 - 189	90.091 - 215
Median	151.00	165.50	147.50
Q1-Q3	135.00 -170.00	152.87 -173.50	126.13 -170.00
Change from baseline			
n	22	7	15
Mean (SD)	-34.96 (49.899)	-29.75 (30.820)	-37.39 (57.514)
95% CL	[-57.09; -12.84]	[-58.25; -1.24]	[-69.24; -5.54]
Min-Max	-127.9 - 93	-79 - 7	-127.9 - 93
Median	-28.11	-25.23	-44.00
Q1-Q3	-69.00 - -7.00	-62.00 - -9.00	-82.00 - -5.00
T-Test	t= -3.29 P= 0.004	t= -2.55 P= 0.043	t= -2.52 P= 0.025
Change from baseline [%]			
n	22	7	15
Mean (SD)	-13.59 (28.945)	-14.91 (14.873)	-12.98 (34.069)
95% CL	[-26.43; -0.76]	[-28.66; -1.15]	[-31.85; 5.89]
Min-Max	-50.35 - 89.423	-36.05 - 4.375	-50.35 - 89.423
Median	-15.12	-14.58	-20.56
Q1-Q3	-32.51 - -4.55	-32.51 - -4.55	-37.79 - -2.96
T-Test	t= -2.20 P= 0.039	t= -2.65 P= 0.038	t= -1.48 P= 0.162

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.2 Change up to approx. 24 weeks after the start of treatment
4.5.1.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	45	9	36
Mean (SD)	195.53 (42.888)	180.57 (24.441)	199.27 (45.868)
95% CL	[182.65; 208.42]	[161.78; 199.36]	[183.75; 214.79]
Min-Max	133.33 - 311	136.94 - 220	133.33 - 311
Median	189.19	172.00	198.50
Q1-Q3	167.00 -220.00	168.00 -199.00	161.50 -223.88
After 24 weeks			
n	33	8	25
Mean (SD)	158.00 (26.714)	156.27 (22.297)	158.55 (28.376)
95% CL	[148.53; 167.47]	[137.63; 174.91]	[146.84; 170.26]
Min-Max	118 - 250.5	118 - 189	119 - 250.5
Median	151.00	154.50	150.50
Q1-Q3	142.00 -177.00	144.57 -172.50	137.00 -177.00
Change from baseline			
n	28	7	21
Mean (SD)	-24.77 (39.582)	-28.29 (20.852)	-23.59 (44.484)
95% CL	[-40.11; -9.42]	[-47.58; -9.01]	[-43.84; -3.34]
Min-Max	-112 - 96.5	-54 - -3	-112 - 96.5
Median	-29.00	-27.00	-31.00
Q1-Q3	-45.52 - -8.00	-48.00 - -9.00	-42.00 - -7.00
T-Test	t= -3.31 P= 0.003	t= -3.59 P= 0.012	t= -2.43 P= 0.025
Change from baseline [%]			
n	28	7	21
Mean (SD)	-11.17 (21.628)	-15.45 (11.381)	-9.74 (24.168)
95% CL	[-19.55; -2.78]	[-25.98; -4.93]	[-20.74; 1.27]
Min-Max	-43.08 - 62.662	-31.4 - -1.786	-43.08 - 62.662
Median	-15.93	-15.70	-16.16
Q1-Q3	-23.22 - -4.97	-24.12 - -5.39	-22.46 - -4.90
T-Test	t= -2.73 P= 0.011	t= -3.59 P= 0.011	t= -1.85 P= 0.080

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.1.3.1 Derived Time in Range - dTIR

Percentage within range	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	34	9	25
Mean (SD)	40.3 (31.35)	50.8 (25.86)	36.6 (32.75)
Min-Max	0 - 100	14.286 - 100	0 - 100
Median	42.9	57.1	28.6
Q1-Q3	14.3 - 57.1	28.6 - 57.1	0.0 - 57.1
After 12 weeks			
n	29	7	22
Mean (SD)	61.6 (31.74)	77.6 (29.57)	56.5 (31.32)
Min-Max	0 - 100	14.286 - 100	0 - 100
Median	71.4	85.7	64.3
Q1-Q3	57.1 - 85.7	71.4 - 100.0	42.9 - 85.7
After 24 weeks			
n	25	8	17
Mean (SD)	75.4 (23.52)	82.1 (26.18)	72.3 (22.29)
Min-Max	28.571 - 100	28.571 - 100	28.571 - 100
Median	85.7	92.9	71.4
Q1-Q3	57.1 - 100.0	71.4 - 100.0	57.1 - 85.7

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.1.3.2 Derived Time below Range - dTBR

Percentage below range	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	34	9	25
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 12 weeks			
n	29	7	22
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 24 weeks			
n	25	8	17
Mean (SD)	0.6 (2.86)	0.0 (0.00)	0.8 (3.46)
Min-Max	0 - 14.286	0 - 0	0 - 14.286
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.1 Full Analysis Set - FGM - SMBG
4.5.1.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.1.3.3 Derived Time above Range - dTAR

Percentage above range	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	34	9	25
Mean (SD)	59.7 (31.35)	49.2 (25.86)	63.4 (32.75)
Min-Max	0 - 100	0 - 85.714	0 - 100
Median	57.1	42.9	71.4
Q1-Q3	42.9 - 85.7	42.9 - 71.4	42.9 - 100.0
After 12 weeks			
n	29	7	22
Mean (SD)	38.4 (31.74)	22.4 (29.57)	43.5 (31.32)
Min-Max	0 - 100	0 - 85.714	0 - 100
Median	28.6	14.3	35.7
Q1-Q3	14.3 - 42.9	0.0 - 28.6	14.3 - 57.1
After 24 weeks			
n	25	8	17
Mean (SD)	24.0 (22.86)	17.9 (26.18)	26.9 (21.36)
Min-Max	0 - 71.429	0 - 71.429	0 - 71.429
Median	14.3	7.1	28.6
Q1-Q3	0.0 - 42.9	0.0 - 28.6	14.3 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	24
Mean (SD)	172.83 (52.406)	169.93 (44.264)
95% CL	[148.30; 197.35]	[151.24; 188.62]
Min-Max	84 - 298	97 - 268
Median	160.50	163.00
Q1-Q3	136.87 -215.32	139.64 -196.00
After 12 weeks		
n	15	26
Mean (SD)	146.74 (47.632)	134.13 (32.331)
95% CL	[120.36; 173.12]	[121.07; 147.19]
Min-Max	90 - 242	77 - 205
Median	126.00	134.00
Q1-Q3	113.00 -169.37	111.00 -154.96
Change from baseline		
n	12	19
Mean (SD)	-29.29 (39.234)	-21.57 (52.743)
95% CL	[-54.22; -4.36]	[-46.99; 3.85]
Min-Max	-105 - 33	-168 - 57
Median	-20.50	-18.00
Q1-Q3	-60.00 - -1.80	-45.00 - 14.00
T-Test	t= -2.59 P= 0.025	t= -1.78 P= 0.092
Change from baseline [%]		
n	12	19
Mean (SD)	-13.32 (23.342)	-9.17 (29.500)
95% CL	[-28.15; 1.52]	[-23.39; 5.05]
Min-Max	-46.46 - 39.286	-62.69 - 58.763
Median	-14.96	-11.24
Q1-Q3	-28.91 - -0.94	-36.02 - 11.57
T-Test	t= -1.98 P= 0.074	t= -1.36 P= 0.192

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	23
Mean (SD)	204.81 (43.038)	216.32 (60.064)
95% CL	[184.67; 224.95]	[190.35; 242.29]
Min-Max	90.091 - 279	120 - 346
Median	199.50	211.00
Q1-Q3	184.10 -228.02	172.00 -228.83
After 12 weeks		
n	13	22
Mean (SD)	208.32 (77.796)	172.42 (33.451)
95% CL	[161.31; 255.33]	[157.59; 187.25]
Min-Max	140.54 - 440	107 - 218
Median	180.00	178.50
Q1-Q3	170.00 -236.04	144.00 -199.00
Change from baseline		
n	11	16
Mean (SD)	-9.08 (52.075)	-30.04 (51.437)
95% CL	[-44.06; 25.91]	[-57.45; -2.63]
Min-Max	-75 - 86	-179 - 34
Median	-24.00	-15.50
Q1-Q3	-48.65 - 36.04	-59.33 - -3.00
T-Test	t= -0.58 P= 0.576	t= -2.34 P= 0.034
Change from baseline [%]		
n	11	16
Mean (SD)	-2.43 (27.176)	-12.30 (20.661)
95% CL	[-20.69; 15.83]	[-23.31; -1.29]
Min-Max	-34.09 - 51.807	-57.74 - 18.889
Median	-11.32	-7.50
Q1-Q3	-25.71 - 18.99	-27.48 - -1.39
T-Test	t= -0.30 P= 0.773	t= -2.38 P= 0.031

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.3 7-point glucose daily profile (mg/dl) - before lunch

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	24
Mean (SD)	181.33 (52.832)	170.53 (38.539)
95% CL	[156.60; 206.05]	[154.26; 186.81]
Min-Max	124.33 - 324	119 - 286
Median	172.39	165.00
Q1-Q3	140.07 -207.00	140.50 -198.00
After 12 weeks		
n	14	25
Mean (SD)	150.13 (33.550)	142.17 (34.623)
95% CL	[130.76; 169.50]	[127.88; 156.46]
Min-Max	95 - 218.02	89 - 214
Median	148.37	133.00
Q1-Q3	130.00 -178.00	115.00 -162.00
Change from baseline		
n	13	18
Mean (SD)	-37.41 (57.316)	-22.80 (33.683)
95% CL	[-72.05; -2.78]	[-39.55; -6.05]
Min-Max	-138 - 43.244	-95 - 25
Median	-35.00	-16.50
Q1-Q3	-59.46 - -3.00	-51.00 - -7.00
T-Test	t= -2.35 P= 0.036	t= -2.87 P= 0.011
Change from baseline [%]		
n	13	18
Mean (SD)	-15.69 (26.762)	-12.97 (19.252)
95% CL	[-31.87; 0.48]	[-22.54; -3.39]
Min-Max	-51.11 - 30.882	-45.24 - 20.161
Median	-22.35	-10.27
Q1-Q3	-26.92 - -1.97	-32.08 - -3.43
T-Test	t= -2.11 P= 0.056	t= -2.86 P= 0.011

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.4 7-point glucose daily profile (mg/dl) - after lunch

	Female (N = 28)	Male (N = 42)
Baseline		
n	19	22
Mean (SD)	215.51 (52.640)	229.95 (61.122)
95% CL	[190.13; 240.88]	[202.85; 257.05]
Min-Max	120.72 - 342	132 - 361
Median	212.61	222.21
Q1-Q3	183.79 -248.65	186.00 -275.00
After 12 weeks		
n	12	22
Mean (SD)	197.25 (49.541)	186.31 (40.240)
95% CL	[165.78; 228.73]	[168.47; 204.15]
Min-Max	131.53 - 293.7	103 - 283
Median	185.50	185.50
Q1-Q3	161.50 -229.00	165.77 -204.00
Change from baseline		
n	11	16
Mean (SD)	2.86 (52.538)	-27.29 (37.399)
95% CL	[-32.43; 38.16]	[-47.22; -7.36]
Min-Max	-76 - 97.298	-79 - 37
Median	10.81	-22.00
Q1-Q3	-48.65 - 35.00	-57.83 - -0.50
T-Test	t= 0.18 P= 0.860	t= -2.92 P= 0.011
Change from baseline [%]		
n	11	16
Mean (SD)	3.57 (26.122)	-10.14 (16.937)
95% CL	[-13.97; 21.12]	[-19.16; -1.11]
Min-Max	-32.76 - 49.541	-30.16 - 22.561
Median	8.96	-9.83
Q1-Q3	-26.47 - 22.73	-25.81 - -0.11
T-Test	t= 0.45 P= 0.660	t= -2.39 P= 0.030

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.5 7-point glucose daily profile (mg/dl) - before dinner

	Female (N = 28)	Male (N = 42)
Baseline		
n	21	24
Mean (SD)	206.52 (82.466)	177.82 (45.218)
95% CL	[168.98; 244.06]	[158.73; 196.92]
Min-Max	97.298 - 396	93 - 275
Median	183.00	178.00
Q1-Q3	149.55 -250.00	140.00 -201.00
After 12 weeks		
n	15	24
Mean (SD)	154.93 (44.202)	156.18 (44.903)
95% CL	[130.45; 179.41]	[137.22; 175.14]
Min-Max	79 - 228.83	88 - 261
Median	142.34	145.50
Q1-Q3	112.00 -194.60	122.50 -183.50
Change from baseline		
n	13	18
Mean (SD)	-42.62 (81.299)	-34.82 (43.997)
95% CL	[-91.75; 6.51]	[-56.70; -12.94]
Min-Max	-190 - 86.487	-167 - 38
Median	-17.00	-26.00
Q1-Q3	-104.5 - -1.80	-52.00 --10.81
T-Test	t= -1.89 P= 0.083	t= -3.36 P= 0.004
Change from baseline [%]		
n	13	18
Mean (SD)	-9.48 (37.811)	-16.31 (21.492)
95% CL	[-32.33; 13.37]	[-27.00; -5.62]
Min-Max	-47.98 - 88.889	-60.73 - 40.86
Median	-11.49	-16.59
Q1-Q3	-42.34 - -0.78	-23.30 - -7.01
T-Test	t= -0.90 P= 0.384	t= -3.22 P= 0.005

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.6 7-point glucose daily profile (mg/dl) - after dinner

	Female (N = 28)	Male (N = 42)
Baseline		
n	18	22
Mean (SD)	230.17 (58.609)	234.92 (67.903)
95% CL	[201.02; 259.31]	[204.82; 265.03]
Min-Max	148 - 403	135.14 - 370
Median	224.00	218.00
Q1-Q3	190.00 -250.45	182.00 -295.00
After 12 weeks		
n	14	22
Mean (SD)	212.25 (78.757)	191.79 (43.337)
95% CL	[166.78; 257.73]	[172.57; 211.00]
Min-Max	149.55 - 390	106.31 - 263
Median	182.50	195.50
Q1-Q3	167.00 -212.61	166.00 -232.00
Change from baseline		
n	11	16
Mean (SD)	-28.04 (33.605)	-37.43 (69.376)
95% CL	[-50.62; -5.47]	[-74.40; -0.46]
Min-Max	-82 - 20	-206 - 81
Median	-30.00	-30.50
Q1-Q3	-55.00 - -3.00	-55.00 - -4.50
T-Test	t= -2.77 P= 0.020	t= -2.16 P= 0.048
Change from baseline [%]		
n	11	16
Mean (SD)	-12.29 (14.992)	-12.77 (25.727)
95% CL	[-22.36; -2.22]	[-26.48; 0.94]
Min-Max	-32.93 - 11.429	-62.24 - 44.505
Median	-15.79	-15.00
Q1-Q3	-22.94 - -1.44	-26.37 - -1.73
T-Test	t= -2.72 P= 0.022	t= -1.98 P= 0.066

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.7 7-point glucose daily profile (mg/dl) - bedtime

	Female (N = 28)	Male (N = 42)
Baseline		
n	17	20
Mean (SD)	217.40 (46.337)	190.47 (42.899)
95% CL	[193.58; 241.23]	[170.39; 210.54]
Min-Max	121 - 274	104 - 263
Median	229.00	198.00
Q1-Q3	172.97 -254.06	154.50 -223.50
After 12 weeks		
n	11	22
Mean (SD)	181.51 (55.871)	160.00 (37.912)
95% CL	[143.98; 219.05]	[143.19; 176.81]
Min-Max	100 - 310	79 - 214
Median	165.00	167.50
Q1-Q3	156.00 -210.81	132.00 -190.00
Change from baseline		
n	8	15
Mean (SD)	-26.15 (47.167)	-28.27 (62.292)
95% CL	[-65.58; 13.28]	[-62.76; 6.23]
Min-Max	-95 - 44	-140 - 110
Median	-13.61	-12.00
Q1-Q3	-67.50 - 2.00	-67.00 - 7.00
T-Test	t= -1.57 P= 0.161	t= -1.76 P= 0.101
Change from baseline [%]		
n	8	15
Mean (SD)	-11.36 (18.366)	-9.36 (38.618)
95% CL	[-26.71; 4.00]	[-30.74; 12.03]
Min-Max	-35.58 - 16.541	-53.85 - 105.77
Median	-7.98	-7.10
Q1-Q3	-28.72 - 0.78	-38.71 - 3.93
T-Test	t= -1.75 P= 0.124	t= -0.94 P= 0.364

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.1 Change up to approx. 12 weeks after the start of treatment
4.5.2.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	Female (N = 28)	Male (N = 42)
Baseline		
n	21	24
Mean (SD)	204.05 (44.785)	188.08 (40.627)
95% CL	[183.66; 224.43]	[170.92; 205.24]
Min-Max	135 - 311	133.33 - 275
Median	198.00	186.00
Q1-Q3	172.00 -226.13	153.00 -211.50
After 12 weeks		
n	15	26
Mean (SD)	170.88 (35.978)	156.50 (27.666)
95% CL	[150.95; 190.80]	[145.33; 167.68]
Min-Max	106.5 - 242	107.21 - 200
Median	163.00	158.28
Q1-Q3	149.00 -181.98	135.00 -179.00
Change from baseline		
n	13	19
Mean (SD)	-22.48 (33.128)	-26.44 (39.199)
95% CL	[-42.49; -2.46]	[-45.34; -7.55]
Min-Max	-75 - 25.225	-155 - 18.018
Median	-11.00	-21.00
Q1-Q3	-45.05 - -5.00	-36.94 - -5.00
T-Test	t= -2.45 P= 0.031	t= -2.94 P= 0.009
Change from baseline [%]		
n	13	19
Mean (SD)	-9.46 (14.949)	-12.69 (16.967)
95% CL	[-18.49; -0.43]	[-20.87; -4.51]
Min-Max	-34.09 - 18.421	-56.36 - 13.514
Median	-6.59	-9.50
Q1-Q3	-22.19 - -2.91	-23.03 - -2.73
T-Test	t= -2.28 P= 0.042	t= -3.26 P= 0.004

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	24
Mean (SD)	172.83 (52.406)	169.93 (44.264)
95% CL	[148.30; 197.35]	[151.24; 188.62]
Min-Max	84 - 298	97 - 268
Median	160.50	163.00
Q1-Q3	136.87 -215.32	139.64 -196.00
After 24 weeks		
n	13	20
Mean (SD)	136.39 (21.906)	142.32 (27.219)
95% CL	[123.15; 149.62]	[129.59; 155.06]
Min-Max	109 - 176.58	98 - 191
Median	132.00	138.97
Q1-Q3	118.00 -145.95	123.50 -158.78
Change from baseline		
n	10	17
Mean (SD)	-37.09 (34.107)	-7.34 (39.968)
95% CL	[-61.49; -12.69]	[-27.89; 13.21]
Min-Max	-106 - 7.2073	-100 - 94
Median	-28.00	-14.00
Q1-Q3	-57.66 --18.00	-21.00 - -3.00
T-Test	t= -3.44 P= 0.007	t= -0.76 P= 0.460
Change from baseline [%]		
n	10	17
Mean (SD)	-19.44 (14.951)	-1.42 (30.274)
95% CL	[-30.14; -8.74]	[-16.98; 14.15]
Min-Max	-46.9 - 5.1948	-42.37 - 96.907
Median	-18.04	-10.67
Q1-Q3	-27.12 - -9.28	-13.50 - -2.29
T-Test	t= -4.11 P= 0.003	t= -0.19 P= 0.850

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	23
Mean (SD)	204.81 (43.038)	216.32 (60.064)
95% CL	[184.67; 224.95]	[190.35; 242.29]
Min-Max	90.091 - 279	120 - 346
Median	199.50	211.00
Q1-Q3	184.10 -228.02	172.00 -228.83
After 24 weeks		
n	12	15
Mean (SD)	174.66 (28.863)	182.66 (62.096)
95% CL	[156.32; 193.00]	[148.27; 217.05]
Min-Max	144.15 - 235	97 - 368
Median	171.49	180.00
Q1-Q3	152.50 -179.99	142.00 -201.00
Change from baseline		
n	11	13
Mean (SD)	-37.49 (45.861)	-15.38 (63.535)
95% CL	[-68.30; -6.68]	[-53.77; 23.02]
Min-Max	-95 - 69	-100.9 - 152
Median	-46.85	-27.00
Q1-Q3	-61.26 --39.00	-52.00 - 8.00
T-Test	t= -2.71 P= 0.022	t= -0.87 P= 0.400
Change from baseline [%]		
n	11	13
Mean (SD)	-15.91 (22.961)	-7.40 (30.405)
95% CL	[-31.33; -0.48]	[-25.78; 10.97]
Min-Max	-39.58 - 41.566	-48.4 - 70.37
Median	-23.81	-11.84
Q1-Q3	-26.77 --19.60	-25.37 - 4.52
T-Test	t= -2.30 P= 0.044	t= -0.88 P= 0.397

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.3 7-point glucose daily profile (mg/dl) - before lunch

	Female (N = 28)	Male (N = 42)
Baseline		
n	20	24
Mean (SD)	181.33 (52.832)	170.53 (38.539)
95% CL	[156.60; 206.05]	[154.26; 186.81]
Min-Max	124.33 - 324	119 - 286
Median	172.39	165.00
Q1-Q3	140.07 -207.00	140.50 -198.00
After 24 weeks		
n	13	19
Mean (SD)	135.55 (22.276)	151.85 (39.693)
95% CL	[122.09; 149.01]	[132.72; 170.98]
Min-Max	110 - 172.97	96 - 274
Median	131.00	158.00
Q1-Q3	112.00 -156.00	118.00 -165.00
Change from baseline		
n	11	16
Mean (SD)	-38.86 (38.426)	-4.78 (43.937)
95% CL	[-64.67; -13.04]	[-28.19; 18.64]
Min-Max	-118.9 - 21.622	-61 - 124
Median	-39.64	-11.00
Q1-Q3	-65.00 - -3.00	-30.50 - 1.50
T-Test	t= -3.35 P= 0.007	t= -0.43 P= 0.670
Change from baseline [%]		
n	11	16
Mean (SD)	-19.58 (18.228)	-1.37 (28.429)
95% CL	[-31.83; -7.34]	[-16.52; 13.78]
Min-Max	-48.89 - 17.391	-30.2 - 82.667
Median	-23.81	-7.11
Q1-Q3	-29.41 - -1.76	-18.02 - 1.14
T-Test	t= -3.56 P= 0.005	t= -0.19 P= 0.850

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.4 7-point glucose daily profile (mg/dl) - after lunch

	Female (N = 28)	Male (N = 42)
Baseline		
n	19	22
Mean (SD)	215.51 (52.640)	229.95 (61.122)
95% CL	[190.13; 240.88]	[202.85; 257.05]
Min-Max	120.72 - 342	132 - 361
Median	212.61	222.21
Q1-Q3	183.79 -248.65	186.00 -275.00
After 24 weeks		
n	12	18
Mean (SD)	154.32 (39.325)	181.46 (44.208)
95% CL	[129.34; 179.31]	[159.48; 203.45]
Min-Max	50.451 - 204	118 - 275
Median	154.78	197.50
Q1-Q3	141.17 -182.50	138.00 -207.00
Change from baseline		
n	11	15
Mean (SD)	-59.85 (61.758)	-23.54 (50.571)
95% CL	[-101.34; -18.36]	[-51.54; 4.47]
Min-Max	-198.2 - 31	-90.09 - 121
Median	-50.00	-29.00
Q1-Q3	-83.00 - -9.00	-48.00 - -6.00
T-Test	t= -3.21 P= 0.009	t= -1.80 P= 0.093
Change from baseline [%]		
n	11	15
Mean (SD)	-25.13 (25.449)	-8.69 (27.562)
95% CL	[-42.22; -8.03]	[-23.95; 6.58]
Min-Max	-79.71 - 20.13	-40.32 - 78.571
Median	-23.81	-11.24
Q1-Q3	-35.66 - -6.29	-24.73 - -2.93
T-Test	t= -3.27 P= 0.008	t= -1.22 P= 0.242

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.5 7-point glucose daily profile (mg/dl) - before dinner

	Female (N = 28)	Male (N = 42)
Baseline		
n	21	24
Mean (SD)	206.52 (82.466)	177.82 (45.218)
95% CL	[168.98; 244.06]	[158.73; 196.92]
Min-Max	97.298 - 396	93 - 275
Median	183.00	178.00
Q1-Q3	149.55 -250.00	140.00 -201.00
After 24 weeks		
n	13	17
Mean (SD)	154.83 (46.957)	171.42 (34.629)
95% CL	[126.45; 183.21]	[153.61; 189.22]
Min-Max	98 - 272.07	122 - 226
Median	140.00	177.00
Q1-Q3	120.00 -182.00	145.00 -197.00
Change from baseline		
n	11	15
Mean (SD)	-54.34 (56.872)	-4.53 (39.753)
95% CL	[-92.54; -16.13]	[-26.55; 17.48]
Min-Max	-164 - 28	-65 - 78
Median	-36.04	-8.00
Q1-Q3	-95.50 --22.00	-30.00 - 15.00
T-Test	t= -3.17 P= 0.010	t= -0.44 P= 0.666
Change from baseline [%]		
n	11	15
Mean (SD)	-20.98 (23.239)	0.78 (24.523)
95% CL	[-36.59; -5.37]	[-12.80; 14.36]
Min-Max	-55.41 - 25	-30.68 - 55.319
Median	-24.32	-4.28
Q1-Q3	-38.74 --16.13	-15.70 - 9.55
T-Test	t= -2.99 P= 0.013	t= 0.12 P= 0.904

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.6 7-point glucose daily profile (mg/dl) - after dinner

	Female (N = 28)	Male (N = 42)
Baseline		
n	18	22
Mean (SD)	230.17 (58.609)	234.92 (67.903)
95% CL	[201.02; 259.31]	[204.82; 265.03]
Min-Max	148 - 403	135.14 - 370
Median	224.00	218.00
Q1-Q3	190.00 -250.45	182.00 -295.00
After 24 weeks		
n	12	15
Mean (SD)	181.34 (50.498)	187.88 (50.294)
95% CL	[149.25; 213.42]	[160.02; 215.73]
Min-Max	102 - 293.7	111 - 318
Median	169.00	188.00
Q1-Q3	155.68 -199.90	146.00 -218.00
Change from baseline		
n	9	13
Mean (SD)	-38.80 (53.604)	-20.62 (79.144)
95% CL	[-80.01; 2.40]	[-68.44; 27.21]
Min-Max	-103 - 35	-211 - 140
Median	-50.45	-9.01
Q1-Q3	-92.00 - 7.21	-37.00 - 7.00
T-Test	t= -2.17 P= 0.062	t= -0.94 P= 0.366
Change from baseline [%]		
n	9	13
Mean (SD)	-15.44 (22.491)	-5.02 (33.026)
95% CL	[-32.73; 1.84]	[-24.98; 14.94]
Min-Max	-39.58 - 16.129	-59.6 - 78.652
Median	-23.73	-6.25
Q1-Q3	-37.45 - 3.70	-13.60 - 4.58
T-Test	t= -2.06 P= 0.073	t= -0.55 P= 0.594

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.7 7-point glucose daily profile (mg/dl) - bedtime

	Female (N = 28)	Male (N = 42)
Baseline		
n	17	20
Mean (SD)	217.40 (46.337)	190.47 (42.899)
95% CL	[193.58; 241.23]	[170.39; 210.54]
Min-Max	121 - 274	104 - 263
Median	229.00	198.00
Q1-Q3	172.97 -254.06	154.50 -223.50
After 24 weeks		
n	13	17
Mean (SD)	143.21 (34.218)	161.42 (26.121)
95% CL	[122.54; 163.89]	[147.99; 174.85]
Min-Max	90.091 - 210.81	112 - 215
Median	143.00	164.00
Q1-Q3	124.00 -158.00	147.00 -174.00
Change from baseline		
n	10	12
Mean (SD)	-58.31 (43.523)	-15.50 (47.902)
95% CL	[-89.45; -27.18]	[-45.94; 14.94]
Min-Max	-127.9 - 9.0091	-97 - 93
Median	-56.50	-13.00
Q1-Q3	-82.00 --25.23	-41.00 - 1.00
T-Test	t= -4.24 P= 0.002	t= -1.12 P= 0.286
Change from baseline [%]		
n	10	12
Mean (SD)	-25.94 (17.275)	-3.31 (33.187)
95% CL	[-38.30; -13.58]	[-24.39; 17.78]
Min-Max	-50.35 - 4.4643	-41.45 - 89.423
Median	-28.02	-7.22
Q1-Q3	-37.79 --14.58	-20.27 - 0.71
T-Test	t= -4.75 P= 0.001	t= -0.35 P= 0.736

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.2 Change up to approx. 24 weeks after the start of treatment
4.5.2.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	Female (N = 28)	Male (N = 42)
Baseline		
n	21	24
Mean (SD)	204.05 (44.785)	188.08 (40.627)
95% CL	[183.66; 224.43]	[170.92; 205.24]
Min-Max	135 - 311	133.33 - 275
Median	198.00	186.00
Q1-Q3	172.00 -226.13	153.00 -211.50
After 24 weeks		
n	13	20
Mean (SD)	149.42 (20.522)	163.57 (29.203)
95% CL	[137.02; 161.82]	[149.91; 177.24]
Min-Max	118 - 188	119 - 250.5
Median	145.95	161.78
Q1-Q3	135.00 -158.00	143.50 -179.00
Change from baseline		
n	11	17
Mean (SD)	-49.36 (30.362)	-8.85 (37.186)
95% CL	[-69.76; -28.96]	[-27.97; 10.27]
Min-Max	-112 - -9	-50 - 96.5
Median	-45.05	-16.22
Q1-Q3	-73.87 --31.00	-33.00 - -5.00
T-Test	t= -5.39 P= 0.000	t= -0.98 P= 0.341
Change from baseline [%]		
n	11	17
Mean (SD)	-23.34 (11.619)	-3.29 (23.177)
95% CL	[-31.14; -15.53]	[-15.20; 8.63]
Min-Max	-43.08 - -5.051	-25.14 - 62.662
Median	-23.81	-10.05
Q1-Q3	-31.40 --17.80	-16.16 - -2.73
T-Test	t= -6.66 P= 0.000	t= -0.58 P= 0.567

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.2.3.1 Derived Time in Range - dTIR

Percentage within range	Female (N = 28)	Male (N = 42)
Baseline		
n	15	19
Mean (SD)	39.0 (28.30)	41.4 (34.30)
Min-Max	0 - 85.714	0 - 100
Median	42.9	42.9
Q1-Q3	14.3 - 57.1	14.3 - 71.4
After 12 weeks		
n	9	20
Mean (SD)	57.1 (41.65)	63.6 (27.21)
Min-Max	0 - 100	0 - 100
Median	71.4	71.4
Q1-Q3	14.3 - 85.7	57.1 - 85.7
After 24 weeks		
n	12	13
Mean (SD)	81.0 (26.78)	70.3 (19.74)
Min-Max	28.571 - 100	28.571 - 100
Median	100.0	71.4
Q1-Q3	57.1 - 100.0	57.1 - 85.7

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.2.3.2 Derived Time below Range - dTBR

Percentage below range	Female (N = 28)	Male (N = 42)
Baseline		
n	15	19
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 12 weeks		
n	9	20
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 24 weeks		
n	12	13
Mean (SD)	1.2 (4.12)	0.0 (0.00)
Min-Max	0 - 14.286	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.2 Full Analysis Set - Subgroups - Gender
4.5.2.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.2.3.3 Derived Time above Range - dTAR

Percentage above range	Female (N = 28)	Male (N = 42)
Baseline		
n	15	19
Mean (SD)	61.0 (28.30)	58.6 (34.30)
Min-Max	14.286 - 100	0 - 100
Median	57.1	57.1
Q1-Q3	42.9 - 85.7	28.6 - 85.7
After 12 weeks		
n	9	20
Mean (SD)	42.9 (41.65)	36.4 (27.21)
Min-Max	0 - 100	0 - 100
Median	28.6	28.6
Q1-Q3	14.3 - 85.7	14.3 - 42.9
After 24 weeks		
n	12	13
Mean (SD)	17.9 (25.21)	29.7 (19.74)
Min-Max	0 - 71.429	0 - 71.429
Median	0.0	28.6
Q1-Q3	0.0 - 42.9	14.3 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	13	17	14
Mean (SD)	170.29 (45.065)	165.86 (41.634)	178.68 (58.146)
95% CL	[143.05; 197.52]	[144.45; 187.26]	[145.10; 212.25]
Min-Max	122 - 268	97 - 237.84	84 - 298
Median	163.00	154.00	171.50
Q1-Q3	135.00 -193.00	142.00 -194.00	138.74 -226.00
After 12 weeks			
n	12	16	13
Mean (SD)	137.18 (29.099)	146.77 (39.919)	130.31 (44.914)
95% CL	[118.69; 155.66]	[125.50; 168.04]	[103.17; 157.45]
Min-Max	100 - 205	90 - 241.44	77 - 242
Median	130.87	140.57	120.00
Q1-Q3	117.50 -151.00	114.00 -168.48	99.00 -158.00
Change from baseline			
n	10	12	9
Mean (SD)	-35.90 (61.300)	-14.86 (36.086)	-24.90 (45.937)
95% CL	[-79.75; 7.95]	[-37.78; 8.07]	[-60.21; 10.41]
Min-Max	-168 - 57	-73.87 - 57	-105 - 33
Median	-17.50	-15.60	-20.00
Q1-Q3	-73.00 - -7.00	-35.50 - 5.50	-56.00 - 14.00
T-Test	t= -1.85 P= 0.097	t= -1.43 P= 0.182	t= -1.63 P= 0.143
Change from baseline [%]			
n	10	12	9
Mean (SD)	-15.76 (27.495)	-6.86 (26.421)	-10.46 (29.300)
95% CL	[-35.43; 3.90]	[-23.65; 9.93]	[-32.98; 12.07]
Min-Max	-62.69 - 38.514	-41.56 - 58.763	-46.46 - 39.286
Median	-13.05	-9.67	-11.24
Q1-Q3	-36.02 - -5.74	-24.14 - 3.12	-36.89 - 11.57
T-Test	t= -1.81 P= 0.103	t= -0.90 P= 0.388	t= -1.07 P= 0.316

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	16	13
Mean (SD)	212.43 (58.486)	209.05 (46.474)	211.75 (57.020)
95% CL	[178.66; 246.20]	[184.28; 233.81]	[177.29; 246.21]
Min-Max	120 - 320	131.53 - 346	90.091 - 320
Median	201.40	202.50	213.00
Q1-Q3	170.00 -252.25	188.60 -224.50	198.00 -228.83
After 12 weeks			
n	10	13	12
Mean (SD)	188.62 (38.875)	169.61 (34.850)	200.85 (81.062)
95% CL	[160.82; 216.43]	[148.55; 190.67]	[149.34; 252.35]
Min-Max	131 - 252	107 - 236.04	109 - 440
Median	178.00	170.00	187.50
Q1-Q3	170.00 -214.00	144.00 -188.00	175.09 -204.00
Change from baseline			
n	9	11	7
Mean (SD)	-13.84 (77.671)	-36.57 (34.140)	-7.67 (29.959)
95% CL	[-73.54; 45.86]	[-59.51; -13.64]	[-35.37; 20.04]
Min-Max	-179 - 86	-81 - 36.036	-57.66 - 30
Median	2.00	-28.00	-12.00
Q1-Q3	-42.00 - 34.00	-66.67 --18.00	-18.00 - 28.00
T-Test	t= -0.53 P= 0.608	t= -3.55 P= 0.005	t= -0.68 P= 0.524
Change from baseline [%]			
n	9	11	7
Mean (SD)	-1.49 (32.597)	-17.78 (16.696)	-2.07 (15.583)
95% CL	[-26.55; 23.57]	[-29.00; -6.57]	[-16.48; 12.35]
Min-Max	-57.74 - 51.807	-43.09 - 18.018	-25.2 - 18.987
Median	1.19	-14.14	-5.69
Q1-Q3	-19.09 - 18.89	-29.76 - -9.50	-9.09 - 17.61
T-Test	t= -0.14 P= 0.894	t= -3.53 P= 0.005	t= -0.35 P= 0.738

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.3 7-point glucose daily profile (mg/dl) - before lunch

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	13
Mean (SD)	164.89 (36.438)	176.89 (43.255)	184.91 (56.647)
95% CL	[143.85; 185.92]	[154.65; 199.13]	[150.68; 219.14]
Min-Max	119 - 243.25	129 - 286	124.33 - 324
Median	155.50	174.78	180.00
Q1-Q3	140.00 -193.00	141.00 -199.00	143.00 -204.00
After 12 weeks			
n	12	14	13
Mean (SD)	138.34 (21.420)	145.14 (37.611)	151.09 (40.334)
95% CL	[124.73; 151.95]	[123.42; 166.85]	[126.71; 175.46]
Min-Max	108 - 171.17	89 - 218.02	97 - 214
Median	143.50	139.87	133.00
Q1-Q3	116.96 -154.00	123.00 -179.00	125.00 -186.00
Change from baseline			
n	11	11	9
Mean (SD)	-26.21 (48.609)	-34.00 (38.643)	-26.05 (51.623)
95% CL	[-58.86; 6.45]	[-59.96; -8.04]	[-65.73; 13.63]
Min-Max	-124.3 - 27.027	-91 - 43.244	-138 - 42
Median	-10.00	-35.00	-15.00
Q1-Q3	-51.00 - 18.00	-62.00 --18.00	-49.00 - -7.00
T-Test	t= -1.79 P= 0.104	t= -2.92 P= 0.015	t= -1.51 P= 0.169
Change from baseline [%]			
n	11	11	9
Mean (SD)	-11.78 (24.257)	-18.79 (21.130)	-11.23 (22.989)
95% CL	[-28.08; 4.51]	[-32.98; -4.59]	[-28.91; 6.44]
Min-Max	-51.11 - 20.161	-48.92 - 24.742	-42.59 - 30.882
Median	-6.76	-22.35	-10.49
Q1-Q3	-32.08 - 12.86	-37.62 --10.05	-26.92 - -3.43
T-Test	t= -1.61 P= 0.138	t= -2.95 P= 0.015	t= -1.47 P= 0.181

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.4 7-point glucose daily profile (mg/dl) - after lunch

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	13	16	12
Mean (SD)	224.80 (70.242)	208.33 (52.578)	241.49 (44.926)
95% CL	[182.35; 267.24]	[180.32; 236.35]	[212.94; 270.03]
Min-Max	120.72 - 361	132 - 283	186 - 342
Median	210.00	204.51	229.72
Q1-Q3	185.00 -253.00	160.50 -256.50	213.00 -264.00
After 12 weeks			
n	10	12	12
Mean (SD)	190.65 (45.347)	187.46 (48.502)	192.48 (39.765)
95% CL	[158.21; 223.09]	[156.64; 218.27]	[167.22; 217.75]
Min-Max	131.53 - 283	132 - 293.7	103 - 245
Median	185.50	174.00	202.00
Q1-Q3	170.00 -198.00	153.50 -204.00	169.38 -223.50
Change from baseline			
n	9	11	7
Mean (SD)	-15.13 (36.775)	-14.85 (62.231)	-15.09 (28.762)
95% CL	[-43.40; 13.14]	[-56.65; 26.96]	[-41.69; 11.51]
Min-Max	-78 - 35	-79 - 97.298	-57.66 - 26
Median	-8.00	-48.65	-7.00
Q1-Q3	-31.00 - 10.81	-71.00 - 37.00	-48.00 - 0.00
T-Test	t= -1.23 P= 0.252	t= -0.79 P= 0.447	t= -1.39 P= 0.214
Change from baseline [%]			
n	9	11	7
Mean (SD)	-4.19 (16.982)	-3.58 (29.901)	-6.55 (13.323)
95% CL	[-17.24; 8.87]	[-23.67; 16.51]	[-18.87; 5.77]
Min-Max	-29.74 - 22.727	-32.76 - 49.541	-25.81 - 13.402
Median	-3.16	-25.82	-3.76
Q1-Q3	-14.62 - 8.96	-27.92 - 22.56	-21.72 - 0.00
T-Test	t= -0.74 P= 0.481	t= -0.40 P= 0.700	t= -1.30 P= 0.241

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.5 7-point glucose daily profile (mg/dl) - before dinner

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	14
Mean (SD)	176.29 (70.037)	196.27 (58.642)	200.01 (72.769)
95% CL	[135.85; 216.73]	[166.12; 226.42]	[157.99; 242.02]
Min-Max	97.298 - 365.77	112 - 296	93 - 396
Median	166.50	187.00	184.00
Q1-Q3	139.00 -183.00	141.00 -246.85	164.00 -232.43
After 12 weeks			
n	12	14	13
Mean (SD)	144.62 (36.538)	151.04 (51.865)	170.95 (40.091)
95% CL	[121.40; 167.83]	[121.09; 180.99]	[146.72; 195.17]
Min-Max	88 - 212	79 - 250	106.31 - 261
Median	133.00	137.00	169.00
Q1-Q3	124.00 -170.89	110.00 -197.00	145.00 -189.00
Change from baseline			
n	11	11	9
Mean (SD)	-43.88 (75.735)	-41.58 (40.434)	-26.76 (68.297)
95% CL	[-94.76; 7.00]	[-68.74; -14.41]	[-79.25; 25.74]
Min-Max	-171.2 - 86.487	-114 - 11	-190 - 40
Median	-25.00	-36.04	-10.81
Q1-Q3	-84.00 - -9.00	-65.00 - -2.00	-33.00 - -2.00
T-Test	t= -1.92 P= 0.084	t= -3.41 P= 0.007	t= -1.18 P= 0.274
Change from baseline [%]			
n	11	11	9
Mean (SD)	-13.67 (40.312)	-19.74 (16.438)	-5.48 (25.982)
95% CL	[-40.75; 13.42]	[-30.79; -8.70]	[-25.45; 14.49]
Min-Max	-60.73 - 88.889	-45.06 - 5.8824	-47.98 - 40.86
Median	-13.66	-19.71	-9.23
Q1-Q3	-46.80 - -6.47	-32.12 - -1.79	-18.54 - -1.19
T-Test	t= -1.12 P= 0.287	t= -3.98 P= 0.003	t= -0.63 P= 0.545

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.6 7-point glucose daily profile (mg/dl) - after dinner

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	12	16	12
Mean (SD)	224.66 (63.285)	230.43 (52.761)	244.05 (78.180)
95% CL	[184.46; 264.87]	[202.31; 258.54]	[194.37; 293.72]
Min-Max	148 - 331	135.14 - 354	144.15 - 403
Median	196.00	241.50	216.50
Q1-Q3	176.50 -292.50	192.30 -253.73	196.20 -288.50
After 12 weeks			
n	11	13	12
Mean (SD)	200.78 (70.902)	195.46 (37.966)	203.44 (71.143)
95% CL	[153.14; 248.41]	[172.52; 218.41]	[158.24; 248.64]
Min-Max	125 - 387.39	142 - 263	106.31 - 390
Median	180.00	189.00	186.50
Q1-Q3	153.15 -232.00	167.00 -212.61	167.00 -225.50
Change from baseline			
n	9	11	7
Mean (SD)	-42.42 (75.870)	-32.79 (59.460)	-23.55 (14.394)
95% CL	[-100.74; 15.89]	[-72.73; 7.16]	[-36.86; -10.24]
Min-Max	-206 - 54	-146 - 81	-37.84 - 2
Median	-31.00	-48.00	-30.00
Q1-Q3	-62.00 - -3.00	-63.06 - 2.00	-37.00 --14.00
T-Test	t= -1.68 P= 0.132	t= -1.83 P= 0.097	t= -4.33 P= 0.005
Change from baseline [%]			
n	9	11	7
Mean (SD)	-14.08 (26.583)	-11.44 (24.509)	-12.41 (8.965)
95% CL	[-34.52; 6.35]	[-27.90; 5.03]	[-20.70; -4.12]
Min-Max	-62.24 - 30.337	-41.24 - 44.505	-26.25 - 1.005
Median	-14.69	-22.92	-15.31
Q1-Q3	-26.50 - -1.66	-29.66 - 1.31	-17.05 - -5.15
T-Test	t= -1.59 P= 0.151	t= -1.55 P= 0.153	t= -3.66 P= 0.011

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.7 7-point glucose daily profile (mg/dl) - bedtime

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	12	15	10
Mean (SD)	201.17 (44.152)	195.27 (48.947)	216.21 (45.122)
95% CL	[173.11; 229.22]	[168.17; 222.38]	[183.93; 248.48]
Min-Max	121 - 260	104 - 274	143 - 266
Median	208.00	187.00	229.50
Q1-Q3	166.00 -236.00	167.00 -243.00	169.00 -254.06
After 12 weeks			
n	10	13	10
Mean (SD)	155.60 (29.045)	175.89 (38.607)	167.40 (64.106)
95% CL	[134.82; 176.38]	[152.56; 199.22]	[121.54; 213.26]
Min-Max	110 - 198	100 - 245.05	79 - 310
Median	166.00	172.00	171.50
Q1-Q3	133.00 -167.00	156.00 -203.00	123.00 -181.00
Change from baseline			
n	9	9	5
Mean (SD)	-53.56 (55.433)	-2.13 (54.271)	-26.40 (49.672)
95% CL	[-96.16; -10.95]	[-43.85; 39.58]	[-88.08; 35.28]
Min-Max	-140 - 7	-95 - 110	-83 - 44
Median	-52.00	-2.00	-17.00
Q1-Q3	-84.00 - -5.00	-16.22 - 9.01	-64.00 --12.00
T-Test	t= -2.90 P= 0.020	t= -0.12 P= 0.909	t= -1.19 P= 0.300
Change from baseline [%]			
n	9	9	5
Mean (SD)	-22.78 (22.561)	5.68 (40.363)	-15.47 (24.102)
95% CL	[-40.12; -5.43]	[-25.34; 36.71]	[-45.40; 14.45]
Min-Max	-53.85 - 4.375	-35.58 - 105.77	-44.76 - 16.541
Median	-23.96	-0.98	-8.59
Q1-Q3	-38.71 - -3.47	-9.38 - 4.46	-33.47 - -7.10
T-Test	t= -3.03 P= 0.016	t= 0.42 P= 0.684	t= -1.44 P= 0.224

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.1 Change up to approx. 12 weeks after the start of treatment
4.5.3.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	14
Mean (SD)	188.81 (44.496)	191.81 (38.575)	206.77 (47.026)
95% CL	[163.12; 214.50]	[171.97; 211.64]	[179.62; 233.93]
Min-Max	135 - 275	133.33 - 260	143 - 311
Median	172.00	189.19	200.00
Q1-Q3	157.00 -210.00	167.00 -220.00	172.07 -226.13
After 12 weeks			
n	12	16	13
Mean (SD)	161.05 (20.329)	162.06 (34.842)	162.05 (37.033)
95% CL	[148.14; 173.97]	[143.49; 180.62]	[139.68; 184.43]
Min-Max	120 - 198	106.5 - 241.44	107.21 - 242
Median	163.58	152.93	164.00
Q1-Q3	152.00 -168.50	144.57 -189.00	133.00 -180.00
Change from baseline			
n	11	12	9
Mean (SD)	-28.16 (49.130)	-19.16 (30.113)	-28.33 (27.881)
95% CL	[-61.16; 4.85]	[-38.29; -0.03]	[-49.76; -6.89]
Min-Max	-155 - 25.225	-75 - 19.82	-78 - -5
Median	-8.00	-16.00	-18.00
Q1-Q3	-48.00 - -1.00	-40.02 - 6.50	-36.94 - -8.00
T-Test	t= -1.90 P= 0.086	t= -2.20 P= 0.050	t= -3.05 P= 0.016
Change from baseline [%]			
n	11	12	9
Mean (SD)	-11.45 (19.402)	-9.52 (15.965)	-13.78 (12.659)
95% CL	[-24.48; 1.59]	[-19.66; 0.63]	[-23.51; -4.05]
Min-Max	-56.36 - 18.421	-34.09 - 13.514	-39.2 - -2.732
Median	-5.19	-8.04	-9.09
Q1-Q3	-22.86 - -0.60	-23.42 - 4.22	-22.19 - -3.98
T-Test	t= -1.96 P= 0.079	t= -2.06 P= 0.063	t= -3.27 P= 0.011

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	13	17	14
Mean (SD)	170.29 (45.065)	165.86 (41.634)	178.68 (58.146)
95% CL	[143.05; 197.52]	[144.45; 187.26]	[145.10; 212.25]
Min-Max	122 - 268	97 - 237.84	84 - 298
Median	163.00	154.00	171.50
Q1-Q3	135.00 -193.00	142.00 -194.00	138.74 -226.00
After 24 weeks			
n	9	15	9
Mean (SD)	138.51 (26.382)	142.60 (25.131)	137.10 (26.234)
95% CL	[118.23; 158.79]	[128.69; 156.52]	[116.93; 157.26]
Min-Max	108 - 186	107 - 191	98 - 178
Median	133.00	140.54	136.94
Q1-Q3	121.00 -142.00	118.00 -158.56	120.00 -156.00
Change from baseline			
n	7	12	8
Mean (SD)	-22.29 (41.339)	-15.89 (43.296)	-18.63 (38.818)
95% CL	[-60.52; 15.95]	[-43.40; 11.62]	[-51.08; 13.83]
Min-Max	-100 - 38	-77.48 - 94	-106 - 26
Median	-21.00	-19.50	-13.00
Q1-Q3	-34.00 - -3.00	-40.00 - -7.00	-21.50 - 0.00
T-Test	t= -1.43 P= 0.204	t= -1.27 P= 0.230	t= -1.36 P= 0.217
Change from baseline [%]			
n	7	12	8
Mean (SD)	-11.35 (20.483)	-4.96 (35.034)	-9.93 (18.835)
95% CL	[-30.29; 7.59]	[-27.22; 17.30]	[-25.68; 5.82]
Min-Max	-42.37 - 25.676	-35.54 - 96.907	-46.9 - 17.105
Median	-12.88	-12.57	-8.06
Q1-Q3	-20.36 - -2.33	-25.71 - -4.66	-16.86 - 0.10
T-Test	t= -1.47 P= 0.193	t= -0.49 P= 0.633	t= -1.49 P= 0.179

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	16	13
Mean (SD)	212.43 (58.486)	209.05 (46.474)	211.75 (57.020)
95% CL	[178.66; 246.20]	[184.28; 233.81]	[177.29; 246.21]
Min-Max	120 - 320	131.53 - 346	90.091 - 320
Median	201.40	202.50	213.00
Q1-Q3	170.00 -252.25	188.60 -224.50	198.00 -228.83
After 24 weeks			
n	8	11	8
Mean (SD)	202.12 (73.622)	163.54 (34.563)	177.49 (31.079)
95% CL	[140.57; 263.67]	[140.32; 186.76]	[151.51; 203.47]
Min-Max	127 - 368	97 - 231	127.93 - 224
Median	180.99	160.00	181.00
Q1-Q3	165.00 -215.00	145.00 -178.00	157.49 -195.50
Change from baseline			
n	7	10	7
Mean (SD)	6.82 (79.984)	-49.53 (30.152)	-23.54 (46.021)
95% CL	[-67.15; 80.79]	[-71.10; -27.96]	[-66.10; 19.03]
Min-Max	-70.27 - 152	-95 - 10	-100.9 - 27
Median	-3.00	-48.52	-32.00
Q1-Q3	-55.00 - 69.00	-61.26 --39.00	-46.85 - 26.00
T-Test	t= 0.23 P= 0.829	t= -5.19 P= 0.001	t= -1.35 P= 0.225
Change from baseline [%]			
n	7	10	7
Mean (SD)	4.64 (38.344)	-23.66 (14.334)	-9.59 (21.594)
95% CL	[-30.82; 40.11]	[-33.91; -13.41]	[-29.56; 10.38]
Min-Max	-29.44 - 70.37	-48.4 - 4.5249	-44.09 - 16.981
Median	-1.79	-24.59	-15.17
Q1-Q3	-27.86 - 41.57	-26.77 --19.60	-21.31 - 13.13
T-Test	t= 0.32 P= 0.760	t= -5.22 P= 0.001	t= -1.18 P= 0.284

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.3 7-point glucose daily profile (mg/dl) - before lunch

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	13
Mean (SD)	164.89 (36.438)	176.89 (43.255)	184.91 (56.647)
95% CL	[143.85; 185.92]	[154.65; 199.13]	[150.68; 219.14]
Min-Max	119 - 243.25	129 - 286	124.33 - 324
Median	155.50	174.78	180.00
Q1-Q3	140.00 -193.00	141.00 -199.00	143.00 -204.00
After 24 weeks			
n	9	14	9
Mean (SD)	132.26 (20.101)	149.71 (23.631)	151.23 (54.489)
95% CL	[116.81; 147.71]	[136.06; 163.35]	[109.34; 193.11]
Min-Max	110 - 158	110 - 189	96 - 274
Median	130.00	156.00	145.95
Q1-Q3	112.00 -153.00	131.00 -167.00	112.00 -165.00
Change from baseline			
n	8	11	8
Mean (SD)	-26.87 (46.186)	-28.46 (34.296)	3.02 (52.428)
95% CL	[-65.48; 11.75]	[-51.50; -5.42]	[-40.81; 46.86]
Min-Max	-118.9 - 34	-68.47 - 48	-41 - 124
Median	-18.00	-35.00	-14.71
Q1-Q3	-47.00 - 0.00	-61.00 - -3.00	-24.50 - 9.81
T-Test	t= -1.65 P= 0.144	t= -2.75 P= 0.020	t= 0.16 P= 0.875
Change from baseline [%]			
n	8	11	8
Mean (SD)	-13.19 (23.711)	-14.02 (19.278)	2.80 (34.693)
95% CL	[-33.01; 6.63]	[-26.98; -1.07]	[-26.20; 31.80]
Min-Max	-48.89 - 27.419	-30.2 - 34.043	-20.1 - 82.667
Median	-12.06	-22.45	-10.50
Q1-Q3	-29.87 - -0.10	-28.36 - -1.76	-17.73 - 8.14
T-Test	t= -1.57 P= 0.160	t= -2.41 P= 0.037	t= 0.23 P= 0.826

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.4 7-point glucose daily profile (mg/dl) - after lunch

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	13	16	12
Mean (SD)	224.80 (70.242)	208.33 (52.578)	241.49 (44.926)
95% CL	[182.35; 267.24]	[180.32; 236.35]	[212.94; 270.03]
Min-Max	120.72 - 361	132 - 283	186 - 342
Median	210.00	204.51	229.72
Q1-Q3	185.00 -253.00	160.50 -256.50	213.00 -264.00
After 24 weeks			
n	8	13	9
Mean (SD)	174.56 (63.613)	159.38 (31.483)	183.32 (38.889)
95% CL	[121.37; 227.74]	[140.35; 178.40]	[153.43; 213.21]
Min-Max	50.451 - 275	118 - 207	123 - 229
Median	178.00	149.55	196.00
Q1-Q3	153.50 -204.00	138.00 -180.00	149.55 -209.00
Change from baseline			
n	7	11	8
Mean (SD)	-24.03 (97.995)	-52.75 (33.343)	-32.87 (37.086)
95% CL	[-114.66; 66.60]	[-75.15; -30.35]	[-63.88; -1.87]
Min-Max	-198.2 - 121	-120 - -9	-90.09 - 10
Median	-41.00	-46.85	-20.50
Q1-Q3	-50.00 - 31.00	-81.00 --21.00	-64.44 - -6.50
T-Test	t= -0.65 P= 0.541	t= -5.25 P= 0.000	t= -2.51 P= 0.041
Change from baseline [%]			
n	7	11	8
Mean (SD)	-5.65 (48.887)	-23.29 (11.231)	-13.86 (16.293)
95% CL	[-50.87; 39.56]	[-30.84; -15.75]	[-27.48; -0.23]
Min-Max	-79.71 - 78.571	-46.15 - -6.294	-40.32 - 5.3763
Median	-19.34	-23.85	-8.34
Q1-Q3	-24.62 - 20.13	-28.62 --11.11	-26.35 - -3.27
T-Test	t= -0.31 P= 0.770	t= -6.88 P= 0.000	t= -2.41 P= 0.047

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.5 7-point glucose daily profile (mg/dl) - before dinner

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	14
Mean (SD)	176.29 (70.037)	196.27 (58.642)	200.01 (72.769)
95% CL	[135.85; 216.73]	[166.12; 226.42]	[157.99; 242.02]
Min-Max	97.298 - 365.77	112 - 296	93 - 396
Median	166.50	187.00	184.00
Q1-Q3	139.00 -183.00	141.00 -246.85	164.00 -232.43
After 24 weeks			
n	9	12	9
Mean (SD)	163.90 (55.690)	160.23 (34.950)	169.90 (33.436)
95% CL	[121.09; 206.70]	[138.02; 182.44]	[144.19; 195.60]
Min-Max	98 - 272.07	111 - 219	122 - 214
Median	147.00	166.69	178.00
Q1-Q3	127.00 -176.00	127.00 -184.69	136.94 -188.00
Change from baseline			
n	8	10	8
Mean (SD)	-18.34 (45.494)	-42.35 (66.600)	-11.94 (39.785)
95% CL	[-56.37; 19.70]	[-89.99; 5.29]	[-45.20; 21.33]
Min-Max	-93.69 - 65	-164 - 78	-95.5 - 29
Median	-24.50	-45.02	-3.00
Q1-Q3	-36.00 - 1.50	-68.47 - -8.00	-28.00 - 16.50
T-Test	t= -1.14 P= 0.292	t= -2.01 P= 0.075	t= -0.85 P= 0.424
Change from baseline [%]			
n	8	10	8
Mean (SD)	-7.79 (22.447)	-14.05 (32.348)	-2.03 (21.492)
95% CL	[-26.56; 10.97]	[-37.19; 9.09]	[-20.00; 15.94]
Min-Max	-25.62 - 40.373	-55.41 - 55.319	-41.09 - 31.183
Median	-17.02	-23.94	-1.65
Q1-Q3	-22.00 - 0.46	-30.68 - -4.28	-12.68 - 11.16
T-Test	t= -0.98 P= 0.359	t= -1.37 P= 0.203	t= -0.27 P= 0.797

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.6 7-point glucose daily profile (mg/dl) - after dinner

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	12	16	12
Mean (SD)	224.66 (63.285)	230.43 (52.761)	244.05 (78.180)
95% CL	[184.46; 264.87]	[202.31; 258.54]	[194.37; 293.72]
Min-Max	148 - 331	135.14 - 354	144.15 - 403
Median	196.00	241.50	216.50
Q1-Q3	176.50 -292.50	192.30 -253.73	196.20 -288.50
After 24 weeks			
n	8	12	7
Mean (SD)	212.46 (66.292)	164.16 (29.702)	189.21 (44.563)
95% CL	[157.04; 267.88]	[145.29; 183.04]	[148.00; 230.43]
Min-Max	111 - 318	102 - 218	135.14 - 252
Median	200.50	162.08	191.00
Q1-Q3	179.00 -255.85	148.00 -178.50	146.00 -235.00
Change from baseline			
n	6	11	5
Mean (SD)	7.67 (81.992)	-59.39 (64.537)	-2.00 (26.458)
95% CL	[-78.38; 93.71]	[-102.74; -16.03]	[-34.85; 30.85]
Min-Max	-100 - 140	-211 - 7.2073	-37 - 35
Median	6.00	-50.45	-8.00
Q1-Q3	-46.00 - 40.00	-95.00 - -5.00	-9.01 - 9.00
T-Test	t= 0.23 P= 0.828	t= -3.05 P= 0.012	t= -0.17 P= 0.874
Change from baseline [%]			
n	6	11	5
Mean (SD)	6.86 (43.015)	-22.02 (20.544)	-0.63 (11.396)
95% CL	[-38.28; 52.00]	[-35.82; -8.22]	[-14.78; 13.52]
Min-Max	-47.39 - 78.652	-59.6 - 4.5752	-13.6 - 16.129
Median	3.53	-23.73	-4.02
Q1-Q3	-19.66 - 22.47	-37.86 - -2.63	-6.25 - 4.59
T-Test	t= 0.39 P= 0.712	t= -3.56 P= 0.005	t= -0.12 P= 0.908

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.7 7-point glucose daily profile (mg/dl) - bedtime

	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	12	15	10
Mean (SD)	201.17 (44.152)	195.27 (48.947)	216.21 (45.122)
95% CL	[173.11; 229.22]	[168.17; 222.38]	[183.93; 248.48]
Min-Max	121 - 260	104 - 274	143 - 266
Median	208.00	187.00	229.50
Q1-Q3	166.00 -236.00	167.00 -243.00	169.00 -254.06
After 24 weeks			
n	8	14	8
Mean (SD)	141.76 (30.524)	157.61 (26.277)	158.16 (38.542)
95% CL	[116.24; 167.28]	[142.44; 172.78]	[125.93; 190.38]
Min-Max	90.091 - 180	108 - 210.81	112 - 215
Median	142.50	156.00	150.00
Q1-Q3	122.50 -167.00	147.00 -170.00	126.13 -193.00
Change from baseline			
n	6	11	5
Mean (SD)	-55.67 (37.829)	-21.38 (54.110)	-39.99 (52.744)
95% CL	[-95.37; -15.97]	[-57.73; 14.97]	[-105.48; 25.50]
Min-Max	-97 - 7	-112 - 93	-127.9 - -5
Median	-65.50	-25.00	-9.00
Q1-Q3	-82.00 --31.00	-51.00 - 9.01	-51.00 - -7.00
T-Test	t= -3.60 P= 0.015	t= -1.31 P= 0.219	t= -1.70 P= 0.165
Change from baseline [%]			
n	6	11	5
Mean (SD)	-26.39 (17.556)	-5.22 (35.536)	-16.66 (20.146)
95% CL	[-44.82; -7.97]	[-29.09; 18.66]	[-41.68; 8.35]
Min-Max	-41.45 - 4.375	-43.08 - 89.423	-50.35 - -2.959
Median	-33.92	-14.53	-4.90
Q1-Q3	-37.79 --15.66	-24.88 - 4.46	-20.56 - -4.55
T-Test	t= -3.68 P= 0.014	t= -0.49 P= 0.637	t= -1.85 P= 0.138

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.2 Change up to approx. 24 weeks after the start of treatment
4.5.3.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	14	17	14
Mean (SD)	188.81 (44.496)	191.81 (38.575)	206.77 (47.026)
95% CL	[163.12; 214.50]	[171.97; 211.64]	[179.62; 233.93]
Min-Max	135 - 275	133.33 - 260	143 - 311
Median	172.00	189.19	200.00
Q1-Q3	157.00 -210.00	167.00 -220.00	172.07 -226.13
After 24 weeks			
n	9	15	9
Mean (SD)	161.95 (38.873)	152.90 (19.573)	162.54 (24.153)
95% CL	[132.07; 191.83]	[142.06; 163.74]	[143.98; 181.11]
Min-Max	118 - 250.5	119 - 189	127.93 - 189
Median	150.50	151.00	177.00
Q1-Q3	137.00 -176.58	144.15 -171.00	142.00 -179.00
Change from baseline			
n	8	12	8
Mean (SD)	-18.11 (51.988)	-30.14 (40.841)	-23.36 (24.836)
95% CL	[-61.57; 25.35]	[-56.09; -4.19]	[-44.13; -2.60]
Min-Max	-73.87 - 96.5	-112 - 52	-80.18 - -5
Median	-29.00	-39.92	-14.11
Q1-Q3	-50.00 - -4.75	-46.52 --14.50	-28.25 - -8.50
T-Test	t= -0.99 P= 0.357	t= -2.56 P= 0.027	t= -2.66 P= 0.032
Change from baseline [%]			
n	8	12	8
Mean (SD)	-7.96 (30.526)	-13.03 (21.728)	-11.57 (10.614)
95% CL	[-33.48; 17.56]	[-26.84; 0.77]	[-20.44; -2.70]
Min-Max	-31.4 - 62.662	-43.08 - 37.956	-35.46 - -2.732
Median	-17.19	-21.97	-8.51
Q1-Q3	-27.32 - -2.96	-23.22 - -7.72	-13.70 - -4.97
T-Test	t= -0.74 P= 0.485	t= -2.08 P= 0.062	t= -3.08 P= 0.018

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.3.3.1 Derived Time in Range - dTIR

Percentage within range	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	11	15	8
Mean (SD)	46.8 (34.46)	41.9 (31.70)	28.6 (26.45)
Min-Max	0 - 85.714	0 - 100	0 - 71.429
Median	57.1	42.9	21.4
Q1-Q3	14.3 - 85.7	28.6 - 57.1	7.1 - 50.0
After 12 weeks			
n	9	11	9
Mean (SD)	71.4 (15.97)	57.1 (41.89)	57.1 (30.30)
Min-Max	42.857 - 85.714	0 - 100	0 - 85.714
Median	71.4	71.4	71.4
Q1-Q3	57.1 - 85.7	14.3 - 100.0	57.1 - 71.4
After 24 weeks			
n	7	11	7
Mean (SD)	73.5 (20.91)	84.4 (18.58)	63.3 (29.57)
Min-Max	42.857 - 100	57.143 - 100	28.571 - 100
Median	85.7	85.7	57.1
Q1-Q3	57.1 - 85.7	57.1 - 100.0	28.6 - 100.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.3.3.2 Derived Time below Range - dTBR

Percentage below range	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	11	15	8
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 12 weeks			
n	9	11	9
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 24 weeks			
n	7	11	7
Mean (SD)	2.0 (5.40)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 14.286	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.3 Full Analysis Set - Subgroups - Age groups
4.5.3.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.3.3.3 Derived Time above Range - dTAR

Percentage above range	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	11	15	8
Mean (SD)	53.2 (34.46)	58.1 (31.70)	71.4 (26.45)
Min-Max	14.286 - 100	0 - 100	28.571 - 100
Median	42.9	57.1	78.6
Q1-Q3	14.3 - 85.7	42.9 - 71.4	50.0 - 92.9
After 12 weeks			
n	9	11	9
Mean (SD)	28.6 (15.97)	42.9 (41.89)	42.9 (30.30)
Min-Max	14.286 - 57.143	0 - 100	14.286 - 100
Median	28.6	28.6	28.6
Q1-Q3	14.3 - 42.9	0.0 - 85.7	28.6 - 42.9
After 24 weeks			
n	7	11	7
Mean (SD)	24.5 (17.91)	15.6 (18.58)	36.7 (29.57)
Min-Max	0 - 42.857	0 - 42.857	0 - 71.429
Median	14.3	14.3	42.9
Q1-Q3	14.3 - 42.9	0.0 - 42.9	0.0 - 71.4

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	34
Mean (SD)	187.60 (55.476)	166.43 (44.781)
95% CL	[147.91; 227.29]	[150.81; 182.06]
Min-Max	121 - 298	84 - 268
Median	169.00	157.50
Q1-Q3	152.00 -229.00	135.00 -199.00
After 12 weeks		
n	10	31
Mean (SD)	136.10 (46.484)	139.60 (36.454)
95% CL	[102.84; 169.35]	[126.23; 152.97]
Min-Max	90 - 242	77 - 241.44
Median	122.50	137.00
Q1-Q3	99.00 -154.96	113.00 -158.00
Change from baseline		
n	7	24
Mean (SD)	-27.71 (30.109)	-23.64 (51.883)
95% CL	[-55.56; 0.13]	[-45.55; -1.73]
Min-Max	-64 - 14	-168 - 57
Median	-37.00	-17.00
Q1-Q3	-56.00 - 7.00	-54.03 - 6.50
T-Test	t= -2.44 P= 0.051	t= -2.23 P= 0.036
Change from baseline [%]		
n	7	24
Mean (SD)	-15.20 (18.189)	-9.49 (29.208)
95% CL	[-32.02; 1.62]	[-21.82; 2.85]
Min-Max	-41.56 - 11.57	-62.69 - 58.763
Median	-18.79	-10.41
Q1-Q3	-25.15 - 4.00	-34.95 - 4.60
T-Test	t= -2.21 P= 0.069	t= -1.59 P= 0.125

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	9	34
Mean (SD)	218.56 (59.800)	208.96 (51.261)
95% CL	[172.59; 264.52]	[191.07; 226.84]
Min-Max	120 - 320	90.091 - 346
Median	220.00	203.00
Q1-Q3	188.00 -240.00	179.00 -228.00
After 12 weeks		
n	8	27
Mean (SD)	193.13 (105.74)	183.57 (32.714)
95% CL	[104.72; 281.53]	[170.63; 196.51]
Min-Max	107 - 440	131 - 252
Median	178.50	180.00
Q1-Q3	127.00 -193.50	169.37 -209.00
Change from baseline		
n	5	22
Mean (SD)	-38.20 (44.381)	-17.70 (53.488)
95% CL	[-93.31; 16.91]	[-41.42; 6.01]
Min-Max	-81 - 28	-179 - 86
Median	-42.00	-15.50
Q1-Q3	-75.00 --21.00	-48.65 - 6.00
T-Test	t= -1.92 P= 0.127	t= -1.55 P= 0.135
Change from baseline [%]		
n	5	22
Mean (SD)	-17.63 (23.606)	-6.15 (23.561)
95% CL	[-46.94; 11.68]	[-16.60; 4.30]
Min-Max	-43.09 - 17.61	-57.74 - 51.807
Median	-19.09	-7.50
Q1-Q3	-34.09 - -9.50	-25.20 - 3.49
T-Test	t= -1.67 P= 0.170	t= -1.22 P= 0.234

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.3 7-point glucose daily profile (mg/dl) - before lunch

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	34
Mean (SD)	199.20 (57.825)	168.45 (39.337)
95% CL	[157.83; 240.57]	[154.73; 182.18]
Min-Max	143 - 324	119 - 286
Median	183.00	164.50
Q1-Q3	151.00 -221.00	136.00 -193.00
After 12 weeks		
n	10	29
Mean (SD)	145.82 (41.426)	144.76 (31.914)
95% CL	[116.18; 175.45]	[132.62; 156.90]
Min-Max	89 - 214	97 - 218.02
Median	134.00	147.75
Q1-Q3	125.00 -186.00	118.92 -162.00
Change from baseline		
n	7	24
Mean (SD)	-48.14 (52.305)	-23.32 (41.997)
95% CL	[-96.52; 0.23]	[-41.06; -5.59]
Min-Max	-138 - 11	-124.3 - 43.244
Median	-32.00	-21.71
Q1-Q3	-91.00 --10.00	-50.00 - 7.50
T-Test	t= -2.44 P= 0.051	t= -2.72 P= 0.012
Change from baseline [%]		
n	7	24
Mean (SD)	-23.35 (21.054)	-11.42 (22.380)
95% CL	[-42.82; -3.88]	[-20.87; -1.96]
Min-Max	-48.92 - 6.1111	-51.11 - 30.882
Median	-19.75	-14.55
Q1-Q3	-42.59 - -6.76	-25.77 - 4.81
T-Test	t= -2.93 P= 0.026	t= -2.50 P= 0.020

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.4 7-point glucose daily profile (mg/dl) - after lunch

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	33
Mean (SD)	247.00 (60.235)	217.50 (55.750)
95% CL	[196.64; 297.36]	[197.73; 237.27]
Min-Max	164 - 342	120.72 - 361
Median	246.00	212.61
Q1-Q3	198.00 -291.00	185.00 -253.00
After 12 weeks		
n	8	26
Mean (SD)	195.75 (22.752)	188.45 (48.159)
95% CL	[176.73; 214.77]	[169.00; 207.91]
Min-Max	156 - 231	103 - 293.7
Median	202.50	179.00
Q1-Q3	180.50 -206.50	154.00 -220.00
Change from baseline		
n	5	22
Mean (SD)	-30.60 (48.829)	-11.46 (45.503)
95% CL	[-91.23; 30.03]	[-31.64; 8.71]
Min-Max	-79 - 37	-78 - 97.298
Median	-28.00	-7.00
Q1-Q3	-76.00 - -7.00	-57.00 - 19.00
T-Test	t= -1.40 P= 0.234	t= -1.18 P= 0.251
Change from baseline [%]		
n	5	22
Mean (SD)	-11.04 (22.044)	-3.08 (21.985)
95% CL	[-38.41; 16.33]	[-12.83; 6.67]
Min-Max	-32.76 - 22.561	-30.16 - 49.541
Median	-13.33	-3.04
Q1-Q3	-27.92 - -3.76	-25.81 - 13.40
T-Test	t= -1.12 P= 0.325	t= -0.66 P= 0.519

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.5 7-point glucose daily profile (mg/dl) - before dinner

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	35
Mean (SD)	212.10 (93.450)	185.25 (56.376)
95% CL	[145.25; 278.95]	[165.88; 204.62]
Min-Max	93 - 396	97.298 - 365.77
Median	203.00	178.00
Q1-Q3	141.00 -262.00	148.00 -223.43
After 12 weeks		
n	9	30
Mean (SD)	163.33 (49.621)	153.41 (42.896)
95% CL	[125.19; 201.48]	[137.39; 169.43]
Min-Max	112 - 261	79 - 250
Median	146.00	143.67
Q1-Q3	131.00 -197.00	118.00 -187.39
Change from baseline		
n	7	24
Mean (SD)	-42.00 (74.216)	-36.95 (58.790)
95% CL	[-110.64; 26.64]	[-61.78; -12.13]
Min-Max	-190 - 38	-171.2 - 86.487
Median	-24.00	-26.00
Q1-Q3	-65.00 - 11.00	-61.00 - -3.50
T-Test	t= -1.50 P= 0.185	t= -3.08 P= 0.005
Change from baseline [%]		
n	7	24
Mean (SD)	-11.27 (29.303)	-14.08 (29.611)
95% CL	[-38.37; 15.83]	[-26.58; -1.58]
Min-Max	-47.98 - 40.86	-60.73 - 88.889
Median	-17.02	-14.90
Q1-Q3	-32.12 - 9.17	-30.26 - -2.26
T-Test	t= -1.02 P= 0.348	t= -2.33 P= 0.029

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.6 7-point glucose daily profile (mg/dl) - after dinner

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	32
Mean (SD)	276.25 (89.474)	221.92 (50.963)
95% CL	[201.45; 351.05]	[203.54; 240.29]
Min-Max	181 - 403	135.14 - 331
Median	262.00	216.50
Q1-Q3	189.00 -362.00	184.00 -253.73
After 12 weeks		
n	8	28
Mean (SD)	216.63 (77.205)	194.92 (54.093)
95% CL	[152.08; 281.17]	[173.95; 215.90]
Min-Max	166 - 390	106.31 - 387.39
Median	185.50	187.00
Q1-Q3	167.50 -235.50	157.50 -222.31
Change from baseline		
n	5	22
Mean (SD)	-36.00 (85.191)	-33.06 (51.176)
95% CL	[-141.78; 69.78]	[-55.75; -10.37]
Min-Max	-146 - 81	-206 - 54
Median	-30.00	-30.50
Q1-Q3	-82.00 - -3.00	-53.00 - -3.60
T-Test	t= -0.94 P= 0.398	t= -3.03 P= 0.006
Change from baseline [%]		
n	5	22
Mean (SD)	-9.33 (33.795)	-13.31 (18.954)
95% CL	[-51.29; 32.64]	[-21.71; -4.91]
Min-Max	-41.24 - 44.505	-62.24 - 30.337
Median	-15.31	-15.24
Q1-Q3	-32.93 - -1.66	-25.26 - -1.44
T-Test	t= -0.62 P= 0.571	t= -3.29 P= 0.003

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.7 7-point glucose daily profile (mg/dl) - bedtime

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	27
Mean (SD)	217.10 (48.624)	197.56 (44.688)
95% CL	[182.32; 251.88]	[179.88; 215.24]
Min-Max	143 - 267	104 - 274
Median	223.00	198.00
Q1-Q3	172.00 -263.00	167.00 -238.00
After 12 weeks		
n	9	24
Mean (SD)	161.33 (68.207)	169.36 (34.360)
95% CL	[108.90; 213.76]	[154.85; 183.87]
Min-Max	79 - 310	100 - 245.05
Median	167.00	167.00
Q1-Q3	123.00 -172.00	152.50 -192.50
Change from baseline		
n	7	16
Mean (SD)	-26.71 (54.018)	-27.89 (59.109)
95% CL	[-76.67; 23.24]	[-59.38; 3.61]
Min-Max	-95 - 44	-140 - 110
Median	-5.00	-14.11
Q1-Q3	-84.00 - 19.00	-59.50 - 1.00
T-Test	t= -1.31 P= 0.239	t= -1.89 P= 0.079
Change from baseline [%]		
n	7	16
Mean (SD)	-13.38 (25.692)	-8.60 (35.767)
95% CL	[-37.14; 10.38]	[-27.66; 10.46]
Min-Max	-44.76 - 16.541	-53.85 - 105.77
Median	-2.91	-7.84
Q1-Q3	-38.71 - 12.75	-26.30 - 0.23
T-Test	t= -1.38 P= 0.218	t= -0.96 P= 0.352

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.1 Change up to approx. 12 weeks after the start of treatment
4.5.4.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	35
Mean (SD)	215.90 (57.724)	189.71 (36.626)
95% CL	[174.61; 257.19]	[177.13; 202.29]
Min-Max	143 - 311	133.33 - 275
Median	220.50	189.00
Q1-Q3	157.00 -260.00	167.00 -212.61
After 12 weeks		
n	10	31
Mean (SD)	160.41 (38.382)	162.20 (29.404)
95% CL	[132.95; 187.86]	[151.41; 172.99]
Min-Max	117 - 242	106.5 - 241.44
Median	151.78	162.16
Q1-Q3	135.00 -179.00	146.00 -180.00
Change from baseline		
n	7	25
Mean (SD)	-33.50 (28.129)	-22.40 (38.475)
95% CL	[-59.52; -7.48]	[-38.29; -6.52]
Min-Max	-75 - -5	-155 - 25.225
Median	-21.50	-8.00
Q1-Q3	-69.00 - -8.00	-36.94 - -1.00
T-Test	t= -3.15 P= 0.020	t= -2.91 P= 0.008
Change from baseline [%]		
n	7	25
Mean (SD)	-15.86 (11.121)	-10.12 (17.105)
95% CL	[-26.14; -5.57]	[-17.19; -3.06]
Min-Max	-34.09 - -2.907	-56.36 - 18.421
Median	-13.69	-5.19
Q1-Q3	-23.03 - -5.59	-22.86 - -0.60
T-Test	t= -3.77 P= 0.009	t= -2.96 P= 0.007

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	34
Mean (SD)	187.60 (55.476)	166.43 (44.781)
95% CL	[147.91; 227.29]	[150.81; 182.06]
Min-Max	121 - 298	84 - 268
Median	169.00	157.50
Q1-Q3	152.00 -229.00	135.00 -199.00
After 24 weeks		
n	6	27
Mean (SD)	136.33 (31.778)	140.80 (23.992)
95% CL	[102.98; 169.68]	[131.31; 150.29]
Min-Max	104 - 176	98 - 191
Median	130.00	136.00
Q1-Q3	107.00 -171.00	121.00 -157.00
Change from baseline		
n	6	21
Mean (SD)	-21.17 (13.348)	-17.56 (45.084)
95% CL	[-35.17; -7.16]	[-38.08; 2.96]
Min-Max	-45 - -4	-106 - 94
Median	-19.50	-18.00
Q1-Q3	-22.00 --17.00	-34.00 - -3.00
T-Test	t= -3.88 P= 0.012	t= -1.78 P= 0.089
Change from baseline [%]		
n	6	21
Mean (SD)	-13.97 (9.025)	-6.41 (30.039)
95% CL	[-23.44; -4.50]	[-20.09; 7.26]
Min-Max	-29.61 - -2.286	-46.9 - 96.907
Median	-13.47	-11.48
Q1-Q3	-15.71 - -9.28	-20.36 - -2.33
T-Test	t= -3.79 P= 0.013	t= -0.98 P= 0.340

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	9	34
Mean (SD)	218.56 (59.800)	208.96 (51.261)
95% CL	[172.59; 264.52]	[191.07; 226.84]
Min-Max	120 - 320	90.091 - 346
Median	220.00	203.00
Q1-Q3	188.00 -240.00	179.00 -228.00
After 24 weeks		
n	5	22
Mean (SD)	164.80 (49.550)	182.35 (49.999)
95% CL	[103.28; 226.32]	[160.19; 204.52]
Min-Max	97 - 231	127 - 368
Median	165.00	176.39
Q1-Q3	145.00 -186.00	153.00 -195.00
Change from baseline		
n	5	19
Mean (SD)	-40.80 (56.650)	-21.49 (56.801)
95% CL	[-111.14; 29.54]	[-48.87; 5.89]
Min-Max	-95 - 27	-100.9 - 152
Median	-55.00	-42.00
Q1-Q3	-91.00 - 10.00	-53.00 - 4.00
T-Test	t= -1.61 P= 0.183	t= -1.65 P= 0.116
Change from baseline [%]		
n	5	19
Mean (SD)	-18.30 (28.151)	-9.46 (27.200)
95% CL	[-53.25; 16.66]	[-22.57; 3.65]
Min-Max	-48.4 - 16.981	-44.09 - 70.37
Median	-25.00	-19.60
Q1-Q3	-39.58 - 4.52	-25.95 - 1.99
T-Test	t= -1.45 P= 0.220	t= -1.52 P= 0.147

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.3 7-point glucose daily profile (mg/dl) - before lunch

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	34
Mean (SD)	199.20 (57.825)	168.45 (39.337)
95% CL	[157.83; 240.57]	[154.73; 182.18]
Min-Max	143 - 324	119 - 286
Median	183.00	164.50
Q1-Q3	151.00 -221.00	136.00 -193.00
After 24 weeks		
n	6	26
Mean (SD)	135.33 (25.311)	147.51 (36.020)
95% CL	[108.77; 161.90]	[132.96; 162.06]
Min-Max	110 - 165	96 - 274
Median	135.50	143.47
Q1-Q3	110.00 -156.00	124.33 -165.00
Change from baseline		
n	6	21
Mean (SD)	-32.17 (25.600)	-14.80 (48.275)
95% CL	[-59.03; -5.30]	[-36.78; 7.17]
Min-Max	-65 - 5	-118.9 - 124
Median	-33.00	-23.42
Q1-Q3	-52.00 --15.00	-39.64 - -2.00
T-Test	t= -3.08 P= 0.028	t= -1.41 P= 0.175
Change from baseline [%]		
n	6	21
Mean (SD)	-18.52 (13.870)	-6.01 (28.210)
95% CL	[-33.07; -3.96]	[-18.85; 6.83]
Min-Max	-32.1 - 3.3784	-48.89 - 82.667
Median	-22.32	-16.08
Q1-Q3	-29.41 - -8.33	-22.45 - -1.10
T-Test	t= -3.27 P= 0.022	t= -0.98 P= 0.340

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.4 7-point glucose daily profile (mg/dl) - after lunch

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	33
Mean (SD)	247.00 (60.235)	217.50 (55.750)
95% CL	[196.64; 297.36]	[197.73; 237.27]
Min-Max	164 - 342	120.72 - 361
Median	246.00	212.61
Q1-Q3	198.00 -291.00	185.00 -253.00
After 24 weeks		
n	5	25
Mean (SD)	163.40 (35.648)	172.05 (45.709)
95% CL	[119.14; 207.66]	[153.18; 190.92]
Min-Max	119 - 202	50.451 - 275
Median	160.00	171.00
Q1-Q3	140.00 -196.00	142.34 -204.00
Change from baseline		
n	5	21
Mean (SD)	-57.20 (48.028)	-34.55 (59.588)
95% CL	[-116.83; 2.43]	[-61.67; -7.42]
Min-Max	-120 - 10	-198.2 - 121
Median	-50.00	-41.00
Q1-Q3	-81.00 --45.00	-51.00 - -9.00
T-Test	t= -2.66 P= 0.056	t= -2.66 P= 0.015
Change from baseline [%]		
n	5	21
Mean (SD)	-24.13 (18.621)	-13.62 (29.150)
95% CL	[-47.25; -1.01]	[-26.89; -0.35]
Min-Max	-46.15 - 5.3763	-79.71 - 78.571
Median	-27.44	-17.04
Q1-Q3	-28.62 --23.81	-24.62 - -5.43
T-Test	t= -2.90 P= 0.044	t= -2.14 P= 0.045

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.5 7-point glucose daily profile (mg/dl) - before dinner

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	35
Mean (SD)	212.10 (93.450)	185.25 (56.376)
95% CL	[145.25; 278.95]	[165.88; 204.62]
Min-Max	93 - 396	97.298 - 365.77
Median	203.00	178.00
Q1-Q3	141.00 -262.00	148.00 -223.43
After 24 weeks		
n	6	24
Mean (SD)	156.67 (46.903)	166.12 (39.697)
95% CL	[107.45; 205.89]	[149.36; 182.88]
Min-Max	98 - 219	111 - 272.07
Median	152.00	176.50
Q1-Q3	122.00 -197.00	131.97 -186.19
Change from baseline		
n	6	20
Mean (SD)	-21.50 (84.831)	-26.83 (42.362)
95% CL	[-110.52; 67.52]	[-46.66; -7.01]
Min-Max	-164 - 78	-98 - 65
Median	-3.50	-28.50
Q1-Q3	-65.00 - 29.00	-45.02 - -3.00
T-Test	t= -0.62 P= 0.562	t= -2.83 P= 0.011
Change from baseline [%]		
n	6	20
Mean (SD)	-0.42 (40.359)	-10.83 (20.750)
95% CL	[-42.77; 41.94]	[-20.54; -1.12]
Min-Max	-55.41 - 55.319	-41.09 - 40.373
Median	-4.39	-14.83
Q1-Q3	-24.81 - 31.18	-24.97 - -1.65
T-Test	t= -0.03 P= 0.981	t= -2.33 P= 0.031

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.6 7-point glucose daily profile (mg/dl) - after dinner

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	32
Mean (SD)	276.25 (89.474)	221.92 (50.963)
95% CL	[201.45; 351.05]	[203.54; 240.29]
Min-Max	181 - 403	135.14 - 331
Median	262.00	216.50
Q1-Q3	189.00 -362.00	184.00 -253.73
After 24 weeks		
n	5	22
Mean (SD)	170.40 (22.479)	188.28 (53.641)
95% CL	[142.49; 198.31]	[164.50; 212.06]
Min-Max	143 - 205	102 - 318
Median	170.00	186.50
Q1-Q3	162.00 -172.00	151.00 -218.00
Change from baseline		
n	5	17
Mean (SD)	-67.20 (91.040)	-16.54 (59.605)
95% CL	[-180.24; 45.84]	[-47.19; 14.10]
Min-Max	-211 - 9	-100 - 140
Median	-20.00	-9.01
Q1-Q3	-103.0 --11.00	-50.45 - 7.21
T-Test	t= -1.65 P= 0.174	t= -1.14 P= 0.269
Change from baseline [%]		
n	5	17
Mean (SD)	-21.91 (26.148)	-5.57 (29.525)
95% CL	[-54.37; 10.56]	[-20.75; 9.61]
Min-Max	-59.6 - 4.5918	-47.39 - 78.652
Median	-10.99	-6.25
Q1-Q3	-37.45 - -6.08	-23.73 - 4.58
T-Test	t= -1.87 P= 0.134	t= -0.78 P= 0.448

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.7 7-point glucose daily profile (mg/dl) - bedtime

	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	27
Mean (SD)	217.10 (48.624)	197.56 (44.688)
95% CL	[182.32; 251.88]	[179.88; 215.24]
Min-Max	143 - 267	104 - 274
Median	223.00	198.00
Q1-Q3	172.00 -263.00	167.00 -238.00
After 24 weeks		
n	6	24
Mean (SD)	145.00 (21.194)	155.66 (32.716)
95% CL	[122.76; 167.24]	[141.85; 169.48]
Min-Max	110 - 174	90.091 - 215
Median	148.00	159.50
Q1-Q3	136.00 -154.00	130.56 -175.00
Change from baseline		
n	6	16
Mean (SD)	-46.00 (48.431)	-30.82 (51.352)
95% CL	[-96.83; 4.83]	[-58.18; -3.46]
Min-Max	-112 - 25	-127.9 - 93
Median	-56.50	-25.11
Q1-Q3	-69.00 - -7.00	-65.00 - -7.00
T-Test	t= -2.33 P= 0.068	t= -2.40 P= 0.030
Change from baseline [%]		
n	6	16
Mean (SD)	-20.65 (22.500)	-10.95 (31.254)
95% CL	[-44.26; 2.96]	[-27.60; 5.71]
Min-Max	-43.08 - 16.779	-50.35 - 89.423
Median	-28.34	-14.56
Q1-Q3	-36.05 - -4.90	-28.02 - -3.75
T-Test	t= -2.25 P= 0.074	t= -1.40 P= 0.182

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.2 Change up to approx. 24 weeks after the start of treatment
4.5.4.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	10	35
Mean (SD)	215.90 (57.724)	189.71 (36.626)
95% CL	[174.61; 257.19]	[177.13; 202.29]
Min-Max	143 - 311	133.33 - 275
Median	220.50	189.00
Q1-Q3	157.00 -260.00	167.00 -212.61
After 24 weeks		
n	6	27
Mean (SD)	140.42 (20.373)	161.91 (26.670)
95% CL	[119.04; 161.80]	[151.35; 172.46]
Min-Max	118 - 171	126 - 250.5
Median	142.00	158.00
Q1-Q3	119.00 -150.50	144.15 -179.00
Change from baseline		
n	6	22
Mean (SD)	-43.75 (39.130)	-19.59 (38.971)
95% CL	[-84.81; -2.69]	[-36.87; -2.31]
Min-Max	-112 - -6.5	-80.18 - 96.5
Median	-41.50	-24.50
Q1-Q3	-54.00 - -7.00	-42.00 - -9.00
T-Test	t= -2.74 P= 0.041	t= -2.36 P= 0.028
Change from baseline [%]		
n	6	22
Mean (SD)	-21.31 (15.111)	-8.40 (22.576)
95% CL	[-37.16; -5.45]	[-18.41; 1.61]
Min-Max	-43.08 - -4.14	-35.46 - 62.662
Median	-22.17	-13.47
Q1-Q3	-31.40 - -4.90	-22.46 - -5.05
T-Test	t= -3.45 P= 0.018	t= -1.74 P= 0.096

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.4.3.1 Derived Time in Range - dTIR

Percentage within range	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	26
Mean (SD)	32.1 (31.25)	42.9 (31.56)
Min-Max	0 - 71.429	0 - 100
Median	28.6	42.9
Q1-Q3	0.0 - 64.3	14.3 - 57.1
After 12 weeks		
n	8	21
Mean (SD)	58.9 (38.51)	62.6 (29.79)
Min-Max	0 - 100	0 - 100
Median	71.4	71.4
Q1-Q3	28.6 - 85.7	57.1 - 85.7
After 24 weeks		
n	5	20
Mean (SD)	80.0 (21.67)	74.3 (24.35)
Min-Max	57.143 - 100	28.571 - 100
Median	85.7	85.7
Q1-Q3	57.1 - 100.0	57.1 - 100.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.4.3.2 Derived Time below Range - dTBR

Percentage below range	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	26
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 12 weeks		
n	8	21
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 24 weeks		
n	5	20
Mean (SD)	0.0 (0.00)	0.7 (3.19)
Min-Max	0 - 0	0 - 14.286
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.4 Full Analysis Set - Subgroups - Body Mass Index
4.5.4.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.4.3.3 Derived Time above Range - dTAR

Percentage above range	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	8	26
Mean (SD)	67.9 (31.25)	57.1 (31.56)
Min-Max	28.571 - 100	0 - 100
Median	71.4	57.1
Q1-Q3	35.7 - 100.0	42.9 - 85.7
After 12 weeks		
n	8	21
Mean (SD)	41.1 (38.51)	37.4 (29.79)
Min-Max	0 - 100	0 - 100
Median	28.6	28.6
Q1-Q3	14.3 - 71.4	14.3 - 42.9
After 24 weeks		
n	5	20
Mean (SD)	20.0 (21.67)	25.0 (23.58)
Min-Max	0 - 42.857	0 - 71.429
Median	14.3	14.3
Q1-Q3	0.0 - 42.9	0.0 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	22
Mean (SD)	181.24 (70.679)	166.16 (34.611)
95% CL	[130.68; 231.80]	[150.81; 181.50]
Min-Max	84 - 298	97 - 236
Median	174.30	163.00
Q1-Q3	122.00 -237.84	144.00 -178.00
After 12 weeks		
n	10	23
Mean (SD)	133.14 (59.075)	146.00 (28.457)
95% CL	[90.88; 175.40]	[133.70; 158.31]
Min-Max	77 - 242	99 - 205.41
Median	114.00	144.15
Q1-Q3	98.00 -126.00	122.00 -159.00
Change from baseline		
n	7	17
Mean (SD)	-38.20 (45.324)	-10.93 (38.259)
95% CL	[-80.12; 3.72]	[-30.60; 8.74]
Min-Max	-105 - 33	-85 - 57
Median	-45.00	-16.00
Q1-Q3	-64.00 - 3.60	-26.00 - 9.01
T-Test	t= -2.23 P= 0.067	t= -1.18 P= 0.256
Change from baseline [%]		
n	7	17
Mean (SD)	-18.12 (30.055)	-3.46 (24.762)
95% CL	[-45.92; 9.68]	[-16.19; 9.27]
Min-Max	-46.46 - 39.286	-36.02 - 58.763
Median	-23.94	-9.58
Q1-Q3	-41.56 - 1.52	-17.78 - 6.94
T-Test	t= -1.60 P= 0.162	t= -0.58 P= 0.572

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	22
Mean (SD)	201.45 (62.823)	205.49 (40.681)
95% CL	[153.16; 249.74]	[187.45; 223.53]
Min-Max	90.091 - 320	120 - 279
Median	198.00	208.00
Q1-Q3	179.00 -220.00	188.00 -228.00
After 12 weeks		
n	9	19
Mean (SD)	198.12 (97.513)	183.32 (37.439)
95% CL	[123.16; 273.07]	[165.28; 201.37]
Min-Max	109 - 440	107 - 252
Median	178.00	180.00
Q1-Q3	145.00 -188.00	146.00 -210.00
Change from baseline		
n	5	15
Mean (SD)	-10.99 (45.627)	-19.46 (46.877)
95% CL	[-67.65; 45.66]	[-45.42; 6.50]
Min-Max	-75 - 36.036	-81 - 86
Median	-18.00	-18.00
Q1-Q3	-28.00 - 30.00	-61.00 - -8.00
T-Test	t= -0.54 P= 0.619	t= -1.61 P= 0.130
Change from baseline [%]		
n	5	15
Mean (SD)	-4.06 (22.624)	-8.49 (24.853)
95% CL	[-32.16; 24.03]	[-22.25; 5.28]
Min-Max	-34.09 - 18.987	-43.09 - 51.807
Median	-9.09	-9.87
Q1-Q3	-14.14 - 18.02	-28.24 - -3.98
T-Test	t= -0.40 P= 0.708	t= -1.32 P= 0.207

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.3 7-point glucose daily profile (mg/dl) - before lunch

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	23
Mean (SD)	185.42 (58.571)	174.07 (39.699)
95% CL	[140.40; 230.44]	[156.91; 191.24]
Min-Max	129 - 324	124 - 260
Median	174.78	162.00
Q1-Q3	150.00 -186.00	141.00 -202.00
After 12 weeks		
n	9	22
Mean (SD)	144.11 (41.467)	148.81 (32.452)
95% CL	[112.24; 175.99]	[134.42; 163.20]
Min-Max	95 - 218.02	89 - 214
Median	133.00	149.00
Q1-Q3	125.00 -178.00	126.00 -171.17
Change from baseline		
n	7	17
Mean (SD)	-40.54 (65.968)	-23.33 (39.990)
95% CL	[-101.55; 20.47]	[-43.89; -2.77]
Min-Max	-138 - 43.244	-124.3 - 27.027
Median	-49.00	-18.00
Q1-Q3	-91.00 - 42.00	-35.00 - -3.00
T-Test	t= -1.63 P= 0.155	t= -2.41 P= 0.029
Change from baseline [%]		
n	7	17
Mean (SD)	-17.21 (32.073)	-11.35 (20.595)
95% CL	[-46.88; 12.45]	[-21.94; -0.76]
Min-Max	-48.92 - 30.882	-51.11 - 20.161
Median	-26.92	-10.05
Q1-Q3	-42.59 - 24.74	-23.81 - -1.97
T-Test	t= -1.42 P= 0.205	t= -2.27 P= 0.037

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.4 7-point glucose daily profile (mg/dl) - after lunch

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	8	21
Mean (SD)	216.83 (52.755)	210.48 (57.058)
95% CL	[172.72; 260.93]	[184.51; 236.45]
Min-Max	143 - 299	120.72 - 342
Median	219.81	205.00
Q1-Q3	175.50 -251.00	164.00 -253.00
After 12 weeks		
n	8	19
Mean (SD)	197.46 (49.715)	180.97 (40.809)
95% CL	[155.89; 239.02]	[161.30; 200.64]
Min-Max	103 - 257.66	131.53 - 293.7
Median	214.00	173.00
Q1-Q3	166.50 -229.00	151.00 -201.00
Change from baseline		
n	5	15
Mean (SD)	5.81 (48.653)	-11.90 (47.868)
95% CL	[-54.60; 66.22]	[-38.41; 14.61]
Min-Max	-76 - 45.045	-71 - 97.298
Median	26.00	-13.00
Q1-Q3	0.00 - 34.00	-57.00 - 19.00
T-Test	t= 0.27 P= 0.803	t= -0.96 P= 0.352
Change from baseline [%]		
n	5	15
Mean (SD)	5.12 (23.107)	-3.62 (24.335)
95% CL	[-23.57; 33.81]	[-17.10; 9.85]
Min-Max	-32.76 - 23.776	-30.16 - 49.541
Median	13.40	-5.04
Q1-Q3	0.00 - 21.19	-26.47 - 14.39
T-Test	t= 0.50 P= 0.646	t= -0.58 P= 0.573

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.5 7-point glucose daily profile (mg/dl) - before dinner

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	23
Mean (SD)	222.42 (75.743)	183.65 (63.509)
95% CL	[168.23; 276.60]	[156.19; 211.12]
Min-Max	149.55 - 396	97.298 - 365.77
Median	204.32	176.00
Q1-Q3	165.00 -253.00	137.00 -223.43
After 12 weeks		
n	10	22
Mean (SD)	169.78 (52.419)	158.91 (39.705)
95% CL	[132.28; 207.28]	[141.31; 176.52]
Min-Max	109 - 261	79 - 250
Median	155.50	161.00
Q1-Q3	127.00 -206.00	131.00 -187.39
Change from baseline		
n	7	17
Mean (SD)	-50.54 (78.229)	-27.01 (52.999)
95% CL	[-122.89; 21.81]	[-54.26; 0.24]
Min-Max	-190 - 40	-171.2 - 86.487
Median	-33.00	-25.00
Q1-Q3	-114.0 - -1.80	-36.04 - -5.00
T-Test	t= -1.71 P= 0.138	t= -2.10 P= 0.052
Change from baseline [%]		
n	7	17
Mean (SD)	-17.33 (26.469)	-8.77 (29.027)
95% CL	[-41.81; 7.15]	[-23.69; 6.16]
Min-Max	-47.98 - 24.39	-46.8 - 88.889
Median	-18.54	-13.66
Q1-Q3	-45.06 - -0.78	-19.71 - -2.73
T-Test	t= -1.73 P= 0.134	t= -1.25 P= 0.231

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.6 7-point glucose daily profile (mg/dl) - after dinner

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	20
Mean (SD)	245.21 (54.005)	216.37 (60.549)
95% CL	[203.69; 286.72]	[188.03; 244.70]
Min-Max	190 - 370	135.14 - 403
Median	240.00	196.80
Q1-Q3	217.00 -250.45	178.00 -244.50
After 12 weeks		
n	9	20
Mean (SD)	215.09 (73.487)	204.84 (56.722)
95% CL	[158.61; 271.58]	[178.29; 231.38]
Min-Max	160 - 390	142 - 387.39
Median	185.00	196.50
Q1-Q3	168.00 -246.85	163.00 -233.50
Change from baseline		
n	5	15
Mean (SD)	-41.52 (29.202)	-5.72 (38.674)
95% CL	[-77.78; -5.26]	[-27.14; 15.69]
Min-Max	-82 - -3.604	-63.06 - 81
Median	-37.00	-11.00
Q1-Q3	-55.00 --30.00	-33.00 - 18.02
T-Test	t= -3.18 P= 0.034	t= -0.57 P= 0.576
Change from baseline [%]		
n	5	15
Mean (SD)	-18.03 (11.480)	-1.98 (20.177)
95% CL	[-32.28; -3.77]	[-13.15; 9.20]
Min-Max	-32.93 - -1.439	-29.66 - 44.505
Median	-17.05	-4.47
Q1-Q3	-22.92 --15.79	-18.54 - 9.26
T-Test	t= -3.51 P= 0.025	t= -0.38 P= 0.710

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.7 7-point glucose daily profile (mg/dl) - bedtime

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	7	19
Mean (SD)	238.14 (44.764)	190.74 (42.445)
95% CL	[196.74; 279.54]	[170.29; 211.20]
Min-Max	162 - 274	104 - 260
Median	263.00	178.00
Q1-Q3	187.00 -267.00	167.00 -229.00
After 12 weeks		
n	8	19
Mean (SD)	193.26 (59.527)	163.24 (32.642)
95% CL	[143.49; 243.02]	[147.51; 178.97]
Min-Max	123 - 310	97 - 214
Median	175.00	167.00
Q1-Q3	157.00 -224.52	139.00 -185.00
Change from baseline		
n	3	14
Mean (SD)	-44.67 (77.022)	-11.73 (45.894)
95% CL	[-236.00; 146.67]	[-38.23; 14.77]
Min-Max	-95 - 44	-84 - 110
Median	-83.00	-11.50
Q1-Q3	-95.00 - 44.00	-40.00 - 7.00
T-Test	t= -1.00 P= 0.421	t= -0.96 P= 0.356
Change from baseline [%]		
n	3	14
Mean (SD)	-17.50 (29.502)	-1.83 (34.022)
95% CL	[-90.79; 55.78]	[-21.48; 17.81]
Min-Max	-35.58 - 16.541	-38.71 - 105.77
Median	-33.47	-6.84
Q1-Q3	-35.58 - 16.54	-23.26 - 3.93
T-Test	t= -1.03 P= 0.412	t= -0.20 P= 0.843

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.1 Change up to approx. 12 weeks after the start of treatment
4.5.5.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	23
Mean (SD)	211.87 (44.929)	187.22 (40.299)
95% CL	[179.73; 244.01]	[169.79; 204.64]
Min-Max	168 - 311	133.33 - 260
Median	198.50	183.00
Q1-Q3	179.00 -221.62	154.00 -212.61
After 12 weeks		
n	10	23
Mean (SD)	165.39 (43.877)	163.42 (25.845)
95% CL	[134.01; 196.78]	[152.24; 174.59]
Min-Max	121 - 242	106.5 - 205.41
Median	151.75	164.00
Q1-Q3	133.00 -180.00	146.00 -181.98
Change from baseline		
n	7	18
Mean (SD)	-36.81 (38.259)	-14.72 (24.595)
95% CL	[-72.20; -1.43]	[-26.95; -2.49]
Min-Max	-78 - 19.82	-68.47 - 25.225
Median	-32.50	-8.00
Q1-Q3	-75.00 - -5.00	-27.00 - -1.00
T-Test	t= -2.55 P= 0.044	t= -2.54 P= 0.021
Change from baseline [%]		
n	7	18
Mean (SD)	-16.57 (17.043)	-7.03 (13.387)
95% CL	[-32.33; -0.81]	[-13.68; -0.37]
Min-Max	-39.2 - 8.9431	-28.57 - 18.421
Median	-17.38	-4.59
Q1-Q3	-34.09 - -2.98	-13.69 - -0.60
T-Test	t= -2.57 P= 0.042	t= -2.23 P= 0.040

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	22
Mean (SD)	181.24 (70.679)	166.16 (34.611)
95% CL	[130.68; 231.80]	[150.81; 181.50]
Min-Max	84 - 298	97 - 236
Median	174.30	163.00
Q1-Q3	122.00 -237.84	144.00 -178.00
After 24 weeks		
n	5	22
Mean (SD)	123.60 (15.518)	145.89 (25.373)
95% CL	[104.33; 142.87]	[134.64; 157.14]
Min-Max	98 - 136	107 - 191
Median	132.00	141.50
Q1-Q3	120.00 -132.00	121.00 -159.00
Change from baseline		
n	3	18
Mean (SD)	-46.67 (51.859)	-17.65 (43.771)
95% CL	[-175.49; 82.16]	[-39.42; 4.12]
Min-Max	-106 - -10	-100 - 94
Median	-24.00	-21.00
Q1-Q3	-106.0 --10.00	-35.00 - -9.00
T-Test	t= -1.56 P= 0.259	t= -1.71 P= 0.105
Change from baseline [%]		
n	3	18
Mean (SD)	-24.54 (20.371)	-6.38 (31.368)
95% CL	[-75.14; 26.07]	[-21.98; 9.21]
Min-Max	-46.9 - -7.042	-42.37 - 96.907
Median	-19.67	-13.11
Q1-Q3	-46.90 - -7.04	-24.31 - -5.45
T-Test	t= -2.09 P= 0.172	t= -0.86 P= 0.400

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	22
Mean (SD)	201.45 (62.823)	205.49 (40.681)
95% CL	[153.16; 249.74]	[187.45; 223.53]
Min-Max	90.091 - 320	120 - 279
Median	198.00	208.00
Q1-Q3	179.00 -220.00	188.00 -228.00
After 24 weeks		
n	4	17
Mean (SD)	172.25 (38.161)	181.41 (57.733)
95% CL	[111.53; 232.97]	[151.72; 211.09]
Min-Max	142 - 224	97 - 368
Median	161.50	174.78
Q1-Q3	143.50 -201.00	153.00 -195.00
Change from baseline		
n	2	16
Mean (SD)	-13.50 (55.861)	-29.97 (61.575)
95% CL	[-515.40; 488.40]	[-62.78; 2.84]
Min-Max	-53 - 26	-95 - 152
Median	-13.50	-43.52
Q1-Q3	-53.00 - 26.00	-58.13 --29.50
T-Test	t= -0.34 P= 0.790	t= -1.95 P= 0.070
Change from baseline [%]		
n	2	16
Mean (SD)	-6.82 (28.213)	-13.54 (29.787)
95% CL	[-260.30; 246.66]	[-29.41; 2.34]
Min-Max	-26.77 - 13.131	-48.4 - 70.37
Median	-6.82	-21.81
Q1-Q3	-26.77 - 13.13	-26.91 --13.50
T-Test	t= -0.34 P= 0.790	t= -1.82 P= 0.089

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.3 7-point glucose daily profile (mg/dl) - before lunch

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	23
Mean (SD)	185.42 (58.571)	174.07 (39.699)
95% CL	[140.40; 230.44]	[156.91; 191.24]
Min-Max	129 - 324	124 - 260
Median	174.78	162.00
Q1-Q3	150.00 -186.00	141.00 -202.00
After 24 weeks		
n	5	21
Mean (SD)	161.00 (69.742)	145.87 (24.298)
95% CL	[74.40; 247.60]	[134.81; 156.93]
Min-Max	96 - 274	110 - 189
Median	156.00	153.00
Q1-Q3	112.00 -167.00	128.00 -164.00
Change from baseline		
n	3	18
Mean (SD)	32.33 (80.077)	-29.06 (39.690)
95% CL	[-166.59; 231.26]	[-48.79; -9.32]
Min-Max	-24 - 124	-118.9 - 48
Median	-3.00	-37.32
Q1-Q3	-24.00 -124.00	-52.00 - -2.00
T-Test	t= 0.70 P= 0.557	t= -3.11 P= 0.006
Change from baseline [%]		
n	3	18
Mean (SD)	21.08 (53.919)	-13.90 (21.289)
95% CL	[-112.86; 155.03]	[-24.49; -3.32]
Min-Max	-17.65 - 82.667	-48.89 - 34.043
Median	-1.76	-21.27
Q1-Q3	-17.65 - 82.67	-28.36 - -1.10
T-Test	t= 0.68 P= 0.568	t= -2.77 P= 0.013

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.4 7-point glucose daily profile (mg/dl) - after lunch

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	8	21
Mean (SD)	216.83 (52.755)	210.48 (57.058)
95% CL	[172.72; 260.93]	[184.51; 236.45]
Min-Max	143 - 299	120.72 - 342
Median	219.81	205.00
Q1-Q3	175.50 -251.00	164.00 -253.00
After 24 weeks		
n	5	19
Mean (SD)	174.40 (44.072)	168.02 (48.945)
95% CL	[119.68; 229.12]	[144.43; 191.61]
Min-Max	123 - 224	50.451 - 275
Median	187.00	168.00
Q1-Q3	134.00 -204.00	140.00 -206.00
Change from baseline		
n	3	17
Mean (SD)	-20.67 (21.962)	-40.09 (65.421)
95% CL	[-75.22; 33.89]	[-73.72; -6.45]
Min-Max	-46 - -7	-198.2 - 121
Median	-9.00	-45.00
Q1-Q3	-46.00 - -7.00	-51.00 --14.00
T-Test	t= -1.63 P= 0.245	t= -2.53 P= 0.022
Change from baseline [%]		
n	3	17
Mean (SD)	-8.98 (7.106)	-15.90 (31.959)
95% CL	[-26.63; 8.67]	[-32.33; 0.53]
Min-Max	-17.04 - -3.608	-79.71 - 78.571
Median	-6.29	-22.55
Q1-Q3	-17.04 - -3.61	-24.73 --10.61
T-Test	t= -2.19 P= 0.160	t= -2.05 P= 0.057

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.5 7-point glucose daily profile (mg/dl) - before dinner

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	23
Mean (SD)	222.42 (75.743)	183.65 (63.509)
95% CL	[168.23; 276.60]	[156.19; 211.12]
Min-Max	149.55 - 396	97.298 - 365.77
Median	204.32	176.00
Q1-Q3	165.00 -253.00	137.00 -223.43
After 24 weeks		
n	5	19
Mean (SD)	169.00 (38.762)	169.89 (43.545)
95% CL	[120.87; 217.13]	[148.90; 190.87]
Min-Max	111 - 214	98 - 272.07
Median	177.00	178.00
Q1-Q3	155.00 -188.00	132.00 -187.39
Change from baseline		
n	3	17
Mean (SD)	-25.00 (64.444)	-25.25 (56.511)
95% CL	[-185.09; 135.09]	[-54.30; 3.81]
Min-Max	-98 - 24	-164 - 78
Median	-1.00	-30.00
Q1-Q3	-98.00 - 24.00	-36.04 - -5.00
T-Test	t= -0.67 P= 0.571	t= -1.84 P= 0.084
Change from baseline [%]		
n	3	17
Mean (SD)	-8.22 (27.497)	-8.42 (27.496)
95% CL	[-76.53; 60.08]	[-22.55; 5.72]
Min-Max	-38.74 - 14.634	-55.41 - 55.319
Median	-0.56	-16.13
Q1-Q3	-38.74 - 14.63	-24.32 - -2.73
T-Test	t= -0.52 P= 0.656	t= -1.26 P= 0.225

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.6 7-point glucose daily profile (mg/dl) - after dinner

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	9	20
Mean (SD)	245.21 (54.005)	216.37 (60.549)
95% CL	[203.69; 286.72]	[188.03; 244.70]
Min-Max	190 - 370	135.14 - 403
Median	240.00	196.80
Q1-Q3	217.00 -250.45	178.00 -244.50
After 24 weeks		
n	4	17
Mean (SD)	161.25 (63.882)	200.39 (46.422)
95% CL	[59.60; 262.90]	[176.52; 224.26]
Min-Max	102 - 252	151 - 318
Median	145.50	191.00
Q1-Q3	123.50 -199.00	168.00 -218.00
Change from baseline		
n	2	15
Mean (SD)	-30.00 (91.924)	-13.35 (58.253)
95% CL	[-855.90; 795.90]	[-45.61; 18.91]
Min-Max	-95 - 35	-103 - 140
Median	-30.00	-11.00
Q1-Q3	-95.00 - 35.00	-50.45 - 7.21
T-Test	t= -0.46 P= 0.725	t= -0.89 P= 0.390
Change from baseline [%]		
n	2	15
Mean (SD)	-11.73 (39.395)	-3.50 (28.477)
95% CL	[-365.67; 342.22]	[-19.27; 12.27]
Min-Max	-39.58 - 16.129	-37.86 - 78.652
Median	-11.73	-6.08
Q1-Q3	-39.58 - 16.13	-23.73 - 4.58
T-Test	t= -0.42 P= 0.746	t= -0.48 P= 0.642

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.7 7-point glucose daily profile (mg/dl) - bedtime

	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	7	19
Mean (SD)	238.14 (44.764)	190.74 (42.445)
95% CL	[196.74; 279.54]	[170.29; 211.20]
Min-Max	162 - 274	104 - 260
Median	263.00	178.00
Q1-Q3	187.00 -267.00	167.00 -229.00
After 24 weeks		
n	5	19
Mean (SD)	155.00 (48.903)	155.51 (29.426)
95% CL	[94.28; 215.72]	[141.33; 169.69]
Min-Max	108 - 215	90.091 - 210.81
Median	143.00	158.00
Q1-Q3	112.00 -197.00	137.00 -174.00
Change from baseline		
n	2	15
Mean (SD)	-47.50 (4.950)	-30.95 (53.618)
95% CL	[-91.97; -3.03]	[-60.64; -1.25]
Min-Max	-51 - -44	-112 - 93
Median	-47.50	-25.00
Q1-Q3	-51.00 --44.00	-79.00 - -5.00
T-Test	t=-13.57 P= 0.047	t= -2.24 P= 0.042
Change from baseline [%]		
n	2	15
Mean (SD)	-22.05 (2.096)	-10.90 (33.228)
95% CL	[-40.88; -3.21]	[-29.31; 7.50]
Min-Max	-23.53 - -20.56	-43.08 - 89.423
Median	-22.05	-14.53
Q1-Q3	-23.53 --20.56	-36.05 - -2.96
T-Test	t=-14.87 P= 0.043	t= -1.27 P= 0.224

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.2 Change up to approx. 24 weeks after the start of treatment
4.5.5.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	10	23
Mean (SD)	211.87 (44.929)	187.22 (40.299)
95% CL	[179.73; 244.01]	[169.79; 204.64]
Min-Max	168 - 311	133.33 - 260
Median	198.50	183.00
Q1-Q3	179.00 -221.62	154.00 -212.61
After 24 weeks		
n	5	22
Mean (SD)	156.80 (24.263)	160.87 (29.578)
95% CL	[126.67; 186.93]	[147.75; 173.98]
Min-Max	132 - 188	118 - 250.5
Median	145.00	154.50
Q1-Q3	142.00 -177.00	144.15 -179.00
Change from baseline		
n	3	19
Mean (SD)	-24.67 (16.166)	-22.95 (45.424)
95% CL	[-64.82; 15.49]	[-44.84; -1.06]
Min-Max	-42 - -10	-112 - 96.5
Median	-22.00	-33.00
Q1-Q3	-42.00 --10.00	-46.00 - -6.50
T-Test	t= -2.64 P= 0.118	t= -2.20 P= 0.041
Change from baseline [%]		
n	3	19
Mean (SD)	-12.86 (8.843)	-9.60 (25.330)
95% CL	[-34.82; 9.11]	[-21.81; 2.61]
Min-Max	-22.46 - -5.051	-43.08 - 62.662
Median	-11.06	-17.80
Q1-Q3	-22.46 - -5.05	-24.12 - -4.14
T-Test	t= -2.52 P= 0.128	t= -1.65 P= 0.116

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.5.3.1 Derived Time in Range - dTIR

Percentage within range	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	6	18
Mean (SD)	35.7 (21.67)	45.2 (33.32)
Min-Max	0 - 57.143	0 - 100
Median	35.7	42.9
Q1-Q3	28.6 - 57.1	14.3 - 71.4
After 12 weeks		
n	6	17
Mean (SD)	52.4 (42.06)	63.9 (28.62)
Min-Max	0 - 100	14.286 - 100
Median	71.4	71.4
Q1-Q3	0.0 - 71.4	57.1 - 85.7
After 24 weeks		
n	4	15
Mean (SD)	71.4 (30.86)	74.3 (24.27)
Min-Max	28.571 - 100	28.571 - 100
Median	78.6	85.7
Q1-Q3	50.0 - 92.9	57.1 - 100.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.5.3.2 Derived Time below Range - dTBR

Percentage below range	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	6	18
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 12 weeks		
n	6	17
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 24 weeks		
n	4	15
Mean (SD)	0.0 (0.00)	1.0 (3.69)
Min-Max	0 - 0	0 - 14.286
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.5 Full Analysis Set - Subgroups - Renal function
4.5.5.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.5.3.3 Derived Time above Range - dTAR

Percentage above range	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	6	18
Mean (SD)	64.3 (21.67)	54.8 (33.32)
Min-Max	42.857 - 100	0 - 100
Median	64.3	57.1
Q1-Q3	42.9 - 71.4	28.6 - 85.7
After 12 weeks		
n	6	17
Mean (SD)	47.6 (42.06)	36.1 (28.62)
Min-Max	0 - 100	0 - 85.714
Median	28.6	28.6
Q1-Q3	28.6 - 100.0	14.3 - 42.9
After 24 weeks		
n	4	15
Mean (SD)	28.6 (30.86)	24.8 (23.20)
Min-Max	0 - 71.429	0 - 71.429
Median	21.4	14.3
Q1-Q3	7.1 - 50.0	0.0 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	27
Mean (SD)	190.32 (32.303)	193.61 (58.453)	160.43 (42.102)
95% CL	[150.21; 230.43]	[154.34; 232.88]	[143.77; 177.08]
Min-Max	163 - 236	129.73 - 298	84 - 250
Median	173.00	194.00	152.00
Q1-Q3	167.00 -212.61	140.00 -232.00	135.00 -193.00
After 12 weeks			
n	5	7	27
Mean (SD)	154.08 (30.552)	153.73 (54.508)	134.52 (34.402)
95% CL	[116.15; 192.02]	[103.32; 204.14]	[120.91; 148.13]
Min-Max	126 - 205.41	98 - 242	81.082 - 241.44
Median	151.00	138.74	121.00
Q1-Q3	137.00 -151.00	100.00 -205.00	111.00 -154.96
Change from baseline			
n	4	5	21
Mean (SD)	-33.55 (35.148)	-35.00 (84.934)	-19.39 (40.641)
95% CL	[-89.48; 22.38]	[-140.46; 70.46]	[-37.89; -0.89]
Min-Max	-85 - -7.207	-168 - 57	-105 - 57
Median	-21.00	-17.00	-18.00
Q1-Q3	-55.50 --11.60	-56.00 - 9.01	-41.00 - 7.00
T-Test	t= -1.91 P= 0.152	t= -0.92 P= 0.409	t= -2.19 P= 0.041
Change from baseline [%]			
n	4	5	21
Mean (SD)	-16.23 (14.150)	-9.63 (37.073)	-8.77 (27.197)
95% CL	[-38.75; 6.28]	[-55.67; 36.40]	[-21.15; 3.61]
Min-Max	-36.02 - -3.39	-62.69 - 38.514	-46.46 - 58.763
Median	-12.77	-12.14	-11.24
Q1-Q3	-25.98 - -6.49	-18.79 - 6.94	-25.15 - 4.00
T-Test	t= -2.29 P= 0.106	t= -0.58 P= 0.592	t= -1.48 P= 0.155

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	26
Mean (SD)	212.81 (44.689)	243.42 (66.293)	195.38 (42.239)
95% CL	[157.32; 268.30]	[198.88; 287.95]	[178.32; 212.44]
Min-Max	166 - 277	131.53 - 346	90.091 - 320
Median	205.00	240.00	199.50
Q1-Q3	180.00 -236.04	192.79 -310.00	172.00 -219.82
After 12 weeks			
n	5	6	23
Mean (SD)	191.47 (42.115)	207.87 (122.91)	178.99 (30.031)
95% CL	[139.18; 243.77]	[78.88; 336.87]	[166.00; 191.98]
Min-Max	144 - 252	109 - 440	107 - 236.04
Median	178.00	162.00	180.00
Q1-Q3	169.37 -214.00	131.00 -243.25	170.00 -199.00
Change from baseline			
n	4	4	19
Mean (SD)	-1.92 (74.616)	-60.14 (94.489)	-17.49 (31.947)
95% CL	[-120.65; 116.81]	[-210.49; 90.22]	[-32.89; -2.09]
Min-Max	-66.67 - 86	-179 - 50.451	-81 - 36.036
Median	-13.50	-56.00	-16.00
Q1-Q3	-63.83 - 60.00	-124.5 - 4.23	-28.00 - 2.00
T-Test	t= -0.05 P= 0.962	t= -1.27 P= 0.293	t= -2.39 P= 0.028
Change from baseline [%]			
n	4	4	19
Mean (SD)	3.17 (39.512)	-20.77 (35.159)	-8.06 (16.469)
95% CL	[-59.70; 66.05]	[-76.71; 35.18]	[-16.00; -0.12]
Min-Max	-29.76 - 51.807	-57.74 - 26.168	-43.09 - 18.987
Median	-4.68	-25.75	-7.89
Q1-Q3	-29.00 - 35.35	-45.07 - 3.54	-14.14 - 1.19
T-Test	t= 0.16 P= 0.883	t= -1.18 P= 0.323	t= -2.13 P= 0.047

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.3 7-point glucose daily profile (mg/dl) - before lunch

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	26
Mean (SD)	185.69 (40.775)	202.36 (66.290)	162.02 (27.514)
95% CL	[135.06; 236.32]	[160.24; 244.48]	[150.91; 173.13]
Min-Max	140 - 241.44	124 - 324	119 - 217
Median	193.00	199.50	164.50
Q1-Q3	152.00 -202.00	140.54 -251.62	136.00 -181.00
After 12 weeks			
n	4	7	26
Mean (SD)	153.75 (23.150)	142.16 (27.479)	147.04 (37.255)
95% CL	[116.91; 190.58]	[116.74; 167.57]	[131.99; 162.09]
Min-Max	126 - 181.98	115 - 186	89 - 218.02
Median	153.50	130.00	142.87
Q1-Q3	137.50 -169.99	118.92 -171.17	112.00 -178.00
Change from baseline			
n	4	6	20
Mean (SD)	-30.12 (44.784)	-56.22 (73.408)	-19.30 (32.809)
95% CL	[-101.38; 41.15]	[-133.25; 20.82]	[-34.66; -3.95]
Min-Max	-76 - 18	-138 - 27.027	-91 - 43.244
Median	-31.23	-63.50	-19.00
Q1-Q3	-67.73 - 7.50	-124.3 - 25.00	-36.50 - -7.50
T-Test	t= -1.34 P= 0.271	t= -1.88 P= 0.120	t= -2.63 P= 0.016
Change from baseline [%]			
n	4	6	20
Mean (SD)	-12.84 (22.595)	-19.96 (32.341)	-11.55 (19.730)
95% CL	[-48.80; 23.11]	[-53.90; 13.98]	[-20.78; -2.31]
Min-Max	-37.62 - 12.857	-51.11 - 20.161	-48.92 - 30.882
Median	-13.30	-31.17	-11.63
Q1-Q3	-31.13 - 5.44	-45.24 - 18.75	-23.08 - -5.08
T-Test	t= -1.14 P= 0.338	t= -1.51 P= 0.191	t= -2.62 P= 0.017

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.4 7-point glucose daily profile (mg/dl) - after lunch

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	24
Mean (SD)	204.28 (49.377)	241.81 (83.032)	216.76 (43.227)
95% CL	[142.97; 265.59]	[186.03; 297.59]	[198.51; 235.01]
Min-Max	154 - 287	120.72 - 361	132 - 299
Median	195.00	248.65	222.21
Q1-Q3	189.00 -196.40	154.00 -332.00	185.50 -246.50
After 12 weeks			
n	4	6	23
Mean (SD)	187.92 (75.077)	200.92 (52.575)	188.59 (36.966)
95% CL	[68.46; 307.39]	[145.75; 256.10]	[172.60; 204.57]
Min-Max	132 - 293.7	131.53 - 283	103 - 257.66
Median	163.00	195.00	190.00
Q1-Q3	134.50 -241.35	170.00 -231.00	165.77 -205.00
Change from baseline			
n	4	4	19
Mean (SD)	4.32 (75.785)	-19.80 (43.486)	-18.07 (40.718)
95% CL	[-116.27; 124.92]	[-88.99; 49.40]	[-37.69; 1.56]
Min-Max	-58 - 97.298	-78 - 16	-79 - 45.045
Median	-11.00	-8.59	-8.00
Q1-Q3	-57.50 - 66.15	-53.00 - 13.41	-57.66 - 19.00
T-Test	t= 0.11 P= 0.916	t= -0.91 P= 0.430	t= -1.93 P= 0.069
Change from baseline [%]			
n	4	4	19
Mean (SD)	3.09 (39.694)	-3.90 (16.041)	-6.30 (19.091)
95% CL	[-60.07; 66.25]	[-29.42; 21.63]	[-15.50; 2.90]
Min-Max	-30.16 - 49.541	-21.61 - 10.39	-32.76 - 23.776
Median	-3.51	-2.19	-3.76
Q1-Q3	-29.95 - 36.13	-17.47 - 9.67	-25.82 - 13.40
T-Test	t= 0.16 P= 0.886	t= -0.49 P= 0.660	t= -1.44 P= 0.168

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.5 7-point glucose daily profile (mg/dl) - before dinner

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	27
Mean (SD)	182.69 (26.962)	214.87 (102.36)	182.77 (49.970)
95% CL	[149.21; 216.16]	[149.83; 279.90]	[163.01; 202.54]
Min-Max	148 - 223.43	97.298 - 396	93 - 279
Median	183.00	196.00	172.00
Q1-Q3	176.00 -183.00	122.16 -285.50	141.00 -230.63
After 12 weeks			
n	5	7	25
Mean (SD)	144.08 (29.806)	174.20 (52.976)	149.50 (40.984)
95% CL	[107.07; 181.09]	[125.20; 223.19]	[132.58; 166.42]
Min-Max	109 - 187.39	108 - 261	79 - 228.83
Median	135.00	183.79	142.34
Q1-Q3	131.00 -158.00	131.00 -206.00	117.00 -178.00
Change from baseline			
n	4	6	20
Mean (SD)	-29.76 (10.820)	-76.11 (115.59)	-28.61 (42.764)
95% CL	[-46.98; -12.54]	[-197.42; 45.19]	[-48.62; -8.59]
Min-Max	-41 - -17	-190 - 86.487	-114 - 40
Median	-30.52	-96.50	-17.50
Q1-Q3	-38.52 --21.00	-171.2 - 11.00	-59.00 - -2.00
T-Test	t= -5.50 P= 0.012	t= -1.61 P= 0.168	t= -2.99 P= 0.008
Change from baseline [%]			
n	4	6	20
Mean (SD)	-16.14 (5.132)	-12.27 (55.719)	-13.00 (22.585)
95% CL	[-24.31; -7.98]	[-70.74; 46.21]	[-23.57; -2.43]
Min-Max	-23.3 - -11.49	-60.73 - 88.889	-48.84 - 40.86
Median	-14.90	-31.47	-10.66
Q1-Q3	-19.71 --12.57	-47.98 - 9.17	-28.47 - -1.49
T-Test	t= -6.29 P= 0.008	t= -0.54 P= 0.613	t= -2.58 P= 0.019

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.6 7-point glucose daily profile (mg/dl) - after dinner

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	10	24
Mean (SD)	205.52 (47.922)	237.61 (88.575)	236.98 (55.605)
95% CL	[146.02; 265.02]	[174.25; 300.97]	[213.50; 260.46]
Min-Max	175 - 290	135.14 - 403	144.15 - 370
Median	190.00	219.00	232.50
Q1-Q3	178.00 -194.60	172.97 -295.00	197.70 -261.23
After 12 weeks			
n	5	7	23
Mean (SD)	194.12 (33.617)	220.94 (115.83)	194.07 (39.595)
95% CL	[152.38; 235.86]	[113.81; 328.06]	[176.95; 211.20]
Min-Max	142 - 232	125 - 390	106.31 - 263
Median	195.00	168.00	185.00
Q1-Q3	189.00 -212.61	145.00 -387.39	167.00 -235.00
Change from baseline			
n	4	4	19
Mean (SD)	11.00 (42.662)	-65.46 (94.498)	-36.29 (46.939)
95% CL	[-56.88; 78.89]	[-215.82; 84.91]	[-58.91; -13.67]
Min-Max	-48 - 54	-206 - -3	-146 - 81
Median	19.01	-26.41	-31.00
Q1-Q3	-14.99 - 37.00	-119.5 --11.41	-62.00 --11.00
T-Test	t= 0.52 P= 0.642	t= -1.39 P= 0.260	t= -3.37 P= 0.003
Change from baseline [%]			
n	4	4	19
Mean (SD)	6.44 (23.159)	-23.47 (26.753)	-14.28 (18.921)
95% CL	[-30.41; 43.29]	[-66.04; 19.10]	[-23.40; -5.16]
Min-Max	-25.26 - 30.337	-62.24 - -1.657	-41.24 - 44.505
Median	10.34	-15.00	-15.79
Q1-Q3	-8.00 - 20.88	-40.39 - -6.56	-26.50 - -4.47
T-Test	t= 0.56 P= 0.617	t= -1.75 P= 0.178	t= -3.29 P= 0.004

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.7 7-point glucose daily profile (mg/dl) - bedtime

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	10	22
Mean (SD)	215.76 (31.250)	199.93 (53.665)	201.23 (46.386)
95% CL	[176.96; 254.56]	[161.54; 238.32]	[180.66; 221.80]
Min-Max	172 - 254	121 - 266	104 - 274
Median	217.00	202.50	198.00
Q1-Q3	201.80 -234.00	144.00 -260.00	167.00 -243.00
After 12 weeks			
n	5	5	21
Mean (SD)	164.76 (29.358)	171.80 (79.471)	164.80 (41.795)
95% CL	[128.31; 201.22]	[73.12; 270.48]	[145.78; 183.83]
Min-Max	132 - 210.81	120 - 310	79 - 245.05
Median	165.00	139.00	168.00
Q1-Q3	149.00 -167.00	123.00 -167.00	156.00 -190.00
Change from baseline			
n	4	4	15
Mean (SD)	-37.50 (32.913)	-26.50 (79.114)	-25.15 (58.192)
95% CL	[-89.87; 14.87]	[-152.39; 99.39]	[-57.37; 7.08]
Min-Max	-67 - 9.0091	-140 - 44	-128 - 110
Median	-46.00	-5.00	-12.00
Q1-Q3	-59.50 --15.50	-72.50 - 19.50	-83.00 - 7.00
T-Test	t= -2.28 P= 0.107	t= -0.67 P= 0.551	t= -1.67 P= 0.116
Change from baseline [%]			
n	4	4	15
Mean (SD)	-17.85 (15.064)	-10.92 (30.091)	-7.74 (37.357)
95% CL	[-41.82; 6.12]	[-58.80; 36.96]	[-28.43; 12.95]
Min-Max	-28.63 - 4.4643	-53.85 - 16.541	-53.78 - 105.77
Median	-23.61	-3.19	-7.10
Q1-Q3	-26.30 - -9.40	-28.66 - 6.82	-35.58 - 3.93
T-Test	t= -2.37 P= 0.099	t= -0.73 P= 0.520	t= -0.80 P= 0.436

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.1 Change up to approx. 12 weeks after the start of treatment
4.5.6.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	27
Mean (SD)	200.92 (34.047)	213.19 (63.267)	186.56 (31.738)
95% CL	[158.65; 243.20]	[173.00; 253.39]	[174.00; 199.11]
Min-Max	166 - 254	135 - 311	133.33 - 263
Median	189.00	230.23	187.00
Q1-Q3	183.00 -212.61	145.47 -260.00	167.00 -213.00
After 12 weeks			
n	5	7	27
Mean (SD)	162.48 (26.486)	163.45 (41.228)	162.03 (30.507)
95% CL	[129.59; 195.37]	[125.32; 201.58]	[149.96; 174.09]
Min-Max	135 - 205.41	120 - 242	106.5 - 241.44
Median	158.00	162.16	162.00
Q1-Q3	149.00 -165.00	125.00 -181.98	144.15 -180.00
Change from baseline			
n	4	6	21
Mean (SD)	-21.80 (23.753)	-46.71 (64.977)	-16.63 (23.450)
95% CL	[-59.60; 16.00]	[-114.90; 21.48]	[-27.30; -5.95]
Min-Max	-54 - -1	-155 - 25.225	-75 - 19.82
Median	-16.10	-38.23	-11.00
Q1-Q3	-39.50 - -4.10	-69.00 - -5.00	-32.50 - -5.00
T-Test	t= -1.84 P= 0.164	t= -1.76 P= 0.139	t= -3.25 P= 0.004
Change from baseline [%]			
n	4	6	21
Mean (SD)	-11.56 (12.657)	-15.93 (25.570)	-8.72 (12.545)
95% CL	[-31.70; 8.58]	[-42.76; 10.91]	[-14.43; -3.01]
Min-Max	-28.57 - -0.602	-56.36 - 18.421	-34.09 - 13.514
Median	-8.53	-13.69	-6.59
Q1-Q3	-21.12 - -2.00	-27.34 - -2.91	-17.38 - -2.73
T-Test	t= -1.83 P= 0.165	t= -1.53 P= 0.188	t= -3.19 P= 0.005

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	27
Mean (SD)	190.32 (32.303)	193.61 (58.453)	160.43 (42.102)
95% CL	[150.21; 230.43]	[154.34; 232.88]	[143.77; 177.08]
Min-Max	163 - 236	129.73 - 298	84 - 250
Median	173.00	194.00	152.00
Q1-Q3	167.00 -212.61	140.00 -232.00	135.00 -193.00
After 24 weeks			
n	5	5	22
Mean (SD)	139.39 (9.379)	155.52 (33.133)	138.50 (24.252)
95% CL	[127.75; 151.04]	[114.38; 196.66]	[127.75; 149.25]
Min-Max	132 - 154.96	118 - 186	104 - 191
Median	136.00	176.00	136.47
Q1-Q3	133.00 -141.00	121.00 -176.58	118.00 -157.00
Change from baseline			
n	4	3	19
Mean (SD)	-53.41 (34.409)	-0.67 (33.546)	-13.48 (40.456)
95% CL	[-108.17; 1.34]	[-84.00; 82.67]	[-32.98; 6.02]
Min-Max	-100 - -22	-22 - 38	-106 - 94
Median	-45.83	-18.00	-14.00
Q1-Q3	-78.83 --28.00	-22.00 - 38.00	-21.00 - -3.00
T-Test	t= -3.10 P= 0.053	t= -0.03 P= 0.976	t= -1.45 P= 0.164
Change from baseline [%]			
n	4	3	19
Mean (SD)	-25.84 (12.347)	0.23 (22.272)	-5.06 (29.340)
95% CL	[-45.48; -6.19]	[-55.10; 55.56]	[-19.20; 9.08]
Min-Max	-42.37 - -13.5	-15.71 - 25.676	-46.9 - 96.907
Median	-23.74	-9.28	-10.67
Q1-Q3	-34.75 --16.93	-15.71 - 25.68	-14.05 - -2.29
T-Test	t= -4.19 P= 0.025	t= 0.02 P= 0.987	t= -0.75 P= 0.462

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	26
Mean (SD)	212.81 (44.689)	243.42 (66.293)	195.38 (42.239)
95% CL	[157.32; 268.30]	[198.88; 287.95]	[178.32; 212.44]
Min-Max	166 - 277	131.53 - 346	90.091 - 320
Median	205.00	240.00	199.50
Q1-Q3	180.00 -236.04	192.79 -310.00	172.00 -219.82
After 24 weeks			
n	5	5	17
Mean (SD)	173.56 (39.958)	211.00 (89.748)	171.36 (34.194)
95% CL	[123.94; 223.17]	[99.56; 322.43]	[153.77; 188.94]
Min-Max	127 - 235	145 - 368	97 - 231
Median	174.78	181.98	172.97
Q1-Q3	153.00 -178.00	165.00 -195.00	145.00 -186.00
Change from baseline			
n	4	4	16
Mean (SD)	-24.32 (62.349)	-17.07 (113.91)	-27.92 (37.784)
95% CL	[-123.53; 74.90]	[-198.32; 164.19]	[-48.06; -7.79]
Min-Max	-61.26 - 69	-95 - 152	-100.9 - 27
Median	-52.50	-62.64	-35.50
Q1-Q3	-57.13 - 8.50	-82.64 - 48.50	-45.95 - 6.00
T-Test	t= -0.78 P= 0.492	t= -0.30 P= 0.784	t= -2.96 P= 0.010
Change from baseline [%]			
n	4	4	16
Mean (SD)	-9.80 (34.291)	-5.52 (50.984)	-13.12 (18.752)
95% CL	[-64.36; 44.77]	[-86.64; 75.61]	[-23.12; -3.13]
Min-Max	-29.44 - 41.566	-39.58 - 70.37	-48.4 - 16.981
Median	-25.66	-26.43	-16.92
Q1-Q3	-27.70 - 8.10	-33.72 - 22.69	-22.56 - 3.26
T-Test	t= -0.57 P= 0.608	t= -0.22 P= 0.843	t= -2.80 P= 0.013

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.3 7-point glucose daily profile (mg/dl) - before lunch

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	26
Mean (SD)	185.69 (40.775)	202.36 (66.290)	162.02 (27.514)
95% CL	[135.06; 236.32]	[160.24; 244.48]	[150.91; 173.13]
Min-Max	140 - 241.44	124 - 324	119 - 217
Median	193.00	199.50	164.50
Q1-Q3	152.00 -202.00	140.54 -251.62	136.00 -181.00
After 24 weeks			
n	5	5	21
Mean (SD)	142.99 (23.582)	141.27 (22.593)	140.57 (27.346)
95% CL	[113.71; 172.28]	[113.21; 169.32]	[128.12; 153.02]
Min-Max	110 - 172.97	110 - 158	96 - 189
Median	141.00	156.00	136.94
Q1-Q3	135.00 -156.00	124.33 -158.00	112.00 -165.00
Change from baseline			
n	4	4	18
Mean (SD)	-44.12 (28.359)	-50.48 (63.335)	-13.86 (23.561)
95% CL	[-89.24; 1.01]	[-151.26; 50.30]	[-25.57; -2.14]
Min-Max	-68.47 - -5	-118.9 - 34	-41 - 48
Median	-51.50	-58.50	-19.21
Q1-Q3	-64.73 --23.50	-91.96 - -9.00	-32.00 - -2.00
T-Test	t= -3.11 P= 0.053	t= -1.59 P= 0.209	t= -2.50 P= 0.023
Change from baseline [%]			
n	4	4	18
Mean (SD)	-22.44 (12.625)	-20.75 (33.246)	-8.18 (15.579)
95% CL	[-42.53; -2.35]	[-73.65; 32.16]	[-15.93; -0.44]
Min-Max	-30.2 - -3.571	-48.89 - 27.419	-27.15 - 34.043
Median	-27.99	-30.76	-12.21
Q1-Q3	-29.28 --15.60	-40.49 - -1.00	-18.24 - -1.10
T-Test	t= -3.55 P= 0.038	t= -1.25 P= 0.301	t= -2.23 P= 0.040

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.4 7-point glucose daily profile (mg/dl) - after lunch

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	11	24
Mean (SD)	204.28 (49.377)	241.81 (83.032)	216.76 (43.227)
95% CL	[142.97; 265.59]	[186.03; 297.59]	[198.51; 235.01]
Min-Max	154 - 287	120.72 - 361	132 - 299
Median	195.00	248.65	222.21
Q1-Q3	189.00 -196.40	154.00 -332.00	185.50 -246.50
After 24 weeks			
n	5	5	19
Mean (SD)	170.71 (24.133)	166.29 (82.982)	168.91 (35.484)
95% CL	[140.74; 200.68]	[63.25; 269.33]	[151.80; 186.01]
Min-Max	147 - 204	50.451 - 275	118 - 229
Median	168.00	160.00	171.00
Q1-Q3	149.55 -185.00	140.00 -206.00	134.00 -202.00
Change from baseline			
n	4	4	17
Mean (SD)	-21.21 (36.973)	-61.80 (136.07)	-37.26 (34.659)
95% CL	[-80.04; 37.62]	[-278.32; 154.72]	[-55.08; -19.44]
Min-Max	-48 - 31	-198.2 - 121	-90.09 - 17
Median	-33.92	-85.00	-41.00
Q1-Q3	-47.42 - 5.00	-159.1 - 35.50	-68.00 - -9.00
T-Test	t= -1.15 P= 0.334	t= -0.91 P= 0.431	t= -4.43 P= 0.000
Change from baseline [%]			
n	4	4	17
Mean (SD)	-9.86 (20.932)	-17.78 (68.216)	-16.42 (14.553)
95% CL	[-43.17; 23.45]	[-126.32; 90.77]	[-23.90; -8.93]
Min-Max	-24.62 - 20.13	-79.71 - 78.571	-40.32 - 9.1892
Median	-17.48	-34.98	-19.34
Q1-Q3	-24.23 - 4.51	-62.93 - 27.38	-27.44 - -5.43
T-Test	t= -0.94 P= 0.416	t= -0.52 P= 0.638	t= -4.65 P= 0.000

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.5 7-point glucose daily profile (mg/dl) - before dinner

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	27
Mean (SD)	182.69 (26.962)	214.87 (102.36)	182.77 (49.970)
95% CL	[149.21; 216.16]	[149.83; 279.90]	[163.01; 202.54]
Min-Max	148 - 223.43	97.298 - 396	93 - 279
Median	183.00	196.00	172.00
Q1-Q3	176.00 -183.00	122.16 -285.50	141.00 -230.63
After 24 weeks			
n	5	5	19
Mean (SD)	135.88 (32.244)	180.81 (70.061)	166.66 (31.807)
95% CL	[95.84; 175.91]	[93.82; 267.81]	[151.32; 181.99]
Min-Max	111 - 187.39	98 - 272.07	120 - 219
Median	122.00	176.00	178.00
Q1-Q3	112.00 -147.00	132.00 -226.00	136.94 -188.00
Change from baseline			
n	4	4	17
Mean (SD)	-40.51 (8.994)	-53.67 (98.082)	-16.94 (46.894)
95% CL	[-54.82; -26.20]	[-209.74; 102.40]	[-41.05; 7.17]
Min-Max	-54 - -36	-164 - 65	-98 - 78
Median	-36.02	-57.85	-12.00
Q1-Q3	-45.02 --36.00	-128.8 - 21.50	-36.00 - 15.00
T-Test	t= -9.01 P= 0.003	t= -1.09 P= 0.354	t= -1.49 P= 0.156
Change from baseline [%]			
n	4	4	17
Mean (SD)	-22.70 (6.290)	-14.75 (40.093)	-4.04 (25.643)
95% CL	[-32.71; -12.69]	[-78.54; 49.05]	[-17.23; 9.14]
Min-Max	-30.68 - -16.13	-55.41 - 40.373	-41.09 - 55.319
Median	-22.00	-21.97	-8.63
Q1-Q3	-27.50 --17.90	-40.51 - 11.02	-23.08 - 9.55
T-Test	t= -7.22 P= 0.005	t= -0.74 P= 0.515	t= -0.65 P= 0.525

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.6 7-point glucose daily profile (mg/dl) - after dinner

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	10	24
Mean (SD)	205.52 (47.922)	237.61 (88.575)	236.98 (55.605)
95% CL	[146.02; 265.02]	[174.25; 300.97]	[213.50; 260.46]
Min-Max	175 - 290	135.14 - 403	144.15 - 370
Median	190.00	219.00	232.50
Q1-Q3	178.00 -194.60	172.97 -295.00	197.70 -261.23
After 24 weeks			
n	5	5	17
Mean (SD)	180.96 (45.683)	231.34 (69.795)	172.51 (37.455)
95% CL	[124.24; 237.68]	[144.68; 318.00]	[153.25; 191.77]
Min-Max	102 - 218	170 - 318	111 - 252
Median	198.00	203.00	162.00
Q1-Q3	185.00 -201.80	172.00 -293.70	146.00 -191.00
Change from baseline			
n	4	3	15
Mean (SD)	16.30 (19.519)	8.67 (122.69)	-47.23 (60.493)
95% CL	[-14.76; 47.36]	[-296.11; 313.44]	[-80.73; -13.73]
Min-Max	-5 - 40	-103 - 140	-211 - 35
Median	15.10	-11.00	-37.00
Q1-Q3	1.10 - 31.50	-103.0 -140.00	-92.00 - -8.00
T-Test	t= 1.67 P= 0.193	t= 0.12 P= 0.914	t= -3.02 P= 0.009
Change from baseline [%]			
n	4	3	15
Mean (SD)	9.17 (10.983)	11.71 (60.061)	-18.40 (21.052)
95% CL	[-8.30; 26.65]	[-137.49; 160.91]	[-30.06; -6.74]
Min-Max	-2.632 - 22.472	-37.45 - 78.652	-59.6 - 16.129
Median	8.42	-6.08	-13.60
Q1-Q3	0.54 - 17.81	-37.45 - 78.65	-37.86 - -4.02
T-Test	t= 1.67 P= 0.193	t= 0.34 P= 0.768	t= -3.39 P= 0.004

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.7 7-point glucose daily profile (mg/dl) - bedtime

	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	10	22
Mean (SD)	215.76 (31.250)	199.93 (53.665)	201.23 (46.386)
95% CL	[176.96; 254.56]	[161.54; 238.32]	[180.66; 221.80]
Min-Max	172 - 254	121 - 266	104 - 274
Median	217.00	202.50	198.00
Q1-Q3	201.80 -234.00	144.00 -260.00	167.00 -243.00
After 24 weeks			
n	5	4	20
Mean (SD)	147.56 (38.195)	132.02 (40.002)	161.40 (24.901)
95% CL	[100.14; 194.99]	[68.37; 195.67]	[149.75; 173.05]
Min-Max	108 - 210.81	90.091 - 180	124 - 215
Median	137.00	129.00	162.50
Q1-Q3	135.00 -147.00	100.05 -164.00	145.37 -172.00
Change from baseline			
n	4	2	16
Mean (SD)	-48.75 (49.443)	-87.00 (35.355)	-25.01 (48.951)
95% CL	[-127.42; 29.93]	[-404.66; 230.66]	[-51.09; 1.07]
Min-Max	-97 - 9.0091	-112 - -62	-127.9 - 93
Median	-53.50	-87.00	-21.11
Q1-Q3	-89.50 - -8.00	-112.0 --62.00	-51.00 - -6.00
T-Test	t= -1.97 P= 0.143	t= -3.48 P= 0.178	t= -2.04 P= 0.059
Change from baseline [%]			
n	4	2	16
Mean (SD)	-22.33 (21.474)	-39.56 (4.971)	-8.16 (30.617)
95% CL	[-56.50; 11.84]	[-84.23; 5.10]	[-24.48; 8.15]
Min-Max	-41.45 - 4.4643	-43.08 - -36.05	-50.35 - 89.423
Median	-26.16	-39.56	-12.07
Q1-Q3	-39.62 - -5.04	-43.08 --36.05	-24.20 - -3.75
T-Test	t= -2.08 P= 0.129	t=-11.25 P= 0.056	t= -1.07 P= 0.303

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.2 Change up to approx. 24 weeks after the start of treatment
4.5.6.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	12	27
Mean (SD)	200.92 (34.047)	213.19 (63.267)	186.56 (31.738)
95% CL	[158.65; 243.20]	[173.00; 253.39]	[174.00; 199.11]
Min-Max	166 - 254	135 - 311	133.33 - 263
Median	189.00	230.23	187.00
Q1-Q3	183.00 -212.61	145.47 -260.00	167.00 -213.00
After 24 weeks			
n	5	5	22
Mean (SD)	145.16 (17.489)	174.62 (49.257)	156.28 (21.017)
95% CL	[123.44; 166.87]	[113.46; 235.78]	[146.96; 165.59]
Min-Max	132 - 174.78	118 - 250.5	119 - 189
Median	137.00	176.58	151.00
Q1-Q3	135.00 -147.00	148.00 -180.00	144.15 -178.00
Change from baseline			
n	4	4	19
Mean (SD)	-39.21 (6.408)	-35.84 (91.452)	-19.54 (29.093)
95% CL	[-49.41; -29.01]	[-181.36; 109.68]	[-33.56; -5.52]
Min-Max	-46 - -31	-112 - 96.5	-80.18 - 52
Median	-39.92	-63.94	-16.22
Q1-Q3	-44.00 --34.42	-92.94 - 21.25	-42.00 - -6.50
T-Test	t=-12.24 P= 0.001	t= -0.78 P= 0.490	t= -2.93 P= 0.009
Change from baseline [%]			
n	4	4	19
Mean (SD)	-20.96 (3.380)	-10.33 (49.028)	-9.29 (16.551)
95% CL	[-26.34; -15.58]	[-88.34; 67.69]	[-17.26; -1.31]
Min-Max	-25.14 - -17.8	-43.08 - 62.662	-35.46 - 37.956
Median	-20.45	-30.45	-10.05
Q1-Q3	-23.68 --18.24	-37.24 - 16.58	-22.46 - -4.14
T-Test	t=-12.40 P= 0.001	t= -0.42 P= 0.702	t= -2.45 P= 0.025

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.6.3.1 Derived Time in Range - dTIR

Percentage within range	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	9	20
Mean (SD)	37.1 (32.89)	38.1 (43.45)	42.1 (26.00)
Min-Max	0 - 85.714	0 - 100	0 - 100
Median	42.9	14.3	42.9
Q1-Q3	14.3 - 42.9	0.0 - 85.7	28.6 - 57.1
After 12 weeks			
n	4	5	19
Mean (SD)	60.7 (35.71)	65.7 (37.25)	60.9 (32.24)
Min-Max	14.286 - 100	0 - 85.714	0 - 100
Median	64.3	85.7	71.4
Q1-Q3	35.7 - 85.7	71.4 - 85.7	42.9 - 85.7
After 24 weeks			
n	5	4	16
Mean (SD)	74.3 (15.65)	75.0 (29.45)	75.9 (25.40)
Min-Max	57.143 - 85.714	42.857 - 100	28.571 - 100
Median	85.7	78.6	85.7
Q1-Q3	57.1 - 85.7	50.0 - 100.0	57.1 - 100.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.6.3.2 Derived Time below Range - dTBR

Percentage below range	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	9	20
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 12 weeks			
n	4	5	19
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 24 weeks			
n	5	4	16
Mean (SD)	0.0 (0.00)	3.6 (7.14)	0.0 (0.00)
Min-Max	0 - 0	0 - 14.286	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 7.1	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.6 Full Analysis Set - Subgroups - Duration of diabetes
4.5.6.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.6.3.3 Derived Time above Range - dTAR

Percentage above range	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	5	9	20
Mean (SD)	62.9 (32.89)	61.9 (43.45)	57.9 (26.00)
Min-Max	14.286 - 100	0 - 100	0 - 100
Median	57.1	85.7	57.1
Q1-Q3	57.1 - 85.7	14.3 - 100.0	42.9 - 71.4
After 12 weeks			
n	4	5	19
Mean (SD)	39.3 (35.71)	34.3 (37.25)	39.1 (32.24)
Min-Max	0 - 85.714	14.286 - 100	0 - 100
Median	35.7	14.3	28.6
Q1-Q3	14.3 - 64.3	14.3 - 28.6	14.3 - 57.1
After 24 weeks			
n	5	4	16
Mean (SD)	25.7 (15.65)	21.4 (24.74)	24.1 (25.40)
Min-Max	14.286 - 42.857	0 - 42.857	0 - 71.429
Median	14.3	21.4	14.3
Q1-Q3	14.3 - 42.9	0.0 - 42.9	0.0 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	21
Mean (SD)	157.17 (35.336)	186.66 (54.918)
95% CL	[141.89; 172.45]	[161.66; 211.66]
Min-Max	97 - 236	84 - 298
Median	145.95	178.00
Q1-Q3	135.14 -178.00	163.00 -226.00
After 12 weeks		
n	21	20
Mean (SD)	134.17 (35.538)	143.55 (41.832)
95% CL	[117.99; 150.35]	[123.97; 163.12]
Min-Max	77 - 205.41	99 - 242
Median	133.00	129.50
Q1-Q3	113.00 -154.00	113.00 -162.16
Change from baseline		
n	16	15
Mean (SD)	-12.57 (41.403)	-37.35 (51.390)
95% CL	[-34.63; 9.50]	[-65.81; -8.89]
Min-Max	-85 - 57	-168 - 33
Median	-12.10	-24.00
Q1-Q3	-41.00 - 15.11	-73.00 - 3.60
T-Test	t= -1.21 P= 0.244	t= -2.81 P= 0.014
Change from baseline [%]		
n	16	15
Mean (SD)	-5.83 (29.133)	-16.05 (24.268)
95% CL	[-21.36; 9.69]	[-29.49; -2.61]
Min-Max	-43.75 - 58.763	-62.69 - 39.286
Median	-7.44	-15.95
Q1-Q3	-30.18 - 11.79	-33.88 - 1.52
T-Test	t= -0.80 P= 0.436	t= -2.56 P= 0.023

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	22	21
Mean (SD)	199.10 (41.099)	223.40 (60.893)
95% CL	[180.87; 217.32]	[195.68; 251.12]
Min-Max	90.091 - 279	120 - 346
Median	206.00	210.00
Q1-Q3	180.00 -220.00	179.00 -252.25
After 12 weeks		
n	18	17
Mean (SD)	175.21 (36.385)	196.92 (70.726)
95% CL	[157.12; 193.30]	[160.55; 233.28]
Min-Max	107 - 243.25	131 - 440
Median	178.00	180.00
Q1-Q3	146.00 -199.00	170.00 -200.00
Change from baseline		
n	14	13
Mean (SD)	-25.63 (42.406)	-17.05 (61.775)
95% CL	[-50.12; -1.15]	[-54.38; 20.28]
Min-Max	-81 - 50.451	-179 - 86
Median	-22.00	-18.00
Q1-Q3	-66.67 - -8.00	-24.00 - 6.00
T-Test	t= -2.26 P= 0.041	t= -0.99 P= 0.339
Change from baseline [%]		
n	14	13
Mean (SD)	-11.45 (21.085)	-4.86 (26.382)
95% CL	[-23.62; 0.73]	[-20.81; 11.08]
Min-Max	-43.09 - 26.168	-57.74 - 51.807
Median	-12.00	-7.89
Q1-Q3	-28.24 - -3.98	-11.32 - 3.49
T-Test	t= -2.03 P= 0.063	t= -0.66 P= 0.519

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.3 7-point glucose daily profile (mg/dl) - before lunch

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	22	22
Mean (SD)	160.67 (36.654)	190.21 (49.112)
95% CL	[144.42; 176.92]	[168.43; 211.98]
Min-Max	124 - 260	119 - 324
Median	147.07	185.50
Q1-Q3	133.33 -180.00	152.00 -210.00
After 12 weeks		
n	19	20
Mean (SD)	138.12 (33.676)	151.59 (33.865)
95% CL	[121.89; 154.35]	[135.74; 167.44]
Min-Max	89 - 202	108 - 218.02
Median	130.00	148.37
Q1-Q3	108.11 -159.00	122.46 -178.50
Change from baseline		
n	15	16
Mean (SD)	-21.32 (35.384)	-36.06 (52.352)
95% CL	[-40.92; -1.73]	[-63.95; -8.16]
Min-Max	-91 - 27.027	-138 - 43.244
Median	-18.00	-31.91
Q1-Q3	-53.00 - 18.00	-63.50 - -5.50
T-Test	t= -2.33 P= 0.035	t= -2.75 P= 0.015
Change from baseline [%]		
n	15	16
Mean (SD)	-12.01 (21.329)	-16.08 (23.741)
95% CL	[-23.82; -0.20]	[-28.73; -3.43]
Min-Max	-48.92 - 20.161	-51.11 - 30.882
Median	-12.77	-17.05
Q1-Q3	-24.63 - 11.60	-34.85 - -4.35
T-Test	t= -2.18 P= 0.047	t= -2.71 P= 0.016

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.4 7-point glucose daily profile (mg/dl) - after lunch

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	21	20
Mean (SD)	206.12 (53.236)	241.25 (56.723)
95% CL	[181.89; 230.35]	[214.71; 267.80]
Min-Max	120.72 - 342	154 - 361
Median	210.00	239.83
Q1-Q3	164.00 -232.43	191.50 -282.00
After 12 weeks		
n	17	17
Mean (SD)	182.00 (39.849)	198.34 (46.270)
95% CL	[161.51; 202.49]	[174.55; 222.13]
Min-Max	131.53 - 293.7	103 - 283
Median	173.00	204.00
Q1-Q3	156.00 -199.00	181.00 -227.00
Change from baseline		
n	14	13
Mean (SD)	-5.68 (46.476)	-25.05 (44.631)
95% CL	[-32.52; 21.15]	[-52.02; 1.92]
Min-Max	-76 - 97.298	-79 - 45.045
Median	-6.50	-31.00
Q1-Q3	-48.00 - 19.00	-64.00 - 5.00
T-Test	t= -0.46 P= 0.655	t= -2.02 P= 0.066
Change from baseline [%]		
n	14	13
Mean (SD)	-0.39 (23.605)	-9.03 (19.591)
95% CL	[-14.02; 13.24]	[-20.87; 2.80]
Min-Max	-32.76 - 49.541	-30.16 - 22.727
Median	-3.35	-14.62
Q1-Q3	-21.72 - 14.39	-26.47 - 2.70
T-Test	t= -0.06 P= 0.952	t= -1.66 P= 0.122

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.5 7-point glucose daily profile (mg/dl) - before dinner

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	22
Mean (SD)	166.37 (49.132)	217.19 (72.412)
95% CL	[145.12; 187.62]	[185.09; 249.30]
Min-Max	93 - 253	112 - 396
Median	161.00	187.50
Q1-Q3	124.33 -215.00	168.00 -262.00
After 12 weeks		
n	20	19
Mean (SD)	153.07 (46.887)	158.46 (41.959)
95% CL	[131.13; 175.02]	[138.24; 178.69]
Min-Max	79 - 261	88 - 228.83
Median	142.00	146.00
Q1-Q3	114.50 -180.89	127.00 -198.00
Change from baseline		
n	15	16
Mean (SD)	-19.76 (44.329)	-55.28 (70.900)
95% CL	[-44.31; 4.79]	[-93.06; -17.50]
Min-Max	-114 - 86.487	-190 - 40
Median	-26.00	-29.00
Q1-Q3	-36.04 - -5.00	-94.25 - -2.00
T-Test	t= -1.73 P= 0.106	t= -3.12 P= 0.007
Change from baseline [%]		
n	15	16
Mean (SD)	-5.76 (32.413)	-20.65 (24.405)
95% CL	[-23.71; 12.19]	[-33.66; -7.65]
Min-Max	-45.06 - 88.889	-60.73 - 24.39
Median	-16.13	-17.39
Q1-Q3	-19.71 - -2.73	-44.57 - -1.49
T-Test	t= -0.69 P= 0.503	t= -3.39 P= 0.004

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.6 7-point glucose daily profile (mg/dl) - after dinner

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	21	19
Mean (SD)	209.82 (61.879)	258.16 (55.556)
95% CL	[181.65; 237.99]	[231.38; 284.94]
Min-Max	135.14 - 403	175 - 370
Median	196.00	250.45
Q1-Q3	178.00 -240.00	212.61 -295.00
After 12 weeks		
n	18	18
Mean (SD)	186.56 (39.357)	212.93 (73.190)
95% CL	[166.99; 206.13]	[176.54; 249.33]
Min-Max	106.31 - 263	125 - 390
Median	181.50	194.00
Q1-Q3	166.00 -210.00	172.00 -240.00
Change from baseline		
n	14	13
Mean (SD)	-9.69 (41.683)	-59.36 (61.132)
95% CL	[-33.76; 14.38]	[-96.30; -22.42]
Min-Max	-82 - 81	-206 - 20
Median	-16.00	-48.00
Q1-Q3	-33.00 - 2.00	-63.06 --30.00
T-Test	t= -0.87 P= 0.400	t= -3.50 P= 0.004
Change from baseline [%]		
n	14	13
Mean (SD)	-4.01 (21.252)	-21.79 (18.650)
95% CL	[-16.28; 8.26]	[-33.06; -10.52]
Min-Max	-32.93 - 44.505	-62.24 - 11.429
Median	-6.74	-22.94
Q1-Q3	-18.54 - 1.31	-29.66 --14.69
T-Test	t= -0.71 P= 0.493	t= -4.21 P= 0.001

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.7 7-point glucose daily profile (mg/dl) - bedtime

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	17	20
Mean (SD)	187.54 (49.502)	215.85 (39.348)
95% CL	[162.09; 212.99]	[197.43; 234.26]
Min-Max	104 - 267	160 - 274
Median	187.00	211.50
Q1-Q3	144.00 -230.00	175.49 -257.00
After 12 weeks		
n	16	17
Mean (SD)	161.24 (36.761)	172.75 (52.099)
95% CL	[141.65; 180.83]	[145.97; 199.54]
Min-Max	79 - 214	97 - 310
Median	167.50	165.00
Q1-Q3	144.00 -180.50	133.00 -198.00
Change from baseline		
n	10	13
Mean (SD)	-12.70 (56.787)	-38.94 (55.533)
95% CL	[-53.32; 27.92]	[-72.50; -5.38]
Min-Max	-95 - 110	-140 - 44
Median	-8.50	-16.22
Q1-Q3	-64.00 - 9.01	-83.00 - -2.00
T-Test	t= -0.71 P= 0.497	t= -2.53 P= 0.027
Change from baseline [%]		
n	10	13
Mean (SD)	-0.80 (41.629)	-17.17 (22.642)
95% CL	[-30.58; 28.97]	[-30.85; -3.48]
Min-Max	-44.76 - 105.77	-53.85 - 16.541
Median	-5.29	-9.38
Q1-Q3	-28.63 - 4.46	-33.47 - -0.98
T-Test	t= -0.06 P= 0.953	t= -2.73 P= 0.018

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.1 Change up to approx. 12 weeks after the start of treatment
4.5.7.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	22
Mean (SD)	178.86 (36.058)	212.97 (43.230)
95% CL	[163.26; 194.45]	[193.80; 232.13]
Min-Max	133.33 - 260	157 - 311
Median	183.00	204.50
Q1-Q3	143.00 -212.61	172.00 -254.00
After 12 weeks		
n	21	20
Mean (SD)	152.51 (27.449)	171.48 (32.818)
95% CL	[140.01; 165.00]	[156.12; 186.84]
Min-Max	106.5 - 205.41	120 - 242
Median	151.35	166.00
Q1-Q3	135.00 -167.00	150.07 -189.99
Change from baseline		
n	16	16
Mean (SD)	-18.34 (29.188)	-31.32 (42.285)
95% CL	[-33.89; -2.78]	[-53.86; -8.79]
Min-Max	-78 - 25.225	-155 - 19.82
Median	-8.00	-19.50
Q1-Q3	-33.75 - -5.00	-51.00 - -3.00
T-Test	t= -2.51 P= 0.024	t= -2.96 P= 0.010
Change from baseline [%]		
n	16	16
Mean (SD)	-9.20 (16.138)	-13.55 (16.096)
95% CL	[-17.80; -0.61]	[-22.13; -4.98]
Min-Max	-39.2 - 18.421	-56.36 - 8.9431
Median	-5.39	-9.30
Q1-Q3	-20.20 - -2.82	-23.33 - -1.75
T-Test	t= -2.28 P= 0.038	t= -3.37 P= 0.004

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	21
Mean (SD)	157.17 (35.336)	186.66 (54.918)
95% CL	[141.89; 172.45]	[161.66; 211.66]
Min-Max	97 - 236	84 - 298
Median	145.95	178.00
Q1-Q3	135.14 -178.00	163.00 -226.00
After 24 weeks		
n	19	14
Mean (SD)	139.02 (27.845)	141.29 (21.690)
95% CL	[125.60; 152.44]	[128.77; 153.82]
Min-Max	98 - 191	108 - 176.58
Median	136.00	138.27
Q1-Q3	118.00 -158.56	126.00 -157.00
Change from baseline		
n	16	11
Mean (SD)	-9.83 (43.611)	-30.77 (31.960)
95% CL	[-33.07; 13.41]	[-52.24; -9.30]
Min-Max	-100 - 94	-106 - -3
Median	-13.50	-21.00
Q1-Q3	-29.50 - 15.32	-34.00 --14.00
T-Test	t= -0.90 P= 0.382	t= -3.19 P= 0.010
Change from baseline [%]		
n	16	11
Mean (SD)	-2.42 (32.274)	-16.33 (13.550)
95% CL	[-19.62; 14.77]	[-25.44; -7.23]
Min-Max	-42.37 - 96.907	-46.9 - -2.286
Median	-8.86	-12.88
Q1-Q3	-21.99 - 11.15	-20.36 - -9.28
T-Test	t= -0.30 P= 0.768	t= -4.00 P= 0.003

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	22	21
Mean (SD)	199.10 (41.099)	223.40 (60.893)
95% CL	[180.87; 217.32]	[195.68; 251.12]
Min-Max	90.091 - 279	120 - 346
Median	206.00	210.00
Q1-Q3	180.00 -220.00	179.00 -252.25
After 24 weeks		
n	15	12
Mean (SD)	177.58 (60.055)	181.01 (34.382)
95% CL	[144.32; 210.84]	[159.17; 202.86]
Min-Max	97 - 368	142 - 235
Median	174.78	175.00
Q1-Q3	145.00 -186.00	149.00 -212.50
Change from baseline		
n	13	11
Mean (SD)	-30.08 (64.194)	-20.12 (47.272)
95% CL	[-68.87; 8.71]	[-51.88; 11.64]
Min-Max	-100.9 - 152	-95 - 69
Median	-46.85	-27.00
Q1-Q3	-55.00 --32.00	-52.00 - 10.00
T-Test	t= -1.69 P= 0.117	t= -1.41 P= 0.188
Change from baseline [%]		
n	13	11
Mean (SD)	-14.24 (30.545)	-7.83 (23.143)
95% CL	[-32.69; 4.22]	[-23.38; 7.71]
Min-Max	-48.4 - 70.37	-39.58 - 41.566
Median	-21.31	-11.84
Q1-Q3	-26.77 --15.17	-25.37 - 4.65
T-Test	t= -1.68 P= 0.119	t= -1.12 P= 0.288

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.3 7-point glucose daily profile (mg/dl) - before lunch

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	22	22
Mean (SD)	160.67 (36.654)	190.21 (49.112)
95% CL	[144.42; 176.92]	[168.43; 211.98]
Min-Max	124 - 260	119 - 324
Median	147.07	185.50
Q1-Q3	133.33 -180.00	152.00 -210.00
After 24 weeks		
n	18	14
Mean (SD)	153.78 (39.048)	134.23 (23.912)
95% CL	[134.36; 173.20]	[120.43; 148.04]
Min-Max	108.11 - 274	96 - 167
Median	157.00	133.47
Q1-Q3	128.00 -167.00	112.00 -156.00
Change from baseline		
n	15	12
Mean (SD)	-2.68 (47.206)	-38.63 (32.307)
95% CL	[-28.83; 23.46]	[-59.16; -18.10]
Min-Max	-68.47 - 124	-118.9 - 5
Median	-5.00	-33.50
Q1-Q3	-41.00 - 21.62	-51.50 --19.50
T-Test	t= -0.22 P= 0.829	t= -4.14 P= 0.002
Change from baseline [%]		
n	15	12
Mean (SD)	0.52 (30.085)	-20.43 (13.516)
95% CL	[-16.14; 17.18]	[-29.02; -11.84]
Min-Max	-32.1 - 82.667	-48.89 - 3.3784
Median	-3.51	-20.34
Q1-Q3	-20.10 - 17.39	-28.52 --12.21
T-Test	t= 0.07 P= 0.947	t= -5.24 P= 0.000

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.4 7-point glucose daily profile (mg/dl) - after lunch

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	21	20
Mean (SD)	206.12 (53.236)	241.25 (56.723)
95% CL	[181.89; 230.35]	[214.71; 267.80]
Min-Max	120.72 - 342	154 - 361
Median	210.00	239.83
Q1-Q3	164.00 -232.43	191.50 -282.00
After 24 weeks		
n	17	13
Mean (SD)	177.79 (44.223)	161.21 (43.033)
95% CL	[155.05; 200.53]	[135.21; 187.22]
Min-Max	118 - 275	50.451 - 207
Median	170.00	171.00
Q1-Q3	147.00 -206.00	140.00 -187.00
Change from baseline		
n	15	11
Mean (SD)	-28.72 (51.186)	-52.79 (64.775)
95% CL	[-57.07; -0.38]	[-96.30; -9.27]
Min-Max	-90.09 - 121	-198.2 - 31
Median	-45.00	-41.44
Q1-Q3	-50.00 - -9.00	-81.00 - -7.00
T-Test	t= -2.17 P= 0.047	t= -2.70 P= 0.022
Change from baseline [%]		
n	15	11
Mean (SD)	-11.87 (28.238)	-20.78 (26.759)
95% CL	[-27.51; 3.76]	[-38.76; -2.80]
Min-Max	-40.32 - 78.571	-79.71 - 20.13
Median	-17.04	-22.08
Q1-Q3	-27.44 - -5.43	-28.62 - -3.61
T-Test	t= -1.63 P= 0.126	t= -2.58 P= 0.028

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.5 7-point glucose daily profile (mg/dl) - before dinner

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	22
Mean (SD)	166.37 (49.132)	217.19 (72.412)
95% CL	[145.12; 187.62]	[185.09; 249.30]
Min-Max	93 - 253	112 - 396
Median	161.00	187.50
Q1-Q3	124.33 -215.00	168.00 -262.00
After 24 weeks		
n	17	13
Mean (SD)	161.67 (38.278)	167.57 (44.696)
95% CL	[141.99; 181.35]	[140.56; 194.58]
Min-Max	98 - 226	112 - 272.07
Median	176.00	172.00
Q1-Q3	126.13 -185.00	132.00 -188.00
Change from baseline		
n	14	12
Mean (SD)	-14.61 (50.340)	-38.43 (55.267)
95% CL	[-43.67; 14.46]	[-73.55; -3.32]
Min-Max	-98 - 78	-164 - 28
Median	-24.00	-31.50
Q1-Q3	-36.00 - 9.01	-66.73 - 3.50
T-Test	t= -1.09 P= 0.297	t= -2.41 P= 0.035
Change from baseline [%]		
n	14	12
Mean (SD)	-3.65 (28.517)	-14.00 (22.486)
95% CL	[-20.12; 12.81]	[-28.29; 0.29]
Min-Max	-41.09 - 55.319	-55.41 - 25
Median	-12.68	-20.01
Q1-Q3	-19.67 - 7.69	-26.68 - 2.64
T-Test	t= -0.48 P= 0.640	t= -2.16 P= 0.054

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.6 7-point glucose daily profile (mg/dl) - after dinner

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	21	19
Mean (SD)	209.82 (61.879)	258.16 (55.556)
95% CL	[181.65; 237.99]	[231.38; 284.94]
Min-Max	135.14 - 403	175 - 370
Median	196.00	250.45
Q1-Q3	178.00 -240.00	212.61 -295.00
After 24 weeks		
n	15	12
Mean (SD)	183.82 (51.002)	186.41 (49.807)
95% CL	[155.58; 212.06]	[154.76; 218.05]
Min-Max	102 - 318	111 - 293.7
Median	170.00	178.50
Q1-Q3	151.00 -205.00	154.08 -208.00
Change from baseline		
n	12	10
Mean (SD)	-5.73 (60.687)	-54.85 (71.681)
95% CL	[-44.29; 32.83]	[-106.12; -3.57]
Min-Max	-95 - 140	-211 - 35
Median	-8.50	-48.23
Q1-Q3	-28.50 - 8.10	-100.0 - -5.00
T-Test	t= -0.33 P= 0.750	t= -2.42 P= 0.039
Change from baseline [%]		
n	12	10
Mean (SD)	-0.37 (30.367)	-19.99 (24.654)
95% CL	[-19.66; 18.93]	[-37.62; -2.35]
Min-Max	-39.58 - 78.652	-59.6 - 16.129
Median	-5.05	-21.69
Q1-Q3	-12.30 - 4.58	-37.45 - -2.63
T-Test	t= -0.04 P= 0.967	t= -2.56 P= 0.031

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.7 7-point glucose daily profile (mg/dl) - bedtime

	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	17	20
Mean (SD)	187.54 (49.502)	215.85 (39.348)
95% CL	[162.09; 212.99]	[197.43; 234.26]
Min-Max	104 - 267	160 - 274
Median	187.00	211.50
Q1-Q3	144.00 -230.00	175.49 -257.00
After 24 weeks		
n	16	14
Mean (SD)	150.07 (32.999)	157.49 (28.641)
95% CL	[132.48; 167.65]	[140.95; 174.03]
Min-Max	108 - 210.81	90.091 - 215
Median	140.00	156.00
Q1-Q3	125.06 -177.00	147.75 -167.00
Change from baseline		
n	11	11
Mean (SD)	-27.63 (62.377)	-42.29 (34.923)
95% CL	[-69.53; 14.28]	[-65.76; -18.83]
Min-Max	-127.9 - 93	-112 - 7
Median	-9.00	-31.00
Q1-Q3	-79.00 - 9.01	-69.00 --17.00
T-Test	t= -1.47 P= 0.173	t= -4.02 P= 0.002
Change from baseline [%]		
n	11	11
Mean (SD)	-7.78 (38.534)	-19.40 (14.154)
95% CL	[-33.67; 18.10]	[-28.91; -9.90]
Min-Max	-50.35 - 89.423	-43.08 - 4.375
Median	-4.90	-15.66
Q1-Q3	-36.05 - 4.46	-31.80 - -9.55
T-Test	t= -0.67 P= 0.518	t= -4.55 P= 0.001

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.2 Change up to approx. 24 weeks after the start of treatment
4.5.7.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	23	22
Mean (SD)	178.86 (36.058)	212.97 (43.230)
95% CL	[163.26; 194.45]	[193.80; 232.13]
Min-Max	133.33 - 260	157 - 311
Median	183.00	204.50
Q1-Q3	143.00 -212.61	172.00 -254.00
After 24 weeks		
n	19	14
Mean (SD)	158.62 (32.874)	157.16 (16.092)
95% CL	[142.77; 174.46]	[147.87; 166.45]
Min-Max	118 - 250.5	135 - 188
Median	151.00	150.75
Q1-Q3	132.00 -179.00	145.00 -171.00
Change from baseline		
n	16	12
Mean (SD)	-16.50 (43.590)	-35.79 (31.980)
95% CL	[-39.73; 6.73]	[-56.10; -15.47]
Min-Max	-80.18 - 96.5	-112 - -3
Median	-27.50	-29.00
Q1-Q3	-44.00 - -6.00	-47.52 - -9.50
T-Test	t= -1.51 P= 0.151	t= -3.88 P= 0.003
Change from baseline [%]		
n	16	12
Mean (SD)	-6.91 (26.187)	-16.83 (12.315)
95% CL	[-20.87; 7.04]	[-24.66; -9.01]
Min-Max	-35.46 - 62.662	-43.08 - -1.786
Median	-13.70	-17.19
Q1-Q3	-23.29 - -3.81	-23.22 - -5.22
T-Test	t= -1.06 P= 0.308	t= -4.74 P= 0.001

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.7.3.1 Derived Time in Range - dTIR

Percentage within range	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	16	18
Mean (SD)	50.0 (33.40)	31.7 (27.53)
Min-Max	0 - 100	0 - 85.714
Median	42.9	28.6
Q1-Q3	21.4 - 78.6	0.0 - 57.1
After 12 weeks		
n	13	16
Mean (SD)	68.1 (26.82)	56.2 (35.17)
Min-Max	14.286 - 100	0 - 100
Median	71.4	64.3
Q1-Q3	57.1 - 85.7	28.6 - 85.7
After 24 weeks		
n	13	12
Mean (SD)	78.0 (23.77)	72.6 (23.95)
Min-Max	28.571 - 100	28.571 - 100
Median	85.7	78.6
Q1-Q3	57.1 - 100.0	57.1 - 92.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.7.3.2 Derived Time below Range - dTBR

Percentage below range	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	16	18
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 12 weeks		
n	13	16
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0
After 24 weeks		
n	13	12
Mean (SD)	0.0 (0.00)	1.2 (4.12)
Min-Max	0 - 0	0 - 14.286
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.5.7.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.7.3.3 Derived Time above Range - dTAR

Percentage above range	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	16	18
Mean (SD)	50.0 (33.40)	68.3 (27.53)
Min-Max	0 - 100	14.286 - 100
Median	57.1	71.4
Q1-Q3	21.4 - 78.6	42.9 - 100.0
After 12 weeks		
n	13	16
Mean (SD)	31.9 (26.82)	43.8 (35.17)
Min-Max	0 - 85.714	0 - 100
Median	28.6	35.7
Q1-Q3	14.3 - 42.9	14.3 - 71.4
After 24 weeks		
n	13	12
Mean (SD)	22.0 (23.77)	26.2 (22.66)
Min-Max	0 - 71.429	0 - 71.429
Median	14.3	21.4
Q1-Q3	0.0 - 42.9	7.1 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	11	21	4
Mean (SD)	169.32 (39.700)	180.26 (67.299)	165.50 (40.858)	180.43 (43.475)
95% CL	[136.13; 202.51]	[135.05; 225.48]	[146.91; 184.10]	[111.25; 249.61]
Min-Max	129 - 226	84 - 298	97 - 250	129.73 - 236
Median	148.97	154.00	163.00	178.00
Q1-Q3	139.50 -211.31	135.00 -232.00	142.00 -193.00	153.87 -207.00
After 12 weeks				
n	7	10	20	4
Mean (SD)	143.62 (36.389)	138.69 (44.489)	133.33 (40.068)	157.44 (18.209)
95% CL	[109.97; 177.28]	[106.86; 170.51]	[114.57; 152.08]	[128.46; 186.41]
Min-Max	111 - 205.41	90 - 242	77 - 241.44	138.74 - 182
Median	126.00	137.50	121.00	154.50
Q1-Q3	111.00 -176.00	100.00 -151.35	112.00 -152.50	144.87 -170.00
Change from baseline				
n	5	7	15	4
Mean (SD)	-26.04 (47.860)	-42.67 (70.379)	-16.03 (37.367)	-23.00 (43.230)
95% CL	[-85.47; 33.38]	[-107.75; 22.42]	[-36.72; 4.66]	[-91.79; 45.79]
Min-Max	-105 - 24	-168 - 33	-73 - 57	-85 - 9.0091
Median	-18.00	-56.00	-17.00	-8.00
Q1-Q3	-24.00 - -7.21	-73.87 - 16.22	-41.00 - 3.60	-52.50 - 6.50
T-Test	t= -1.22 P= 0.291	t= -1.60 P= 0.160	t= -1.66 P= 0.119	t= -1.06 P= 0.365
Change from baseline [%]				
n	5	7	15	4
Mean (SD)	-13.16 (22.718)	-13.44 (35.859)	-9.08 (27.726)	-9.52 (19.275)
95% CL	[-41.37; 15.05]	[-46.60; 19.73]	[-24.43; 6.28]	[-40.19; 21.16]
Min-Max	-46.46 - 15.789	-62.69 - 39.286	-43.75 - 58.763	-36.02 - 6.9444
Median	-13.95	-18.79	-12.14	-4.49
Q1-Q3	-17.78 - -3.39	-41.56 - 12.00	-25.15 - 1.52	-23.63 - 4.60
T-Test	t= -1.30 P= 0.265	t= -0.99 P= 0.360	t= -1.27 P= 0.226	t= -0.99 P= 0.396

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	10	21	4
Mean (SD)	209.95 (54.313)	223.73 (63.193)	207.28 (52.815)	200.45 (20.299)
95% CL	[164.54; 255.35]	[178.52; 268.93]	[183.24; 231.32]	[168.15; 232.75]
Min-Max	131.53 - 320	158 - 346	90.091 - 320	180 - 228
Median	205.00	216.41	210.00	196.90
Q1-Q3	185.00 -224.02	170.00 -252.25	179.00 -228.83	186.40 -214.50
After 12 weeks				
n	6	8	17	4
Mean (SD)	182.06 (10.203)	189.57 (105.03)	178.37 (37.955)	215.06 (20.879)
95% CL	[171.35; 192.77]	[101.76; 277.38]	[158.85; 197.88]	[181.84; 248.28]
Min-Max	169.37 - 199	109 - 440	107 - 252	193 - 243.25
Median	179.00	160.50	178.00	212.00
Q1-Q3	178.00 -188.00	135.77 -187.50	146.00 -200.00	201.50 -228.62
Change from baseline				
n	5	5	13	4
Mean (SD)	-22.93 (26.902)	-48.93 (86.235)	-21.51 (45.465)	14.61 (32.839)
95% CL	[-56.34; 10.47]	[-156.01; 58.15]	[-48.98; 5.96]	[-37.64; 66.87]
Min-Max	-66.67 - 6	-179 - 30	-81 - 86	-18 - 50.451
Median	-18.00	-48.65	-21.00	13.00
Q1-Q3	-24.00 --12.00	-75.00 - 28.00	-57.66 --12.00	-13.00 - 42.23
T-Test	t= -1.91 P= 0.129	t= -1.27 P= 0.273	t= -1.71 P= 0.114	t= 0.89 P= 0.439
Change from baseline [%]				
n	5	5	13	4
Mean (SD)	-10.17 (11.574)	-16.19 (33.607)	-9.60 (24.278)	8.30 (16.778)
95% CL	[-24.54; 4.20]	[-57.92; 25.54]	[-24.28; 5.07]	[-18.40; 34.99]
Min-Max	-28.24 - 3.4884	-57.74 - 18.987	-43.09 - 51.807	-7.895 - 26.168
Median	-9.09	-25.71	-9.87	7.45
Q1-Q3	-11.32 - -5.69	-34.09 - 17.61	-25.20 - -5.71	-5.94 - 22.53
T-Test	t= -1.97 P= 0.121	t= -1.08 P= 0.342	t= -1.43 P= 0.179	t= 0.99 P= 0.396

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.3 7-point glucose daily profile (mg/dl) - before lunch

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	20	4
Mean (SD)	168.17 (39.529)	193.04 (63.413)	169.67 (36.753)	166.04 (28.680)
95% CL	[135.13; 201.22]	[152.75; 233.33]	[152.46; 186.87]	[120.40; 211.67]
Min-Max	132 - 241.44	124.33 - 324	119 - 260	140 - 199
Median	153.00	181.00	166.00	162.57
Q1-Q3	136.47 -196.50	138.17 -226.62	144.50 -195.00	142.07 -190.00
After 12 weeks				
n	6	9	20	4
Mean (SD)	156.52 (37.727)	133.19 (25.910)	140.41 (35.356)	177.54 (18.464)
95% CL	[116.93; 196.12]	[113.27; 153.10]	[123.86; 156.95]	[148.16; 206.92]
Min-Max	108 - 197	95 - 186	89 - 218.02	158 - 202
Median	170.08	128.00	132.50	175.09
Q1-Q3	112.00 -181.98	118.92 -147.75	117.00 -154.00	164.59 -190.50
Change from baseline				
n	5	7	15	4
Mean (SD)	-22.09 (41.031)	-77.31 (47.308)	-19.41 (31.932)	11.51 (21.337)
95% CL	[-73.04; 28.85]	[-121.06; -33.55]	[-37.10; -1.73]	[-22.45; 45.46]
Min-Max	-59.46 - 42	-138 - -15	-76 - 43.244	-20 - 27.027
Median	-35.00	-91.00	-18.00	19.50
Q1-Q3	-51.00 - -7.00	-124.3 --28.83	-38.00 - -3.00	-1.00 - 24.01
T-Test	t= -1.20 P= 0.295	t= -4.32 P= 0.005	t= -2.35 P= 0.034	t= 1.08 P= 0.360
Change from baseline [%]				
n	5	7	15	4
Mean (SD)	-10.61 (25.518)	-34.52 (16.477)	-11.73 (19.221)	8.29 (12.618)
95% CL	[-42.30; 21.07]	[-49.75; -19.28]	[-22.37; -1.08]	[-11.79; 28.37]
Min-Max	-32.08 - 30.882	-51.11 - -10.49	-41.06 - 24.742	-10.05 - 18.75
Median	-23.81	-42.59	-12.77	12.23
Q1-Q3	-24.63 - -3.43	-48.92 --16.33	-22.35 - -1.97	0.78 - 15.80
T-Test	t= -0.93 P= 0.405	t= -5.54 P= 0.001	t= -2.36 P= 0.033	t= 1.31 P= 0.280

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.4 7-point glucose daily profile (mg/dl) - after lunch

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	10	19	4
Mean (SD)	219.12 (56.720)	240.19 (51.276)	218.42 (60.384)	212.18 (70.013)
95% CL	[171.70; 266.54]	[203.51; 276.87]	[189.32; 247.53]	[100.77; 323.59]
Min-Max	140.54 - 332	183.79 - 361	132 - 342	120.72 - 275
Median	208.70	232.22	212.00	226.50
Q1-Q3	189.50 -242.00	210.00 -248.65	157.00 -270.00	157.86 -266.50
After 12 weeks				
n	5	8	17	4
Mean (SD)	208.74 (51.757)	202.14 (46.590)	181.61 (37.453)	179.38 (54.765)
95% CL	[144.47; 273.00]	[163.19; 241.09]	[162.36; 200.87]	[92.24; 266.53]
Min-Max	167 - 293.7	135.14 - 283	103 - 257.66	131.53 - 245
Median	190.00	203.00	181.00	170.50
Q1-Q3	173.00 -220.00	167.50 -229.00	165.77 -201.00	134.27 -224.50
Change from baseline				
n	5	5	13	4
Mean (SD)	3.26 (64.255)	-41.93 (37.031)	-6.20 (41.388)	-32.80 (38.246)
95% CL	[-76.52; 83.04]	[-87.91; 4.05]	[-31.21; 18.81]	[-93.65; 28.06]
Min-Max	-64 - 97.298	-78 - 0	-79 - 45.045	-71 - 10.811
Median	5.00	-48.65	-6.00	-35.50
Q1-Q3	-48.00 - 26.00	-76.00 - -7.00	-31.00 - 34.00	-64.50 - -1.09
T-Test	t= 0.11 P= 0.915	t= -2.53 P= 0.065	t= -0.54 P= 0.599	t= -1.72 P= 0.185
Change from baseline [%]				
n	5	5	13	4
Mean (SD)	3.24 (30.935)	-16.92 (14.348)	-0.22 (20.654)	-12.91 (18.166)
95% CL	[-35.17; 41.66]	[-34.73; 0.90]	[-12.70; 12.26]	[-41.82; 16.00]
Min-Max	-27.71 - 49.541	-32.76 - 0	-30.16 - 23.776	-29.74 - 8.9552
Median	2.70	-21.61	-2.93	-15.43
Q1-Q3	-21.72 - 13.40	-26.47 - -3.76	-14.62 - 21.19	-27.78 - 1.96
T-Test	t= 0.23 P= 0.826	t= -2.64 P= 0.058	t= -0.04 P= 0.970	t= -1.42 P= 0.250

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.5 7-point glucose daily profile (mg/dl) - before dinner

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	21	4
Mean (SD)	169.72 (41.348)	214.62 (95.617)	189.97 (54.753)	170.57 (50.883)
95% CL	[135.15; 204.29]	[153.86; 275.37]	[165.04; 214.89]	[89.61; 251.54]
Min-Max	112 - 228	93 - 396	117.12 - 296	97.298 - 215
Median	168.00	199.50	178.00	185.00
Q1-Q3	140.16 -200.71	149.17 -260.92	148.00 -241.00	140.15 -201.00
After 12 weeks				
n	6	9	20	4
Mean (SD)	145.73 (49.001)	170.33 (51.787)	146.81 (41.350)	182.20 (17.166)
95% CL	[94.31; 197.16]	[130.52; 210.13]	[127.45; 166.16]	[154.88; 209.51]
Min-Max	88 - 204	108 - 261	79 - 250	158 - 198
Median	143.00	166.00	135.00	186.39
Q1-Q3	109.00 -187.39	131.00 -206.00	122.50 -166.50	170.89 -193.50
Change from baseline				
n	5	7	15	4
Mean (SD)	-26.81 (47.617)	-92.81 (89.601)	-29.57 (32.193)	11.62 (52.795)
95% CL	[-85.93; 32.32]	[-175.68; -9.94]	[-47.40; -11.75]	[-72.39; 95.63]
Min-Max	-84 - 40	-190 - 38	-114 - 11	-26 - 86.487
Median	-36.04	-104.5	-24.00	-7.00
Q1-Q3	-52.00 - -2.00	-171.2 - -2.00	-41.00 - -9.00	-25.50 - 48.74
T-Test	t= -1.26 P= 0.277	t= -2.74 P= 0.034	t= -3.56 P= 0.003	t= 0.44 P= 0.690
Change from baseline [%]				
n	5	7	15	4
Mean (SD)	-13.03 (26.991)	-27.18 (35.360)	-15.36 (13.939)	17.25 (48.573)
95% CL	[-46.55; 20.48]	[-59.89; 5.52]	[-23.08; -7.64]	[-60.04; 94.54]
Min-Max	-48.84 - 24.39	-60.73 - 40.86	-45.06 - 9.1667	-13.66 - 88.889
Median	-16.13	-42.34	-16.15	-3.11
Q1-Q3	-22.81 - -1.79	-47.98 - -1.19	-23.30 - -6.47	-12.88 - 47.39
T-Test	t= -1.08 P= 0.341	t= -2.03 P= 0.088	t= -4.27 P= 0.001	t= 0.71 P= 0.529

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.6 7-point glucose daily profile (mg/dl) - after dinner

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	8	20	4
Mean (SD)	217.84 (45.025)	236.08 (61.415)	240.55 (73.800)	217.24 (49.413)
95% CL	[180.20; 255.48]	[184.73; 287.42]	[206.01; 275.09]	[138.62; 295.87]
Min-Max	135.14 - 295	148 - 331	144.15 - 403	172.97 - 272
Median	216.50	230.81	227.00	212.00
Q1-Q3	202.80 -237.00	193.00 -281.00	181.50 -282.50	175.49 -259.00
After 12 weeks				
n	6	9	17	4
Mean (SD)	189.60 (13.561)	216.99 (102.01)	189.54 (40.751)	219.54 (45.755)
95% CL	[175.37; 203.83]	[138.58; 295.41]	[168.59; 210.49]	[146.73; 292.34]
Min-Max	178 - 212.61	125 - 390	106.31 - 263	153.15 - 258
Median	184.50	167.00	193.00	233.50
Q1-Q3	180.00 -198.00	160.00 -240.00	171.00 -208.00	192.58 -246.50
Change from baseline				
n	5	5	13	4
Mean (SD)	-24.20 (26.741)	-82.21 (72.702)	-29.57 (56.886)	2.29 (34.664)
95% CL	[-57.40; 9.01]	[-172.48; 8.06]	[-63.95; 4.80]	[-52.86; 57.45]
Min-Max	-53 - 18.018	-206 - -30	-146 - 81	-19.82 - 54
Median	-31.00	-63.06	-33.00	-12.50
Q1-Q3	-37.00 --18.00	-82.00 --30.00	-55.00 - 2.00	-16.91 - 21.50
T-Test	t= -2.02 P= 0.113	t= -2.53 P= 0.065	t= -1.87 P= 0.085	t= 0.13 P= 0.903
Change from baseline [%]				
n	5	5	13	4
Mean (SD)	-10.75 (12.350)	-31.18 (19.096)	-10.69 (23.004)	2.32 (18.944)
95% CL	[-26.09; 4.58]	[-54.90; -7.47]	[-24.59; 3.21]	[-27.83; 32.46]
Min-Max	-22.94 - 9.2593	-62.24 - -15.31	-41.24 - 44.505	-11.46 - 30.337
Median	-14.69	-29.66	-18.54	-4.81
Q1-Q3	-17.05 - -8.33	-32.93 --15.79	-26.25 - 1.01	-8.30 - 12.93
T-Test	t= -1.95 P= 0.123	t= -3.65 P= 0.022	t= -1.68 P= 0.120	t= 0.24 P= 0.823

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.7 7-point glucose daily profile (mg/dl) - bedtime

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	7	10	17	3
Mean (SD)	194.45 (40.733)	208.20 (55.070)	203.06 (47.661)	203.33 (28.378)
95% CL	[156.78; 232.12]	[168.81; 247.60]	[178.55; 227.56]	[132.84; 273.83]
Min-Max	142.34 - 248	121 - 267	104 - 274	178 - 234
Median	199.00	218.00	205.00	198.00
Q1-Q3	160.00 -243.00	162.00 -260.00	172.00 -238.00	178.00 -234.00
After 12 weeks				
n	5	7	18	3
Mean (SD)	169.56 (24.165)	165.54 (74.626)	165.39 (40.894)	177.67 (9.452)
95% CL	[139.56; 199.57]	[96.52; 234.55]	[145.06; 185.73]	[154.19; 201.15]
Min-Max	149 - 210.81	79 - 310	97 - 245.05	167 - 185
Median	165.00	156.76	167.50	181.00
Q1-Q3	156.00 -167.00	120.00 -198.00	133.00 -195.00	167.00 -185.00
Change from baseline				
n	4	5	11	3
Mean (SD)	-19.50 (43.280)	-54.24 (71.078)	-18.82 (60.474)	-25.67 (37.754)
95% CL	[-88.37; 49.37]	[-142.50; 34.01]	[-59.45; 21.81]	[-119.45; 68.12]
Min-Max	-83 - 9.0091	-140 - 44	-128 - 110	-67 - 7
Median	-2.00	-64.00	-8.00	-17.00
Q1-Q3	-47.00 - 8.00	-95.00 --16.22	-52.00 - -2.00	-67.00 - 7.00
T-Test	t= -0.90 P= 0.434	t= -1.71 P= 0.163	t= -1.03 P= 0.326	t= -1.18 P= 0.360
Change from baseline [%]				
n	4	5	11	3
Mean (SD)	-7.80 (17.879)	-25.40 (28.737)	-3.61 (40.989)	-11.10 (16.427)
95% CL	[-36.25; 20.65]	[-61.09; 10.28]	[-31.14; 23.93]	[-51.90; 29.71]
Min-Max	-33.47 - 4.4643	-53.85 - 16.541	-53.78 - 105.77	-28.63 - 3.9326
Median	-1.11	-35.58	-4.04	-8.59
Q1-Q3	-20.03 - 4.42	-44.76 - -9.38	-23.96 - -0.98	-28.63 - 3.93
T-Test	t= -0.87 P= 0.447	t= -1.98 P= 0.119	t= -0.29 P= 0.776	t= -1.17 P= 0.363

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.1 Change up to approx. 12 weeks after the start of treatment
4.5.8.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	21	4
Mean (SD)	188.63 (27.418)	210.09 (57.863)	192.80 (40.080)	179.98 (29.807)
95% CL	[165.71; 211.55]	[173.33; 246.86]	[174.56; 211.05]	[132.56; 227.41]
Min-Max	136.94 - 213.5	133.33 - 311	137 - 263	136.94 - 201
Median	198.50	216.50	183.00	191.00
Q1-Q3	169.50 -211.31	155.50 -253.73	166.00 -221.00	159.97 -200.00
After 12 weeks				
n	7	10	20	4
Mean (SD)	171.78 (19.919)	160.55 (37.503)	155.66 (32.780)	177.79 (20.620)
95% CL	[153.36; 190.20]	[133.72; 187.38]	[140.32; 171.00]	[144.98; 210.60]
Min-Max	149 - 205.41	120 - 242	106.5 - 241.44	158 - 198
Median	167.00	148.18	158.25	177.58
Q1-Q3	156.00 -186.50	135.00 -181.98	134.00 -174.00	160.08 -195.50
Change from baseline				
n	5	8	15	4
Mean (SD)	-13.64 (8.951)	-50.94 (54.491)	-20.67 (26.925)	-2.19 (20.873)
95% CL	[-24.76; -2.53]	[-96.49; -5.38]	[-35.58; -5.76]	[-35.41; 31.02]
Min-Max	-27 - -5	-155 - 18.018	-78 - 19.82	-25 - 25.225
Median	-11.00	-56.76	-21.00	-4.50
Q1-Q3	-18.00 - -7.21	-72.00 - -6.50	-36.94 - -1.00	-16.50 - 12.11
T-Test	t= -3.41 P= 0.027	t= -2.64 P= 0.033	t= -2.97 P= 0.010	t= -0.21 P= 0.847
Change from baseline [%]				
n	5	8	15	4
Mean (SD)	-6.92 (4.068)	-19.86 (21.429)	-11.40 (14.449)	0.07 (13.442)
95% CL	[-11.97; -1.87]	[-37.77; -1.94]	[-19.40; -3.39]	[-21.32; 21.46]
Min-Max	-12.65 - -2.907	-56.36 - 13.514	-39.2 - 10.219	-13.66 - 18.421
Median	-6.59	-23.00	-9.50	-2.24
Q1-Q3	-9.09 - -3.39	-30.71 - -4.29	-23.03 - -0.60	-8.82 - 8.96
T-Test	t= -3.81 P= 0.019	t= -2.62 P= 0.034	t= -3.05 P= 0.009	t= 0.01 P= 0.992

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	11	21	4
Mean (SD)	169.32 (39.700)	180.26 (67.299)	165.50 (40.858)	180.43 (43.475)
95% CL	[136.13; 202.51]	[135.05; 225.48]	[146.91; 184.10]	[111.25; 249.61]
Min-Max	129 - 226	84 - 298	97 - 250	129.73 - 236
Median	148.97	154.00	163.00	178.00
Q1-Q3	139.50 -211.31	135.00 -232.00	142.00 -193.00	153.87 -207.00
After 24 weeks				
n	7	7	16	3
Mean (SD)	133.85 (24.335)	140.09 (23.843)	140.62 (28.533)	150.67 (12.741)
95% CL	[111.35; 156.36]	[118.04; 162.14]	[125.42; 155.83]	[119.02; 182.32]
Min-Max	109 - 178	104 - 176.58	98 - 191	136 - 159
Median	126.00	140.54	136.47	157.00
Q1-Q3	117.00 -154.96	121.00 -158.56	118.00 -163.50	136.00 -159.00
Change from baseline				
n	6	4	14	3
Mean (SD)	-32.28 (45.921)	-15.96 (44.247)	-7.01 (34.559)	-46.67 (46.199)
95% CL	[-80.47; 15.92]	[-86.37; 54.44]	[-26.97; 12.94]	[-161.43; 68.10]
Min-Max	-106 - 26	-77.48 - 23.424	-45 - 94	-100 - -19
Median	-26.50	-4.90	-16.00	-21.00
Q1-Q3	-57.66 - -3.00	-47.24 - 15.32	-22.00 - -7.21	-100.0 --19.00
T-Test	t= -1.72 P= 0.146	t= -0.72 P= 0.523	t= -0.76 P= 0.461	t= -1.75 P= 0.222
Change from baseline [%]				
n	6	4	14	3
Mean (SD)	-16.15 (22.079)	-6.76 (23.128)	-2.12 (31.117)	-21.61 (17.986)
95% CL	[-39.32; 7.02]	[-43.57; 30.04]	[-20.09; 15.85]	[-66.29; 23.06]
Min-Max	-46.9 - 17.105	-35.54 - 17.333	-29.61 - 96.907	-42.37 - -10.67
Median	-18.82	-4.43	-10.38	-11.80
Q1-Q3	-27.12 - -2.33	-24.79 - 11.26	-15.71 - -5.00	-42.37 --10.67
T-Test	t= -1.79 P= 0.133	t= -0.58 P= 0.600	t= -0.25 P= 0.803	t= -2.08 P= 0.173

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4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	10	21	4
Mean (SD)	209.95 (54.313)	223.73 (63.193)	207.28 (52.815)	200.45 (20.299)
95% CL	[164.54; 255.35]	[178.52; 268.93]	[183.24; 231.32]	[168.15; 232.75]
Min-Max	131.53 - 320	158 - 346	90.091 - 320	180 - 228
Median	205.00	216.41	210.00	196.90
Q1-Q3	185.00 -224.02	170.00 -252.25	179.00 -228.83	186.40 -214.50
After 24 weeks				
n	7	5	12	3
Mean (SD)	180.83 (20.263)	176.02 (19.498)	179.74 (71.128)	177.67 (43.924)
95% CL	[162.09; 199.57]	[151.81; 200.23]	[134.55; 224.94]	[68.55; 286.78]
Min-Max	160 - 224	144.15 - 195	97 - 368	127 - 205
Median	178.00	181.98	159.00	201.00
Q1-Q3	170.00 -180.00	172.97 -186.00	143.50 -207.00	127.00 -205.00
Change from baseline				
n	6	4	11	3
Mean (SD)	-23.38 (33.236)	-33.79 (42.125)	-23.72 (77.185)	-25.33 (28.537)
95% CL	[-58.26; 11.50]	[-100.82; 33.24]	[-75.57; 28.14]	[-96.22; 45.56]
Min-Max	-61.26 - 26	-70.27 - 27	-100.9 - 152	-53 - 4
Median	-35.50	-45.95	-52.00	-27.00
Q1-Q3	-42.00 - 8.00	-58.56 - -9.02	-91.00 - 10.00	-53.00 - 4.00
T-Test	t= -1.72 P= 0.146	t= -1.60 P= 0.207	t= -1.02 P= 0.332	t= -1.54 P= 0.264
Change from baseline [%]				
n	6	4	11	3
Mean (SD)	-10.46 (15.608)	-14.00 (20.829)	-10.29 (37.048)	-13.10 (15.755)
95% CL	[-26.84; 5.92]	[-47.14; 19.14]	[-35.18; 14.60]	[-52.24; 26.04]
Min-Max	-25.95 - 13.131	-27.86 - 16.981	-48.4 - 70.37	-29.44 - 1.99
Median	-17.38	-22.56	-25.00	-11.84
Q1-Q3	-19.81 - 4.65	-25.83 - -2.17	-39.58 - 4.52	-29.44 - 1.99
T-Test	t= -1.64 P= 0.162	t= -1.34 P= 0.271	t= -0.92 P= 0.379	t= -1.44 P= 0.287

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.3 7-point glucose daily profile (mg/dl) - before lunch

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	20	4
Mean (SD)	168.17 (39.529)	193.04 (63.413)	169.67 (36.753)	166.04 (28.680)
95% CL	[135.13; 201.22]	[152.75; 233.33]	[152.46; 186.87]	[120.40; 211.67]
Min-Max	132 - 241.44	124.33 - 324	119 - 260	140 - 199
Median	153.00	181.00	166.00	162.57
Q1-Q3	136.47 -196.50	138.17 -226.62	144.50 -195.00	142.07 -190.00
After 24 weeks				
n	7	6	16	3
Mean (SD)	139.57 (24.563)	141.20 (18.252)	146.38 (43.981)	160.33 (22.745)
95% CL	[116.85; 162.28]	[122.05; 160.36]	[122.95; 169.82]	[103.83; 216.83]
Min-Max	112 - 172.97	118 - 164	96 - 274	135 - 179
Median	131.00	141.44	147.00	167.00
Q1-Q3	112.00 -163.00	124.33 -158.00	110.00 -165.00	135.00 -179.00
Change from baseline				
n	6	4	14	3
Mean (SD)	-33.08 (22.122)	-40.48 (58.452)	-7.46 (50.417)	-13.00 (16.523)
95% CL	[-56.29; -9.86]	[-133.49; 52.53]	[-36.57; 21.65]	[-54.04; 28.04]
Min-Max	-68.47 - -1	-118.9 - 21.622	-65 - 124	-32 - -2
Median	-32.00	-32.32	-11.00	-5.00
Q1-Q3	-41.00 --24.00	-79.28 - -1.69	-42.00 - 5.00	-32.00 - -2.00
T-Test	t= -3.66 P= 0.015	t= -1.39 P= 0.260	t= -0.55 P= 0.589	t= -1.36 P= 0.306
Change from baseline [%]				
n	6	4	14	3
Mean (SD)	-18.15 (9.411)	-17.86 (27.244)	-2.59 (32.113)	-6.92 (8.029)
95% CL	[-28.03; -8.28]	[-61.21; 25.49]	[-21.13; 15.95]	[-26.86; 13.03]
Min-Max	-28.36 - -0.758	-48.89 - 17.391	-32.1 - 82.667	-16.08 - -1.105
Median	-19.17	-19.97	-7.11	-3.57
Q1-Q3	-23.81 --17.65	-35.67 - -0.05	-27.63 - 3.38	-16.08 - -1.10
T-Test	t= -4.72 P= 0.005	t= -1.31 P= 0.281	t= -0.30 P= 0.767	t= -1.49 P= 0.274

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.4 7-point glucose daily profile (mg/dl) - after lunch

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	10	19	4
Mean (SD)	219.12 (56.720)	240.19 (51.276)	218.42 (60.384)	212.18 (70.013)
95% CL	[171.70; 266.54]	[203.51; 276.87]	[189.32; 247.53]	[100.77; 323.59]
Min-Max	140.54 - 332	183.79 - 361	132 - 342	120.72 - 275
Median	208.70	232.22	212.00	226.50
Q1-Q3	189.50 -242.00	210.00 -248.65	157.00 -270.00	157.86 -266.50
After 24 weeks				
n	7	6	14	3
Mean (SD)	185.94 (21.333)	147.06 (55.341)	167.95 (45.684)	194.33 (42.442)
95% CL	[166.21; 205.67]	[88.98; 205.13]	[141.58; 194.33]	[88.90; 299.77]
Min-Max	149.55 - 209	50.451 - 206	118 - 275	147 - 229
Median	187.00	145.95	164.00	207.00
Q1-Q3	170.00 -204.00	138.00 -196.00	133.33 -199.00	147.00 -229.00
Change from baseline				
n	6	4	13	3
Mean (SD)	-30.47 (36.317)	-78.13 (88.605)	-28.55 (59.974)	-48.33 (19.502)
95% CL	[-68.59; 7.64]	[-219.12; 62.86]	[-64.79; 7.70]	[-96.78; 0.11]
Min-Max	-83 - 17	-198.2 - 10	-120 - 121	-68 - -29
Median	-29.42	-62.16	-41.00	-48.00
Q1-Q3	-51.00 - -7.00	-140.5 --15.72	-50.00 - -9.00	-68.00 --29.00
T-Test	t= -2.06 P= 0.095	t= -1.76 P= 0.176	t= -1.72 P= 0.112	t= -4.29 P= 0.050
Change from baseline [%]				
n	6	4	13	3
Mean (SD)	-13.10 (15.686)	-33.14 (35.453)	-10.38 (31.651)	-20.19 (7.755)
95% CL	[-29.56; 3.36]	[-89.55; 23.28]	[-29.51; 8.74]	[-39.46; -0.93]
Min-Max	-32.81 - 9.1892	-79.71 - 5.3763	-46.15 - 78.571	-24.73 - -11.24
Median	-13.75	-29.10	-17.04	-24.62
Q1-Q3	-23.85 - -3.61	-57.68 - -8.59	-27.44 - -6.29	-24.73 --11.24
T-Test	t= -2.05 P= 0.096	t= -1.87 P= 0.158	t= -1.18 P= 0.260	t= -4.51 P= 0.046

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.5 7-point glucose daily profile (mg/dl) - before dinner

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	21	4
Mean (SD)	169.72 (41.348)	214.62 (95.617)	189.97 (54.753)	170.57 (50.883)
95% CL	[135.15; 204.29]	[153.86; 275.37]	[165.04; 214.89]	[89.61; 251.54]
Min-Max	112 - 228	93 - 396	117.12 - 296	97.298 - 215
Median	168.00	199.50	178.00	185.00
Q1-Q3	140.16 -200.71	149.17 -260.92	148.00 -241.00	140.15 -201.00
After 24 weeks				
n	7	5	15	3
Mean (SD)	156.20 (36.109)	177.08 (58.464)	162.48 (41.325)	170.33 (20.429)
95% CL	[122.80; 189.59]	[104.49; 249.67]	[139.59; 185.36]	[119.59; 221.08]
Min-Max	111 - 202	122 - 272.07	98 - 226	147 - 185
Median	145.00	176.00	172.00	179.00
Q1-Q3	120.00 -188.00	136.94 -178.38	126.13 -197.00	147.00 -185.00
Change from baseline				
n	6	4	13	3
Mean (SD)	-12.17 (29.902)	-57.17 (58.753)	-22.31 (64.380)	-24.67 (14.742)
95% CL	[-43.55; 19.21]	[-150.65; 36.32]	[-61.21; 16.60]	[-61.29; 11.96]
Min-Max	-36.04 - 28	-95.5 - 29	-164 - 78	-36 - -8
Median	-26.50	-81.08	-12.00	-30.00
Q1-Q3	-36.00 - 24.00	-94.60 --19.73	-54.00 - 9.01	-36.00 - -8.00
T-Test	t= -1.00 P= 0.364	t= -1.95 P= 0.147	t= -1.25 P= 0.235	t= -2.90 P= 0.101
Change from baseline [%]				
n	6	4	13	3
Mean (SD)	-4.45 (19.441)	-15.81 (32.071)	-7.02 (30.737)	-12.63 (7.781)
95% CL	[-24.85; 15.96]	[-66.85; 35.22]	[-25.60; 11.55]	[-31.96; 6.70]
Min-Max	-23.08 - 25	-41.09 - 31.183	-55.41 - 55.319	-19.67 - -4.278
Median	-13.55	-26.68	-8.63	-13.95
Q1-Q3	-16.13 - 14.63	-34.41 - 2.78	-24.81 - 7.69	-19.67 - -4.28
T-Test	t= -0.56 P= 0.600	t= -0.99 P= 0.397	t= -0.82 P= 0.426	t= -2.81 P= 0.107

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.6 7-point glucose daily profile (mg/dl) - after dinner

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	8	20	4
Mean (SD)	217.84 (45.025)	236.08 (61.415)	240.55 (73.800)	217.24 (49.413)
95% CL	[180.20; 255.48]	[184.73; 287.42]	[206.01; 275.09]	[138.62; 295.87]
Min-Max	135.14 - 295	148 - 331	144.15 - 403	172.97 - 272
Median	216.50	230.81	227.00	212.00
Q1-Q3	202.80 -237.00	193.00 -281.00	181.50 -282.50	175.49 -259.00
After 24 weeks				
n	6	5	13	3
Mean (SD)	164.30 (56.587)	204.84 (54.080)	177.93 (46.702)	223.67 (9.815)
95% CL	[104.92; 223.69]	[137.70; 271.99]	[149.71; 206.16]	[199.28; 248.05]
Min-Max	102 - 252	160.36 - 293.7	135.14 - 318	218 - 235
Median	159.50	203.00	170.00	218.00
Q1-Q3	111.00 -201.80	162.16 -205.00	146.00 -188.00	218.00 -235.00
Change from baseline				
n	5	2	12	3
Mean (SD)	-42.56 (60.526)	-20.73 (42.038)	-28.17 (84.002)	-8.33 (42.099)
95% CL	[-117.71; 32.59]	[-398.42; 356.97]	[-81.54; 25.20]	[-112.91; 96.25]
Min-Max	-100 - 35	-50.45 - 9	-211 - 140	-37 - 40
Median	-63.00	-20.73	-10.00	-28.00
Q1-Q3	-92.00 - 7.21	-50.45 - 9.00	-70.50 - 1.00	-37.00 - 40.00
T-Test	t= -1.57 P= 0.191	t= -0.70 P= 0.612	t= -1.16 P= 0.270	t= -0.34 P= 0.764
Change from baseline [%]				
n	5	2	12	3
Mean (SD)	-18.54 (27.289)	-9.57 (20.026)	-7.49 (34.159)	-0.84 (20.217)
95% CL	[-52.42; 15.35]	[-189.49; 170.36]	[-29.19; 14.21]	[-51.06; 49.38]
Min-Max	-47.39 - 16.129	-23.73 - 4.5918	-59.6 - 78.652	-13.6 - 22.472
Median	-27.27	-9.57	-6.16	-11.38
Q1-Q3	-37.86 - 3.70	-23.73 - 4.59	-28.56 - 0.97	-13.60 - 22.47
T-Test	t= -1.52 P= 0.203	t= -0.68 P= 0.622	t= -0.76 P= 0.463	t= -0.07 P= 0.949

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.7 7-point glucose daily profile (mg/dl) - bedtime

	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	7	10	17	3
Mean (SD)	194.45 (40.733)	208.20 (55.070)	203.06 (47.661)	203.33 (28.378)
95% CL	[156.78; 232.12]	[168.81; 247.60]	[178.55; 227.56]	[132.84; 273.83]
Min-Max	142.34 - 248	121 - 267	104 - 274	178 - 234
Median	199.00	218.00	205.00	198.00
Q1-Q3	160.00 -243.00	162.00 -260.00	172.00 -238.00	178.00 -234.00
After 24 weeks				
n	6	6	15	3
Mean (SD)	167.47 (35.747)	141.66 (32.382)	150.94 (29.373)	162.33 (26.026)
95% CL	[129.95; 204.98]	[107.68; 175.64]	[134.68; 167.21]	[97.68; 226.98]
Min-Max	108 - 210.81	90.091 - 180	110 - 215	137 - 189
Median	165.50	141.87	148.00	161.00
Q1-Q3	158.00 -197.00	126.13 -170.00	126.13 -167.00	137.00 -189.00
Change from baseline				
n	5	3	11	3
Mean (SD)	-24.60 (38.819)	-53.38 (65.197)	-33.00 (55.961)	-41.00 (48.662)
95% CL	[-72.80; 23.60]	[-215.34; 108.57]	[-70.59; 4.59]	[-161.88; 79.88]
Min-Max	-79 - 9.0091	-127.9 - -7	-112 - 93	-97 - -9
Median	-9.00	-25.23	-44.00	-17.00
Q1-Q3	-51.00 - 7.00	-127.9 - -7.00	-69.00 - -5.00	-97.00 - -9.00
T-Test	t= -1.42 P= 0.229	t= -1.42 P= 0.292	t= -1.96 P= 0.079	t= -1.46 P= 0.282
Change from baseline [%]				
n	5	3	11	3
Mean (SD)	-9.92 (16.244)	-23.28 (23.944)	-11.28 (37.564)	-18.52 (20.021)
95% CL	[-30.09; 10.24]	[-82.76; 36.20]	[-36.51; 13.96]	[-68.25; 31.22]
Min-Max	-32.51 - 4.4643	-50.35 - -4.895	-43.08 - 89.423	-41.45 - -4.545
Median	-5.39	-14.58	-23.53	-9.55
Q1-Q3	-20.56 - 4.38	-50.35 - -4.90	-36.05 - -2.96	-41.45 - -4.55
T-Test	t= -1.37 P= 0.244	t= -1.68 P= 0.234	t= -1.00 P= 0.343	t= -1.60 P= 0.250

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.2 Change up to approx. 24 weeks after the start of treatment
4.5.8.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	8	12	21	4
Mean (SD)	188.63 (27.418)	210.09 (57.863)	192.80 (40.080)	179.98 (29.807)
95% CL	[165.71; 211.55]	[173.33; 246.86]	[174.56; 211.05]	[132.56; 227.41]
Min-Max	136.94 - 213.5	133.33 - 311	137 - 263	136.94 - 201
Median	198.50	216.50	183.00	191.00
Q1-Q3	169.50 -211.31	155.50 -253.73	166.00 -221.00	159.97 -200.00
After 24 weeks				
n	7	7	16	3
Mean (SD)	161.11 (20.202)	156.03 (16.696)	155.56 (33.348)	168.33 (27.592)
95% CL	[142.43; 179.79]	[140.59; 171.47]	[137.79; 173.33]	[99.79; 236.88]
Min-Max	132 - 188	136 - 180	118 - 250.5	137 - 189
Median	158.00	151.00	147.50	179.00
Q1-Q3	145.00 -179.00	144.15 -176.58	131.46 -174.00	137.00 -189.00
Change from baseline				
n	6	5	14	3
Mean (SD)	-27.72 (15.650)	-36.18 (44.882)	-19.16 (49.020)	-26.00 (17.776)
95% CL	[-44.15; -11.30]	[-91.90; 19.55]	[-47.46; 9.15]	[-70.16; 18.16]
Min-Max	-48 - -9	-80.18 - 25.225	-112 - 96.5	-46 - -12
Median	-30.75	-45.05	-26.50	-20.00
Q1-Q3	-37.84 --10.00	-73.87 - -7.00	-42.00 - -5.00	-46.00 --12.00
T-Test	t= -4.34 P= 0.007	t= -1.80 P= 0.146	t= -1.46 P= 0.167	t= -2.53 P= 0.127
Change from baseline [%]				
n	6	5	14	3
Mean (SD)	-14.04 (7.465)	-14.95 (22.130)	-8.04 (27.612)	-13.72 (10.096)
95% CL	[-21.87; -6.20]	[-42.43; 12.53]	[-23.98; 7.91]	[-38.80; 11.36]
Min-Max	-24.12 - -5.051	-35.46 - 18.919	-43.08 - 62.662	-25.14 - -5.97
Median	-15.93	-23.81	-14.96	-10.05
Q1-Q3	-17.80 - -5.39	-29.50 - -4.90	-22.46 - -2.73	-25.14 - -5.97
T-Test	t= -4.61 P= 0.006	t= -1.51 P= 0.205	t= -1.09 P= 0.296	t= -2.35 P= 0.143

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.8.3.1 Derived Time in Range - dTIR

Percentage within range	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	7	8	16	3
Mean (SD)	44.9 (34.43)	35.7 (32.40)	42.9 (33.40)	28.6 (14.29)
Min-Max	0 - 100	0 - 85.714	0 - 100	14.286 - 42.857
Median	42.9	28.6	42.9	28.6
Q1-Q3	14.3 - 71.4	7.1 - 64.3	7.1 - 64.3	14.3 - 42.9
After 12 weeks				
n	4	7	15	3
Mean (SD)	64.3 (34.01)	69.4 (36.35)	62.9 (28.98)	33.3 (32.99)
Min-Max	14.286 - 85.714	0 - 100	0 - 100	14.286 - 71.429
Median	78.6	85.7	71.4	14.3
Q1-Q3	42.9 - 85.7	42.9 - 100.0	57.1 - 85.7	14.3 - 71.4
After 24 weeks				
n	6	5	11	3
Mean (SD)	76.2 (28.09)	71.4 (26.73)	81.8 (18.17)	57.1 (28.57)
Min-Max	28.571 - 100	42.857 - 100	57.143 - 100	28.571 - 85.714
Median	85.7	57.1	85.7	57.1
Q1-Q3	57.1 - 100.0	57.1 - 100.0	57.1 - 100.0	28.6 - 85.7

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.8.3.2 Derived Time below Range - dTBR

Percentage below range	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	7	8	16	3
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 12 weeks				
n	4	7	15	3
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 24 weeks				
n	6	5	11	3
Mean (SD)	0.0 (0.00)	2.9 (6.39)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 14.286	0 - 0	0 - 0
Median	0.0	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.5.8.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.8.3.3 Derived Time above Range - dTAR

Percentage above range	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	7	8	16	3
Mean (SD)	55.1 (34.43)	64.3 (32.40)	57.1 (33.40)	71.4 (14.29)
Min-Max	0 - 100	14.286 - 100	0 - 100	57.143 - 85.714
Median	57.1	71.4	57.1	71.4
Q1-Q3	28.6 - 85.7	35.7 - 92.9	35.7 - 92.9	57.1 - 85.7
After 12 weeks				
n	4	7	15	3
Mean (SD)	35.7 (34.01)	30.6 (36.35)	37.1 (28.98)	66.7 (32.99)
Min-Max	14.286 - 85.714	0 - 100	0 - 100	28.571 - 85.714
Median	21.4	14.3	28.6	85.7
Q1-Q3	14.3 - 57.1	0.0 - 57.1	14.3 - 42.9	28.6 - 85.7
After 24 weeks				
n	6	5	11	3
Mean (SD)	23.8 (28.09)	25.7 (23.47)	18.2 (18.17)	42.9 (28.57)
Min-Max	0 - 71.429	0 - 42.857	0 - 42.857	14.286 - 71.429
Median	14.3	42.9	14.3	42.9
Q1-Q3	0.0 - 42.9	0.0 - 42.9	0.0 - 42.9	14.3 - 71.4

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.1 7-point glucose daily profile (mg/dl) - before breakfast

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	21
Mean (SD)	191.06 (43.744)	183.33 (9.238)	153.14 (48.419)
95% CL	[169.97; 212.14]	[160.39; 206.28]	[131.10; 175.18]
Min-Max	129.73 - 268	178 - 194	84 - 298
Median	194.60	178.00	145.95
Q1-Q3	144.15 -229.00	178.00 -194.00	122.00 -165.00
After 12 weeks			
n	18	2	21
Mean (SD)	138.63 (40.390)	170.00 (16.971)	135.86 (38.249)
95% CL	[118.55; 158.72]	[17.53; 322.47]	[118.45; 153.27]
Min-Max	81.082 - 241.44	158 - 182	77 - 242
Median	127.50	170.00	126.00
Q1-Q3	111.00 -154.96	158.00 -182.00	115.00 -151.00
Change from baseline			
n	12	2	17
Mean (SD)	-43.62 (57.816)	-8.00 (16.971)	-13.05 (38.100)
95% CL	[-80.35; -6.89]	[-160.47; 144.47]	[-32.64; 6.54]
Min-Max	-168 - 24	-20 - 4	-73.87 - 57
Median	-37.50	-8.00	-17.00
Q1-Q3	-79.00 - 6.31	-20.00 - 4.00	-37.00 - 7.00
T-Test	t= -2.61 P= 0.024	t= -0.67 P= 0.626	t= -1.41 P= 0.177
Change from baseline [%]			
n	12	2	17
Mean (SD)	-20.25 (26.062)	-4.49 (9.534)	-4.83 (27.912)
95% CL	[-36.81; -3.69]	[-90.15; 81.17]	[-19.18; 9.52]
Min-Max	-62.69 - 15.789	-11.24 - 2.2472	-41.56 - 58.763
Median	-24.55	-4.49	-12.14
Q1-Q3	-40.79 - 4.23	-11.24 - 2.25	-18.79 - 4.00
T-Test	t= -2.69 P= 0.021	t= -0.67 P= 0.626	t= -0.71 P= 0.486

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.2 7-point glucose daily profile (mg/dl) - after breakfast

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	20
Mean (SD)	221.37 (62.131)	223.00 (19.975)	198.84 (45.988)
95% CL	[191.42; 251.32]	[173.38; 272.62]	[177.31; 220.36]
Min-Max	90.091 - 320	201 - 240	131.53 - 346
Median	211.00	228.00	194.10
Q1-Q3	192.79 -277.00	201.00 -240.00	167.00 -220.00
After 12 weeks			
n	13	2	20
Mean (SD)	179.83 (39.331)	201.50 (12.021)	188.03 (67.628)
95% CL	[156.07; 203.60]	[93.50; 309.50]	[156.38; 219.68]
Min-Max	109 - 243.25	193 - 210	107 - 440
Median	180.00	201.50	178.00
Q1-Q3	169.37 -199.00	193.00 -210.00	145.50 -194.00
Change from baseline			
n	10	2	15
Mean (SD)	-25.28 (66.511)	-13.00 (7.071)	-20.11 (45.896)
95% CL	[-72.86; 22.30]	[-76.53; 50.53]	[-45.53; 5.31]
Min-Max	-179 - 50.451	-18 - -8	-81 - 86
Median	-15.00	-13.00	-21.00
Q1-Q3	-57.66 - 34.00	-18.00 - -8.00	-61.00 - 6.00
T-Test	t= -1.20 P= 0.260	t= -2.60 P= 0.234	t= -1.70 P= 0.112
Change from baseline [%]			
n	10	2	15
Mean (SD)	-8.27 (25.377)	-5.94 (2.768)	-8.59 (24.795)
95% CL	[-26.43; 9.88]	[-30.81; 18.93]	[-22.32; 5.14]
Min-Max	-57.74 - 26.168	-7.895 - -3.98	-43.09 - 51.807
Median	-7.40	-5.94	-9.87
Q1-Q3	-25.20 - 18.02	-7.89 - -3.98	-29.76 - 3.49
T-Test	t= -1.03 P= 0.329	t= -3.03 P= 0.203	t= -1.34 P= 0.201

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.3 7-point glucose daily profile (mg/dl) - before lunch

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	21
Mean (SD)	181.08 (41.326)	200.33 (20.033)	169.22 (50.513)
95% CL	[161.16; 201.00]	[150.57; 250.10]	[146.22; 192.21]
Min-Max	128 - 260	181 - 221	119 - 324
Median	180.00	199.00	152.00
Q1-Q3	140.00 -210.00	181.00 -221.00	141.00 -180.00
After 12 weeks			
n	17	2	20
Mean (SD)	151.37 (30.943)	190.50 (16.263)	135.09 (33.710)
95% CL	[135.47; 167.28]	[44.38; 336.62]	[119.31; 150.86]
Min-Max	108.11 - 218.02	179 - 202	89 - 214
Median	149.00	190.50	129.00
Q1-Q3	126.00 -171.17	179.00 -202.00	109.50 -149.50
Change from baseline			
n	12	2	17
Mean (SD)	-21.83 (52.531)	0.50 (28.991)	-37.40 (39.974)
95% CL	[-55.20; 11.55]	[-259.98; 260.98]	[-57.95; -16.85]
Min-Max	-124.3 - 43.244	-20 - 21	-138 - 25
Median	-16.71	0.50	-32.00
Q1-Q3	-48.73 - 22.51	-20.00 - 21.00	-53.00 --12.00
T-Test	t= -1.44 P= 0.178	t= 0.02 P= 0.984	t= -3.86 P= 0.001
Change from baseline [%]			
n	12	2	17
Mean (SD)	-8.49 (26.412)	0.78 (15.311)	-19.83 (18.816)
95% CL	[-25.27; 8.29]	[-136.78; 138.34]	[-29.50; -10.16]
Min-Max	-51.11 - 30.882	-10.05 - 11.602	-48.92 - 20.161
Median	-12.26	0.78	-19.75
Q1-Q3	-23.49 - 15.80	-10.05 - 11.60	-35.33 - -7.02
T-Test	t= -1.11 P= 0.289	t= 0.07 P= 0.954	t= -4.35 P= 0.001

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.4 7-point glucose daily profile (mg/dl) - after lunch

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	17	3	20
Mean (SD)	239.93 (66.805)	264.33 (9.292)	202.47 (46.090)
95% CL	[205.58; 274.28]	[241.25; 287.41]	[180.90; 224.04]
Min-Max	120.72 - 361	258 - 275	132 - 283
Median	223.43	260.00	197.00
Q1-Q3	196.40 -287.00	258.00 -275.00	160.50 -231.50
After 12 weeks			
n	13	2	19
Mean (SD)	197.36 (59.671)	224.50 (28.991)	181.64 (27.841)
95% CL	[161.30; 233.42]	[-35.98; 484.98]	[168.22; 195.06]
Min-Max	103 - 293.7	204 - 245	132 - 231
Median	177.00	224.50	182.00
Q1-Q3	165.77 -245.00	204.00 -245.00	156.00 -201.00
Change from baseline			
n	10	2	15
Mean (SD)	-3.65 (56.226)	-42.00 (41.012)	-18.98 (39.091)
95% CL	[-43.87; 36.57]	[-410.48; 326.48]	[-40.62; 2.67]
Min-Max	-78 - 97.298	-71 - -13	-79 - 37
Median	1.41	-42.00	-7.00
Q1-Q3	-57.66 - 34.00	-71.00 --13.00	-57.00 - 16.00
T-Test	t= -0.21 P= 0.842	t= -1.45 P= 0.385	t= -1.88 P= 0.081
Change from baseline [%]			
n	10	2	15
Mean (SD)	1.48 (26.259)	-15.43 (14.693)	-7.13 (19.330)
95% CL	[-17.30; 20.27]	[-147.44; 116.59]	[-17.83; 3.58]
Min-Max	-29.74 - 49.541	-25.82 - -5.039	-32.76 - 22.727
Median	2.90	-15.43	-3.76
Q1-Q3	-21.72 - 21.19	-25.82 - -5.04	-27.71 - 10.39
T-Test	t= 0.18 P= 0.862	t= -1.48 P= 0.377	t= -1.43 P= 0.175

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.5 7-point glucose daily profile (mg/dl) - before dinner

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	20	3	21
Mean (SD)	195.16 (65.164)	232.67 (56.607)	179.58 (68.981)
95% CL	[164.66; 225.65]	[92.05; 373.29]	[148.18; 210.98]
Min-Max	97.298 - 365.77	187 - 296	93 - 396
Median	184.00	215.00	165.00
Q1-Q3	153.28 -235.82	187.00 -296.00	139.00 -183.00
After 12 weeks			
n	16	2	21
Mean (SD)	166.68 (53.336)	193.50 (6.364)	143.73 (34.085)
95% CL	[138.26; 195.10]	[136.32; 250.68]	[128.22; 159.25]
Min-Max	79 - 261	189 - 198	88 - 212
Median	167.00	193.50	135.00
Q1-Q3	122.50 -199.30	189.00 -198.00	117.00 -166.00
Change from baseline			
n	12	2	17
Mean (SD)	-44.36 (77.118)	-7.50 (26.163)	-37.27 (52.573)
95% CL	[-93.36; 4.64]	[-242.56; 227.56]	[-64.30; -10.23]
Min-Max	-171.2 - 86.487	-26 - 11	-190 - 38
Median	-30.52	-7.50	-26.00
Q1-Q3	-92.00 - -6.31	-26.00 - 11.00	-53.00 - -5.00
T-Test	t= -1.99 P= 0.072	t= -0.41 P= 0.755	t= -2.92 P= 0.010
Change from baseline [%]			
n	12	2	17
Mean (SD)	-12.18 (39.442)	-3.11 (12.711)	-15.56 (22.048)
95% CL	[-37.24; 12.88]	[-117.30; 111.09]	[-26.89; -4.22]
Min-Max	-60.73 - 88.889	-12.09 - 5.8824	-48.84 - 40.86
Median	-14.90	-3.11	-17.02
Q1-Q3	-41.15 - -3.89	-12.09 - 5.88	-24.81 - -2.73
T-Test	t= -1.07 P= 0.308	t= -0.35 P= 0.788	t= -2.91 P= 0.010

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.6 7-point glucose daily profile (mg/dl) - after dinner

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	17	3	20
Mean (SD)	250.21 (76.949)	264.33 (15.948)	213.24 (48.347)
95% CL	[210.65; 289.77]	[224.72; 303.95]	[190.61; 235.86]
Min-Max	144.15 - 403	246 - 275	135.14 - 354
Median	240.00	272.00	205.00
Q1-Q3	194.60 -302.00	246.00 -275.00	181.50 -238.50
After 12 weeks			
n	14	2	20
Mean (SD)	203.95 (67.440)	246.50 (16.263)	192.13 (55.482)
95% CL	[165.01; 242.89]	[100.38; 392.62]	[166.16; 218.09]
Min-Max	106.31 - 387.39	235 - 258	142 - 390
Median	199.50	246.50	178.00
Q1-Q3	168.00 -232.00	235.00 -258.00	163.00 -198.00
Change from baseline			
n	10	2	15
Mean (SD)	-40.62 (71.437)	-12.50 (2.121)	-31.74 (51.195)
95% CL	[-91.73; 10.48]	[-31.56; 6.56]	[-60.09; -3.39]
Min-Max	-206 - 54	-14 - -11	-146 - 81
Median	-28.41	-12.50	-31.00
Q1-Q3	-55.00 - -3.60	-14.00 --11.00	-62.00 - 2.00
T-Test	t= -1.80 P= 0.106	t= -8.33 P= 0.076	t= -2.40 P= 0.031
Change from baseline [%]			
n	10	2	15
Mean (SD)	-14.35 (25.045)	-4.81 (0.478)	-12.42 (21.345)
95% CL	[-32.27; 3.56]	[-9.10; -0.52]	[-24.24; -0.60]
Min-Max	-62.24 - 30.337	-5.147 - -4.472	-41.24 - 44.505
Median	-14.25	-4.81	-15.79
Q1-Q3	-26.25 - -1.44	-5.15 - -4.47	-26.50 - 1.01
T-Test	t= -1.81 P= 0.103	t=-14.24 P= 0.045	t= -2.25 P= 0.041

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.7 7-point glucose daily profile (mg/dl) - bedtime

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	13	3	20
Mean (SD)	221.68 (38.432)	212.00 (42.755)	186.67 (46.953)
95% CL	[198.45; 244.90]	[105.79; 318.21]	[164.69; 208.64]
Min-Max	121 - 263	178 - 260	104 - 274
Median	230.00	198.00	172.00
Q1-Q3	201.80 -248.00	178.00 -260.00	154.50 -211.50
After 12 weeks			
n	11	2	20
Mean (SD)	161.17 (47.784)	183.00 (2.828)	168.89 (46.451)
95% CL	[129.07; 193.27]	[157.59; 208.41]	[147.15; 190.63]
Min-Max	100 - 245.05	181 - 185	79 - 310
Median	165.00	183.00	167.00
Q1-Q3	120.00 -204.00	181.00 -185.00	152.50 -185.00
Change from baseline			
n	6	2	15
Mean (SD)	-82.17 (52.901)	-5.00 (16.971)	-8.68 (47.349)
95% CL	[-137.68; -26.65]	[-157.47; 147.47]	[-34.90; 17.54]
Min-Max	-140 - 9.0091	-17 - 7	-95 - 110
Median	-83.50	-5.00	-8.00
Q1-Q3	-128.0 --67.00	-17.00 - 7.00	-40.00 - 7.00
T-Test	t= -3.80 P= 0.013	t= -0.42 P= 0.749	t= -0.71 P= 0.489
Change from baseline [%]			
n	6	2	15
Mean (SD)	-34.00 (21.522)	-2.33 (8.852)	-1.51 (34.029)
95% CL	[-56.58; -11.41]	[-81.86; 77.20]	[-20.35; 17.34]
Min-Max	-53.85 - 4.4643	-8.586 - 3.9326	-44.76 - 105.77
Median	-36.09	-2.33	-4.04
Q1-Q3	-53.78 --28.63	-8.59 - 3.93	-23.26 - 4.38
T-Test	t= -3.87 P= 0.012	t= -0.37 P= 0.773	t= -0.17 P= 0.866

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.1 Change up to approx. 12 weeks after the start of treatment
4.5.9.1.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	20	3	21
Mean (SD)	201.48 (45.100)	220.00 (34.655)	184.91 (41.277)
95% CL	[180.38; 222.59]	[133.91; 306.09]	[166.12; 203.70]
Min-Max	133.33 - 275	199 - 260	136.94 - 311
Median	210.00	201.00	172.00
Q1-Q3	164.54 -236.04	199.00 -260.00	166.00 -199.00
After 12 weeks			
n	18	2	21
Mean (SD)	158.28 (34.769)	195.50 (3.536)	161.53 (28.427)
95% CL	[140.99; 175.57]	[163.73; 227.27]	[148.59; 174.47]
Min-Max	106.5 - 241.44	193 - 198	117 - 242
Median	158.28	195.50	163.00
Q1-Q3	133.00 -180.00	193.00 -198.00	145.00 -170.00
Change from baseline			
n	13	2	17
Mean (SD)	-28.97 (46.616)	-4.50 (4.950)	-24.06 (29.356)
95% CL	[-57.14; -0.80]	[-48.97; 39.97]	[-39.16; -8.97]
Min-Max	-155 - 25.225	-8 - -1	-78 - 14
Median	-25.00	-4.50	-8.00
Q1-Q3	-36.94 - -7.21	-8.00 - -1.00	-45.05 - -5.00
T-Test	t= -2.24 P= 0.045	t= -1.29 P= 0.421	t= -3.38 P= 0.004
Change from baseline [%]			
n	13	2	17
Mean (SD)	-12.40 (19.658)	-2.24 (2.459)	-11.67 (13.961)
95% CL	[-24.28; -0.52]	[-24.33; 19.85]	[-18.85; -4.50]
Min-Max	-56.36 - 18.421	-3.98 - -0.503	-39.2 - 10.219
Median	-13.66	-2.24	-5.59
Q1-Q3	-22.86 - -3.39	-3.98 - -0.50	-23.03 - -2.91
T-Test	t= -2.27 P= 0.042	t= -1.29 P= 0.420	t= -3.45 P= 0.003

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.1 7-point glucose daily profile (mg/dl) - before breakfast

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	21
Mean (SD)	191.06 (43.744)	183.33 (9.238)	153.14 (48.419)
95% CL	[169.97; 212.14]	[160.39; 206.28]	[131.10; 175.18]
Min-Max	129.73 - 268	178 - 194	84 - 298
Median	194.60	178.00	145.95
Q1-Q3	144.15 -229.00	178.00 -194.00	122.00 -165.00
After 24 weeks			
n	11	3	18
Mean (SD)	144.46 (20.310)	164.00 (10.440)	132.92 (27.532)
95% CL	[130.81; 158.10]	[138.06; 189.94]	[119.23; 146.61]
Min-Max	118 - 178	157 - 176	98 - 191
Median	136.94	159.00	129.00
Q1-Q3	132.00 -158.56	157.00 -176.00	109.00 -141.00
Change from baseline			
n	8	3	15
Mean (SD)	-31.56 (51.287)	-19.33 (1.528)	-12.83 (38.432)
95% CL	[-74.43; 11.32]	[-23.13; -15.54]	[-34.11; 8.45]
Min-Max	-106 - 26	-21 - -18	-77.48 - 94
Median	-15.50	-19.00	-18.00
Q1-Q3	-78.83 - 8.11	-21.00 --18.00	-34.00 - -4.00
T-Test	t= -1.74 P= 0.125	t=-21.92 P= 0.002	t= -1.29 P= 0.217
Change from baseline [%]			
n	8	3	15
Mean (SD)	-13.36 (24.309)	-10.58 (1.262)	-5.67 (31.709)
95% CL	[-33.68; 6.96]	[-13.72; -7.45]	[-23.23; 11.89]
Min-Max	-46.9 - 17.333	-11.8 - -9.278	-35.54 - 96.907
Median	-9.96	-10.67	-13.50
Q1-Q3	-34.75 - 6.05	-11.80 - -9.28	-20.36 - -2.33
T-Test	t= -1.55 P= 0.164	t=-14.52 P= 0.005	t= -0.69 P= 0.500

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.2 7-point glucose daily profile (mg/dl) - after breakfast

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	20
Mean (SD)	221.37 (62.131)	223.00 (19.975)	198.84 (45.988)
95% CL	[191.42; 251.32]	[173.38; 272.62]	[177.31; 220.36]
Min-Max	90.091 - 320	201 - 240	131.53 - 346
Median	211.00	228.00	194.10
Q1-Q3	192.79 -277.00	201.00 -240.00	167.00 -220.00
After 24 weeks			
n	8	3	15
Mean (SD)	162.71 (33.309)	183.67 (33.546)	187.34 (59.934)
95% CL	[134.86; 190.56]	[100.33; 267.00]	[154.15; 220.53]
Min-Max	127 - 224	145 - 205	97 - 368
Median	159.89	201.00	178.00
Q1-Q3	134.96 -180.49	145.00 -205.00	160.00 -195.00
Change from baseline			
n	7	3	13
Mean (SD)	-49.20 (39.248)	-39.33 (50.639)	-7.93 (63.926)
95% CL	[-85.50; -12.91]	[-165.13; 86.46]	[-46.56; 30.70]
Min-Max	-100.9 - 26	-95 - 4	-91 - 152
Median	-53.00	-27.00	-39.00
Q1-Q3	-70.27 --32.00	-95.00 - 4.00	-45.05 - 10.00
T-Test	t= -3.32 P= 0.016	t= -1.35 P= 0.311	t= -0.45 P= 0.663
Change from baseline [%]			
n	7	3	13
Mean (SD)	-22.31 (17.779)	-16.48 (21.171)	-3.41 (31.840)
95% CL	[-38.75; -5.86]	[-69.07; 36.11]	[-22.65; 15.83]
Min-Max	-44.09 - 13.131	-39.58 - 1.99	-48.4 - 70.37
Median	-26.77	-11.84	-18.67
Q1-Q3	-29.44 --15.17	-39.58 - 1.99	-23.81 - 4.65
T-Test	t= -3.32 P= 0.016	t= -1.35 P= 0.310	t= -0.39 P= 0.706

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.3 7-point glucose daily profile (mg/dl) - before lunch

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	19	3	21
Mean (SD)	181.08 (41.326)	200.33 (20.033)	169.22 (50.513)
95% CL	[161.16; 201.00]	[150.57; 250.10]	[146.22; 192.21]
Min-Max	128 - 260	181 - 221	119 - 324
Median	180.00	199.00	152.00
Q1-Q3	140.00 -210.00	181.00 -221.00	141.00 -180.00
After 24 weeks			
n	10	3	18
Mean (SD)	135.94 (26.877)	167.33 (11.504)	146.66 (40.023)
95% CL	[116.71; 155.17]	[138.76; 195.91]	[126.76; 166.57]
Min-Max	96 - 172.97	156 - 179	110 - 274
Median	131.50	167.00	138.97
Q1-Q3	112.00 -163.00	156.00 -179.00	112.00 -164.00
Change from baseline			
n	8	3	15
Mean (SD)	-34.85 (41.365)	-33.00 (31.512)	-9.84 (47.679)
95% CL	[-69.43; -0.27]	[-111.28; 45.28]	[-36.25; 16.56]
Min-Max	-118.9 - 5	-65 - -2	-61 - 124
Median	-23.71	-32.00	-25.00
Q1-Q3	-54.73 - -4.00	-65.00 - -2.00	-41.00 - -1.00
T-Test	t= -2.38 P= 0.049	t= -1.81 P= 0.211	t= -0.80 P= 0.437
Change from baseline [%]			
n	8	3	15
Mean (SD)	-16.84 (16.836)	-15.53 (14.161)	-4.89 (31.230)
95% CL	[-30.92; -2.77]	[-50.71; 19.65]	[-22.19; 12.40]
Min-Max	-48.89 - 3.3784	-29.41 - -1.105	-32.1 - 82.667
Median	-17.73	-16.08	-17.48
Q1-Q3	-24.23 - -2.67	-29.41 - -1.10	-27.15 - -0.76
T-Test	t= -2.83 P= 0.025	t= -1.90 P= 0.198	t= -0.61 P= 0.554

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.4 7-point glucose daily profile (mg/dl) - after lunch

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	17	3	20
Mean (SD)	239.93 (66.805)	264.33 (9.292)	202.47 (46.090)
95% CL	[205.58; 274.28]	[241.25; 287.41]	[180.90; 224.04]
Min-Max	120.72 - 361	258 - 275	132 - 283
Median	223.43	260.00	197.00
Q1-Q3	196.40 -287.00	258.00 -275.00	160.50 -231.50
After 24 weeks			
n	8	3	18
Mean (SD)	141.67 (47.020)	192.00 (46.357)	181.07 (38.558)
95% CL	[102.36; 180.98]	[76.84; 307.16]	[161.90; 200.25]
Min-Max	50.451 - 209	140 - 229	118 - 275
Median	140.50	207.00	182.50
Q1-Q3	128.17 -168.28	140.00 -229.00	160.00 -202.00
Change from baseline			
n	7	3	15
Mean (SD)	-58.73 (68.343)	-72.33 (45.654)	-20.03 (51.226)
95% CL	[-121.94; 4.47]	[-185.75; 41.08]	[-48.40; 8.34]
Min-Max	-198.2 - -7	-120 - -29	-83 - 121
Median	-46.85	-68.00	-41.00
Q1-Q3	-90.09 - -9.00	-120.0 --29.00	-50.00 - 10.00
T-Test	t= -2.27 P= 0.063	t= -2.74 P= 0.111	t= -1.51 P= 0.152
Change from baseline [%]			
n	7	3	15
Mean (SD)	-26.26 (27.107)	-27.37 (17.607)	-7.00 (28.127)
95% CL	[-51.33; -1.19]	[-71.11; 16.36]	[-22.58; 8.57]
Min-Max	-79.71 - -3.608	-46.15 - -11.24	-32.81 - 78.571
Median	-23.85	-24.73	-17.04
Q1-Q3	-40.32 - -5.43	-46.15 --11.24	-23.81 - 5.38
T-Test	t= -2.56 P= 0.043	t= -2.69 P= 0.115	t= -0.96 P= 0.351

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.5 7-point glucose daily profile (mg/dl) - before dinner

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	20	3	21
Mean (SD)	195.16 (65.164)	232.67 (56.607)	179.58 (68.981)
95% CL	[164.66; 225.65]	[92.05; 373.29]	[148.18; 210.98]
Min-Max	97.298 - 365.77	187 - 296	93 - 396
Median	184.00	215.00	165.00
Q1-Q3	153.28 -235.82	187.00 -296.00	139.00 -183.00
After 24 weeks			
n	10	3	16
Mean (SD)	184.56 (40.432)	165.33 (29.023)	153.02 (40.320)
95% CL	[155.64; 213.48]	[93.24; 237.43]	[131.54; 174.51]
Min-Max	126.13 - 272.07	132 - 185	98 - 226
Median	184.69	179.00	142.50
Q1-Q3	155.00 -202.00	132.00 -185.00	121.00 -178.19
Change from baseline			
n	8	3	14
Mean (SD)	-30.22 (46.647)	-67.33 (84.435)	-9.03 (45.231)
95% CL	[-69.21; 8.78]	[-277.08; 142.42]	[-35.15; 17.08]
Min-Max	-98 - 24	-164 - -8	-68.47 - 78
Median	-31.00	-30.00	-17.00
Q1-Q3	-64.87 - 12.00	-164.0 - -8.00	-36.00 - 28.00
T-Test	t= -1.83 P= 0.110	t= -1.38 P= 0.301	t= -0.75 P= 0.468
Change from baseline [%]			
n	8	3	14
Mean (SD)	-9.96 (18.917)	-24.55 (27.160)	-1.77 (28.229)
95% CL	[-25.77; 5.86]	[-92.01; 42.92]	[-18.06; 14.53]
Min-Max	-38.74 - 14.634	-55.41 - -4.278	-30.68 - 55.319
Median	-13.77	-13.95	-12.17
Q1-Q3	-22.64 - 8.62	-55.41 - -4.28	-24.32 - 25.00
T-Test	t= -1.49 P= 0.180	t= -1.57 P= 0.258	t= -0.23 P= 0.819

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.6 7-point glucose daily profile (mg/dl) - after dinner

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	17	3	20
Mean (SD)	250.21 (76.949)	264.33 (15.948)	213.24 (48.347)
95% CL	[210.65; 289.77]	[224.72; 303.95]	[190.61; 235.86]
Min-Max	144.15 - 403	246 - 275	135.14 - 354
Median	240.00	272.00	205.00
Q1-Q3	194.60 -302.00	246.00 -275.00	181.50 -238.50
After 24 weeks			
n	7	3	16
Mean (SD)	198.81 (60.482)	208.33 (32.593)	176.07 (48.185)
95% CL	[142.87; 254.74]	[127.37; 289.30]	[150.40; 201.75]
Min-Max	135.14 - 293.7	172 - 235	102 - 318
Median	201.80	218.00	169.00
Q1-Q3	145.00 -252.00	172.00 -235.00	155.50 -194.50
Change from baseline			
n	5	3	14
Mean (SD)	-4.36 (54.516)	-56.00 (40.951)	-30.53 (78.168)
95% CL	[-72.05; 63.33]	[-157.73; 45.73]	[-75.67; 14.60]
Min-Max	-95 - 40	-103 - -28	-211 - 140
Median	7.21	-37.00	-15.50
Q1-Q3	-9.01 - 35.00	-103.0 --28.00	-63.00 - 7.00
T-Test	t= -0.18 P= 0.867	t= -2.37 P= 0.141	t= -1.46 P= 0.168
Change from baseline [%]			
n	5	3	14
Mean (SD)	-0.71 (24.404)	-20.81 (14.455)	-9.88 (32.982)
95% CL	[-31.01; 29.60]	[-56.72; 15.09]	[-28.92; 9.17]
Min-Max	-39.58 - 22.472	-37.45 - -11.38	-59.6 - 78.652
Median	3.70	-13.60	-8.53
Q1-Q3	-6.25 - 16.13	-37.45 --11.38	-27.27 - 4.58
T-Test	t= -0.06 P= 0.952	t= -2.49 P= 0.130	t= -1.12 P= 0.283

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.7 7-point glucose daily profile (mg/dl) - bedtime

	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	13	3	20
Mean (SD)	221.68 (38.432)	212.00 (42.755)	186.67 (46.953)
95% CL	[198.45; 244.90]	[105.79; 318.21]	[164.69; 208.64]
Min-Max	121 - 263	178 - 260	104 - 274
Median	230.00	198.00	172.00
Q1-Q3	201.80 -248.00	178.00 -260.00	154.50 -211.50
After 24 weeks			
n	9	3	17
Mean (SD)	154.56 (43.304)	166.00 (20.952)	152.40 (25.348)
95% CL	[121.27; 187.85]	[113.95; 218.05]	[139.36; 165.43]
Min-Max	90.091 - 215	148 - 189	108 - 197
Median	143.00	161.00	158.00
Q1-Q3	126.13 -197.00	148.00 -189.00	136.00 -167.00
Change from baseline			
n	5	3	13
Mean (SD)	-50.40 (39.014)	-46.00 (57.297)	-19.33 (46.776)
95% CL	[-98.84; -1.96]	[-188.33; 96.33]	[-47.59; 8.94]
Min-Max	-97 - 9.0091	-112 - -9	-82 - 93
Median	-51.00	-17.00	-25.00
Q1-Q3	-69.00 --44.00	-112.0 - -9.00	-51.00 - -5.00
T-Test	t= -2.89 P= 0.045	t= -1.39 P= 0.299	t= -1.49 P= 0.162
Change from baseline [%]			
n	5	3	13
Mean (SD)	-22.58 (17.157)	-19.06 (20.951)	-6.05 (32.857)
95% CL	[-43.88; -1.27]	[-71.10; 32.99]	[-25.91; 13.80]
Min-Max	-41.45 - 4.4643	-43.08 - -4.545	-37.79 - 89.423
Median	-23.53	-9.55	-14.53
Q1-Q3	-31.80 --20.56	-43.08 - -4.55	-24.88 - -2.96
T-Test	t= -2.94 P= 0.042	t= -1.58 P= 0.256	t= -0.66 P= 0.519

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.2 Change up to approx. 24 weeks after the start of treatment
4.5.9.2.8 Median of 7-point glucose daily profile (mg/dl)

Median of daily 7-point glucose	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	20	3	21
Mean (SD)	201.48 (45.100)	220.00 (34.655)	184.91 (41.277)
95% CL	[180.38; 222.59]	[133.91; 306.09]	[166.12; 203.70]
Min-Max	133.33 - 275	199 - 260	136.94 - 311
Median	210.00	201.00	172.00
Q1-Q3	164.54 -236.04	199.00 -260.00	166.00 -199.00
After 24 weeks			
n	11	3	18
Mean (SD)	155.03 (21.729)	172.00 (21.378)	158.15 (31.031)
95% CL	[140.43; 169.63]	[118.90; 225.10]	[142.72; 173.58]
Min-Max	126 - 188	148 - 189	118 - 250.5
Median	150.50	179.00	151.00
Q1-Q3	137.00 -176.58	148.00 -189.00	136.00 -177.00
Change from baseline			
n	9	3	15
Mean (SD)	-26.86 (28.526)	-48.00 (55.570)	-15.17 (40.974)
95% CL	[-48.78; -4.93]	[-186.04; 90.04]	[-37.86; 7.52]
Min-Max	-73.87 - 25.225	-112 - -12	-54 - 96.5
Median	-34.50	-20.00	-27.00
Q1-Q3	-42.00 --10.00	-112.0 --12.00	-45.05 - -5.00
T-Test	t= -2.82 P= 0.022	t= -1.50 P= 0.273	t= -1.43 P= 0.174
Change from baseline [%]			
n	9	3	15
Mean (SD)	-12.51 (14.592)	-19.70 (20.348)	-7.03 (25.380)
95% CL	[-23.72; -1.29]	[-70.25; 30.85]	[-21.09; 7.02]
Min-Max	-29.5 - 18.919	-43.08 - -5.97	-31.4 - 62.662
Median	-16.16	-10.05	-15.70
Q1-Q3	-22.46 - -5.05	-43.08 - -5.97	-22.62 - -2.73
T-Test	t= -2.57 P= 0.033	t= -1.68 P= 0.236	t= -1.07 P= 0.301

Changes are calculated only for patients with values available on both visits

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.9.3.1 Derived Time in Range - dTIR

Percentage within range	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	12	3	19
Mean (SD)	20.2 (26.17)	14.3 (14.29)	57.1 (26.08)
Min-Max	0 - 85.714	0 - 28.571	0 - 100
Median	14.3	14.3	57.1
Q1-Q3	0.0 - 35.7	0.0 - 28.6	42.9 - 71.4
After 12 weeks			
n	9	2	18
Mean (SD)	55.6 (28.97)	14.3 (0.00)	69.8 (30.16)
Min-Max	0 - 85.714	14.286 - 14.286	0 - 100
Median	71.4	14.3	85.7
Q1-Q3	57.1 - 71.4	14.3 - 14.3	57.1 - 85.7
After 24 weeks			
n	7	3	14
Mean (SD)	69.4 (27.88)	61.9 (35.95)	79.6 (18.34)
Min-Max	28.571 - 100	28.571 - 100	57.143 - 100
Median	71.4	57.1	85.7
Q1-Q3	42.9 - 100.0	28.6 - 100.0	57.1 - 100.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.9.3.2 Derived Time below Range - dTBR

Percentage below range	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	12	3	19
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 12 weeks			
n	9	2	18
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 0	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
After 24 weeks			
n	7	3	14
Mean (SD)	2.0 (5.40)	0.0 (0.00)	0.0 (0.00)
Min-Max	0 - 14.286	0 - 0	0 - 0
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.5 Absolute and relative change in glucose in the 7-point glucose daily profile
4.5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.5.9.3 Derived Time in Range on base of the 7-point glucose daily profile
4.5.9.3.3 Derived Time above Range - dTAR

Percentage above range	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	12	3	19
Mean (SD)	79.8 (26.17)	85.7 (14.29)	42.9 (26.08)
Min-Max	14.286 - 100	71.429 - 100	0 - 100
Median	85.7	85.7	42.9
Q1-Q3	64.3 - 100.0	71.4 - 100.0	28.6 - 57.1
After 12 weeks			
n	9	2	18
Mean (SD)	44.4 (28.97)	85.7 (0.00)	30.2 (30.16)
Min-Max	14.286 - 100	85.714 - 85.714	0 - 100
Median	28.6	85.7	14.3
Q1-Q3	28.6 - 42.9	85.7 - 85.7	14.3 - 42.9
After 24 weeks			
n	7	3	14
Mean (SD)	28.6 (26.08)	38.1 (35.95)	20.4 (18.34)
Min-Max	0 - 71.429	0 - 71.429	0 - 42.857
Median	28.6	42.9	14.3
Q1-Q3	0.0 - 42.9	0.0 - 71.4	0.0 - 42.9

Only patients from whom 7 measurements are documented

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.1 Full Analysis Set - FGM - SMBG
4.6.1.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 12 weeks			
n	65	20	45
Mean (SD)	40.11 (9.753)	41.65 (9.149)	39.42 (10.033)
95% CL	[37.69; 42.52]	[37.37; 45.93]	[36.41; 42.44]
Min-Max	14 - 60	30 - 60	14 - 60
Median	38.00	39.00	36.00
Q1-Q3	34.00 - 48.00	34.50 - 50.00	34.00 - 42.00
Change from baseline			
n	65	20	45
Mean (SD)	10.11 (9.753)	11.65 (9.149)	9.42 (10.033)
95% CL	[7.69; 12.52]	[7.37; 15.93]	[6.41; 12.44]
Min-Max	-16 - 30	0 - 30	-16 - 30
Median	8.00	9.00	6.00
Q1-Q3	4.00 - 18.00	4.50 - 20.00	4.00 - 12.00
T-Test	t= 8.36 P= 0.000	t= 5.69 P= 0.000	t= 6.30 P= 0.000
Change from baseline [%]			
n	65	20	45
Mean (SD)	33.69 (32.511)	38.83 (30.498)	31.41 (33.443)
95% CL	[25.64; 41.75]	[24.56; 53.11]	[21.36; 41.45]
Min-Max	-53.33 - 100	0 - 100	-53.33 - 100
Median	26.67	30.00	20.00
Q1-Q3	13.33 - 60.00	15.00 - 66.67	13.33 - 40.00
T-Test	t= 8.36 P= 0.000	t= 5.69 P= 0.000	t= 6.30 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.1 Full Analysis Set - FGM - SMBG
4.6.1.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	70	20	50
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 24 weeks			
n	64	20	44
Mean (SD)	41.14 (9.518)	43.30 (9.755)	40.16 (9.356)
95% CL	[38.76; 43.52]	[38.73; 47.87]	[37.31; 43.00]
Min-Max	10 - 60	30 - 60	10 - 60
Median	40.00	41.00	39.00
Q1-Q3	35.50 - 48.00	35.50 - 50.00	35.50 - 46.00
Change from baseline			
n	64	20	44
Mean (SD)	11.14 (9.518)	13.30 (9.755)	10.16 (9.356)
95% CL	[8.76; 13.52]	[8.73; 17.87]	[7.31; 13.00]
Min-Max	-20 - 30	0 - 30	-20 - 30
Median	10.00	11.00	9.00
Q1-Q3	5.50 - 18.00	5.50 - 20.00	5.50 - 16.00
T-Test	t= 9.36 P= 0.000	t= 6.10 P= 0.000	t= 7.20 P= 0.000
Change from baseline [%]			
n	64	20	44
Mean (SD)	37.14 (31.728)	44.33 (32.518)	33.86 (31.186)
95% CL	[29.21; 45.06]	[29.11; 59.55]	[24.38; 43.35]
Min-Max	-66.67 - 100	0 - 100	-66.67 - 100
Median	33.33	36.67	30.00
Q1-Q3	18.33 - 60.00	18.33 - 66.67	18.33 - 53.33
T-Test	t= 9.36 P= 0.000	t= 6.10 P= 0.000	t= 7.20 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.1 Full Analysis Set - FGM - SMBG
4.6.1.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
After 4 weeks			
n	53	16	37
Mean (SD)	2.32 (3.975)	3.63 (5.807)	1.76 (2.773)
95% CL	[1.23; 3.42]	[0.53; 6.72]	[0.83; 2.68]
Min-Max	0 - 20	0 - 20	0 - 13
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 3.00	0.00 - 4.00	0.00 - 2.00
After 8 weeks			
n	52	16	36
Mean (SD)	0.98 (1.488)	0.81 (1.559)	1.06 (1.472)
95% CL	[0.57; 1.40]	[-0.02; 1.64]	[0.56; 1.55]
Min-Max	0 - 6	0 - 6	0 - 5
Median	0.00	0.00	0.50
Q1-Q3	0.00 - 1.50	0.00 - 1.00	0.00 - 2.00
After 12 weeks			
n	63	20	43
Mean (SD)	1.76 (3.025)	1.60 (2.909)	1.84 (3.109)
95% CL	[1.00; 2.52]	[0.24; 2.96]	[0.88; 2.79]
Min-Max	0 - 18	0 - 10	0 - 18
Median	1.00	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 1.50	0.00 - 2.00
After 16 weeks			
n	48	16	32
Mean (SD)	0.35 (0.601)	0.25 (0.447)	0.41 (0.665)
95% CL	[0.18; 0.53]	[0.01; 0.49]	[0.17; 0.65]
Min-Max	0 - 2	0 - 1	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 0.50	0.00 - 1.00
After 20 weeks			
n	49	16	33
Mean (SD)	0.29 (0.612)	0.19 (0.544)	0.33 (0.645)
95% CL	[0.11; 0.46]	[-0.10; 0.48]	[0.10; 0.56]
Min-Max	0 - 2	0 - 2	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00	0.00 - 0.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.1 Full Analysis Set - FGM - SMBG
4.6.1.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
After 24 weeks			
n	64	19	45
Mean (SD)	1.58 (6.794)	0.53 (1.172)	2.02 (8.052)
95% CL	[-0.12; 3.28]	[-0.04; 1.09]	[-0.40; 4.44]
Min-Max	0 - 54	0 - 4	0 - 54
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 0.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.2 Full Analysis Set - Subgroups - Gender
4.6.2.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 12 weeks		
n	27	38
Mean (SD)	38.81 (9.907)	41.03 (9.669)
95% CL	[34.90; 42.73]	[37.85; 44.20]
Min-Max	14 - 60	22 - 60
Median	36.00	38.00
Q1-Q3	34.00 - 42.00	35.00 - 50.00
Change from baseline		
n	27	38
Mean (SD)	8.81 (9.907)	11.03 (9.669)
95% CL	[4.90; 12.73]	[7.85; 14.20]
Min-Max	-16 - 30	-8 - 30
Median	6.00	8.00
Q1-Q3	4.00 - 12.00	5.00 - 20.00
T-Test	t= 4.62 P= 0.000	t= 7.03 P= 0.000
Change from baseline [%]		
n	27	38
Mean (SD)	29.38 (33.025)	36.75 (32.229)
95% CL	[16.32; 42.45]	[26.16; 47.35]
Min-Max	-53.33 - 100	-26.67 - 100
Median	20.00	26.67
Q1-Q3	13.33 - 40.00	16.67 - 66.67
T-Test	t= 4.62 P= 0.000	t= 7.03 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.2 Full Analysis Set - Subgroups - Gender
4.6.2.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	Female (N = 28)	Male (N = 42)
Baseline		
n	28	42
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 24 weeks		
n	24	40
Mean (SD)	38.96 (10.642)	42.45 (8.653)
95% CL	[34.46; 43.45]	[39.68; 45.22]
Min-Max	10 - 60	26 - 60
Median	39.00	40.00
Q1-Q3	35.00 - 45.00	36.00 - 48.00
Change from baseline		
n	24	40
Mean (SD)	8.96 (10.642)	12.45 (8.653)
95% CL	[4.46; 13.45]	[9.68; 15.22]
Min-Max	-20 - 30	-4 - 30
Median	9.00	10.00
Q1-Q3	5.00 - 15.00	6.00 - 18.00
T-Test	t= 4.12 P= 0.000	t= 9.10 P= 0.000
Change from baseline [%]		
n	24	40
Mean (SD)	29.86 (35.474)	41.50 (28.842)
95% CL	[14.88; 44.84]	[32.28; 50.72]
Min-Max	-66.67 - 100	-13.33 - 100
Median	30.00	33.33
Q1-Q3	16.67 - 50.00	20.00 - 60.00
T-Test	t= 4.12 P= 0.000	t= 9.10 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.2 Full Analysis Set - Subgroups - Gender
4.6.2.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	Female (N = 28)	Male (N = 42)
After 4 weeks		
n	24	29
Mean (SD)	1.13 (2.232)	3.31 (4.797)
95% CL	[0.18; 2.07]	[1.49; 5.13]
Min-Max	0 - 10	0 - 20
Median	0.00	2.00
Q1-Q3	0.00 - 1.00	0.00 - 4.00
After 8 weeks		
n	23	29
Mean (SD)	0.78 (1.278)	1.14 (1.642)
95% CL	[0.23; 1.34]	[0.51; 1.76]
Min-Max	0 - 5	0 - 6
Median	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
After 12 weeks		
n	27	36
Mean (SD)	2.41 (3.954)	1.28 (2.009)
95% CL	[0.84; 3.97]	[0.60; 1.96]
Min-Max	0 - 18	0 - 10
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
After 16 weeks		
n	21	27
Mean (SD)	0.19 (0.512)	0.48 (0.643)
95% CL	[-0.04; 0.42]	[0.23; 0.74]
Min-Max	0 - 2	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00
After 20 weeks		
n	21	28
Mean (SD)	0.05 (0.218)	0.46 (0.744)
95% CL	[-0.05; 0.15]	[0.18; 0.75]
Min-Max	0 - 1	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.2 Full Analysis Set - Subgroups - Gender
4.6.2.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	Female (N = 28)	Male (N = 42)
After 24 weeks		
n	25	39
Mean (SD)	2.64 (10.751)	0.90 (1.518)
95% CL	[-1.80; 7.08]	[0.41; 1.39]
Min-Max	0 - 54	0 - 8
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.3 Full Analysis Set - Subgroups - Age groups
4.6.3.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 12 weeks			
n	23	22	20
Mean (SD)	43.17 (9.178)	41.95 (11.206)	34.55 (6.022)
95% CL	[39.20; 47.14]	[36.99; 46.92]	[31.73; 37.37]
Min-Max	30 - 60	14 - 60	22 - 54
Median	42.00	40.00	35.50
Q1-Q3	36.00 - 50.00	35.00 - 50.00	31.00 - 36.00
Change from baseline			
n	23	22	20
Mean (SD)	13.17 (9.178)	11.95 (11.206)	4.55 (6.022)
95% CL	[9.20; 17.14]	[6.99; 16.92]	[1.73; 7.37]
Min-Max	0 - 30	-16 - 30	-8 - 24
Median	12.00	10.00	5.50
Q1-Q3	6.00 - 20.00	5.00 - 20.00	1.00 - 6.00
T-Test	t= 6.88 P= 0.000	t= 5.00 P= 0.000	t= 3.38 P= 0.003
Change from baseline [%]			
n	23	22	20
Mean (SD)	43.91 (30.594)	39.85 (37.353)	15.17 (20.072)
95% CL	[30.68; 57.14]	[23.29; 56.41]	[5.77; 24.56]
Min-Max	0 - 100	-53.33 - 100	-26.67 - 80
Median	40.00	33.33	18.33
Q1-Q3	20.00 - 66.67	16.67 - 66.67	3.33 - 20.00
T-Test	t= 6.88 P= 0.000	t= 5.00 P= 0.000	t= 3.38 P= 0.003

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.3 Full Analysis Set - Subgroups - Age groups
4.6.3.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	22
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 24 weeks			
n	23	21	20
Mean (SD)	43.35 (8.947)	42.33 (11.302)	37.35 (7.118)
95% CL	[39.48; 47.22]	[37.19; 47.48]	[34.02; 40.68]
Min-Max	30 - 60	10 - 60	22 - 60
Median	40.00	40.00	38.00
Q1-Q3	36.00 - 50.00	36.00 - 50.00	35.00 - 38.00
Change from baseline			
n	23	21	20
Mean (SD)	13.35 (8.947)	12.33 (11.302)	7.35 (7.118)
95% CL	[9.48; 17.22]	[7.19; 17.48]	[4.02; 10.68]
Min-Max	0 - 30	-20 - 30	-8 - 30
Median	10.00	10.00	8.00
Q1-Q3	6.00 - 20.00	6.00 - 20.00	5.00 - 8.00
T-Test	t= 7.15 P= 0.000	t= 5.00 P= 0.000	t= 4.62 P= 0.000
Change from baseline [%]			
n	23	21	20
Mean (SD)	44.49 (29.825)	41.11 (37.673)	24.50 (23.725)
95% CL	[31.60; 57.39]	[23.96; 58.26]	[13.40; 35.60]
Min-Max	0 - 100	-66.67 - 100	-26.67 - 100
Median	33.33	33.33	26.67
Q1-Q3	20.00 - 66.67	20.00 - 66.67	16.67 - 26.67
T-Test	t= 7.15 P= 0.000	t= 5.00 P= 0.000	t= 4.62 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.3 Full Analysis Set - Subgroups - Age groups
4.6.3.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
After 4 weeks			
n	17	18	18
Mean (SD)	3.00 (5.788)	2.44 (3.552)	1.56 (1.756)
95% CL	[0.02; 5.98]	[0.68; 4.21]	[0.68; 2.43]
Min-Max	0 - 20	0 - 13	0 - 5
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 3.00	0.00 - 2.00	0.00 - 3.00
After 8 weeks			
n	16	19	17
Mean (SD)	1.19 (2.136)	1.16 (1.302)	0.59 (0.795)
95% CL	[0.05; 2.33]	[0.53; 1.79]	[0.18; 1.00]
Min-Max	0 - 6	0 - 5	0 - 2
Median	0.00	1.00	0.00
Q1-Q3	0.00 - 1.50	0.00 - 2.00	0.00 - 1.00
After 12 weeks			
n	22	22	19
Mean (SD)	1.82 (2.481)	1.95 (2.572)	1.47 (4.060)
95% CL	[0.72; 2.92]	[0.81; 3.10]	[-0.48; 3.43]
Min-Max	0 - 10	0 - 10	0 - 18
Median	1.00	2.00	0.00
Q1-Q3	0.00 - 3.00	0.00 - 2.00	0.00 - 1.00
After 16 weeks			
n	15	16	17
Mean (SD)	0.40 (0.632)	0.44 (0.629)	0.24 (0.562)
95% CL	[0.05; 0.75]	[0.10; 0.77]	[-0.05; 0.52]
Min-Max	0 - 2	0 - 2	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 0.00
After 20 weeks			
n	16	16	17
Mean (SD)	0.13 (0.500)	0.38 (0.719)	0.35 (0.606)
95% CL	[-0.14; 0.39]	[-0.01; 0.76]	[0.04; 0.66]
Min-Max	0 - 2	0 - 2	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.50	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.3 Full Analysis Set - Subgroups - Age groups
4.6.3.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
After 24 weeks			
n	23	21	20
Mean (SD)	2.74 (11.197)	1.24 (2.047)	0.60 (0.821)
95% CL	[-2.10; 7.58]	[0.31; 2.17]	[0.22; 0.98]
Min-Max	0 - 54	0 - 8	0 - 3
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.4 Full Analysis Set - Subgroups - Body Mass Index
4.6.4.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 12 weeks		
n	15	50
Mean (SD)	42.00 (10.330)	39.54 (9.609)
95% CL	[36.28; 47.72]	[36.81; 42.27]
Min-Max	22 - 60	14 - 60
Median	40.00	36.00
Q1-Q3	35.00 - 50.00	34.00 - 44.00
Change from baseline		
n	15	50
Mean (SD)	12.00 (10.330)	9.54 (9.609)
95% CL	[6.28; 17.72]	[6.81; 12.27]
Min-Max	-8 - 30	-16 - 30
Median	10.00	6.00
Q1-Q3	5.00 - 20.00	4.00 - 14.00
T-Test	t= 4.50 P= 0.001	t= 7.02 P= 0.000
Change from baseline [%]		
n	15	50
Mean (SD)	40.00 (34.434)	31.80 (32.030)
95% CL	[20.93; 59.07]	[22.70; 40.90]
Min-Max	-26.67 - 100	-53.33 - 100
Median	33.33	20.00
Q1-Q3	16.67 - 66.67	13.33 - 46.67
T-Test	t= 4.50 P= 0.001	t= 7.02 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.4 Full Analysis Set - Subgroups - Body Mass Index
4.6.4.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	18	52
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 24 weeks		
n	14	50
Mean (SD)	40.07 (7.985)	41.44 (9.957)
95% CL	[35.46; 44.68]	[38.61; 44.27]
Min-Max	26 - 56	10 - 60
Median	38.00	40.00
Q1-Q3	35.00 - 46.00	36.00 - 48.00
Change from baseline		
n	14	50
Mean (SD)	10.07 (7.985)	11.44 (9.957)
95% CL	[5.46; 14.68]	[8.61; 14.27]
Min-Max	-4 - 26	-20 - 30
Median	8.00	10.00
Q1-Q3	5.00 - 16.00	6.00 - 18.00
T-Test	t= 4.72 P= 0.000	t= 8.12 P= 0.000
Change from baseline [%]		
n	14	50
Mean (SD)	33.57 (26.617)	38.13 (33.191)
95% CL	[18.20; 48.94]	[28.70; 47.57]
Min-Max	-13.33 - 86.667	-66.67 - 100
Median	26.67	33.33
Q1-Q3	16.67 - 53.33	20.00 - 60.00
T-Test	t= 4.72 P= 0.000	t= 8.12 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.4 Full Analysis Set - Subgroups - Body Mass Index
4.6.4.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
After 4 weeks		
n	15	38
Mean (SD)	4.13 (5.866)	1.61 (2.707)
95% CL	[0.88; 7.38]	[0.72; 2.49]
Min-Max	0 - 20	0 - 15
Median	2.00	1.00
Q1-Q3	0.00 - 5.00	0.00 - 2.00
After 8 weeks		
n	12	40
Mean (SD)	0.83 (1.467)	1.03 (1.510)
95% CL	[-0.10; 1.77]	[0.54; 1.51]
Min-Max	0 - 5	0 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
After 12 weeks		
n	15	48
Mean (SD)	2.67 (4.952)	1.48 (2.104)
95% CL	[-0.08; 5.41]	[0.87; 2.09]
Min-Max	0 - 18	0 - 10
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
After 16 weeks		
n	11	37
Mean (SD)	0.09 (0.302)	0.43 (0.647)
95% CL	[-0.11; 0.29]	[0.22; 0.65]
Min-Max	0 - 1	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00
After 20 weeks		
n	11	38
Mean (SD)	0.18 (0.603)	0.32 (0.620)
95% CL	[-0.22; 0.59]	[0.11; 0.52]
Min-Max	0 - 2	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.4 Full Analysis Set - Subgroups - Body Mass Index
4.6.4.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
After 24 weeks		
n	13	51
Mean (SD)	0.38 (0.870)	1.88 (7.583)
95% CL	[-0.14; 0.91]	[-0.25; 4.02]
Min-Max	0 - 3	0 - 54
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.5 Full Analysis Set - Subgroups - Renal function
4.6.5.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 12 weeks		
n	16	37
Mean (SD)	40.44 (9.953)	38.41 (8.022)
95% CL	[35.13; 45.74]	[35.73; 41.08]
Min-Max	28 - 60	14 - 60
Median	36.00	36.00
Q1-Q3	34.50 - 49.00	34.00 - 40.00
Change from baseline		
n	16	37
Mean (SD)	10.44 (9.953)	8.41 (8.022)
95% CL	[5.13; 15.74]	[5.73; 11.08]
Min-Max	-2 - 30	-16 - 30
Median	6.00	6.00
Q1-Q3	4.50 - 19.00	4.00 - 10.00
T-Test	t= 4.19 P= 0.001	t= 6.37 P= 0.000
Change from baseline [%]		
n	16	37
Mean (SD)	34.79 (33.177)	28.02 (26.741)
95% CL	[17.11; 52.47]	[19.10; 36.93]
Min-Max	-6.667 - 100	-53.33 - 100
Median	20.00	20.00
Q1-Q3	15.00 - 63.33	13.33 - 33.33
T-Test	t= 4.19 P= 0.001	t= 6.37 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.5 Full Analysis Set - Subgroups - Renal function
4.6.5.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	17	39
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 24 weeks		
n	14	39
Mean (SD)	39.79 (8.059)	40.74 (9.455)
95% CL	[35.13; 44.44]	[37.68; 43.81]
Min-Max	22 - 56	10 - 60
Median	38.00	40.00
Q1-Q3	38.00 - 40.00	35.00 - 48.00
Change from baseline		
n	14	39
Mean (SD)	9.79 (8.059)	10.74 (9.455)
95% CL	[5.13; 14.44]	[7.68; 13.81]
Min-Max	-8 - 26	-20 - 30
Median	8.00	10.00
Q1-Q3	8.00 - 10.00	5.00 - 18.00
T-Test	t= 4.54 P= 0.001	t= 7.10 P= 0.000
Change from baseline [%]		
n	14	39
Mean (SD)	32.62 (26.864)	35.81 (31.518)
95% CL	[17.11; 48.13]	[25.59; 46.03]
Min-Max	-26.67 - 86.667	-66.67 - 100
Median	26.67	33.33
Q1-Q3	26.67 - 33.33	16.67 - 60.00
T-Test	t= 4.54 P= 0.001	t= 7.10 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.5 Full Analysis Set - Subgroups - Renal function
4.6.5.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
After 4 weeks		
n	16	30
Mean (SD)	2.56 (4.899)	2.20 (3.336)
95% CL	[-0.05; 5.17]	[0.95; 3.45]
Min-Max	0 - 20	0 - 15
Median	1.00	1.00
Q1-Q3	0.00 - 2.50	0.00 - 3.00
After 8 weeks		
n	15	31
Mean (SD)	0.80 (1.082)	1.10 (1.777)
95% CL	[0.20; 1.40]	[0.45; 1.75]
Min-Max	0 - 3	0 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
After 12 weeks		
n	16	36
Mean (SD)	1.63 (4.440)	1.75 (2.298)
95% CL	[-0.74; 3.99]	[0.97; 2.53]
Min-Max	0 - 18	0 - 10
Median	0.00	1.00
Q1-Q3	0.00 - 1.50	0.00 - 2.00
After 16 weeks		
n	15	28
Mean (SD)	0.13 (0.516)	0.50 (0.638)
95% CL	[-0.15; 0.42]	[0.25; 0.75]
Min-Max	0 - 2	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00
After 20 weeks		
n	14	29
Mean (SD)	0.29 (0.611)	0.28 (0.591)
95% CL	[-0.07; 0.64]	[0.05; 0.50]
Min-Max	0 - 2	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.5 Full Analysis Set - Subgroups - Renal function
4.6.5.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
After 24 weeks		
n	13	39
Mean (SD)	0.62 (0.961)	1.90 (8.629)
95% CL	[0.03; 1.20]	[-0.90; 4.69]
Min-Max	0 - 3	0 - 54
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.6 Full Analysis Set - Subgroups - Duration of diabetes
4.6.6.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 12 weeks			
n	7	19	36
Mean (SD)	36.14 (3.934)	41.89 (7.951)	40.50 (11.310)
95% CL	[32.50; 39.78]	[38.06; 45.73]	[36.67; 44.33]
Min-Max	30 - 42	30 - 58	14 - 60
Median	36.00	40.00	37.00
Q1-Q3	34.00 - 40.00	35.00 - 50.00	34.00 - 49.00
Change from baseline			
n	7	19	36
Mean (SD)	6.14 (3.934)	11.89 (7.951)	10.50 (11.310)
95% CL	[2.50; 9.78]	[8.06; 15.73]	[6.67; 14.33]
Min-Max	0 - 12	0 - 28	-16 - 30
Median	6.00	10.00	7.00
Q1-Q3	4.00 - 10.00	5.00 - 20.00	4.00 - 19.00
T-Test	t= 4.13 P= 0.006	t= 6.52 P= 0.000	t= 5.57 P= 0.000
Change from baseline [%]			
n	7	19	36
Mean (SD)	20.48 (13.113)	39.65 (26.502)	35.00 (37.700)
95% CL	[8.35; 32.60]	[26.88; 52.42]	[22.24; 47.76]
Min-Max	0 - 40	0 - 93.333	-53.33 - 100
Median	20.00	33.33	23.33
Q1-Q3	13.33 - 33.33	16.67 - 66.67	13.33 - 63.33
T-Test	t= 4.13 P= 0.006	t= 6.52 P= 0.000	t= 5.57 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.6 Full Analysis Set - Subgroups - Duration of diabetes
4.6.6.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	21	39
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 24 weeks			
n	7	18	36
Mean (SD)	38.71 (6.184)	41.61 (7.686)	41.67 (10.967)
95% CL	[33.00; 44.43]	[37.79; 45.43]	[37.96; 45.38]
Min-Max	30 - 50	34 - 59	10 - 60
Median	40.00	39.00	40.00
Q1-Q3	35.00 - 40.00	36.00 - 50.00	37.00 - 49.00
Change from baseline			
n	7	18	36
Mean (SD)	8.71 (6.184)	11.61 (7.686)	11.67 (10.967)
95% CL	[3.00; 14.43]	[7.79; 15.43]	[7.96; 15.38]
Min-Max	0 - 20	4 - 29	-20 - 30
Median	10.00	9.00	10.00
Q1-Q3	5.00 - 10.00	6.00 - 20.00	7.00 - 19.00
T-Test	t= 3.73 P= 0.010	t= 6.41 P= 0.000	t= 6.38 P= 0.000
Change from baseline [%]			
n	7	18	36
Mean (SD)	29.05 (20.612)	38.70 (25.620)	38.89 (36.558)
95% CL	[9.98; 48.11]	[25.96; 51.44]	[26.52; 51.26]
Min-Max	0 - 66.667	13.333 - 96.667	-66.67 - 100
Median	33.33	30.00	33.33
Q1-Q3	16.67 - 33.33	20.00 - 66.67	23.33 - 63.33
T-Test	t= 3.73 P= 0.010	t= 6.41 P= 0.000	t= 6.38 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.6 Full Analysis Set - Subgroups - Duration of diabetes
4.6.6.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
After 4 weeks			
n	6	16	29
Mean (SD)	0.67 (0.816)	3.94 (5.961)	1.93 (2.751)
95% CL	[-0.19; 1.52]	[0.76; 7.11]	[0.88; 2.98]
Min-Max	0 - 2	0 - 20	0 - 13
Median	0.50	1.50	1.00
Q1-Q3	0.00 - 1.00	0.00 - 4.50	0.00 - 3.00
After 8 weeks			
n	7	15	28
Mean (SD)	1.14 (1.864)	0.33 (0.724)	1.36 (1.638)
95% CL	[-0.58; 2.87]	[-0.07; 0.73]	[0.72; 1.99]
Min-Max	0 - 5	0 - 2	0 - 6
Median	0.00	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 0.00	0.00 - 2.00
After 12 weeks			
n	7	19	34
Mean (SD)	2.14 (1.574)	2.05 (4.490)	1.56 (2.299)
95% CL	[0.69; 3.60]	[-0.11; 4.22]	[0.76; 2.36]
Min-Max	0 - 5	0 - 18	0 - 10
Median	2.00	1.00	1.00
Q1-Q3	1.00 - 3.00	0.00 - 1.00	0.00 - 2.00
After 16 weeks			
n	5	13	28
Mean (SD)	1.00 (1.000)	0.23 (0.439)	0.32 (0.548)
95% CL	[-0.24; 2.24]	[-0.03; 0.50]	[0.11; 0.53]
Min-Max	0 - 2	0 - 1	0 - 2
Median	1.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 0.00	0.00 - 1.00
After 20 weeks			
n	6	14	27
Mean (SD)	0.17 (0.408)	0.29 (0.726)	0.30 (0.609)
95% CL	[-0.26; 0.60]	[-0.13; 0.71]	[0.06; 0.54]
Min-Max	0 - 1	0 - 2	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00	0.00 - 0.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.6 Full Analysis Set - Subgroups - Duration of diabetes
4.6.6.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
After 24 weeks			
n	7	18	36
Mean (SD)	0.43 (0.787)	3.61 (12.715)	0.81 (1.064)
95% CL	[-0.30; 1.16]	[-2.71; 9.93]	[0.45; 1.17]
Min-Max	0 - 2	0 - 54	0 - 4
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.6.7.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 12 weeks		
n	36	29
Mean (SD)	36.19 (7.532)	44.97 (10.119)
95% CL	[33.65; 38.74]	[41.12; 48.81]
Min-Max	14 - 56	28 - 60
Median	36.00	44.00
Q1-Q3	32.50 - 39.00	36.00 - 54.00
Change from baseline		
n	36	29
Mean (SD)	6.19 (7.532)	14.97 (10.119)
95% CL	[3.65; 8.74]	[11.12; 18.81]
Min-Max	-16 - 26	-2 - 30
Median	6.00	14.00
Q1-Q3	2.50 - 9.00	6.00 - 24.00
T-Test	t= 4.93 P= 0.000	t= 7.96 P= 0.000
Change from baseline [%]		
n	36	29
Mean (SD)	20.65 (25.107)	49.89 (33.730)
95% CL	[12.15; 29.14]	[37.06; 62.72]
Min-Max	-53.33 - 86.667	-6.667 - 100
Median	20.00	46.67
Q1-Q3	8.33 - 30.00	20.00 - 80.00
T-Test	t= 4.93 P= 0.000	t= 7.96 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.6.7.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	32
Mean (SD)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]
Min-Max	30 - 30	30 - 30
Median	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00
After 24 weeks		
n	37	27
Mean (SD)	38.76 (8.942)	44.41 (9.468)
95% CL	[35.78; 41.74]	[40.66; 48.15]
Min-Max	10 - 60	22 - 60
Median	38.00	40.00
Q1-Q3	35.00 - 42.00	38.00 - 50.00
Change from baseline		
n	37	27
Mean (SD)	8.76 (8.942)	14.41 (9.468)
95% CL	[5.78; 11.74]	[10.66; 18.15]
Min-Max	-20 - 30	-8 - 30
Median	8.00	10.00
Q1-Q3	5.00 - 12.00	8.00 - 20.00
T-Test	t= 5.96 P= 0.000	t= 7.91 P= 0.000
Change from baseline [%]		
n	37	27
Mean (SD)	29.19 (29.808)	48.02 (31.559)
95% CL	[19.25; 39.13]	[35.54; 60.51]
Min-Max	-66.67 - 100	-26.67 - 100
Median	26.67	33.33
Q1-Q3	16.67 - 40.00	26.67 - 66.67
T-Test	t= 5.96 P= 0.000	t= 7.91 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.6.7.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<8.5% (N = 38)	>=8.5% (N = 32)
After 4 weeks		
n	30	23
Mean (SD)	1.37 (1.712)	3.57 (5.534)
95% CL	[0.73; 2.01]	[1.17; 5.96]
Min-Max	0 - 6	0 - 20
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 4.00
After 8 weeks		
n	30	22
Mean (SD)	0.80 (1.270)	1.23 (1.744)
95% CL	[0.33; 1.27]	[0.45; 2.00]
Min-Max	0 - 6	0 - 5
Median	0.00	0.50
Q1-Q3	0.00 - 1.00	0.00 - 2.00
After 12 weeks		
n	35	28
Mean (SD)	1.00 (1.350)	2.71 (4.126)
95% CL	[0.54; 1.46]	[1.11; 4.31]
Min-Max	0 - 6	0 - 18
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 3.00
After 16 weeks		
n	30	18
Mean (SD)	0.40 (0.675)	0.28 (0.461)
95% CL	[0.15; 0.65]	[0.05; 0.51]
Min-Max	0 - 2	0 - 1
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00
After 20 weeks		
n	30	19
Mean (SD)	0.20 (0.484)	0.42 (0.769)
95% CL	[0.02; 0.38]	[0.05; 0.79]
Min-Max	0 - 2	0 - 2
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.6.7.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	<8.5% (N = 38)	>=8.5% (N = 32)
After 24 weeks		
n	38	26
Mean (SD)	0.47 (1.006)	3.19 (10.500)
95% CL	[0.14; 0.80]	[-1.05; 7.43]
Min-Max	0 - 4	0 - 54
Median	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.6.8.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 12 weeks				
n	9	22	29	5
Mean (SD)	42.78 (11.443)	41.27 (9.612)	39.31 (10.018)	34.80 (3.033)
95% CL	[33.98; 51.57]	[37.01; 45.53]	[35.50; 43.12]	[31.03; 38.57]
Min-Max	30 - 60	22 - 60	14 - 60	30 - 38
Median	36.00	39.00	36.00	36.00
Q1-Q3	35.00 - 54.00	36.00 - 50.00	34.00 - 46.00	34.00 - 36.00
Change from baseline				
n	9	22	29	5
Mean (SD)	12.78 (11.443)	11.27 (9.612)	9.31 (10.018)	4.80 (3.033)
95% CL	[3.98; 21.57]	[7.01; 15.53]	[5.50; 13.12]	[1.03; 8.57]
Min-Max	0 - 30	-8 - 30	-16 - 30	0 - 8
Median	6.00	9.00	6.00	6.00
Q1-Q3	5.00 - 24.00	6.00 - 20.00	4.00 - 16.00	4.00 - 6.00
T-Test	t= 3.35 P= 0.010	t= 5.50 P= 0.000	t= 5.00 P= 0.000	t= 3.54 P= 0.024
Change from baseline [%]				
n	9	22	29	5
Mean (SD)	42.59 (38.144)	37.58 (32.041)	31.03 (33.394)	16.00 (10.111)
95% CL	[13.27; 71.91]	[23.37; 51.78]	[18.33; 43.74]	[3.45; 28.55]
Min-Max	0 - 100	-26.67 - 100	-53.33 - 100	0 - 26.667
Median	20.00	30.00	20.00	20.00
Q1-Q3	16.67 - 80.00	20.00 - 66.67	13.33 - 53.33	13.33 - 20.00
T-Test	t= 3.35 P= 0.010	t= 5.50 P= 0.000	t= 5.00 P= 0.000	t= 3.54 P= 0.024

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.6.8.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	24	29	6
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 24 weeks				
n	10	22	27	5
Mean (SD)	48.20 (11.631)	40.77 (9.542)	38.96 (8.519)	40.40 (3.847)
95% CL	[39.88; 56.52]	[36.54; 45.00]	[35.59; 42.33]	[35.62; 45.18]
Min-Max	30 - 60	22 - 60	10 - 55	36 - 46
Median	50.00	40.00	38.00	40.00
Q1-Q3	38.00 - 60.00	35.00 - 50.00	35.00 - 46.00	38.00 - 42.00
Change from baseline				
n	10	22	27	5
Mean (SD)	18.20 (11.631)	10.77 (9.542)	8.96 (8.519)	10.40 (3.847)
95% CL	[9.88; 26.52]	[6.54; 15.00]	[5.59; 12.33]	[5.62; 15.18]
Min-Max	0 - 30	-8 - 30	-20 - 25	6 - 16
Median	20.00	10.00	8.00	10.00
Q1-Q3	8.00 - 30.00	5.00 - 20.00	5.00 - 16.00	8.00 - 12.00
T-Test	t= 4.95 P= 0.001	t= 5.30 P= 0.000	t= 5.47 P= 0.000	t= 6.04 P= 0.004
Change from baseline [%]				
n	10	22	27	5
Mean (SD)	60.67 (38.771)	35.91 (31.805)	29.88 (28.397)	34.67 (12.824)
95% CL	[32.93; 88.40]	[21.81; 50.01]	[18.64; 41.11]	[18.74; 50.59]
Min-Max	0 - 100	-26.67 - 100	-66.67 - 83.333	20 - 53.333
Median	66.67	33.33	26.67	33.33
Q1-Q3	26.67 -100.00	16.67 - 66.67	16.67 - 53.33	26.67 - 40.00
T-Test	t= 4.95 P= 0.001	t= 5.30 P= 0.000	t= 5.47 P= 0.000	t= 6.04 P= 0.004

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.6.8.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
After 4 weeks				
n	7	19	21	6
Mean (SD)	1.14 (1.069)	3.11 (5.343)	2.48 (3.600)	0.67 (0.816)
95% CL	[0.15; 2.13]	[0.53; 5.68]	[0.84; 4.12]	[-0.19; 1.52]
Min-Max	0 - 3	0 - 20	0 - 13	0 - 2
Median	1.00	1.00	1.00	0.50
Q1-Q3	0.00 - 2.00	0.00 - 4.00	0.00 - 4.00	0.00 - 1.00
After 8 weeks				
n	7	19	21	5
Mean (SD)	0.43 (0.787)	0.79 (1.228)	1.48 (1.887)	0.40 (0.548)
95% CL	[-0.30; 1.16]	[0.20; 1.38]	[0.62; 2.34]	[-0.28; 1.08]
Min-Max	0 - 2	0 - 5	0 - 6	0 - 1
Median	0.00	0.00	1.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 2.00	0.00 - 1.00
After 12 weeks				
n	9	21	28	5
Mean (SD)	1.78 (2.489)	1.33 (3.890)	2.29 (2.692)	0.60 (0.548)
95% CL	[-0.14; 3.69]	[-0.44; 3.10]	[1.24; 3.33]	[-0.08; 1.28]
Min-Max	0 - 8	0 - 18	0 - 10	0 - 1
Median	1.00	0.00	2.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	0.00 - 3.00	0.00 - 1.00
After 16 weeks				
n	7	18	18	5
Mean (SD)	0.71 (0.951)	0.33 (0.485)	0.11 (0.323)	0.80 (0.837)
95% CL	[-0.17; 1.59]	[0.09; 0.57]	[-0.05; 0.27]	[-0.24; 1.84]
Min-Max	0 - 2	0 - 1	0 - 1	0 - 2
Median	0.00	0.00	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	0.00 - 0.00	0.00 - 1.00
After 20 weeks				
n	7	19	18	5
Mean (SD)	0.14 (0.378)	0.32 (0.749)	0.17 (0.383)	0.80 (0.837)
95% CL	[-0.21; 0.49]	[-0.05; 0.68]	[-0.02; 0.36]	[-0.24; 1.84]
Min-Max	0 - 1	0 - 2	0 - 1	0 - 2
Median	0.00	0.00	0.00	1.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00	0.00 - 0.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.6.8.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
After 24 weeks				
n	10	22	27	5
Mean (SD)	1.10 (1.449)	3.27 (11.465)	0.59 (1.047)	0.40 (0.548)
95% CL	[0.06; 2.14]	[-1.81; 8.36]	[0.18; 1.01]	[-0.28; 1.08]
Min-Max	0 - 4	0 - 54	0 - 4	0 - 1
Median	0.50	0.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.6.9.1 Change in iGlarLixi dose steps/day up to approx. 12 weeks after the start of treatment

iGlarLixi dose steps/day	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 12 weeks			
n	25	9	30
Mean (SD)	39.60 (10.017)	39.33 (5.916)	41.10 (10.597)
95% CL	[35.47; 43.73]	[34.79; 43.88]	[37.14; 45.06]
Min-Max	14 - 60	32 - 50	22 - 60
Median	38.00	38.00	38.00
Q1-Q3	35.00 - 42.00	36.00 - 40.00	34.00 - 50.00
Change from baseline			
n	25	9	30
Mean (SD)	9.60 (10.017)	9.33 (5.916)	11.10 (10.597)
95% CL	[5.47; 13.73]	[4.79; 13.88]	[7.14; 15.06]
Min-Max	-16 - 30	2 - 20	-8 - 30
Median	8.00	8.00	8.00
Q1-Q3	5.00 - 12.00	6.00 - 10.00	4.00 - 20.00
T-Test	t= 4.79 P= 0.000	t= 4.73 P= 0.001	t= 5.74 P= 0.000
Change from baseline [%]			
n	25	9	30
Mean (SD)	32.00 (33.389)	31.11 (19.720)	37.00 (35.324)
95% CL	[18.22; 45.78]	[15.95; 46.27]	[23.81; 50.19]
Min-Max	-53.33 - 100	6.6667 - 66.667	-26.67 - 100
Median	26.67	26.67	26.67
Q1-Q3	16.67 - 40.00	20.00 - 33.33	13.33 - 66.67
T-Test	t= 4.79 P= 0.000	t= 4.73 P= 0.001	t= 5.74 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.6.9.2 Change in iGlarLixi dose steps/day up to approx. 24 weeks after the start of treatment

iGlarLixi dose steps/day	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	28	9	32
Mean (SD)	30.00 (0.000)	30.00 (0.000)	30.00 (0.000)
95% CL	[;]	[;]	[;]
Min-Max	30 - 30	30 - 30	30 - 30
Median	30.00	30.00	30.00
Q1-Q3	30.00 - 30.00	30.00 - 30.00	30.00 - 30.00
After 24 weeks			
n	24	9	30
Mean (SD)	41.54 (9.961)	40.89 (6.092)	41.10 (10.317)
95% CL	[37.34; 45.75]	[36.21; 45.57]	[37.25; 44.95]
Min-Max	10 - 60	32 - 50	22 - 60
Median	39.00	40.00	40.00
Q1-Q3	38.00 - 48.00	36.00 - 46.00	34.00 - 50.00
Change from baseline			
n	24	9	30
Mean (SD)	11.54 (9.961)	10.89 (6.092)	11.10 (10.317)
95% CL	[7.34; 15.75]	[6.21; 15.57]	[7.25; 14.95]
Min-Max	-20 - 30	2 - 20	-8 - 30
Median	9.00	10.00	10.00
Q1-Q3	8.00 - 18.00	6.00 - 16.00	4.00 - 20.00
T-Test	t= 5.68 P= 0.000	t= 5.36 P= 0.001	t= 5.89 P= 0.000
Change from baseline [%]			
n	24	9	30
Mean (SD)	38.47 (33.202)	36.30 (20.306)	37.00 (34.390)
95% CL	[24.45; 52.49]	[20.69; 51.91]	[24.16; 49.84]
Min-Max	-66.67 - 100	6.6667 - 66.667	-26.67 - 100
Median	30.00	33.33	33.33
Q1-Q3	26.67 - 60.00	20.00 - 53.33	13.33 - 66.67
T-Test	t= 5.68 P= 0.000	t= 5.36 P= 0.001	t= 5.89 P= 0.000

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.6.9.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
After 4 weeks			
n	21	9	22
Mean (SD)	1.19 (1.601)	5.78 (6.016)	2.09 (4.023)
95% CL	[0.46; 1.92]	[1.15; 10.40]	[0.31; 3.87]
Min-Max	0 - 5	1 - 20	0 - 15
Median	1.00	4.00	1.00
Q1-Q3	0.00 - 2.00	2.00 - 6.00	0.00 - 2.00
After 8 weeks			
n	21	9	21
Mean (SD)	1.14 (1.590)	1.33 (1.936)	0.67 (1.197)
95% CL	[0.42; 1.87]	[-0.16; 2.82]	[0.12; 1.21]
Min-Max	0 - 5	0 - 6	0 - 5
Median	0.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 1.00
After 12 weeks			
n	24	9	29
Mean (SD)	1.17 (1.435)	2.11 (3.516)	2.21 (3.793)
95% CL	[0.56; 1.77]	[-0.59; 4.81]	[0.76; 3.65]
Min-Max	0 - 5	0 - 10	0 - 18
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	0.00 - 2.00
After 16 weeks			
n	20	8	19
Mean (SD)	0.30 (0.657)	0.38 (0.518)	0.42 (0.607)
95% CL	[-0.01; 0.61]	[-0.06; 0.81]	[0.13; 0.71]
Min-Max	0 - 2	0 - 1	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00	0.00 - 1.00
After 20 weeks			
n	20	8	20
Mean (SD)	0.20 (0.523)	0.50 (0.756)	0.30 (0.657)
95% CL	[-0.04; 0.44]	[-0.13; 1.13]	[-0.01; 0.61]
Min-Max	0 - 2	0 - 2	0 - 2
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 1.00	0.00 - 0.00

4 Effectiveness (secondary)
4.6 Absolute and relative change in iGlarLixi dose (dose steps/day)
4.6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.6.9.3 Frequency of dose changes in the last 4 weeks (monthly)

Dose changes in the last 4 weeks	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
After 24 weeks			
n	25	8	30
Mean (SD)	2.84 (10.711)	0.25 (0.463)	0.93 (1.701)
95% CL	[-1.58; 7.26]	[-0.14; 0.64]	[0.30; 1.57]
Min-Max	0 - 54	0 - 1	0 - 8
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 0.50	0.00 - 1.00

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	174.34 (44.592)	159.31 (27.283)	180.60 (48.964)
95% CL	[163.55; 185.13]	[146.54; 172.08]	[166.39; 194.82]
Min-Max	89 - 300	113 - 232.43	89 - 300
Median	162.50	159.00	167.00
Q1-Q3	146.47 -192.50	144.50 -174.29	146.97 -214.00
After 4 weeks			
n	50	15	35
Mean (SD)	147.18 (38.090)	139.84 (22.120)	150.32 (43.075)
95% CL	[136.35; 158.00]	[127.59; 152.09]	[135.53; 165.12]
Min-Max	94 - 320.72	94 - 171.17	98 - 320.72
Median	135.57	135.14	136.00
Q1-Q3	127.00 -168.00	127.00 -161.00	126.13 -171.00
After 8 weeks			
n	48	14	34
Mean (SD)	147.03 (40.922)	139.54 (29.707)	150.11 (44.764)
95% CL	[135.15; 158.91]	[122.39; 156.70]	[134.49; 165.73]
Min-Max	77 - 254	101 - 209	77 - 254
Median	133.00	129.87	141.07
Q1-Q3	118.50 -172.49	122.52 -155.00	118.00 -172.97
After 12 weeks			
n	67	20	47
Mean (SD)	146.04 (36.535)	142.16 (30.480)	147.69 (39.015)
95% CL	[137.13; 154.95]	[127.90; 156.43]	[136.23; 159.14]
Min-Max	77 - 246.85	88 - 200	77 - 246.85
Median	137.00	140.50	137.00
Q1-Q3	122.00 -172.97	124.00 -162.50	116.00 -173.00
After 16 weeks			
n	45	14	31
Mean (SD)	140.32 (34.231)	129.18 (30.187)	145.35 (35.207)
95% CL	[130.03; 150.60]	[111.75; 146.61]	[132.44; 158.26]
Min-Max	85 - 259.46	85 - 180	99 - 259.46
Median	134.00	126.46	138.00
Q1-Q3	119.00 -162.00	102.00 -165.00	121.00 -162.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
After 20 weeks			
n	41	16	25
Mean (SD)	134.70 (31.290)	133.91 (34.111)	135.20 (30.065)
95% CL	[124.82; 144.57]	[115.74; 152.09]	[122.79; 147.61]
Min-Max	85 - 230	96 - 230	85 - 190.99
Median	131.00	128.87	131.00
Q1-Q3	110.00 -146.00	112.00 -134.00	110.00 -147.00
After 24 weeks			
n	64	19	45
Mean (SD)	140.82 (33.724)	139.04 (26.278)	141.57 (36.660)
95% CL	[132.39; 149.24]	[126.38; 151.71]	[130.56; 152.58]
Min-Max	90 - 263	111 - 213	90 - 263
Median	132.50	128.00	135.00
Q1-Q3	119.46 -157.50	120.00 -154.00	113.00 -167.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	174.34 (44.592)	159.31 (27.283)	180.60 (48.964)
95% CL	[163.55; 185.13]	[146.54; 172.08]	[166.39; 194.82]
Min-Max	89 - 300	113 - 232.43	89 - 300
Median	162.50	159.00	167.00
Q1-Q3	146.47 -192.50	144.50 -174.29	146.97 -214.00
After 4 weeks			
n	48	15	33
Mean (SD)	148.12 (38.497)	139.84 (22.120)	151.89 (43.771)
95% CL	[136.95; 159.30]	[127.59; 152.09]	[136.37; 167.41]
Min-Max	94 - 320.72	94 - 171.17	98 - 320.72
Median	135.57	135.14	136.00
Q1-Q3	128.37 -168.00	127.00 -161.00	129.73 -171.00
Absolute change after approx. 4 weeks			
n	48	15	33
Mean (SD)	-20.20 (32.859)	-26.03 (24.145)	-17.55 (36.161)
95% CL	[-29.74; -10.66]	[-39.40; -12.66]	[-30.37; -4.73]
Min-Max	-83 - 70.271	-77 - 4	-83 - 70.271
Median	-23.00	-21.00	-24.00
Q1-Q3	-41.50 - -5.60	-25.23 - -9.00	-44.00 - 6.00
T-Test	t= -4.26 P= 0.000	t= -4.18 P= 0.001	t= -2.79 P= 0.009
Relative change after approx. 4 weeks			
n	48	15	33
Mean (SD)	-10.58 (18.737)	-14.70 (13.003)	-8.71 (20.739)
95% CL	[-16.02; -5.14]	[-21.90; -7.49]	[-16.06; -1.35]
Min-Max	-45.03 - 32	-45.03 - 3.4483	-38.79 - 32
Median	-13.48	-12.79	-14.29
Q1-Q3	-23.20 - -3.69	-15.63 - -6.43	-23.73 - 3.61
T-Test	t= -3.91 P= 0.000	t= -4.38 P= 0.001	t= -2.41 P= 0.022
After 8 weeks			

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
n	46	14	32
Mean (SD)	148.53 (40.949)	139.54 (29.707)	152.46 (44.851)
95% CL	[136.37; 160.69]	[122.39; 156.70]	[136.29; 168.63]
Min-Max	77 - 254	101 - 209	77 - 254
Median	136.00	129.87	148.57
Q1-Q3	119.00 -172.97	122.52 -155.00	118.50 -176.99
Absolute change after approx. 8 weeks			
n	46	14	32
Mean (SD)	-19.28 (37.630)	-26.47 (29.177)	-16.14 (40.804)
95% CL	[-30.46; -8.11]	[-43.31; -9.62]	[-30.85; -1.43]
Min-Max	-115 - 81	-81.08 - 22	-115 - 81
Median	-17.00	-18.00	-13.00
Q1-Q3	-45.00 - 6.00	-46.85 --12.00	-41.50 - 10.71
T-Test	t= -3.48 P= 0.001	t= -3.39 P= 0.005	t= -2.24 P= 0.033
Relative change after approx. 8 weeks			
n	46	14	32
Mean (SD)	-10.08 (21.958)	-15.33 (14.939)	-7.78 (24.257)
95% CL	[-16.60; -3.56]	[-23.96; -6.71]	[-16.53; 0.96]
Min-Max	-53.74 - 46.821	-36.11 - 11.765	-53.74 - 46.821
Median	-12.25	-13.16	-7.12
Q1-Q3	-26.53 - 3.61	-28.48 - -6.98	-21.31 - 8.12
T-Test	t= -3.11 P= 0.003	t= -3.84 P= 0.002	t= -1.81 P= 0.079
After 12 weeks			
n	65	20	45
Mean (SD)	147.07 (36.521)	142.16 (30.480)	149.25 (39.026)
95% CL	[138.02; 156.12]	[127.90; 156.43]	[137.53; 160.98]
Min-Max	77 - 246.85	88 - 200	77 - 246.85
Median	139.00	140.50	137.00
Q1-Q3	125.00 -172.97	124.00 -162.50	125.00 -173.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Absolute change after approx. 12 weeks			
n	65	20	45
Mean (SD)	-27.60 (48.245)	-17.15 (36.586)	-32.25 (52.304)
95% CL	[-39.56; -15.65]	[-34.27; -0.02]	[-47.97; -16.54]
Min-Max	-132 - 65	-90.09 - 65	-132 - 63.064
Median	-29.00	-15.00	-34.23
Q1-Q3	-55.00 - 4.00	-42.92 - 2.00	-62.00 - 4.00
T-Test	t= -4.61 P= 0.000	t= -2.10 P= 0.050	t= -4.14 P= 0.000
Relative change after approx. 12 weeks			
n	65	20	45
Mean (SD)	-12.07 (25.883)	-8.88 (23.816)	-13.48 (26.886)
95% CL	[-18.48; -5.66]	[-20.03; 2.26]	[-21.56; -5.41]
Min-Max	-54.17 - 57.522	-40.14 - 57.522	-54.17 - 46.053
Median	-18.33	-10.85	-22.08
Q1-Q3	-27.33 - 2.56	-25.45 - 1.28	-31.96 - 2.67
T-Test	t= -3.76 P= 0.000	t= -1.67 P= 0.112	t= -3.36 P= 0.002
After 16 weeks			
n	43	14	29
Mean (SD)	141.47 (34.581)	129.18 (30.187)	147.41 (35.477)
95% CL	[130.83; 152.12]	[111.75; 146.61]	[133.91; 160.90]
Min-Max	85 - 259.46	85 - 180	99 - 259.46
Median	136.94	126.46	140.00
Q1-Q3	119.00 -163.97	102.00 -165.00	130.00 -162.00
Absolute change after approx. 16 weeks			
n	43	14	29
Mean (SD)	-26.31 (34.787)	-35.87 (36.644)	-21.69 (33.527)
95% CL	[-37.01; -15.60]	[-57.02; -14.71]	[-34.45; -8.94]
Min-Max	-100.9 - 31	-100.9 - 25	-88.29 - 31
Median	-21.00	-26.61	-16.22
Q1-Q3	-47.00 - -1.00	-55.00 --15.00	-38.00 - 3.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
T-Test	t= -4.96 P= 0.000	t= -3.66 P= 0.003	t= -3.48 P= 0.002
Relative change after approx. 16 weeks			
n	43	14	29
Mean (SD)	-13.97 (18.561)	-20.43 (19.597)	-10.85 (17.537)
95% CL	[-19.68; -8.25]	[-31.74; -9.11]	[-17.52; -4.18]
Min-Max	-52.78 - 21.678	-52.78 - 17.606	-41.07 - 21.678
Median	-13.28	-16.99	-10.67
Q1-Q3	-29.75 - -0.71	-30.61 --10.70	-23.84 - 3.06
T-Test	t= -4.93 P= 0.000	t= -3.90 P= 0.002	t= -3.33 P= 0.002
After 20 weeks			
n	39	16	23
Mean (SD)	135.48 (31.812)	133.91 (34.111)	136.56 (30.849)
95% CL	[125.16; 145.79]	[115.74; 152.09]	[123.22; 149.91]
Min-Max	85 - 230	96 - 230	85 - 190.99
Median	131.00	128.87	132.00
Q1-Q3	110.00 -147.00	112.00 -134.00	110.00 -158.00
Absolute change after approx. 20 weeks			
n	39	16	23
Mean (SD)	-28.16 (37.435)	-30.79 (39.284)	-26.33 (36.876)
95% CL	[-40.29; -16.02]	[-51.72; -9.85]	[-42.28; -10.38]
Min-Max	-105 - 43	-99.1 - 43	-105 - 42
Median	-24.00	-32.00	-19.00
Q1-Q3	-54.00 - -8.00	-54.53 --10.50	-47.00 - 7.00
T-Test	t= -4.70 P= 0.000	t= -3.13 P= 0.007	t= -3.42 P= 0.002
Relative change after approx. 20 weeks			
n	39	16	23
Mean (SD)	-15.20 (20.793)	-17.35 (21.807)	-13.71 (20.417)
95% CL	[-21.94; -8.46]	[-28.97; -5.73]	[-22.54; -4.88]
Min-Max	-50.97 - 29.371	-43.86 - 27.027	-50.97 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.1 Full Analysis Set - FGM - SMBG
4.7.1.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Median	-16.25	-19.62	-12.67
Q1-Q3	-30.61 - -4.82	-32.71 - -6.60	-28.06 - 4.09
T-Test	t= -4.57 P= 0.000	t= -3.18 P= 0.006	t= -3.22 P= 0.004
After 24 weeks			
n	62	19	43
Mean (SD)	141.44 (34.052)	139.04 (26.278)	142.50 (37.208)
95% CL	[132.79; 150.09]	[126.38; 151.71]	[131.05; 153.95]
Min-Max	90 - 263	111 - 213	90 - 263
Median	133.17	128.00	136.94
Q1-Q3	120.00 -158.00	120.00 -154.00	112.00 -167.00
Absolute change after approx. 24 weeks			
n	62	19	43
Mean (SD)	-32.87 (46.329)	-21.18 (31.964)	-38.04 (50.895)
95% CL	[-44.64; -21.11]	[-36.58; -5.77]	[-53.70; -22.38]
Min-Max	-172 - 44	-102.7 - 44	-172 - 34
Median	-22.50	-21.00	-25.00
Q1-Q3	-52.00 - -4.00	-36.00 - -2.00	-60.00 - -4.00
T-Test	t= -5.59 P= 0.000	t= -2.89 P= 0.010	t= -4.90 P= 0.000
Relative change after approx. 24 weeks			
n	62	19	43
Mean (SD)	-15.63 (20.999)	-11.53 (18.582)	-17.45 (21.943)
95% CL	[-20.97; -10.30]	[-20.48; -2.57]	[-24.20; -10.69]
Min-Max	-62.5 - 38.938	-44.19 - 38.938	-62.5 - 22.378
Median	-14.34	-14.29	-14.39
Q1-Q3	-27.70 - -1.87	-23.08 - -1.64	-27.92 - -1.87
T-Test	t= -5.86 P= 0.000	t= -2.70 P= 0.015	t= -5.21 P= 0.000

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	Female (N = 28)	Male (N = 42)
Baseline		
n	28	40
Mean (SD)	167.88 (43.340)	178.86 (45.440)
95% CL	[151.08; 184.69]	[164.33; 193.39]
Min-Max	89 - 256	113 - 300
Median	158.56	168.50
Q1-Q3	139.50 -187.00	149.00 -198.50
After 4 weeks		
n	22	28
Mean (SD)	147.98 (49.446)	146.55 (27.026)
95% CL	[126.05; 169.90]	[136.07; 157.03]
Min-Max	98 - 320.72	94 - 221
Median	133.50	140.00
Q1-Q3	114.00 -162.16	132.00 -168.00
After 8 weeks		
n	21	27
Mean (SD)	157.26 (47.784)	139.07 (33.472)
95% CL	[135.51; 179.01]	[125.83; 152.31]
Min-Max	96 - 254	77 - 209
Median	151.35	129.73
Q1-Q3	122.52 -181.00	118.00 -169.00
After 12 weeks		
n	26	41
Mean (SD)	151.12 (43.392)	142.81 (31.595)
95% CL	[133.59; 168.65]	[132.84; 152.79]
Min-Max	88 - 246.85	77 - 205
Median	140.67	137.00
Q1-Q3	126.00 -187.39	121.00 -168.00
After 16 weeks		
n	19	26
Mean (SD)	144.52 (46.194)	137.25 (22.420)
95% CL	[122.25; 166.78]	[128.19; 146.30]
Min-Max	85 - 259.46	95 - 180
Median	131.53	136.97
Q1-Q3	102.00 -182.00	121.00 -156.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	Female (N = 28)	Male (N = 42)
After 20 weeks		
n	17	24
Mean (SD)	129.00 (33.874)	138.73 (29.386)
95% CL	[111.59; 146.42]	[126.32; 151.14]
Min-Max	85 - 190.99	96 - 230
Median	129.73	132.50
Q1-Q3	102.00 -143.00	125.00 -152.50
After 24 weeks		
n	25	39
Mean (SD)	133.74 (29.992)	145.36 (35.542)
95% CL	[121.36; 146.12]	[133.84; 156.88]
Min-Max	100 - 214.42	90 - 263
Median	126.13	141.00
Q1-Q3	117.00 -147.75	120.00 -167.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Female (N = 28)	Male (N = 42)
Baseline		
n	28	40
Mean (SD)	167.88 (43.340)	178.86 (45.440)
95% CL	[151.08; 184.69]	[164.33; 193.39]
Min-Max	89 - 256	113 - 300
Median	158.56	168.50
Q1-Q3	139.50 -187.00	149.00 -198.50
After 4 weeks		
n	22	26
Mean (SD)	147.98 (49.446)	148.25 (27.062)
95% CL	[126.05; 169.90]	[137.32; 159.18]
Min-Max	98 - 320.72	94 - 221
Median	133.50	146.00
Q1-Q3	114.00 -162.16	133.00 -168.00
Absolute change after approx. 4 weeks		
n	22	26
Mean (SD)	-22.30 (36.269)	-18.43 (30.295)
95% CL	[-38.38; -6.22]	[-30.67; -6.19]
Min-Max	-70 - 70.271	-83 - 43.244
Median	-24.00	-17.00
Q1-Q3	-50.45 - 0.00	-37.00 - -7.21
T-Test	t= -2.88 P= 0.009	t= -3.10 P= 0.005
Relative change after approx. 4 weeks		
n	22	26
Mean (SD)	-11.95 (19.786)	-9.41 (18.114)
95% CL	[-20.73; -3.18]	[-16.73; -2.10]
Min-Max	-38.89 - 28.09	-45.03 - 32
Median	-14.79	-10.24
Q1-Q3	-26.36 - 0.00	-17.96 - -5.06
T-Test	t= -2.83 P= 0.010	t= -2.65 P= 0.014
After 8 weeks		

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Female (N = 28)	Male (N = 42)
n	21	25
Mean (SD)	157.26 (47.784)	141.19 (33.445)
95% CL	[135.51; 179.01]	[127.39; 155.00]
Min-Max	96 - 254	77 - 209
Median	151.35	129.73
Q1-Q3	122.52 -181.00	119.00 -169.00
Absolute change after approx. 8 weeks		
n	21	25
Mean (SD)	-13.45 (38.267)	-24.18 (37.149)
95% CL	[-30.87; 3.97]	[-39.51; -8.84]
Min-Max	-81.08 - 81	-115 - 29
Median	-17.00	-19.00
Q1-Q3	-30.63 - 7.00	-49.00 - -1.80
T-Test	t= -1.61 P= 0.123	t= -3.25 P= 0.003
Relative change after approx. 8 weeks		
n	21	25
Mean (SD)	-6.06 (23.379)	-13.45 (20.558)
95% CL	[-16.70; 4.58]	[-21.94; -4.97]
Min-Max	-42.86 - 46.821	-53.74 - 18.44
Median	-10.00	-13.38
Q1-Q3	-20.00 - 7.14	-28.48 - -1.03
T-Test	t= -1.19 P= 0.249	t= -3.27 P= 0.003
After 12 weeks		
n	26	39
Mean (SD)	151.12 (43.392)	144.37 (31.446)
95% CL	[133.59; 168.65]	[134.18; 154.56]
Min-Max	88 - 246.85	77 - 205
Median	140.67	137.00
Q1-Q3	126.00 -187.39	121.00 -169.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Female (N = 28)	Male (N = 42)
Absolute change after approx. 12 weeks		
n	26	39
Mean (SD)	-17.12 (39.671)	-34.59 (52.529)
95% CL	[-33.14; -1.10]	[-51.62; -17.57]
Min-Max	-90.09 - 55.856	-132 - 65
Median	-11.50	-33.00
Q1-Q3	-54.00 - 7.00	-57.00 - -3.00
T-Test	t= -2.20 P= 0.037	t= -4.11 P= 0.000
Relative change after approx. 12 weeks		
n	26	39
Mean (SD)	-7.62 (23.982)	-15.04 (26.968)
95% CL	[-17.30; 2.07]	[-23.78; -6.30]
Min-Max	-40.14 - 43.82	-54.17 - 57.522
Median	-5.98	-22.08
Q1-Q3	-25.93 - 5.04	-34.81 - -2.34
T-Test	t= -1.62 P= 0.118	t= -3.48 P= 0.001
After 16 weeks		
n	19	24
Mean (SD)	144.52 (46.194)	139.06 (22.361)
95% CL	[122.25; 166.78]	[129.62; 148.50]
Min-Max	85 - 259.46	95 - 180
Median	131.53	137.50
Q1-Q3	102.00 -182.00	127.00 -159.00
Absolute change after approx. 16 weeks		
n	19	24
Mean (SD)	-27.04 (39.433)	-25.73 (31.499)
95% CL	[-46.05; -8.04]	[-39.03; -12.43]
Min-Max	-100.9 - 25	-84 - 31
Median	-21.00	-20.50
Q1-Q3	-51.00 - 9.01	-45.00 - -5.50

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Female (N = 28)	Male (N = 42)
T-Test	t= -2.99 P= 0.008	t= -4.00 P= 0.001
Relative change after approx. 16 weeks		
n	19	24
Mean (SD)	-13.93 (20.820)	-13.99 (17.026)
95% CL	[-23.97; -3.90]	[-21.18; -6.80]
Min-Max	-52.78 - 14.451	-44.44 - 21.678
Median	-15.00	-13.07
Q1-Q3	-30.61 - 3.60	-27.37 - -3.24
T-Test	t= -2.92 P= 0.009	t= -4.03 P= 0.001
After 20 weeks		
n	17	22
Mean (SD)	129.00 (33.874)	140.48 (29.948)
95% CL	[111.59; 146.42]	[127.20; 153.76]
Min-Max	85 - 190.99	96 - 230
Median	129.73	134.00
Q1-Q3	102.00 -143.00	125.00 -158.00
Absolute change after approx. 20 weeks		
n	17	22
Mean (SD)	-30.48 (37.332)	-26.37 (38.292)
95% CL	[-49.67; -11.29]	[-43.34; -9.39]
Min-Max	-99.1 - 40	-105 - 43
Median	-26.00	-19.00
Q1-Q3	-45.00 --16.00	-54.00 - -8.00
T-Test	t= -3.37 P= 0.004	t= -3.23 P= 0.004
Relative change after approx. 20 weeks		
n	17	22
Mean (SD)	-16.76 (21.592)	-14.00 (20.583)
95% CL	[-27.86; -5.66]	[-23.13; -4.88]
Min-Max	-49.4 - 27.027	-50.97 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.2 Full Analysis Set - Subgroups - Gender
4.7.2.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Female (N = 28)	Male (N = 42)
Median	-17.14	-12.67
Q1-Q3	-30.61 - -9.88	-28.89 - -4.82
T-Test	t= -3.20 P= 0.006	t= -3.19 P= 0.004
After 24 weeks		
n	25	37
Mean (SD)	133.74 (29.992)	146.65 (36.001)
95% CL	[121.36; 146.12]	[134.64; 158.65]
Min-Max	100 - 214.42	90 - 263
Median	126.13	143.00
Q1-Q3	117.00 -147.75	120.00 -167.00
Absolute change after approx. 24 weeks		
n	25	37
Mean (SD)	-31.78 (30.634)	-33.61 (54.863)
95% CL	[-44.43; -19.14]	[-51.90; -15.32]
Min-Max	-104.5 - 27	-172 - 44
Median	-27.03	-18.00
Q1-Q3	-47.00 --21.00	-57.66 - 1.00
T-Test	t= -5.19 P= 0.000	t= -3.73 P= 0.001
Relative change after approx. 24 weeks		
n	25	37
Mean (SD)	-17.10 (15.419)	-14.64 (24.211)
95% CL	[-23.47; -10.74]	[-22.71; -6.57]
Min-Max	-44.19 - 15.607	-62.5 - 38.938
Median	-17.65	-10.47
Q1-Q3	-25.42 --13.64	-27.92 - 0.60
T-Test	t= -5.55 P= 0.000	t= -3.68 P= 0.001

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	23	24	21
Mean (SD)	171.36 (37.398)	175.70 (41.221)	176.05 (56.154)
95% CL	[155.19; 187.53]	[158.29; 193.11]	[150.49; 201.61]
Min-Max	113 - 252.25	122 - 279	89 - 300
Median	160.00	164.50	162.00
Q1-Q3	142.00 -187.00	147.50 -200.00	145.95 -214.00
After 4 weeks			
n	16	17	17
Mean (SD)	156.30 (33.446)	153.42 (49.769)	132.36 (23.654)
95% CL	[138.47; 174.12]	[127.83; 179.01]	[120.20; 144.52]
Min-Max	110 - 221	94 - 320.72	98 - 172.97
Median	142.00	150.00	131.00
Q1-Q3	133.00 -173.19	133.00 -169.00	114.00 -150.00
After 8 weeks			
n	14	17	17
Mean (SD)	161.26 (47.331)	144.11 (38.409)	138.23 (36.814)
95% CL	[133.93; 188.58]	[124.36; 163.86]	[119.30; 157.16]
Min-Max	115 - 254	96 - 243.25	77 - 192.79
Median	143.50	130.00	128.00
Q1-Q3	123.00 -187.00	114.00 -167.00	105.00 -171.00
After 12 weeks			
n	24	23	20
Mean (SD)	151.00 (34.749)	144.13 (35.626)	142.28 (40.682)
95% CL	[136.33; 165.68]	[128.72; 159.53]	[123.24; 161.31]
Min-Max	100 - 220	88 - 246.85	77 - 242
Median	141.57	137.00	128.50
Q1-Q3	126.50 -186.19	122.00 -160.00	113.36 -168.50
After 16 weeks			
n	16	15	14
Mean (SD)	142.94 (28.808)	139.62 (42.228)	138.07 (32.764)
95% CL	[127.59; 158.29]	[116.24; 163.01]	[119.15; 156.99]
Min-Max	85 - 198	95 - 259.46	100 - 206
Median	136.27	136.94	132.00
Q1-Q3	122.50 -165.48	111.00 -143.00	111.00 -165.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
After 20 weeks			
n	13	14	14
Mean (SD)	144.29 (36.015)	119.49 (29.277)	141.00 (23.965)
95% CL	[122.52; 166.05]	[102.59; 136.39]	[127.16; 154.84]
Min-Max	108 - 230	85 - 190.99	100 - 185
Median	134.00	112.76	139.00
Q1-Q3	128.00 -144.00	100.00 -131.00	125.00 -159.00
After 24 weeks			
n	22	22	20
Mean (SD)	141.92 (32.909)	135.15 (30.491)	145.85 (38.485)
95% CL	[127.33; 156.51]	[121.63; 148.66]	[127.84; 163.86]
Min-Max	90 - 213	90 - 214.42	92 - 263
Median	132.17	126.87	135.97
Q1-Q3	117.00 -157.00	111.00 -158.56	127.03 -157.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	23	24	21
Mean (SD)	171.36 (37.398)	175.70 (41.221)	176.05 (56.154)
95% CL	[155.19; 187.53]	[158.29; 193.11]	[150.49; 201.61]
Min-Max	113 - 252.25	122 - 279	89 - 300
Median	160.00	164.50	162.00
Q1-Q3	142.00 -187.00	147.50 -200.00	145.95 -214.00
After 4 weeks			
n	15	17	16
Mean (SD)	157.52 (34.250)	153.42 (49.769)	133.69 (23.759)
95% CL	[138.55; 176.48]	[127.83; 179.01]	[121.03; 146.35]
Min-Max	110 - 221	94 - 320.72	98 - 172.97
Median	146.00	150.00	132.00
Q1-Q3	131.00 -178.38	133.00 -169.00	117.00 -151.00
Absolute change after approx. 4 weeks			
n	15	17	16
Mean (SD)	-14.45 (26.005)	-24.64 (36.492)	-20.88 (35.716)
95% CL	[-28.86; -0.05]	[-43.40; -5.88]	[-39.91; -1.84]
Min-Max	-70 - 43.244	-77 - 70.271	-83 - 40
Median	-18.02	-24.00	-28.22
Q1-Q3	-24.00 - -9.00	-60.00 - -8.00	-47.00 - 9.21
T-Test	t= -2.15 P= 0.049	t= -2.78 P= 0.013	t= -2.34 P= 0.034
Relative change after approx. 4 weeks			
n	15	17	16
Mean (SD)	-7.68 (15.773)	-13.64 (17.891)	-10.04 (22.518)
95% CL	[-16.41; 1.06]	[-22.84; -4.44]	[-22.04; 1.96]
Min-Max	-38.89 - 32	-45.03 - 28.058	-38.79 - 31.25
Median	-10.56	-15.29	-17.77
Q1-Q3	-14.19 - -6.36	-25.00 - -5.26	-27.58 - 6.27
T-Test	t= -1.88 P= 0.080	t= -3.14 P= 0.006	t= -1.78 P= 0.095
After 8 weeks			

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
n	13	17	16
Mean (SD)	163.51 (48.478)	144.11 (38.409)	141.06 (36.066)
95% CL	[134.21; 192.80]	[124.36; 163.86]	[121.84; 160.28]
Min-Max	115 - 254	96 - 243.25	77 - 192.79
Median	153.00	130.00	136.07
Q1-Q3	123.00 -187.00	114.00 -167.00	113.00 -171.99
Absolute change after approx. 8 weeks			
n	13	17	16
Mean (SD)	-13.76 (38.030)	-30.23 (30.473)	-12.13 (43.402)
95% CL	[-36.74; 9.22]	[-45.90; -14.56]	[-35.26; 10.99]
Min-Max	-65 - 81	-87 - 26	-115 - 39
Median	-17.00	-25.00	-2.40
Q1-Q3	-33.00 - -5.00	-45.00 - -9.01	-46.50 - 22.50
T-Test	t= -1.30 P= 0.217	t= -4.09 P= 0.001	t= -1.12 P= 0.281
Relative change after approx. 8 weeks			
n	13	17	16
Mean (SD)	-7.84 (21.449)	-16.89 (16.384)	-4.66 (26.529)
95% CL	[-20.80; 5.12]	[-25.32; -8.47]	[-18.79; 9.48]
Min-Max	-36.11 - 46.821	-42.86 - 18.44	-53.74 - 43.82
Median	-10.00	-17.99	-1.79
Q1-Q3	-20.76 - -2.86	-26.67 - -4.24	-24.58 - 14.96
T-Test	t= -1.32 P= 0.212	t= -4.25 P= 0.001	t= -0.70 P= 0.493
After 12 weeks			
n	23	23	19
Mean (SD)	152.05 (35.143)	144.13 (35.626)	144.61 (40.402)
95% CL	[136.85; 167.24]	[128.72; 159.53]	[125.13; 164.08]
Min-Max	100 - 220	88 - 246.85	77 - 242
Median	144.15	137.00	129.00
Q1-Q3	126.00 -187.39	122.00 -160.00	115.00 -169.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Absolute change after approx. 12 weeks			
n	23	23	19
Mean (SD)	-19.31 (54.993)	-31.61 (37.391)	-32.79 (52.287)
95% CL	[-43.09; 4.47]	[-47.78; -15.44]	[-57.99; -7.59]
Min-Max	-130 - 65	-106 - 63.064	-132 - 39
Median	-25.00	-29.00	-33.00
Q1-Q3	-46.00 - 19.82	-59.00 - -3.60	-69.00 - 7.00
T-Test	t= -1.68 P= 0.106	t= -4.05 P= 0.001	t= -2.73 P= 0.014
Relative change after approx. 12 weeks			
n	23	23	19
Mean (SD)	-6.93 (30.259)	-16.08 (20.198)	-13.43 (26.608)
95% CL	[-20.01; 6.16]	[-24.82; -7.35]	[-26.25; -0.61]
Min-Max	-54.17 - 57.522	-40.14 - 46.053	-53.06 - 43.82
Median	-15.63	-18.64	-20.75
Q1-Q3	-25.71 - 14.67	-34.81 - -1.44	-32.24 - 7.14
T-Test	t= -1.10 P= 0.284	t= -3.82 P= 0.001	t= -2.20 P= 0.041
After 16 weeks			
n	15	15	13
Mean (SD)	144.47 (29.140)	139.62 (42.228)	140.15 (33.123)
95% CL	[128.33; 160.60]	[116.24; 163.01]	[120.14; 160.17]
Min-Max	85 - 198	95 - 259.46	100 - 206
Median	140.54	136.94	134.00
Q1-Q3	125.00 -167.00	111.00 -143.00	121.00 -165.00
Absolute change after approx. 16 weeks			
n	15	15	13
Mean (SD)	-26.89 (39.767)	-37.46 (31.817)	-12.77 (29.241)
95% CL	[-48.91; -4.86]	[-55.08; -19.84]	[-30.44; 4.90]
Min-Max	-95 - 25	-100.9 - 9.0091	-84 - 31
Median	-25.23	-37.84	-8.00
Q1-Q3	-55.00 - 8.00	-69.00 --10.00	-21.00 - 3.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
T-Test	t= -2.62 P= 0.020	t= -4.56 P= 0.000	t= -1.57 P= 0.141
Relative change after approx. 16 weeks			
n	15	15	13
Mean (SD)	-13.54 (20.855)	-21.00 (16.100)	-6.34 (16.460)
95% CL	[-25.09; -1.99]	[-29.92; -12.09]	[-16.29; 3.61]
Min-Max	-52.78 - 17.606	-44.44 - 3.5971	-39.25 - 21.678
Median	-16.47	-21.65	-5.47
Q1-Q3	-30.56 - 4.65	-33.50 - -6.67	-13.21 - 3.06
T-Test	t= -2.51 P= 0.025	t= -5.05 P= 0.000	t= -1.39 P= 0.190
After 20 weeks			
n	12	14	13
Mean (SD)	147.23 (35.949)	119.49 (29.277)	141.85 (24.725)
95% CL	[124.39; 170.07]	[102.59; 136.39]	[126.91; 156.79]
Min-Max	108 - 230	85 - 190.99	100 - 185
Median	134.00	112.76	143.00
Q1-Q3	128.87 -166.00	100.00 -131.00	125.00 -159.00
Absolute change after approx. 20 weeks			
n	12	14	13
Mean (SD)	-22.87 (41.048)	-48.56 (31.691)	-11.08 (31.237)
95% CL	[-48.95; 3.21]	[-66.85; -30.26]	[-29.95; 7.80]
Min-Max	-92 - 43	-105 - -8	-71 - 42
Median	-25.00	-42.00	-12.00
Q1-Q3	-45.00 - 4.00	-75.00 --21.62	-19.00 - 9.00
T-Test	t= -1.93 P= 0.080	t= -5.73 P= 0.000	t= -1.28 P= 0.225
Relative change after approx. 20 weeks			
n	12	14	13
Mean (SD)	-12.28 (21.952)	-28.10 (15.558)	-4.01 (18.073)
95% CL	[-26.23; 1.67]	[-37.09; -19.12]	[-14.93; 6.91]
Min-Max	-40 - 27.027	-50.97 - -4.819	-33.18 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.3 Full Analysis Set - Subgroups - Age groups
4.7.3.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Median	-16.70	-30.54	-7.55
Q1-Q3	-25.62 - 1.81	-42.64 --12.67	-12.67 - 7.76
T-Test	t= -1.94 P= 0.079	t= -6.76 P= 0.000	t= -0.80 P= 0.440
After 24 weeks			
n	21	22	19
Mean (SD)	143.30 (33.066)	135.15 (30.491)	146.68 (39.354)
95% CL	[128.24; 158.35]	[121.63; 148.66]	[127.72; 165.65]
Min-Max	90 - 213	90 - 214.42	92 - 263
Median	133.33	126.87	136.94
Q1-Q3	120.00 -157.00	111.00 -158.56	126.13 -158.00
Absolute change after approx. 24 weeks			
n	21	22	19
Mean (SD)	-31.02 (50.765)	-40.94 (36.749)	-25.58 (51.915)
95% CL	[-54.12; -7.91]	[-57.23; -24.65]	[-50.61; -0.56]
Min-Max	-150 - 44	-159 - 2	-172 - 32
Median	-26.00	-32.00	-14.00
Q1-Q3	-53.00 - -1.80	-57.66 --21.00	-30.63 - 4.00
T-Test	t= -2.80 P= 0.011	t= -5.23 P= 0.000	t= -2.15 P= 0.046
Relative change after approx. 24 weeks			
n	21	22	19
Mean (SD)	-14.37 (25.006)	-21.60 (15.174)	-10.13 (21.300)
95% CL	[-25.75; -2.99]	[-28.32; -14.87]	[-20.39; 0.14]
Min-Max	-62.5 - 38.938	-56.99 - 1.4184	-62.45 - 22.378
Median	-17.57	-20.62	-8.14
Q1-Q3	-28.89 - -1.33	-29.75 --12.28	-19.32 - 3.45
T-Test	t= -2.63 P= 0.016	t= -6.68 P= 0.000	t= -2.07 P= 0.053

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	17	51
Mean (SD)	172.18 (49.120)	175.06 (43.478)
95% CL	[146.93; 197.44]	[162.83; 187.29]
Min-Max	98 - 277	89 - 300
Median	151.00	166.00
Q1-Q3	140.00 -194.00	150.00 -191.00
After 4 weeks		
n	14	36
Mean (SD)	139.01 (24.411)	150.36 (42.104)
95% CL	[124.91; 153.10]	[136.11; 164.60]
Min-Max	98 - 180	94 - 320.72
Median	132.50	144.00
Q1-Q3	127.00 -163.00	128.56 -168.50
After 8 weeks		
n	10	38
Mean (SD)	135.50 (38.033)	150.06 (41.593)
95% CL	[108.29; 162.71]	[136.39; 163.73]
Min-Max	93 - 209	77 - 254
Median	127.50	141.07
Q1-Q3	105.00 -154.00	121.00 -172.97
After 12 weeks		
n	17	50
Mean (SD)	146.59 (42.025)	145.85 (34.944)
95% CL	[124.98; 168.19]	[135.92; 155.78]
Min-Max	88 - 242	77 - 246.85
Median	132.00	139.50
Q1-Q3	116.00 -175.00	125.00 -169.00
After 16 weeks		
n	11	34
Mean (SD)	126.14 (19.905)	144.91 (36.791)
95% CL	[112.77; 139.51]	[132.07; 157.74]
Min-Max	101 - 167	85 - 259.46
Median	121.00	136.97
Q1-Q3	111.00 -140.54	125.00 -165.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
After 20 weeks		
n	9	32
Mean (SD)	146.44 (41.116)	131.39 (27.852)
95% CL	[114.84; 178.05]	[121.35; 141.43]
Min-Max	102 - 230	85 - 190.99
Median	135.00	131.00
Q1-Q3	116.00 -160.00	108.50 -143.50
After 24 weeks		
n	15	49
Mean (SD)	153.36 (44.750)	136.98 (29.059)
95% CL	[128.57; 178.14]	[128.63; 145.33]
Min-Max	107 - 263	90 - 214.42
Median	135.00	131.00
Q1-Q3	122.00 -173.00	117.00 -156.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	17	51
Mean (SD)	172.18 (49.120)	175.06 (43.478)
95% CL	[146.93; 197.44]	[162.83; 187.29]
Min-Max	98 - 277	89 - 300
Median	151.00	166.00
Q1-Q3	140.00 -194.00	150.00 -191.00
After 4 weeks		
n	13	35
Mean (SD)	141.16 (23.983)	150.71 (42.664)
95% CL	[126.67; 155.65]	[136.05; 165.37]
Min-Max	98 - 180	94 - 320.72
Median	134.00	146.00
Q1-Q3	129.73 -163.00	126.13 -169.00
Absolute change after approx. 4 weeks		
n	13	35
Mean (SD)	-20.30 (36.613)	-20.16 (31.928)
95% CL	[-42.43; 1.82]	[-31.13; -9.20]
Min-Max	-83 - 43.244	-77 - 70.271
Median	-21.00	-24.00
Q1-Q3	-44.00 - -7.21	-39.00 - -4.00
T-Test	t= -2.00 P= 0.069	t= -3.74 P= 0.001
Relative change after approx. 4 weeks		
n	13	35
Mean (SD)	-9.34 (21.214)	-11.04 (18.047)
95% CL	[-22.16; 3.48]	[-17.24; -4.84]
Min-Max	-38.79 - 32	-45.03 - 28.09
Median	-12.83	-14.12
Q1-Q3	-25.00 - -5.26	-22.67 - -2.33
T-Test	t= -1.59 P= 0.138	t= -3.62 P= 0.001
After 8 weeks		

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
n	9	37
Mean (SD)	140.22 (37.100)	150.55 (42.056)
95% CL	[111.70; 168.74]	[136.53; 164.57]
Min-Max	99 - 209	77 - 254
Median	130.00	144.15
Q1-Q3	118.00 -154.00	121.00 -172.97
Absolute change after approx. 8 weeks		
n	9	37
Mean (SD)	-18.22 (43.002)	-19.54 (36.861)
95% CL	[-51.28; 14.83]	[-31.83; -7.25]
Min-Max	-115 - 29	-87 - 81
Median	-14.00	-19.00
Q1-Q3	-33.00 - 7.00	-46.85 - -1.80
T-Test	t= -1.27 P= 0.239	t= -3.22 P= 0.003
Relative change after approx. 8 weeks		
n	9	37
Mean (SD)	-9.16 (21.755)	-10.30 (22.300)
95% CL	[-25.88; 7.56]	[-17.74; -2.87]
Min-Max	-53.74 - 18.239	-48.67 - 46.821
Median	-9.46	-13.38
Q1-Q3	-20.62 - 7.14	-26.67 - -1.03
T-Test	t= -1.26 P= 0.242	t= -2.81 P= 0.008
After 12 weeks		
n	16	49
Mean (SD)	149.62 (41.432)	146.24 (35.199)
95% CL	[127.54; 171.70]	[136.13; 156.35]
Min-Max	88 - 242	77 - 246.85
Median	135.50	142.00
Q1-Q3	120.50 -181.00	125.00 -169.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Absolute change after approx. 12 weeks		
n	16	49
Mean (SD)	-22.82 (39.830)	-29.17 (50.966)
95% CL	[-44.04; -1.60]	[-43.81; -14.53]
Min-Max	-102 - 63.064	-132 - 65
Median	-23.50	-29.00
Q1-Q3	-55.00 - 2.00	-55.00 - 4.00
T-Test	t= -2.29 P= 0.037	t= -4.01 P= 0.000
Relative change after approx. 12 weeks		
n	16	49
Mean (SD)	-10.54 (22.231)	-12.57 (27.162)
95% CL	[-22.39; 1.30]	[-20.37; -4.77]
Min-Max	-40.14 - 46.053	-54.17 - 57.522
Median	-13.42	-18.33
Q1-Q3	-24.91 - 2.30	-30.00 - 2.56
T-Test	t= -1.90 P= 0.077	t= -3.24 P= 0.002
After 16 weeks		
n	10	33
Mean (SD)	127.65 (20.304)	145.66 (37.093)
95% CL	[113.13; 142.18]	[132.51; 158.81]
Min-Max	101 - 167	85 - 259.46
Median	125.50	137.00
Q1-Q3	115.00 -140.54	127.93 -165.00
Absolute change after approx. 16 weeks		
n	10	33
Mean (SD)	-27.66 (27.278)	-25.90 (37.126)
95% CL	[-47.17; -8.15]	[-39.06; -12.73]
Min-Max	-84 - 5.4055	-100.9 - 31
Median	-21.00	-17.00
Q1-Q3	-45.00 - -7.00	-47.00 - -1.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
T-Test	t= -3.21 P= 0.011	t= -4.01 P= 0.000
Relative change after approx. 16 weeks		
n	10	33
Mean (SD)	-15.73 (14.267)	-13.43 (19.841)
95% CL	[-25.94; -5.52]	[-20.47; -6.40]
Min-Max	-39.25 - 4	-52.78 - 21.678
Median	-14.10	-13.28
Q1-Q3	-26.29 - -5.47	-29.75 - -0.71
T-Test	t= -3.49 P= 0.007	t= -3.89 P= 0.000
After 20 weeks		
n	8	31
Mean (SD)	148.50 (43.458)	132.12 (28.006)
95% CL	[112.17; 184.83]	[121.84; 142.39]
Min-Max	102 - 230	85 - 190.99
Median	141.00	131.00
Q1-Q3	113.00 -174.00	108.00 -144.00
Absolute change after approx. 20 weeks		
n	8	31
Mean (SD)	-4.13 (36.188)	-34.36 (35.718)
95% CL	[-34.38; 26.13]	[-47.46; -21.26]
Min-Max	-54 - 43	-105 - 42
Median	-2.50	-26.00
Q1-Q3	-34.50 - 26.00	-55.00 --11.00
T-Test	t= -0.32 P= 0.757	t= -5.36 P= 0.000
Relative change after approx. 20 weeks		
n	8	31
Mean (SD)	-1.60 (21.854)	-18.71 (19.342)
95% CL	[-19.87; 16.67]	[-25.81; -11.62]
Min-Max	-30.61 - 27.027	-50.97 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.4 Full Analysis Set - Subgroups - Body Mass Index
4.7.4.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Median	-1.04	-16.56
Q1-Q3	-21.19 - 17.62	-33.18 - -7.56
T-Test	t= -0.21 P= 0.842	t= -5.39 P= 0.000
After 24 weeks		
n	14	48
Mean (SD)	155.02 (45.953)	137.48 (29.153)
95% CL	[128.49; 181.56]	[129.02; 145.95]
Min-Max	107 - 263	90 - 214.42
Median	138.00	131.50
Q1-Q3	122.00 -173.00	117.96 -156.50
Absolute change after approx. 24 weeks		
n	14	48
Mean (SD)	-13.99 (23.056)	-38.38 (50.014)
95% CL	[-27.30; -0.67]	[-52.90; -23.86]
Min-Max	-67 - 26	-172 - 44
Median	-16.00	-27.51
Q1-Q3	-23.00 - -1.80	-55.86 - -6.00
T-Test	t= -2.27 P= 0.041	t= -5.32 P= 0.000
Relative change after approx. 24 weeks		
n	14	48
Mean (SD)	-7.52 (12.931)	-18.00 (22.377)
95% CL	[-14.98; -0.05]	[-24.50; -11.50]
Min-Max	-27.92 - 13.904	-62.5 - 38.938
Median	-7.94	-17.89
Q1-Q3	-15.65 - -1.33	-30.46 - -3.73
T-Test	t= -2.17 P= 0.049	t= -5.57 P= 0.000

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	38
Mean (SD)	166.31 (44.257)	174.15 (44.967)
95% CL	[142.73; 189.90]	[159.37; 188.93]
Min-Max	89 - 256	98 - 300
Median	160.28	164.50
Q1-Q3	143.00 -179.00	148.00 -180.00
After 4 weeks		
n	15	29
Mean (SD)	144.25 (54.049)	148.39 (31.366)
95% CL	[114.32; 174.18]	[136.46; 160.33]
Min-Max	98 - 320.72	94 - 221
Median	131.00	142.00
Q1-Q3	112.00 -163.00	133.00 -168.00
After 8 weeks		
n	15	28
Mean (SD)	135.80 (48.267)	150.90 (38.519)
95% CL	[109.07; 162.53]	[135.97; 165.84]
Min-Max	77 - 243.25	105 - 254
Median	125.00	144.68
Q1-Q3	99.00 -181.00	122.26 -170.50
After 12 weeks		
n	16	38
Mean (SD)	147.48 (53.578)	148.53 (28.979)
95% CL	[118.93; 176.03]	[139.00; 158.06]
Min-Max	77 - 246.85	101 - 220
Median	130.50	142.17
Q1-Q3	102.00 -194.90	127.00 -169.00
After 16 weeks		
n	13	29
Mean (SD)	136.73 (45.009)	139.86 (28.499)
95% CL	[109.53; 163.93]	[129.02; 150.70]
Min-Max	99 - 259.46	85 - 198
Median	130.00	136.94
Q1-Q3	102.00 -141.00	120.00 -162.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
After 20 weeks		
n	13	25
Mean (SD)	134.85 (38.531)	135.14 (28.857)
95% CL	[111.56; 158.13]	[123.23; 147.06]
Min-Max	85 - 230	89 - 190.99
Median	131.00	131.00
Q1-Q3	102.00 -146.00	116.00 -144.00
After 24 weeks		
n	15	37
Mean (SD)	146.09 (38.429)	142.95 (33.250)
95% CL	[124.81; 167.37]	[131.86; 154.03]
Min-Max	100 - 214.42	90 - 263
Median	135.00	133.33
Q1-Q3	120.00 -156.00	120.00 -158.56

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	16	38
Mean (SD)	166.31 (44.257)	174.15 (44.967)
95% CL	[142.73; 189.90]	[159.37; 188.93]
Min-Max	89 - 256	98 - 300
Median	160.28	164.50
Q1-Q3	143.00 -179.00	148.00 -180.00
After 4 weeks		
n	14	28
Mean (SD)	146.62 (55.271)	148.77 (31.877)
95% CL	[114.71; 178.53]	[136.40; 161.13]
Min-Max	98 - 320.72	94 - 221
Median	132.00	144.00
Q1-Q3	114.00 -163.00	132.00 -169.50
Absolute change after approx. 4 weeks		
n	14	28
Mean (SD)	-14.67 (43.634)	-19.35 (28.284)
95% CL	[-39.86; 10.53]	[-30.32; -8.38]
Min-Max	-83 - 70.271	-77 - 43.244
Median	-24.00	-18.51
Q1-Q3	-50.00 - 15.00	-30.63 - -8.00
T-Test	t= -1.26 P= 0.231	t= -3.62 P= 0.001
Relative change after approx. 4 weeks		
n	14	28
Mean (SD)	-7.52 (25.509)	-10.35 (16.287)
95% CL	[-22.25; 7.21]	[-16.66; -4.03]
Min-Max	-38.79 - 31.25	-45.03 - 32
Median	-14.06	-11.16
Q1-Q3	-30.86 - 10.79	-17.19 - -5.20
T-Test	t= -1.10 P= 0.290	t= -3.36 P= 0.002
After 8 weeks		

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
n	14	27
Mean (SD)	138.86 (48.558)	151.60 (39.071)
95% CL	[110.82; 166.90]	[136.15; 167.06]
Min-Max	77 - 243.25	105 - 254
Median	126.00	151.35
Q1-Q3	101.00 -181.00	122.00 -172.00
Absolute change after approx. 8 weeks		
n	14	27
Mean (SD)	-20.93 (44.502)	-18.73 (33.403)
95% CL	[-46.62; 4.77]	[-31.94; -5.51]
Min-Max	-115 - 39	-81.08 - 81
Median	-16.00	-19.00
Q1-Q3	-50.00 - 19.00	-45.00 - -1.80
T-Test	t= -1.76 P= 0.102	t= -2.91 P= 0.007
Relative change after approx. 8 weeks		
n	14	27
Mean (SD)	-10.89 (27.672)	-10.19 (18.965)
95% CL	[-26.86; 5.09]	[-17.69; -2.68]
Min-Max	-53.74 - 43.82	-36.11 - 46.821
Median	-12.25	-13.38
Q1-Q3	-29.24 - 11.73	-26.53 - -1.03
T-Test	t= -1.47 P= 0.165	t= -2.79 P= 0.010
After 12 weeks		
n	15	37
Mean (SD)	150.78 (53.751)	149.11 (29.153)
95% CL	[121.01; 180.54]	[139.39; 158.83]
Min-Max	77 - 246.85	101 - 220
Median	132.00	142.34
Q1-Q3	106.00 -197.00	129.73 -169.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Absolute change after approx. 12 weeks		
n	15	37
Mean (SD)	-15.42 (37.338)	-25.02 (45.701)
95% CL	[-36.10; 5.25]	[-40.26; -9.78]
Min-Max	-73 - 39	-132 - 55.856
Median	-14.00	-26.00
Q1-Q3	-57.00 - 13.00	-47.00 - 4.00
T-Test	t= -1.60 P= 0.132	t= -3.33 P= 0.002
Relative change after approx. 12 weeks		
n	15	37
Mean (SD)	-8.08 (25.664)	-10.76 (22.527)
95% CL	[-22.29; 6.13]	[-18.27; -3.25]
Min-Max	-48.67 - 43.82	-44.49 - 40.26
Median	-5.47	-15.95
Q1-Q3	-26.64 - 6.95	-26.53 - 2.56
T-Test	t= -1.22 P= 0.243	t= -2.91 P= 0.006
After 16 weeks		
n	12	28
Mean (SD)	138.87 (46.312)	140.57 (28.761)
95% CL	[109.45; 168.30]	[129.41; 151.72]
Min-Max	99 - 259.46	85 - 198
Median	130.00	138.47
Q1-Q3	101.50 -154.00	122.00 -162.98
Absolute change after approx. 16 weeks		
n	12	28
Mean (SD)	-22.75 (31.324)	-27.15 (37.355)
95% CL	[-42.65; -2.85]	[-41.64; -12.67]
Min-Max	-84 - 20	-100.9 - 31
Median	-18.00	-23.11
Q1-Q3	-37.50 - 1.00	-49.00 - 1.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
T-Test	t= -2.52 P= 0.029	t= -3.85 P= 0.001
Relative change after approx. 16 weeks		
n	12	28
Mean (SD)	-13.09 (17.720)	-14.03 (19.739)
95% CL	[-24.35; -1.84]	[-21.69; -6.38]
Min-Max	-41.07 - 12.36	-52.78 - 21.678
Median	-11.81	-15.74
Q1-Q3	-24.08 - -0.94	-28.02 - 1.18
T-Test	t= -2.56 P= 0.027	t= -3.76 P= 0.001
After 20 weeks		
n	12	24
Mean (SD)	135.25 (40.216)	136.23 (28.948)
95% CL	[109.70; 160.80]	[124.01; 148.46]
Min-Max	85 - 230	89 - 190.99
Median	131.00	131.50
Q1-Q3	101.00 -153.00	119.26 -151.00
Absolute change after approx. 20 weeks		
n	12	24
Mean (SD)	-17.08 (34.760)	-29.38 (36.387)
95% CL	[-39.17; 5.00]	[-44.75; -14.02]
Min-Max	-83 - 43	-99.1 - 42
Median	-17.50	-25.00
Q1-Q3	-42.00 - 8.00	-53.03 - -9.50
T-Test	t= -1.70 P= 0.117	t= -3.96 P= 0.001
Relative change after approx. 20 weeks		
n	12	24
Mean (SD)	-9.98 (21.166)	-15.89 (20.325)
95% CL	[-23.43; 3.47]	[-24.48; -7.31]
Min-Max	-49.4 - 22.995	-43.86 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.5 Full Analysis Set - Subgroups - Renal function
4.7.5.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Median	-11.27	-16.70
Q1-Q3	-26.65 - 6.61	-30.54 - -6.60
T-Test	t= -1.63 P= 0.131	t= -3.83 P= 0.001
After 24 weeks		
n	14	36
Mean (SD)	147.24 (39.611)	143.78 (33.328)
95% CL	[124.37; 170.11]	[132.50; 155.05]
Min-Max	100 - 214.42	90 - 263
Median	135.97	137.17
Q1-Q3	120.00 -156.00	120.00 -162.78
Absolute change after approx. 24 weeks		
n	14	36
Mean (SD)	-12.55 (23.547)	-32.25 (45.631)
95% CL	[-26.14; 1.05]	[-47.69; -16.81]
Min-Max	-67 - 26	-172 - 34
Median	-11.50	-21.50
Q1-Q3	-25.00 - 4.00	-52.50 - -3.50
T-Test	t= -1.99 P= 0.068	t= -4.24 P= 0.000
Relative change after approx. 24 weeks		
n	14	36
Mean (SD)	-6.95 (14.472)	-15.44 (19.670)
95% CL	[-15.30; 1.41]	[-22.10; -8.79]
Min-Max	-39.88 - 13.904	-57.33 - 22.378
Median	-6.82	-13.89
Q1-Q3	-15.65 - 3.45	-28.30 - -2.48
T-Test	t= -1.80 P= 0.096	t= -4.71 P= 0.000

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	20	38
Mean (SD)	184.52 (28.937)	176.98 (44.617)	169.52 (45.512)
95% CL	[157.75; 211.28]	[156.10; 197.86]	[154.56; 184.48]
Min-Max	157 - 236	98 - 256	89 - 300
Median	173.00	170.00	158.78
Q1-Q3	163.00 -212.61	141.00 -210.00	143.00 -174.78
After 4 weeks			
n	6	15	27
Mean (SD)	162.69 (42.528)	145.24 (29.108)	147.08 (42.117)
95% CL	[118.06; 207.32]	[129.12; 161.36]	[130.42; 163.74]
Min-Max	110 - 221	98 - 216.22	94 - 320.72
Median	154.08	135.00	136.00
Q1-Q3	133.00 -204.00	127.00 -168.00	126.13 -171.00
After 8 weeks			
n	7	13	26
Mean (SD)	168.23 (49.395)	149.83 (43.280)	143.56 (36.069)
95% CL	[122.55; 213.91]	[123.68; 175.98]	[128.99; 158.13]
Min-Max	115 - 254	93 - 245.05	96 - 243.25
Median	153.00	134.00	131.00
Q1-Q3	127.00 -203.61	123.00 -171.00	114.00 -172.00
After 12 weeks			
n	7	20	37
Mean (SD)	149.42 (35.082)	149.79 (41.630)	144.56 (34.094)
95% CL	[116.98; 181.87]	[130.30; 169.27]	[133.19; 155.93]
Min-Max	126 - 220	98 - 242	88 - 246.85
Median	132.00	133.50	142.34
Q1-Q3	127.00 -172.97	117.50 -188.19	121.00 -165.00
After 16 weeks			
n	6	13	24
Mean (SD)	149.57 (43.453)	146.66 (30.281)	135.35 (35.687)
95% CL	[103.97; 195.17]	[128.36; 164.95]	[120.28; 150.42]
Min-Max	85 - 198	101 - 206	95 - 259.46
Median	144.00	143.00	130.77
Q1-Q3	130.00 -196.40	121.00 -167.00	111.00 -140.77

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
After 20 weeks			
n	6	12	21
Mean (SD)	149.17 (33.711)	139.79 (35.609)	128.06 (29.157)
95% CL	[113.79; 184.54]	[117.17; 162.42]	[114.79; 141.34]
Min-Max	108 - 190.99	101 - 230	85 - 185
Median	138.00	134.00	128.00
Q1-Q3	131.00 -189.00	119.26 -139.00	102.00 -147.00
After 24 weeks			
n	7	16	38
Mean (SD)	149.79 (28.968)	139.73 (33.299)	140.21 (36.228)
95% CL	[123.00; 176.59]	[121.99; 157.47]	[128.30; 152.12]
Min-Max	117 - 200	90 - 213	90 - 263
Median	141.00	132.50	132.00
Q1-Q3	128.00 -172.00	116.96 -160.50	113.00 -157.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	20	38
Mean (SD)	184.52 (28.937)	176.98 (44.617)	169.52 (45.512)
95% CL	[157.75; 211.28]	[156.10; 197.86]	[154.56; 184.48]
Min-Max	157 - 236	98 - 256	89 - 300
Median	173.00	170.00	158.78
Q1-Q3	163.00 -212.61	141.00 -210.00	143.00 -174.78
After 4 weeks			
n	6	14	26
Mean (SD)	162.69 (42.528)	147.68 (28.562)	147.43 (42.911)
95% CL	[118.06; 207.32]	[131.19; 164.18]	[130.09; 164.76]
Min-Max	110 - 221	98 - 216.22	94 - 320.72
Median	154.08	143.18	135.50
Q1-Q3	133.00 -204.00	131.00 -168.00	126.13 -171.00
Absolute change after approx. 4 weeks			
n	6	14	26
Mean (SD)	-25.41 (34.380)	-22.73 (26.178)	-16.50 (37.042)
95% CL	[-61.49; 10.67]	[-37.85; -7.62]	[-31.46; -1.54]
Min-Max	-70 - 31	-62 - 40	-83 - 70.271
Median	-24.00	-24.50	-17.00
Q1-Q3	-50.45 --15.00	-37.00 - -9.00	-39.00 - 6.00
T-Test	t= -1.81 P= 0.130	t= -3.25 P= 0.006	t= -2.27 P= 0.032
Relative change after approx. 4 weeks			
n	6	14	26
Mean (SD)	-13.41 (18.926)	-11.47 (15.356)	-8.47 (20.870)
95% CL	[-33.27; 6.45]	[-20.33; -2.60]	[-16.90; -0.04]
Min-Max	-38.89 - 17.919	-30.93 - 31.25	-45.03 - 32
Median	-14.70	-14.24	-10.24
Q1-Q3	-23.73 - -6.36	-17.96 - -6.43	-22.67 - 3.61
T-Test	t= -1.74 P= 0.143	t= -2.79 P= 0.015	t= -2.07 P= 0.049
After 8 weeks			

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
n	7	12	25
Mean (SD)	168.23 (49.395)	154.56 (41.537)	144.02 (36.734)
95% CL	[122.55; 213.91]	[128.17; 180.96]	[128.86; 159.18]
Min-Max	115 - 254	105 - 245.05	96 - 243.25
Median	153.00	144.00	130.00
Q1-Q3	127.00 -203.61	124.00 -178.00	114.00 -172.00
Absolute change after approx. 8 weeks			
n	7	12	25
Mean (SD)	-16.29 (46.949)	-18.59 (30.765)	-17.85 (39.238)
95% CL	[-59.71; 27.13]	[-38.14; 0.96]	[-34.05; -1.65]
Min-Max	-65 - 81	-87 - 22	-115 - 39
Median	-25.00	-10.60	-15.00
Q1-Q3	-49.00 - -9.01	-41.50 - 2.00	-45.00 - 14.41
T-Test	t= -0.92 P= 0.394	t= -2.09 P= 0.060	t= -2.27 P= 0.032
Relative change after approx. 8 weeks			
n	7	12	25
Mean (SD)	-8.39 (26.308)	-9.51 (15.865)	-8.88 (23.389)
95% CL	[-32.72; 15.94]	[-19.59; 0.57]	[-18.54; 0.77]
Min-Max	-36.11 - 46.821	-42.23 - 11.765	-53.74 - 43.82
Median	-15.34	-6.29	-11.56
Q1-Q3	-20.76 - -4.24	-20.36 - 2.40	-28.48 - 9.09
T-Test	t= -0.84 P= 0.431	t= -2.08 P= 0.062	t= -1.90 P= 0.070
After 12 weeks			
n	7	19	36
Mean (SD)	149.42 (35.082)	152.51 (40.897)	145.05 (34.447)
95% CL	[116.98; 181.87]	[132.80; 172.22]	[133.39; 156.70]
Min-Max	126 - 220	100 - 242	88 - 246.85
Median	132.00	135.00	143.67
Q1-Q3	127.00 -172.97	125.00 -189.00	118.50 -166.50

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Absolute change after approx. 12 weeks			
n	7	19	36
Mean (SD)	-35.09 (45.188)	-24.94 (53.320)	-24.63 (46.641)
95% CL	[-76.88; 6.70]	[-50.64; 0.76]	[-40.41; -8.85]
Min-Max	-105 - 47	-130 - 55.856	-132 - 65
Median	-39.64	-14.00	-31.00
Q1-Q3	-54.00 --25.00	-64.87 - 13.00	-50.00 - 4.00
T-Test	t= -2.05 P= 0.086	t= -2.04 P= 0.056	t= -3.17 P= 0.003
Relative change after approx. 12 weeks			
n	7	19	36
Mean (SD)	-17.59 (22.162)	-10.02 (27.505)	-10.51 (26.121)
95% CL	[-38.09; 2.91]	[-23.28; 3.24]	[-19.35; -1.67]
Min-Max	-44.49 - 27.168	-54.17 - 40.26	-53.06 - 57.522
Median	-18.64	-6.08	-19.54
Q1-Q3	-30.00 --15.92	-31.96 - 7.14	-25.60 - 2.62
T-Test	t= -2.10 P= 0.080	t= -1.59 P= 0.130	t= -2.41 P= 0.021
After 16 weeks			
n	6	12	23
Mean (SD)	149.57 (43.453)	149.63 (29.581)	136.02 (36.336)
95% CL	[103.97; 195.17]	[130.83; 168.42]	[120.31; 151.73]
Min-Max	85 - 198	101 - 206	95 - 259.46
Median	144.00	150.78	131.53
Q1-Q3	130.00 -196.40	126.50 -167.00	111.00 -141.00
Absolute change after approx. 16 weeks			
n	6	12	23
Mean (SD)	-38.54 (43.763)	-19.71 (34.806)	-27.06 (34.631)
95% CL	[-84.46; 7.39]	[-41.82; 2.41]	[-42.03; -12.08]
Min-Max	-95 - 25	-88.29 - 25	-100.9 - 31
Median	-32.50	-14.00	-21.00
Q1-Q3	-80.00 --16.22	-39.50 - 5.50	-47.00 - -1.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
T-Test	t= -2.16 P= 0.084	t= -1.96 P= 0.076	t= -3.75 P= 0.001
Relative change after approx. 16 weeks			
n	6	12	23
Mean (SD)	-19.90 (22.895)	-8.97 (17.342)	-15.06 (19.051)
95% CL	[-43.93; 4.13]	[-19.98; 2.05]	[-23.30; -6.82]
Min-Max	-52.78 - 14.451	-35 - 17.606	-44.44 - 21.678
Median	-19.78	-8.08	-13.28
Q1-Q3	-33.90 - -7.63	-21.89 - 3.86	-30.56 - -0.71
T-Test	t= -2.13 P= 0.086	t= -1.79 P= 0.101	t= -3.79 P= 0.001
After 20 weeks			
n	6	11	20
Mean (SD)	149.17 (33.711)	140.68 (37.207)	129.02 (29.577)
95% CL	[113.79; 184.54]	[115.69; 165.68]	[115.17; 142.86]
Min-Max	108 - 190.99	101 - 230	85 - 185
Median	138.00	134.00	129.00
Q1-Q3	131.00 -189.00	116.00 -143.00	101.00 -152.50
Absolute change after approx. 20 weeks			
n	6	11	20
Mean (SD)	-38.94 (38.458)	-20.37 (45.636)	-29.91 (35.168)
95% CL	[-79.30; 1.42]	[-51.03; 10.29]	[-46.36; -13.45]
Min-Max	-92 - 16	-105 - 43	-99.1 - 42
Median	-32.00	-24.00	-29.00
Q1-Q3	-72.00 --21.62	-54.05 - 12.00	-53.00 - -9.50
T-Test	t= -2.48 P= 0.056	t= -1.48 P= 0.170	t= -3.80 P= 0.001
Relative change after approx. 20 weeks			
n	6	11	20
Mean (SD)	-19.80 (18.599)	-9.83 (24.677)	-16.90 (20.649)
95% CL	[-39.32; -0.28]	[-26.41; 6.75]	[-26.56; -7.23]
Min-Max	-40 - 9.2486	-50.97 - 27.027	-49.4 - 29.371

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.6 Full Analysis Set - Subgroups - Duration of diabetes
4.7.6.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Median	-19.46	-16.25	-18.95
Q1-Q3	-38.98 --10.17	-30.61 - 12.24	-30.54 - -6.18
T-Test	t= -2.61 P= 0.048	t= -1.32 P= 0.216	t= -3.66 P= 0.002
After 24 weeks			
n	7	15	37
Mean (SD)	149.79 (28.968)	140.38 (34.363)	140.95 (36.439)
95% CL	[123.00; 176.59]	[121.35; 159.41]	[128.80; 153.10]
Min-Max	117 - 200	90 - 213	90 - 263
Median	141.00	135.00	133.00
Q1-Q3	128.00 -172.00	115.00 -167.00	120.00 -157.00
Absolute change after approx. 24 weeks			
n	7	15	37
Mean (SD)	-34.72 (31.437)	-34.88 (53.133)	-29.45 (43.351)
95% CL	[-63.80; -5.65]	[-64.30; -5.45]	[-43.91; -15.00]
Min-Max	-64 - 27	-150 - 34	-172 - 44
Median	-52.00	-21.00	-21.00
Q1-Q3	-54.05 --22.00	-57.66 - 7.00	-39.00 - -4.00
T-Test	t= -2.92 P= 0.027	t= -2.54 P= 0.023	t= -4.13 P= 0.000
Relative change after approx. 24 weeks			
n	7	15	37
Mean (SD)	-18.06 (16.250)	-15.85 (24.265)	-14.41 (20.361)
95% CL	[-33.09; -3.03]	[-29.29; -2.42]	[-21.20; -7.62]
Min-Max	-31.18 - 15.607	-62.5 - 22.368	-62.45 - 38.938
Median	-25.42	-14.29	-13.58
Q1-Q3	-28.89 --13.50	-32.65 - 5.47	-23.08 - -1.87
T-Test	t= -2.94 P= 0.026	t= -2.53 P= 0.024	t= -4.30 P= 0.000

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	37	31
Mean (SD)	166.14 (42.489)	184.13 (45.743)
95% CL	[151.97; 180.30]	[167.35; 200.91]
Min-Max	98 - 300	89 - 277
Median	157.00	171.00
Q1-Q3	142.00 -174.78	156.00 -232.00
After 4 weeks		
n	27	23
Mean (SD)	139.26 (28.609)	156.47 (45.792)
95% CL	[127.95; 150.58]	[136.67; 176.27]
Min-Max	94 - 221	108 - 320.72
Median	135.00	138.00
Q1-Q3	120.00 -154.00	129.73 -171.17
After 8 weeks		
n	27	21
Mean (SD)	138.25 (34.090)	158.32 (46.763)
95% CL	[124.76; 151.74]	[137.03; 179.60]
Min-Max	77 - 203.61	96 - 254
Median	127.00	151.35
Q1-Q3	113.00 -171.00	125.00 -181.00
After 12 weeks		
n	36	31
Mean (SD)	136.94 (32.312)	156.60 (38.782)
95% CL	[126.01; 147.87]	[142.37; 170.82]
Min-Max	77 - 205	106 - 246.85
Median	132.00	142.34
Q1-Q3	113.36 -159.98	127.00 -187.00
After 16 weeks		
n	26	19
Mean (SD)	134.32 (30.341)	148.52 (38.245)
95% CL	[122.07; 146.58]	[130.09; 166.96]
Min-Max	85 - 206	99 - 259.46
Median	131.00	140.00
Q1-Q3	111.00 -156.00	121.00 -167.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
After 20 weeks		
n	25	16
Mean (SD)	128.57 (24.718)	144.27 (38.378)
95% CL	[118.37; 138.77]	[123.82; 164.72]
Min-Max	89 - 190.99	85 - 230
Median	129.73	134.50
Q1-Q3	110.00 -134.00	119.50 -169.00
After 24 weeks		
n	36	28
Mean (SD)	133.74 (25.416)	149.92 (40.785)
95% CL	[125.14; 142.34]	[134.11; 165.74]
Min-Max	90 - 186	90 - 263
Median	128.00	144.50
Q1-Q3	119.46 -154.00	118.50 -170.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	37	31
Mean (SD)	166.14 (42.489)	184.13 (45.743)
95% CL	[151.97; 180.30]	[167.35; 200.91]
Min-Max	98 - 300	89 - 277
Median	157.00	171.00
Q1-Q3	142.00 -174.78	156.00 -232.00
After 4 weeks		
n	26	22
Mean (SD)	140.35 (28.601)	157.31 (46.688)
95% CL	[128.80; 151.90]	[136.61; 178.01]
Min-Max	94 - 221	108 - 320.72
Median	135.07	141.00
Q1-Q3	126.13 -154.00	129.73 -171.17
Absolute change after approx. 4 weeks		
n	26	22
Mean (SD)	-19.63 (28.488)	-20.87 (38.072)
95% CL	[-31.14; -8.13]	[-37.75; -3.99]
Min-Max	-77 - 43.244	-83 - 70.271
Median	-20.50	-24.00
Q1-Q3	-32.43 - -8.00	-50.00 - -4.00
T-Test	t= -3.51 P= 0.002	t= -2.57 P= 0.018
Relative change after approx. 4 weeks		
n	26	22
Mean (SD)	-10.95 (17.264)	-10.14 (20.751)
95% CL	[-17.92; -3.97]	[-19.34; -0.94]
Min-Max	-45.03 - 32	-38.79 - 31.25
Median	-12.28	-14.15
Q1-Q3	-20.45 - -5.06	-26.19 - -2.33
T-Test	t= -3.23 P= 0.003	t= -2.29 P= 0.032
After 8 weeks		

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
n	26	20
Mean (SD)	139.99 (33.519)	159.63 (47.577)
95% CL	[126.45; 153.53]	[137.37; 181.90]
Min-Max	77 - 203.61	96 - 254
Median	128.37	152.18
Q1-Q3	114.00 -171.00	123.00 -183.00
Absolute change after approx. 8 weeks		
n	26	20
Mean (SD)	-20.82 (28.827)	-17.27 (47.464)
95% CL	[-32.47; -9.18]	[-39.49; 4.94]
Min-Max	-73 - 34.235	-115 - 81
Median	-19.00	-10.60
Q1-Q3	-45.00 - -1.80	-45.00 - 16.00
T-Test	t= -3.68 P= 0.001	t= -1.63 P= 0.120
Relative change after approx. 8 weeks		
n	26	20
Mean (SD)	-12.27 (17.580)	-7.23 (26.836)
95% CL	[-19.37; -5.17]	[-19.79; 5.33]
Min-Max	-48.67 - 21.591	-53.74 - 46.821
Median	-14.11	-6.17
Q1-Q3	-26.53 - -1.23	-25.55 - 9.64
T-Test	t= -3.56 P= 0.002	t= -1.20 P= 0.243
After 12 weeks		
n	35	30
Mean (SD)	138.05 (32.076)	157.59 (39.047)
95% CL	[127.04; 149.07]	[143.01; 172.17]
Min-Max	77 - 205	106 - 246.85
Median	132.00	143.67
Q1-Q3	115.00 -165.00	128.00 -187.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
Absolute change after approx. 12 weeks		
n	35	30
Mean (SD)	-28.05 (46.697)	-27.08 (50.789)
95% CL	[-44.09; -12.01]	[-46.05; -8.12]
Min-Max	-132 - 55.856	-130 - 65
Median	-29.00	-30.50
Q1-Q3	-54.00 - 4.00	-62.00 - 4.00
T-Test	t= -3.55 P= 0.001	t= -2.92 P= 0.007
Relative change after approx. 12 weeks		
n	35	30
Mean (SD)	-13.56 (24.147)	-10.33 (28.090)
95% CL	[-21.85; -5.26]	[-20.82; 0.16]
Min-Max	-53.06 - 40.26	-54.17 - 57.522
Median	-18.33	-19.02
Q1-Q3	-30.00 - 2.67	-26.64 - 2.56
T-Test	t= -3.32 P= 0.002	t= -2.01 P= 0.053
After 16 weeks		
n	25	18
Mean (SD)	135.25 (30.584)	150.11 (38.706)
95% CL	[122.63; 147.88]	[130.86; 169.36]
Min-Max	85 - 206	99 - 259.46
Median	132.00	140.50
Q1-Q3	111.00 -156.00	130.00 -167.00
Absolute change after approx. 16 weeks		
n	25	18
Mean (SD)	-24.24 (31.187)	-29.18 (40.021)
95% CL	[-37.12; -11.37]	[-49.08; -9.27]
Min-Max	-95 - 31	-100.9 - 25
Median	-21.00	-25.00
Q1-Q3	-43.00 - -8.00	-69.00 - 8.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
T-Test	t= -3.89 P= 0.001	t= -3.09 P= 0.007
Relative change after approx. 16 weeks		
n	25	18
Mean (SD)	-13.86 (18.065)	-14.12 (19.759)
95% CL	[-21.31; -6.40]	[-23.94; -4.29]
Min-Max	-52.78 - 21.678	-43.41 - 14.451
Median	-13.28	-14.12
Q1-Q3	-25.00 - -4.07	-33.50 - 3.60
T-Test	t= -3.84 P= 0.001	t= -3.03 P= 0.008
After 20 weeks		
n	24	15
Mean (SD)	128.51 (25.248)	146.62 (38.514)
95% CL	[117.85; 139.17]	[125.29; 167.95]
Min-Max	89 - 190.99	85 - 230
Median	128.87	135.00
Q1-Q3	109.00 -138.50	130.00 -178.00
Absolute change after approx. 20 weeks		
n	24	15
Mean (SD)	-32.09 (30.619)	-21.87 (46.849)
95% CL	[-45.02; -19.16]	[-47.82; 4.07]
Min-Max	-92 - 42	-105 - 43
Median	-26.00	-11.00
Q1-Q3	-53.03 --16.00	-54.00 - 11.00
T-Test	t= -5.13 P= 0.000	t= -1.81 P= 0.092
Relative change after approx. 20 weeks		
n	24	15
Mean (SD)	-18.29 (17.704)	-10.27 (24.822)
95% CL	[-25.76; -10.81]	[-24.01; 3.48]
Min-Max	-43.86 - 29.371	-50.97 - 27.027

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.7.7.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	<8.5% (N = 38)	>=8.5% (N = 32)
Median	-16.85	-7.80
Q1-Q3	-30.61 - -8.86	-25.23 - 9.25
T-Test	t= -5.06 P= 0.000	t= -1.60 P= 0.132
After 24 weeks		
n	35	27
Mean (SD)	133.84 (25.779)	151.29 (40.902)
95% CL	[124.99; 142.70]	[135.11; 167.47]
Min-Max	90 - 186	90 - 263
Median	128.00	146.00
Q1-Q3	118.92 -154.00	120.00 -173.00
Absolute change after approx. 24 weeks		
n	35	27
Mean (SD)	-33.77 (46.302)	-31.71 (47.219)
95% CL	[-49.67; -17.86]	[-50.39; -13.03]
Min-Max	-172 - 34	-150 - 44
Median	-25.00	-21.00
Q1-Q3	-47.00 - -6.00	-67.00 - 1.00
T-Test	t= -4.31 P= 0.000	t= -3.49 P= 0.002
Relative change after approx. 24 weeks		
n	35	27
Mean (SD)	-16.77 (19.528)	-14.16 (23.064)
95% CL	[-23.48; -10.06]	[-23.29; -5.04]
Min-Max	-62.45 - 22.378	-62.5 - 38.938
Median	-15.92	-10.82
Q1-Q3	-27.12 - -3.75	-31.18 - 0.60
T-Test	t= -5.08 P= 0.000	t= -3.19 P= 0.004

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	22	29	6
Mean (SD)	164.66 (32.138)	178.33 (45.116)	176.27 (50.474)	168.12 (37.683)
95% CL	[143.07; 186.25]	[158.32; 198.33]	[157.08; 195.47]	[128.58; 207.67]
Min-Max	122 - 232	89 - 256	98 - 300	128 - 236
Median	157.00	165.50	168.00	167.00
Q1-Q3	143.00 -176.58	147.00 -214.00	148.00 -191.00	138.74 -172.00
After 4 weeks				
n	7	18	20	5
Mean (SD)	142.05 (20.468)	145.11 (29.065)	145.88 (49.670)	167.00 (35.637)
95% CL	[123.13; 160.98]	[130.65; 159.56]	[122.64; 169.13]	[122.75; 211.25]
Min-Max	112 - 171	94 - 216.22	98 - 320.72	124 - 221
Median	135.14	136.50	134.00	168.00
Q1-Q3	129.73 -162.16	127.00 -168.00	115.00 -157.50	150.00 -172.00
After 8 weeks				
n	6	18	20	4
Mean (SD)	155.48 (33.795)	154.96 (37.827)	134.56 (46.524)	161.00 (26.420)
95% CL	[120.01; 190.94]	[136.15; 173.77]	[112.79; 156.33]	[118.96; 203.04]
Min-Max	122.52 - 203.61	93 - 245.05	77 - 254	125 - 187
Median	149.37	153.18	119.50	166.00
Q1-Q3	127.00 -181.00	128.00 -172.97	107.00 -148.57	142.50 -179.50
After 12 weeks				
n	11	22	29	5
Mean (SD)	150.71 (31.123)	142.08 (38.053)	145.84 (39.610)	154.32 (28.029)
95% CL	[129.81; 171.62]	[125.20; 158.95]	[130.77; 160.91]	[119.52; 189.12]
Min-Max	110 - 200	88 - 242	77 - 246.85	125 - 194.6
Median	144.15	136.00	137.00	156.00
Q1-Q3	122.00 -172.97	115.00 -154.96	116.00 -173.00	131.00 -165.00
After 16 weeks				
n	5	18	17	5
Mean (SD)	162.07 (31.273)	137.72 (29.906)	133.09 (41.105)	152.51 (17.942)
95% CL	[123.23; 200.90]	[122.85; 152.59]	[111.95; 154.22]	[130.23; 174.79]
Min-Max	127.93 - 196.4	95 - 206	85 - 259.46	121 - 165
Median	174.00	136.97	129.00	158.56
Q1-Q3	130.00 -182.00	111.00 -163.97	111.00 -140.00	156.00 -162.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
After 20 weeks				
n	6	16	15	4
Mean (SD)	150.87 (29.811)	132.15 (35.269)	127.13 (29.650)	149.00 (11.576)
95% CL	[119.59; 182.16]	[113.35; 150.94]	[110.71; 143.55]	[130.58; 167.42]
Min-Max	122.52 - 190.99	96 - 230	85 - 189	135 - 159
Median	138.50	131.67	125.00	151.00
Q1-Q3	129.73 -185.00	102.50 -138.50	108.00 -132.00	139.50 -158.50
After 24 weeks				
n	10	21	29	4
Mean (SD)	135.26 (20.569)	133.82 (29.265)	145.43 (40.871)	158.00 (16.391)
95% CL	[120.55; 149.97]	[120.50; 147.15]	[129.88; 160.98]	[131.92; 184.08]
Min-Max	115 - 175	90 - 213	90 - 263	135 - 172
Median	128.56	130.00	133.00	162.50
Q1-Q3	120.00 -156.00	113.00 -150.00	117.00 -173.00	146.50 -169.50

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	22	29	6
Mean (SD)	164.66 (32.138)	178.33 (45.116)	176.27 (50.474)	168.12 (37.683)
95% CL	[143.07; 186.25]	[158.32; 198.33]	[157.08; 195.47]	[128.58; 207.67]
Min-Max	122 - 232	89 - 256	98 - 300	128 - 236
Median	157.00	165.50	168.00	167.00
Q1-Q3	143.00 -176.58	147.00 -214.00	148.00 -191.00	138.74 -172.00
After 4 weeks				
n	7	16	20	5
Mean (SD)	142.05 (20.468)	147.68 (29.486)	145.88 (49.670)	167.00 (35.637)
95% CL	[123.13; 160.98]	[131.97; 163.39]	[122.64; 169.13]	[122.75; 211.25]
Min-Max	112 - 171	94 - 216.22	98 - 320.72	124 - 221
Median	135.14	142.50	134.00	168.00
Q1-Q3	129.73 -162.16	129.00 -168.50	115.00 -157.50	150.00 -172.00
Absolute change after approx. 4 weeks				
n	7	16	20	5
Mean (SD)	-20.99 (26.880)	-22.66 (30.563)	-21.27 (37.954)	-7.00 (31.765)
95% CL	[-45.85; 3.87]	[-38.94; -6.37]	[-39.03; -3.50]	[-46.44; 32.44]
Min-Max	-50.45 - 28	-77 - 43.244	-83 - 70.271	-44 - 40
Median	-24.00	-24.00	-21.50	-15.00
Q1-Q3	-50.00 - -7.21	-36.52 - -8.00	-56.00 - 2.00	-22.00 - 6.00
T-Test	t= -2.07 P= 0.084	t= -2.97 P= 0.010	t= -2.51 P= 0.021	t= -0.49 P= 0.648
Relative change after approx. 4 weeks				
n	7	16	20	5
Mean (SD)	-11.66 (16.080)	-10.72 (19.048)	-12.21 (19.505)	-2.09 (21.550)
95% CL	[-26.53; 3.21]	[-20.87; -0.57]	[-21.33; -3.08]	[-28.85; 24.66]
Min-Max	-30.86 - 19.58	-45.03 - 32	-38.89 - 28.058	-26.19 - 31.25
Median	-14.29	-14.24	-12.34	-6.36
Q1-Q3	-23.73 - -5.26	-19.21 - -5.37	-27.96 - 1.72	-12.79 - 3.61
T-Test	t= -1.92 P= 0.104	t= -2.25 P= 0.040	t= -2.80 P= 0.011	t= -0.22 P= 0.839
After 8 weeks				

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
n	6	16	20	4
Mean (SD)	155.48 (33.795)	160.27 (36.062)	134.56 (46.524)	161.00 (26.420)
95% CL	[120.01; 190.94]	[141.06; 179.49]	[112.79; 156.33]	[118.96; 203.04]
Min-Max	122.52 - 203.61	113 - 245.05	77 - 254	125 - 187
Median	149.37	161.00	119.50	166.00
Q1-Q3	127.00 -181.00	129.00 -178.99	107.00 -148.57	142.50 -179.50
Absolute change after approx. 8 weeks				
n	6	16	20	4
Mean (SD)	-11.91 (29.324)	-11.04 (37.320)	-29.04 (41.911)	-14.50 (24.145)
95% CL	[-42.69; 18.86]	[-30.93; 8.84]	[-48.65; -9.42]	[-52.92; 23.92]
Min-Max	-46.85 - 26	-87 - 39	-115 - 81	-49 - 6
Median	-19.50	-6.10	-29.00	-7.50
Q1-Q3	-30.63 - 19.00	-31.00 - 18.21	-52.50 --11.10	-30.50 - 1.50
T-Test	t= -1.00 P= 0.365	t= -1.18 P= 0.255	t= -3.10 P= 0.006	t= -1.20 P= 0.316
Relative change after approx. 8 weeks				
n	6	16	20	4
Mean (SD)	-6.66 (18.379)	-3.64 (22.055)	-16.95 (23.690)	-6.62 (10.379)
95% CL	[-25.95; 12.63]	[-15.39; 8.11]	[-28.04; -5.86]	[-23.13; 9.90]
Min-Max	-26.53 - 18.182	-42.23 - 43.82	-53.74 - 46.821	-20.76 - 3.6145
Median	-11.67	-2.99	-19.30	-4.66
Q1-Q3	-20.00 - 11.73	-16.74 - 10.43	-29.90 - -6.44	-13.87 - 0.64
T-Test	t= -0.89 P= 0.415	t= -0.66 P= 0.519	t= -3.20 P= 0.005	t= -1.28 P= 0.292
After 12 weeks				
n	11	20	29	5
Mean (SD)	150.71 (31.123)	145.03 (38.432)	145.84 (39.610)	154.32 (28.029)
95% CL	[129.81; 171.62]	[127.05; 163.02]	[130.77; 160.91]	[119.52; 189.12]
Min-Max	110 - 200	88 - 242	77 - 246.85	125 - 194.6
Median	144.15	138.00	137.00	156.00
Q1-Q3	122.00 -172.97	120.50 -169.98	116.00 -173.00	131.00 -165.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Absolute change after approx. 12 weeks				
n	11	20	29	5
Mean (SD)	-13.95 (49.630)	-34.46 (50.082)	-30.43 (45.965)	-13.83 (57.764)
95% CL	[-47.29; 19.39]	[-57.90; -11.02]	[-47.92; -12.95]	[-85.55; 57.89]
Min-Max	-122 - 63.064	-130 - 47	-132 - 65	-105 - 55.856
Median	-9.01	-31.00	-34.23	-7.00
Q1-Q3	-39.64 - 26.00	-66.93 - 4.50	-54.00 - -3.60	-10.00 - -3.00
T-Test	t= -0.93 P= 0.373	t= -3.08 P= 0.006	t= -3.57 P= 0.001	t= -0.54 P= 0.621
Relative change after approx. 12 weeks				
n	11	20	29	5
Mean (SD)	-5.05 (27.099)	-15.12 (26.695)	-14.13 (24.752)	-3.33 (30.013)
95% CL	[-23.25; 13.16]	[-27.61; -2.62]	[-23.55; -4.72]	[-40.60; 33.93]
Min-Max	-52.59 - 46.053	-54.17 - 43.82	-48.67 - 57.522	-44.49 - 40.26
Median	-5.88	-18.86	-22.30	-4.07
Q1-Q3	-24.38 - 18.18	-35.37 - 2.06	-27.33 - -1.44	-6.02 - -2.34
T-Test	t= -0.62 P= 0.550	t= -2.53 P= 0.020	t= -3.08 P= 0.005	t= -0.25 P= 0.816
After 16 weeks				
n	5	16	17	5
Mean (SD)	162.07 (31.273)	140.50 (30.608)	133.09 (41.105)	152.51 (17.942)
95% CL	[123.23; 200.90]	[124.19; 156.81]	[111.95; 154.22]	[130.23; 174.79]
Min-Max	127.93 - 196.4	95 - 206	85 - 259.46	121 - 165
Median	174.00	137.50	129.00	158.56
Q1-Q3	130.00 -182.00	121.27 -165.48	111.00 -140.00	156.00 -162.00
Absolute change after approx. 16 weeks				
n	5	16	17	5
Mean (SD)	-3.49 (27.058)	-30.79 (37.895)	-31.94 (32.249)	-15.64 (37.698)
95% CL	[-37.08; 30.11]	[-50.98; -10.60]	[-48.52; -15.36]	[-62.44; 31.17]
Min-Max	-27 - 31	-100.9 - 25	-95 - 25	-80 - 19.82
Median	-16.22	-24.50	-30.00	-7.00
Q1-Q3	-25.23 - 20.00	-58.00 - 2.20	-51.00 --15.00	-7.00 - -4.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
T-Test	t= -0.29 P= 0.787	t= -3.25 P= 0.005	t= -4.08 P= 0.001	t= -0.93 P= 0.406
Relative change after approx. 16 weeks				
n	5	16	17	5
Mean (SD)	-1.45 (17.585)	-15.35 (19.727)	-18.60 (17.172)	-6.31 (17.365)
95% CL	[-23.29; 20.38]	[-25.86; -4.84]	[-27.42; -9.77]	[-27.87; 15.25]
Min-Max	-17.2 - 21.678	-44.44 - 17.606	-52.78 - 14.451	-33.9 - 14.286
Median	-7.63	-15.35	-17.54	-4.07
Q1-Q3	-16.47 - 12.35	-32.05 - 1.65	-26.29 --10.67	-5.47 - -2.41
T-Test	t= -0.18 P= 0.862	t= -3.11 P= 0.007	t= -4.46 P= 0.000	t= -0.81 P= 0.462
After 20 weeks				
n	6	14	15	4
Mean (SD)	150.87 (29.811)	133.95 (37.285)	127.13 (29.650)	149.00 (11.576)
95% CL	[119.59; 182.16]	[112.42; 155.48]	[110.71; 143.55]	[130.58; 167.42]
Min-Max	122.52 - 190.99	96 - 230	85 - 189	135 - 159
Median	138.50	133.67	125.00	151.00
Q1-Q3	129.73 -185.00	102.00 -143.00	108.00 -132.00	139.50 -158.50
Absolute change after approx. 20 weeks				
n	6	14	15	4
Mean (SD)	-16.52 (31.614)	-32.22 (46.447)	-29.47 (30.696)	-26.50 (44.486)
95% CL	[-49.69; 16.66]	[-59.04; -5.40]	[-46.47; -12.47]	[-97.29; 44.29]
Min-Max	-54.05 - 42	-105 - 43	-83 - 16	-92 - 7
Median	-22.52	-32.00	-38.00	-10.50
Q1-Q3	-26.00 --16.00	-71.00 - -8.00	-52.00 - 7.00	-52.50 - -0.50
T-Test	t= -1.28 P= 0.257	t= -2.60 P= 0.022	t= -3.72 P= 0.002	t= -1.19 P= 0.319
Relative change after approx. 20 weeks				
n	6	14	15	4
Mean (SD)	-8.86 (20.190)	-16.64 (24.845)	-17.39 (18.641)	-11.47 (19.178)
95% CL	[-30.05; 12.33]	[-30.99; -2.30]	[-27.71; -7.07]	[-41.99; 19.04]
Min-Max	-30.61 - 29.371	-50.97 - 27.027	-49.4 - 12.245	-38.98 - 5.4688

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.7.8.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Median	-12.73	-19.17	-22.35	-6.19
Q1-Q3	-16.56 - -9.88	-34.81 - -5.63	-28.89 - 4.09	-23.27 - 0.32
T-Test	t= -1.07 P= 0.332	t= -2.51 P= 0.026	t= -3.61 P= 0.003	t= -1.20 P= 0.317
After 24 weeks				
n	10	19	29	4
Mean (SD)	135.26 (20.569)	135.12 (30.412)	145.43 (40.871)	158.00 (16.391)
95% CL	[120.55; 149.97]	[120.46; 149.78]	[129.88; 160.98]	[131.92; 184.08]
Min-Max	115 - 175	90 - 213	90 - 263	135 - 172
Median	128.56	133.33	133.00	162.50
Q1-Q3	120.00 -156.00	111.00 -154.00	117.00 -173.00	146.50 -169.50
Absolute change after approx. 24 weeks				
n	10	19	29	4
Mean (SD)	-32.17 (39.637)	-39.57 (51.313)	-30.84 (47.941)	-17.50 (32.234)
95% CL	[-60.53; -3.82]	[-64.30; -14.84]	[-49.08; -12.61]	[-68.79; 33.79]
Min-Max	-117 - 32	-153 - 26	-172 - 44	-64 - 7
Median	-28.01	-23.00	-21.62	-6.50
Q1-Q3	-54.05 - -6.00	-47.00 - -6.00	-52.00 - -4.00	-39.00 - 4.00
T-Test	t= -2.57 P= 0.030	t= -3.36 P= 0.003	t= -3.46 P= 0.002	t= -1.09 P= 0.357
Relative change after approx. 24 weeks				
n	10	19	29	4
Mean (SD)	-16.62 (19.537)	-18.75 (21.766)	-14.40 (22.201)	-7.30 (14.364)
95% CL	[-30.60; -2.65]	[-29.24; -8.26]	[-22.84; -5.95]	[-30.15; 15.56]
Min-Max	-50.43 - 22.378	-62.5 - 13.904	-57.33 - 38.938	-27.12 - 5.4688
Median	-17.89	-15.65	-13.64	-3.77
Q1-Q3	-25.42 - -3.70	-29.75 - -3.75	-27.92 - -1.87	-17.63 - 3.04
T-Test	t= -2.69 P= 0.025	t= -3.76 P= 0.001	t= -3.49 P= 0.002	t= -1.02 P= 0.384

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	182.12 (48.387)	167.11 (22.558)	170.17 (46.686)
95% CL	[162.98; 201.26]	[149.77; 184.45]	[153.05; 187.30]
Min-Max	98 - 279	116 - 194	89 - 300
Median	171.00	171.00	157.00
Q1-Q3	139.00 -232.00	160.00 -180.00	147.00 -176.58
After 4 weeks			
n	19	9	21
Mean (SD)	159.04 (53.271)	142.11 (24.318)	139.62 (23.163)
95% CL	[133.37; 184.72]	[123.42; 160.80]	[129.08; 150.16]
Min-Max	98 - 320.72	94 - 172	98 - 180
Median	152.00	150.00	135.00
Q1-Q3	124.00 -172.97	134.00 -161.00	131.00 -151.35
After 8 weeks			
n	19	8	20
Mean (SD)	160.41 (51.761)	148.63 (34.818)	132.38 (26.761)
95% CL	[135.46; 185.36]	[119.52; 177.73]	[119.86; 144.90]
Min-Max	93 - 254	101 - 209	77 - 188
Median	169.00	154.50	128.87
Q1-Q3	114.00 -192.79	119.00 -166.00	120.50 -144.68
After 12 weeks			
n	26	9	32
Mean (SD)	149.94 (41.878)	141.67 (31.607)	144.10 (33.876)
95% CL	[133.02; 166.85]	[117.37; 165.96]	[131.89; 156.31]
Min-Max	98 - 246.85	95 - 200	77 - 242
Median	145.00	142.00	134.50
Q1-Q3	111.71 -187.39	132.00 -156.00	126.00 -164.00
After 16 weeks			
n	17	9	19
Mean (SD)	156.55 (42.508)	133.44 (27.695)	129.05 (22.601)
95% CL	[134.69; 178.40]	[112.16; 154.73]	[118.16; 139.95]
Min-Max	101 - 259.46	95 - 167	85 - 180
Median	156.00	132.00	131.53
Q1-Q3	121.00 -182.00	111.00 -162.00	119.00 -140.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.1 Absolute values of fasting glucose level

Fasting glucose level in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
After 20 weeks			
n	13	8	20
Mean (SD)	146.15 (33.745)	141.63 (42.214)	124.48 (21.577)
95% CL	[125.76; 166.55]	[106.33; 176.92]	[114.38; 134.58]
Min-Max	89 - 190.99	96 - 230	85 - 188
Median	144.00	131.00	129.87
Q1-Q3	130.00 -178.00	114.00 -158.50	108.50 -132.67
After 24 weeks			
n	25	9	29
Mean (SD)	141.89 (35.579)	159.00 (31.193)	134.69 (32.308)
95% CL	[127.21; 156.58]	[135.02; 182.98]	[122.40; 146.98]
Min-Max	90 - 214.42	111 - 213	90 - 263
Median	136.94	158.00	128.00
Q1-Q3	112.00 -167.00	150.00 -173.00	120.00 -141.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	182.12 (48.387)	167.11 (22.558)	170.17 (46.686)
95% CL	[162.98; 201.26]	[149.77; 184.45]	[153.05; 187.30]
Min-Max	98 - 279	116 - 194	89 - 300
Median	171.00	171.00	157.00
Q1-Q3	139.00 -232.00	160.00 -180.00	147.00 -176.58
After 4 weeks			
n	18	9	20
Mean (SD)	161.71 (53.492)	142.11 (24.318)	139.70 (23.761)
95% CL	[135.11; 188.31]	[123.42; 160.80]	[128.58; 150.82]
Min-Max	98 - 320.72	94 - 172	98 - 180
Median	153.00	150.00	134.00
Q1-Q3	129.73 -172.97	134.00 -161.00	129.00 -159.68
Absolute change after approx. 4 weeks			
n	18	9	20
Mean (SD)	-12.50 (40.120)	-25.00 (27.536)	-24.36 (28.605)
95% CL	[-32.45; 7.45]	[-46.17; -3.83]	[-37.75; -10.98]
Min-Max	-83 - 70.271	-77 - 6	-70 - 43.244
Median	-15.00	-22.00	-24.00
Q1-Q3	-44.00 - 15.00	-25.00 - -8.00	-45.50 - -8.50
T-Test	t= -1.32 P= 0.204	t= -2.72 P= 0.026	t= -3.81 P= 0.001
Relative change after approx. 4 weeks			
n	18	9	20
Mean (SD)	-6.00 (21.357)	-13.97 (15.658)	-12.67 (17.947)
95% CL	[-16.63; 4.62]	[-26.01; -1.94]	[-21.07; -4.27]
Min-Max	-38.79 - 31.25	-45.03 - 3.6145	-38.89 - 32
Median	-8.14	-12.79	-14.24
Q1-Q3	-23.73 - 10.79	-15.63 - -5.06	-23.84 - -6.05
T-Test	t= -1.19 P= 0.249	t= -2.68 P= 0.028	t= -3.16 P= 0.005
After 8 weeks			

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
n	18	8	19
Mean (SD)	164.16 (50.544)	148.63 (34.818)	132.40 (27.494)
95% CL	[139.02; 189.29]	[119.52; 177.73]	[119.15; 145.65]
Min-Max	99 - 254	101 - 209	77 - 188
Median	170.00	154.50	128.00
Q1-Q3	118.00 -192.79	119.00 -166.00	119.00 -151.35
Absolute change after approx. 8 weeks			
n	18	8	19
Mean (SD)	-10.93 (41.244)	-18.00 (26.651)	-29.50 (37.596)
95% CL	[-31.44; 9.58]	[-40.28; 4.28]	[-47.62; -11.38]
Min-Max	-115 - 81	-55 - 22	-87 - 39
Median	-7.21	-13.50	-30.00
Q1-Q3	-33.00 - 7.00	-42.50 - 0.50	-65.00 --14.00
T-Test	t= -1.12 P= 0.276	t= -1.91 P= 0.098	t= -3.42 P= 0.003
Relative change after approx. 8 weeks			
n	18	8	19
Mean (SD)	-4.87 (22.219)	-10.91 (15.091)	-15.67 (23.868)
95% CL	[-15.92; 6.18]	[-23.53; 1.70]	[-27.18; -4.17]
Min-Max	-53.74 - 46.821	-30.56 - 11.765	-48.67 - 43.82
Median	-2.87	-9.95	-19.11
Q1-Q3	-20.09 - 7.14	-24.55 - 0.24	-34.88 - -9.46
T-Test	t= -0.93 P= 0.366	t= -2.05 P= 0.080	t= -2.86 P= 0.010
After 12 weeks			
n	25	9	31
Mean (SD)	152.01 (41.351)	141.67 (31.607)	144.65 (34.290)
95% CL	[134.94; 169.08]	[117.37; 165.96]	[132.07; 157.23]
Min-Max	100 - 246.85	95 - 200	77 - 242
Median	145.00	142.00	137.00
Q1-Q3	115.00 -187.39	132.00 -156.00	126.00 -168.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Absolute change after approx. 12 weeks			
n	25	9	31
Mean (SD)	-30.97 (58.270)	-25.44 (23.335)	-25.52 (45.701)
95% CL	[-55.02; -6.91]	[-43.38; -7.51]	[-42.28; -8.76]
Min-Max	-130 - 63.064	-62 - 13	-132 - 65
Median	-35.00	-25.00	-26.00
Q1-Q3	-64.87 - 7.00	-33.00 --10.00	-54.00 - 4.00
T-Test	t= -2.66 P= 0.014	t= -3.27 P= 0.011	t= -3.11 P= 0.004
Relative change after approx. 12 weeks			
n	25	9	31
Mean (SD)	-12.18 (29.011)	-15.44 (13.159)	-11.00 (26.553)
95% CL	[-24.16; -0.21]	[-25.55; -5.32]	[-20.74; -1.26]
Min-Max	-54.17 - 46.053	-34.81 - 6.9519	-48.67 - 57.522
Median	-23.18	-16.96	-15.95
Q1-Q3	-26.64 - 7.14	-18.33 - -6.02	-30.00 - 2.56
T-Test	t= -2.10 P= 0.046	t= -3.52 P= 0.008	t= -2.31 P= 0.028
After 16 weeks			
n	16	9	18
Mean (SD)	159.40 (42.195)	133.44 (27.695)	129.56 (23.147)
95% CL	[136.91; 181.88]	[112.16; 154.73]	[118.05; 141.07]
Min-Max	101 - 259.46	95 - 167	85 - 180
Median	157.28	132.00	131.77
Q1-Q3	125.50 -189.20	111.00 -162.00	119.00 -140.00
Absolute change after approx. 16 weeks			
n	16	9	18
Mean (SD)	-18.53 (38.745)	-33.67 (24.708)	-29.54 (35.796)
95% CL	[-39.18; 2.11]	[-52.66; -14.67]	[-47.34; -11.74]
Min-Max	-88.29 - 31	-76 - -4	-100.9 - 25
Median	-12.11	-28.00	-23.11
Q1-Q3	-36.92 - 14.41	-51.00 --15.00	-45.00 - -1.00

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
T-Test	t= -1.91 P= 0.075	t= -4.09 P= 0.003	t= -3.50 P= 0.003
Relative change after approx. 16 weeks			
n	16	9	18
Mean (SD)	-8.24 (19.164)	-19.85 (13.916)	-16.11 (19.544)
95% CL	[-18.45; 1.97]	[-30.55; -9.15]	[-25.83; -6.39]
Min-Max	-39.25 - 21.678	-44.44 - -2.41	-52.78 - 17.606
Median	-6.55	-17.50	-15.74
Q1-Q3	-22.75 - 7.97	-29.75 --10.70	-30.61 - -0.71
T-Test	t= -1.72 P= 0.106	t= -4.28 P= 0.003	t= -3.50 P= 0.003
After 20 weeks			
n	12	8	19
Mean (SD)	147.50 (34.880)	141.63 (42.214)	125.29 (21.850)
95% CL	[125.34; 169.66]	[106.33; 176.92]	[114.76; 135.83]
Min-Max	89 - 190.99	96 - 230	85 - 188
Median	145.00	131.00	130.00
Q1-Q3	122.50 -181.50	114.00 -158.50	108.00 -133.33
Absolute change after approx. 20 weeks			
n	12	8	19
Mean (SD)	-20.72 (39.655)	-22.13 (38.316)	-35.40 (36.306)
95% CL	[-45.91; 4.48]	[-54.16; 9.91]	[-52.90; -17.90]
Min-Max	-92 - 42	-75 - 43	-105 - 40
Median	-18.81	-19.50	-26.00
Q1-Q3	-46.50 - 9.50	-53.50 - 0.50	-54.05 --12.00
T-Test	t= -1.81 P= 0.098	t= -1.63 P= 0.146	t= -4.25 P= 0.000
Relative change after approx. 20 weeks			
n	12	8	19
Mean (SD)	-9.63 (21.755)	-13.18 (22.405)	-19.58 (19.636)
95% CL	[-23.45; 4.19]	[-31.91; 5.55]	[-29.04; -10.11]
Min-Max	-38.98 - 29.371	-43.86 - 22.995	-50.97 - 27.027

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.7 Fasting glucose level measured by patient
4.7.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.7.9.2 Absolute and relative change every 4 weeks up to approx. 24 weeks after start of treatment

Fasting glucose measured by patient in mg/dl	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Median	-10.02	-11.90	-17.14
Q1-Q3	-29.26 - 7.36	-31.85 - 1.47	-30.61 - -7.80
T-Test	t= -1.53 P= 0.153	t= -1.66 P= 0.140	t= -4.35 P= 0.000
After 24 weeks			
n	24	9	28
Mean (SD)	142.39 (36.256)	159.00 (31.193)	135.47 (32.625)
95% CL	[127.08; 157.70]	[135.02; 182.98]	[122.82; 148.12]
Min-Max	90 - 214.42	111 - 213	90 - 263
Median	141.47	158.00	128.87
Q1-Q3	111.50 -167.28	150.00 -173.00	120.00 -142.00
Absolute change after approx. 24 weeks			
n	24	9	28
Mean (SD)	-44.01 (55.967)	-8.11 (20.763)	-31.36 (41.665)
95% CL	[-67.64; -20.38]	[-24.07; 7.85]	[-47.52; -15.21]
Min-Max	-159 - 32	-47 - 26	-172 - 44
Median	-27.50	-6.00	-25.50
Q1-Q3	-71.50 - -5.50	-21.00 - 4.00	-52.50 - -8.00
T-Test	t= -3.85 P= 0.001	t= -1.17 P= 0.275	t= -3.98 P= 0.000
Relative change after approx. 24 weeks			
n	24	9	28
Mean (SD)	-19.40 (23.793)	-4.89 (12.406)	-15.72 (20.416)
95% CL	[-29.45; -9.36]	[-14.43; 4.65]	[-23.64; -7.81]
Min-Max	-62.5 - 22.378	-29.75 - 13.904	-57.33 - 38.938
Median	-17.27	-3.75	-16.75
Q1-Q3	-34.24 - -3.51	-10.82 - 2.78	-28.40 - -3.35
T-Test	t= -4.00 P= 0.001	t= -1.18 P= 0.271	t= -4.08 P= 0.000

Fasting blood glucose in mg/dL = Fasting blood glucose in mmol/L * 18.0182
Changes only for patients with values at baseline und at the relevant visit

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.1 Full Analysis Set - FGM - SMBG
4.8.1.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	104.25 (22.534)	107.00 (23.108)	103.10 (22.438)
95% CL	[98.80; 109.70]	[96.18; 117.82]	[96.59; 109.62]
Min-Max	56 - 158	68 - 158	56 - 154
Median	103.00	103.50	98.50
Q1-Q3	84.50 -122.00	92.00 -120.00	84.00 -122.00
After 12 weeks			
n	59	16	43
Mean (SD)	103.88 (21.400)	112.07 (21.722)	100.83 (20.708)
95% CL	[98.30; 109.45]	[100.49; 123.64]	[94.45; 107.20]
Min-Max	56 - 165	78 - 165	56 - 140.1
Median	103.00	110.00	100.00
Q1-Q3	89.00 -120.00	96.50 -123.00	85.00 -120.00
Absolute change after approx. 12 weeks			
n	59	16	43
Mean (SD)	-1.41 (5.375)	-1.99 (4.096)	-1.20 (5.807)
95% CL	[-2.81; -0.01]	[-4.18; 0.19]	[-2.98; 0.59]
Min-Max	-24 - 8	-8 - 7	-24 - 8
Median	0.00	-1.50	0.00
Q1-Q3	-3.00 - 1.00	-5.00 - 0.00	-2.00 - 1.00
T-Test	t= -2.02 P= 0.048	t= -1.95 P= 0.070	t= -1.35 P= 0.184
Relative change after approx. 12 weeks			
n	59	16	43
Mean (SD)	-1.19 (4.516)	-1.98 (3.430)	-0.89 (4.861)
95% CL	[-2.36; -0.01]	[-3.81; -0.16]	[-2.39; 0.61]
Min-Max	-15.58 - 8.1176	-7.767 - 4.4304	-15.58 - 8.1176
Median	0.00	-1.40	0.00
Q1-Q3	-3.28 - 1.22	-4.84 - 0.00	-2.04 - 1.39
T-Test	t= -2.02 P= 0.048	t= -2.31 P= 0.035	t= -1.20 P= 0.237

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.1 Full Analysis Set - FGM - SMBG
4.8.1.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	104.25 (22.534)	107.00 (23.108)	103.10 (22.438)
95% CL	[98.80; 109.70]	[96.18; 117.82]	[96.59; 109.62]
Min-Max	56 - 158	68 - 158	56 - 154
Median	103.00	103.50	98.50
Q1-Q3	84.50 -122.00	92.00 -120.00	84.00 -122.00
After 24 weeks			
n	68	20	48
Mean (SD)	101.29 (21.552)	102.55 (22.816)	100.76 (21.231)
95% CL	[96.07; 106.50]	[91.87; 113.22]	[94.60; 106.93]
Min-Max	56 - 155	67 - 155	56 - 143
Median	100.00	102.00	100.00
Q1-Q3	85.70 -117.90	87.00 -115.50	85.70 -118.90
Absolute change after approx. 24 weeks			
n	68	20	48
Mean (SD)	-2.96 (7.528)	-4.46 (6.054)	-2.34 (8.039)
95% CL	[-4.79; -1.14]	[-7.29; -1.62]	[-4.68; -0.01]
Min-Max	-35 - 7	-20 - 2	-35 - 7
Median	-1.00	-2.50	-0.35
Q1-Q3	-4.00 - 1.00	-6.00 - 0.00	-3.45 - 2.00
T-Test	t= -3.25 P= 0.002	t= -3.29 P= 0.004	t= -2.02 P= 0.049
Relative change after approx. 24 weeks			
n	68	20	48
Mean (SD)	-2.53 (6.199)	-4.08 (5.216)	-1.88 (6.506)
95% CL	[-4.03; -1.03]	[-6.52; -1.64]	[-3.77; 0.01]
Min-Max	-25.93 - 7.0707	-16.39 - 1.6949	-25.93 - 7.0707
Median	-0.83	-1.81	-0.29
Q1-Q3	-4.27 - 1.16	-6.64 - 0.00	-3.38 - 2.00
T-Test	t= -3.36 P= 0.001	t= -3.50 P= 0.002	t= -2.00 P= 0.051

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.2 Full Analysis Set - Subgroups - Gender
4.8.2.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	Female (N = 28)	Male (N = 42)
Baseline		
n	26	42
Mean (SD)	97.42 (23.418)	108.48 (21.156)
95% CL	[87.96; 106.88]	[101.88; 115.07]
Min-Max	56 - 143	72 - 158
Median	98.00	104.50
Q1-Q3	75.00 -118.00	90.00 -123.00
After 12 weeks		
n	19	40
Mean (SD)	96.76 (22.560)	107.26 (20.242)
95% CL	[85.88; 107.63]	[100.78; 113.73]
Min-Max	56 - 130	73 - 165
Median	97.10	104.75
Q1-Q3	74.00 -118.00	91.45 -121.00
Absolute change after approx. 12 weeks		
n	19	40
Mean (SD)	-1.19 (4.567)	-1.52 (5.771)
95% CL	[-3.39; 1.01]	[-3.36; 0.33]
Min-Max	-15 - 7	-24 - 8
Median	-1.00	0.00
Q1-Q3	-2.70 - 1.00	-3.50 - 1.50
T-Test	t= -1.14 P= 0.271	t= -1.66 P= 0.104
Relative change after approx. 12 weeks		
n	19	40
Mean (SD)	-1.28 (4.244)	-1.14 (4.691)
95% CL	[-3.33; 0.76]	[-2.64; 0.36]
Min-Max	-13.64 - 6.1224	-15.58 - 8.1176
Median	-1.27	0.00
Q1-Q3	-3.28 - 0.78	-3.56 - 1.41
T-Test	t= -1.32 P= 0.204	t= -1.54 P= 0.133

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.2 Full Analysis Set - Subgroups - Gender
4.8.2.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	Female (N = 28)	Male (N = 42)
Baseline		
n	26	42
Mean (SD)	97.42 (23.418)	108.48 (21.156)
95% CL	[87.96; 106.88]	[101.88; 115.07]
Min-Max	56 - 143	72 - 158
Median	98.00	104.50
Q1-Q3	75.00 -118.00	90.00 -123.00
After 24 weeks		
n	26	42
Mean (SD)	95.05 (23.778)	105.14 (19.350)
95% CL	[85.45; 104.66]	[99.11; 111.17]
Min-Max	56 - 142.4	72 - 155
Median	93.55	102.75
Q1-Q3	72.00 -113.50	89.00 -118.80
Absolute change after approx. 24 weeks		
n	26	42
Mean (SD)	-2.37 (6.317)	-3.33 (8.240)
95% CL	[-4.92; 0.18]	[-5.90; -0.77]
Min-Max	-20 - 6	-35 - 7
Median	-0.80	-1.00
Q1-Q3	-4.90 - 2.00	-4.00 - 1.00
T-Test	t= -1.91 P= 0.067	t= -2.62 P= 0.012
Relative change after approx. 24 weeks		
n	26	42
Mean (SD)	-2.39 (5.853)	-2.62 (6.472)
95% CL	[-4.75; -0.03]	[-4.63; -0.60]
Min-Max	-17.27 - 5.102	-25.93 - 7.0707
Median	-0.60	-0.85
Q1-Q3	-4.76 - 1.69	-4.04 - 1.12
T-Test	t= -2.08 P= 0.048	t= -2.62 P= 0.012

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.3 Full Analysis Set - Subgroups - Age groups
4.8.3.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	20
Mean (SD)	113.21 (23.609)	99.25 (20.638)	99.50 (21.063)
95% CL	[103.24; 123.18]	[90.54; 107.96]	[89.64; 109.36]
Min-Max	68 - 158	65 - 138	56 - 130
Median	112.00	96.50	98.00
Q1-Q3	99.00 -128.50	83.00 -118.00	83.50 -118.00
After 12 weeks			
n	21	21	17
Mean (SD)	110.82 (21.565)	101.12 (21.294)	98.69 (20.253)
95% CL	[101.01; 120.64]	[91.43; 110.82]	[88.28; 109.11]
Min-Max	72.2 - 165	65 - 140.1	56 - 130
Median	107.00	97.00	95.00
Q1-Q3	97.10 -121.00	85.00 -118.00	89.70 -113.00
Absolute change after approx. 12 weeks			
n	21	21	17
Mean (SD)	-2.70 (7.478)	-0.54 (3.568)	-0.89 (3.931)
95% CL	[-6.10; 0.70]	[-2.17; 1.08]	[-2.92; 1.13]
Min-Max	-24 - 8	-8 - 7	-8 - 6.9
Median	-1.00	0.00	-1.00
Q1-Q3	-3.90 - 2.00	-2.00 - 1.00	-1.40 - 1.00
T-Test	t= -1.65 P= 0.114	t= -0.70 P= 0.494	t= -0.94 P= 0.362
Relative change after approx. 12 weeks			
n	21	21	17
Mean (SD)	-2.17 (5.717)	-0.60 (3.405)	-0.69 (4.072)
95% CL	[-4.78; 0.43]	[-2.15; 0.95]	[-2.79; 1.40]
Min-Max	-15.58 - 8.0808	-6.78 - 6.1224	-7.767 - 8.1176
Median	-1.27	0.00	-0.78
Q1-Q3	-3.28 - 1.43	-2.04 - 1.19	-1.33 - 1.11
T-Test	t= -1.74 P= 0.097	t= -0.81 P= 0.430	t= -0.70 P= 0.494

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.3 Full Analysis Set - Subgroups - Age groups
4.8.3.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	20
Mean (SD)	113.21 (23.609)	99.25 (20.638)	99.50 (21.063)
95% CL	[103.24; 123.18]	[90.54; 107.96]	[89.64; 109.36]
Min-Max	68 - 158	65 - 138	56 - 130
Median	112.00	96.50	98.00
Q1-Q3	99.00 -128.50	83.00 -118.00	83.50 -118.00
After 24 weeks			
n	24	24	20
Mean (SD)	106.54 (21.569)	97.92 (21.848)	99.03 (21.033)
95% CL	[97.43; 115.65]	[88.69; 107.14]	[89.18; 108.87]
Min-Max	67 - 155	67 - 143	56 - 129.2
Median	103.00	96.00	95.00
Q1-Q3	93.00 -119.00	83.50 -118.00	86.65 -117.40
Absolute change after approx. 24 weeks			
n	24	24	20
Mean (SD)	-6.67 (10.301)	-1.33 (5.298)	-0.48 (3.187)
95% CL	[-11.02; -2.32]	[-3.57; 0.90]	[-1.97; 1.02]
Min-Max	-35 - 7	-16 - 6	-8.7 - 4
Median	-2.70	-1.00	0.00
Q1-Q3	-9.50 - -0.25	-3.50 - 2.15	-1.00 - 1.60
T-Test	t= -3.17 P= 0.004	t= -1.23 P= 0.230	t= -0.67 P= 0.513
Relative change after approx. 24 weeks			
n	24	24	20
Mean (SD)	-5.35 (7.957)	-1.47 (5.122)	-0.42 (3.312)
95% CL	[-8.71; -1.99]	[-3.63; 0.69]	[-1.97; 1.13]
Min-Max	-25.93 - 7.0707	-13.56 - 5.102	-8.969 - 4.8193
Median	-2.50	-0.90	0.00
Q1-Q3	-7.54 - -0.21	-4.25 - 2.43	-0.98 - 1.40
T-Test	t= -3.29 P= 0.003	t= -1.41 P= 0.173	t= -0.56 P= 0.580

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.4 Full Analysis Set - Subgroups - Body Mass Index
4.8.4.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	16	52
Mean (SD)	80.94 (11.096)	111.42 (20.197)
95% CL	[75.02; 86.85]	[105.80; 117.05]
Min-Max	56 - 99	65 - 158
Median	82.50	114.00
Q1-Q3	74.50 - 87.00	98.00 -125.00
After 12 weeks		
n	13	46
Mean (SD)	83.99 (13.343)	109.50 (19.907)
95% CL	[75.93; 92.06]	[103.58; 115.41]
Min-Max	56 - 107	65 - 165
Median	84.00	110.00
Q1-Q3	74.00 - 91.90	96.00 -123.00
Absolute change after approx. 12 weeks		
n	13	46
Mean (SD)	1.76 (2.876)	-2.31 (5.594)
95% CL	[0.02; 3.50]	[-3.97; -0.65]
Min-Max	-1 - 8	-24 - 7
Median	1.00	-1.20
Q1-Q3	0.00 - 2.00	-4.00 - 1.00
T-Test	t= 2.21 P= 0.047	t= -2.80 P= 0.008
Relative change after approx. 12 weeks		
n	13	46
Mean (SD)	1.94 (3.177)	-2.07 (4.469)
95% CL	[0.02; 3.86]	[-3.40; -0.74]
Min-Max	-1.333 - 8.1176	-15.58 - 6.1224
Median	1.22	-1.03
Q1-Q3	0.00 - 2.13	-4.08 - 0.78
T-Test	t= 2.20 P= 0.048	t= -3.14 P= 0.003

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.4 Full Analysis Set - Subgroups - Body Mass Index
4.8.4.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	16	52
Mean (SD)	80.94 (11.096)	111.42 (20.197)
95% CL	[75.02; 86.85]	[105.80; 117.05]
Min-Max	56 - 99	65 - 158
Median	82.50	114.00
Q1-Q3	74.50 - 87.00	98.00 -125.00
After 24 weeks		
n	16	52
Mean (SD)	81.67 (12.640)	107.32 (20.134)
95% CL	[74.93; 88.40]	[101.72; 112.93]
Min-Max	56 - 106	67 - 155
Median	83.00	104.00
Q1-Q3	72.00 - 88.70	90.50 -122.50
Absolute change after approx. 24 weeks		
n	16	52
Mean (SD)	0.73 (2.371)	-4.10 (8.197)
95% CL	[-0.53; 1.99]	[-6.38; -1.82]
Min-Max	-3 - 7	-35 - 6
Median	0.15	-1.50
Q1-Q3	-0.50 - 1.50	-5.50 - 0.75
T-Test	t= 1.23 P= 0.236	t= -3.61 P= 0.001
Relative change after approx. 24 weeks		
n	16	52
Mean (SD)	0.70 (2.700)	-3.52 (6.638)
95% CL	[-0.74; 2.14]	[-5.37; -1.68]
Min-Max	-4 - 7.0707	-25.93 - 5.102
Median	0.19	-1.32
Q1-Q3	-0.67 - 1.67	-5.71 - 0.65
T-Test	t= 1.04 P= 0.314	t= -3.83 P= 0.000

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.5 Full Analysis Set - Subgroups - Renal function
4.8.5.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	15	39
Mean (SD)	95.47 (17.940)	105.05 (22.428)
95% CL	[85.53; 105.40]	[97.78; 112.32]
Min-Max	65 - 129	56 - 143
Median	98.00	105.00
Q1-Q3	83.00 -107.00	84.00 -122.00
After 12 weeks		
n	13	34
Mean (SD)	97.14 (18.191)	105.02 (21.736)
95% CL	[86.15; 108.13]	[97.44; 112.61]
Min-Max	65 - 130	56 - 142
Median	95.00	108.50
Q1-Q3	87.20 -105.60	85.00 -121.00
Absolute change after approx. 12 weeks		
n	13	34
Mean (SD)	-0.86 (3.719)	-0.62 (3.294)
95% CL	[-3.11; 1.39]	[-1.77; 0.53]
Min-Max	-8 - 6	-8 - 8
Median	-1.00	0.00
Q1-Q3	-2.00 - 1.00	-2.00 - 1.00
T-Test	t= -0.84 P= 0.420	t= -1.10 P= 0.278
Relative change after approx. 12 weeks		
n	13	34
Mean (SD)	-0.85 (3.838)	-0.62 (3.063)
95% CL	[-3.17; 1.47]	[-1.69; 0.45]
Min-Max	-7.767 - 6.1224	-6.78 - 8.0808
Median	-0.88	0.00
Q1-Q3	-2.04 - 0.78	-2.43 - 1.39
T-Test	t= -0.80 P= 0.438	t= -1.18 P= 0.246

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.5 Full Analysis Set - Subgroups - Renal function
4.8.5.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	15	39
Mean (SD)	95.47 (17.940)	105.05 (22.428)
95% CL	[85.53; 105.40]	[97.78; 112.32]
Min-Max	65 - 129	56 - 143
Median	98.00	105.00
Q1-Q3	83.00 -107.00	84.00 -122.00
After 24 weeks		
n	15	39
Mean (SD)	95.17 (18.236)	103.10 (22.960)
95% CL	[85.07; 105.27]	[95.65; 110.54]
Min-Max	67 - 129	56 - 143
Median	90.00	102.00
Q1-Q3	83.00 -109.00	85.00 -120.00
Absolute change after approx. 24 weeks		
n	15	39
Mean (SD)	-0.29 (3.949)	-1.95 (5.135)
95% CL	[-2.48; 1.89]	[-3.62; -0.29]
Min-Max	-8 - 5	-20 - 7
Median	0.50	-1.00
Q1-Q3	-3.00 - 2.00	-4.00 - 0.30
T-Test	t= -0.29 P= 0.778	t= -2.38 P= 0.023
Relative change after approx. 24 weeks		
n	15	39
Mean (SD)	-0.27 (4.216)	-1.90 (4.601)
95% CL	[-2.61; 2.06]	[-3.39; -0.41]
Min-Max	-8.495 - 5.102	-16.39 - 7.0707
Median	0.49	-0.85
Q1-Q3	-3.51 - 3.08	-4.04 - 0.38
T-Test	t= -0.25 P= 0.804	t= -2.58 P= 0.014

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.6 Full Analysis Set - Subgroups - Duration of diabetes
4.8.6.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	19	39
Mean (SD)	108.29 (14.092)	102.74 (27.763)	103.13 (21.801)
95% CL	[95.25; 121.32]	[89.36; 116.12]	[96.06; 110.20]
Min-Max	89 - 129	56 - 154	65 - 158
Median	105.00	105.00	98.00
Q1-Q3	98.00 -122.00	79.00 -123.00	84.00 -122.00
After 12 weeks			
n	7	15	34
Mean (SD)	107.87 (17.140)	98.25 (23.472)	104.35 (21.961)
95% CL	[92.02; 123.72]	[85.25; 111.24]	[96.69; 112.01]
Min-Max	85 - 129	56 - 142	65 - 165
Median	103.00	96.00	102.00
Q1-Q3	96.00 -129.00	78.00 -118.00	89.70 -120.00
Absolute change after approx. 12 weeks			
n	7	15	34
Mean (SD)	-0.41 (3.895)	-3.62 (7.435)	-0.62 (4.607)
95% CL	[-4.02; 3.19]	[-7.74; 0.50]	[-2.23; 0.99]
Min-Max	-4 - 7	-24 - 4	-15 - 8
Median	-2.00	-1.00	0.00
Q1-Q3	-3.90 - 2.00	-8.00 - 0.50	-2.00 - 1.00
T-Test	t= -0.28 P= 0.788	t= -1.89 P= 0.080	t= -0.79 P= 0.438
Relative change after approx. 12 weeks			
n	7	15	34
Mean (SD)	-0.69 (3.550)	-2.89 (5.685)	-0.52 (4.224)
95% CL	[-3.97; 2.60]	[-6.04; 0.26]	[-1.99; 0.95]
Min-Max	-4.494 - 5.7377	-15.58 - 4.8193	-11.11 - 8.1176
Median	-1.90	-1.27	0.00
Q1-Q3	-3.86 - 1.75	-6.78 - 0.48	-1.54 - 1.39
T-Test	t= -0.51 P= 0.627	t= -1.97 P= 0.069	t= -0.72 P= 0.477

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.6 Full Analysis Set - Subgroups - Duration of diabetes
4.8.6.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	19	39
Mean (SD)	108.29 (14.092)	102.74 (27.763)	103.13 (21.801)
95% CL	[95.25; 121.32]	[89.36; 116.12]	[96.06; 110.20]
Min-Max	89 - 129	56 - 154	65 - 158
Median	105.00	105.00	98.00
Q1-Q3	98.00 -122.00	79.00 -123.00	84.00 -122.00
After 24 weeks			
n	7	19	39
Mean (SD)	107.09 (15.727)	97.91 (25.043)	101.19 (21.464)
95% CL	[92.54; 121.63]	[85.84; 109.98]	[94.23; 108.15]
Min-Max	85 - 128	56 - 142.4	67 - 155
Median	102.00	91.00	100.00
Q1-Q3	96.10 -125.00	79.30 -122.00	85.10 -117.00
Absolute change after approx. 24 weeks			
n	7	19	39
Mean (SD)	-1.20 (4.531)	-4.83 (8.790)	-1.94 (6.999)
95% CL	[-5.39; 2.99]	[-9.06; -0.59]	[-4.20; 0.33]
Min-Max	-5 - 6	-29 - 4	-35 - 7
Median	-4.00	-1.00	0.00
Q1-Q3	-4.90 - 4.00	-4.00 - 0.00	-3.00 - 2.00
T-Test	t= -0.70 P= 0.510	t= -2.39 P= 0.028	t= -1.73 P= 0.092
Relative change after approx. 24 weeks			
n	7	19	39
Mean (SD)	-1.24 (4.211)	-4.01 (6.975)	-1.68 (5.889)
95% CL	[-5.13; 2.66]	[-7.37; -0.65]	[-3.59; 0.23]
Min-Max	-4.851 - 4.918	-18.83 - 4.8193	-25.93 - 7.0707
Median	-3.10	-0.95	0.00
Q1-Q3	-4.76 - 4.08	-4.04 - 0.00	-4.00 - 1.97
T-Test	t= -0.78 P= 0.467	t= -2.50 P= 0.022	t= -1.78 P= 0.082

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.8.7.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	30
Mean (SD)	104.82 (21.847)	103.53 (23.734)
95% CL	[97.63; 112.00]	[94.67; 112.40]
Min-Max	56 - 143	72 - 158
Median	103.50	98.00
Q1-Q3	85.00 -122.00	83.00 -118.00
After 12 weeks		
n	33	26
Mean (SD)	104.28 (20.037)	103.37 (23.411)
95% CL	[97.17; 111.38]	[93.91; 112.83]
Min-Max	56 - 142	72.2 - 165
Median	104.00	101.50
Q1-Q3	91.90 -121.00	85.00 -118.00
Absolute change after approx. 12 weeks		
n	33	26
Mean (SD)	-1.27 (4.642)	-1.59 (6.276)
95% CL	[-2.92; 0.38]	[-4.13; 0.94]
Min-Max	-15 - 8	-24 - 7
Median	-0.50	0.00
Q1-Q3	-3.00 - 1.00	-2.00 - 2.00
T-Test	t= -1.57 P= 0.126	t= -1.29 P= 0.208
Relative change after approx. 12 weeks		
n	33	26
Mean (SD)	-1.10 (4.456)	-1.29 (4.677)
95% CL	[-2.68; 0.48]	[-3.18; 0.60]
Min-Max	-13.64 - 8.1176	-15.58 - 6.1224
Median	-0.39	0.00
Q1-Q3	-3.28 - 0.82	-2.43 - 1.52
T-Test	t= -1.42 P= 0.164	t= -1.41 P= 0.172

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.8.7.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	30
Mean (SD)	104.82 (21.847)	103.53 (23.734)
95% CL	[97.63; 112.00]	[94.67; 112.40]
Min-Max	56 - 143	72 - 158
Median	103.50	98.00
Q1-Q3	85.00 -122.00	83.00 -118.00
After 24 weeks		
n	38	30
Mean (SD)	103.16 (21.681)	98.92 (21.518)
95% CL	[96.03; 110.28]	[90.88; 106.95]
Min-Max	56 - 142.4	71.6 - 155
Median	102.00	96.50
Q1-Q3	87.40 -122.00	83.00 -114.00
Absolute change after approx. 24 weeks		
n	38	30
Mean (SD)	-1.66 (5.916)	-4.62 (9.012)
95% CL	[-3.61; 0.28]	[-7.98; -1.25]
Min-Max	-20 - 7	-35 - 5
Median	-0.40	-1.50
Q1-Q3	-3.00 - 2.00	-6.00 - 0.00
T-Test	t= -1.73 P= 0.092	t= -2.81 P= 0.009
Relative change after approx. 24 weeks		
n	38	30
Mean (SD)	-1.42 (5.367)	-3.94 (6.954)
95% CL	[-3.18; 0.35]	[-6.54; -1.34]
Min-Max	-17.27 - 7.0707	-25.93 - 5.102
Median	-0.29	-1.53
Q1-Q3	-3.51 - 1.97	-6.49 - 0.00
T-Test	t= -1.63 P= 0.112	t= -3.10 P= 0.004

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.8.8.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	23	29	5
Mean (SD)	117.64 (19.679)	103.04 (20.901)	97.76 (22.674)	118.00 (22.204)
95% CL	[104.42; 130.86]	[94.01; 112.08]	[89.13; 106.38]	[90.43; 145.57]
Min-Max	82 - 154	74 - 140	56 - 158	83 - 143
Median	122.00	103.00	98.00	118.00
Q1-Q3	98.00 -128.00	84.00 -122.00	84.00 -114.00	117.00 -129.00
After 12 weeks				
n	10	18	28	3
Mean (SD)	116.90 (16.162)	103.88 (19.949)	97.60 (22.591)	119.00 (9.539)
95% CL	[105.34; 128.46]	[93.96; 113.80]	[88.84; 106.36]	[95.30; 142.70]
Min-Max	83 - 130	72.2 - 142	56 - 165	110 - 129
Median	122.50	98.50	96.55	118.00
Q1-Q3	110.00 -129.00	91.00 -118.00	84.50 -114.50	110.00 -129.00
Absolute change after approx. 12 weeks				
n	10	18	28	3
Mean (SD)	-3.00 (8.313)	-0.68 (5.300)	-1.22 (4.324)	-2.33 (4.041)
95% CL	[-8.95; 2.95]	[-3.31; 1.96]	[-2.89; 0.46]	[-12.37; 7.71]
Min-Max	-24 - 7	-15 - 8	-15 - 7	-7 - 0
Median	-0.50	-0.25	0.00	0.00
Q1-Q3	-4.00 - 1.00	-2.00 - 2.00	-3.30 - 1.00	-7.00 - 0.00
T-Test	t= -1.14 P= 0.283	t= -0.54 P= 0.594	t= -1.49 P= 0.148	t= -1.00 P= 0.423
Relative change after approx. 12 weeks				
n	10	18	28	3
Mean (SD)	-2.07 (5.739)	-0.53 (5.167)	-1.20 (3.806)	-1.99 (3.454)
95% CL	[-6.18; 2.03]	[-3.10; 2.04]	[-2.68; 0.27]	[-10.58; 6.59]
Min-Max	-15.58 - 5.7377	-13.64 - 8.1176	-11.11 - 6.1224	-5.983 - 0
Median	-0.39	-0.20	0.00	0.00
Q1-Q3	-3.28 - 0.78	-2.43 - 1.52	-3.76 - 1.29	-5.98 - 0.00
T-Test	t= -1.14 P= 0.283	t= -0.44 P= 0.668	t= -1.67 P= 0.106	t= -1.00 P= 0.423

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.8.8.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	23	29	5
Mean (SD)	117.64 (19.679)	103.04 (20.901)	97.76 (22.674)	118.00 (22.204)
95% CL	[104.42; 130.86]	[94.01; 112.08]	[89.13; 106.38]	[90.43; 145.57]
Min-Max	82 - 154	74 - 140	56 - 158	83 - 143
Median	122.00	103.00	98.00	118.00
Q1-Q3	98.00 -128.00	84.00 -122.00	84.00 -114.00	117.00 -129.00
After 24 weeks				
n	11	23	29	5
Mean (SD)	110.84 (17.300)	101.09 (21.599)	95.16 (21.317)	116.68 (21.597)
95% CL	[99.21; 122.46]	[91.75; 110.43]	[87.05; 103.27]	[89.86; 143.50]
Min-Max	83 - 129.2	71.6 - 143	56 - 155	83 - 142.4
Median	115.00	95.00	96.10	117.00
Q1-Q3	102.00 -128.00	87.00 -116.00	85.00 -104.00	116.00 -125.00
Absolute change after approx. 24 weeks				
n	11	23	29	5
Mean (SD)	-6.80 (11.562)	-1.95 (6.258)	-2.60 (7.035)	-1.32 (1.553)
95% CL	[-14.57; 0.97]	[-4.66; 0.75]	[-5.27; 0.08]	[-3.25; 0.61]
Min-Max	-29 - 6	-19 - 7	-35 - 5	-4 - 0
Median	0.00	-1.00	-1.00	-1.00
Q1-Q3	-16.00 - 2.00	-4.00 - 2.30	-4.00 - 0.50	-1.00 - -0.60
T-Test	t= -1.95 P= 0.080	t= -1.50 P= 0.149	t= -1.99 P= 0.057	t= -1.90 P= 0.130
Relative change after approx. 24 weeks				
n	11	23	29	5
Mean (SD)	-5.24 (8.878)	-1.87 (5.914)	-2.28 (5.694)	-1.04 (1.203)
95% CL	[-11.21; 0.72]	[-4.43; 0.68]	[-4.44; -0.11]	[-2.54; 0.45]
Min-Max	-18.83 - 4.918	-17.27 - 7.0707	-25.93 - 5.102	-3.101 - 0
Median	0.00	-0.95	-0.81	-0.85
Q1-Q3	-13.56 - 1.69	-4.04 - 1.97	-3.92 - 0.49	-0.85 - -0.42
T-Test	t= -1.96 P= 0.079	t= -1.52 P= 0.143	t= -2.15 P= 0.040	t= -1.94 P= 0.124

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.8.9.1 Change in body weight in kg up to approx. 12 weeks after the start of treatment

Body weight in kg	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	105.00 (25.701)	104.11 (16.556)	104.29 (21.779)
95% CL	[94.83; 115.17]	[91.38; 116.84]	[96.30; 112.28]
Min-Max	56 - 154	74 - 130	68 - 158
Median	105.00	103.00	101.00
Q1-Q3	83.00 -128.00	99.00 -117.00	85.00 -119.00
After 12 weeks			
n	24	9	26
Mean (SD)	100.82 (23.250)	101.22 (16.037)	107.62 (21.373)
95% CL	[91.00; 110.64]	[88.89; 113.55]	[98.98; 116.25]
Min-Max	56 - 130	74 - 128	73 - 165
Median	99.50	97.00	106.30
Q1-Q3	85.00 -124.75	95.00 -110.00	91.90 -118.00
Absolute change after approx. 12 weeks			
n	24	9	26
Mean (SD)	-2.47 (7.036)	-2.89 (3.296)	0.08 (3.720)
95% CL	[-5.44; 0.50]	[-5.42; -0.36]	[-1.43; 1.58]
Min-Max	-24 - 7	-8 - 0	-8 - 8
Median	-0.25	-2.00	0.00
Q1-Q3	-3.35 - 1.00	-6.00 - 0.00	-2.00 - 2.00
T-Test	t= -1.72 P= 0.099	t= -2.63 P= 0.030	t= 0.11 P= 0.917
Relative change after approx. 12 weeks			
n	24	9	26
Mean (SD)	-1.97 (5.576)	-2.68 (3.099)	0.05 (3.558)
95% CL	[-4.32; 0.39]	[-5.06; -0.30]	[-1.39; 1.49]
Min-Max	-15.58 - 6.1224	-7.767 - 0	-6.78 - 8.1176
Median	-0.20	-1.54	0.00
Q1-Q3	-3.87 - 0.97	-5.83 - 0.00	-1.63 - 1.72
T-Test	t= -1.73 P= 0.098	t= -2.60 P= 0.032	t= 0.07 P= 0.942

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.8 Absolute and relative change in body weight in kg
4.8.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.8.9.2 Change in body weight in kg up to approx. 24 weeks after the start of treatment

Body weight in kg	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	105.00 (25.701)	104.11 (16.556)	104.29 (21.779)
95% CL	[94.83; 115.17]	[91.38; 116.84]	[96.30; 112.28]
Min-Max	56 - 154	74 - 130	68 - 158
Median	105.00	103.00	101.00
Q1-Q3	83.00 -128.00	99.00 -117.00	85.00 -119.00
After 24 weeks			
n	27	9	31
Mean (SD)	100.74 (23.825)	102.39 (16.699)	101.92 (21.507)
95% CL	[91.32; 110.17]	[89.55; 115.22]	[94.03; 109.81]
Min-Max	56 - 142.4	72 - 128	67 - 155
Median	97.00	103.50	102.00
Q1-Q3	83.00 -125.00	95.00 -116.00	85.00 -115.00
Absolute change after approx. 24 weeks			
n	27	9	31
Mean (SD)	-4.26 (9.913)	-1.72 (2.489)	-2.37 (6.040)
95% CL	[-8.18; -0.33]	[-3.64; 0.19]	[-4.59; -0.16]
Min-Max	-35 - 6	-7 - 1	-20 - 7
Median	-1.00	-1.00	-1.00
Q1-Q3	-5.00 - 1.00	-2.00 - 0.00	-4.90 - 2.00
T-Test	t= -2.23 P= 0.035	t= -2.08 P= 0.072	t= -2.19 P= 0.037
Relative change after approx. 24 weeks			
n	27	9	31
Mean (SD)	-3.45 (7.801)	-1.69 (2.489)	-2.14 (5.419)
95% CL	[-6.54; -0.37]	[-3.60; 0.23]	[-4.13; -0.15]
Min-Max	-25.93 - 5.102	-6.796 - 1.1236	-16.39 - 7.0707
Median	-0.77	-0.85	-0.81
Q1-Q3	-4.76 - 0.94	-2.70 - 0.00	-4.85 - 1.87
T-Test	t= -2.30 P= 0.030	t= -2.03 P= 0.077	t= -2.20 P= 0.036

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.1 Full Analysis Set - FGM - SMBG
4.9.1.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	35.10 (7.165)	35.82 (7.640)	34.81 (7.020)
95% CL	[33.37; 36.84]	[32.24; 39.39]	[32.77; 36.85]
Min-Max	21.6 - 51.59	25.59 - 51.59	21.6 - 51.27
Median	34.44	34.24	34.44
Q1-Q3	30.10 - 39.18	30.62 - 40.01	29.86 - 38.75
After 12 weeks			
n	59	16	43
Mean (SD)	34.77 (6.940)	36.92 (8.215)	33.98 (6.325)
95% CL	[32.97; 36.58]	[32.54; 41.29]	[32.03; 35.93]
Min-Max	21.6 - 53.88	25.76 - 53.88	21.6 - 49.54
Median	33.95	34.81	33.66
Q1-Q3	29.64 - 39.25	30.52 - 42.15	29.64 - 37.77
Absolute change after approx. 12 weeks			
n	59	16	43
Mean (SD)	-0.48 (1.769)	-0.62 (1.316)	-0.42 (1.921)
95% CL	[-0.94; -0.02]	[-1.33; 0.08]	[-1.01; 0.17]
Min-Max	-7.75 - 2.33	-2.47 - 2.29	-7.75 - 2.33
Median	0.00	-0.47	0.00
Q1-Q3	-1.11 - 0.39	-1.74 - 0.00	-0.76 - 0.39
T-Test	t= -2.07 P= 0.042	t= -1.90 P= 0.077	t= -1.45 P= 0.156
Relative change after approx. 12 weeks			
n	59	16	43
Mean (SD)	-1.18 (4.514)	-1.98 (3.431)	-0.89 (4.859)
95% CL	[-2.36; -0.01]	[-3.81; -0.16]	[-2.38; 0.61]
Min-Max	-15.59 - 8.084	-7.77 - 4.4388	-15.59 - 8.084
Median	0.00	-1.39	0.00
Q1-Q3	-3.29 - 1.20	-4.84 - 0.00	-2.04 - 1.42
T-Test	t= -2.02 P= 0.048	t= -2.31 P= 0.035	t= -1.20 P= 0.238

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.1 Full Analysis Set - FGM - SMBG
4.9.1.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Baseline			
n	68	20	48
Mean (SD)	35.10 (7.165)	35.82 (7.640)	34.81 (7.020)
95% CL	[33.37; 36.84]	[32.24; 39.39]	[32.77; 36.85]
Min-Max	21.6 - 51.59	25.59 - 51.59	21.6 - 51.27
Median	34.44	34.24	34.44
Q1-Q3	30.10 - 39.18	30.62 - 40.01	29.86 - 38.75
After 24 weeks			
n	68	20	48
Mean (SD)	34.10 (6.802)	34.32 (7.487)	34.01 (6.577)
95% CL	[32.45; 35.74]	[30.81; 37.82]	[32.10; 35.92]
Min-Max	21.6 - 51.06	25.22 - 50.61	21.6 - 51.06
Median	32.62	31.67	32.90
Q1-Q3	29.14 - 37.72	29.03 - 38.95	29.14 - 37.14
Absolute change after approx. 24 weeks			
n	68	20	48
Mean (SD)	-1.01 (2.504)	-1.50 (2.052)	-0.80 (2.662)
95% CL	[-1.61; -0.40]	[-2.46; -0.54]	[-1.57; -0.03]
Min-Max	-11.56 - 2.04	-7.53 - 0.67	-11.56 - 2.04
Median	-0.31	-0.90	-0.13
Q1-Q3	-1.32 - 0.35	-2.21 - 0.00	-1.19 - 0.63
T-Test	t= -3.32 P= 0.001	t= -3.27 P= 0.004	t= -2.09 P= 0.042
Relative change after approx. 24 weeks			
n	68	20	48
Mean (SD)	-2.53 (6.199)	-4.08 (5.213)	-1.88 (6.507)
95% CL	[-4.03; -1.03]	[-6.52; -1.64]	[-3.77; 0.01]
Min-Max	-25.93 - 7.0515	-16.4 - 1.6796	-25.93 - 7.0515
Median	-0.82	-1.81	-0.29
Q1-Q3	-4.27 - 1.15	-6.63 - 0.00	-3.36 - 2.00
T-Test	t= -3.36 P= 0.001	t= -3.50 P= 0.002	t= -2.00 P= 0.051

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.2 Full Analysis Set - Subgroups - Gender
4.9.2.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	Female (N = 28)	Male (N = 42)
Baseline		
n	26	42
Mean (SD)	36.13 (7.880)	34.47 (6.704)
95% CL	[32.95; 39.31]	[32.38; 36.56]
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.72	34.03
Q1-Q3	30.67 - 40.01	29.07 - 37.92
After 12 weeks		
n	19	40
Mean (SD)	36.15 (7.817)	34.12 (6.485)
95% CL	[32.39; 39.92]	[32.05; 36.19]
Min-Max	21.6 - 49.54	23.57 - 53.88
Median	34.88	32.39
Q1-Q3	30.44 - 41.65	29.48 - 38.00
Absolute change after approx. 12 weeks		
n	19	40
Mean (SD)	-0.45 (1.617)	-0.49 (1.856)
95% CL	[-1.23; 0.33]	[-1.09; 0.10]
Min-Max	-5.31 - 2.26	-7.75 - 2.33
Median	-0.33	0.00
Q1-Q3	-1.11 - 0.39	-1.14 - 0.46
T-Test	t= -1.20 P= 0.244	t= -1.68 P= 0.101
Relative change after approx. 12 weeks		
n	19	40
Mean (SD)	-1.28 (4.245)	-1.14 (4.689)
95% CL	[-3.33; 0.76]	[-2.64; 0.36]
Min-Max	-13.63 - 6.1348	-15.59 - 8.084
Median	-1.26	0.00
Q1-Q3	-3.29 - 0.79	-3.56 - 1.42
T-Test	t= -1.32 P= 0.204	t= -1.53 P= 0.133

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.2 Full Analysis Set - Subgroups - Gender
4.9.2.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	Female (N = 28)	Male (N = 42)
Baseline		
n	26	42
Mean (SD)	36.13 (7.880)	34.47 (6.704)
95% CL	[32.95; 39.31]	[32.38; 36.56]
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.72	34.03
Q1-Q3	30.67 - 40.01	29.07 - 37.92
After 24 weeks		
n	26	42
Mean (SD)	35.25 (7.984)	33.38 (5.946)
95% CL	[32.03; 38.48]	[31.53; 35.24]
Min-Max	21.6 - 51.06	23.24 - 50.61
Median	35.16	31.67
Q1-Q3	29.22 - 40.56	29.06 - 36.93
Absolute change after approx. 24 weeks		
n	26	42
Mean (SD)	-0.88 (2.284)	-1.09 (2.655)
95% CL	[-1.80; 0.04]	[-1.91; -0.26]
Min-Max	-7.53 - 1.93	-11.56 - 2.04
Median	-0.27	-0.31
Q1-Q3	-1.80 - 0.66	-1.30 - 0.33
T-Test	t= -1.96 P= 0.061	t= -2.65 P= 0.011
Relative change after approx. 24 weeks		
n	26	42
Mean (SD)	-2.39 (5.851)	-2.62 (6.473)
95% CL	[-4.75; -0.03]	[-4.63; -0.60]
Min-Max	-17.27 - 5.0979	-25.93 - 7.0515
Median	-0.60	-0.85
Q1-Q3	-4.77 - 1.68	-4.06 - 1.13
T-Test	t= -2.08 P= 0.048	t= -2.62 P= 0.012

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.3 Full Analysis Set - Subgroups - Age groups
4.9.3.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	20
Mean (SD)	38.06 (8.451)	33.54 (4.341)	33.44 (7.397)
95% CL	[34.49; 41.63]	[31.71; 35.37]	[29.98; 36.90]
Min-Max	25.59 - 51.59	26.57 - 40.12	21.6 - 49.15
Median	37.66	33.69	33.82
Q1-Q3	30.88 - 46.49	30.10 - 37.58	28.57 - 36.36
After 12 weeks			
n	21	21	17
Mean (SD)	37.29 (7.902)	33.85 (4.610)	32.81 (7.514)
95% CL	[33.69; 40.88]	[31.75; 35.95]	[28.95; 36.68]
Min-Max	25.76 - 53.88	27.73 - 41.65	21.6 - 49.54
Median	35.67	32.49	31.49
Q1-Q3	31.26 - 41.97	29.64 - 37.77	29.32 - 34.88
Absolute change after approx. 12 weeks			
n	21	21	17
Mean (SD)	-0.92 (2.462)	-0.19 (1.176)	-0.29 (1.276)
95% CL	[-2.04; 0.20]	[-0.72; 0.35]	[-0.94; 0.37]
Min-Max	-7.75 - 2.33	-2.36 - 2.26	-2.52 - 2.27
Median	-0.33	0.00	-0.28
Q1-Q3	-1.43 - 0.57	-0.71 - 0.33	-0.46 - 0.39
T-Test	t= -1.72 P= 0.101	t= -0.73 P= 0.473	t= -0.93 P= 0.367
Relative change after approx. 12 weeks			
n	21	21	17
Mean (SD)	-2.18 (5.714)	-0.60 (3.406)	-0.69 (4.068)
95% CL	[-4.78; 0.43]	[-2.15; 0.95]	[-2.78; 1.41]
Min-Max	-15.59 - 8.0539	-6.772 - 6.1348	-7.77 - 8.084
Median	-1.26	0.00	-0.77
Q1-Q3	-3.29 - 1.42	-2.04 - 1.20	-1.32 - 1.12
T-Test	t= -1.74 P= 0.096	t= -0.80 P= 0.431	t= -0.69 P= 0.497

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.3 Full Analysis Set - Subgroups - Age groups
4.9.3.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Baseline			
n	24	24	20
Mean (SD)	38.06 (8.451)	33.54 (4.341)	33.44 (7.397)
95% CL	[34.49; 41.63]	[31.71; 35.37]	[29.98; 36.90]
Min-Max	25.59 - 51.59	26.57 - 40.12	21.6 - 49.15
Median	37.66	33.69	33.82
Q1-Q3	30.88 - 46.49	30.10 - 37.58	28.57 - 36.36
After 24 weeks			
n	24	24	20
Mean (SD)	35.80 (7.810)	33.09 (4.972)	33.26 (7.326)
95% CL	[32.51; 39.10]	[30.99; 35.19]	[29.83; 36.69]
Min-Max	25.22 - 51.06	25.51 - 41.32	21.6 - 49.15
Median	33.69	31.15	32.50
Q1-Q3	29.76 - 39.37	29.03 - 37.80	28.97 - 35.96
Absolute change after approx. 24 weeks			
n	24	24	20
Mean (SD)	-2.26 (3.427)	-0.45 (1.720)	-0.18 (1.106)
95% CL	[-3.70; -0.81]	[-1.18; 0.27]	[-0.69; 0.34]
Min-Max	-11.56 - 2.04	-4.72 - 1.93	-3.01 - 1.2
Median	-1.00	-0.32	0.00
Q1-Q3	-2.89 - -0.11	-1.27 - 0.79	-0.33 - 0.50
T-Test	t= -3.22 P= 0.004	t= -1.29 P= 0.211	t= -0.72 P= 0.483
Relative change after approx. 24 weeks			
n	24	24	20
Mean (SD)	-5.35 (7.960)	-1.47 (5.115)	-0.42 (3.311)
95% CL	[-8.71; -1.99]	[-3.63; 0.69]	[-1.97; 1.13]
Min-Max	-25.93 - 7.0515	-13.54 - 5.0979	-8.969 - 4.8426
Median	-2.49	-0.90	0.00
Q1-Q3	-7.54 - -0.20	-4.24 - 2.43	-0.98 - 1.41
T-Test	t= -3.29 P= 0.003	t= -1.41 P= 0.172	t= -0.56 P= 0.581

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.4 Full Analysis Set - Subgroups - Body Mass Index
4.9.4.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	16	52
Mean (SD)	26.78 (2.270)	37.67 (6.121)
95% CL	[25.57; 27.99]	[35.96; 39.37]
Min-Max	21.6 - 29.64	30.08 - 51.59
Median	27.29	36.06
Q1-Q3	25.33 - 28.67	33.60 - 39.95
After 12 weeks		
n	13	46
Mean (SD)	27.24 (2.789)	36.90 (6.243)
95% CL	[25.56; 28.93]	[35.05; 38.76]
Min-Max	21.6 - 31.26	28.73 - 53.88
Median	27.75	35.33
Q1-Q3	25.76 - 29.07	31.67 - 39.64
Absolute change after approx. 12 weeks		
n	13	46
Mean (SD)	0.53 (0.885)	-0.76 (1.856)
95% CL	[-0.00; 1.07]	[-1.32; -0.21]
Min-Max	-0.33 - 2.33	-7.75 - 2.29
Median	0.33	-0.36
Q1-Q3	0.00 - 0.58	-1.47 - 0.35
T-Test	t= 2.18 P= 0.050	t= -2.79 P= 0.008
Relative change after approx. 12 weeks		
n	13	46
Mean (SD)	1.94 (3.167)	-2.07 (4.469)
95% CL	[0.03; 3.85]	[-3.39; -0.74]
Min-Max	-1.317 - 8.084	-15.59 - 6.1348
Median	1.20	-1.01
Q1-Q3	0.00 - 2.13	-4.08 - 0.79
T-Test	t= 2.21 P= 0.047	t= -3.14 P= 0.003

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.4 Full Analysis Set - Subgroups - Body Mass Index
4.9.4.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Baseline		
n	16	52
Mean (SD)	26.78 (2.270)	37.67 (6.121)
95% CL	[25.57; 27.99]	[35.96; 39.37]
Min-Max	21.6 - 29.64	30.08 - 51.59
Median	27.29	36.06
Q1-Q3	25.33 - 28.67	33.60 - 39.95
After 24 weeks		
n	16	52
Mean (SD)	26.97 (2.488)	36.29 (6.175)
95% CL	[25.65; 28.30]	[34.57; 38.01]
Min-Max	21.6 - 30.97	27.12 - 51.06
Median	27.74	35.28
Q1-Q3	25.37 - 28.86	31.15 - 39.19
Absolute change after approx. 24 weeks		
n	16	52
Mean (SD)	0.20 (0.744)	-1.38 (2.735)
95% CL	[-0.20; 0.59]	[-2.14; -0.62]
Min-Max	-1.06 - 2.04	-11.56 - 1.93
Median	0.05	-0.47
Q1-Q3	-0.16 - 0.46	-2.02 - 0.25
T-Test	t= 1.06 P= 0.308	t= -3.63 P= 0.001
Relative change after approx. 24 weeks		
n	16	52
Mean (SD)	0.70 (2.695)	-3.52 (6.637)
95% CL	[-0.73; 2.14]	[-5.37; -1.68]
Min-Max	-3.989 - 7.0515	-25.93 - 5.0979
Median	0.19	-1.31
Q1-Q3	-0.66 - 1.67	-5.70 - 0.65
T-Test	t= 1.05 P= 0.312	t= -3.83 P= 0.000

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.5 Full Analysis Set - Subgroups - Renal function
4.9.5.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	15	39
Mean (SD)	33.73 (7.161)	35.00 (6.957)
95% CL	[29.77; 37.70]	[32.74; 37.25]
Min-Max	24.78 - 49.15	21.6 - 51.27
Median	33.75	34.85
Q1-Q3	28.41 - 36.00	30.12 - 39.46
After 12 weeks		
n	13	34
Mean (SD)	34.36 (7.465)	34.79 (6.784)
95% CL	[29.85; 38.87]	[32.43; 37.16]
Min-Max	24.73 - 49.54	21.6 - 48.91
Median	34.01	34.35
Q1-Q3	29.32 - 36.85	29.64 - 39.51
Absolute change after approx. 12 weeks		
n	13	34
Mean (SD)	-0.29 (1.253)	-0.21 (1.054)
95% CL	[-1.05; 0.47]	[-0.58; 0.15]
Min-Max	-2.47 - 2.13	-2.36 - 2.33
Median	-0.32	0.00
Q1-Q3	-0.71 - 0.39	-0.76 - 0.36
T-Test	t= -0.83 P= 0.421	t= -1.19 P= 0.244
Relative change after approx. 12 weeks		
n	13	34
Mean (SD)	-0.85 (3.846)	-0.62 (3.060)
95% CL	[-3.17; 1.47]	[-1.69; 0.45]
Min-Max	-7.77 - 6.1348	-6.772 - 8.0539
Median	-0.86	0.00
Q1-Q3	-2.04 - 0.79	-2.44 - 1.42
T-Test	t= -0.80 P= 0.441	t= -1.18 P= 0.246

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.5 Full Analysis Set - Subgroups - Renal function
4.9.5.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Baseline		
n	15	39
Mean (SD)	33.73 (7.161)	35.00 (6.957)
95% CL	[29.77; 37.70]	[32.74; 37.25]
Min-Max	24.78 - 49.15	21.6 - 51.27
Median	33.75	34.85
Q1-Q3	28.41 - 36.00	30.12 - 39.46
After 24 weeks		
n	15	39
Mean (SD)	33.63 (7.242)	34.30 (6.908)
95% CL	[29.62; 37.64]	[32.06; 36.54]
Min-Max	24.73 - 49.15	21.6 - 51.06
Median	32.76	32.47
Q1-Q3	28.73 - 36.14	29.32 - 38.67
Absolute change after approx. 24 weeks		
n	15	39
Mean (SD)	-0.11 (1.411)	-0.70 (1.733)
95% CL	[-0.89; 0.67]	[-1.26; -0.13]
Min-Max	-2.94 - 1.77	-7.53 - 2.04
Median	0.15	-0.31
Q1-Q3	-1.06 - 0.97	-1.24 - 0.10
T-Test	t= -0.30 P= 0.771	t= -2.51 P= 0.016
Relative change after approx. 24 weeks		
n	15	39
Mean (SD)	-0.27 (4.216)	-1.90 (4.597)
95% CL	[-2.61; 2.06]	[-3.39; -0.41]
Min-Max	-8.504 - 5.0979	-16.4 - 7.0515
Median	0.47	-0.83
Q1-Q3	-3.49 - 3.05	-4.06 - 0.38
T-Test	t= -0.25 P= 0.805	t= -2.58 P= 0.014

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.6 Full Analysis Set - Subgroups - Duration of diabetes
4.9.6.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	19	39
Mean (SD)	38.27 (5.499)	34.94 (9.026)	34.17 (6.378)
95% CL	[33.18; 43.36]	[30.59; 39.29]	[32.10; 36.24]
Min-Max	30.08 - 48.07	21.6 - 51.27	23.24 - 51.59
Median	38.52	33.90	33.63
Q1-Q3	34.72 - 40.01	28.41 - 42.94	30.12 - 37.24
After 12 weeks			
n	7	15	34
Mean (SD)	38.11 (6.343)	33.16 (7.707)	34.32 (6.689)
95% CL	[32.24; 43.97]	[28.89; 37.42]	[31.98; 36.65]
Min-Max	28.73 - 48.91	21.6 - 48.56	23.57 - 53.88
Median	38.52	32.28	31.73
Q1-Q3	34.01 - 41.65	28.41 - 34.98	30.35 - 37.77
Absolute change after approx. 12 weeks			
n	7	15	34
Mean (SD)	-0.16 (1.327)	-1.18 (2.449)	-0.22 (1.509)
95% CL	[-1.39; 1.06]	[-2.54; 0.17]	[-0.75; 0.31]
Min-Max	-1.43 - 2.26	-7.75 - 1.2	-4.95 - 2.33
Median	-0.71	-0.33	0.00
Q1-Q3	-1.35 - 0.84	-2.36 - 0.16	-0.61 - 0.39
T-Test	t= -0.33 P= 0.754	t= -1.87 P= 0.082	t= -0.85 P= 0.403
Relative change after approx. 12 weeks			
n	7	15	34
Mean (SD)	-0.69 (3.547)	-2.89 (5.686)	-0.52 (4.220)
95% CL	[-3.97; 2.59]	[-6.04; 0.26]	[-1.99; 0.95]
Min-Max	-4.488 - 5.7375	-15.59 - 4.8426	-11.1 - 8.084
Median	-1.90	-1.26	0.00
Q1-Q3	-3.85 - 1.75	-6.77 - 0.47	-1.52 - 1.42
T-Test	t= -0.51 P= 0.627	t= -1.97 P= 0.069	t= -0.72 P= 0.478

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.6 Full Analysis Set - Subgroups - Duration of diabetes
4.9.6.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Baseline			
n	7	19	39
Mean (SD)	38.27 (5.499)	34.94 (9.026)	34.17 (6.378)
95% CL	[33.18; 43.36]	[30.59; 39.29]	[32.10; 36.24]
Min-Max	30.08 - 48.07	21.6 - 51.27	23.24 - 51.59
Median	38.52	33.90	33.63
Q1-Q3	34.72 - 40.01	28.41 - 42.94	30.12 - 37.24
After 24 weeks			
n	7	19	39
Mean (SD)	37.83 (5.848)	33.34 (8.353)	33.52 (6.226)
95% CL	[32.42; 43.23]	[29.32; 37.37]	[31.50; 35.53]
Min-Max	28.73 - 47.86	21.6 - 51.06	23.24 - 50.61
Median	37.33	30.13	31.94
Q1-Q3	35.30 - 41.32	28.73 - 40.35	29.41 - 36.49
Absolute change after approx. 24 weeks			
n	7	19	39
Mean (SD)	-0.44 (1.556)	-1.60 (2.852)	-0.65 (2.309)
95% CL	[-1.88; 0.99]	[-2.98; -0.23]	[-1.40; 0.09]
Min-Max	-1.91 - 1.93	-9.37 - 1.2	-11.56 - 2.04
Median	-1.19	-0.33	0.00
Q1-Q3	-1.80 - 1.42	-1.24 - 0.00	-1.19 - 0.66
T-Test	t= -0.76 P= 0.479	t= -2.45 P= 0.025	t= -1.77 P= 0.085
Relative change after approx. 24 weeks			
n	7	19	39
Mean (SD)	-1.24 (4.208)	-4.01 (6.980)	-1.68 (5.885)
95% CL	[-5.13; 2.66]	[-7.37; -0.64]	[-3.59; 0.22]
Min-Max	-4.852 - 4.8997	-18.85 - 4.8426	-25.93 - 7.0515
Median	-3.09	-0.97	0.00
Q1-Q3	-4.77 - 4.09	-4.06 - 0.00	-3.99 - 1.98
T-Test	t= -0.78 P= 0.467	t= -2.50 P= 0.022	t= -1.79 P= 0.082

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.9.7.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	30
Mean (SD)	35.02 (6.611)	35.22 (7.926)
95% CL	[32.84; 37.19]	[32.26; 38.18]
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.79	34.03
Q1-Q3	30.41 - 38.97	29.06 - 39.46
After 12 weeks		
n	33	26
Mean (SD)	34.42 (5.868)	35.23 (8.202)
95% CL	[32.34; 36.50]	[31.91; 38.54]
Min-Max	21.6 - 48.56	23.57 - 53.88
Median	33.66	34.30
Q1-Q3	30.86 - 37.77	28.41 - 39.64
Absolute change after approx. 12 weeks		
n	33	26
Mean (SD)	-0.44 (1.529)	-0.53 (2.064)
95% CL	[-0.98; 0.11]	[-1.37; 0.30]
Min-Max	-5.31 - 2.33	-7.75 - 2.29
Median	-0.15	0.00
Q1-Q3	-1.11 - 0.35	-0.76 - 0.57
T-Test	t= -1.63 P= 0.112	t= -1.31 P= 0.201
Relative change after approx. 12 weeks		
n	33	26
Mean (SD)	-1.10 (4.451)	-1.29 (4.679)
95% CL	[-2.68; 0.48]	[-3.18; 0.60]
Min-Max	-13.63 - 8.084	-15.59 - 6.1348
Median	-0.40	0.00
Q1-Q3	-3.29 - 0.82	-2.44 - 1.52
T-Test	t= -1.42 P= 0.164	t= -1.40 P= 0.172

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.9.7.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	<8.5% (N = 38)	>=8.5% (N = 32)
Baseline		
n	38	30
Mean (SD)	35.02 (6.611)	35.22 (7.926)
95% CL	[32.84; 37.19]	[32.26; 38.18]
Min-Max	21.6 - 51.27	23.24 - 51.59
Median	34.79	34.03
Q1-Q3	30.41 - 38.97	29.06 - 39.46
After 24 weeks		
n	38	30
Mean (SD)	34.44 (6.418)	33.66 (7.347)
95% CL	[32.33; 36.55]	[30.92; 36.40]
Min-Max	21.6 - 51.06	23.24 - 50.61
Median	33.89	31.68
Q1-Q3	30.55 - 38.39	28.73 - 36.93
Absolute change after approx. 24 weeks		
n	38	30
Mean (SD)	-0.58 (2.040)	-1.56 (2.936)
95% CL	[-1.25; 0.10]	[-2.65; -0.46]
Min-Max	-7.53 - 2.04	-11.56 - 1.77
Median	-0.13	-0.56
Q1-Q3	-1.19 - 0.67	-2.13 - 0.00
T-Test	t= -1.74 P= 0.090	t= -2.90 P= 0.007
Relative change after approx. 24 weeks		
n	38	30
Mean (SD)	-1.42 (5.363)	-3.94 (6.956)
95% CL	[-3.18; 0.35]	[-6.54; -1.34]
Min-Max	-17.27 - 7.0515	-25.93 - 5.0979
Median	-0.29	-1.52
Q1-Q3	-3.49 - 1.98	-6.48 - 0.00
T-Test	t= -1.63 P= 0.112	t= -3.10 P= 0.004

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.9.8.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	23	29	5
Mean (SD)	38.78 (7.156)	34.30 (6.306)	33.77 (7.375)	38.44 (8.054)
95% CL	[33.97; 43.58]	[31.58; 37.03]	[30.97; 36.58]	[28.44; 48.44]
Min-Max	27.4 - 49.72	24.78 - 47.88	21.6 - 51.59	29.06 - 51.27
Median	38.22	33.90	31.79	37.24
Q1-Q3	34.72 - 45.92	28.93 - 38.97	29.64 - 37.10	36.11 - 38.52
After 12 weeks				
n	10	18	28	3
Mean (SD)	38.62 (6.304)	34.09 (6.495)	33.65 (7.467)	36.57 (2.358)
95% CL	[34.11; 43.13]	[30.86; 37.32]	[30.75; 36.54]	[30.71; 42.43]
Min-Max	27.73 - 49.54	25.76 - 48.56	21.6 - 53.88	33.95 - 38.52
Median	39.06	31.98	31.52	37.24
Q1-Q3	34.01 - 41.97	30.35 - 37.77	29.19 - 36.88	33.95 - 38.52
Absolute change after approx. 12 weeks				
n	10	18	28	3
Mean (SD)	-0.96 (2.679)	-0.26 (1.771)	-0.42 (1.453)	-0.72 (1.247)
95% CL	[-2.88; 0.95]	[-1.14; 0.62]	[-0.98; 0.15]	[-3.82; 2.38]
Min-Max	-7.75 - 2.26	-5.31 - 2.33	-4.95 - 2.29	-2.16 - 0
Median	-0.14	-0.07	0.00	0.00
Q1-Q3	-1.51 - 0.33	-0.76 - 0.68	-1.23 - 0.38	-2.16 - 0.00
T-Test	t= -1.14 P= 0.285	t= -0.63 P= 0.540	t= -1.52 P= 0.140	t= -1.00 P= 0.423
Relative change after approx. 12 weeks				
n	10	18	28	3
Mean (SD)	-2.07 (5.739)	-0.53 (5.163)	-1.20 (3.806)	-1.99 (3.454)
95% CL	[-6.18; 2.03]	[-3.10; 2.03]	[-2.68; 0.28]	[-10.57; 6.59]
Min-Max	-15.59 - 5.7375	-13.63 - 8.084	-11.1 - 6.1348	-5.982 - 0
Median	-0.38	-0.20	0.00	0.00
Q1-Q3	-3.29 - 0.79	-2.44 - 1.52	-3.75 - 1.31	-5.98 - 0.00
T-Test	t= -1.14 P= 0.283	t= -0.44 P= 0.667	t= -1.67 P= 0.107	t= -1.00 P= 0.423

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.9.8.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Baseline				
n	11	23	29	5
Mean (SD)	38.78 (7.156)	34.30 (6.306)	33.77 (7.375)	38.44 (8.054)
95% CL	[33.97; 43.58]	[31.58; 37.03]	[30.97; 36.58]	[28.44; 48.44]
Min-Max	27.4 - 49.72	24.78 - 47.88	21.6 - 51.59	29.06 - 51.27
Median	38.22	33.90	31.79	37.24
Q1-Q3	34.72 - 45.92	28.93 - 38.97	29.64 - 37.10	36.11 - 38.52
After 24 weeks				
n	11	23	29	5
Mean (SD)	36.56 (6.546)	33.60 (6.299)	32.88 (6.938)	38.04 (8.014)
95% CL	[32.16; 40.96]	[30.88; 36.32]	[30.24; 35.52]	[28.08; 47.99]
Min-Max	27.12 - 49.15	25.51 - 47.88	21.6 - 50.61	29.06 - 51.06
Median	36.95	31.35	31.40	36.93
Q1-Q3	30.13 - 40.56	29.05 - 38.67	28.84 - 35.30	35.80 - 37.33
Absolute change after approx. 24 weeks				
n	11	23	29	5
Mean (SD)	-2.21 (3.833)	-0.70 (2.085)	-0.90 (2.362)	-0.40 (0.457)
95% CL	[-4.79; 0.36]	[-1.60; 0.20]	[-1.79; 0.00]	[-0.97; 0.16]
Min-Max	-9.37 - 1.93	-6.73 - 2.04	-11.56 - 1.77	-1.19 - 0
Median	0.00	-0.33	-0.29	-0.31
Q1-Q3	-4.72 - 0.67	-1.24 - 0.75	-1.30 - 0.15	-0.31 - -0.21
T-Test	t= -1.92 P= 0.084	t= -1.61 P= 0.121	t= -2.04 P= 0.051	t= -1.98 P= 0.119
Relative change after approx. 24 weeks				
n	11	23	29	5
Mean (SD)	-5.24 (8.877)	-1.87 (5.914)	-2.28 (5.692)	-1.04 (1.199)
95% CL	[-11.21; 0.72]	[-4.43; 0.68]	[-4.44; -0.11]	[-2.53; 0.45]
Min-Max	-18.85 - 4.8997	-17.27 - 7.0515	-25.93 - 5.0979	-3.089 - 0
Median	0.00	-0.97	-0.82	-0.83
Q1-Q3	-13.54 - 1.68	-4.06 - 1.98	-3.91 - 0.47	-0.86 - -0.41
T-Test	t= -1.96 P= 0.079	t= -1.52 P= 0.143	t= -2.15 P= 0.040	t= -1.94 P= 0.125

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.9.9.1 Change in body mass index kg/m² up to approx. 12 weeks after the start of treatment

Body mass index kg/m²	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	36.13 (7.987)	33.21 (3.884)	34.79 (7.292)
95% CL	[32.97; 39.29]	[30.23; 36.20]	[32.12; 37.47]
Min-Max	21.6 - 51.27	28.41 - 40.12	23.24 - 51.59
Median	36.00	31.79	34.15
Q1-Q3	30.41 - 40.01	30.56 - 36.11	29.07 - 38.22
After 12 weeks			
n	24	9	26
Mean (SD)	34.66 (6.984)	32.31 (3.849)	35.73 (7.678)
95% CL	[31.72; 37.61]	[29.35; 35.27]	[32.63; 38.83]
Min-Max	21.6 - 49.54	28.41 - 39.51	23.57 - 53.88
Median	34.10	31.40	34.40
Q1-Q3	29.87 - 39.38	29.63 - 33.95	30.48 - 39.89
Absolute change after approx. 12 weeks			
n	24	9	26
Mean (SD)	-0.85 (2.334)	-0.90 (1.031)	0.01 (1.209)
95% CL	[-1.83; 0.14]	[-1.70; -0.11]	[-0.48; 0.50]
Min-Max	-7.75 - 2.26	-2.47 - 0	-2.36 - 2.33
Median	-0.07	-0.61	0.00
Q1-Q3	-1.29 - 0.37	-1.96 - 0.00	-0.57 - 0.61
T-Test	t= -1.78 P= 0.088	t= -2.63 P= 0.030	t= 0.05 P= 0.962
Relative change after approx. 12 weeks			
n	24	9	26
Mean (SD)	-1.96 (5.577)	-2.68 (3.101)	0.05 (3.552)
95% CL	[-4.32; 0.39]	[-5.07; -0.30]	[-1.38; 1.49]
Min-Max	-15.59 - 6.1348	-7.77 - 0	-6.772 - 8.084
Median	-0.20	-1.52	0.00
Q1-Q3	-3.87 - 0.97	-5.83 - 0.00	-1.60 - 1.72
T-Test	t= -1.72 P= 0.098	t= -2.60 P= 0.032	t= 0.07 P= 0.942

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.9 Absolute and Relative change in body mass index kg/m²
4.9.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.9.9.2 Change in body mass index kg/m² up to approx. 24 weeks after the start of treatment

Body mass index kg/m²	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Baseline			
n	27	9	31
Mean (SD)	36.13 (7.987)	33.21 (3.884)	34.79 (7.292)
95% CL	[32.97; 39.29]	[30.23; 36.20]	[32.12; 37.47]
Min-Max	21.6 - 51.27	28.41 - 40.12	23.24 - 51.59
Median	36.00	31.79	34.15
Q1-Q3	30.41 - 40.01	30.56 - 36.11	29.07 - 38.22
After 24 weeks			
n	27	9	31
Mean (SD)	34.69 (7.490)	32.65 (3.873)	33.97 (7.050)
95% CL	[31.73; 37.65]	[29.67; 35.62]	[31.39; 36.56]
Min-Max	21.6 - 51.06	28.73 - 39.51	23.24 - 50.61
Median	33.03	31.40	32.47
Q1-Q3	29.06 - 38.86	29.32 - 35.80	28.87 - 36.14
Absolute change after approx. 24 weeks			
n	27	9	31
Mean (SD)	-1.44 (3.286)	-0.56 (0.806)	-0.82 (2.020)
95% CL	[-2.74; -0.14]	[-1.18; 0.06]	[-1.56; -0.08]
Min-Max	-11.56 - 1.93	-2.28 - 0.32	-7.53 - 2.04
Median	-0.33	-0.31	-0.29
Q1-Q3	-1.91 - 0.35	-0.80 - 0.00	-1.68 - 0.61
T-Test	t= -2.28 P= 0.031	t= -2.10 P= 0.069	t= -2.26 P= 0.031
Relative change after approx. 24 weeks			
n	27	9	31
Mean (SD)	-3.45 (7.804)	-1.68 (2.486)	-2.14 (5.415)
95% CL	[-6.54; -0.37]	[-3.59; 0.23]	[-4.12; -0.15]
Min-Max	-25.93 - 5.0979	-6.78 - 1.1264	-16.4 - 7.0515
Median	-0.77	-0.86	-0.82
Q1-Q3	-4.77 - 0.96	-2.70 - 0.00	-4.85 - 1.87
T-Test	t= -2.30 P= 0.030	t= -2.03 P= 0.077	t= -2.20 P= 0.036

Patient [redacted] and [redacted] excluded from calculation because weight was not documented after 24 weeks

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.1 Full Analysis Set - Patients using FGM
4.10.1.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	FGM (N = 20)
Baseline	
n	20
Mean (SD)	148.95 (23.808)
95% CL	[137.808;160.093]
Min-Max	120 - 199
Median	148.37
Q1-Q3	126.13 -162.00
After 12 weeks	
n	17
Mean (SD)	142.87 (32.328)
95% CL	[126.249;159.492]
Min-Max	113 - 214
Median	128.00
Q1-Q3	127.00 -140.54
Absolute change after approx. 12 weeks	
n	17
Mean (SD)	-5.19 (27.680)
95% CL	[-19.421; 9.043]
Min-Max	-59 - 71
Median	-3.60
Q1-Q3	-23.00 - 6.00
T-Test	t= -0.77 P= 0.451
Relative change after approx. 12 weeks	
n	17
Mean (SD)	-2.83 (18.214)
95% CL	[-12.198; 6.531]
Min-Max	-33.15 - 50.355
Median	-2.86
Q1-Q3	-15.67 - 4.92
T-Test	t= -0.64 P= 0.530

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.1 Full Analysis Set - Patients using FGM
4.10.1.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	FGM (N = 20)
Baseline	
n	20
Mean (SD)	148.95 (23.808)
95% CL	[137.808;160.093]
Min-Max	120 - 199
Median	148.37
Q1-Q3	126.13 -162.00
After 24 weeks	
n	16
Mean (SD)	137.66 (18.616)
95% CL	[127.742;147.582]
Min-Max	118 - 191
Median	130.50
Q1-Q3	125.50 -146.50
Absolute change after approx. 24 weeks	
n	16
Mean (SD)	-9.53 (21.987)
95% CL	[-21.242; 2.190]
Min-Max	-49 - 28
Median	-5.80
Q1-Q3	-23.00 - 4.40
T-Test	t= -1.73 P= 0.104
Relative change after approx. 24 weeks	
n	16
Mean (SD)	-5.02 (13.937)
95% CL	[-12.451; 2.402]
Min-Max	-27.53 - 20.896
Median	-3.44
Q1-Q3	-15.72 - 3.63
T-Test	t= -1.44 P= 0.170

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.1 Full Analysis Set - Patients using FGM
4.10.1.3 Acquisition of the glycaemic variability from FGM
4.10.1.3.1 Time in range in percent

Time in range in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	56.5 (18.30)
Min-Max	20 - 87
Median	57.0
Q1-Q3	42.5 - 70.0
After 12 weeks	
n	17
Mean (SD)	64.8 (24.37)
Min-Max	17 - 94
Median	75.0
Q1-Q3	53.0 - 79.0
After 24 weeks	
n	16
Mean (SD)	74.5 (11.18)
Min-Max	46 - 88
Median	77.5
Q1-Q3	71.0 - 81.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.1 Full Analysis Set - Patients using FGM
4.10.1.3 Acquisition of the glycaemic variability from FGM
4.10.1.3.2 Time above range in percent

Time above range in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	36.5 (16.47)
Min-Max	9 - 75
Median	34.0
Q1-Q3	26.0 - 45.0
After 12 weeks	
n	17
Mean (SD)	31.8 (23.75)
Min-Max	6 - 80
Median	25.0
Q1-Q3	18.0 - 41.0
After 24 weeks	
n	16
Mean (SD)	22.6 (10.25)
Min-Max	10 - 54
Median	22.0
Q1-Q3	16.5 - 25.5

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.1 Full Analysis Set - Patients using FGM
4.10.1.3 Acquisition of the glycaemic variability from FGM
4.10.1.3.3 Time below range in percent

Time below range in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	6.9 (8.14)
Min-Max	0 - 25
Median	4.5
Q1-Q3	0.0 - 11.0
After 12 weeks	
n	17
Mean (SD)	3.4 (6.77)
Min-Max	0 - 20
Median	0.0
Q1-Q3	0.0 - 3.0
After 24 weeks	
n	16
Mean (SD)	3.5 (6.07)
Min-Max	0 - 20
Median	0.0
Q1-Q3	0.0 - 4.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.2 Full Analysis Set - FGM - Subgroups - Gender
4.10.2.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	143.36 (19.637)	152.68 (26.378)
95% CL	[126.943;159.776]	[135.917;169.437]
Min-Max	120 - 178	124 - 199
Median	148.37	148.00
Q1-Q3	124.06 -152.00	129.56 -169.50
After 12 weeks		
n	7	10
Mean (SD)	126.90 (7.935)	154.05 (38.452)
95% CL	[119.558;134.235]	[126.546;181.559]
Min-Max	116 - 140.54	113 - 214
Median	128.00	132.50
Q1-Q3	119.00 -129.73	127.00 -184.00
Absolute change after approx. 12 weeks		
n	7	10
Mean (SD)	-15.23 (24.955)	1.84 (28.525)
95% CL	[-38.308; 7.850]	[-18.566; 22.245]
Min-Max	-59 - 8	-29 - 71
Median	-7.21	-1.30
Q1-Q3	-33.00 - 6.00	-21.00 - 13.00
T-Test	t= -1.61 P= 0.158	t= 0.20 P= 0.843
Relative change after approx. 12 weeks		
n	7	10
Mean (SD)	-8.88 (15.319)	1.40 (19.620)
95% CL	[-23.050; 5.285]	[-12.635; 15.435]
Min-Max	-33.15 - 6.6667	-17.9 - 50.355
Median	-4.88	-1.03
Q1-Q3	-22.15 - 4.92	-14.84 - 7.54
T-Test	t= -1.53 P= 0.176	t= 0.23 P= 0.826

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.2 Full Analysis Set - FGM - Subgroups - Gender
4.10.2.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	143.36 (19.637)	152.68 (26.378)
95% CL	[126.943;159.776]	[135.917;169.437]
Min-Max	120 - 178	124 - 199
Median	148.37	148.00
Q1-Q3	124.06 -152.00	129.56 -169.50
After 24 weeks		
n	7	9
Mean (SD)	131.67 (7.819)	142.33 (23.409)
95% CL	[124.434;138.897]	[124.331;160.320]
Min-Max	122.52 - 147	118 - 191
Median	129.00	144.00
Q1-Q3	127.00 -135.14	124.00 -147.00
Absolute change after approx. 24 weeks		
n	7	9
Mean (SD)	-10.46 (20.369)	-8.80 (24.370)
95% CL	[-29.297; 8.378]	[-27.533; 9.933]
Min-Max	-49 - 10	-49 - 28
Median	-3.60	-8.00
Q1-Q3	-23.00 - 7.00	-23.00 - 1.80
T-Test	t= -1.36 P= 0.223	t= -1.08 P= 0.310
Relative change after approx. 24 weeks		
n	7	9
Mean (SD)	-5.91 (12.426)	-4.34 (15.722)
95% CL	[-17.401; 5.582]	[-16.421; 7.749]
Min-Max	-27.53 - 8.1967	-25.39 - 20.896
Median	-2.86	-4.02
Q1-Q3	-15.13 - 5.83	-16.31 - 1.43
T-Test	t= -1.26 P= 0.255	t= -0.83 P= 0.432

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.2 Full Analysis Set - FGM - Subgroups - Gender
4.10.2.3 Acquisition of the glycaemic variability from FGM
4.10.2.3.1 Time in range in percent

Time in range in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	48.5 (18.33)	61.8 (16.94)
Min-Max	20 - 71	35 - 87
Median	48.5	63.0
Q1-Q3	35.0 - 65.0	48.5 - 74.5
After 12 weeks		
n	7	10
Mean (SD)	62.7 (24.90)	66.3 (25.23)
Min-Max	17 - 92	26 - 94
Median	75.0	70.0
Q1-Q3	45.0 - 75.0	53.0 - 91.0
After 24 weeks		
n	7	9
Mean (SD)	72.3 (9.21)	76.2 (12.76)
Min-Max	55 - 80	46 - 88
Median	78.0	77.0
Q1-Q3	65.0 - 78.0	75.0 - 84.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.2 Full Analysis Set - FGM - Subgroups - Gender
4.10.2.3 Acquisition of the glycaemic variability from FGM
4.10.2.3.2 Time above range in percent

Time above range in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	40.0 (16.20)	34.2 (16.93)
Min-Max	25 - 75	9 - 60
Median	37.5	32.5
Q1-Q3	27.5 - 45.0	22.0 - 47.0
After 12 weeks		
n	7	10
Mean (SD)	32.0 (22.77)	31.7 (25.64)
Min-Max	8 - 80	6 - 74
Median	25.0	21.5
Q1-Q3	21.0 - 35.0	9.0 - 47.0
After 24 weeks		
n	7	9
Mean (SD)	23.4 (4.08)	21.9 (13.54)
Min-Max	17 - 30	10 - 54
Median	22.0	18.0
Q1-Q3	22.0 - 26.0	13.0 - 23.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.2 Full Analysis Set - FGM - Subgroups - Gender
4.10.2.3 Acquisition of the glycaemic variability from FGM
4.10.2.3.3 Time below range in percent

Time below range in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	11.5 (8.83)	3.8 (6.21)
Min-Max	2 - 25	0 - 20
Median	7.5	1.0
Q1-Q3	5.0 - 20.0	0.0 - 4.5
After 12 weeks		
n	7	10
Mean (SD)	5.3 (7.41)	2.0 (6.32)
Min-Max	0 - 20	0 - 20
Median	3.0	0.0
Q1-Q3	0.0 - 10.0	0.0 - 0.0
After 24 weeks		
n	7	9
Mean (SD)	5.6 (7.09)	1.9 (4.96)
Min-Max	0 - 20	0 - 15
Median	3.0	0.0
Q1-Q3	0.0 - 9.0	0.0 - 0.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.3 Full Analysis Set - FGM - Subgroups - Age groups
4.10.3.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	152.28 (26.354)	141.84 (19.739)	155.50 (30.406)
95% CL	[134.579;169.989]	[123.584;160.095]	[-117.68;428.683]
Min-Max	120 - 199	122 - 178	134 - 177
Median	152.00	141.00	155.50
Q1-Q3	126.13 -162.00	126.00 -152.00	134.00 -177.00
After 12 weeks			
n	9	7	1
Mean (SD)	148.86 (33.565)	139.44 (32.687)	113.00 ( )
95% CL	[123.058;174.660]	[109.208;169.668]	[;]
Min-Max	116 - 214	119 - 212	113 - 113
Median	132.00	127.00	113.00
Q1-Q3	128.00 -175.00	122.52 -140.54	113.00 -113.00
Absolute change after approx. 12 weeks			
n	9	7	1
Mean (SD)	-5.60 (18.523)	-2.40 (39.176)	-21.00 ( )
95% CL	[-19.838; 8.638]	[-38.633; 33.830]	[;]
Min-Max	-33 - 15	-59 - 71	-21 - -21
Median	3.60	-3.60	-21.00
Q1-Q3	-23.00 - 8.00	-25.00 - 6.00	-21.00 --21.00
T-Test	t= -0.91 P= 0.391	t= -0.16 P= 0.876	t= P=
Relative change after approx. 12 weeks			
n	9	7	1
Mean (SD)	-3.47 (11.878)	-0.18 (25.695)	-15.67 ( )
95% CL	[-12.601; 5.659]	[-23.944; 23.583]	[;]
Min-Max	-22.15 - 8.0247	-33.15 - 50.355	-15.67 - -15.67
Median	2.86	-2.86	-15.67
Q1-Q3	-14.84 - 6.67	-16.45 - 4.92	-15.67 --15.67
T-Test	t= -0.88 P= 0.406	t= -0.02 P= 0.986	t= P=

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.3 Full Analysis Set - FGM - Subgroups - Age groups
4.10.3.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	152.28 (26.354)	141.84 (19.739)	155.50 (30.406)
95% CL	[134.579;169.989]	[123.584;160.095]	[-117.68;428.683]
Min-Max	120 - 199	122 - 178	134 - 177
Median	152.00	141.00	155.50
Q1-Q3	126.13 -162.00	126.00 -152.00	134.00 -177.00
After 24 weeks			
n	8	7	1
Mean (SD)	140.32 (23.277)	131.15 (8.760)	162.00 ( )
95% CL	[120.856;159.775]	[123.051;139.253]	[;]
Min-Max	121 - 191	118 - 147	162 - 162
Median	135.50	129.00	162.00
Q1-Q3	123.26 -146.50	127.93 -135.14	162.00 -162.00
Absolute change after approx. 24 weeks			
n	8	7	1
Mean (SD)	-13.20 (18.373)	-10.69 (23.674)	28.00 ( )
95% CL	[-28.561; 2.160]	[-32.582; 11.208]	[;]
Min-Max	-49 - 7	-49 - 21	28 - 28
Median	-5.80	-12.61	28.00
Q1-Q3	-23.50 - -2.50	-23.00 - 10.00	28.00 - 28.00
T-Test	t= -2.03 P= 0.082	t= -1.19 P= 0.277	t= P=
Relative change after approx. 24 weeks			
n	8	7	1
Mean (SD)	-7.51 (10.400)	-5.89 (15.438)	20.90 ( )
95% CL	[-16.203; 1.186]	[-20.166; 8.390]	[;]
Min-Max	-25.39 - 5.8333	-27.53 - 16.667	20.896 - 20.896
Median	-3.44	-8.54	20.90
Q1-Q3	-14.94 - -1.88	-16.31 - 8.20	20.90 - 20.90
T-Test	t= -2.04 P= 0.080	t= -1.01 P= 0.352	t= P=

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.3 Full Analysis Set - FGM - Subgroups - Age groups
4.10.3.3 Acquisition of the glycaemic variability from FGM
4.10.3.3.1 Time in range in percent

Time in range in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	52.6 (17.69)	58.3 (19.51)	71.5 (17.68)
Min-Max	20 - 71	30 - 87	59 - 84
Median	53.0	55.0	71.5
Q1-Q3	40.0 - 70.0	45.0 - 79.0	59.0 - 84.0
After 12 weeks			
n	9	7	1
Mean (SD)	66.4 (22.23)	58.7 (27.30)	93.0
Min-Max	26 - 92	17 - 94	93 - 93
Median	75.0	62.0	93.0
Q1-Q3	53.0 - 79.0	28.0 - 75.0	93.0 - 93.0
After 24 weeks			
n	8	7	1
Mean (SD)	73.4 (14.72)	76.4 (7.09)	70.0
Min-Max	46 - 87	65 - 88	70 - 70
Median	78.0	77.0	70.0
Q1-Q3	66.0 - 83.0	72.0 - 80.0	70.0 - 70.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.3 Full Analysis Set - FGM - Subgroups - Age groups
4.10.3.3 Acquisition of the glycaemic variability from FGM
4.10.3.3.2 Time above range in percent

Time above range in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	42.9 (16.68)	29.4 (13.31)	26.0 (16.97)
Min-Max	25 - 75	9 - 45	14 - 38
Median	35.0	28.0	26.0
Q1-Q3	30.0 - 59.0	19.0 - 45.0	14.0 - 38.0
After 12 weeks			
n	9	7	1
Mean (SD)	31.3 (20.77)	36.0 (28.40)	7.0
Min-Max	8 - 74	6 - 80	7 - 7
Median	25.0	25.0	7.0
Q1-Q3	21.0 - 41.0	18.0 - 72.0	7.0 - 7.0
After 24 weeks			
n	8	7	1
Mean (SD)	23.9 (12.76)	20.0 (7.33)	30.0
Min-Max	13 - 54	10 - 30	30 - 30
Median	21.5	22.0	30.0
Q1-Q3	17.0 - 23.5	12.0 - 26.0	30.0 - 30.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.3 Full Analysis Set - FGM - Subgroups - Age groups
4.10.3.3 Acquisition of the glycaemic variability from FGM
4.10.3.3.3 Time below range in percent

Time below range in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	4.5 (6.36)	12.3 (9.25)	1.0 (1.41)
Min-Max	0 - 20	2 - 25	0 - 2
Median	2.0	10.0	1.0
Q1-Q3	0.0 - 5.0	4.0 - 20.0	0.0 - 2.0
After 12 weeks			
n	9	7	1
Mean (SD)	2.2 (6.67)	5.3 (7.41)	0.0
Min-Max	0 - 20	0 - 20	0 - 0
Median	0.0	3.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 10.0	0.0 - 0.0
After 24 weeks			
n	8	7	1
Mean (SD)	2.8 (7.01)	4.9 (5.46)	0.0
Min-Max	0 - 20	0 - 15	0 - 0
Median	0.0	3.0	0.0
Q1-Q3	0.0 - 1.0	0.0 - 9.0	0.0 - 0.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.4 Full Analysis Set - FGM - Subgroups - Body Mass Index
4.10.4.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	162.25 (34.102)	145.63 (20.651)
95% CL	[107.987;216.513]	[134.621;156.629]
Min-Max	120 - 199	122 - 193
Median	165.00	144.37
Q1-Q3	136.00 -188.50	126.13 -158.50
After 12 weeks		
n	3	14
Mean (SD)	153.67 (52.444)	140.56 (28.817)
95% CL	[23.389;283.944]	[123.918;157.196]
Min-Max	119 - 214	113 - 212
Median	128.00	128.87
Q1-Q3	119.00 -214.00	127.00 -140.54
Absolute change after approx. 12 weeks		
n	3	14
Mean (SD)	-12.00 (40.853)	-3.73 (25.947)
95% CL	[-113.49; 89.485]	[-18.710; 11.252]
Min-Max	-59 - 15	-33 - 71
Median	8.00	-5.41
Q1-Q3	-59.00 - 15.00	-23.00 - 4.00
T-Test	t= -0.51 P= 0.661	t= -0.54 P= 0.600
Relative change after approx. 12 weeks		
n	3	14
Mean (SD)	-6.31 (23.241)	-2.09 (17.939)
95% CL	[-64.049; 51.421]	[-12.445; 8.270]
Min-Max	-33.15 - 7.5377	-22.15 - 50.355
Median	6.67	-3.76
Q1-Q3	-33.15 - 7.54	-15.67 - 3.23
T-Test	t= -0.47 P= 0.684	t= -0.44 P= 0.670

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.4 Full Analysis Set - FGM - Subgroups - Body Mass Index
4.10.4.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	162.25 (34.102)	145.63 (20.651)
95% CL	[107.987;216.513]	[134.621;156.629]
Min-Max	120 - 199	122 - 193
Median	165.00	144.37
Q1-Q3	136.00 -188.50	126.13 -158.50
After 24 weeks		
n	3	13
Mean (SD)	149.00 (36.387)	135.05 (13.152)
95% CL	[58.610;239.390]	[127.098;142.993]
Min-Max	127 - 191	118 - 162
Median	129.00	132.00
Q1-Q3	127.00 -191.00	124.00 -146.00
Absolute change after approx. 24 weeks		
n	3	13
Mean (SD)	-16.67 (28.989)	-7.88 (21.179)
95% CL	[-88.678; 55.345]	[-20.676; 4.920]
Min-Max	-49 - 7	-49 - 28
Median	-8.00	-3.60
Q1-Q3	-49.00 - 7.00	-23.00 - 1.80
T-Test	t= -1.00 P= 0.424	t= -1.34 P= 0.205
Relative change after approx. 24 weeks		
n	3	13
Mean (SD)	-8.57 (17.140)	-4.21 (13.783)
95% CL	[-51.150; 34.007]	[-12.535; 4.123]
Min-Max	-27.53 - 5.8333	-25.39 - 20.896
Median	-4.02	-2.86
Q1-Q3	-27.53 - 5.83	-15.13 - 1.43
T-Test	t= -0.87 P= 0.478	t= -1.10 P= 0.293

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.4 Full Analysis Set - FGM - Subgroups - Body Mass Index
4.10.4.3 Acquisition of the glycaemic variability from FGM
4.10.4.3.1 Time in range in percent

Time in range in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	40.3 (21.61)	60.6 (15.58)
Min-Max	20 - 70	35 - 87
Median	35.5	59.5
Q1-Q3	25.0 - 55.5	48.5 - 70.5
After 12 weeks		
n	3	14
Mean (SD)	39.3 (31.21)	70.3 (19.97)
Min-Max	17 - 75	28 - 94
Median	26.0	75.0
Q1-Q3	17.0 - 75.0	59.0 - 91.0
After 24 weeks		
n	3	13
Mean (SD)	67.3 (18.48)	76.2 (9.14)
Min-Max	46 - 78	55 - 88
Median	78.0	77.0
Q1-Q3	46.0 - 78.0	72.0 - 82.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.4 Full Analysis Set - FGM - Subgroups - Body Mass Index
4.10.4.3 Acquisition of the glycaemic variability from FGM
4.10.4.3.2 Time above range in percent

Time above range in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	51.0 (21.23)	32.9 (13.54)
Min-Max	25 - 75	9 - 60
Median	52.0	32.5
Q1-Q3	35.0 - 67.0	26.0 - 39.0
After 12 weeks		
n	3	14
Mean (SD)	59.7 (30.17)	25.9 (18.36)
Min-Max	25 - 80	6 - 72
Median	74.0	21.5
Q1-Q3	25.0 - 80.0	9.0 - 35.0
After 24 weeks		
n	3	13
Mean (SD)	32.7 (18.48)	20.2 (6.56)
Min-Max	22 - 54	10 - 30
Median	22.0	21.0
Q1-Q3	22.0 - 54.0	16.0 - 25.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.4 Full Analysis Set - FGM - Subgroups - Body Mass Index
4.10.4.3 Acquisition of the glycaemic variability from FGM
4.10.4.3.3 Time below range in percent

Time below range in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	8.8 (11.09)	6.4 (7.62)
Min-Max	0 - 25	0 - 20
Median	5.0	3.0
Q1-Q3	2.5 - 15.0	0.0 - 11.0
After 12 weeks		
n	3	14
Mean (SD)	1.0 (1.73)	3.9 (7.38)
Min-Max	0 - 3	0 - 20
Median	0.0	0.0
Q1-Q3	0.0 - 3.0	0.0 - 4.0
After 24 weeks		
n	3	13
Mean (SD)	3.0 (5.20)	3.6 (6.44)
Min-Max	0 - 9	0 - 20
Median	0.0	0.0
Q1-Q3	0.0 - 9.0	0.0 - 3.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.5 Full Analysis Set - FGM - Subgroups - Renal function
4.10.5.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	170.33 (33.171)	145.93 (21.384)
95% CL	[87.931;252.735]	[134.092;157.776]
Min-Max	134 - 199	120 - 193
Median	178.00	147.75
Q1-Q3	134.00 -199.00	126.13 -162.00
After 12 weeks		
n	3	12
Mean (SD)	148.67 (56.660)	143.57 (29.931)
95% CL	[7.916;289.417]	[124.549;162.584]
Min-Max	113 - 214	116 - 212
Median	119.00	128.87
Q1-Q3	113.00 -214.00	127.00 -157.77
Absolute change after approx. 12 weeks		
n	3	12
Mean (SD)	-21.67 (37.005)	-0.35 (27.007)
95% CL	[-113.59; 70.258]	[-17.510; 16.809]
Min-Max	-59 - 15	-33 - 71
Median	-21.00	-1.30
Q1-Q3	-59.00 - 15.00	-17.00 - 7.00
T-Test	t= -1.01 P= 0.417	t= -0.04 P= 0.965
Relative change after approx. 12 weeks		
n	3	12
Mean (SD)	-13.76 (20.409)	0.39 (18.613)
95% CL	[-64.459; 36.939]	[-11.433; 12.219]
Min-Max	-33.15 - 7.5377	-22.15 - 50.355
Median	-15.67	-1.03
Q1-Q3	-33.15 - 7.54	-10.66 - 5.79
T-Test	t= -1.17 P= 0.363	t= 0.07 P= 0.943

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.5 Full Analysis Set - FGM - Subgroups - Renal function
4.10.5.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	170.33 (33.171)	145.93 (21.384)
95% CL	[87.931;252.735]	[134.092;157.776]
Min-Max	134 - 199	120 - 193
Median	178.00	147.75
Q1-Q3	134.00 -199.00	126.13 -162.00
After 24 weeks		
n	3	11
Mean (SD)	160.67 (31.021)	134.14 (10.419)
95% CL	[83.605;237.728]	[127.145;141.144]
Min-Max	129 - 191	118 - 147
Median	162.00	132.00
Q1-Q3	129.00 -191.00	127.00 -146.00
Absolute change after approx. 24 weeks		
n	3	11
Mean (SD)	-9.67 (38.527)	-8.13 (19.384)
95% CL	[-105.37; 86.040]	[-21.151; 4.894]
Min-Max	-49 - 28	-49 - 21
Median	-8.00	-3.60
Q1-Q3	-49.00 - 28.00	-23.00 - 7.00
T-Test	t= -0.43 P= 0.706	t= -1.39 P= 0.194
Relative change after approx. 24 weeks		
n	3	11
Mean (SD)	-3.55 (24.215)	-4.30 (12.237)
95% CL	[-63.705; 56.603]	[-12.523; 3.919]
Min-Max	-27.53 - 20.896	-25.39 - 16.667
Median	-4.02	-2.86
Q1-Q3	-27.53 - 20.90	-15.13 - 5.83
T-Test	t= -0.25 P= 0.823	t= -1.17 P= 0.271

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.5 Full Analysis Set - FGM - Subgroups - Renal function
4.10.5.3 Acquisition of the glycaemic variability from FGM
4.10.5.3.1 Time in range in percent

Time in range in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	51.7 (28.54)	56.9 (17.96)
Min-Max	30 - 84	20 - 87
Median	41.0	59.0
Q1-Q3	30.0 - 84.0	44.0 - 70.0
After 12 weeks		
n	3	12
Mean (SD)	45.3 (41.53)	67.4 (20.13)
Min-Max	17 - 93	28 - 94
Median	26.0	68.5
Q1-Q3	17.0 - 93.0	56.0 - 83.0
After 24 weeks		
n	3	11
Mean (SD)	64.7 (16.65)	76.3 (9.65)
Min-Max	46 - 78	55 - 88
Median	70.0	78.0
Q1-Q3	46.0 - 78.0	72.0 - 84.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.5 Full Analysis Set - FGM - Subgroups - Renal function
4.10.5.3 Acquisition of the glycaemic variability from FGM
4.10.5.3.2 Time above range in percent

Time above range in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	39.3 (23.03)	36.3 (17.00)
Min-Max	14 - 59	9 - 75
Median	45.0	33.0
Q1-Q3	14.0 - 59.0	25.0 - 45.0
After 12 weeks		
n	3	12
Mean (SD)	53.7 (40.53)	28.1 (18.90)
Min-Max	7 - 80	6 - 72
Median	74.0	25.0
Q1-Q3	7.0 - 80.0	13.5 - 38.0
After 24 weeks		
n	3	11
Mean (SD)	35.3 (16.65)	19.6 (6.44)
Min-Max	22 - 54	10 - 30
Median	30.0	22.0
Q1-Q3	22.0 - 54.0	13.0 - 25.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.5 Full Analysis Set - FGM - Subgroups - Renal function
4.10.5.3 Acquisition of the glycaemic variability from FGM
4.10.5.3.3 Time below range in percent

Time below range in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	9.0 (13.89)	6.5 (7.48)
Min-Max	0 - 25	0 - 20
Median	2.0	5.0
Q1-Q3	0.0 - 25.0	0.0 - 10.0
After 12 weeks		
n	3	12
Mean (SD)	1.0 (1.73)	4.5 (7.82)
Min-Max	0 - 3	0 - 20
Median	0.0	0.0
Q1-Q3	0.0 - 3.0	0.0 - 7.0
After 24 weeks		
n	3	11
Mean (SD)	3.0 (5.20)	4.1 (6.92)
Min-Max	0 - 9	0 - 20
Median	0.0	0.0
Q1-Q3	0.0 - 9.0	0.0 - 5.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.6 Full Analysis Set - FGM - Subgroups - Duration of diabetes
4.10.6.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	149.00 ( )	155.02 (31.572)	147.16 (19.938)
95% CL	[;]	[125.819;184.217]	[133.764;160.554]
Min-Max	149 - 149	120 - 199	122 - 178
Median	149.00	152.00	147.75
Q1-Q3	149.00 -149.00	126.13 -193.00	126.00 -162.00
After 12 weeks			
n	1	5	10
Mean (SD)	116.00 ( )	156.30 (40.562)	140.15 (30.311)
95% CL	[;]	[105.940;206.669]	[118.471;161.838]
Min-Max	116 - 116	122.52 - 214	113 - 212
Median	116.00	133.00	128.00
Q1-Q3	116.00 -116.00	128.00 -184.00	127.00 -140.54
Absolute change after approx. 12 weeks			
n	1	5	10
Mean (SD)	-33.00 ( )	-3.72 (16.991)	-4.02 (33.713)
95% CL	[;]	[-24.818; 17.376]	[-28.138; 20.096]
Min-Max	-33 - -33	-29 - 15	-59 - 71
Median	-33.00	-3.60	-3.10
Q1-Q3	-33.00 --33.00	-9.00 - 8.00	-23.00 - 6.00
T-Test	t= P=	t= -0.49 P= 0.650	t= -0.38 P= 0.715
Relative change after approx. 12 weeks			
n	1	5	10
Mean (SD)	-22.15 ( )	-2.24 (10.325)	-1.77 (22.268)
95% CL	[;]	[-15.064; 10.577]	[-17.696; 14.163]
Min-Max	-22.15 - -22.15	-17.9 - 7.5377	-33.15 - 50.355
Median	-22.15	-2.86	-2.04
Q1-Q3	-22.15 --22.15	-4.66 - 6.67	-15.67 - 4.92
T-Test	t= P=	t= -0.49 P= 0.652	t= -0.25 P= 0.808

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.6 Full Analysis Set - FGM - Subgroups - Duration of diabetes
4.10.6.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	149.00 ( )	155.02 (31.572)	147.16 (19.938)
95% CL	[;]	[125.819;184.217]	[133.764;160.554]
Min-Max	149 - 149	120 - 199	122 - 178
Median	149.00	152.00	147.75
Q1-Q3	149.00 -149.00	126.13 -193.00	126.00 -162.00
After 24 weeks			
n	1	5	9
Mean (SD)	147.00 ( )	147.19 (26.027)	133.02 (13.805)
95% CL	[;]	[114.870;179.502]	[122.404;143.626]
Min-Max	147 - 147	127 - 191	118 - 162
Median	147.00	144.00	129.00
Q1-Q3	147.00 -147.00	127.93 -146.00	124.00 -135.14
Absolute change after approx. 24 weeks			
n	1	5	9
Mean (SD)	-2.00 ( )	-12.84 (22.074)	-9.18 (25.384)
95% CL	[;]	[-40.248; 14.568]	[-28.691; 10.333]
Min-Max	-2 - -2	-49 - 7	-49 - 28
Median	-2.00	-8.00	-12.61
Q1-Q3	-2.00 - -2.00	-16.00 - 1.80	-23.00 - 10.00
T-Test	t= P=	t= -1.30 P= 0.263	t= -1.08 P= 0.310
Relative change after approx. 24 weeks			
n	1	5	9
Mean (SD)	-1.34 ( )	-6.40 (12.137)	-4.91 (16.943)
95% CL	[;]	[-21.475; 8.666]	[-17.931; 8.116]
Min-Max	-1.342 - -1.342	-25.39 - 5.8333	-27.53 - 20.896
Median	-1.34	-4.02	-8.54
Q1-Q3	-1.34 - -1.34	-9.88 - 1.43	-16.31 - 8.20
T-Test	t= P=	t= -1.18 P= 0.303	t= -0.87 P= 0.410

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.6 Full Analysis Set - FGM - Subgroups - Duration of diabetes
4.10.6.3 Acquisition of the glycaemic variability from FGM
4.10.6.3.1 Time in range in percent

Time in range in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	71.0	47.9 (18.42)	62.2 (17.22)
Min-Max	71 - 71	20 - 70	30 - 87
Median	71.0	44.0	60.0
Q1-Q3	71.0 - 71.0	35.0 - 70.0	52.0 - 79.0
After 12 weeks			
n	1	5	10
Mean (SD)	92.0	61.4 (24.42)	65.8 (25.64)
Min-Max	92 - 92	26 - 91	17 - 94
Median	92.0	62.0	75.0
Q1-Q3	92.0 - 92.0	53.0 - 75.0	59.0 - 79.0
After 24 weeks			
n	1	5	9
Mean (SD)	78.0	74.0 (16.36)	76.6 (6.82)
Min-Max	78 - 78	46 - 87	65 - 88
Median	78.0	78.0	77.0
Q1-Q3	78.0 - 78.0	75.0 - 84.0	72.0 - 80.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.6 Full Analysis Set - FGM - Subgroups - Duration of diabetes
4.10.6.3 Acquisition of the glycaemic variability from FGM
4.10.6.3.2 Time above range in percent

Time above range in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	27.0	47.1 (20.14)	30.3 (11.82)
Min-Max	27 - 27	25 - 75	9 - 45
Median	27.0	56.0	33.0
Q1-Q3	27.0 - 27.0	25.0 - 60.0	19.0 - 38.0
After 12 weeks			
n	1	5	10
Mean (SD)	8.0	34.6 (26.12)	32.5 (25.12)
Min-Max	8 - 8	9 - 74	6 - 80
Median	8.0	25.0	23.5
Q1-Q3	8.0 - 8.0	18.0 - 47.0	21.0 - 41.0
After 24 weeks			
n	1	5	9
Mean (SD)	22.0	23.0 (17.89)	22.1 (5.99)
Min-Max	22 - 22	10 - 54	12 - 30
Median	22.0	16.0	22.0
Q1-Q3	22.0 - 22.0	13.0 - 22.0	18.0 - 26.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.6 Full Analysis Set - FGM - Subgroups - Duration of diabetes
4.10.6.3 Acquisition of the glycaemic variability from FGM
4.10.6.3.3 Time below range in percent

Time below range in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	2.0	5.0 (7.07)	7.3 (8.58)
Min-Max	2 - 2	0 - 20	0 - 25
Median	2.0	5.0	4.0
Q1-Q3	2.0 - 2.0	0.0 - 5.0	0.0 - 12.0
After 12 weeks			
n	1	5	10
Mean (SD)	0.0	4.0 (8.94)	1.7 (3.27)
Min-Max	0 - 0	0 - 20	0 - 10
Median	0.0	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 3.0
After 24 weeks			
n	1	5	9
Mean (SD)	0.0	3.0 (6.71)	2.3 (3.04)
Min-Max	0 - 0	0 - 15	0 - 9
Median	0.0	0.0	2.0
Q1-Q3	0.0 - 0.0	0.0 - 0.0	0.0 - 3.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.7 Full Analysis Set - FGM - Subgroups - Baseline HbA1c
4.10.7.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	142.79 (20.720)	160.39 (26.483)
95% CL	[130.268;155.310]	[135.900;184.885]
Min-Max	120 - 178	124 - 199
Median	134.00	152.00
Q1-Q3	126.13 -162.00	147.75 -193.00
After 12 weeks		
n	11	6
Mean (SD)	136.66 (29.915)	154.26 (36.248)
95% CL	[116.562;156.757]	[116.217;192.297]
Min-Max	113 - 212	127 - 214
Median	128.00	136.27
Q1-Q3	119.00 -133.00	128.00 -184.00
Absolute change after approx. 12 weeks		
n	11	6
Mean (SD)	-3.91 (33.198)	-7.53 (15.410)
95% CL	[-26.212; 18.393]	[-23.706; 8.637]
Min-Max	-59 - 71	-25 - 15
Median	1.00	-8.10
Q1-Q3	-29.00 - 8.00	-23.00 - 4.00
T-Test	t= -0.39 P= 0.704	t= -1.20 P= 0.285
Relative change after approx. 12 weeks		
n	11	6
Mean (SD)	-1.65 (21.934)	-5.01 (9.517)
95% CL	[-16.382; 13.089]	[-14.998; 4.976]
Min-Max	-33.15 - 50.355	-16.45 - 7.5377
Median	0.79	-4.77
Q1-Q3	-17.90 - 6.67	-14.84 - 3.23
T-Test	t= -0.25 P= 0.808	t= -1.29 P= 0.254

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.7 Full Analysis Set - FGM - Subgroups - Baseline HbA1c
4.10.7.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	142.79 (20.720)	160.39 (26.483)
95% CL	[130.268;155.310]	[135.900;184.885]
Min-Max	120 - 178	124 - 199
Median	134.00	152.00
Q1-Q3	126.13 -162.00	147.75 -193.00
After 24 weeks		
n	10	6
Mean (SD)	135.85 (13.882)	140.69 (25.984)
95% CL	[125.914;145.776]	[113.421;167.958]
Min-Max	118 - 162	121 - 191
Median	130.50	132.07
Q1-Q3	127.00 -147.00	124.00 -144.00
Absolute change after approx. 24 weeks		
n	10	6
Mean (SD)	-2.58 (22.395)	-21.10 (17.037)
95% CL	[-18.600; 13.440]	[-38.981; -3.223]
Min-Max	-49 - 28	-49 - -3
Median	-0.10	-17.81
Q1-Q3	-16.00 - 10.00	-31.00 - -8.00
T-Test	t= -0.36 P= 0.724	t= -3.03 P= 0.029
Relative change after approx. 24 weeks		
n	10	6
Mean (SD)	-0.49 (14.707)	-12.58 (9.149)
95% CL	[-11.010; 10.031]	[-22.184; -2.982]
Min-Max	-27.53 - 20.896	-25.39 - -2.419
Median	0.04	-11.83
Q1-Q3	-9.88 - 8.20	-20.00 - -4.02
T-Test	t= -0.11 P= 0.918	t= -3.37 P= 0.020

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.7 Full Analysis Set - FGM - Subgroups - Baseline HbA1c
4.10.7.3 Acquisition of the glycaemic variability from FGM
4.10.7.3.1 Time in range in percent

Time in range in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	62.1 (18.10)	46.1 (14.58)
Min-Max	30 - 87	20 - 68
Median	67.0	45.0
Q1-Q3	55.0 - 71.0	41.0 - 53.0
After 12 weeks		
n	11	6
Mean (SD)	66.5 (27.06)	61.8 (20.47)
Min-Max	17 - 94	26 - 79
Median	75.0	67.5
Q1-Q3	45.0 - 92.0	53.0 - 78.0
After 24 weeks		
n	10	6
Mean (SD)	75.5 (8.90)	72.8 (15.07)
Min-Max	55 - 88	46 - 87
Median	77.5	78.5
Q1-Q3	72.0 - 78.0	65.0 - 82.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.7 Full Analysis Set - FGM - Subgroups - Baseline HbA1c
4.10.7.3 Acquisition of the glycaemic variability from FGM
4.10.7.3.2 Time above range in percent

Time above range in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	30.8 (13.52)	47.1 (17.04)
Min-Max	9 - 60	28 - 75
Median	30.0	45.0
Q1-Q3	25.0 - 38.0	32.0 - 59.0
After 12 weeks		
n	11	6
Mean (SD)	29.6 (25.75)	35.8 (21.20)
Min-Max	6 - 80	21 - 74
Median	25.0	26.0
Q1-Q3	8.0 - 41.0	21.0 - 47.0
After 24 weeks		
n	10	6
Mean (SD)	20.8 (6.29)	25.5 (15.08)
Min-Max	10 - 30	13 - 54
Median	22.0	19.5
Q1-Q3	16.0 - 25.0	17.0 - 30.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.7 Full Analysis Set - FGM - Subgroups - Baseline HbA1c
4.10.7.3 Acquisition of the glycaemic variability from FGM
4.10.7.3.3 Time below range in percent

Time below range in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	6.9 (8.68)	6.7 (7.67)
Min-Max	0 - 25	0 - 20
Median	4.0	5.0
Q1-Q3	2.0 - 5.0	0.0 - 12.0
After 12 weeks		
n	11	6
Mean (SD)	3.9 (8.01)	2.3 (4.08)
Min-Max	0 - 20	0 - 10
Median	0.0	0.0
Q1-Q3	0.0 - 3.0	0.0 - 4.0
After 24 weeks		
n	10	6
Mean (SD)	4.6 (7.44)	1.7 (2.07)
Min-Max	0 - 20	0 - 5
Median	0.0	1.0
Q1-Q3	0.0 - 9.0	0.0 - 3.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.8 Full Analysis Set - FGM - Subgroups - Previous basal insulin therapy
4.10.8.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	136.25 (15.872)	159.08 (25.958)	137.80 (17.556)	177.00 ( )
95% CL	[116.544;155.958]	[139.130;179.036]	[116.002;159.598]	[;]
Min-Max	122 - 155	126 - 199	120 - 162	177 - 177
Median	126.13	152.00	134.00	177.00
Q1-Q3	126.13 -152.00	141.00 -178.00	124.00 -149.00	177.00 -177.00
After 12 weeks				
n	5	7	5	0
Mean (SD)	127.85 (3.531)	161.36 (40.948)	132.00 (24.990)	( )
95% CL	[123.467;132.235]	[123.492;199.234]	[100.971;163.029]	[;]
Min-Max	122.52 - 132	119 - 214	113 - 175	-
Median	128.00	140.54	128.00	
Q1-Q3	127.00 -129.73	127.00 -212.00	116.00 -128.00	-
Absolute change after approx. 12 weeks				
n	5	7	5	0
Mean (SD)	-8.40 (14.690)	-2.46 (40.166)	-5.80 (20.067)	( )
95% CL	[-26.640; 9.840]	[-39.605; 34.689]	[-30.717; 19.117]	[;]
Min-Max	-25 - 6	-59 - 71	-33 - 13	-
Median	-3.60	-7.21	4.00	
Q1-Q3	-23.00 - 3.60	-29.00 - 15.00	-21.00 - 8.00	-
T-Test	t= -1.28 P= 0.270	t= -0.16 P= 0.877	t= -0.65 P= 0.553	t= P=
Relative change after approx. 12 weeks				
n	5	7	5	0
Mean (SD)	-5.27 (9.902)	-0.27 (26.004)	-3.98 (13.930)	( )
95% CL	[-17.568; 7.021]	[-24.321; 23.778]	[-21.276; 13.316]	[;]
Min-Max	-16.45 - 4.918	-33.15 - 50.355	-22.15 - 8.0247	-
Median	-2.86	-4.66	3.23	
Q1-Q3	-14.84 - 2.86	-17.90 - 7.54	-15.67 - 6.67	-
T-Test	t= -1.19 P= 0.300	t= -0.03 P= 0.979	t= -0.64 P= 0.558	t= P=

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.8 Full Analysis Set - FGM - Subgroups - Previous basal insulin therapy
4.10.8.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	136.25 (15.872)	159.08 (25.958)	137.80 (17.556)	177.00 ( )
95% CL	[116.544;155.958]	[139.130;179.036]	[116.002;159.598]	[;]
Min-Max	122 - 155	126 - 199	120 - 162	177 - 177
Median	126.13	152.00	134.00	177.00
Q1-Q3	126.13 -152.00	141.00 -178.00	124.00 -149.00	177.00 -177.00
After 24 weeks				
n	5	7	4	0
Mean (SD)	127.09 (3.836)	144.31 (23.097)	139.25 (18.804)	( )
95% CL	[122.328;131.854]	[122.944;165.667]	[109.329;169.171]	[;]
Min-Max	122.52 - 132	118 - 191	121 - 162	-
Median	127.93	144.00	137.00	
Q1-Q3	124.00 -129.00	129.00 -147.00	124.00 -154.50	-
Absolute change after approx. 24 weeks				
n	5	7	4	0
Mean (SD)	-9.16 (17.224)	-19.52 (24.444)	7.50 (14.387)	( )
95% CL	[-30.547; 12.226]	[-42.123; 3.090]	[-15.394; 30.394]	[;]
Min-Max	-31 - 10	-49 - 21	-3 - 28	-
Median	-3.60	-16.00	2.50	
Q1-Q3	-23.00 - 1.80	-49.00 - -8.00	-2.50 - 17.50	-
T-Test	t= -1.19 P= 0.300	t= -2.11 P= 0.079	t= 1.04 P= 0.374	t= P=
Relative change after approx. 24 weeks				
n	5	7	4	0
Mean (SD)	-5.67 (11.678)	-10.71 (14.885)	5.74 (10.746)	( )
95% CL	[-20.172; 8.827]	[-24.480; 3.053]	[-11.358; 22.841]	[;]
Min-Max	-20 - 8.1967	-27.53 - 16.667	-2.419 - 20.896	-
Median	-2.86	-9.88	2.25	
Q1-Q3	-15.13 - 1.43	-25.39 - -4.02	-1.88 - 13.36	-
T-Test	t= -1.09 P= 0.338	t= -1.90 P= 0.106	t= 1.07 P= 0.364	t= P=

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.8 Full Analysis Set - FGM - Subgroups - Previous basal insulin therapy
4.10.8.3 Acquisition of the glycaemic variability from FGM
4.10.8.3.1 Time in range in percent

Time in range in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	52.0 (7.38)	50.1 (23.12)	72.0 (6.89)	59.0
Min-Max	40 - 60	20 - 87	67 - 84	59 - 59
Median	53.0	44.0	70.0	59.0
Q1-Q3	52.0 - 55.0	35.0 - 70.0	68.0 - 71.0	59.0 - 59.0
After 12 weeks				
n	5	7	5	0
Mean (SD)	67.2 (13.97)	52.7 (31.15)	79.4 (13.97)	
Min-Max	45 - 79	17 - 94	59 - 93	
Median	75.0	53.0	78.0	
Q1-Q3	62.0 - 75.0	26.0 - 91.0	75.0 - 92.0	
After 24 weeks				
n	5	7	4	0
Mean (SD)	72.8 (10.71)	75.0 (14.99)	75.8 (3.86)	
Min-Max	55 - 82	46 - 88	70 - 78	
Median	75.0	78.0	77.5	
Q1-Q3	72.0 - 80.0	65.0 - 87.0	73.5 - 78.0	

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.8 Full Analysis Set - FGM - Subgroups - Previous basal insulin therapy
4.10.8.3 Acquisition of the glycaemic variability from FGM
4.10.8.3.2 Time above range in percent

Time above range in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	32.6 (6.02)	44.2 (21.31)	26.2 (7.60)	38.0
Min-Max	25 - 40	9 - 75	14 - 33	38 - 38
Median	35.0	45.0	27.0	38.0
Q1-Q3	28.0 - 35.0	30.0 - 59.0	25.0 - 32.0	38.0 - 38.0
After 12 weeks				
n	5	7	5	0
Mean (SD)	24.0 (6.63)	45.4 (31.20)	20.6 (13.97)	
Min-Max	18 - 35	6 - 80	7 - 41	
Median	21.0	47.0	22.0	
Q1-Q3	21.0 - 25.0	9.0 - 74.0	8.0 - 25.0	
After 24 weeks				
n	5	7	4	0
Mean (SD)	19.2 (6.53)	24.3 (14.55)	23.8 (4.19)	
Min-Max	10 - 26	12 - 54	21 - 30	
Median	18.0	22.0	22.0	
Q1-Q3	17.0 - 25.0	13.0 - 30.0	21.5 - 26.0	

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.8 Full Analysis Set - FGM - Subgroups - Previous basal insulin therapy
4.10.8.3 Acquisition of the glycaemic variability from FGM
4.10.8.3.3 Time below range in percent

Time below range in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	15.4 (6.77)	5.7 (7.95)	1.8 (2.05)	0.0
Min-Max	5 - 20	0 - 25	0 - 5	0 - 0
Median	20.0	4.0	2.0	0.0
Q1-Q3	12.0 - 20.0	0.0 - 5.0	0.0 - 2.0	0.0 - 0.0
After 12 weeks				
n	5	7	5	0
Mean (SD)	8.8 (10.35)	1.9 (3.76)	0.0 (0.00)	
Min-Max	0 - 20	0 - 10	0 - 0	
Median	4.0	0.0	0.0	
Q1-Q3	0.0 - 20.0	0.0 - 3.0	0.0 - 0.0	
After 24 weeks				
n	5	7	4	0
Mean (SD)	8.0 (8.92)	2.0 (3.61)	0.5 (1.00)	
Min-Max	0 - 20	0 - 9	0 - 2	
Median	3.0	0.0	0.0	
Q1-Q3	2.0 - 15.0	0.0 - 5.0	0.0 - 1.0	

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.9 Full Analysis Set - FGM - Subgroups - Time of iGlarLixi administration
4.10.9.1 Change in the median value of glucose up to approx. 12 weeks after the start of treatment

Median value of glucose in mg/dL	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	157.29 (25.689)	144.46 (22.476)
95% CL	[133.528;181.044]	[130.880;158.044]
Min-Max	126 - 199	120 - 193
Median	162.00	147.75
Q1-Q3	134.00 -177.00	126.13 -152.00
After 12 weeks		
n	6	11
Mean (SD)	162.33 (44.361)	132.25 (18.355)
95% CL	[115.780;208.887]	[119.923;144.586]
Min-Max	113 - 214	116 - 184
Median	154.00	128.00
Q1-Q3	127.00 -212.00	122.52 -132.00
Absolute change after approx. 12 weeks		
n	6	11
Mean (SD)	8.33 (35.500)	-12.56 (20.646)
95% CL	[-28.922; 45.589]	[-26.434; 1.306]
Min-Max	-29 - 71	-59 - 8
Median	7.00	-7.21
Q1-Q3	-21.00 - 15.00	-25.00 - 4.00
T-Test	t= 0.57 P= 0.590	t= -2.02 P= 0.071
Relative change after approx. 12 weeks		
n	6	11
Mean (SD)	5.52 (24.660)	-7.39 (12.727)
95% CL	[-20.356; 31.402]	[-15.942; 1.158]
Min-Max	-17.9 - 50.355	-33.15 - 6.6667
Median	4.17	-4.66
Q1-Q3	-15.67 - 8.02	-16.45 - 3.23
T-Test	t= 0.55 P= 0.607	t= -1.93 P= 0.083

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.9 Full Analysis Set - FGM - Subgroups - Time of iGlarLixi administration
4.10.9.2 Change in the median value of glucose up to approx. 24 weeks after the start of treatment

Median value of glucose in mg/dL	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	157.29 (25.689)	144.46 (22.476)
95% CL	[133.528;181.044]	[130.880;158.044]
Min-Max	126 - 199	120 - 193
Median	162.00	147.75
Q1-Q3	134.00 -177.00	126.13 -152.00
After 24 weeks		
n	5	11
Mean (SD)	152.80 (26.621)	130.78 (8.348)
95% CL	[119.745;185.855]	[125.173;136.389]
Min-Max	118 - 191	121 - 147
Median	147.00	129.00
Q1-Q3	146.00 -162.00	124.00 -135.14
Absolute change after approx. 24 weeks		
n	5	11
Mean (SD)	0.40 (22.766)	-14.04 (21.123)
95% CL	[-27.868; 28.668]	[-28.228; 0.153]
Min-Max	-23 - 28	-49 - 10
Median	-8.00	-3.60
Q1-Q3	-16.00 - 21.00	-31.00 - 1.80
T-Test	t= 0.04 P= 0.971	t= -2.20 P= 0.052
Relative change after approx. 24 weeks		
n	5	11
Mean (SD)	1.47 (16.457)	-7.98 (12.342)
95% CL	[-18.964; 21.905]	[-16.269; 0.315]
Min-Max	-16.31 - 20.896	-27.53 - 8.1967
Median	-4.02	-2.86
Q1-Q3	-9.88 - 16.67	-20.00 - 1.43
T-Test	t= 0.20 P= 0.851	t= -2.14 P= 0.058

Median values measured by Flash Glucose Monitoring (FGM) system

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.9 Full Analysis Set - FGM - Subgroups - Time of iGlarLixi administration
4.10.9.3 Acquisition of the glycaemic variability from FGM
4.10.9.3.1 Time in range in percent

Time in range in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	69.6 (16.00)	49.5 (15.77)
Min-Max	41 - 87	20 - 71
Median	70.0	52.0
Q1-Q3	59.0 - 84.0	40.0 - 60.0
After 12 weeks		
n	6	11
Mean (SD)	65.2 (32.33)	64.6 (20.67)
Min-Max	26 - 94	17 - 92
Median	75.0	75.0
Q1-Q3	28.0 - 93.0	53.0 - 78.0
After 24 weeks		
n	5	11
Mean (SD)	73.0 (16.58)	75.2 (8.70)
Min-Max	46 - 88	55 - 87
Median	77.0	78.0
Q1-Q3	70.0 - 84.0	72.0 - 80.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.9 Full Analysis Set - FGM - Subgroups - Time of iGlarLixi administration
4.10.9.3 Acquisition of the glycaemic variability from FGM
4.10.9.3.2 Time above range in percent

Time above range in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	28.9 (16.95)	40.6 (15.28)
Min-Max	9 - 59	25 - 75
Median	30.0	35.0
Q1-Q3	14.0 - 38.0	28.0 - 45.0
After 12 weeks		
n	6	11
Mean (SD)	34.8 (32.33)	30.2 (19.28)
Min-Max	6 - 74	8 - 80
Median	25.0	25.0
Q1-Q3	7.0 - 72.0	21.0 - 35.0
After 24 weeks		
n	5	11
Mean (SD)	27.0 (16.58)	20.5 (5.77)
Min-Max	12 - 54	10 - 30
Median	23.0	22.0
Q1-Q3	16.0 - 30.0	17.0 - 25.0

4 Effectiveness (secondary)
4.10 Absolute and relative change in the median value of glucose
4.10.9 Full Analysis Set - FGM - Subgroups - Time of iGlarLixi administration
4.10.9.3 Acquisition of the glycaemic variability from FGM
4.10.9.3.3 Time below range in percent

Time below range in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	1.1 (1.57)	9.9 (8.63)
Min-Max	0 - 4	0 - 25
Median	0.0	5.0
Q1-Q3	0.0 - 2.0	5.0 - 20.0
After 12 weeks		
n	6	11
Mean (SD)	0.0 (0.00)	5.2 (7.93)
Min-Max	0 - 0	0 - 20
Median	0.0	0.0
Q1-Q3	0.0 - 0.0	0.0 - 10.0
After 24 weeks		
n	5	11
Mean (SD)	0.0 (0.00)	5.1 (6.80)
Min-Max	0 - 0	0 - 20
Median	0.0	2.0
Q1-Q3	0.0 - 0.0	0.0 - 9.0

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	3 (4.48%)	1 (5.26%)	2 (4.17%)
	[0.93; 12.53]	[0.13; 26.03]	[0.51; 14.25]
After 12 weeks	3 (4.76%)	none	3 (6.52%)
	[0.99; 13.29]		[1.37; 17.90]
After 24 weeks	2 (3.57%)	none	2 (5.13%)
	[0.44; 12.31]		[0.63; 17.32]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.1 Incidence of Hypoglycaemia
4.11.1.1.1.1 Incidence of Hypoglycaemia - Week 12 compared to Baseline

Incidence of Hypoglycaemia	FAS (N = 61) N (%)	FGM (N = 16) N (%)	SMBG (N = 45) N (%)
Baseline	2 (3.28%)	1 (6.25%)	1 (2.22%)
After 12 weeks	3 (4.92%)	none	3 (6.67%)
Fisher's exact	P = 1.000	P = 1.000	P = 0.616

Only patients with measurement at baseline and at the considered visit post baseline

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.1 Incidence of Hypoglycaemia
4.11.1.1.1.2 Incidence of Hypoglycaemia - Week 24 compared to Baseline

Incidence of Hypoglycaemia	FAS (N = 54) N (%)	FGM (N = 16) N (%)	SMBG (N = 38) N (%)
Baseline	2 (3.70%)	1 (6.25%)	1 (2.63%)
After 24 weeks	2 (3.70%)	none	2 (5.26%)
Fisher's exact	P = 1.000	P = 1.000	P = 1.000

Only patients with measurement at baseline and at the considered visit post baseline

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.2 Number of events

Visit Number of events	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Not documented	3	1	2
0	64 (95.5%)	18 (94.7%)	46 (95.8%)
2	1 (1.5%)	0 (0.0%)	1 (2.1%)
3	1 (1.5%)	0 (0.0%)	1 (2.1%)
4	1 (1.5%)	1 (5.3%)	0 (0.0%)
Non-missing	67 (100.0%)	19 (100.0%)	48 (100.0%)
After 12 weeks			
Not documented	7	3	4
0	60 (95.2%)	17 (100.0%)	43 (93.5%)
1	2 (3.2%)	0 (0.0%)	2 (4.3%)
2	1 (1.6%)	0 (0.0%)	1 (2.2%)
Non-missing	63 (100.0%)	17 (100.0%)	46 (100.0%)
After 24 weeks			
Not documented	13	3	10
0	54 (96.4%)	17 (100.0%)	37 (94.9%)
3	1 (1.8%)	0 (0.0%)	1 (2.6%)
4	1 (1.8%)	0 (0.0%)	1 (2.6%)
Non-missing	56 (100.0%)	17 (100.0%)	39 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.2 Number of events
4.11.1.1.2.1 Events per patient year

Visit		FAS	FGM	SMBG
Baseline	Patients documented	67	19	48
	Number of events	9	4	5
	Patient years	15.42	4.37	11.05
	Events per patient year	0.584	0.915	0.453
After 12 weeks	Patients documented	63	17	46
	Number of events	4	0	4
	Patient years	15.45	4.35	11.10
	Events per patient year	0.259	0.000	0.360
After 24 weeks	Patients documented	56	17	39
	Number of events	7	0	7
	Patient years	13.48	3.91	9.58
	Events per patient year	0.519	0.000	0.731

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	1 (1.49%)	1 (5.26%)	none
	[0.04; 8.04]	[0.13; 26.03]	
After 12 weeks	1 (1.59%)	none	1 (2.17%)
	[0.04; 8.53]		[0.06; 11.53]
After 24 weeks	1 (1.79%)	none	1 (2.56%)
	[0.05; 9.55]		[0.06; 13.48]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.4 Number of nocturnal events

Visit Number of events	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Not documented	3	1	2
0	66 (98.5%)	18 (94.7%)	48 (100.0%)
4	1 (1.5%)	1 (5.3%)	0 (0.0%)
Non-missing	67 (100.0%)	19 (100.0%)	48 (100.0%)
After 12 weeks			
Not documented	7	3	4
0	62 (98.4%)	17 (100.0%)	45 (97.8%)
1	1 (1.6%)	0 (0.0%)	1 (2.2%)
Non-missing	63 (100.0%)	17 (100.0%)	46 (100.0%)
After 24 weeks			
Not documented	13	3	10
0	55 (98.2%)	17 (100.0%)	38 (97.4%)
4	1 (1.8%)	0 (0.0%)	1 (2.6%)
Non-missing	56 (100.0%)	17 (100.0%)	39 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.1 Full Analysis Set - FGM - SMBG
4.11.1.1.4 Number of nocturnal events
4.11.1.1.4.1 Nocturnal events per patient year

Visit		FAS	FGM	SMBG
Baseline	Patients documented	67	19	48
	Number of events	4	4	0
	Patient years	15.42	4.37	11.05
	Events per patient year	0.259	0.915	0.000
After 12 weeks	Patients documented	63	17	46
	Number of events	1	0	1
	Patient years	15.45	4.35	11.10
	Events per patient year	0.065	0.000	0.090
After 24 weeks	Patients documented	56	17	39
	Number of events	4	0	4
	Patient years	13.48	3.91	9.58
	Events per patient year	0.297	0.000	0.418

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	1 (3.70%)	2 (5.00%)
	[0.09; 18.97]	[0.61; 16.92]
After 12 weeks	1 (4.35%)	2 (5.00%)
	[0.11; 21.95]	[0.61; 16.92]
After 24 weeks	1 (5.26%)	1 (2.70%)
	[0.13; 26.03]	[0.07; 14.16]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.2 Number of events

Visit Number of events	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Not documented	1	2
0	26 (96.3%)	38 (95.0%)
2	0 (0.0%)	1 (2.5%)
3	1 (3.7%)	0 (0.0%)
4	0 (0.0%)	1 (2.5%)
Non-missing	27 (100.0%)	40 (100.0%)
After 12 weeks		
Not documented	5	2
0	22 (95.7%)	38 (95.0%)
1	0 (0.0%)	2 (5.0%)
2	1 (4.3%)	0 (0.0%)
Non-missing	23 (100.0%)	40 (100.0%)
After 24 weeks		
Not documented	8	5
0	18 (94.7%)	36 (97.3%)
3	1 (5.3%)	0 (0.0%)
4	0 (0.0%)	1 (2.7%)
Non-missing	19 (100.0%)	37 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.2 Number of events
4.11.1.2.2.1 Events per patient year

Visit		Female	Male
Baseline	Patients documented	27	40
	Number of events	3	6
	Patient years	6.21	9.21
	Events per patient year	0.483	0.652
After 12 weeks	Patients documented	23	40
	Number of events	2	2
	Patient years	5.53	9.91
	Events per patient year	0.361	0.202
After 24 weeks	Patients documented	19	37
	Number of events	3	4
	Patient years	4.70	8.79
	Events per patient year	0.639	0.455

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	none	1 (2.50%)
		[0.06; 13.16]
After 12 weeks	none	1 (2.50%)
		[0.06; 13.16]
After 24 weeks	none	1 (2.70%)
		[0.07; 14.16]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.4 Number of nocturnal events

Visit Number of events	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Not documented	1	2
0	27 (100.0%)	39 (97.5%)
4	0 (0.0%)	1 (2.5%)
Non-missing	27 (100.0%)	40 (100.0%)
After 12 weeks		
Not documented	5	2
0	23 (100.0%)	39 (97.5%)
1	0 (0.0%)	1 (2.5%)
Non-missing	23 (100.0%)	40 (100.0%)
After 24 weeks		
Not documented	8	5
0	19 (100.0%)	36 (97.3%)
4	0 (0.0%)	1 (2.7%)
Non-missing	19 (100.0%)	37 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.2 Full Analysis Set - Subgroups - Gender
4.11.1.2.4 Number of nocturnal events
4.11.1.2.4.1 Nocturnal events per patient year

Visit		Female	Male
Baseline	Patients documented	27	40
	Number of events	0	4
	Patient years	6.21	9.21
	Events per patient year	0.000	0.435
After 12 weeks	Patients documented	23	40
	Number of events	0	1
	Patient years	5.53	9.91
	Events per patient year	0.000	0.101
After 24 weeks	Patients documented	19	37
	Number of events	0	4
	Patient years	4.70	8.79
	Events per patient year	0.000	0.455

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]˚	>60 - <70 years (N = 24) N (%) [95% CI]˚	>=70 years (N = 22) N (%) [95% CI]˚
Baseline	none	1 (4.55%) [0.12; 22.84]	2 (9.52%) [1.17; 30.38]
After 12 weeks	none	2 (8.33%) [1.03; 27.00]	1 (5.26%) [0.13; 26.03]
After 24 weeks	1 (5.00%) [0.13; 24.87]	1 (5.00%) [0.13; 24.87]	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.2 Number of events

Visit Number of events	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Not documented	0	2	1
0	24 (100.0%)	21 (95.5%)	19 (90.5%)
2	0 (0.0%)	1 (4.5%)	0 (0.0%)
3	0 (0.0%)	0 (0.0%)	1 (4.8%)
4	0 (0.0%)	0 (0.0%)	1 (4.8%)
Non-missing	24 (100.0%)	22 (100.0%)	21 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	20 (100.0%)	22 (91.7%)	18 (94.7%)
1	0 (0.0%)	1 (4.2%)	1 (5.3%)
2	0 (0.0%)	1 (4.2%)	0 (0.0%)
Non-missing	20 (100.0%)	24 (100.0%)	19 (100.0%)
After 24 weeks			
Not documented	4	4	5
0	19 (95.0%)	19 (95.0%)	16 (100.0%)
3	1 (5.0%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	1 (5.0%)	0 (0.0%)
Non-missing	20 (100.0%)	20 (100.0%)	16 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.2 Number of events
4.11.1.3.2.1 Events per patient year

Visit		<= 60 years	>60 - <70 years	>=70 years
Baseline	Patients documented	24	22	21
	Number of events	0	2	7
	Patient years	5.52	5.06	4.83
	Events per patient year	0.000	0.395	1.448
After 12 weeks	Patients documented	20	24	19
	Number of events	0	3	1
	Patient years	5.11	5.80	4.54
	Events per patient year	0.000	0.517	0.220
After 24 weeks	Patients documented	20	20	16
	Number of events	3	4	0
	Patient years	4.93	4.57	3.99
	Events per patient year	0.609	0.875	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]˚	>60 - <70 years (N = 24) N (%) [95% CI]˚	>=70 years (N = 22) N (%) [95% CI]˚
Baseline	none	none	1 (4.76%) [0.12; 23.82]
After 12 weeks	none	1 (4.17%) [0.11; 21.12]	none
After 24 weeks	none	1 (5.00%) [0.13; 24.87]	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.4 Number of nocturnal events

Visit Number of events	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Not documented	0	2	1
0	24 (100.0%)	22 (100.0%)	20 (95.2%)
4	0 (0.0%)	0 (0.0%)	1 (4.8%)
Non-missing	24 (100.0%)	22 (100.0%)	21 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	20 (100.0%)	23 (95.8%)	19 (100.0%)
1	0 (0.0%)	1 (4.2%)	0 (0.0%)
Non-missing	20 (100.0%)	24 (100.0%)	19 (100.0%)
After 24 weeks			
Not documented	4	4	5
0	20 (100.0%)	19 (95.0%)	16 (100.0%)
4	0 (0.0%)	1 (5.0%)	0 (0.0%)
Non-missing	20 (100.0%)	20 (100.0%)	16 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.3 Full Analysis Set - Subgroups - Age groups
4.11.1.3.4 Number of nocturnal events
4.11.1.3.4.1 Nocturnal events per patient year

Visit		<= 60 years	>60 - <70 years	>=70 years
Baseline	Patients documented	24	22	21
	Number of events	0	0	4
	Patient years	5.52	5.06	4.83
	Events per patient year	0.000	0.000	0.828
After 12 weeks	Patients documented	20	24	19
	Number of events	0	1	0
	Patient years	5.11	5.80	4.54
	Events per patient year	0.000	0.172	0.000
After 24 weeks	Patients documented	20	20	16
	Number of events	0	4	0
	Patient years	4.93	4.57	3.99
	Events per patient year	0.000	0.875	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]˚	>=30 kg/m² (N = 52) N (%) [95% CI]˚
Baseline	1 (6.25%)	2 (3.92%)
	[0.16; 30.23]	[0.48; 13.46]
After 12 weeks	1 (7.14%)	2 (4.08%)
	[0.18; 33.87]	[0.50; 13.98]
After 24 weeks	none	2 (4.35%)
		[0.53; 14.84]

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.2 Number of events

Visit Number of events	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Not documented	2	1
0	15 (93.8%)	49 (96.1%)
2	0 (0.0%)	1 (2.0%)
3	1 (6.3%)	0 (0.0%)
4	0 (0.0%)	1 (2.0%)
Non-missing	16 (100.0%)	51 (100.0%)
After 12 weeks		
Not documented	4	3
0	13 (92.9%)	47 (95.9%)
1	1 (7.1%)	1 (2.0%)
2	0 (0.0%)	1 (2.0%)
Non-missing	14 (100.0%)	49 (100.0%)
After 24 weeks		
Not documented	7	6
0	10 (100.0%)	44 (95.7%)
3	0 (0.0%)	1 (2.2%)
4	0 (0.0%)	1 (2.2%)
Non-missing	10 (100.0%)	46 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.2 Number of events
4.11.1.4.2.1 Events per patient year

Visit		<30 kg/m²	>=30 kg/m²
Baseline	Patients documented	16	51
	Number of events	3	6
	Patient years	3.68	11.74
	Events per patient year	0.815	0.511
After 12 weeks	Patients documented	14	49
	Number of events	1	3
	Patient years	3.37	12.08
	Events per patient year	0.297	0.248
After 24 weeks	Patients documented	10	46
	Number of events	0	7
	Patient years	2.32	11.17
	Events per patient year	0.000	0.627

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]˚	>=30 kg/m² (N = 52) N (%) [95% CI]˚
Baseline	none	1 (1.96%)
		[0.05; 10.45]
After 12 weeks	none	1 (2.04%)
		[0.05; 10.85]
After 24 weeks	none	1 (2.17%)
		[0.06; 11.53]

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.4 Number of nocturnal events

Visit Number of events	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Not documented	2	1
0	16 (100.0%)	50 (98.0%)
4	0 (0.0%)	1 (2.0%)
Non-missing	16 (100.0%)	51 (100.0%)
After 12 weeks		
Not documented	4	3
0	14 (100.0%)	48 (98.0%)
1	0 (0.0%)	1 (2.0%)
Non-missing	14 (100.0%)	49 (100.0%)
After 24 weeks		
Not documented	7	6
0	10 (100.0%)	45 (97.8%)
4	0 (0.0%)	1 (2.2%)
Non-missing	10 (100.0%)	46 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.1.4.4 Number of nocturnal events
4.11.1.4.4.1 Nocturnal events per patient year

Visit		<30 kg/m²	>=30 kg/m²
Baseline	Patients documented	16	51
	Number of events	0	4
	Patient years	3.68	11.74
	Events per patient year	0.000	0.341
After 12 weeks	Patients documented	14	49
	Number of events	0	1
	Patient years	3.37	12.08
	Events per patient year	0.000	0.083
After 24 weeks	Patients documented	10	46
	Number of events	0	4
	Patient years	2.32	11.17
	Events per patient year	0.000	0.358

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]°	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]°
Baseline	2 (11.76%)	1 (2.70%)
	[1.46; 36.44]	[0.07; 14.16]
After 12 weeks	none	2 (5.88%)
		[0.72; 19.68]
After 24 weeks	none	1 (3.13%)
		[0.08; 16.22]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.2 Number of events

Visit Number of events	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Not documented	0	2
0	15 (88.2%)	36 (97.3%)
2	0 (0.0%)	1 (2.7%)
3	1 (5.9%)	0 (0.0%)
4	1 (5.9%)	0 (0.0%)
Non-missing	17 (100.0%)	37 (100.0%)
After 12 weeks		
Not documented	2	5
0	15 (100.0%)	32 (94.1%)
1	0 (0.0%)	1 (2.9%)
2	0 (0.0%)	1 (2.9%)
Non-missing	15 (100.0%)	34 (100.0%)
After 24 weeks		
Not documented	5	7
0	11 (100.0%)	31 (96.9%)
3	0 (0.0%)	1 (3.1%)
Non-missing	11 (100.0%)	32 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.2 Number of events
4.11.1.5.2.1 Events per patient year

Visit		<=60 ml/min/1.73 m²	>60 ml/min/1.73 m²
Baseline	Patients documented	17	37
	Number of events	7	2
	Patient years	3.91	8.52
	Events per patient year	1.789	0.235
After 12 weeks	Patients documented	15	34
	Number of events	0	3
	Patient years	3.59	8.34
	Events per patient year	0.000	0.360
After 24 weeks	Patients documented	11	32
	Number of events	0	3
	Patient years	2.70	7.48
	Events per patient year	0.000	0.401

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]°	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]°
Baseline	1 (5.88%)	none
	[0.15; 28.69]	
After 12 weeks	none	1 (2.94%)
		[0.07; 15.33]
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.4 Number of nocturnal events

Visit Number of events	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Not documented	0	2
0	16 (94.1%)	37 (100.0%)
4	1 (5.9%)	0 (0.0%)
Non-missing	17 (100.0%)	37 (100.0%)
After 12 weeks		
Not documented	2	5
0	15 (100.0%)	33 (97.1%)
1	0 (0.0%)	1 (2.9%)
Non-missing	15 (100.0%)	34 (100.0%)
After 24 weeks		
Not documented	5	7
0	11 (100.0%)	32 (100.0%)
Non-missing	11 (100.0%)	32 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.5 Full Analysis Set - Subgroups - Renal function
4.11.1.5.4 Number of nocturnal events
4.11.1.5.4.1 Nocturnal events per patient year

Visit		<=60 ml/min/1.73 m²	>60 ml/min/1.73 m²
Baseline	Patients documented	17	37
	Number of events	4	0
	Patient years	3.91	8.52
	Events per patient year	1.022	0.000
After 12 weeks	Patients documented	15	34
	Number of events	0	1
	Patient years	3.59	8.34
	Events per patient year	0.000	0.120
After 24 weeks	Patients documented	11	32
	Number of events	0	0
	Patient years	2.70	7.48
	Events per patient year	0.000	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]˚	5 to 10 years (N = 21) N (%) [95% CI]˚	over 10 years (N = 39) N (%) [95% CI]˚
Baseline	none	1 (5.00%) [0.13; 24.87]	2 (5.41%) [0.66; 18.19]
After 12 weeks	none	none	3 (7.69%) [1.62; 20.87]
After 24 weeks	none	2 (14.29%) [1.78; 42.81]	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.2 Number of events

Visit Number of events	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Not documented	0	1	2
0	7 (100.0%)	19 (95.0%)	35 (94.6%)
2	0 (0.0%)	0 (0.0%)	1 (2.7%)
3	0 (0.0%)	1 (5.0%)	0 (0.0%)
4	0 (0.0%)	0 (0.0%)	1 (2.7%)
Non-missing	7 (100.0%)	20 (100.0%)	37 (100.0%)
After 12 weeks			
Not documented	1	5	0
0	6 (100.0%)	16 (100.0%)	36 (92.3%)
1	0 (0.0%)	0 (0.0%)	2 (5.1%)
2	0 (0.0%)	0 (0.0%)	1 (2.6%)
Non-missing	6 (100.0%)	16 (100.0%)	39 (100.0%)
After 24 weeks			
Not documented	2	6	4
0	5 (100.0%)	12 (85.7%)	35 (100.0%)
3	0 (0.0%)	1 (7.1%)	0 (0.0%)
4	0 (0.0%)	1 (7.1%)	0 (0.0%)
Non-missing	5 (100.0%)	14 (100.0%)	35 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.2 Number of events
4.11.1.6.2.1 Events per patient year

Visit		up to 5 years	5 to 10 years	over 10 years
Baseline	Patients documented	7	20	37
	Number of events	0	3	6
	Patient years	1.61	4.60	8.52
	Events per patient year	0.000	0.652	0.705
After 12 weeks	Patients documented	6	16	39
	Number of events	0	0	4
	Patient years	1.55	4.00	9.50
	Events per patient year	0.000	0.000	0.421
After 24 weeks	Patients documented	5	14	35
	Number of events	0	7	0
	Patient years	1.18	3.50	8.25
	Events per patient year	0.000	2.002	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
Baseline	none	none	1 (2.70%) [0.07; 14.16]
After 12 weeks	none	none	1 (2.56%) [0.06; 13.48]
After 24 weeks	none	1 (7.14%) [0.18; 33.87]	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.4 Number of nocturnal events

Visit Number of events	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Not documented	0	1	2
0	7 (100.0%)	20 (100.0%)	36 (97.3%)
4	0 (0.0%)	0 (0.0%)	1 (2.7%)
Non-missing	7 (100.0%)	20 (100.0%)	37 (100.0%)
After 12 weeks			
Not documented	1	5	0
0	6 (100.0%)	16 (100.0%)	38 (97.4%)
1	0 (0.0%)	0 (0.0%)	1 (2.6%)
Non-missing	6 (100.0%)	16 (100.0%)	39 (100.0%)
After 24 weeks			
Not documented	2	6	4
0	5 (100.0%)	13 (92.9%)	35 (100.0%)
4	0 (0.0%)	1 (7.1%)	0 (0.0%)
Non-missing	5 (100.0%)	14 (100.0%)	35 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.1.6.4 Number of nocturnal events
4.11.1.6.4.1 Nocturnal events per patient year

Visit		up to 5 years	5 to 10 years	over 10 years
Baseline	Patients documented	7	20	37
	Number of events	0	0	4
	Patient years	1.61	4.60	8.52
	Events per patient year	0.000	0.000	0.470
After 12 weeks	Patients documented	6	16	39
	Number of events	0	0	1
	Patient years	1.55	4.00	9.50
	Events per patient year	0.000	0.000	0.105
After 24 weeks	Patients documented	5	14	35
	Number of events	0	4	0
	Patient years	1.18	3.50	8.25
	Events per patient year	0.000	1.144	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	2 (5.56%)	1 (3.23%)
	[0.68; 18.66]	[0.08; 16.70]
After 12 weeks	3 (8.57%)	none
	[1.80; 23.06]	
After 24 weeks	none	2 (7.69%)
		[0.95; 25.13]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.2 Number of events

Visit Number of events	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Not documented	2	1
0	34 (94.4%)	30 (96.8%)
2	1 (2.8%)	0 (0.0%)
3	0 (0.0%)	1 (3.2%)
4	1 (2.8%)	0 (0.0%)
Non-missing	36 (100.0%)	31 (100.0%)
After 12 weeks		
Not documented	3	4
0	32 (91.4%)	28 (100.0%)
1	2 (5.7%)	0 (0.0%)
2	1 (2.9%)	0 (0.0%)
Non-missing	35 (100.0%)	28 (100.0%)
After 24 weeks		
Not documented	8	5
0	30 (100.0%)	24 (92.3%)
3	0 (0.0%)	1 (3.8%)
4	0 (0.0%)	1 (3.8%)
Non-missing	30 (100.0%)	26 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.2 Number of events
4.11.1.7.2.1 Events per patient year

Visit		<8.5%	>=8.5%
Baseline	Patients documented	36	31
	Number of events	6	3
	Patient years	8.28	7.13
	Events per patient year	0.724	0.421
After 12 weeks	Patients documented	35	28
	Number of events	4	0
	Patient years	8.73	6.72
	Events per patient year	0.458	0.000
After 24 weeks	Patients documented	30	26
	Number of events	0	7
	Patient years	7.24	6.25
	Events per patient year	0.000	1.120

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	1 (2.78%) [0.07; 14.53]	none
After 12 weeks	1 (2.86%) [0.07; 14.92]	none
After 24 weeks	none	1 (3.85%) [0.10; 19.64]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.4 Number of nocturnal events

Visit Number of events	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Not documented	2	1
0	35 (97.2%)	31 (100.0%)
4	1 (2.8%)	0 (0.0%)
Non-missing	36 (100.0%)	31 (100.0%)
After 12 weeks		
Not documented	3	4
0	34 (97.1%)	28 (100.0%)
1	1 (2.9%)	0 (0.0%)
Non-missing	35 (100.0%)	28 (100.0%)
After 24 weeks		
Not documented	8	5
0	30 (100.0%)	25 (96.2%)
4	0 (0.0%)	1 (3.8%)
Non-missing	30 (100.0%)	26 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.1.7.4 Number of nocturnal events
4.11.1.7.4.1 Nocturnal events per patient year

Visit		<8.5%	>=8.5%
Baseline	Patients documented	36	31
	Number of events	4	0
	Patient years	8.28	7.13
	Events per patient year	0.483	0.000
After 12 weeks	Patients documented	35	28
	Number of events	1	0
	Patient years	8.73	6.72
	Events per patient year	0.115	0.000
After 24 weeks	Patients documented	30	26
	Number of events	0	4
	Patient years	7.24	6.25
	Events per patient year	0.000	0.640

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]˚	Glargin 100 (N = 24) N (%) [95% CI]˚	Glargin 300 (N = 29) N (%) [95% CI]˚	Degludec (N = 6) N (%) [95% CI]˚
Baseline	none	none	2 (7.14%) [0.88; 23.50]	1 (16.67%) [0.42; 64.12]
After 12 weeks	none	1 (4.55%) [0.12; 22.84]	2 (7.41%) [0.91; 24.29]	none
After 24 weeks	none	2 (10.53%) [1.30; 33.14]	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.2 Number of events

Visit Number of events	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Not documented	1	1	1	0
0	10 (100.0%)	23 (100.0%)	26 (92.9%)	5 (83.3%)
2	0 (0.0%)	0 (0.0%)	1 (3.6%)	0 (0.0%)
3	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
4	0 (0.0%)	0 (0.0%)	1 (3.6%)	0 (0.0%)
Non-missing	10 (100.0%)	23 (100.0%)	28 (100.0%)	6 (100.0%)
After 12 weeks				
Not documented	1	2	2	2
0	10 (100.0%)	21 (95.5%)	25 (92.6%)	4 (100.0%)
1	0 (0.0%)	1 (4.5%)	1 (3.7%)	0 (0.0%)
2	0 (0.0%)	0 (0.0%)	1 (3.7%)	0 (0.0%)
Non-missing	10 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Not documented	3	4	4	2
0	8 (100.0%)	17 (89.5%)	25 (100.0%)	4 (100.0%)
3	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
Non-missing	8 (100.0%)	19 (100.0%)	25 (100.0%)	4 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.2 Number of events
4.11.1.8.2.1 Events per patient year

Visit		Detemir	Glargin 100	Glargin 300	Degludec
Baseline	Patients documented	10	23	28	6
	Number of events	0	0	6	3
	Patient years	2.30	5.29	6.44	1.38
	Events per patient year	0.000	0.000	0.931	2.173
After 12 weeks	Patients documented	10	22	27	4
	Number of events	0	1	3	0
	Patient years	2.43	5.59	6.47	0.95
	Events per patient year	0.000	0.179	0.464	0.000
After 24 weeks	Patients documented	8	19	25	4
	Number of events	0	7	0	0
	Patient years	1.88	4.63	6.03	0.94
	Events per patient year	0.000	1.511	0.000	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]˚	Glargin 100 (N = 24) N (%) [95% CI]˚	Glargin 300 (N = 29) N (%) [95% CI]˚	Degludec (N = 6) N (%) [95% CI]˚
Baseline	none	none	1 (3.57%) [0.09; 18.35]	none
After 12 weeks	none	none	1 (3.70%) [0.09; 18.97]	none
After 24 weeks	none	1 (5.26%) [0.13; 26.03]	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.4 Number of nocturnal events

Visit Number of events	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Not documented	1	1	1	0
0	10 (100.0%)	23 (100.0%)	27 (96.4%)	6 (100.0%)
4	0 (0.0%)	0 (0.0%)	1 (3.6%)	0 (0.0%)
Non-missing	10 (100.0%)	23 (100.0%)	28 (100.0%)	6 (100.0%)
After 12 weeks				
Not documented	1	2	2	2
0	10 (100.0%)	22 (100.0%)	26 (96.3%)	4 (100.0%)
1	0 (0.0%)	0 (0.0%)	1 (3.7%)	0 (0.0%)
Non-missing	10 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Not documented	3	4	4	2
0	8 (100.0%)	18 (94.7%)	25 (100.0%)	4 (100.0%)
4	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
Non-missing	8 (100.0%)	19 (100.0%)	25 (100.0%)	4 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.1.8.4 Number of nocturnal events
4.11.1.8.4.1 Nocturnal events per patient year

Visit		Detemir	Glargin 100	Glargin 300	Degludec
Baseline	Patients documented	10	23	28	6
	Number of events	0	0	4	3
	Patient years	2.30	5.29	6.44	1.38
	Events per patient year	0.000	0.000	0.621	2.173
After 12 weeks	Patients documented	10	22	27	4
	Number of events	0	0	1	0
	Patient years	2.43	5.59	6.47	0.95
	Events per patient year	0.000	0.000	0.155	0.000
After 24 weeks	Patients documented	8	19	25	4
	Number of events	0	4	0	0
	Patient years	1.88	4.63	6.03	0.94
	Events per patient year	0.000	0.863	0.000	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]˚	before lunch (N = 9) N (%) [95% CI]˚	before dinner (N = 32) N (%) [95% CI]˚
Baseline	1 (3.85%)	1 (12.50%)	1 (3.13%)
	[0.10; 19.64]	[0.32; 52.65]	[0.08; 16.22]
After 12 weeks	1 (4.17%)	none	2 (6.90%)
	[0.11; 21.12]		[0.85; 22.77]
After 24 weeks	1 (4.76%)	none	1 (4.00%)
	[0.12; 23.82]		[0.10; 20.35]

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.2 Number of events

Visit Number of events	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Not documented	2	1	0
0	25 (96.2%)	7 (87.5%)	31 (96.9%)
2	0 (0.0%)	0 (0.0%)	1 (3.1%)
3	1 (3.8%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	1 (12.5%)	0 (0.0%)
Non-missing	26 (100.0%)	8 (100.0%)	32 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	23 (95.8%)	9 (100.0%)	27 (93.1%)
1	0 (0.0%)	0 (0.0%)	2 (6.9%)
2	1 (4.2%)	0 (0.0%)	0 (0.0%)
Non-missing	24 (100.0%)	9 (100.0%)	29 (100.0%)
After 24 weeks			
Not documented	7	0	6
0	20 (95.2%)	9 (100.0%)	24 (96.0%)
3	1 (4.8%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	0 (0.0%)	1 (4.0%)
Non-missing	21 (100.0%)	9 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.2 Number of events
4.11.1.9.2.1 Events per patient year

Visit		before breakfast	before lunch	before dinner
Baseline	Patients documented	26	8	32
	Number of events	3	4	2
	Patient years	5.98	1.84	7.36
	Events per patient year	0.501	2.173	0.272
After 12 weeks	Patients documented	24	9	29
	Number of events	2	0	2
	Patient years	5.97	2.32	6.92
	Events per patient year	0.335	0.000	0.289
After 24 weeks	Patients documented	21	9	25
	Number of events	3	0	4
	Patient years	5.28	2.04	5.90
	Events per patient year	0.568	0.000	0.678

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]°	before lunch (N = 9) N (%) [95% CI]°	before dinner (N = 32) N (%) [95% CI]°
Baseline	none	1 (12.50%) [0.32; 52.65]	none
After 12 weeks	none	none	1 (3.45%) [0.09; 17.76]
After 24 weeks	none	none	1 (4.00%) [0.10; 20.35]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.4 Number of nocturnal events

Visit Number of events	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Not documented	2	1	0
0	26 (100.0%)	7 (87.5%)	32 (100.0%)
4	0 (0.0%)	1 (12.5%)	0 (0.0%)
Non-missing	26 (100.0%)	8 (100.0%)	32 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	24 (100.0%)	9 (100.0%)	28 (96.6%)
1	0 (0.0%)	0 (0.0%)	1 (3.4%)
Non-missing	24 (100.0%)	9 (100.0%)	29 (100.0%)
After 24 weeks			
Not documented	7	0	6
0	21 (100.0%)	9 (100.0%)	24 (96.0%)
4	0 (0.0%)	0 (0.0%)	1 (4.0%)
Non-missing	21 (100.0%)	9 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.1 Hypoglycaemia with glucose < 70 mg/dl and >= 54 mg/dl
4.11.1.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.1.9.4 Number of nocturnal events
4.11.1.9.4.1 Nocturnal events per patient year

Visit		before breakfast	before lunch	before dinner
Baseline	Patients documented	26	8	32
	Number of events	0	4	0
	Patient years	5.98	1.84	7.36
	Events per patient year	0.000	2.173	0.000
After 12 weeks	Patients documented	24	9	29
	Number of events	0	0	1
	Patient years	5.97	2.32	6.92
	Events per patient year	0.000	0.000	0.144
After 24 weeks	Patients documented	21	9	25
	Number of events	0	0	4
	Patient years	5.28	2.04	5.90
	Events per patient year	0.000	0.000	0.678

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	1 (1.59%)	none	1 (2.17%)
	[0.04; 8.53]		[0.06; 11.53]
After 24 weeks	2 (3.57%)	none	2 (5.13%)
	[0.44; 12.31]		[0.63; 17.32]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.1 Incidence of Hypoglycaemia
4.11.1.1.1.1 Incidence of Hypoglycaemia - Week 12 compared to Baseline

Incidence of Hypoglycaemia	FAS (N = 62) N (%)	FGM (N = 16) N (%)	SMBG (N = 46) N (%)
Baseline	none	none	none
After 12 weeks	1 (1.61%)	none	1 (2.17%)
Fisher's exact	P = 1.000		P = 1.000

Only patients with measurement at baseline and at the considered visit post baseline

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.1 Incidence of Hypoglycaemia
4.11.1.1.1.2 Incidence of Hypoglycaemia - Week 24 compared to Baseline

Incidence of Hypoglycaemia	FAS (N = 55) N (%)	FGM (N = 16) N (%)	SMBG (N = 39) N (%)
Baseline	none	none	none
After 24 weeks	2 (3.64%)	none	2 (5.13%)
Fisher's exact	P = 0.495		P = 0.494

Only patients with measurement at baseline and at the considered visit post baseline

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.2 Number of events

Visit Number of events	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Not documented	1	1	0
0	69 (100.0%)	19 (100.0%)	50 (100.0%)
Non-missing	69 (100.0%)	19 (100.0%)	50 (100.0%)
After 12 weeks			
Not documented	7	3	4
0	62 (98.4%)	17 (100.0%)	45 (97.8%)
2	1 (1.6%)	0 (0.0%)	1 (2.2%)
Non-missing	63 (100.0%)	17 (100.0%)	46 (100.0%)
After 24 weeks			
Not documented	13	3	10
0	54 (96.4%)	17 (100.0%)	37 (94.9%)
1	1 (1.8%)	0 (0.0%)	1 (2.6%)
4	1 (1.8%)	0 (0.0%)	1 (2.6%)
Non-missing	56 (100.0%)	17 (100.0%)	39 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.2 Number of events
4.11.2.1.2.1 Events per patient year

Visit		FAS	FGM	SMBG
Baseline	Patients documented	69	19	50
	Number of events	0	0	0
	Patient years	15.88	4.37	11.51
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	63	17	46
	Number of events	2	0	2
	Patient years	15.45	4.35	11.10
	Events per patient year	0.129	0.000	0.180
After 24 weeks	Patients documented	56	17	39
	Number of events	5	0	5
	Patient years	13.50	3.91	9.59
	Events per patient year	0.370	0.000	0.521

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	1 (1.79%) [0.05; 9.55]	none	1 (2.56%) [0.06; 13.48]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.4 Number of nocturnal events

Visit Number of nocturnal events	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Not documented	1	1	0
0	69 (100.0%)	19 (100.0%)	50 (100.0%)
Non-missing	69 (100.0%)	19 (100.0%)	50 (100.0%)
After 12 weeks			
Not documented	7	3	4
0	63 (100.0%)	17 (100.0%)	46 (100.0%)
Non-missing	63 (100.0%)	17 (100.0%)	46 (100.0%)
After 24 weeks			
Not documented	13	3	10
0	55 (98.2%)	17 (100.0%)	38 (97.4%)
3	1 (1.8%)	0 (0.0%)	1 (2.6%)
Non-missing	56 (100.0%)	17 (100.0%)	39 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.1 Full Analysis Set - FGM - SMBG
4.11.2.1.4 Number of nocturnal events
4.11.2.1.4.1 Nocturnal events per patient year

Visit		FAS	FGM	SMBG
Baseline	Patients documented	69	19	50
	Number of events	0	0	0
	Patient years	15.88	4.37	11.51
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	63	17	46
	Number of events	0	0	0
	Patient years	15.45	4.35	11.10
	Events per patient year	0.000	0.000	0.000
After 24 weeks	Patients documented	56	17	39
	Number of events	3	0	3
	Patient years	13.50	3.91	9.59
	Events per patient year	0.222	0.000	0.313

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	1 (2.50%) [0.06; 13.16]
After 24 weeks	1 (5.00%) [0.13; 24.87]	1 (2.78%) [0.07; 14.53]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.2 Number of events

Visit Number of events	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Not documented	0	1
0	28 (100.0%)	41 (100.0%)
Non-missing	28 (100.0%)	41 (100.0%)
After 12 weeks		
Not documented	5	2
0	23 (100.0%)	39 (97.5%)
2	0 (0.0%)	1 (2.5%)
Non-missing	23 (100.0%)	40 (100.0%)
After 24 weeks		
Not documented	7	6
0	19 (95.0%)	35 (97.2%)
1	1 (5.0%)	0 (0.0%)
4	0 (0.0%)	1 (2.8%)
Non-missing	20 (100.0%)	36 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.2 Number of events
4.11.2.2.2.1 Events per patient year

Visit		Female	Male
Baseline	Patients documented	28	41
	Number of events	0	0
	Patient years	6.44	9.44
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	23	40
	Number of events	0	2
	Patient years	5.53	9.91
	Events per patient year	0.000	0.202
After 24 weeks	Patients documented	20	36
	Number of events	1	4
	Patient years	4.97	8.53
	Events per patient year	0.201	0.469

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	1 (2.78%) [0.07; 14.53]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.4 Number of nocturnal events

Visit Number of nocturnal events	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Not documented	0	1
0	28 (100.0%)	41 (100.0%)
Non-missing	28 (100.0%)	41 (100.0%)
After 12 weeks		
Not documented	5	2
0	23 (100.0%)	40 (100.0%)
Non-missing	23 (100.0%)	40 (100.0%)
After 24 weeks		
Not documented	7	6
0	20 (100.0%)	35 (97.2%)
3	0 (0.0%)	1 (2.8%)
Non-missing	20 (100.0%)	36 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.2 Full Analysis Set - Subgroups - Gender
4.11.2.2.4 Number of nocturnal events
4.11.2.2.4.1 Nocturnal events per patient year

Visit		Female	Male
Baseline	Patients documented	28	41
	Number of events	0	0
	Patient years	6.44	9.44
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	23	40
	Number of events	0	0
	Patient years	5.53	9.91
	Events per patient year	0.000	0.000
After 24 weeks	Patients documented	20	36
	Number of events	0	3
	Patient years	4.97	8.53
	Events per patient year	0.000	0.352

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]˚	>60 - <70 years (N = 24) N (%) [95% CI]˚	>=70 years (N = 22) N (%) [95% CI]˚
Baseline	none	none	none
After 12 weeks	none	none	1 (5.26%) [0.13; 26.03]
After 24 weeks	1 (5.26%) [0.13; 26.03]	1 (4.76%) [0.12; 23.82]	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.2 Number of events

Visit Number of events	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Not documented	0	1	0
0	24 (100.0%)	23 (100.0%)	22 (100.0%)
Non-missing	24 (100.0%)	23 (100.0%)	22 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	20 (100.0%)	24 (100.0%)	18 (94.7%)
2	0 (0.0%)	0 (0.0%)	1 (5.3%)
Non-missing	20 (100.0%)	24 (100.0%)	19 (100.0%)
After 24 weeks			
Not documented	5	3	5
0	18 (94.7%)	20 (95.2%)	16 (100.0%)
1	1 (5.3%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	1 (4.8%)	0 (0.0%)
Non-missing	19 (100.0%)	21 (100.0%)	16 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.2 Number of events
4.11.2.3.2.1 Events per patient year

Visit		<= 60 years	>60 - <70 years	>=70 years
Baseline	Patients documented	24	23	22
	Number of events	0	0	0
	Patient years	5.52	5.29	5.06
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	20	24	19
	Number of events	0	0	2
	Patient years	5.11	5.80	4.54
	Events per patient year	0.000	0.000	0.441
After 24 weeks	Patients documented	19	21	16
	Number of events	1	4	0
	Patient years	4.67	4.84	3.99
	Events per patient year	0.214	0.826	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]°	>60 - <70 years (N = 24) N (%) [95% CI]°	>=70 years (N = 22) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	1 (4.76%) [0.12; 23.82]	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.4 Number of nocturnal events

Visit Number of nocturnal events	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Not documented	0	1	0
0	24 (100.0%)	23 (100.0%)	22 (100.0%)
Non-missing	24 (100.0%)	23 (100.0%)	22 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	20 (100.0%)	24 (100.0%)	19 (100.0%)
Non-missing	20 (100.0%)	24 (100.0%)	19 (100.0%)
After 24 weeks			
Not documented	5	3	5
0	19 (100.0%)	20 (95.2%)	16 (100.0%)
3	0 (0.0%)	1 (4.8%)	0 (0.0%)
Non-missing	19 (100.0%)	21 (100.0%)	16 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.3 Full Analysis Set - Subgroups - Age groups
4.11.2.3.4 Number of nocturnal events
4.11.2.3.4.1 Nocturnal events per patient year

Visit		<= 60 years	>60 - <70 years	>=70 years
Baseline	Patients documented	24	23	22
	Number of events	0	0	0
	Patient years	5.52	5.29	5.06
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	20	24	19
	Number of events	0	0	0
	Patient years	5.11	5.80	4.54
	Events per patient year	0.000	0.000	0.000
After 24 weeks	Patients documented	19	21	16
	Number of events	0	3	0
	Patient years	4.67	4.84	3.99
	Events per patient year	0.000	0.619	0.000

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]°	>=30 kg/m² (N = 52) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	1 (7.14%) [0.18; 33.87]	none
After 24 weeks	none	2 (4.35%) [0.53; 14.84]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.2 Number of events

Visit Number of events	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Not documented	0	1
0	18 (100.0%)	51 (100.0%)
Non-missing	18 (100.0%)	51 (100.0%)
After 12 weeks		
Not documented	4	3
0	13 (92.9%)	49 (100.0%)
2	1 (7.1%)	0 (0.0%)
Non-missing	14 (100.0%)	49 (100.0%)
After 24 weeks		
Not documented	7	6
0	10 (100.0%)	44 (95.7%)
1	0 (0.0%)	1 (2.2%)
4	0 (0.0%)	1 (2.2%)
Non-missing	10 (100.0%)	46 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.2 Number of events
4.11.2.4.2.1 Events per patient year

Visit		<30 kg/m²	>=30 kg/m²
Baseline	Patients documented	18	51
	Number of events	0	0
	Patient years	4.14	11.74
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	14	49
	Number of events	2	0
	Patient years	3.37	12.08
	Events per patient year	0.593	0.000
After 24 weeks	Patients documented	10	46
	Number of events	0	5
	Patient years	2.32	11.18
	Events per patient year	0.000	0.447

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]°	>=30 kg/m² (N = 52) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	1 (2.17%) [0.06; 11.53]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.4 Number of nocturnal events

Visit Number of nocturnal events	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Not documented	0	1
0	18 (100.0%)	51 (100.0%)
Non-missing	18 (100.0%)	51 (100.0%)
After 12 weeks		
Not documented	4	3
0	14 (100.0%)	49 (100.0%)
Non-missing	14 (100.0%)	49 (100.0%)
After 24 weeks		
Not documented	7	6
0	10 (100.0%)	45 (97.8%)
3	0 (0.0%)	1 (2.2%)
Non-missing	10 (100.0%)	46 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.2.4.4 Number of nocturnal events
4.11.2.4.4.1 Nocturnal events per patient year

Visit		<30 kg/m²	>=30 kg/m²
Baseline	Patients documented	18	51
	Number of events	0	0
	Patient years	4.14	11.74
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	14	49
	Number of events	0	0
	Patient years	3.37	12.08
	Events per patient year	0.000	0.000
After 24 weeks	Patients documented	10	46
	Number of events	0	3
	Patient years	2.32	11.18
	Events per patient year	0.000	0.268

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]˚	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]˚
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	1 (3.03%) [0.08; 15.76]

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.2 Number of events

Visit Number of events	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Not documented	0	1
0	17 (100.0%)	38 (100.0%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Not documented	2	5
0	15 (100.0%)	34 (100.0%)
Non-missing	15 (100.0%)	34 (100.0%)
After 24 weeks		
Not documented	5	6
0	11 (100.0%)	32 (97.0%)
1	0 (0.0%)	1 (3.0%)
Non-missing	11 (100.0%)	33 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.2 Number of events
4.11.2.5.2.1 Events per patient year

Visit		<=60 ml/min/1.73 m²	>60 ml/min/1.73 m²
Baseline	Patients documented	17	38
	Number of events	0	0
	Patient years	3.91	8.75
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	15	34
	Number of events	0	0
	Patient years	3.59	8.34
	Events per patient year	0.000	0.000
After 24 weeks	Patients documented	11	33
	Number of events	0	1
	Patient years	2.70	7.75
	Events per patient year	0.000	0.129

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]˚	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]˚
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.4 Number of nocturnal events

Visit Number of nocturnal events	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Not documented	0	1
0	17 (100.0%)	38 (100.0%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Not documented	2	5
0	15 (100.0%)	34 (100.0%)
Non-missing	15 (100.0%)	34 (100.0%)
After 24 weeks		
Not documented	5	6
0	11 (100.0%)	33 (100.0%)
Non-missing	11 (100.0%)	33 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.5 Full Analysis Set - Subgroups - Renal function
4.11.2.5.4 Number of nocturnal events
4.11.2.5.4.1 Nocturnal events per patient year

Visit		<=60 ml/min/1.73 m²	>60 ml/min/1.73 m²
Baseline	Patients documented	17	38
	Number of events	0	0
	Patient years	3.91	8.75
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	15	34
	Number of events	0	0
	Patient years	3.59	8.34
	Events per patient year	0.000	0.000
After 24 weeks	Patients documented	11	33
	Number of events	0	0
	Patient years	2.70	7.75
	Events per patient year	0.000	0.000

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	1 (2.56%) [0.06; 13.48]
After 24 weeks	none	2 (15.38%) [1.92; 45.45]	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.2 Number of events

Visit Number of events	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Not documented	0	0	1
0	7 (100.0%)	21 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
After 12 weeks			
Not documented	1	5	0
0	6 (100.0%)	16 (100.0%)	38 (97.4%)
2	0 (0.0%)	0 (0.0%)	1 (2.6%)
Non-missing	6 (100.0%)	16 (100.0%)	39 (100.0%)
After 24 weeks			
Not documented	2	7	3
0	5 (100.0%)	11 (84.6%)	36 (100.0%)
1	0 (0.0%)	1 (7.7%)	0 (0.0%)
4	0 (0.0%)	1 (7.7%)	0 (0.0%)
Non-missing	5 (100.0%)	13 (100.0%)	36 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.2 Number of events
4.11.2.6.2.1 Events per patient year

Visit		up to 5 years	5 to 10 years	over 10 years
Baseline	Patients documented	7	21	38
	Number of events	0	0	0
	Patient years	1.61	4.83	8.75
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	6	16	39
	Number of events	0	0	2
	Patient years	1.55	4.00	9.50
	Events per patient year	0.000	0.000	0.211
After 24 weeks	Patients documented	5	13	36
	Number of events	0	5	0
	Patient years	1.18	3.24	8.53
	Events per patient year	0.000	1.544	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]°	5 to 10 years (N = 21) N (%) [95% CI]°	over 10 years (N = 39) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	1 (7.69%) [0.19; 36.03]	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.4 Number of nocturnal events

Visit Number of nocturnal events	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Not documented	0	0	1
0	7 (100.0%)	21 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
After 12 weeks			
Not documented	1	5	0
0	6 (100.0%)	16 (100.0%)	39 (100.0%)
Non-missing	6 (100.0%)	16 (100.0%)	39 (100.0%)
After 24 weeks			
Not documented	2	7	3
0	5 (100.0%)	12 (92.3%)	36 (100.0%)
3	0 (0.0%)	1 (7.7%)	0 (0.0%)
Non-missing	5 (100.0%)	13 (100.0%)	36 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.2.6.4 Number of nocturnal events
4.11.2.6.4.1 Nocturnal events per patient year

Visit		up to 5 years	5 to 10 years	over 10 years
Baseline	Patients documented	7	21	38
	Number of events	0	0	0
	Patient years	1.61	4.83	8.75
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	6	16	39
	Number of events	0	0	0
	Patient years	1.55	4.00	9.50
	Events per patient year	0.000	0.000	0.000
After 24 weeks	Patients documented	5	13	36
	Number of events	0	3	0
	Patient years	1.18	3.24	8.53
	Events per patient year	0.000	0.926	0.000

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	1 (2.86%) [0.07; 14.92]	none
After 24 weeks	none	2 (8.00%) [0.98; 26.03]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.2 Number of events

Visit Number of events	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Not documented	1	0
0	37 (100.0%)	32 (100.0%)
Non-missing	37 (100.0%)	32 (100.0%)
After 12 weeks		
Not documented	3	4
0	34 (97.1%)	28 (100.0%)
2	1 (2.9%)	0 (0.0%)
Non-missing	35 (100.0%)	28 (100.0%)
After 24 weeks		
Not documented	7	6
0	31 (100.0%)	23 (92.0%)
1	0 (0.0%)	1 (4.0%)
4	0 (0.0%)	1 (4.0%)
Non-missing	31 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.2 Number of events
4.11.2.7.2.1 Events per patient year

Visit		<8.5%	>=8.5%
Baseline	Patients documented	37	32
	Number of events	0	0
	Patient years	8.52	7.36
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	35	28
	Number of events	2	0
	Patient years	8.73	6.72
	Events per patient year	0.229	0.000
After 24 weeks	Patients documented	31	25
	Number of events	0	5
	Patient years	7.51	5.99
	Events per patient year	0.000	0.834

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	1 (4.00%) [0.10; 20.35]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.4 Number of nocturnal events

Visit Number of nocturnal events	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Not documented	1	0
0	37 (100.0%)	32 (100.0%)
Non-missing	37 (100.0%)	32 (100.0%)
After 12 weeks		
Not documented	3	4
0	35 (100.0%)	28 (100.0%)
Non-missing	35 (100.0%)	28 (100.0%)
After 24 weeks		
Not documented	7	6
0	31 (100.0%)	24 (96.0%)
3	0 (0.0%)	1 (4.0%)
Non-missing	31 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.2.7.4 Number of nocturnal events
4.11.2.7.4.1 Nocturnal events per patient year

Visit		<8.5%	>=8.5%
Baseline	Patients documented	37	32
	Number of events	0	0
	Patient years	8.52	7.36
	Events per patient year	0.000	0.000
After 12 weeks	Patients documented	35	28
	Number of events	0	0
	Patient years	8.73	6.72
	Events per patient year	0.000	0.000
After 24 weeks	Patients documented	31	25
	Number of events	0	3
	Patient years	7.51	5.99
	Events per patient year	0.000	0.501

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
Baseline	none	none	none	none
After 12 weeks	none	1 (4.55%) [0.12; 22.84]	none	none
After 24 weeks	none	2 (10.53%) [1.30; 33.14]	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.2 Number of events

Visit Number of events	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Not documented	0	1	0	0
0	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Not documented	1	2	2	2
0	10 (100.0%)	21 (95.5%)	27 (100.0%)	4 (100.0%)
2	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)
Non-missing	10 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Not documented	4	4	3	2
0	7 (100.0%)	17 (89.5%)	26 (100.0%)	4 (100.0%)
1	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
Non-missing	7 (100.0%)	19 (100.0%)	26 (100.0%)	4 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.2 Number of events
4.11.2.8.2.1 Events per patient year

Visit		Detemir	Glargin 100	Glargin 300	Degludec
Baseline	Patients documented	11	23	29	6
	Number of events	0	0	0	3
	Patient years	2.53	5.29	6.67	1.38
	Events per patient year	0.000	0.000	0.000	2.173
After 12 weeks	Patients documented	10	22	27	4
	Number of events	0	2	0	0
	Patient years	2.43	5.59	6.47	0.95
	Events per patient year	0.000	0.358	0.000	0.000
After 24 weeks	Patients documented	7	19	26	4
	Number of events	0	5	0	0
	Patient years	1.63	4.63	6.30	0.94
	Events per patient year	0.000	1.079	0.000	0.000

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
Baseline	none	none	none	none
After 12 weeks	none	none	none	none
After 24 weeks	none	1 (5.26%) [0.13; 26.03]	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.4 Number of nocturnal events

Visit Number of nocturnal events	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Not documented	0	1	0	0
0	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Not documented	1	2	2	2
0	10 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
Non-missing	10 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Not documented	4	4	3	2
0	7 (100.0%)	18 (94.7%)	26 (100.0%)	4 (100.0%)
3	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
Non-missing	7 (100.0%)	19 (100.0%)	26 (100.0%)	4 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.2.8.4 Number of nocturnal events
4.11.2.8.4.1 Nocturnal events per patient year

Visit		Detemir	Glargin 100	Glargin 300	Degludec
Baseline	Patients documented	11	23	29	6
	Number of events	0	0	0	3
	Patient years	2.53	5.29	6.67	1.38
	Events per patient year	0.000	0.000	0.000	2.173
After 12 weeks	Patients documented	10	22	27	4
	Number of events	0	0	0	0
	Patient years	2.43	5.59	6.47	0.95
	Events per patient year	0.000	0.000	0.000	0.000
After 24 weeks	Patients documented	7	19	26	4
	Number of events	0	3	0	0
	Patient years	1.63	4.63	6.30	0.94
	Events per patient year	0.000	0.648	0.000	0.000

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]°	before lunch (N = 9) N (%) [95% CI]°	before dinner (N = 32) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	1 (3.45%) [0.09; 17.76]
After 24 weeks	1 (4.76%) [0.12; 23.82]	none	1 (4.00%) [0.10; 20.35]

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.2 Number of events

Visit Number of events	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Not documented	0	1	0
0	28 (100.0%)	8 (100.0%)	32 (100.0%)
Non-missing	28 (100.0%)	8 (100.0%)	32 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	24 (100.0%)	9 (100.0%)	28 (96.6%)
2	0 (0.0%)	0 (0.0%)	1 (3.4%)
Non-missing	24 (100.0%)	9 (100.0%)	29 (100.0%)
After 24 weeks			
Not documented	7	0	6
0	20 (95.2%)	9 (100.0%)	24 (96.0%)
1	1 (4.8%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	0 (0.0%)	1 (4.0%)
Non-missing	21 (100.0%)	9 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.2 Number of events
4.11.2.9.2.1 Events per patient year

Visit		before breakfast	before lunch	before dinner
Baseline	Patients documented	28	8	32
	Number of events	0	0	0
	Patient years	6.44	1.84	7.36
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	24	9	29
	Number of events	0	0	2
	Patient years	5.97	2.32	6.92
	Events per patient year	0.000	0.000	0.289
After 24 weeks	Patients documented	21	9	25
	Number of events	1	0	4
	Patient years	5.29	2.04	5.90
	Events per patient year	0.189	0.000	0.678

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.3 Incidence of nocturnal Hypoglycaemia

Incidence of Nocturnal Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]˚	before lunch (N = 9) N (%) [95% CI]˚	before dinner (N = 32) N (%) [95% CI]˚
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	1 (4.00%) [0.10; 20.35]

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.4 Number of nocturnal events

Visit Number of nocturnal events	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Not documented	0	1	0
0	28 (100.0%)	8 (100.0%)	32 (100.0%)
Non-missing	28 (100.0%)	8 (100.0%)	32 (100.0%)
After 12 weeks			
Not documented	4	0	3
0	24 (100.0%)	9 (100.0%)	29 (100.0%)
Non-missing	24 (100.0%)	9 (100.0%)	29 (100.0%)
After 24 weeks			
Not documented	7	0	6
0	21 (100.0%)	9 (100.0%)	24 (96.0%)
3	0 (0.0%)	0 (0.0%)	1 (4.0%)
Non-missing	21 (100.0%)	9 (100.0%)	25 (100.0%)

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.2 Hypoglycaemia with glucose < 54 mg/dl
4.11.2.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.2.9.4 Number of nocturnal events
4.11.2.9.4.1 Nocturnal events per patient year

Visit		before breakfast	before lunch	before dinner
Baseline	Patients documented	28	8	32
	Number of events	0	0	0
	Patient years	6.44	1.84	7.36
	Events per patient year	0.000	0.000	0.000
After 12 weeks	Patients documented	24	9	29
	Number of events	0	0	0
	Patient years	5.97	2.32	6.92
	Events per patient year	0.000	0.000	0.000
After 24 weeks	Patients documented	21	9	25
	Number of events	0	0	3
	Patient years	5.29	2.04	5.90
	Events per patient year	0.000	0.000	0.508

Percentages related to the number of patients with results non-missing

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.1 Full Analysis Set - FGM - SMBG
4.11.3.1.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	1 (1.45%) [0.04; 7.81]	1 (5.26%) [0.13; 26.03]	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.1 Full Analysis Set - FGM - SMBG
4.11.3.1.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.1 Full Analysis Set - FGM - SMBG
4.11.3.1.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.1 Full Analysis Set - FGM - SMBG
4.11.3.1.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.2 Full Analysis Set - Subgroups - Gender
4.11.3.2.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	none	1 (2.44%) [0.06; 12.86]
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.2 Full Analysis Set - Subgroups - Gender
4.11.3.2.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.2 Full Analysis Set - Subgroups - Gender
4.11.3.2.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	Female (N = 28) N (%) [95% CI]°	Male (N = 42) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.2 Full Analysis Set - Subgroups - Gender
4.11.3.2.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.3 Full Analysis Set - Subgroups - Age groups
4.11.3.3.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]˚	>60 - <70 years (N = 24) N (%) [95% CI]˚	>=70 years (N = 22) N (%) [95% CI]˚
Baseline	1 (4.17%) [0.11; 21.12]	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.3 Full Analysis Set - Subgroups - Age groups
4.11.3.3.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.3 Full Analysis Set - Subgroups - Age groups
4.11.3.3.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	<= 60 years (N = 24) N (%) [95% CI]˚	>60 - <70 years (N = 24) N (%) [95% CI]˚	>=70 years (N = 22) N (%) [95% CI]˚
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.3 Full Analysis Set - Subgroups - Age groups
4.11.3.3.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.3.4.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]˚	>=30 kg/m² (N = 52) N (%) [95% CI]˚
Baseline	none	1 (1.96%) [0.05; 10.45]
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.3.4.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.3.4.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	<30 kg/m² (N = 18) N (%) [95% CI]˚	>=30 kg/m² (N = 52) N (%) [95% CI]˚
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.4 Full Analysis Set - Subgroups - Body Mass Index
4.11.3.4.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.5 Full Analysis Set - Subgroups - Renal function
4.11.3.5.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]˚	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]˚
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.5 Full Analysis Set - Subgroups - Renal function
4.11.3.5.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.5 Full Analysis Set - Subgroups - Renal function
4.11.3.5.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	<=60 ml/min/1.73 m² (N = 17) N (%) [95% CI]˚	>60 ml/min/1.73 m² (N = 39) N (%) [95% CI]˚
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.5 Full Analysis Set - Subgroups - Renal function
4.11.3.5.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.3.6.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]˚	5 to 10 years (N = 21) N (%) [95% CI]˚	over 10 years (N = 39) N (%) [95% CI]˚
Baseline	none	none	1 (2.63%) [0.07; 13.81]
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.3.6.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.3.6.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	up to 5 years (N = 7) N (%) [95% CI]˚	5 to 10 years (N = 21) N (%) [95% CI]˚	over 10 years (N = 39) N (%) [95% CI]˚
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.6 Full Analysis Set - Subgroups - Duration of diabetes
4.11.3.6.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.3.7.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	none	1 (3.13%) [0.08; 16.22]
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.3.7.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.3.7.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	<8.5% (N = 38) N (%) [95% CI]°	>=8.5% (N = 32) N (%) [95% CI]°
Baseline	none	none
After 12 weeks	none	none
After 24 weeks	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.11.3.7.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.3.8.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]°	Glargin 100 (N = 24) N (%) [95% CI]°	Glargin 300 (N = 29) N (%) [95% CI]°	Degludec (N = 6) N (%) [95% CI]°
Baseline	1 (9.09%) [0.23; 41.28]	none	none	none
After 12 weeks	none	none	none	none
After 24 weeks	none	none	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.3.8.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.3.8.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	Detemir (N = 11) N (%) [95% CI]˚	Glargin 100 (N = 24) N (%) [95% CI]˚	Glargin 300 (N = 29) N (%) [95% CI]˚	Degludec (N = 6) N (%) [95% CI]˚
Baseline	none	none	none	none
After 12 weeks	none	none	none	none
After 24 weeks	none	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.11.3.8.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.3.9.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]˚	before lunch (N = 9) N (%) [95% CI]˚	before dinner (N = 32) N (%) [95% CI]˚
Baseline	none	none	1 (3.13%) [0.08; 16.22]
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.3.9.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.3.9.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	before breakfast (N = 28) N (%) [95% CI]˚	before lunch (N = 9) N (%) [95% CI]˚	before dinner (N = 32) N (%) [95% CI]˚
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
˚ 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.3 Hypoglycaemia with symptomatology and the Glucose value is not known
4.11.3.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.11.3.9.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.4 Severe Hypoglycaemia
4.11.4.1 Full Analysis Set - FGM - SMBG
4.11.4.1.1 Incidence of Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.4 Severe Hypoglycaemia
4.11.4.1 Full Analysis Set - FGM - SMBG
4.11.4.1.2 Number of events

NOTE

Not applicable
No events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.4 Severe Hypoglycaemia
4.11.4.1 Full Analysis Set - FGM - SMBG
4.11.4.1.3 Incidence of nocturnal Hypoglycaemia

Incidence of Hypoglycaemia	FAS (N = 70) N (%) [95% CI]°	FGM (N = 20) N (%) [95% CI]°	SMBG (N = 50) N (%) [95% CI]°
Baseline	none	none	none
After 12 weeks	none	none	none
After 24 weeks	none	none	none

Percentages related to the number of patients with results non-missing
° 95% CI according to Clopper-Pearson

4 Effectiveness (secondary)
4.11 Incidence and rate of hypoglycaemia
4.11.4 Severe Hypoglycaemia
4.11.4.1 Full Analysis Set - FGM - SMBG
4.11.4.1.4 Number of nocturnal events

NOTE

Not applicable
No nocturnal events of Hypoglycaemia were documented

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.1 Satisfaction with current treatment

Satisfaction with current treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	3.97 (1.754)	3.60 (1.603)	4.13 (1.809)
95% CL	[3.539; 4.401]	[2.850; 4.350]	[3.593; 4.668]
Min-Max	0 - 6	1 - 6	0 - 6
Median	4.00	3.00	5.00
Q1-Q3	3.00 - 6.00	2.50 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	4.74 (1.436)	4.90 (0.912)	4.66 (1.637)
95% CL	[4.370; 5.106]	[4.473; 5.327]	[4.142; 5.175]
Min-Max	0 - 6	2 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 5.00	4.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	0.73 (1.939)	1.30 (1.342)	0.45 (2.136)
95% CL	[0.233; 1.234]	[0.672; 1.928]	[-0.233; 1.133]
Min-Max	-4 - 5	-1 - 4	-4 - 5
Median	1.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	-1.00 - 2.00
T-Test	t= 2.93 P= 0.005	t= 4.33 P= 0.000	t= 1.33 P= 0.190
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.1 Satisfaction with current treatment

Satisfaction with current treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
n	60	19	41
Mean (SD)	1.75 (1.457)	1.58 (0.961)	1.83 (1.642)
95% CL	[1.374; 2.126]	[1.116; 2.042]	[1.311; 2.347]
Min-Max	-3 - 3	0 - 3	-3 - 3
Median	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	3.77 (1.444)	4.00 (1.026)	3.67 (1.592)
95% CL	[3.418; 4.128]	[3.520; 4.480]	[3.201; 4.147]
Min-Max	0 - 6	1 - 5	0 - 6
Median	4.00	4.00	4.00
Q1-Q3	3.00 - 5.00	4.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	60	20	40
Mean (SD)	2.48 (1.568)	2.20 (1.473)	2.63 (1.612)
95% CL	[2.078; 2.888]	[1.511; 2.889]	[2.109; 3.141]
Min-Max	0 - 6	0 - 6	0 - 6
Median	2.50	2.00	3.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00	1.00 - 4.00
DTSQs[2] Difference to Baseline			
n	59	20	39
Mean (SD)	-1.25 (1.728)	-1.80 (1.473)	-0.97 (1.799)
95% CL	[-1.705; -0.804]	[-2.489; -1.111]	[-1.558; -0.391]
Min-Max	-5 - 4	-4 - 1	-5 - 4
Median	-1.00	-2.00	-1.00
Q1-Q3	-2.00 - 0.00	-3.00 - -1.00	-2.00 - 0.00
T-Test	t= -5.58 P= 0.000	t= -5.47 P= 0.000	t= -3.38 P= 0.002
Observed days[2]			
n	59	20	39
Mean (SD)	174.76 (16.331)	176.35 (12.508)	173.95 (18.079)
95% CL	[170.507;179.019]	[170.496;182.204]	[168.088;179.809]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	172.00
Q1-Q3	168.00 -181.00	170.00 -180.00	168.00 -181.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQc[3] Change after 24 Weeks			
n	61	20	41
Mean (SD)	-0.89 (1.674)	-1.90 (0.718)	-0.39 (1.787)
95% CL	[-1.314; -0.456]	[-2.236; -1.564]	[-0.954; 0.174]
Min-Max	-3 - 3	-3 - 0	-3 - 3
Median	-1.00	-2.00	-1.00
Q1-Q3	-2.00 - 0.00	-2.00 - -2.00	-2.00 - 1.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	0.92 (1.244)	1.10 (1.021)	0.85 (1.333)
95% CL	[0.618; 1.230]	[0.622; 1.578]	[0.452; 1.244]
Min-Max	0 - 6	0 - 3	0 - 6
Median	0.50	1.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 1.00
DTSQs[1] Status after 24 weeks			
n	60	19	41
Mean (SD)	0.78 (1.223)	0.26 (0.562)	1.02 (1.369)
95% CL	[0.468; 1.099]	[-0.008; 0.534]	[0.592; 1.457]
Min-Max	0 - 6	0 - 2	0 - 6
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.50	0.00 - 0.00	0.00 - 2.00
DTSQs[2] Difference to Baseline			
n	59	19	40
Mean (SD)	-0.14 (1.766)	-0.79 (1.084)	0.18 (1.947)
95% CL	[-0.596; 0.325]	[-1.312; -0.267]	[-0.448; 0.798]
Min-Max	-4 - 6	-3 - 0	-4 - 6
Median	0.00	0.00	0.00
Q1-Q3	-1.00 - 0.00	-2.00 - 0.00	-0.50 - 1.00
T-Test	t= -0.59 P= 0.558	t= -3.17 P= 0.005	t= 0.57 P= 0.573
Observed days[2]			
n	59	19	40
Mean (SD)	174.07 (15.710)	174.63 (10.139)	173.80 (17.870)
95% CL	[169.974;178.162]	[169.745;179.518]	[168.085;179.515]
Min-Max	118 - 241	156 - 206	118 - 241
Median	172.00	172.00	171.50
Q1-Q3	168.00 -178.00	170.00 -178.00	168.00 -179.50

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQc[3] Change after 24 Weeks			
n	61	20	41
Mean (SD)	-1.15 (1.611)	-1.25 (1.251)	-1.10 (1.772)
95% CL	[-1.560; -0.735]	[-1.836; -0.664]	[-1.657; -0.538]
Min-Max	-3 - 3	-3 - 0	-3 - 3
Median	-2.00	-1.50	-2.00
Q1-Q3	-2.00 - 0.00	-2.00 - 0.00	-3.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	3.97 (1.559)	3.70 (1.342)	4.09 (1.644)
95% CL	[3.586; 4.353]	[3.072; 4.328]	[3.599; 4.575]
Min-Max	0 - 6	2 - 6	0 - 6
Median	4.00	3.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	4.90 (1.193)	4.70 (1.081)	5.00 (1.245)
95% CL	[4.596; 5.207]	[4.194; 5.206]	[4.607; 5.393]
Min-Max	1 - 6	3 - 6	1 - 6
Median	5.00	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 5.50	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	0.93 (1.471)	1.00 (1.026)	0.90 (1.661)
95% CL	[0.553; 1.313]	[0.520; 1.480]	[0.369; 1.431]
Min-Max	-4 - 4	-1 - 3	-4 - 4
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 4.91 P= 0.000	t= 4.36 P= 0.000	t= 3.43 P= 0.001
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
n	61	20	41
Mean (SD)	1.90 (1.234)	1.60 (0.995)	2.05 (1.322)
95% CL	[1.586; 2.218]	[1.134; 2.066]	[1.632; 2.466]
Min-Max	-2 - 3	0 - 3	-2 - 3
Median	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	4.00 (1.529)	3.85 (1.461)	4.07 (1.569)
95% CL	[3.624; 4.376]	[3.166; 4.534]	[3.599; 4.531]
Min-Max	0 - 6	2 - 6	0 - 6
Median	4.00	3.50	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	4.93 (1.167)	4.85 (0.875)	4.98 (1.294)
95% CL	[4.635; 5.233]	[4.440; 5.260]	[4.567; 5.384]
Min-Max	0 - 6	3 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 5.50	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	0.93 (1.413)	1.00 (1.124)	0.90 (1.549)
95% CL	[0.568; 1.298]	[0.474; 1.526]	[0.405; 1.395]
Min-Max	-3 - 5	-1 - 3	-3 - 5
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 5.12 P= 0.000	t= 3.98 P= 0.001	t= 3.67 P= 0.001
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQc[3] Change after 24 Weeks			
n	60	20	40
Mean (SD)	1.85 (1.176)	1.40 (1.095)	2.08 (1.163)
95% CL	[1.546; 2.154]	[0.887; 1.913]	[1.703; 2.447]
Min-Max	-2 - 3	-1 - 3	-2 - 3
Median	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	0.50 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	4.08 (1.407)	3.95 (1.276)	4.13 (1.470)
95% CL	[3.730; 4.422]	[3.353; 4.547]	[3.694; 4.567]
Min-Max	0 - 6	1 - 6	0 - 6
Median	4.00	4.00	4.50
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	4.82 (1.118)	5.00 (0.858)	4.73 (1.225)
95% CL	[4.533; 5.106]	[4.598; 5.402]	[4.345; 5.118]
Min-Max	0 - 6	4 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	4.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	0.67 (1.422)	1.05 (0.887)	0.48 (1.601)
95% CL	[0.299; 1.034]	[0.635; 1.465]	[-0.037; 0.987]
Min-Max	-2 - 4	0 - 3	-2 - 4
Median	0.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	-0.50 - 1.50
T-Test	t= 3.63 P= 0.001	t= 5.29 P= 0.000	t= 1.88 P= 0.068
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQc[3] Change after 24 Weeks			
n	61	20	41
Mean (SD)	2.05 (0.921)	1.75 (1.020)	2.20 (0.843)
95% CL	[1.813; 2.285]	[1.273; 2.227]	[1.929; 2.461]
Min-Max	0 - 3	0 - 3	0 - 3
Median	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.50	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.7 Recommend treatment to others

Recommend treatment to others	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	4.29 (1.345)	4.15 (1.348)	4.35 (1.353)
95% CL	[3.957; 4.618]	[3.519; 4.781]	[3.946; 4.750]
Min-Max	2 - 6	2 - 6	2 - 6
Median	4.00	4.00	4.50
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	5.11 (1.066)	5.25 (0.851)	5.05 (1.161)
95% CL	[4.842; 5.388]	[4.852; 5.648]	[4.682; 5.415]
Min-Max	2 - 6	3 - 6	2 - 6
Median	5.00	5.00	5.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	0.75 (1.580)	1.10 (1.021)	0.58 (1.781)
95% CL	[0.342; 1.158]	[0.622; 1.578]	[0.005; 1.145]
Min-Max	-3 - 4	0 - 3	-3 - 4
Median	1.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	-0.50 - 1.50
T-Test	t= 3.68 P= 0.001	t= 4.82 P= 0.000	t= 2.04 P= 0.048
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.7 Recommend treatment to others

Recommend treatment to others	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
n	61	20	41
Mean (SD)	1.85 (1.302)	1.40 (1.046)	2.07 (1.367)
95% CL	[1.519; 2.186]	[0.910; 1.890]	[1.642; 2.505]
Min-Max	-2 - 3	0 - 3	-2 - 3
Median	2.00	1.50	3.00
Q1-Q3	1.00 - 3.00	0.50 - 2.00	2.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQs[1] Status baseline			
n	66	20	46
Mean (SD)	3.85 (1.694)	3.85 (1.348)	3.85 (1.837)
95% CL	[3.432; 4.265]	[3.219; 4.481]	[3.302; 4.393]
Min-Max	0 - 6	2 - 6	0 - 6
Median	4.00	4.00	4.00
Q1-Q3	2.00 - 5.00	3.00 - 5.00	2.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	61	20	41
Mean (SD)	5.05 (1.488)	5.25 (0.967)	4.95 (1.687)
95% CL	[4.668; 5.430]	[4.798; 5.702]	[4.419; 5.484]
Min-Max	0 - 6	2 - 6	0 - 6
Median	6.00	5.00	6.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	60	20	40
Mean (SD)	1.18 (2.095)	1.40 (1.095)	1.08 (2.454)
95% CL	[0.642; 1.725]	[0.887; 1.913]	[0.290; 1.860]
Min-Max	-5 - 6	0 - 4	-5 - 6
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	1.00 - 2.00	0.00 - 2.00
T-Test	t= 4.37 P= 0.000	t= 5.72 P= 0.000	t= 2.77 P= 0.009
Observed days[2]			
n	60	20	40
Mean (SD)	174.65 (16.216)	176.35 (12.508)	173.80 (17.870)
95% CL	[170.461;178.839]	[170.496;182.204]	[168.085;179.515]
Min-Max	118 - 241	156 - 209	118 - 241
Median	172.00	172.50	171.50
Q1-Q3	168.00 -179.50	170.00 -180.00	168.00 -179.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
DTSQc[3] Change after 24 Weeks			
n	61	20	41
Mean (SD)	2.13 (1.408)	1.90 (0.788)	2.24 (1.625)
95% CL	[1.771; 2.492]	[1.531; 2.269]	[1.731; 2.757]
Min-Max	-3 - 3	0 - 3	-3 - 3
Median	3.00	2.00	3.00
Q1-Q3	2.00 - 3.00	1.50 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.9 DTSQs - sum of scores

DTSQs sum of scores°	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Sum of scores baseline			
n	66	20	46
Mean (SD)	24.15 (7.744)	23.10 (6.897)	24.61 (8.114)
95% CL	[22.25; 26.06]	[19.87; 26.33]	[22.20; 27.02]
Min-Max	6 - 36	13 - 32	6 - 36
Median	24.50	21.00	25.50
Q1-Q3	18.00 - 31.00	18.00 - 31.00	19.00 - 32.00
Sum of scores after 24 weeks			
n	61	20	41
Mean (SD)	29.56 (5.918)	29.95 (4.273)	29.37 (6.613)
95% CL	[28.04; 31.07]	[27.95; 31.95]	[27.28; 31.45]
Min-Max	14 - 36	21 - 36	14 - 36
Median	31.00	29.00	31.00
Q1-Q3	28.00 - 34.00	28.00 - 34.00	28.00 - 34.00
Difference to Baseline			
n	60	20	40
Mean (SD)	5.20 (8.262)	6.85 (4.452)	4.38 (9.567)
95% CL	[3.07; 7.33]	[4.77; 8.93]	[1.32; 7.43]
Min-Max	-20 - 25	2 - 17	-20 - 25
Median	5.00	5.00	4.50
Q1-Q3	1.50 - 9.50	3.00 - 10.00	-0.50 - 8.50
T-Test	t= 4.88 P= 0.000	t= 6.88 P= 0.000	t= 2.89 P= 0.006

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.1 Full Analysis Set - FGM - SMBG
4.12.1.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	FAS (N = 70)	FGM (N = 20)	SMBG (N = 50)
Sum of scores after 24 weeks			
n	59	19	40
Mean (SD)	11.73 (6.122)	9.47 (4.695)	12.80 (6.474)
95% CL	[10.13; 13.32]	[7.21; 11.74]	[10.73; 14.87]
Min-Max	-6 - 18	0 - 18	-6 - 18
Median	14.00	11.00	15.00
Q1-Q3	9.00 - 16.00	6.00 - 12.00	12.50 - 17.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.1 Satisfaction with current treatment

Satisfaction with current treatment	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.08 (1.869)	3.90 (1.700)
95% CL	[3.308; 4.852]	[3.366; 4.439]
Min-Max	0 - 6	0 - 6
Median	5.00	4.00
Q1-Q3	2.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	5.13 (1.058)	4.50 (1.590)
95% CL	[4.673; 5.588]	[3.977; 5.023]
Min-Max	2 - 6	0 - 6
Median	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	1.00 (1.718)	0.58 (2.062)
95% CL	[0.238; 1.762]	[-0.099; 1.257]
Min-Max	-4 - 4	-4 - 5
Median	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 2.73 P= 0.013	t= 1.73 P= 0.092
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.1 Satisfaction with current treatment

Satisfaction with current treatment	Female (N = 28)	Male (N = 42)
n	23	37
Mean (SD)	2.04 (1.224)	1.57 (1.573)
95% CL	[1.514; 2.573]	[1.043; 2.092]
Min-Max	-2 - 3	-3 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.04 (1.369)	3.61 (1.481)
95% CL	[3.475; 4.605]	[3.142; 4.077]
Min-Max	0 - 6	0 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	37
Mean (SD)	2.52 (1.780)	2.46 (1.445)
95% CL	[1.752; 3.292]	[1.978; 2.941]
Min-Max	0 - 6	0 - 5
Median	2.00	3.00
Q1-Q3	1.00 - 4.00	1.00 - 3.00
DTSQs[2] Difference to Baseline		
n	22	37
Mean (SD)	-1.50 (1.472)	-1.11 (1.868)
95% CL	[-2.153; -0.847]	[-1.731; -0.485]
Min-Max	-4 - 1	-5 - 4
Median	-2.00	-1.00
Q1-Q3	-2.00 - -1.00	-2.00 - 0.00
T-Test	t= -4.78 P= 0.000	t= -3.61 P= 0.001
Observed days[2]		
n	22	37
Mean (SD)	176.05 (18.579)	174.00 (15.057)
95% CL	[167.808;184.283]	[168.980;179.020]
Min-Max	140 - 241	118 - 215
Median	171.50	174.00
Q1-Q3	168.00 -181.00	169.00 -178.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	Female (N = 28)	Male (N = 42)
DTSQc[3] Change after 24 Weeks		
n	23	38
Mean (SD)	-0.87 (1.938)	-0.89 (1.521)
95% CL	[-1.708; -0.032]	[-1.395; -0.395]
Min-Max	-3 - 3	-3 - 3
Median	-2.00	-1.00
Q1-Q3	-2.00 - 1.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	0.72 (1.061)	1.05 (1.341)
95% CL	[0.282; 1.158]	[0.626; 1.472]
Min-Max	0 - 3	0 - 6
Median	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
DTSQs[1] Status after 24 weeks		
n	23	37
Mean (SD)	0.83 (1.154)	0.76 (1.278)
95% CL	[0.327; 1.325]	[0.331; 1.183]
Min-Max	0 - 3	0 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
DTSQs[2] Difference to Baseline		
n	22	37
Mean (SD)	0.14 (1.552)	-0.30 (1.884)
95% CL	[-0.552; 0.825]	[-0.925; 0.331]
Min-Max	-3 - 3	-4 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	-1.00 - 0.00
T-Test	t= 0.41 P= 0.684	t= -0.96 P= 0.343
Observed days[2]		
n	22	37
Mean (SD)	176.05 (18.579)	172.89 (13.872)
95% CL	[167.808;184.283]	[168.267;177.517]
Min-Max	140 - 241	118 - 215
Median	171.50	172.00
Q1-Q3	168.00 -181.00	168.00 -177.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	Female (N = 28)	Male (N = 42)
DTSQc[3] Change after 24 Weeks		
n	23	38
Mean (SD)	-1.04 (1.770)	-1.21 (1.527)
95% CL	[-1.809; -0.278]	[-1.713; -0.708]
Min-Max	-3 - 3	-3 - 3
Median	-1.00	-2.00
Q1-Q3	-3.00 - 0.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.32 (1.406)	3.76 (1.625)
95% CL	[3.740; 4.900]	[3.243; 4.269]
Min-Max	2 - 6	0 - 6
Median	5.00	4.00
Q1-Q3	3.00 - 6.00	2.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	5.09 (1.125)	4.79 (1.234)
95% CL	[4.601; 5.573]	[4.384; 5.195]
Min-Max	2 - 6	1 - 6
Median	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	0.77 (1.541)	1.03 (1.442)
95% CL	[0.090; 1.456]	[0.552; 1.500]
Min-Max	-4 - 3	-1 - 4
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 2.35 P= 0.029	t= 4.39 P= 0.000
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	Female (N = 28)	Male (N = 42)
n	23	38
Mean (SD)	2.13 (1.180)	1.76 (1.261)
95% CL	[1.620; 2.641]	[1.349; 2.178]
Min-Max	-2 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.24 (1.268)	3.85 (1.667)
95% CL	[3.717; 4.763]	[3.328; 4.380]
Min-Max	2 - 6	0 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	5.04 (0.928)	4.87 (1.298)
95% CL	[4.642; 5.445]	[4.442; 5.295]
Min-Max	2 - 6	0 - 6
Median	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	0.86 (1.390)	0.97 (1.442)
95% CL	[0.247; 1.480]	[0.500; 1.448]
Min-Max	-3 - 3	-1 - 5
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 2.91 P= 0.008	t= 4.16 P= 0.000
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	Female (N = 28)	Male (N = 42)
DTSQc[3] Change after 24 Weeks		
n	23	37
Mean (SD)	2.04 (1.224)	1.73 (1.146)
95% CL	[1.514; 2.573]	[1.348; 2.112]
Min-Max	-2 - 3	-1 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.32 (1.282)	3.93 (1.473)
95% CL	[3.791; 4.849]	[3.462; 4.392]
Min-Max	1 - 6	0 - 6
Median	5.00	4.00
Q1-Q3	4.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	4.65 (1.027)	4.92 (1.171)
95% CL	[4.208; 5.096]	[4.536; 5.306]
Min-Max	3 - 6	0 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	0.23 (1.307)	0.92 (1.440)
95% CL	[-0.352; 0.807]	[0.448; 1.394]
Min-Max	-2 - 3	-1 - 4
Median	0.00	0.00
Q1-Q3	-1.00 - 1.00	0.00 - 2.00
T-Test	t= 0.82 P= 0.424	t= 3.94 P= 0.000
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	Female (N = 28)	Male (N = 42)
DTSQc[3] Change after 24 Weeks		
n	23	38
Mean (SD)	2.13 (0.815)	2.00 (0.986)
95% CL	[1.778; 2.483]	[1.676; 2.324]
Min-Max	0 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.7 Recommend treatment to others

Recommend treatment to others	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.44 (1.294)	4.20 (1.382)
95% CL	[3.906; 4.974]	[3.759; 4.631]
Min-Max	2 - 6	2 - 6
Median	5.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	4.96 (1.022)	5.21 (1.094)
95% CL	[4.515; 5.398]	[4.851; 5.570]
Min-Max	3 - 6	2 - 6
Median	5.00	6.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	0.50 (1.336)	0.89 (1.705)
95% CL	[-0.092; 1.092]	[0.334; 1.455]
Min-Max	-3 - 3	-3 - 4
Median	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
T-Test	t= 1.75 P= 0.094	t= 3.23 P= 0.003
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.7 Recommend treatment to others

Recommend treatment to others	Female (N = 28)	Male (N = 42)
n	23	38
Mean (SD)	1.91 (1.240)	1.82 (1.353)
95% CL	[1.377; 2.449]	[1.371; 2.260]
Min-Max	-2 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	Female (N = 28)	Male (N = 42)
DTSQs[1] Status baseline		
n	25	41
Mean (SD)	4.12 (1.641)	3.68 (1.724)
95% CL	[3.443; 4.797]	[3.139; 4.227]
Min-Max	0 - 6	0 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 6.00	2.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	23	38
Mean (SD)	5.13 (1.180)	5.00 (1.660)
95% CL	[4.620; 5.641]	[4.454; 5.546]
Min-Max	2 - 6	0 - 6
Median	5.00	6.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	22	38
Mean (SD)	1.00 (1.512)	1.29 (2.381)
95% CL	[0.330; 1.670]	[0.507; 2.072]
Min-Max	-4 - 3	-5 - 6
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 3.00
T-Test	t= 3.10 P= 0.005	t= 3.34 P= 0.002
Observed days[2]		
n	22	38
Mean (SD)	176.05 (18.579)	173.84 (14.884)
95% CL	[167.808;184.283]	[168.950;178.734]
Min-Max	140 - 241	118 - 215
Median	171.50	173.00
Q1-Q3	168.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	Female (N = 28)	Male (N = 42)
DTSQc[3] Change after 24 Weeks		
n	23	38
Mean (SD)	2.26 (1.214)	2.05 (1.524)
95% CL	[1.736; 2.786]	[1.552; 2.553]
Min-Max	-2 - 3	-3 - 3
Median	3.00	3.00
Q1-Q3	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.9 DTSQs - sum of scores

DTSQs sum of scores°	Female (N = 28)	Male (N = 42)
Sum of scores baseline		
n	25	41
Mean (SD)	25.52 (7.451)	23.32 (7.891)
95% CL	[22.44; 28.60]	[20.83; 25.81]
Min-Max	10 - 36	6 - 36
Median	27.00	24.00
Q1-Q3	19.00 - 32.00	18.00 - 29.00
Sum of scores after 24 weeks		
n	23	38
Mean (SD)	30.00 (5.486)	29.29 (6.221)
95% CL	[27.63; 32.37]	[27.24; 31.33]
Min-Max	14 - 36	14 - 36
Median	31.00	30.00
Q1-Q3	28.00 - 34.00	28.00 - 34.00
Difference to Baseline		
n	22	38
Mean (SD)	4.36 (7.493)	5.68 (8.737)
95% CL	[1.04; 7.69]	[2.81; 8.56]
Min-Max	-20 - 14	-15 - 25
Median	4.50	5.00
Q1-Q3	1.00 - 10.00	2.00 - 9.00
T-Test	t= 2.73 P= 0.013	t= 4.01 P= 0.000

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.2 Full Analysis Set - Subgroups - Gender
4.12.2.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	Female (N = 28)	Male (N = 42)
Sum of scores after 24 weeks		
n	23	36
Mean (SD)	12.52 (5.583)	11.22 (6.468)
95% CL	[10.11; 14.94]	[9.03; 13.41]
Min-Max	-5 - 18	-6 - 18
Median	14.00	14.00
Q1-Q3	11.00 - 16.00	6.50 - 16.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.1 Satisfaction with current treatment

Satisfaction with current treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	3.96 (1.461)	3.96 (1.805)	4.00 (2.082)
95% CL	[3.325; 4.588]	[3.196; 4.721]	[2.997; 5.003]
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.00	4.50	5.00
Q1-Q3	3.00 - 5.00	2.00 - 6.00	2.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	4.61 (1.644)	4.95 (1.203)	4.65 (1.455)
95% CL	[3.898; 5.320]	[4.405; 5.500]	[3.899; 5.395]
Min-Max	0 - 6	2 - 6	1 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	0.65 (1.873)	1.05 (2.179)	0.44 (1.750)
95% CL	[-0.158; 1.462]	[0.056; 2.039]	[-0.495; 1.370]
Min-Max	-4 - 4	-4 - 5	-4 - 4
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	-0.50 - 1.00
T-Test	t= 1.67 P= 0.109	t= 2.20 P= 0.039	t= 1.00 P= 0.333
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.1 Satisfaction with current treatment

Satisfaction with current treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
n	23	20	17
Mean (SD)	1.61 (1.469)	1.90 (1.447)	1.76 (1.522)
95% CL	[0.973; 2.244]	[1.223; 2.577]	[0.982; 2.547]
Min-Max	-3 - 3	-2 - 3	-3 - 3
Median	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	4.04 (1.186)	3.92 (1.349)	3.26 (1.759)
95% CL	[3.531; 4.556]	[3.347; 4.486]	[2.415; 4.111]
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.00	4.00	3.00
Q1-Q3	4.00 - 5.00	3.00 - 5.00	2.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	23	20	17
Mean (SD)	2.78 (1.858)	2.25 (1.251)	2.35 (1.498)
95% CL	[1.979; 3.586]	[1.664; 2.836]	[1.583; 3.123]
Min-Max	0 - 6	0 - 4	0 - 5
Median	2.00	2.00	3.00
Q1-Q3	1.00 - 5.00	2.00 - 3.00	1.00 - 3.00
DTSQs[2] Difference to Baseline			
n	23	20	16
Mean (SD)	-1.26 (1.573)	-1.70 (1.380)	-0.69 (2.213)
95% CL	[-1.941; -0.581]	[-2.346; -1.054]	[-1.867; 0.492]
Min-Max	-4 - 1	-4 - 1	-5 - 4
Median	-1.00	-2.00	-0.50
Q1-Q3	-2.00 - 0.00	-2.50 - -0.50	-2.00 - 1.00
T-Test	t= -3.84 P= 0.001	t= -5.51 P= 0.000	t= -1.24 P= 0.233
Observed days[2]			
n	23	20	16
Mean (SD)	181.26 (17.881)	171.25 (16.345)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.601;178.899]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.50 -178.50	162.50 -175.50

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQc[3] Change after 24 Weeks			
n	23	21	17
Mean (SD)	-0.91 (1.832)	-0.95 (1.596)	-0.76 (1.640)
95% CL	[-1.705; -0.121]	[-1.679; -0.226]	[-1.608; 0.079]
Min-Max	-3 - 3	-3 - 2	-3 - 3
Median	-2.00	-1.00	-1.00
Q1-Q3	-2.00 - 0.00	-2.00 - 0.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	0.83 (1.029)	0.79 (1.062)	1.21 (1.653)
95% CL	[0.381; 1.271]	[0.343; 1.240]	[0.414; 2.007]
Min-Max	0 - 4	0 - 3	0 - 6
Median	1.00	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 2.00
DTSQs[1] Status after 24 weeks			
n	23	20	17
Mean (SD)	0.83 (1.466)	0.60 (1.046)	0.94 (1.088)
95% CL	[0.192; 1.460]	[0.110; 1.090]	[0.382; 1.501]
Min-Max	0 - 6	0 - 3	0 - 3
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 2.00
DTSQs[2] Difference to Baseline			
n	23	20	16
Mean (SD)	0.00 (1.931)	-0.10 (1.447)	-0.38 (1.962)
95% CL	[-0.835; 0.835]	[-0.777; 0.577]	[-1.421; 0.671]
Min-Max	-4 - 6	-3 - 3	-4 - 2
Median	0.00	0.00	0.00
Q1-Q3	-1.00 - 0.00	-1.00 - 0.00	-1.50 - 1.00
T-Test	t= 0.00 P= 1.000	t= -0.31 P= 0.761	t= -0.76 P= 0.456
Observed days[2]			
n	23	20	16
Mean (SD)	181.26 (17.881)	169.20 (13.721)	169.81 (10.796)
95% CL	[173.528;188.993]	[162.778;175.622]	[164.059;175.566]
Min-Max	167 - 241	118 - 184	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -174.00	162.50 -175.50

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQc[3] Change after 24 Weeks			
n	23	21	17
Mean (SD)	-0.91 (1.756)	-1.81 (1.327)	-0.65 (1.539)
95% CL	[-1.672; -0.154]	[-2.414; -1.205]	[-1.438; 0.144]
Min-Max	-3 - 3	-3 - 1	-3 - 3
Median	-1.00	-2.00	-1.00
Q1-Q3	-2.00 - 0.00	-3.00 - -1.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	3.70 (1.396)	4.25 (1.452)	3.95 (1.870)
95% CL	[3.092; 4.299]	[3.637; 4.863]	[3.046; 4.849]
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.00	4.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.50	2.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	4.87 (1.217)	4.95 (1.161)	4.88 (1.269)
95% CL	[4.343; 5.396]	[4.424; 5.481]	[4.230; 5.535]
Min-Max	2 - 6	2 - 6	1 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	1.17 (1.337)	0.76 (1.609)	0.81 (1.515)
95% CL	[0.596; 1.752]	[0.029; 1.495]	[0.005; 1.620]
Min-Max	-1 - 4	-4 - 4	-1 - 4
Median	1.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 4.21 P= 0.000	t= 2.17 P= 0.042	t= 2.14 P= 0.049
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
n	23	21	17
Mean (SD)	1.70 (1.146)	2.19 (0.928)	1.82 (1.629)
95% CL	[1.200; 2.191]	[1.768; 2.613]	[0.986; 2.661]
Min-Max	0 - 3	0 - 3	-2 - 3
Median	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	3.91 (1.593)	4.13 (1.424)	3.95 (1.649)
95% CL	[3.224; 4.602]	[3.524; 4.726]	[3.153; 4.742]
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.00	4.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.50	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	4.96 (1.022)	4.95 (1.117)	4.88 (1.453)
95% CL	[4.515; 5.398]	[4.444; 5.461]	[4.135; 5.629]
Min-Max	2 - 6	2 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	1.04 (1.461)	0.76 (1.446)	1.00 (1.366)
95% CL	[0.412; 1.675]	[0.104; 1.420]	[0.272; 1.728]
Min-Max	-1 - 5	-3 - 3	-1 - 3
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 3.43 P= 0.002	t= 2.41 P= 0.025	t= 2.93 P= 0.010
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQc[3] Change after 24 Weeks			
n	23	21	16
Mean (SD)	1.43 (1.273)	2.24 (0.768)	1.94 (1.340)
95% CL	[0.884; 1.985]	[1.888; 2.588]	[1.223; 2.652]
Min-Max	-1 - 3	0 - 3	-2 - 3
Median	2.00	2.00	2.00
Q1-Q3	0.00 - 3.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	4.04 (1.397)	4.25 (1.189)	3.89 (1.696)
95% CL	[3.439; 4.648]	[3.748; 4.752]	[3.077; 4.712]
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.00	4.50	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	4.96 (0.928)	4.95 (0.865)	4.47 (1.546)
95% CL	[4.555; 5.358]	[4.559; 5.346]	[3.676; 5.265]
Min-Max	3 - 6	3 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	4.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	0.91 (1.411)	0.57 (1.207)	0.44 (1.711)
95% CL	[0.303; 1.523]	[0.022; 1.121]	[-0.474; 1.349]
Min-Max	-1 - 4	-2 - 3	-2 - 4
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	-1.00 - 2.00
T-Test	t= 3.10 P= 0.005	t= 2.17 P= 0.042	t= 1.02 P= 0.323
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQc[3] Change after 24 Weeks			
n	23	21	17
Mean (SD)	1.70 (1.146)	2.24 (0.625)	2.29 (0.772)
95% CL	[1.200; 2.191]	[1.954; 2.523]	[1.897; 2.691]
Min-Max	0 - 3	1 - 3	1 - 3
Median	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.7 Recommend treatment to others

Recommend treatment to others	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	4.35 (1.402)	4.17 (1.308)	4.37 (1.383)
95% CL	[3.742; 4.954]	[3.614; 4.719]	[3.702; 5.035]
Min-Max	2 - 6	2 - 6	2 - 6
Median	5.00	4.00	5.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	5.09 (1.083)	5.00 (1.095)	5.29 (1.047)
95% CL	[4.618; 5.555]	[4.501; 5.499]	[4.756; 5.832]
Min-Max	2 - 6	3 - 6	3 - 6
Median	5.00	5.00	6.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	0.74 (1.484)	0.76 (1.546)	0.75 (1.844)
95% CL	[0.097; 1.381]	[0.058; 1.466]	[-0.233; 1.733]
Min-Max	-2 - 4	-3 - 4	-3 - 4
Median	1.00	1.00	0.50
Q1-Q3	0.00 - 2.00	0.00 - 1.00	-0.50 - 2.00
T-Test	t= 2.39 P= 0.026	t= 2.26 P= 0.035	t= 1.63 P= 0.125
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.7 Recommend treatment to others

Recommend treatment to others	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
n	23	21	17
Mean (SD)	1.30 (1.363)	2.24 (0.889)	2.12 (1.453)
95% CL	[0.715; 1.894]	[1.833; 2.643]	[1.371; 2.865]
Min-Max	-2 - 3	0 - 3	-2 - 3
Median	2.00	2.00	3.00
Q1-Q3	0.00 - 2.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQs[1] Status baseline			
n	23	24	19
Mean (SD)	3.70 (1.460)	4.29 (1.517)	3.47 (2.091)
95% CL	[3.064; 4.327]	[3.651; 4.932]	[2.466; 4.482]
Min-Max	1 - 6	1 - 6	0 - 6
Median	4.00	5.00	4.00
Q1-Q3	2.00 - 5.00	3.00 - 5.50	2.00 - 6.00
DTSQs[1] Status after 24 weeks			
n	23	21	17
Mean (SD)	5.09 (1.535)	5.05 (1.359)	5.00 (1.658)
95% CL	[4.423; 5.751]	[4.429; 5.666]	[4.147; 5.853]
Min-Max	0 - 6	1 - 6	1 - 6
Median	6.00	5.00	6.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	23	21	16
Mean (SD)	1.39 (1.803)	0.81 (2.040)	1.38 (2.579)
95% CL	[0.612; 2.171]	[-0.119; 1.738]	[0.001; 2.749]
Min-Max	-4 - 5	-4 - 5	-5 - 6
Median	1.00	1.00	1.00
Q1-Q3	1.00 - 2.00	0.00 - 2.00	0.00 - 3.00
T-Test	t= 3.70 P= 0.001	t= 1.82 P= 0.084	t= 2.13 P= 0.050
Observed days[2]			
n	23	21	16
Mean (SD)	181.26 (17.881)	171.10 (15.946)	169.81 (10.796)
95% CL	[173.528;188.993]	[163.836;178.354]	[164.059;175.566]
Min-Max	167 - 241	118 - 209	140 - 187
Median	175.00	170.00	173.00
Q1-Q3	170.00 -183.00	168.00 -175.00	162.50 -175.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
DTSQc[3] Change after 24 Weeks			
n	23	21	17
Mean (SD)	1.83 (1.497)	2.24 (1.338)	2.41 (1.372)
95% CL	[1.179; 2.473]	[1.629; 2.847]	[1.706; 3.117]
Min-Max	-3 - 3	-3 - 3	-2 - 3
Median	2.00	3.00	3.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00	3.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.9 DTSQs - sum of scores

DTSQs sum of scores°	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Sum of scores baseline			
n	23	24	19
Mean (SD)	23.65 (6.991)	25.04 (7.469)	23.63 (9.160)
95% CL	[20.63; 26.68]	[21.89; 28.20]	[19.22; 28.05]
Min-Max	11 - 36	10 - 36	6 - 36
Median	23.00	26.00	24.00
Q1-Q3	18.00 - 31.00	19.00 - 31.50	17.00 - 32.00
Sum of scores after 24 weeks			
n	23	21	17
Mean (SD)	29.57 (5.976)	29.86 (5.902)	29.18 (6.197)
95% CL	[26.98; 32.15]	[27.17; 32.54]	[25.99; 32.36]
Min-Max	15 - 36	14 - 36	14 - 36
Median	30.00	30.00	31.00
Q1-Q3	28.00 - 34.00	28.00 - 35.00	29.00 - 33.00
Difference to Baseline			
n	23	21	16
Mean (SD)	5.91 (7.366)	4.71 (8.928)	4.81 (9.020)
95% CL	[2.73; 9.10]	[0.65; 8.78]	[0.01; 9.62]
Min-Max	-10 - 25	-20 - 24	-15 - 20
Median	5.00	5.00	4.00
Q1-Q3	3.00 - 10.00	2.00 - 9.00	-1.00 - 10.00
T-Test	t= 3.85 P= 0.001	t= 2.42 P= 0.025	t= 2.13 P= 0.050

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.3 Full Analysis Set - Subgroups - Age groups
4.12.3.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	<= 60 years (N = 24)	>60 - <70 years (N = 24)	>=70 years (N = 22)
Sum of scores after 24 weeks			
n	23	20	16
Mean (SD)	9.57 (6.815)	13.05 (5.306)	13.19 (5.419)
95% CL	[6.62; 12.51]	[10.57; 15.53]	[10.30; 16.07]
Min-Max	-6 - 18	-4 - 18	-5 - 17
Median	11.00	14.00	14.50
Q1-Q3	4.00 - 16.00	11.50 - 17.00	13.50 - 16.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.1 Satisfaction with current treatment

Satisfaction with current treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	3.56 (2.097)	4.10 (1.632)
95% CL	[2.445; 4.680]	[3.636; 4.564]
Min-Max	0 - 6	1 - 6
Median	4.50	4.00
Q1-Q3	2.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.29 (1.437)	4.87 (1.424)
95% CL	[3.456; 5.116]	[4.454; 5.290]
Min-Max	1 - 6	0 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	0.64 (1.865)	0.76 (1.980)
95% CL	[-0.434; 1.720]	[0.173; 1.349]
Min-Max	-3 - 4	-4 - 5
Median	0.50	1.00
Q1-Q3	-1.00 - 2.00	0.00 - 2.00
T-Test	t= 1.29 P= 0.220	t= 2.61 P= 0.012
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.1 Satisfaction with current treatment

Satisfaction with current treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
n	13	47
Mean (SD)	1.00 (1.683)	1.96 (1.334)
95% CL	[-0.017; 2.017]	[1.566; 2.349]
Min-Max	-2 - 3	-3 - 3
Median	2.00	2.00
Q1-Q3	0.00 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	4.00 (1.673)	3.70 (1.374)
95% CL	[3.108; 4.892]	[3.310; 4.090]
Min-Max	0 - 6	0 - 6
Median	4.50	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	14	46
Mean (SD)	2.71 (1.541)	2.41 (1.586)
95% CL	[1.825; 3.604]	[1.942; 2.884]
Min-Max	0 - 6	0 - 6
Median	3.00	2.00
Q1-Q3	2.00 - 4.00	1.00 - 3.00
DTSQs[2] Difference to Baseline		
n	14	45
Mean (SD)	-1.43 (1.453)	-1.20 (1.817)
95% CL	[-2.267; -0.590]	[-1.746; -0.654]
Min-Max	-5 - 1	-4 - 4
Median	-1.50	-1.00
Q1-Q3	-2.00 - -1.00	-3.00 - 0.00
T-Test	t= -3.68 P= 0.003	t= -4.43 P= 0.000
Observed days[2]		
n	14	45
Mean (SD)	167.14 (15.216)	177.13 (16.091)
95% CL	[158.358;175.928]	[172.299;181.968]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQc[3] Change after 24 Weeks		
n	13	48
Mean (SD)	-0.08 (1.320)	-1.10 (1.704)
95% CL	[-0.875; 0.721]	[-1.599; -0.609]
Min-Max	-2 - 2	-3 - 3
Median	0.00	-2.00
Q1-Q3	-1.00 - 1.00	-2.00 - -1.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	1.13 (1.258)	0.86 (1.246)
95% CL	[0.454; 1.796]	[0.506; 1.214]
Min-Max	0 - 4	0 - 6
Median	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
DTSQs[1] Status after 24 weeks		
n	14	46
Mean (SD)	0.64 (1.008)	0.83 (1.288)
95% CL	[0.061; 1.225]	[0.444; 1.208]
Min-Max	0 - 3	0 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
DTSQs[2] Difference to Baseline		
n	14	45
Mean (SD)	-0.64 (1.906)	0.02 (1.712)
95% CL	[-1.743; 0.457]	[-0.492; 0.537]
Min-Max	-4 - 3	-4 - 6
Median	-0.50	0.00
Q1-Q3	-2.00 - 0.00	0.00 - 0.00
T-Test	t= -1.26 P= 0.229	t= 0.09 P= 0.931
Observed days[2]		
n	14	45
Mean (SD)	167.14 (15.216)	176.22 (15.392)
95% CL	[158.358;175.928]	[171.598;180.846]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQc[3] Change after 24 Weeks		
n	13	48
Mean (SD)	-1.23 (1.423)	-1.13 (1.671)
95% CL	[-2.091; -0.371]	[-1.610; -0.640]
Min-Max	-3 - 1	-3 - 3
Median	-2.00	-1.50
Q1-Q3	-2.00 - 0.00	-2.50 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	3.75 (1.770)	4.04 (1.498)
95% CL	[2.807; 4.693]	[3.614; 4.466]
Min-Max	0 - 6	1 - 6
Median	4.00	4.00
Q1-Q3	2.50 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.50 (1.454)	5.02 (1.093)
95% CL	[3.660; 5.340]	[4.700; 5.342]
Min-Max	1 - 6	2 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	0.79 (1.051)	0.98 (1.584)
95% CL	[0.179; 1.392]	[0.508; 1.449]
Min-Max	-1 - 3	-4 - 4
Median	1.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
T-Test	t= 2.80 P= 0.015	t= 4.19 P= 0.000
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
n	13	48
Mean (SD)	1.77 (1.235)	1.94 (1.245)
95% CL	[1.023; 2.516]	[1.576; 2.299]
Min-Max	0 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	3.81 (1.759)	4.06 (1.463)
95% CL	[2.875; 4.750]	[3.644; 4.476]
Min-Max	0 - 6	1 - 6
Median	4.00	4.00
Q1-Q3	2.50 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.43 (1.651)	5.09 (0.952)
95% CL	[3.475; 5.382]	[4.806; 5.365]
Min-Max	0 - 6	2 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	0.71 (1.069)	1.00 (1.506)
95% CL	[0.097; 1.332]	[0.553; 1.447]
Min-Max	-1 - 3	-3 - 5
Median	0.50	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
T-Test	t= 2.50 P= 0.027	t= 4.50 P= 0.000
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQc[3] Change after 24 Weeks		
n	13	47
Mean (SD)	1.46 (0.967)	1.96 (1.215)
95% CL	[0.877; 2.046]	[1.601; 2.314]
Min-Max	0 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	3.75 (1.844)	4.18 (1.240)
95% CL	[2.767; 4.733]	[3.828; 4.532]
Min-Max	0 - 6	1 - 6
Median	4.50	4.00
Q1-Q3	2.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.64 (1.499)	4.87 (0.992)
95% CL	[3.777; 5.508]	[4.581; 5.163]
Min-Max	0 - 6	3 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	0.79 (1.369)	0.63 (1.451)
95% CL	[-0.005; 1.576]	[0.200; 1.061]
Min-Max	-1 - 4	-2 - 4
Median	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
T-Test	t= 2.15 P= 0.051	t= 2.95 P= 0.005
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQc[3] Change after 24 Weeks		
n	13	48
Mean (SD)	1.69 (1.182)	2.15 (0.825)
95% CL	[0.978; 2.407]	[1.906; 2.385]
Min-Max	0 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.7 Recommend treatment to others

Recommend treatment to others	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	4.19 (1.424)	4.32 (1.332)
95% CL	[3.428; 4.947]	[3.942; 4.698]
Min-Max	2 - 6	2 - 6
Median	4.50	4.00
Q1-Q3	3.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.93 (1.072)	5.17 (1.070)
95% CL	[4.310; 5.547]	[4.856; 5.484]
Min-Max	3 - 6	2 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	0.71 (1.490)	0.76 (1.622)
95% CL	[-0.146; 1.575]	[0.279; 1.243]
Min-Max	-1 - 4	-3 - 4
Median	0.50	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
T-Test	t= 1.79 P= 0.096	t= 3.18 P= 0.003
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.7 Recommend treatment to others

Recommend treatment to others	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
n	13	48
Mean (SD)	1.46 (1.266)	1.96 (1.304)
95% CL	[0.697; 2.227]	[1.580; 2.337]
Min-Max	0 - 3	-2 - 3
Median	1.00	2.00
Q1-Q3	0.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQs[1] Status baseline		
n	16	50
Mean (SD)	3.13 (1.962)	4.08 (1.550)
95% CL	[2.079; 4.171]	[3.640; 4.520]
Min-Max	0 - 6	1 - 6
Median	2.50	4.00
Q1-Q3	2.00 - 4.50	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	14	47
Mean (SD)	4.57 (1.604)	5.19 (1.439)
95% CL	[3.646; 5.497]	[4.769; 5.614]
Min-Max	1 - 6	0 - 6
Median	5.00	6.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	14	46
Mean (SD)	1.43 (2.209)	1.11 (2.079)
95% CL	[0.153; 2.704]	[0.491; 1.726]
Min-Max	-3 - 6	-5 - 5
Median	1.00	1.00
Q1-Q3	0.00 - 3.00	0.00 - 2.00
T-Test	t= 2.42 P= 0.031	t= 3.62 P= 0.001
Observed days[2]		
n	14	46
Mean (SD)	167.14 (15.216)	176.93 (15.969)
95% CL	[158.358;175.928]	[172.193;181.677]
Min-Max	118 - 183	140 - 241
Median	170.00	174.00
Q1-Q3	167.00 -174.00	169.00 -182.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
DTSQc[3] Change after 24 Weeks		
n	13	48
Mean (SD)	1.69 (1.797)	2.25 (1.280)
95% CL	[0.606; 2.778]	[1.878; 2.622]
Min-Max	-3 - 3	-3 - 3
Median	2.00	3.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.9 DTSQs - sum of scores

DTSQs sum of scores°	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Sum of scores baseline		
n	16	50
Mean (SD)	22.19 (9.404)	24.78 (7.129)
95% CL	[17.18; 27.20]	[22.75; 26.81]
Min-Max	6 - 36	10 - 36
Median	25.50	24.00
Q1-Q3	13.00 - 30.00	19.00 - 31.00
Sum of scores after 24 weeks		
n	14	47
Mean (SD)	27.36 (6.629)	30.21 (5.599)
95% CL	[23.53; 31.18]	[28.57; 31.86]
Min-Max	14 - 35	14 - 36
Median	29.00	31.00
Q1-Q3	24.00 - 32.00	28.00 - 35.00
Difference to Baseline		
n	14	46
Mean (SD)	5.07 (7.395)	5.24 (8.585)
95% CL	[0.80; 9.34]	[2.69; 7.79]
Min-Max	-7 - 20	-20 - 25
Median	4.00	5.00
Q1-Q3	2.00 - 9.00	1.00 - 10.00
T-Test	t= 2.57 P= 0.023	t= 4.14 P= 0.000

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.4 Full Analysis Set - Subgroups - Body Mass Index
4.12.4.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	<30 kg/m² (N = 18)	>=30 kg/m² (N = 52)
Sum of scores after 24 weeks		
n	13	46
Mean (SD)	9.08 (7.005)	12.48 (5.711)
95% CL	[4.84; 13.31]	[10.78; 14.17]
Min-Max	-4 - 17	-6 - 18
Median	11.00	14.00
Q1-Q3	4.00 - 14.00	11.00 - 17.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.1 Satisfaction with current treatment

Satisfaction with current treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.93 (1.710)	4.00 (1.633)
95% CL	[3.986; 5.880]	[3.456; 4.544]
Min-Max	0 - 6	1 - 6
Median	5.00	4.00
Q1-Q3	5.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	4.92 (1.441)	4.83 (1.231)
95% CL	[4.052; 5.794]	[4.417; 5.250]
Min-Max	2 - 6	0 - 6
Median	5.00	5.00
Q1-Q3	5.00 - 6.00	4.50 - 6.00
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	-0.33 (1.875)	0.89 (1.785)
95% CL	[-1.525; 0.858]	[0.285; 1.493]
Min-Max	-4 - 2	-4 - 5
Median	0.00	1.00
Q1-Q3	-0.50 - 1.00	0.00 - 2.00
T-Test	t= -0.62 P= 0.551	t= 2.99 P= 0.005
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.1 Satisfaction with current treatment

Satisfaction with current treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
n	12	35
Mean (SD)	1.67 (1.826)	1.60 (1.499)
95% CL	[0.507; 2.827]	[1.085; 2.115]
Min-Max	-3 - 3	-3 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	3.33 (1.915)	3.86 (1.316)
95% CL	[2.273; 4.394]	[3.426; 4.304]
Min-Max	0 - 6	1 - 6
Median	4.00	4.00
Q1-Q3	2.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	35
Mean (SD)	1.92 (1.754)	2.51 (1.483)
95% CL	[0.863; 2.983]	[2.005; 3.024]
Min-Max	0 - 5	0 - 6
Median	2.00	3.00
Q1-Q3	0.00 - 3.00	1.00 - 3.00
DTSQs[2] Difference to Baseline		
n	12	35
Mean (SD)	-1.25 (2.340)	-1.34 (1.494)
95% CL	[-2.737; 0.237]	[-1.856; -0.830]
Min-Max	-5 - 4	-4 - 1
Median	-1.00	-2.00
Q1-Q3	-2.50 - -0.50	-2.00 - 0.00
T-Test	t= -1.85 P= 0.091	t= -5.32 P= 0.000
Observed days[2]		
n	12	35
Mean (SD)	169.58 (12.580)	174.46 (9.853)
95% CL	[161.590;177.577]	[171.073;177.842]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	169.00 -177.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQc³ Change after 24 Weeks		
n	12	36
Mean (SD)	-0.33 (1.775)	-1.17 (1.521)
95% CL	[-1.461; 0.795]	[-1.681; -0.652]
Min-Max	-2 - 3	-3 - 2
Median	-1.00	-1.50
Q1-Q3	-2.00 - 1.00	-2.00 - 0.00

¹Rating scale 6 = the most time - 0 = at no time
²Only patients with values at baseline and after 24 weeks
³Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	1.27 (1.751)	0.86 (1.159)
95% CL	[0.297; 2.236]	[0.479; 1.251]
Min-Max	0 - 6	0 - 4
Median	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
DTSQs[1] Status after 24 weeks		
n	13	35
Mean (SD)	0.62 (0.961)	0.37 (0.808)
95% CL	[0.035; 1.196]	[0.094; 0.649]
Min-Max	0 - 2	0 - 3
Median	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 0.00
DTSQs[2] Difference to Baseline		
n	12	35
Mean (SD)	-0.75 (1.913)	-0.49 (1.380)
95% CL	[-1.965; 0.465]	[-0.960; -0.012]
Min-Max	-4 - 2	-4 - 3
Median	-0.50	0.00
Q1-Q3	-1.50 - 0.00	-1.00 - 0.00
T-Test	t= -1.36 P= 0.202	t= -2.08 P= 0.045
Observed days[2]		
n	12	35
Mean (SD)	169.58 (12.580)	173.29 (7.861)
95% CL	[161.590;177.577]	[170.585;175.986]
Min-Max	140 - 187	156 - 206
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.00 -175.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQc³ Change after 24 Weeks		
n	12	36
Mean (SD)	-0.92 (1.564)	-1.44 (1.463)
95% CL	[-1.911; 0.077]	[-1.939; -0.950]
Min-Max	-3 - 3	-3 - 2
Median	-1.00	-2.00
Q1-Q3	-2.00 - 0.00	-3.00 - 0.00

¹Rating scale 6 = the most time - 0 = at no time
²Only patients with values at baseline and after 24 weeks
³Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.93 (1.335)	3.86 (1.494)
95% CL	[4.194; 5.672]	[3.367; 4.363]
Min-Max	2 - 6	1 - 6
Median	5.00	4.00
Q1-Q3	4.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	5.15 (1.144)	4.83 (1.056)
95% CL	[4.463; 5.845]	[4.476; 5.190]
Min-Max	2 - 6	2 - 6
Median	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	0.08 (1.564)	0.97 (1.207)
95% CL	[-0.911; 1.077]	[0.564; 1.381]
Min-Max	-4 - 2	-1 - 4
Median	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00
T-Test	t= 0.18 P= 0.857	t= 4.83 P= 0.000
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
n	12	36
Mean (SD)	1.75 (1.545)	1.81 (1.064)
95% CL	[0.768; 2.732]	[1.445; 2.166]
Min-Max	-2 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.67 (1.234)	3.95 (1.527)
95% CL	[3.983; 5.350]	[3.437; 4.455]
Min-Max	2 - 6	1 - 6
Median	5.00	4.00
Q1-Q3	4.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	5.15 (1.214)	4.89 (0.950)
95% CL	[4.420; 5.888]	[4.568; 5.210]
Min-Max	2 - 6	2 - 6
Median	6.00	5.00
Q1-Q3	5.00 - 6.00	4.50 - 5.50
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	0.50 (1.567)	0.92 (1.204)
95% CL	[-0.495; 1.495]	[0.509; 1.324]
Min-Max	-3 - 3	-1 - 3
Median	0.50	1.00
Q1-Q3	0.00 - 1.50	0.00 - 2.00
T-Test	t= 1.11 P= 0.293	t= 4.57 P= 0.000
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQc³ Change after 24 Weeks		
n	11	36
Mean (SD)	2.18 (0.982)	1.69 (1.167)
95% CL	[1.522; 2.841]	[1.300; 2.089]
Min-Max	0 - 3	-1 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.53 (1.407)	4.00 (1.291)
95% CL	[3.754; 5.313]	[3.570; 4.430]
Min-Max	1 - 6	1 - 6
Median	5.00	4.00
Q1-Q3	4.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	4.77 (1.013)	4.97 (0.910)
95% CL	[4.157; 5.381]	[4.664; 5.280]
Min-Max	3 - 6	3 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 5.00	4.00 - 6.00
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	0.00 (1.348)	0.92 (1.228)
95% CL	[-0.857; 0.857]	[0.501; 1.332]
Min-Max	-2 - 2	-1 - 4
Median	0.00	1.00
Q1-Q3	-1.00 - 1.00	0.00 - 2.00
T-Test	t= 0.00 P= 1.000	t= 4.48 P= 0.000
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQc³ Change after 24 Weeks		
n	12	36
Mean (SD)	2.08 (0.900)	1.81 (0.951)
95% CL	[1.511; 2.655]	[1.484; 2.127]
Min-Max	0 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.50

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.7 Recommend treatment to others

Recommend treatment to others	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.67 (1.234)	4.32 (1.355)
95% CL	[3.983; 5.350]	[3.873; 4.776]
Min-Max	3 - 6	2 - 6
Median	5.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	4.92 (1.038)	5.11 (1.141)
95% CL	[4.296; 5.550]	[4.725; 5.497]
Min-Max	3 - 6	2 - 6
Median	5.00	5.50
Q1-Q3	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	0.17 (1.946)	0.75 (1.402)
95% CL	[-1.070; 1.403]	[0.276; 1.224]
Min-Max	-3 - 3	-2 - 4
Median	0.00	1.00
Q1-Q3	-1.00 - 2.00	0.00 - 1.00
T-Test	t= 0.30 P= 0.772	t= 3.21 P= 0.003
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.7 Recommend treatment to others

Recommend treatment to others	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
n	12	36
Mean (SD)	1.67 (0.985)	1.72 (1.344)
95% CL	[1.041; 2.292]	[1.267; 2.177]
Min-Max	0 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 2.00	0.50 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQs[1] Status baseline		
n	15	37
Mean (SD)	4.53 (1.885)	4.00 (1.509)
95% CL	[3.490; 5.577]	[3.497; 4.503]
Min-Max	0 - 6	1 - 6
Median	5.00	4.00
Q1-Q3	4.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	13	36
Mean (SD)	4.69 (1.843)	5.17 (1.363)
95% CL	[3.578; 5.806]	[4.706; 5.628]
Min-Max	1 - 6	0 - 6
Median	6.00	6.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	12	36
Mean (SD)	0.00 (2.256)	1.19 (1.849)
95% CL	[-1.434; 1.434]	[0.569; 1.820]
Min-Max	-5 - 2	-4 - 5
Median	0.50	1.00
Q1-Q3	0.00 - 1.50	0.00 - 2.00
T-Test	t= 0.00 P= 1.000	t= 3.88 P= 0.000
Observed days[2]		
n	12	36
Mean (SD)	169.58 (12.580)	174.28 (9.771)
95% CL	[161.590;177.577]	[170.972;177.584]
Min-Max	140 - 187	156 - 209
Median	169.50	172.00
Q1-Q3	162.50 -178.00	168.50 -176.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
DTSQc³ Change after 24 Weeks		
n	12	36
Mean (SD)	2.33 (0.985)	1.94 (1.511)
95% CL	[1.708; 2.959]	[1.433; 2.456]
Min-Max	0 - 3	-3 - 3
Median	3.00	2.00
Q1-Q3	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.9 DTSQs - sum of scores

DTSQs sum of scores°	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Sum of scores baseline		
n	15	37
Mean (SD)	28.27 (7.620)	24.14 (7.138)
95% CL	[24.05; 32.49]	[21.76; 26.52]
Min-Max	10 - 36	10 - 36
Median	31.00	24.00
Q1-Q3	25.00 - 33.00	19.00 - 30.00
Sum of scores after 24 weeks		
n	13	36
Mean (SD)	29.62 (6.552)	29.81 (5.285)
95% CL	[25.66; 33.57]	[28.02; 31.59]
Min-Max	14 - 36	15 - 36
Median	32.00	30.00
Q1-Q3	26.00 - 34.00	28.00 - 34.00
Difference to Baseline		
n	12	36
Mean (SD)	0.42 (9.434)	5.64 (7.039)
95% CL	[-5.58; 6.41]	[3.26; 8.02]
Min-Max	-20 - 12	-10 - 24
Median	2.00	5.00
Q1-Q3	-1.50 - 6.50	2.50 - 9.50
T-Test	t= 0.15 P= 0.881	t= 4.81 P= 0.000

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.5 Full Analysis Set - Subgroups - Renal function
4.12.5.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	<=60 ml/min/1.73 m² (N = 17)	>60 ml/min/1.73 m² (N = 39)
Sum of scores after 24 weeks		
n	11	35
Mean (SD)	12.82 (4.143)	10.51 (6.482)
95% CL	[10.03; 15.60]	[8.29; 12.74]
Min-Max	4 - 18	-6 - 18
Median	14.00	12.00
Q1-Q3	11.00 - 16.00	6.00 - 16.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.1 Satisfaction with current treatment

Satisfaction with current treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	5.50 (0.837)	3.45 (1.849)	4.03 (1.658)
95% CL	[4.622; 6.378]	[2.585; 4.315]	[3.474; 4.580]
Min-Max	4 - 6	0 - 6	0 - 6
Median	6.00	3.00	4.00
Q1-Q3	5.00 - 6.00	2.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.80 (1.789)	4.47 (1.700)	4.89 (1.237)
95% CL	[2.579; 7.021]	[3.597; 5.345]	[4.470; 5.307]
Min-Max	2 - 6	0 - 6	1 - 6
Median	6.00	5.00	5.00
Q1-Q3	4.00 - 6.00	4.00 - 5.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	-0.60 (1.949)	0.88 (2.118)	0.86 (1.574)
95% CL	[-3.020; 1.820]	[-0.207; 1.971]	[0.316; 1.398]
Min-Max	-4 - 1	-4 - 4	-3 - 4
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 0.00	0.00 - 3.00	0.00 - 2.00
T-Test	t= -0.69 P= 0.529	t= 1.72 P= 0.105	t= 3.22 P= 0.003
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.1 Satisfaction with current treatment

Satisfaction with current treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
n	5	16	36
Mean (SD)	2.20 (0.837)	1.13 (1.821)	2.06 (1.040)
95% CL	[1.161; 3.239]	[0.155; 2.095]	[1.704; 2.408]
Min-Max	1 - 3	-3 - 3	-2 - 3
Median	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	0.00 - 2.50	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	4.00 (1.414)	4.05 (1.572)	3.65 (1.358)
95% CL	[2.516; 5.484]	[3.314; 4.786]	[3.196; 4.102]
Min-Max	2 - 6	0 - 6	0 - 6
Median	4.00	4.50	4.00
Q1-Q3	3.00 - 5.00	3.50 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	35
Mean (SD)	1.80 (1.304)	2.88 (2.027)	2.34 (1.305)
95% CL	[0.181; 3.419]	[1.840; 3.925]	[1.895; 2.791]
Min-Max	0 - 3	0 - 6	0 - 5
Median	2.00	2.00	3.00
Q1-Q3	1.00 - 3.00	1.00 - 5.00	1.00 - 3.00
DTSQs[2] Difference to Baseline			
n	5	17	34
Mean (SD)	-1.80 (0.837)	-1.35 (1.730)	-1.24 (1.597)
95% CL	[-2.839; -0.761]	[-2.242; -0.463]	[-1.792; -0.678]
Min-Max	-3 - -1	-5 - 1	-4 - 1
Median	-2.00	-1.00	-1.50
Q1-Q3	-2.00 - -1.00	-2.00 - 0.00	-2.00 - 0.00
T-Test	t= -4.81 P= 0.009	t= -3.22 P= 0.005	t= -4.51 P= 0.000
Observed days[2]			
n	5	17	34
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.74 (14.600)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.641;176.830]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	171.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQc[3] Change after 24 Weeks			
n	5	16	37
Mean (SD)	-1.40 (2.074)	-0.75 (2.017)	-0.97 (1.404)
95% CL	[-3.975; 1.175]	[-1.825; 0.325]	[-1.441; -0.505]
Min-Max	-3 - 2	-3 - 3	-3 - 2
Median	-2.00	-2.00	-1.00
Q1-Q3	-3.00 - -1.00	-2.00 - 0.50	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	0.17 (0.408)	1.00 (1.257)	0.89 (1.048)
95% CL	[-0.262; 0.595]	[0.412; 1.588]	[0.542; 1.241]
Min-Max	0 - 1	0 - 4	0 - 3
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 0.00	0.00 - 1.50	0.00 - 2.00
DTSQs[1] Status after 24 weeks			
n	5	17	35
Mean (SD)	1.00 (1.414)	0.71 (0.920)	0.80 (1.368)
95% CL	[-0.756; 2.756]	[0.233; 1.179]	[0.330; 1.270]
Min-Max	0 - 3	0 - 3	0 - 6
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00	0.00 - 2.00
DTSQs[2] Difference to Baseline			
n	5	17	34
Mean (SD)	0.80 (1.643)	-0.41 (1.661)	0.00 (1.775)
95% CL	[-1.240; 2.840]	[-1.266; 0.442]	[-0.619; 0.619]
Min-Max	-1 - 3	-4 - 2	-3 - 6
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 0.00	-1.00 - 0.00
T-Test	t= 1.09 P= 0.338	t= -1.02 P= 0.322	t= 0.00 P= 1.000
Observed days[2]			
n	5	17	34
Mean (SD)	180.80 (15.320)	179.47 (20.314)	170.53 (13.039)
95% CL	[161.778;199.822]	[169.026;189.915]	[165.980;175.079]
Min-Max	168 - 206	162 - 241	118 - 188
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -178.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQc[3] Change after 24 Weeks			
n	5	16	37
Mean (SD)	-0.40 (1.817)	-0.81 (2.007)	-1.49 (1.193)
95% CL	[-2.656; 1.856]	[-1.882; 0.257]	[-1.884; -1.089]
Min-Max	-3 - 2	-3 - 3	-3 - 1
Median	0.00	-0.50	-2.00
Q1-Q3	-1.00 - 0.00	-3.00 - 0.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	4.50 (1.517)	4.00 (1.298)	3.86 (1.653)
95% CL	[2.908; 6.092]	[3.393; 4.607]	[3.314; 4.416]
Min-Max	2 - 6	2 - 6	0 - 6
Median	4.50	4.00	4.00
Q1-Q3	4.00 - 6.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.60 (1.949)	4.88 (1.166)	4.94 (1.170)
95% CL	[2.180; 7.020]	[4.283; 5.482]	[4.549; 5.340]
Min-Max	2 - 6	3 - 6	1 - 6
Median	6.00	5.00	5.00
Q1-Q3	3.00 - 6.00	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	0.00 (2.345)	0.88 (1.453)	1.09 (1.245)
95% CL	[-2.912; 2.912]	[0.135; 1.629]	[0.658; 1.514]
Min-Max	-4 - 2	-1 - 4	-1 - 4
Median	1.00	0.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 0.00 P= 1.000	t= 2.50 P= 0.023	t= 5.16 P= 0.000
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
n	5	16	37
Mean (SD)	2.00 (1.225)	1.44 (1.504)	2.16 (0.898)
95% CL	[0.479; 3.521]	[0.636; 2.239]	[1.863; 2.462]
Min-Max	0 - 3	-2 - 3	0 - 3
Median	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	0.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	4.50 (1.643)	4.00 (1.338)	3.92 (1.622)
95% CL	[2.776; 6.224]	[3.374; 4.626]	[3.378; 4.460]
Min-Max	2 - 6	1 - 6	0 - 6
Median	5.00	4.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.40 (1.817)	5.00 (0.866)	4.97 (1.253)
95% CL	[2.144; 6.656]	[4.555; 5.445]	[4.548; 5.396]
Min-Max	2 - 6	3 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	3.00 - 6.00	5.00 - 6.00	4.50 - 6.00
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	-0.40 (1.517)	1.00 (1.620)	1.09 (1.197)
95% CL	[-2.283; 1.483]	[0.167; 1.833]	[0.674; 1.497]
Min-Max	-3 - 1	-1 - 5	-1 - 3
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 0.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= -0.59 P= 0.587	t= 2.54 P= 0.022	t= 5.36 P= 0.000
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQc[3] Change after 24 Weeks			
n	5	16	37
Mean (SD)	2.00 (1.225)	1.19 (1.471)	2.16 (0.898)
95% CL	[0.479; 3.521]	[0.404; 1.971]	[1.863; 2.462]
Min-Max	0 - 3	-2 - 3	0 - 3
Median	2.00	1.50	2.00
Q1-Q3	2.00 - 3.00	0.00 - 2.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	4.00 (1.265)	4.10 (1.553)	4.03 (1.384)
95% CL	[2.673; 5.327]	[3.373; 4.827]	[3.566; 4.489]
Min-Max	2 - 5	1 - 6	0 - 6
Median	4.50	5.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.60 (1.342)	5.00 (1.000)	4.72 (1.186)
95% CL	[2.934; 6.266]	[4.486; 5.514]	[4.321; 5.123]
Min-Max	3 - 6	3 - 6	0 - 6
Median	4.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	4.00 - 5.50
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	0.20 (1.924)	0.71 (1.490)	0.71 (1.319)
95% CL	[-2.188; 2.588]	[-0.060; 1.472]	[0.261; 1.167]
Min-Max	-2 - 3	-2 - 4	-1 - 4
Median	0.00	0.00	0.00
Q1-Q3	-1.00 - 1.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 0.23 P= 0.828	t= 1.95 P= 0.069	t= 3.20 P= 0.003
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQc[3] Change after 24 Weeks			
n	5	16	37
Mean (SD)	1.80 (1.304)	1.94 (1.181)	2.14 (0.751)
95% CL	[0.181; 3.419]	[1.308; 2.567]	[1.885; 2.386]
Min-Max	0 - 3	0 - 3	0 - 3
Median	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.7 Recommend treatment to others

Recommend treatment to others	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	5.00 (1.265)	4.45 (1.317)	4.08 (1.320)
95% CL	[3.673; 6.327]	[3.834; 5.066]	[3.641; 4.521]
Min-Max	3 - 6	2 - 6	2 - 6
Median	5.50	5.00	4.00
Q1-Q3	4.00 - 6.00	3.50 - 5.50	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.60 (1.517)	5.00 (1.173)	5.28 (0.914)
95% CL	[2.717; 6.483]	[4.397; 5.603]	[4.969; 5.587]
Min-Max	3 - 6	2 - 6	3 - 6
Median	5.00	5.00	5.50
Q1-Q3	3.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	-0.80 (1.643)	0.41 (1.502)	1.17 (1.272)
95% CL	[-2.840; 1.240]	[-0.361; 1.184]	[0.735; 1.608]
Min-Max	-3 - 1	-2 - 4	-1 - 4
Median	0.00	0.00	1.00
Q1-Q3	-2.00 - 0.00	0.00 - 1.00	0.00 - 2.00
T-Test	t= -1.09 P= 0.338	t= 1.13 P= 0.275	t= 5.45 P= 0.000
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.7 Recommend treatment to others

Recommend treatment to others	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
n	5	16	37
Mean (SD)	2.00 (1.225)	1.06 (1.652)	2.24 (0.925)
95% CL	[0.479; 3.521]	[0.182; 1.943]	[1.935; 2.552]
Min-Max	0 - 3	-2 - 3	0 - 3
Median	2.00	1.00	2.00
Q1-Q3	2.00 - 3.00	0.00 - 2.50	2.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQs[1] Status baseline			
n	6	20	37
Mean (SD)	4.67 (1.506)	3.55 (1.820)	3.89 (1.612)
95% CL	[3.087; 6.247]	[2.698; 4.402]	[3.354; 4.429]
Min-Max	2 - 6	0 - 6	0 - 6
Median	5.00	3.50	4.00
Q1-Q3	4.00 - 6.00	2.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	5	17	36
Mean (SD)	4.80 (1.789)	4.82 (1.811)	5.28 (1.162)
95% CL	[2.579; 7.021]	[3.892; 5.755]	[4.885; 5.671]
Min-Max	2 - 6	0 - 6	1 - 6
Median	6.00	6.00	6.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	5	17	35
Mean (SD)	0.20 (2.490)	1.18 (2.128)	1.40 (1.735)
95% CL	[-2.892; 3.292]	[0.082; 2.271]	[0.804; 1.996]
Min-Max	-4 - 2	-4 - 5	-3 - 6
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 3.00	0.00 - 2.00
T-Test	t= 0.18 P= 0.866	t= 2.28 P= 0.037	t= 4.77 P= 0.000
Observed days[2]			
n	5	17	35
Mean (SD)	180.80 (15.320)	179.47 (20.314)	171.63 (14.398)
95% CL	[161.778;199.822]	[169.026;189.915]	[166.683;176.574]
Min-Max	168 - 206	162 - 241	118 - 209
Median	175.00	174.00	170.00
Q1-Q3	171.00 -184.00	168.00 -178.00	168.00 -181.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
DTSQc[3] Change after 24 Weeks			
n	5	16	37
Mean (SD)	2.20 (1.304)	1.56 (1.825)	2.43 (1.144)
95% CL	[0.581; 3.819]	[0.590; 2.535]	[2.051; 2.814]
Min-Max	0 - 3	-3 - 3	-3 - 3
Median	3.00	2.00	3.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.9 DTSQs - sum of scores

DTSQs sum of scores°	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Sum of scores baseline			
n	6	20	37
Mean (SD)	28.17 (5.776)	23.55 (7.473)	23.81 (7.842)
95% CL	[22.10; 34.23]	[20.05; 27.05]	[21.20; 26.43]
Min-Max	20 - 34	10 - 36	6 - 36
Median	29.50	22.00	24.00
Q1-Q3	23.00 - 33.00	18.50 - 31.00	18.00 - 31.00
Sum of scores after 24 weeks			
n	5	17	36
Mean (SD)	27.80 (9.859)	29.18 (5.971)	30.08 (5.400)
95% CL	[15.56; 40.04]	[26.11; 32.25]	[28.26; 31.91]
Min-Max	14 - 36	15 - 36	14 - 36
Median	32.00	30.00	31.00
Q1-Q3	21.00 - 36.00	28.00 - 34.00	28.50 - 34.00
Difference to Baseline			
n	5	17	35
Mean (SD)	-1.40 (10.502)	5.06 (8.227)	6.31 (6.588)
95% CL	[-14.44; 11.64]	[0.83; 9.29]	[4.05; 8.58]
Min-Max	-20 - 5	-10 - 25	-7 - 20
Median	3.00	3.00	5.00
Q1-Q3	1.00 - 4.00	2.00 - 10.00	2.00 - 10.00
T-Test	t= -0.30 P= 0.780	t= 2.54 P= 0.022	t= 5.67 P= 0.000

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.6 Full Analysis Set - Subgroups - Duration of diabetes
4.12.6.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	up to 5 years (N = 7)	5 to 10 years (N = 21)	over 10 years (N = 39)
Sum of scores after 24 weeks			
n	5	16	36
Mean (SD)	12.20 (6.943)	8.31 (7.718)	13.19 (4.774)
95% CL	[3.58; 20.82]	[4.20; 12.42]	[11.58; 14.81]
Min-Max	1 - 18	-6 - 18	-4 - 18
Median	12.00	9.00	14.00
Q1-Q3	12.00 - 18.00	3.50 - 14.50	12.00 - 16.50

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.1 Satisfaction with current treatment

Satisfaction with current treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	4.03 (1.765)	3.90 (1.768)
95% CL	[3.431; 4.625]	[3.240; 4.560]
Min-Max	0 - 6	0 - 6
Median	4.00	4.50
Q1-Q3	3.00 - 6.00	2.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	4.58 (1.538)	4.96 (1.274)
95% CL	[4.063; 5.104]	[4.434; 5.486]
Min-Max	0 - 6	1 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	0.51 (2.174)	1.04 (1.541)
95% CL	[-0.233; 1.261]	[0.404; 1.676]
Min-Max	-4 - 5	-2 - 4
Median	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 1.40 P= 0.171	t= 3.38 P= 0.003
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.1 Satisfaction with current treatment

Satisfaction with current treatment	<8.5% (N = 38)	>=8.5% (N = 32)
n	35	25
Mean (SD)	1.54 (1.597)	2.04 (1.207)
95% CL	[0.994; 2.091]	[1.542; 2.538]
Min-Max	-3 - 3	-2 - 3
Median	2.00	2.00
Q1-Q3	1.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	3.53 (1.276)	4.07 (1.596)
95% CL	[3.096; 3.959]	[3.471; 4.663]
Min-Max	1 - 5	0 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	35	25
Mean (SD)	2.40 (1.538)	2.60 (1.633)
95% CL	[1.872; 2.928]	[1.926; 3.274]
Min-Max	0 - 6	0 - 6
Median	2.00	3.00
Q1-Q3	1.00 - 3.00	1.00 - 4.00
DTSQs[2] Difference to Baseline		
n	34	25
Mean (SD)	-1.06 (1.757)	-1.52 (1.686)
95% CL	[-1.672; -0.446]	[-2.216; -0.824]
Min-Max	-4 - 4	-5 - 1
Median	-1.00	-2.00
Q1-Q3	-2.00 - 0.00	-3.00 - 0.00
T-Test	t= -3.51 P= 0.001	t= -4.51 P= 0.000
Observed days[2]		
n	34	25
Mean (SD)	176.79 (15.521)	172.00 (17.306)
95% CL	[171.379;182.210]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	173.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQc[3] Change after 24 Weeks		
n	36	25
Mean (SD)	-1.28 (1.542)	-0.32 (1.725)
95% CL	[-1.800; -0.756]	[-1.032; 0.392]
Min-Max	-3 - 3	-3 - 3
Median	-2.00	-1.00
Q1-Q3	-2.00 - -1.00	-2.00 - 1.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	1.08 (1.339)	0.73 (1.112)
95% CL	[0.630; 1.536]	[0.318; 1.149]
Min-Max	0 - 6	0 - 4
Median	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
DTSQs[1] Status after 24 weeks		
n	35	25
Mean (SD)	0.77 (1.060)	0.80 (1.443)
95% CL	[0.407; 1.135]	[0.204; 1.396]
Min-Max	0 - 3	0 - 6
Median	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
DTSQs[2] Difference to Baseline		
n	34	25
Mean (SD)	-0.26 (1.543)	0.04 (2.051)
95% CL	[-0.803; 0.274]	[-0.807; 0.887]
Min-Max	-4 - 2	-4 - 6
Median	0.00	0.00
Q1-Q3	-1.00 - 0.00	-1.00 - 0.00
T-Test	t= -1.00 P= 0.325	t= 0.10 P= 0.923
Observed days[2]		
n	34	25
Mean (SD)	175.59 (14.502)	172.00 (17.306)
95% CL	[170.528;180.648]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -178.00	168.00 -178.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQc[3] Change after 24 Weeks		
n	36	25
Mean (SD)	-1.08 (1.663)	-1.24 (1.562)
95% CL	[-1.646; -0.521]	[-1.885; -0.595]
Min-Max	-3 - 3	-3 - 2
Median	-1.00	-2.00
Q1-Q3	-2.50 - 0.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	3.94 (1.689)	4.00 (1.414)
95% CL	[3.373; 4.516]	[3.472; 4.528]
Min-Max	0 - 6	2 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 5.50	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	4.69 (1.305)	5.20 (0.957)
95% CL	[4.253; 5.136]	[4.805; 5.595]
Min-Max	1 - 6	3 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	0.69 (1.549)	1.28 (1.308)
95% CL	[0.154; 1.218]	[0.740; 1.820]
Min-Max	-4 - 4	-1 - 4
Median	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 2.62 P= 0.013	t= 4.89 P= 0.000
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	<8.5% (N = 38)	>=8.5% (N = 32)
n	36	25
Mean (SD)	1.64 (1.376)	2.28 (0.891)
95% CL	[1.173; 2.105]	[1.912; 2.648]
Min-Max	-2 - 3	0 - 3
Median	2.00	3.00
Q1-Q3	0.50 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	3.92 (1.663)	4.10 (1.373)
95% CL	[3.354; 4.479]	[3.587; 4.613]
Min-Max	0 - 6	1 - 6
Median	4.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	4.67 (1.373)	5.32 (0.627)
95% CL	[4.202; 5.131]	[5.061; 5.579]
Min-Max	0 - 6	4 - 6
Median	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	0.74 (1.442)	1.20 (1.354)
95% CL	[0.248; 1.238]	[0.641; 1.759]
Min-Max	-3 - 3	-1 - 5
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 3.05 P= 0.004	t= 4.43 P= 0.000
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQc[3] Change after 24 Weeks		
n	35	25
Mean (SD)	1.60 (1.333)	2.20 (0.816)
95% CL	[1.142; 2.058]	[1.863; 2.537]
Min-Max	-2 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	0.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	4.22 (1.396)	3.90 (1.423)
95% CL	[3.750; 4.695]	[3.369; 4.431]
Min-Max	0 - 6	1 - 6
Median	4.50	4.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	4.89 (1.237)	4.72 (0.936)
95% CL	[4.470; 5.307]	[4.334; 5.106]
Min-Max	0 - 6	3 - 6
Median	5.00	5.00
Q1-Q3	4.50 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	0.66 (1.327)	0.68 (1.574)
95% CL	[0.201; 1.113]	[0.030; 1.330]
Min-Max	-2 - 3	-1 - 4
Median	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 1.00
T-Test	t= 2.93 P= 0.006	t= 2.16 P= 0.041
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQc[3] Change after 24 Weeks		
n	36	25
Mean (SD)	2.14 (0.931)	1.92 (0.909)
95% CL	[1.824; 2.454]	[1.545; 2.295]
Min-Max	0 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	1.50 - 3.00	2.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.7 Recommend treatment to others

Recommend treatment to others	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	4.42 (1.402)	4.13 (1.279)
95% CL	[3.942; 4.891]	[3.656; 4.611]
Min-Max	2 - 6	2 - 6
Median	5.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	5.00 (1.219)	5.28 (0.792)
95% CL	[4.588; 5.412]	[4.953; 5.607]
Min-Max	2 - 6	3 - 6
Median	5.00	5.00
Q1-Q3	4.50 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	0.51 (1.721)	1.08 (1.320)
95% CL	[-0.077; 1.106]	[0.535; 1.625]
Min-Max	-3 - 4	-1 - 4
Median	0.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 1.77 P= 0.086	t= 4.09 P= 0.000
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00
DTSQc[3] Change after 24 Weeks		

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.7 Recommend treatment to others

Recommend treatment to others	<8.5% (N = 38)	>=8.5% (N = 32)
n	36	25
Mean (SD)	1.75 (1.481)	2.00 (1.000)
95% CL	[1.249; 2.251]	[1.587; 2.413]
Min-Max	-2 - 3	0 - 3
Median	2.00	2.00
Q1-Q3	0.50 - 3.00	2.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQs[1] Status baseline		
n	36	30
Mean (SD)	3.69 (1.737)	4.03 (1.650)
95% CL	[3.107; 4.282]	[3.417; 4.650]
Min-Max	0 - 6	0 - 6
Median	4.00	4.00
Q1-Q3	2.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks		
n	36	25
Mean (SD)	4.75 (1.730)	5.48 (0.918)
95% CL	[4.165; 5.335]	[5.101; 5.859]
Min-Max	0 - 6	2 - 6
Median	5.00	6.00
Q1-Q3	4.50 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline		
n	35	25
Mean (SD)	1.00 (2.449)	1.44 (1.474)
95% CL	[0.159; 1.841]	[0.831; 2.049]
Min-Max	-5 - 6	-1 - 5
Median	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00
T-Test	t= 2.42 P= 0.021	t= 4.88 P= 0.000
Observed days[2]		
n	35	25
Mean (SD)	176.54 (15.363)	172.00 (17.306)
95% CL	[171.265;181.820]	[164.856;179.144]
Min-Max	156 - 241	118 - 215
Median	172.00	172.00
Q1-Q3	169.00 -181.00	168.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	<8.5% (N = 38)	>=8.5% (N = 32)
DTSQc[3] Change after 24 Weeks		
n	36	25
Mean (SD)	1.86 (1.659)	2.52 (0.823)
95% CL	[1.300; 2.422]	[2.180; 2.860]
Min-Max	-3 - 3	0 - 3
Median	2.00	3.00
Q1-Q3	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.9 DTSQs - sum of scores

DTSQs sum of scores°	<8.5% (N = 38)	>=8.5% (N = 32)
Sum of scores baseline		
n	36	30
Mean (SD)	24.22 (8.201)	24.07 (7.296)
95% CL	[21.45; 27.00]	[21.34; 26.79]
Min-Max	6 - 36	10 - 36
Median	25.00	23.50
Q1-Q3	18.00 - 31.50	18.00 - 31.00
Sum of scores after 24 weeks		
n	36	25
Mean (SD)	28.58 (6.959)	30.96 (3.668)
95% CL	[26.23; 30.94]	[29.45; 32.47]
Min-Max	14 - 36	21 - 36
Median	30.00	32.00
Q1-Q3	24.50 - 34.50	28.00 - 34.00
Difference to Baseline		
n	35	25
Mean (SD)	4.11 (9.164)	6.72 (6.687)
95% CL	[0.97; 7.26]	[3.96; 9.48]
Min-Max	-20 - 24	-6 - 25
Median	4.00	6.00
Q1-Q3	0.00 - 10.00	3.00 - 9.00
T-Test	t= 2.66 P= 0.012	t= 5.03 P= 0.000

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.7 Full Analysis Set - Subgroups - Baseline HbA1c
4.12.7.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	<8.5% (N = 38)	>=8.5% (N = 32)
Sum of scores after 24 weeks		
n	34	25
Mean (SD)	10.82 (7.009)	12.96 (4.504)
95% CL	[8.38; 13.27]	[11.10; 14.82]
Min-Max	-6 - 18	0 - 18
Median	13.00	14.00
Q1-Q3	7.00 - 16.00	11.00 - 16.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.1 Satisfaction with current treatment

Satisfaction with current treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.00 (1.483)	3.42 (1.976)	4.28 (1.646)	4.83 (1.329)
95% CL	[3.004; 4.996]	[2.582; 4.251]	[3.600; 4.960]	[3.438; 6.228]
Min-Max	2 - 6	0 - 6	1 - 6	3 - 6
Median	3.00	3.50	5.00	5.00
Q1-Q3	3.00 - 6.00	2.00 - 5.00	3.00 - 6.00	4.00 - 6.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	4.64 (1.629)	4.90 (1.300)	4.71 (1.628)	4.40 (0.548)
95% CL	[3.542; 5.731]	[4.313; 5.497]	[4.021; 5.396]	[3.720; 5.080]
Min-Max	1 - 6	1 - 6	0 - 6	4 - 5
Median	5.00	5.00	5.00	4.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	4.50 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.64 (2.248)	1.24 (1.546)	0.52 (2.233)	-0.20 (0.837)
95% CL	[-0.874; 2.147]	[0.534; 1.942]	[-0.444; 1.488]	[-1.239; 0.839]
Min-Max	-4 - 4	-1 - 4	-4 - 5	-1 - 1
Median	1.00	1.00	0.00	0.00
Q1-Q3	-1.00 - 2.00	0.00 - 3.00	0.00 - 2.00	-1.00 - 0.00
T-Test	t= 0.94 P= 0.370	t= 3.67 P= 0.002	t= 1.12 P= 0.275	t= -0.53 P= 0.621
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00
DTSQc[3] Change after 24 Weeks				

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.1 Satisfaction with current treatment

Satisfaction with current treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
n	11	20	24	5
Mean (SD)	2.45 (0.688)	1.80 (1.152)	1.33 (1.903)	2.00 (0.707)
95% CL	[1.993; 2.916]	[1.261; 2.339]	[0.530; 2.137]	[1.122; 2.878]
Min-Max	1 - 3	0 - 3	-3 - 3	1 - 3
Median	3.00	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	1.00 - 2.50	2.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.09 (1.044)	3.83 (1.404)	3.72 (1.568)	3.17 (1.835)
95% CL	[3.389; 4.793]	[3.241; 4.426]	[3.073; 4.367]	[1.241; 5.092]
Min-Max	2 - 5	1 - 6	0 - 6	0 - 5
Median	4.00	4.00	4.00	3.00
Q1-Q3	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks				
n	11	21	23	5
Mean (SD)	1.36 (0.674)	2.95 (1.746)	2.70 (1.521)	2.00 (1.414)
95% CL	[0.911; 1.817]	[2.158; 3.747]	[2.038; 3.353]	[0.244; 3.756]
Min-Max	0 - 2	0 - 6	0 - 5	0 - 3
Median	1.00	3.00	3.00	3.00
Q1-Q3	1.00 - 2.00	2.00 - 4.00	2.00 - 4.00	1.00 - 3.00
DTSQs[2] Difference to Baseline				
n	11	21	22	5
Mean (SD)	-2.73 (1.009)	-0.76 (1.640)	-0.86 (1.670)	-1.80 (2.049)
95% CL	[-3.405; -2.049]	[-1.509; -0.015]	[-1.604; -0.123]	[-4.345; 0.745]
Min-Max	-4 - -1	-4 - 1	-3 - 4	-5 - 0
Median	-3.00	-1.00	-1.00	-2.00
Q1-Q3	-4.00 - -2.00	-2.00 - 1.00	-2.00 - 0.00	-2.00 - 0.00
T-Test	t= -8.96 P= 0.000	t= -2.13 P= 0.046	t= -2.43 P= 0.024	t= -1.96 P= 0.121
Observed days[2]				
n	11	21	22	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.95 (15.604)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.036;179.873]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	173.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQc[3] Change after 24 Weeks				
n	11	21	24	5
Mean (SD)	-1.91 (0.539)	-0.62 (1.910)	-0.54 (1.744)	-1.40 (1.140)
95% CL	[-2.271; -1.547]	[-1.488; 0.250]	[-1.278; 0.195]	[-2.816; 0.016]
Min-Max	-3 - -1	-3 - 3	-3 - 3	-3 - 0
Median	-2.00	-1.00	-1.00	-1.00
Q1-Q3	-2.00 - -2.00	-2.00 - 1.00	-2.00 - 1.00	-2.00 - -1.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	0.73 (1.191)	0.67 (0.761)	1.16 (1.546)	1.33 (1.506)
95% CL	[-0.073; 1.527]	[0.345; 0.988]	[0.522; 1.798]	[-0.247; 2.913]
Min-Max	0 - 3	0 - 2	0 - 6	0 - 4
Median	0.00	0.50	1.00	1.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 2.00	0.00 - 2.00
DTSQs[1] Status after 24 weeks				
n	11	20	24	5
Mean (SD)	0.36 (0.674)	0.85 (0.988)	1.04 (1.601)	0.20 (0.447)
95% CL	[-0.089; 0.817]	[0.388; 1.312]	[0.366; 1.718]	[-0.355; 0.755]
Min-Max	0 - 2	0 - 3	0 - 6	0 - 1
Median	0.00	0.50	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 2.00	0.00 - 0.00
DTSQs[2] Difference to Baseline				
n	11	20	23	5
Mean (SD)	-0.36 (1.502)	0.25 (1.164)	-0.09 (2.214)	-1.40 (1.817)
95% CL	[-1.372; 0.645]	[-0.295; 0.795]	[-1.044; 0.870]	[-3.656; 0.856]
Min-Max	-3 - 2	-2 - 2	-4 - 6	-4 - 1
Median	0.00	0.00	0.00	-1.00
Q1-Q3	-1.00 - 0.00	0.00 - 1.00	-1.00 - 0.00	-2.00 - -1.00
T-Test	t= -0.80 P= 0.441	t= 0.96 P= 0.349	t= -0.19 P= 0.852	t= -1.72 P= 0.160
Observed days[2]				
n	11	20	23	5
Mean (SD)	173.73 (8.451)	177.10 (20.530)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[167.492;186.708]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	174.50	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -181.50	168.00 -182.00	168.00 -171.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQc[3] Change after 24 Weeks				
n	11	21	24	5
Mean (SD)	-1.27 (1.191)	-0.81 (1.750)	-1.25 (1.675)	-1.80 (1.643)
95% CL	[-2.073; -0.473]	[-1.606; -0.013]	[-1.957; -0.543]	[-3.840; 0.240]
Min-Max	-3 - 0	-3 - 3	-3 - 3	-3 - 0
Median	-1.00	-1.00	-2.00	-3.00
Q1-Q3	-2.00 - 0.00	-2.00 - 0.00	-2.50 - 0.00	-3.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.64 (1.286)	3.46 (1.587)	4.16 (1.491)	4.00 (1.897)
95% CL	[3.772; 5.501]	[2.788; 4.129]	[3.545; 4.775]	[2.009; 5.991]
Min-Max	3 - 6	0 - 6	1 - 6	2 - 6
Median	5.00	3.00	4.00	4.00
Q1-Q3	3.00 - 6.00	2.00 - 5.00	3.00 - 5.00	2.00 - 6.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	4.91 (1.300)	4.67 (1.494)	5.17 (0.868)	4.60 (0.894)
95% CL	[4.036; 5.783]	[3.986; 5.347]	[4.800; 5.533]	[3.489; 5.711]
Min-Max	2 - 6	1 - 6	3 - 6	3 - 5
Median	5.00	5.00	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00	5.00 - 6.00	5.00 - 5.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.27 (1.849)	1.14 (1.153)	1.04 (1.522)	1.00 (1.581)
95% CL	[-0.969; 1.515]	[0.618; 1.668]	[0.385; 1.702]	[-0.963; 2.963]
Min-Max	-4 - 2	0 - 4	-1 - 4	-1 - 3
Median	0.00	1.00	1.00	1.00
Q1-Q3	-1.00 - 2.00	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 0.49 P= 0.635	t= 4.54 P= 0.000	t= 3.29 P= 0.003	t= 1.41 P= 0.230
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00
DTSQc[3] Change after 24 Weeks				

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
n	11	21	24	5
Mean (SD)	2.27 (0.905)	1.86 (1.389)	1.79 (1.285)	1.80 (1.095)
95% CL	[1.665; 2.880]	[1.225; 2.489]	[1.249; 2.334]	[0.440; 3.160]
Min-Max	0 - 3	-2 - 3	-2 - 3	0 - 3
Median	2.00	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	1.00 - 3.00	2.00 - 2.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.55 (1.128)	3.63 (1.740)	4.16 (1.405)	3.83 (1.722)
95% CL	[3.788; 5.303]	[2.890; 4.360]	[3.580; 4.740]	[2.026; 5.641]
Min-Max	3 - 6	0 - 6	2 - 6	2 - 6
Median	4.00	3.50	4.00	4.00
Q1-Q3	4.00 - 6.00	2.50 - 5.00	3.00 - 6.00	2.00 - 5.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	4.73 (1.272)	4.76 (1.513)	5.25 (0.676)	4.60 (1.140)
95% CL	[3.873; 5.582]	[4.073; 5.451]	[4.965; 5.535]	[3.184; 6.016]
Min-Max	2 - 6	0 - 6	4 - 6	3 - 6
Median	5.00	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	4.00 - 6.00	5.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.18 (1.471)	1.14 (1.389)	1.09 (1.411)	1.00 (1.225)
95% CL	[-0.806; 1.170]	[0.511; 1.775]	[0.477; 1.697]	[-0.521; 2.521]
Min-Max	-3 - 2	-1 - 5	-1 - 3	-1 - 2
Median	0.00	1.00	1.00	1.00
Q1-Q3	-1.00 - 1.00	0.00 - 2.00	0.00 - 3.00	1.00 - 2.00
T-Test	t= 0.41 P= 0.690	t= 3.77 P= 0.001	t= 3.69 P= 0.001	t= 1.83 P= 0.142
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQc[3] Change after 24 Weeks				
n	11	21	23	5
Mean (SD)	2.09 (0.944)	1.62 (1.465)	1.96 (1.022)	1.80 (1.095)
95% CL	[1.457; 2.725]	[0.952; 2.286]	[1.515; 2.398]	[0.440; 3.160]
Min-Max	0 - 3	-2 - 3	0 - 3	0 - 3
Median	2.00	2.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	1.00 - 3.00	2.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	3.91 (0.944)	3.88 (1.752)	4.24 (1.300)	4.50 (1.049)
95% CL	[3.275; 4.543]	[3.135; 4.615]	[3.703; 4.777]	[3.399; 5.601]
Min-Max	3 - 5	0 - 6	2 - 6	3 - 6
Median	4.00	4.00	4.00	4.50
Q1-Q3	3.00 - 5.00	2.50 - 5.00	4.00 - 5.00	4.00 - 5.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	4.27 (1.009)	4.76 (1.513)	5.13 (0.680)	4.80 (0.837)
95% CL	[3.595; 4.951]	[4.073; 5.451]	[4.838; 5.412]	[3.761; 5.839]
Min-Max	3 - 6	0 - 6	4 - 6	4 - 6
Median	4.00	5.00	5.00	5.00
Q1-Q3	3.00 - 5.00	4.00 - 6.00	5.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.36 (1.286)	0.71 (1.454)	0.83 (1.497)	0.40 (1.517)
95% CL	[-0.501; 1.228]	[0.052; 1.376]	[0.179; 1.473]	[-1.483; 2.283]
Min-Max	-2 - 3	-2 - 4	-1 - 4	-1 - 2
Median	0.00	0.00	0.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 2.00	-1.00 - 2.00
T-Test	t= 0.94 P= 0.371	t= 2.25 P= 0.036	t= 2.65 P= 0.015	t= 0.59 P= 0.587
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQc[3] Change after 24 Weeks				
n	11	21	24	5
Mean (SD)	1.82 (0.751)	2.05 (1.071)	2.25 (0.794)	1.60 (1.140)
95% CL	[1.314; 2.323]	[1.560; 2.535]	[1.915; 2.585]	[0.184; 3.016]
Min-Max	1 - 3	0 - 3	0 - 3	0 - 3
Median	2.00	2.00	2.00	2.00
Q1-Q3	1.00 - 2.00	2.00 - 3.00	2.00 - 3.00	1.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.7 Recommend treatment to others

Recommend treatment to others	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.55 (1.368)	4.21 (1.474)	4.08 (1.320)	5.00 (0.632)
95% CL	[3.626; 5.465]	[3.586; 4.831]	[3.535; 4.625]	[4.336; 5.664]
Min-Max	3 - 6	2 - 6	2 - 6	4 - 6
Median	5.00	4.50	4.00	5.00
Q1-Q3	3.00 - 6.00	3.00 - 5.50	3.00 - 5.00	5.00 - 5.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	5.00 (1.000)	5.24 (1.091)	5.08 (1.100)	5.00 (1.225)
95% CL	[4.328; 5.672]	[4.741; 5.735]	[4.619; 5.548]	[3.479; 6.521]
Min-Max	3 - 6	3 - 6	2 - 6	3 - 6
Median	5.00	6.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.45 (1.368)	0.81 (1.250)	1.00 (1.931)	0.00 (1.581)
95% CL	[-0.465; 1.374]	[0.241; 1.378]	[0.165; 1.835]	[-1.963; 1.963]
Min-Max	-3 - 2	-1 - 4	-3 - 4	-2 - 2
Median	1.00	1.00	1.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 1.00	0.00 - 3.00	-1.00 - 1.00
T-Test	t= 1.10 P= 0.296	t= 2.97 P= 0.008	t= 2.48 P= 0.021	t= 0.00 P= 1.000
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00
DTSQc[3] Change after 24 Weeks				

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.7 Recommend treatment to others

Recommend treatment to others	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
n	11	21	24	5
Mean (SD)	2.09 (1.044)	1.71 (1.454)	1.92 (1.283)	1.60 (1.517)
95% CL	[1.389; 2.793]	[1.052; 2.376]	[1.375; 2.458]	[-0.283; 3.483]
Min-Max	0 - 3	-2 - 3	-2 - 3	0 - 3
Median	2.00	2.00	2.00	2.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00	2.00 - 3.00	0.00 - 3.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQs[1] Status baseline				
n	11	24	25	6
Mean (SD)	4.36 (1.502)	3.38 (1.813)	3.96 (1.645)	4.33 (1.633)
95% CL	[3.355; 5.372]	[2.609; 4.141]	[3.281; 4.639]	[2.620; 6.047]
Min-Max	2 - 6	0 - 6	1 - 6	2 - 6
Median	4.00	3.50	4.00	4.50
Q1-Q3	3.00 - 6.00	2.00 - 5.00	2.00 - 5.00	3.00 - 6.00
DTSQs[1] Status after 24 weeks				
n	11	21	24	5
Mean (SD)	5.18 (1.168)	5.29 (1.347)	4.83 (1.857)	4.80 (0.447)
95% CL	[4.397; 5.966]	[4.673; 5.899]	[4.049; 5.618]	[4.245; 5.355]
Min-Max	2 - 6	2 - 6	0 - 6	4 - 5
Median	5.00	6.00	6.00	5.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00	5.00 - 5.00
DTSQs[2] Difference to Baseline				
n	11	21	23	5
Mean (SD)	0.82 (2.089)	1.67 (1.683)	1.00 (2.558)	0.80 (1.304)
95% CL	[-0.585; 2.222]	[0.900; 2.433]	[-0.106; 2.106]	[-0.819; 2.419]
Min-Max	-4 - 4	0 - 6	-5 - 5	-1 - 2
Median	1.00	1.00	1.00	1.00
Q1-Q3	0.00 - 2.00	1.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 1.30 P= 0.223	t= 4.54 P= 0.000	t= 1.87 P= 0.074	t= 1.37 P= 0.242
Observed days[2]				
n	11	21	23	5
Mean (SD)	173.73 (8.451)	178.62 (21.186)	172.74 (15.280)	168.80 (4.764)
95% CL	[168.050;179.405]	[168.975;188.263]	[166.132;179.347]	[162.884;174.716]
Min-Max	163 - 194	140 - 241	118 - 206	162 - 175
Median	172.00	175.00	172.00	168.00
Q1-Q3	170.00 -175.00	169.00 -182.00	168.00 -182.00	168.00 -171.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
DTSQc[3] Change after 24 Weeks				
n	11	21	24	5
Mean (SD)	2.36 (0.809)	2.10 (1.338)	2.08 (1.742)	2.00 (1.225)
95% CL	[1.820; 2.907]	[1.486; 2.704]	[1.348; 2.819]	[0.479; 3.521]
Min-Max	1 - 3	-2 - 3	-3 - 3	0 - 3
Median	3.00	3.00	3.00	2.00
Q1-Q3	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.9 DTSQs - sum of scores

DTSQs sum of scores°	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Sum of scores baseline				
n	11	24	25	6
Mean (SD)	26.00 (6.164)	21.96 (8.483)	24.88 (7.601)	26.50 (7.450)
95% CL	[21.86; 30.14]	[18.38; 25.54]	[21.74; 28.02]	[18.68; 34.32]
Min-Max	19 - 34	6 - 36	10 - 36	17 - 36
Median	26.00	20.50	26.00	26.50
Q1-Q3	19.00 - 33.00	16.00 - 30.50	18.00 - 31.00	20.00 - 33.00
Sum of scores after 24 weeks				
n	11	21	24	5
Mean (SD)	28.73 (5.884)	29.62 (6.697)	30.17 (5.753)	28.20 (4.207)
95% CL	[24.77; 32.68]	[26.57; 32.67]	[27.74; 32.60]	[22.98; 33.42]
Min-Max	14 - 36	14 - 36	15 - 36	21 - 32
Median	29.00	31.00	32.00	29.00
Q1-Q3	28.00 - 33.00	26.00 - 35.00	28.50 - 34.00	29.00 - 30.00
Difference to Baseline				
n	11	21	23	5
Mean (SD)	2.73 (8.615)	6.71 (6.466)	5.48 (9.857)	3.00 (6.519)
95% CL	[-3.06; 8.51]	[3.77; 9.66]	[1.22; 9.74]	[-5.09; 11.09]
Min-Max	-20 - 10	-1 - 25	-15 - 24	-6 - 12
Median	3.00	5.00	5.00	3.00
Q1-Q3	1.00 - 9.00	3.00 - 10.00	1.00 - 14.00	1.00 - 5.00
T-Test	t= 1.05 P= 0.318	t= 4.76 P= 0.000	t= 2.67 P= 0.014	t= 1.03 P= 0.362

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
4.12.8.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	Detemir (N = 11)	Glargin 100 (N = 24)	Glargin 300 (N = 29)	Degludec (N = 6)
Sum of scores after 24 weeks				
n	11	20	23	5
Mean (SD)	13.09 (4.134)	11.05 (7.067)	11.87 (6.384)	10.80 (5.541)
95% CL	[10.31; 15.87]	[7.74; 14.36]	[9.11; 14.63]	[3.92; 17.68]
Min-Max	5 - 18	-5 - 18	-6 - 18	1 - 14
Median	13.00	15.00	14.00	13.00
Q1-Q3	11.00 - 17.00	5.00 - 16.50	9.00 - 16.00	12.00 - 14.00

° Sum of DTSQc scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.1 Satisfaction with current treatment

Satisfaction with current treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	4.17 (1.736)	4.11 (1.764)	3.72 (1.782)
95% CL	[3.434; 4.900]	[2.755; 5.467]	[3.076; 4.361]
Min-Max	1 - 6	1 - 6	0 - 6
Median	5.00	5.00	4.00
Q1-Q3	2.50 - 6.00	3.00 - 5.00	2.50 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	5.18 (1.220)	4.89 (0.782)	4.34 (1.675)
95% CL	[4.641; 5.723]	[4.288; 5.490]	[3.708; 4.982]
Min-Max	1 - 6	4 - 6	0 - 6
Median	5.50	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 5.00	4.00 - 5.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	1.10 (1.998)	0.78 (1.394)	0.52 (2.064)
95% CL	[0.186; 2.005]	[-0.294; 1.850]	[-0.268; 1.302]
Min-Max	-2 - 5	0 - 4	-4 - 3
Median	0.00	0.00	1.00
Q1-Q3	0.00 - 3.00	0.00 - 1.00	0.00 - 2.00
T-Test	t= 2.51 P= 0.021	t= 1.67 P= 0.133	t= 1.35 P= 0.188
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.1 Satisfaction with current treatment

Satisfaction with current treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
n	22	8	29
Mean (SD)	2.45 (0.858)	0.63 (1.408)	1.52 (1.617)
95% CL	[2.074; 2.835]	[-0.552; 1.802]	[0.902; 2.132]
Min-Max	0 - 3	-2 - 2	-3 - 3
Median	3.00	0.50	2.00
Q1-Q3	2.00 - 3.00	0.00 - 2.00	2.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	3.46 (1.641)	3.44 (1.333)	4.13 (1.289)
95% CL	[2.765; 4.151]	[2.420; 4.469]	[3.660; 4.590]
Min-Max	0 - 6	1 - 5	1 - 6
Median	4.00	4.00	4.00
Q1-Q3	2.50 - 5.00	3.00 - 4.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	28
Mean (SD)	2.09 (1.797)	1.89 (1.453)	3.00 (1.305)
95% CL	[1.294; 2.888]	[0.772; 3.006]	[2.494; 3.506]
Min-Max	0 - 6	0 - 4	1 - 6
Median	2.00	2.00	3.00
Q1-Q3	1.00 - 3.00	1.00 - 3.00	2.00 - 4.00
DTSQs[2] Difference to Baseline			
n	21	9	28
Mean (SD)	-1.33 (1.798)	-1.56 (1.509)	-1.11 (1.812)
95% CL	[-2.152; -0.515]	[-2.716; -0.395]	[-1.810; -0.404]
Min-Max	-5 - 1	-4 - 0	-4 - 4
Median	-1.00	-1.00	-2.00
Q1-Q3	-2.00 - 0.00	-2.00 - -1.00	-2.00 - 0.50
T-Test	t= -3.40 P= 0.003	t= -3.09 P= 0.015	t= -3.23 P= 0.003
Observed days[2]			
n	21	9	28
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.64 (14.830)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.892;178.393]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.50
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -180.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.2 Impression how often blood glucose was unacceptably high

Impression how often blood glucose was unacceptably high	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQc[3] Change after 24 Weeks			
n	22	9	29
Mean (SD)	-0.77 (1.660)	-1.33 (1.118)	-0.79 (1.859)
95% CL	[-1.509; -0.037]	[-2.193; -0.474]	[-1.500; -0.086]
Min-Max	-3 - 3	-3 - 1	-3 - 3
Median	-1.00	-1.00	-2.00
Q1-Q3	-2.00 - 0.00	-2.00 - -1.00	-2.00 - 1.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	0.88 (1.076)	1.00 (0.866)	0.97 (1.470)
95% CL	[0.421; 1.329]	[0.334; 1.666]	[0.439; 1.499]
Min-Max	0 - 4	0 - 2	0 - 6
Median	1.00	1.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 2.00	0.00 - 1.50
DTSQs[1] Status after 24 weeks			
n	22	8	29
Mean (SD)	1.05 (1.558)	0.13 (0.354)	0.72 (1.032)
95% CL	[0.355; 1.736]	[-0.171; 0.421]	[0.332; 1.117]
Min-Max	0 - 6	0 - 1	0 - 3
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 0.00	0.00 - 2.00
DTSQs[2] Difference to Baseline			
n	21	8	29
Mean (SD)	0.24 (1.786)	-0.75 (0.886)	-0.31 (1.892)
95% CL	[-0.575; 1.051]	[-1.491; -0.009]	[-1.030; 0.409]
Min-Max	-4 - 6	-2 - 0	-4 - 3
Median	0.00	-0.50	0.00
Q1-Q3	0.00 - 1.00	-1.50 - 0.00	-1.00 - 0.00
T-Test	t= 0.61 P= 0.548	t= -2.39 P= 0.048	t= -0.88 P= 0.385
Observed days[2]			
n	21	8	29
Mean (SD)	177.38 (19.151)	170.25 (8.876)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.829;177.671]	[166.934;178.032]
Min-Max	161 - 241	156 - 187	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -174.50	170.00 -178.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.3 Impression how often blood glucose was unacceptably low

Impression how often blood glucose was unacceptably low	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQc[3] Change after 24 Weeks			
n	22	9	29
Mean (SD)	-1.05 (1.759)	-1.67 (1.414)	-1.03 (1.592)
95% CL	[-1.825; -0.266]	[-2.754; -0.580]	[-1.640; -0.429]
Min-Max	-3 - 3	-3 - 0	-3 - 3
Median	-1.50	-2.00	-1.00
Q1-Q3	-2.00 - 0.00	-3.00 - 0.00	-2.00 - 0.00

[1]Rating scale 6 = the most time - 0 = at no time
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more often - -3 now much more rarely

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	4.29 (1.706)	3.89 (1.453)	3.72 (1.486)
95% CL	[3.571; 5.012]	[2.772; 5.006]	[3.183; 4.255]
Min-Max	1 - 6	2 - 6	0 - 6
Median	5.00	4.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	5.41 (0.959)	5.22 (0.833)	4.41 (1.296)
95% CL	[4.984; 5.834]	[4.582; 5.863]	[3.921; 4.907]
Min-Max	3 - 6	4 - 6	1 - 6
Median	6.00	5.00	5.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	1.19 (1.750)	1.33 (1.000)	0.66 (1.370)
95% CL	[0.394; 1.987]	[0.565; 2.102]	[0.134; 1.176]
Min-Max	-1 - 4	0 - 3	-4 - 3
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 3.00	1.00 - 2.00	0.00 - 2.00
T-Test	t= 3.12 P= 0.005	t= 4.00 P= 0.004	t= 2.58 P= 0.016
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.4 Practicability/comfort of treatment

Practicability/ comfort of treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
n	22	9	29
Mean (SD)	2.27 (1.241)	1.56 (1.130)	1.69 (1.228)
95% CL	[1.722; 2.823]	[0.687; 2.424]	[1.223; 2.157]
Min-Max	-2 - 3	0 - 3	-2 - 3
Median	3.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.00	1.00 - 2.00

[1]Rating scale 6 = very practical/comfortable - 0 = very impractical/uncomfortable
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more practical/comfortable - -3 now much less practical/comfortable

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	4.25 (1.539)	4.00 (1.581)	3.78 (1.539)
95% CL	[3.600; 4.900]	[2.785; 5.215]	[3.226; 4.336]
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.50	4.00	4.00
Q1-Q3	3.00 - 6.00	3.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	5.36 (0.848)	5.00 (0.866)	4.59 (1.376)
95% CL	[4.988; 5.739]	[4.334; 5.666]	[4.063; 5.110]
Min-Max	3 - 6	4 - 6	0 - 6
Median	6.00	5.00	5.00
Q1-Q3	5.00 - 6.00	4.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	1.19 (1.601)	1.00 (1.000)	0.76 (1.405)
95% CL	[0.462; 1.919]	[0.231; 1.769]	[0.224; 1.293]
Min-Max	-1 - 5	-1 - 2	-3 - 3
Median	1.00	1.00	1.00
Q1-Q3	0.00 - 3.00	1.00 - 2.00	0.00 - 2.00
T-Test	t= 3.41 P= 0.003	t= 3.00 P= 0.017	t= 2.91 P= 0.007
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.5 Satisfaction with the flexibility of treatment

Satisfaction with the flexibility of treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQc[3] Change after 24 Weeks			
n	22	9	28
Mean (SD)	2.23 (1.270)	1.33 (1.225)	1.71 (1.049)
95% CL	[1.664; 2.790]	[0.392; 2.275]	[1.308; 2.121]
Min-Max	-2 - 3	-1 - 3	0 - 3
Median	3.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 2.00	1.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	4.29 (1.197)	4.44 (0.882)	3.75 (1.606)
95% CL	[3.786; 4.797]	[3.767; 5.122]	[3.171; 4.329]
Min-Max	2 - 6	3 - 6	0 - 6
Median	4.00	4.00	4.00
Q1-Q3	3.50 - 5.00	4.00 - 5.00	2.50 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	4.86 (1.125)	5.33 (0.707)	4.62 (1.208)
95% CL	[4.365; 5.363]	[4.790; 5.877]	[4.161; 5.080]
Min-Max	3 - 6	4 - 6	0 - 6
Median	5.00	5.00	5.00
Q1-Q3	4.00 - 6.00	5.00 - 6.00	4.00 - 5.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	0.62 (1.717)	0.89 (0.928)	0.69 (1.339)
95% CL	[-0.162; 1.401]	[0.176; 1.602]	[0.180; 1.199]
Min-Max	-2 - 4	0 - 2	-2 - 4
Median	0.00	1.00	0.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 1.00
T-Test	t= 1.65 P= 0.114	t= 2.87 P= 0.021	t= 2.77 P= 0.010
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.6 Satisfaction with knowledge/understanding of diabetes

Satisfaction with knowledge/understanding of diabetes	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQc[3] Change after 24 Weeks			
n	22	9	29
Mean (SD)	2.36 (1.002)	1.89 (1.054)	1.86 (0.789)
95% CL	[1.919; 2.808]	[1.079; 2.699]	[1.562; 2.162]
Min-Max	0 - 3	0 - 3	0 - 3
Median	3.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	2.00 - 2.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.7 Recommend treatment to others

Recommend treatment to others	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	4.54 (1.444)	4.44 (1.130)	4.03 (1.332)
95% CL	[3.932; 5.151]	[3.576; 5.313]	[3.551; 4.511]
Min-Max	2 - 6	2 - 6	2 - 6
Median	5.00	5.00	4.00
Q1-Q3	3.00 - 6.00	4.00 - 5.00	3.00 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	5.32 (0.945)	5.56 (0.726)	4.79 (1.177)
95% CL	[4.899; 5.737]	[4.997; 6.114]	[4.346; 5.241]
Min-Max	3 - 6	4 - 6	2 - 6
Median	6.00	6.00	5.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	4.00 - 6.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	0.71 (1.765)	1.11 (1.054)	0.66 (1.632)
95% CL	[-0.089; 1.518]	[0.301; 1.921]	[0.034; 1.276]
Min-Max	-2 - 4	0 - 3	-3 - 4
Median	0.00	1.00	1.00
Q1-Q3	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
T-Test	t= 1.85 P= 0.078	t= 3.16 P= 0.013	t= 2.16 P= 0.039
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00
DTSQc[3] Change after 24 Weeks			

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.7 Recommend treatment to others

Recommend treatment to others	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
n	22	9	29
Mean (SD)	2.23 (1.343)	1.89 (1.054)	1.52 (1.299)
95% CL	[1.632; 2.823]	[1.079; 2.699]	[1.023; 2.011]
Min-Max	-2 - 3	0 - 3	-2 - 3
Median	3.00	2.00	2.00
Q1-Q3	2.00 - 3.00	1.00 - 3.00	0.00 - 2.00

[1]Rating scale 6 = definitely recommend the treatment - 0 = not recommend the treatment in any case
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more probable - -3 now much less probably

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQs[1] Status baseline			
n	24	9	32
Mean (SD)	3.92 (1.863)	3.78 (1.481)	3.81 (1.693)
95% CL	[3.130; 4.703]	[2.639; 4.916]	[3.202; 4.423]
Min-Max	1 - 6	2 - 6	0 - 6
Median	4.00	3.00	4.00
Q1-Q3	2.00 - 6.00	3.00 - 5.00	2.50 - 5.00
DTSQs[1] Status after 24 weeks			
n	22	9	29
Mean (SD)	5.36 (1.217)	5.44 (0.726)	4.69 (1.795)
95% CL	[4.824; 5.903]	[4.886; 6.003]	[4.007; 5.372]
Min-Max	2 - 6	4 - 6	0 - 6
Median	6.00	6.00	5.00
Q1-Q3	5.00 - 6.00	5.00 - 6.00	5.00 - 6.00
DTSQs[2] Difference to Baseline			
n	21	9	29
Mean (SD)	1.57 (1.832)	1.67 (1.323)	0.76 (2.444)
95% CL	[0.737; 2.405]	[0.650; 2.684]	[-0.171; 1.688]
Min-Max	-1 - 5	0 - 4	-5 - 6
Median	1.00	2.00	1.00
Q1-Q3	0.00 - 3.00	1.00 - 2.00	0.00 - 2.00
T-Test	t= 3.93 P= 0.001	t= 3.78 P= 0.005	t= 1.67 P= 0.106
Observed days[2]			
n	21	9	29
Mean (SD)	177.38 (19.151)	174.56 (15.355)	172.48 (14.589)
95% CL	[168.664;186.098]	[162.753;186.358]	[166.934;178.032]
Min-Max	161 - 241	156 - 209	118 - 206
Median	171.00	168.00	173.00
Q1-Q3	169.00 -176.00	167.00 -175.00	170.00 -178.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.8 Satisfaction with continuing current treatment

Satisfaction with continuing current treatment	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
DTSQc[3] Change after 24 Weeks			
n	22	9	29
Mean (SD)	2.55 (1.224)	2.11 (0.601)	1.79 (1.656)
95% CL	[2.003; 3.088]	[1.649; 2.573]	[1.163; 2.423]
Min-Max	-2 - 3	1 - 3	-3 - 3
Median	3.00	2.00	2.00
Q1-Q3	3.00 - 3.00	2.00 - 2.00	1.00 - 3.00

[1]Rating scale 6 = very satisfied - 0 = very dissatisfied
[2]Only patients with values at baseline and after 24 weeks
[3]Rating scale 3 = now much more satisfied - -3 now much less satisfied

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.9 DTSQs - sum of scores

DTSQs sum of scores°	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Sum of scores baseline			
n	24	9	32
Mean (SD)	25.46 (8.032)	24.67 (6.837)	22.81 (7.814)
95% CL	[22.07; 28.85]	[19.41; 29.92]	[20.00; 25.63]
Min-Max	10 - 36	13 - 32	6 - 36
Median	26.00	24.00	23.00
Q1-Q3	19.50 - 33.00	21.00 - 31.00	18.00 - 29.00
Sum of scores after 24 weeks			
n	22	9	29
Mean (SD)	31.50 (4.993)	31.44 (3.245)	27.45 (6.674)
95% CL	[29.29; 33.71]	[28.95; 33.94]	[24.91; 29.99]
Min-Max	18 - 36	28 - 36	14 - 36
Median	33.50	30.00	29.00
Q1-Q3	30.00 - 35.00	29.00 - 34.00	24.00 - 32.00
Difference to Baseline			
n	21	9	29
Mean (SD)	6.38 (8.992)	6.78 (4.764)	4.03 (8.683)
95% CL	[2.29; 10.47]	[3.12; 10.44]	[0.73; 7.34]
Min-Max	-6 - 25	2 - 17	-20 - 20
Median	3.00	5.00	5.00
Q1-Q3	0.00 - 11.00	5.00 - 7.00	3.00 - 9.00
T-Test	t= 3.25 P= 0.004	t= 4.27 P= 0.003	t= 2.50 P= 0.018

° Sum of DTSQs scores 1,4,5,6,7,8

4 Effectiveness (secondary)
4.12 Absolute values in therapy satisfaction (DTSQs and DTSQc)
4.12.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
4.12.9.10 DTSQc - sum of scores after 24 weeks

DTSQc sum of scores°	before breakfast (N = 28)	before lunch (N = 9)	before dinner (N = 32)
Sum of scores after 24 weeks			
n	22	8	28
Mean (SD)	14.09 (5.911)	9.13 (4.883)	10.50 (6.215)
95% CL	[11.47; 16.71]	[5.04; 13.21]	[8.09; 12.91]
Min-Max	-5 - 18	3 - 17	-6 - 18
Median	16.00	8.00	12.00
Q1-Q3	14.00 - 17.00	5.50 - 13.00	8.50 - 14.50

° Sum of DTSQc scores 1,4,5,6,7,8

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.1 Median target blood glucose and limit value for low glucose
5.1.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	FGM (N = 20)
Baseline	
n	20
Mean (SD)	139.4 (13.90)
95% CL	[132.86;145.88]
Min-Max	117.12 - 154
Median	140.0
Q1-Q3	126.1 - 154.0
After 12 weeks	
n	17
Mean (SD)	132.3 (12.51)
95% CL	[125.88;138.75]
Min-Max	117.12 - 150
Median	130.0
Q1-Q3	120.0 - 150.0
After 24 weeks	
n	16
Mean (SD)	137.6 (15.85)
95% CL	[129.20;146.09]
Min-Max	115 - 154
Median	135.0
Q1-Q3	125.0 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.1 Median target blood glucose and limit value for low glucose
5.1.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	FGM (N = 20)
Baseline	
n	20
Mean (SD)	69.3 (6.03)
95% CL	[66.49; 72.13]
Min-Max	60 - 90.091
Median	70.0
Q1-Q3	70.0 - 70.0
After 12 weeks	
n	17
Mean (SD)	72.2 (6.51)
95% CL	[68.82; 75.52]
Min-Max	60 - 90.091
Median	70.0
Q1-Q3	70.0 - 70.0
After 24 weeks	
n	16
Mean (SD)	71.0 (4.31)
95% CL	[68.65; 73.25]
Min-Max	63.064 - 81.082
Median	70.0
Q1-Q3	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	56.50 (18.297)
Min-Max	20 - 87
Median	57.00
Q1-Q3	42.50 - 70.00
After 12 weeks	
n	17
Mean (SD)	64.82 (24.370)
Min-Max	17 - 94
Median	75.00
Q1-Q3	53.00 - 79.00
Absolute change after approx. 12 weeks	
n	17
Mean (SD)	5.06 (18.660)
Min-Max	-51 - 26
Median	9.00
Q1-Q3	5.00 - 15.00
T-Test	t= 1.12 P= 0.280
After 24 weeks	
n	16
Mean (SD)	74.50 (11.177)
Min-Max	46 - 88
Median	77.50
Q1-Q3	71.00 - 81.00
Absolute change after approx. 24 weeks	
n	16
Mean (SD)	15.19 (16.429)
Min-Max	-14 - 48
Median	13.00

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	FGM (N = 20)
Q1-Q3	7.50 - 24.00
T-Test	t= 3.70 P= 0.002

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	36.50 (16.472)
Min-Max	9 - 75
Median	34.00
Q1-Q3	26.00 - 45.00
After 12 weeks	
n	17
Mean (SD)	31.82 (23.755)
Min-Max	6 - 80
Median	25.00
Q1-Q3	18.00 - 41.00
Absolute change after approx. 12 weeks	
n	17
Mean (SD)	-0.94 (19.354)
Min-Max	-21 - 53
Median	-7.00
Q1-Q3	-10.00 - 0.00
T-Test	t= -0.20 P= 0.844
After 24 weeks	
n	16
Mean (SD)	22.56 (10.250)
Min-Max	10 - 54
Median	22.00
Q1-Q3	16.50 - 25.50
Absolute change after approx. 24 weeks	
n	16
Mean (SD)	-10.19 (13.566)
Min-Max	-43 - 16
Median	-11.00

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	FGM (N = 20)
Q1-Q3	-15.00 - -5.00
T-Test	t= -3.00 P= 0.009

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	FGM (N = 20)
Baseline	
n	20
Mean (SD)	6.85 (8.139)
Min-Max	0 - 25
Median	4.50
Q1-Q3	0.00 - 11.00
After 12 weeks	
n	17
Mean (SD)	3.35 (6.773)
Min-Max	0 - 20
Median	0.00
Q1-Q3	0.00 - 3.00
Absolute change after approx. 12 weeks	
n	17
Mean (SD)	-4.12 (6.489)
Min-Max	-22 - 0
Median	-2.00
Q1-Q3	-5.00 - 0.00
T-Test	t= -2.62 P= 0.019
After 24 weeks	
n	16
Mean (SD)	3.50 (6.066)
Min-Max	0 - 20
Median	0.00
Q1-Q3	0.00 - 4.00
Absolute change after approx. 24 weeks	
n	16
Mean (SD)	-4.44 (5.715)
Min-Max	-17 - 2
Median	-2.50

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.2 Change in total time
5.1.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	FGM (N = 20)
Q1-Q3	-5.00 - 0.00
T-Test	t= -3.11 P= 0.007

5 Effectiveness (Additional for FGM patients)
5.1 Full Analysis Set - FGM
5.1.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.1 Median target blood glucose and limit value for low glucose
5.2.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	134.7 (12.44)	142.5 (14.44)
95% CL	[124.25;145.06]	[133.34;151.68]
Min-Max	117.12 - 154	120 - 154
Median	140.0	152.0
Q1-Q3	123.1 - 140.0	128.1 - 154.0
After 12 weeks		
n	7	10
Mean (SD)	130.5 (9.83)	133.6 (14.47)
95% CL	[121.38;139.55]	[123.26;143.96]
Min-Max	117.12 - 150	120 - 150
Median	130.0	128.1
Q1-Q3	126.1 - 130.0	120.0 - 150.0
After 24 weeks		
n	7	9
Mean (SD)	130.3 (12.79)	143.3 (16.27)
95% CL	[118.49;142.15]	[130.84;155.85]
Min-Max	117.12 - 154	115 - 154
Median	126.1	154.0
Q1-Q3	120.0 - 140.0	126.1 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.1 Median target blood glucose and limit value for low glucose
5.2.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	70.4 (8.87)	68.6 (3.36)
95% CL	[62.98; 77.81]	[66.45; 70.72]
Min-Max	60 - 90.091	60 - 70
Median	70.0	70.0
Q1-Q3	66.5 - 70.0	70.0 - 70.0
After 12 weeks		
n	7	10
Mean (SD)	73.7 (7.54)	71.1 (5.87)
95% CL	[66.71; 80.65]	[66.91; 75.31]
Min-Max	70 - 90.091	60 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 75.7	70.0 - 70.0
After 24 weeks		
n	7	9
Mean (SD)	70.6 (5.30)	71.2 (3.69)
95% CL	[65.69; 75.49]	[68.39; 74.07]
Min-Max	63.064 - 81.082	70 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	48.50 (18.330)	61.83 (16.937)
Min-Max	20 - 71	35 - 87
Median	48.50	63.00
Q1-Q3	35.00 - 65.00	48.50 - 74.50
After 12 weeks		
n	7	10
Mean (SD)	62.71 (24.905)	66.30 (25.228)
Min-Max	17 - 92	26 - 94
Median	75.00	70.00
Q1-Q3	45.00 - 75.00	53.00 - 91.00
Absolute change after approx. 12 weeks		
n	7	10
Mean (SD)	10.14 (12.375)	1.50 (21.971)
Min-Max	-13 - 23	-51 - 26
Median	15.00	8.00
Q1-Q3	5.00 - 21.00	-8.00 - 10.00
T-Test	t= 2.17 P= 0.073	t= 0.22 P= 0.834
After 24 weeks		
n	7	9
Mean (SD)	72.29 (9.214)	76.22 (12.765)
Min-Max	55 - 80	46 - 88
Median	78.00	77.00
Q1-Q3	65.00 - 78.00	75.00 - 84.00
Absolute change after approx. 24 weeks		
n	7	9
Mean (SD)	19.71 (14.430)	11.67 (17.833)
Min-Max	7 - 48	-14 - 43
Median	15.00	9.00

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	Female (N = 8)	Male (N = 12)
Q1-Q3	8.00 - 28.00	5.00 - 20.00
T-Test	t= 3.61 P= 0.011	t= 1.96 P= 0.085

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	40.00 (16.204)	34.17 (16.932)
Min-Max	25 - 75	9 - 60
Median	37.50	32.50
Q1-Q3	27.50 - 45.00	22.00 - 47.00
After 12 weeks		
n	7	10
Mean (SD)	32.00 (22.774)	31.70 (25.639)
Min-Max	8 - 80	6 - 74
Median	25.00	21.50
Q1-Q3	21.00 - 35.00	9.00 - 47.00
Absolute change after approx. 12 weeks		
n	7	10
Mean (SD)	-3.00 (17.898)	0.50 (21.136)
Min-Max	-19 - 35	-21 - 53
Median	-7.00	-7.00
Q1-Q3	-15.00 - 0.00	-10.00 - 8.00
T-Test	t= -0.44 P= 0.673	t= 0.07 P= 0.942
After 24 weeks		
n	7	9
Mean (SD)	23.43 (4.077)	21.89 (13.541)
Min-Max	17 - 30	10 - 54
Median	22.00	18.00
Q1-Q3	22.00 - 26.00	13.00 - 23.00
Absolute change after approx. 24 weeks		
n	7	9
Mean (SD)	-11.57 (6.803)	-9.11 (17.532)
Min-Max	-23 - -3	-43 - 16
Median	-11.00	-11.00

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	Female (N = 8)	Male (N = 12)
Q1-Q3	-15.00 - -5.00	-15.00 - -5.00
T-Test	t= -4.50 P= 0.004	t= -1.56 P= 0.158

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	Female (N = 8)	Male (N = 12)
Baseline		
n	8	12
Mean (SD)	11.50 (8.832)	3.75 (6.210)
Min-Max	2 - 25	0 - 20
Median	7.50	1.00
Q1-Q3	5.00 - 20.00	0.00 - 4.50
After 12 weeks		
n	7	10
Mean (SD)	5.29 (7.410)	2.00 (6.325)
Min-Max	0 - 20	0 - 20
Median	3.00	0.00
Q1-Q3	0.00 - 10.00	0.00 - 0.00
Absolute change after approx. 12 weeks		
n	7	10
Mean (SD)	-7.14 (8.533)	-2.00 (3.771)
Min-Max	-22 - 0	-12 - 0
Median	-5.00	0.00
Q1-Q3	-16.00 - 0.00	-2.00 - 0.00
T-Test	t= -2.21 P= 0.069	t= -1.68 P= 0.128
After 24 weeks		
n	7	9
Mean (SD)	5.57 (7.091)	1.89 (4.961)
Min-Max	0 - 20	0 - 15
Median	3.00	0.00
Q1-Q3	0.00 - 9.00	0.00 - 0.00
Absolute change after approx. 24 weeks		
n	7	9
Mean (SD)	-6.86 (6.817)	-2.56 (4.157)
Min-Max	-17 - 0	-12 - 2
Median	-5.00	-2.00

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.2 Change in total time
5.2.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	Female (N = 8)	Male (N = 12)
Q1-Q3	-16.00 - -2.00	-4.00 - 0.00
T-Test	t= -2.66 P= 0.037	t= -1.84 P= 0.102

5 Effectiveness (Additional for FGM patients)
5.2 Full Analysis Set - Subgroups - Gender
5.2.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.1 Median target blood glucose and limit value for low glucose
5.3.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	139.7 (15.50)	137.2 (13.67)	145.0 (7.07)
95% CL	[129.32;150.15]	[124.54;149.82]	[81.47;208.53]
Min-Max	117.12 - 154	120 - 154	140 - 150
Median	140.0	140.0	145.0
Q1-Q3	120.0 - 154.0	126.1 - 154.0	140.0 - 150.0
After 12 weeks			
n	9	7	1
Mean (SD)	131.9 (14.29)	130.3 (9.39)	150.0
95% CL	[120.92;142.89]	[121.64;139.01]	
Min-Max	117.12 - 150	120 - 150	150 - 150
Median	130.0	130.0	150.0
Q1-Q3	120.0 - 150.0	126.1 - 130.0	150.0 - 150.0
After 24 weeks			
n	8	7	1
Mean (SD)	137.9 (17.82)	135.0 (14.31)	154.0
95% CL	[122.99;152.78]	[121.80;148.28]	
Min-Max	115 - 154	120 - 154	154 - 154
Median	142.0	126.1	154.0
Q1-Q3	121.1 - 154.0	125.0 - 154.0	154.0 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.1 Median target blood glucose and limit value for low glucose
5.3.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	67.6 (4.27)	71.9 (8.44)	70.0 (0.00)
95% CL	[64.68; 70.42]	[64.08; 79.68]	
Min-Max	60 - 70	63.064 - 90.091	70 - 70
Median	70.0	70.0	70.0
Q1-Q3	63.1 - 70.0	70.0 - 70.0	70.0 - 70.0
After 12 weeks			
n	9	7	1
Mean (SD)	69.5 (4.03)	75.9 (8.00)	70.0
95% CL	[66.42; 72.62]	[68.48; 83.28]	
Min-Max	60 - 75.676	70 - 90.091	70 - 70
Median	70.0	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 81.1	70.0 - 70.0
After 24 weeks			
n	8	7	1
Mean (SD)	69.1 (2.45)	73.2 (5.41)	70.0
95% CL	[67.08; 71.18]	[68.17; 78.17]	
Min-Max	63.064 - 70	70 - 81.082	70 - 70
Median	70.0	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 81.1	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	52.64 (17.688)	58.29 (19.508)	71.50 (17.678)
Min-Max	20 - 71	30 - 87	59 - 84
Median	53.00	55.00	71.50
Q1-Q3	40.00 - 70.00	45.00 - 79.00	59.00 - 84.00
After 12 weeks			
n	9	7	1
Mean (SD)	66.44 (22.227)	58.71 (27.299)	93.00 ( )
Min-Max	26 - 92	17 - 94	93 - 93
Median	75.00	62.00	93.00
Q1-Q3	53.00 - 79.00	28.00 - 75.00	93.00 - 93.00
Absolute change after approx. 12 weeks			
n	9	7	1
Mean (SD)	8.22 (13.553)	0.43 (25.317)	9.00 ( )
Min-Max	-15 - 26	-51 - 23	9 - 9
Median	9.00	7.00	9.00
Q1-Q3	5.00 - 21.00	-13.00 - 15.00	9.00 - 9.00
T-Test	t= 1.82 P= 0.106	t= 0.04 P= 0.966	t= P=
After 24 weeks			
n	8	7	1
Mean (SD)	73.38 (14.716)	76.43 (7.091)	70.00 ( )
Min-Max	46 - 87	65 - 88	70 - 70
Median	78.00	77.00	70.00
Q1-Q3	66.00 - 83.00	72.00 - 80.00	70.00 - 70.00
Absolute change after approx. 24 weeks			
n	8	7	1
Mean (SD)	16.25 (13.188)	18.14 (17.837)	-14.00 ( )
Min-Max	5 - 43	-10 - 48	-14 - -14
Median	11.50	20.00	-14.00

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Q1-Q3	7.50 - 22.00	9.00 - 28.00	-14.00 --14.00
T-Test	t= 3.49 P= 0.010	t= 2.69 P= 0.036	t= P=

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	42.91 (16.676)	29.43 (13.315)	26.00 (16.971)
Min-Max	25 - 75	9 - 45	14 - 38
Median	35.00	28.00	26.00
Q1-Q3	30.00 - 59.00	19.00 - 45.00	14.00 - 38.00
After 12 weeks			
n	9	7	1
Mean (SD)	31.33 (20.767)	36.00 (28.396)	7.00 ( )
Min-Max	8 - 74	6 - 80	7 - 7
Median	25.00	25.00	7.00
Q1-Q3	21.00 - 41.00	18.00 - 72.00	7.00 - 7.00
Absolute change after approx. 12 weeks			
n	9	7	1
Mean (SD)	-6.11 (12.025)	6.57 (26.343)	-7.00 ( )
Min-Max	-21 - 15	-15 - 53	-7 - -7
Median	-9.00	-7.00	-7.00
Q1-Q3	-14.00 - 0.00	-10.00 - 35.00	-7.00 - -7.00
T-Test	t= -1.52 P= 0.166	t= 0.66 P= 0.534	t= P=
After 24 weeks			
n	8	7	1
Mean (SD)	23.88 (12.755)	20.00 (7.326)	30.00 ( )
Min-Max	13 - 54	10 - 30	30 - 30
Median	21.50	22.00	30.00
Q1-Q3	17.00 - 23.50	12.00 - 26.00	30.00 - 30.00
Absolute change after approx. 24 weeks			
n	8	7	1
Mean (SD)	-14.13 (12.778)	-9.43 (11.574)	16.00 ( )
Min-Max	-43 - -3	-23 - 14	16 - 16
Median	-12.50	-11.00	16.00

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Q1-Q3	-16.00 - -5.00	-15.00 - -7.00	16.00 - 16.00
T-Test	t= -3.13 P= 0.017	t= -2.16 P= 0.075	t= P=

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Baseline			
n	11	7	2
Mean (SD)	4.45 (6.362)	12.29 (9.250)	1.00 (1.414)
Min-Max	0 - 20	2 - 25	0 - 2
Median	2.00	10.00	1.00
Q1-Q3	0.00 - 5.00	4.00 - 20.00	0.00 - 2.00
After 12 weeks			
n	9	7	1
Mean (SD)	2.22 (6.667)	5.29 (7.410)	0.00 ( )
Min-Max	0 - 20	0 - 20	0 - 0
Median	0.00	3.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 10.00	0.00 - 0.00
Absolute change after approx. 12 weeks			
n	9	7	1
Mean (SD)	-2.11 (4.076)	-7.00 (8.583)	-2.00 ( )
Min-Max	-12 - 0	-22 - 0	-2 - -2
Median	0.00	-4.00	-2.00
Q1-Q3	-2.00 - 0.00	-16.00 - 0.00	-2.00 - -2.00
T-Test	t= -1.55 P= 0.159	t= -2.16 P= 0.074	t= P=
After 24 weeks			
n	8	7	1
Mean (SD)	2.75 (7.005)	4.86 (5.460)	0.00 ( )
Min-Max	0 - 20	0 - 15	0 - 0
Median	0.00	3.00	0.00
Q1-Q3	0.00 - 1.00	0.00 - 9.00	0.00 - 0.00
Absolute change after approx. 24 weeks			
n	8	7	1
Mean (SD)	-2.13 (4.486)	-7.43 (6.294)	-2.00 ( )
Min-Max	-12 - 2	-17 - -2	-2 - -2
Median	0.00	-5.00	-2.00

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.2 Change in total time
5.3.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<= 60 years (N = 11)	>60 - <70 years (N = 7)	>=70 years (N = 2)
Q1-Q3	-3.50 - 0.00	-16.00 - -3.00	-2.00 - -2.00
T-Test	t= -1.34 P= 0.222	t= -3.12 P= 0.021	t= P=

5 Effectiveness (Additional for FGM patients)
5.3 Full Analysis Set - Subgroups - Age groups
5.3.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.1 Median target blood glucose and limit value for low glucose
5.4.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	138.5 (13.99)	139.6 (14.33)
95% CL	[116.24;160.76]	[131.95;147.22]
Min-Max	120 - 154	117.12 - 154
Median	140.0	140.0
Q1-Q3	130.0 - 147.0	126.1 - 154.0
After 12 weeks		
n	3	14
Mean (SD)	126.7 (5.77)	133.5 (13.36)
95% CL	[112.32;141.01]	[125.81;141.24]
Min-Max	120 - 130	117.12 - 150
Median	130.0	130.0
Q1-Q3	120.0 - 130.0	120.0 - 150.0
After 24 weeks		
n	3	13
Mean (SD)	136.3 (15.50)	138.0 (16.53)
95% CL	[97.82;174.84]	[127.96;147.94]
Min-Max	125 - 154	115 - 154
Median	130.0	140.0
Q1-Q3	125.0 - 154.0	125.0 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.1 Median target blood glucose and limit value for low glucose
5.4.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	67.5 (5.00)	69.8 (6.32)
95% CL	[59.54; 75.46]	[66.40; 73.13]
Min-Max	60 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	65.0 - 70.0	70.0 - 70.0
After 12 weeks		
n	3	14
Mean (SD)	70.0 (0.00)	72.6 (7.13)
95% CL		[68.51; 76.75]
Min-Max	70 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 75.7
After 24 weeks		
n	3	13
Mean (SD)	70.0 (0.00)	71.2 (4.79)
95% CL		[68.27; 74.07]
Min-Max	70 - 70	63.064 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	40.25 (21.608)	60.56 (15.578)
Min-Max	20 - 70	35 - 87
Median	35.50	59.50
Q1-Q3	25.00 - 55.50	48.50 - 70.50
After 12 weeks		
n	3	14
Mean (SD)	39.33 (31.214)	70.29 (19.975)
Min-Max	17 - 75	28 - 94
Median	26.00	75.00
Q1-Q3	17.00 - 75.00	59.00 - 91.00
Absolute change after approx. 12 weeks		
n	3	14
Mean (SD)	-7.67 (11.015)	7.79 (19.092)
Min-Max	-15 - 5	-51 - 26
Median	-13.00	9.50
Q1-Q3	-15.00 - 5.00	7.00 - 21.00
T-Test	t= -1.21 P= 0.351	t= 1.53 P= 0.151
After 24 weeks		
n	3	13
Mean (SD)	67.33 (18.475)	76.15 (9.136)
Min-Max	46 - 78	55 - 88
Median	78.00	77.00
Q1-Q3	46.00 - 78.00	72.00 - 82.00
Absolute change after approx. 24 weeks		
n	3	13
Mean (SD)	20.33 (24.007)	14.00 (15.270)
Min-Max	5 - 48	-14 - 43
Median	8.00	14.00

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Q1-Q3	5.00 - 48.00	9.00 - 20.00
T-Test	t= 1.47 P= 0.280	t= 3.31 P= 0.006

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	51.00 (21.229)	32.88 (13.544)
Min-Max	25 - 75	9 - 60
Median	52.00	32.50
Q1-Q3	35.00 - 67.00	26.00 - 39.00
After 12 weeks		
n	3	14
Mean (SD)	59.67 (30.172)	25.86 (18.363)
Min-Max	25 - 80	6 - 72
Median	74.00	21.50
Q1-Q3	25.00 - 80.00	9.00 - 35.00
Absolute change after approx. 12 weeks		
n	3	14
Mean (SD)	16.67 (17.559)	-4.71 (18.074)
Min-Max	0 - 35	-21 - 53
Median	15.00	-8.00
Q1-Q3	0.00 - 35.00	-14.00 - -5.00
T-Test	t= 1.64 P= 0.242	t= -0.98 P= 0.347
After 24 weeks		
n	3	13
Mean (SD)	32.67 (18.475)	20.23 (6.559)
Min-Max	22 - 54	10 - 30
Median	22.00	21.00
Q1-Q3	22.00 - 54.00	16.00 - 25.00
Absolute change after approx. 24 weeks		
n	3	13
Mean (SD)	-10.33 (11.015)	-10.15 (14.485)
Min-Max	-23 - -3	-43 - 16
Median	-5.00	-11.00

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Q1-Q3	-23.00 - -3.00	-15.00 - -7.00
T-Test	t= -1.62 P= 0.246	t= -2.53 P= 0.027

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Baseline		
n	4	16
Mean (SD)	8.75 (11.087)	6.38 (7.623)
Min-Max	0 - 25	0 - 20
Median	5.00	3.00
Q1-Q3	2.50 - 15.00	0.00 - 11.00
After 12 weeks		
n	3	14
Mean (SD)	1.00 (1.732)	3.86 (7.378)
Min-Max	0 - 3	0 - 20
Median	0.00	0.00
Q1-Q3	0.00 - 3.00	0.00 - 4.00
Absolute change after approx. 12 weeks		
n	3	14
Mean (SD)	-9.00 (11.533)	-3.07 (4.969)
Min-Max	-22 - 0	-16 - 0
Median	-5.00	-1.00
Q1-Q3	-22.00 - 0.00	-4.00 - 0.00
T-Test	t= -1.35 P= 0.309	t= -2.31 P= 0.038
After 24 weeks		
n	3	13
Mean (SD)	3.00 (5.196)	3.62 (6.436)
Min-Max	0 - 9	0 - 20
Median	0.00	0.00
Q1-Q3	0.00 - 9.00	0.00 - 3.00
Absolute change after approx. 24 weeks		
n	3	13
Mean (SD)	-7.00 (8.185)	-3.85 (5.257)
Min-Max	-16 - 0	-17 - 2
Median	-5.00	-2.00

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.2 Change in total time
5.4.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<30 kg/m² (N = 4)	>=30 kg/m² (N = 16)
Q1-Q3	-16.00 - 0.00	-5.00 - 0.00
T-Test	t= -1.48 P= 0.277	t= -2.64 P= 0.022

5 Effectiveness (Additional for FGM patients)
5.4 Full Analysis Set - Subgroups - Body Mass Index
5.4.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.1 Median target blood glucose and limit value for low glucose
5.5.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	141.3 (18.58)	140.9 (13.29)
95% CL	[95.17;187.50]	[133.53;148.25]
Min-Max	120 - 154	117.12 - 154
Median	150.0	140.0
Q1-Q3	120.0 - 154.0	126.1 - 154.0
After 12 weeks		
n	3	12
Mean (SD)	133.3 (15.28)	133.3 (13.03)
95% CL	[95.39;171.28]	[125.00;141.56]
Min-Max	120 - 150	117.12 - 150
Median	130.0	130.0
Q1-Q3	120.0 - 150.0	123.1 - 150.0
After 24 weeks		
n	3	11
Mean (SD)	144.3 (16.74)	139.0 (15.42)
95% CL	[102.74;185.93]	[128.67;149.39]
Min-Max	125 - 154	117.12 - 154
Median	154.0	140.0
Q1-Q3	125.0 - 154.0	126.1 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.1 Median target blood glucose and limit value for low glucose
5.5.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	70.0 (0.00)	69.1 (7.01)
95% CL		[65.20; 72.96]
Min-Max	70 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	63.1 - 70.0
After 12 weeks		
n	3	12
Mean (SD)	70.0 (0.00)	73.1 (7.66)
95% CL		[68.20; 77.94]
Min-Max	70 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 77.8
After 24 weeks		
n	3	11
Mean (SD)	70.0 (0.00)	71.4 (5.22)
95% CL		[67.88; 74.89]
Min-Max	70 - 70	63.064 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	51.67 (28.537)	56.93 (17.958)
Min-Max	30 - 84	20 - 87
Median	41.00	59.00
Q1-Q3	30.00 - 84.00	44.00 - 70.00
After 12 weeks		
n	3	12
Mean (SD)	45.33 (41.525)	67.42 (20.133)
Min-Max	17 - 93	28 - 94
Median	26.00	68.50
Q1-Q3	17.00 - 93.00	56.00 - 83.00
Absolute change after approx. 12 weeks		
n	3	12
Mean (SD)	-6.33 (13.317)	5.75 (19.905)
Min-Max	-15 - 9	-51 - 23
Median	-13.00	8.00
Q1-Q3	-15.00 - 9.00	5.00 - 18.00
T-Test	t= -0.82 P= 0.497	t= 1.00 P= 0.338
After 24 weeks		
n	3	11
Mean (SD)	64.67 (16.653)	76.27 (9.655)
Min-Max	46 - 78	55 - 88
Median	70.00	78.00
Q1-Q3	46.00 - 78.00	72.00 - 84.00
Absolute change after approx. 24 weeks		
n	3	11
Mean (SD)	13.00 (31.765)	15.09 (13.368)
Min-Max	-14 - 48	-10 - 43
Median	5.00	14.00

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Q1-Q3	-14.00 - 48.00	8.00 - 20.00
T-Test	t= 0.71 P= 0.552	t= 3.74 P= 0.004

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	39.33 (23.029)	36.33 (17.003)
Min-Max	14 - 59	9 - 75
Median	45.00	33.00
Q1-Q3	14.00 - 59.00	25.00 - 45.00
After 12 weeks		
n	3	12
Mean (SD)	53.67 (40.526)	28.08 (18.904)
Min-Max	7 - 80	6 - 72
Median	74.00	25.00
Q1-Q3	7.00 - 80.00	13.50 - 38.00
Absolute change after approx. 12 weeks		
n	3	12
Mean (SD)	14.33 (21.008)	-2.92 (19.332)
Min-Max	-7 - 35	-21 - 53
Median	15.00	-7.00
Q1-Q3	-7.00 - 35.00	-12.50 - -1.50
T-Test	t= 1.18 P= 0.359	t= -0.52 P= 0.612
After 24 weeks		
n	3	11
Mean (SD)	35.33 (16.653)	19.64 (6.439)
Min-Max	22 - 54	10 - 30
Median	30.00	22.00
Q1-Q3	22.00 - 54.00	13.00 - 25.00
Absolute change after approx. 24 weeks		
n	3	11
Mean (SD)	-4.00 (19.519)	-11.18 (13.512)
Min-Max	-23 - 16	-43 - 14
Median	-5.00	-11.00

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Q1-Q3	-23.00 - 16.00	-15.00 - -5.00
T-Test	t= -0.35 P= 0.757	t= -2.74 P= 0.021

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Baseline		
n	3	15
Mean (SD)	9.00 (13.892)	6.53 (7.482)
Min-Max	0 - 25	0 - 20
Median	2.00	5.00
Q1-Q3	0.00 - 25.00	0.00 - 10.00
After 12 weeks		
n	3	12
Mean (SD)	1.00 (1.732)	4.50 (7.822)
Min-Max	0 - 3	0 - 20
Median	0.00	0.00
Q1-Q3	0.00 - 3.00	0.00 - 7.00
Absolute change after approx. 12 weeks		
n	3	12
Mean (SD)	-8.00 (12.166)	-2.83 (4.609)
Min-Max	-22 - 0	-16 - 0
Median	-2.00	-1.00
Q1-Q3	-22.00 - 0.00	-4.50 - 0.00
T-Test	t= -1.14 P= 0.373	t= -2.13 P= 0.057
After 24 weeks		
n	3	11
Mean (SD)	3.00 (5.196)	4.09 (6.920)
Min-Max	0 - 9	0 - 20
Median	0.00	0.00
Q1-Q3	0.00 - 9.00	0.00 - 5.00
Absolute change after approx. 24 weeks		
n	3	11
Mean (SD)	-6.00 (8.718)	-3.91 (4.784)
Min-Max	-16 - 0	-17 - 0
Median	-2.00	-3.00

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.2 Change in total time
5.5.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<=60 ml/min/1.73 m² (N = 3)	>60 ml/min/1.73 m² (N = 15)
Q1-Q3	-16.00 - 0.00	-5.00 - 0.00
T-Test	t= -1.19 P= 0.355	t= -2.71 P= 0.022

5 Effectiveness (Additional for FGM patients)
5.5 Full Analysis Set - Subgroups - Renal function
5.5.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.1 Median target blood glucose and limit value for low glucose
5.6.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	154.0	141.2 (13.97)	138.9 (13.30)
95% CL		[128.24;154.08]	[129.99;147.85]
Min-Max	154 - 154	120 - 154	120 - 154
Median	154.0	140.0	140.0
Q1-Q3	154.0 - 154.0	126.1 - 154.0	126.1 - 154.0
After 12 weeks			
n	1	5	10
Mean (SD)	150.0	129.2 (12.37)	133.6 (11.95)
95% CL		[113.87;144.58]	[125.07;142.16]
Min-Max	150 - 150	120 - 150	120 - 150
Median	150.0	126.1	130.0
Q1-Q3	150.0 - 150.0	120.0 - 130.0	126.1 - 150.0
After 24 weeks			
n	1	5	9
Mean (SD)	154.0	143.6 (14.27)	134.8 (15.86)
95% CL		[125.90;161.35]	[122.60;146.98]
Min-Max	154 - 154	126.13 - 154	115 - 154
Median	154.0	154.0	126.1
Q1-Q3	154.0 - 154.0	130.0 - 154.0	125.0 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.1 Median target blood glucose and limit value for low glucose
5.6.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	70.0	66.2 (4.91)	71.8 (6.06)
95% CL		[61.61; 70.69]	[67.76; 75.90]
Min-Max	70 - 70	60 - 70	70 - 90.091
Median	70.0	70.0	70.0
Q1-Q3	70.0 - 70.0	60.0 - 70.0	70.0 - 70.0
After 12 weeks			
n	1	5	10
Mean (SD)	70.0	70.2 (7.46)	73.0 (6.77)
95% CL		[60.95; 79.48]	[68.16; 77.86]
Min-Max	70 - 70	60 - 81.082	70 - 90.091
Median	70.0	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0	70.0 - 70.0
After 24 weeks			
n	1	5	9
Mean (SD)	70.0	72.2 (4.96)	71.2 (3.69)
95% CL		[66.06; 78.37]	[68.39; 74.07]
Min-Max	70 - 70	70 - 81.082	70 - 81.082
Median	70.0	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	71.00 ( )	47.86 (18.416)	62.18 (17.221)
Min-Max	71 - 71	20 - 70	30 - 87
Median	71.00	44.00	60.00
Q1-Q3	71.00 - 71.00	35.00 - 70.00	52.00 - 79.00
After 12 weeks			
n	1	5	10
Mean (SD)	92.00 ( )	61.40 (24.419)	65.80 (25.642)
Min-Max	92 - 92	26 - 91	17 - 94
Median	92.00	62.00	75.00
Q1-Q3	92.00 - 92.00	53.00 - 75.00	59.00 - 79.00
Absolute change after approx. 12 weeks			
n	1	5	10
Mean (SD)	21.00 ( )	5.40 (12.992)	3.30 (22.633)
Min-Max	21 - 21	-15 - 21	-51 - 26
Median	21.00	7.00	9.50
Q1-Q3	21.00 - 21.00	5.00 - 9.00	-8.00 - 15.00
T-Test	t= P=	t= 0.93 P= 0.405	t= 0.46 P= 0.656
After 24 weeks			
n	1	5	9
Mean (SD)	78.00 ( )	74.00 (16.355)	76.56 (6.821)
Min-Max	78 - 78	46 - 87	65 - 88
Median	78.00	78.00	77.00
Q1-Q3	78.00 - 78.00	75.00 - 84.00	72.00 - 80.00
Absolute change after approx. 24 weeks			
n	1	5	9
Mean (SD)	7.00 ( )	18.00 (15.116)	14.56 (19.443)
Min-Max	7 - 7	5 - 43	-14 - 48
Median	7.00	14.00	12.00

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Q1-Q3	7.00 - 7.00	8.00 - 20.00	9.00 - 28.00
T-Test	t= P=	t= 2.66 P= 0.056	t= 2.25 P= 0.055

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	27.00 ( )	47.14 (20.145)	30.27 (11.824)
Min-Max	27 - 27	25 - 75	9 - 45
Median	27.00	56.00	33.00
Q1-Q3	27.00 - 27.00	25.00 - 60.00	19.00 - 38.00
After 12 weeks			
n	1	5	10
Mean (SD)	8.00 ( )	34.60 (26.121)	32.50 (25.119)
Min-Max	8 - 8	9 - 74	6 - 80
Median	8.00	25.00	23.50
Q1-Q3	8.00 - 8.00	18.00 - 47.00	21.00 - 41.00
Absolute change after approx. 12 weeks			
n	1	5	10
Mean (SD)	-19.00 ( )	-4.40 (13.221)	3.00 (22.940)
Min-Max	-19 - -19	-21 - 15	-15 - 53
Median	-19.00	-7.00	-7.00
Q1-Q3	-19.00 - -19.00	-9.00 - 0.00	-10.00 - 8.00
T-Test	t= P=	t= -0.74 P= 0.498	t= 0.41 P= 0.689
After 24 weeks			
n	1	5	9
Mean (SD)	22.00 ( )	23.00 (17.889)	22.11 (5.988)
Min-Max	22 - 22	10 - 54	12 - 30
Median	22.00	16.00	22.00
Q1-Q3	22.00 - 22.00	13.00 - 22.00	18.00 - 26.00
Absolute change after approx. 24 weeks			
n	1	5	9
Mean (SD)	-5.00 ( )	-16.00 (16.000)	-7.00 (13.351)
Min-Max	-5 - -5	-43 - -3	-23 - 16
Median	-5.00	-14.00	-11.00

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Q1-Q3	-5.00 - -5.00	-15.00 - -5.00	-15.00 - -7.00
T-Test	t= P=	t= -2.24 P= 0.089	t= -1.57 P= 0.154

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Baseline			
n	1	7	11
Mean (SD)	2.00 ( )	5.00 (7.071)	7.27 (8.580)
Min-Max	2 - 2	0 - 20	0 - 25
Median	2.00	5.00	4.00
Q1-Q3	2.00 - 2.00	0.00 - 5.00	0.00 - 12.00
After 12 weeks			
n	1	5	10
Mean (SD)	0.00 ( )	4.00 (8.944)	1.70 (3.268)
Min-Max	0 - 0	0 - 20	0 - 10
Median	0.00	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00	0.00 - 3.00
Absolute change after approx. 12 weeks			
n	1	5	10
Mean (SD)	-2.00 ( )	-1.00 (2.236)	-6.30 (7.718)
Min-Max	-2 - -2	-5 - 0	-22 - 0
Median	-2.00	0.00	-3.00
Q1-Q3	-2.00 - -2.00	0.00 - 0.00	-12.00 - 0.00
T-Test	t= P=	t= -1.00 P= 0.374	t= -2.58 P= 0.030
After 24 weeks			
n	1	5	9
Mean (SD)	0.00 ( )	3.00 (6.708)	2.33 (3.041)
Min-Max	0 - 0	0 - 15	0 - 9
Median	0.00	0.00	2.00
Q1-Q3	0.00 - 0.00	0.00 - 0.00	0.00 - 3.00
Absolute change after approx. 24 weeks			
n	1	5	9
Mean (SD)	-2.00 ( )	-2.00 (2.739)	-6.56 (6.747)
Min-Max	-2 - -2	-5 - 0	-17 - 2
Median	-2.00	0.00	-4.00

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.2 Change in total time
5.6.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	up to 5 years (N = 1)	5 to 10 years (N = 7)	over 10 years (N = 11)
Q1-Q3	-2.00 - -2.00	-5.00 - 0.00	-12.00 - -2.00
T-Test	t= P=	t= -1.63 P= 0.178	t= -2.91 P= 0.019

5 Effectiveness (Additional for FGM patients)
5.6 Full Analysis Set - Subgroups - Duration of diabetes
5.6.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.1 Median target blood glucose and limit value for low glucose
5.7.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	140.2 (14.71)	137.7 (13.22)
95% CL	[131.36;149.14]	[125.51;149.96]
Min-Max	117.12 - 154	120 - 154
Median	140.0	140.0
Q1-Q3	126.1 - 154.0	126.1 - 154.0
After 12 weeks		
n	11	6
Mean (SD)	136.7 (13.39)	124.4 (4.98)
95% CL	[127.66;145.65]	[119.13;129.58]
Min-Max	117.12 - 150	120 - 130
Median	130.0	123.1
Q1-Q3	126.1 - 150.0	120.0 - 130.0
After 24 weeks		
n	10	6
Mean (SD)	140.8 (14.96)	132.4 (17.23)
95% CL	[130.12;151.53]	[114.28;150.43]
Min-Max	117.12 - 154	115 - 154
Median	147.0	125.6
Q1-Q3	126.1 - 154.0	120.0 - 154.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.1 Median target blood glucose and limit value for low glucose
5.7.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	68.2 (3.56)	71.4 (9.03)
95% CL	[66.01; 70.32]	[63.09; 79.79]
Min-Max	60 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0
After 12 weeks		
n	11	6
Mean (SD)	72.4 (4.36)	71.7 (9.87)
95% CL	[69.50; 75.36]	[61.33; 82.04]
Min-Max	70 - 81.082	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 75.7	70.0 - 70.0
After 24 weeks		
n	10	6
Mean (SD)	70.4 (4.34)	71.8 (4.52)
95% CL	[67.31; 73.52]	[67.10; 76.59]
Min-Max	63.064 - 81.082	70 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	62.08 (18.099)	46.14 (14.577)
Min-Max	30 - 87	20 - 68
Median	67.00	45.00
Q1-Q3	55.00 - 71.00	41.00 - 53.00
After 12 weeks		
n	11	6
Mean (SD)	66.45 (27.064)	61.83 (20.469)
Min-Max	17 - 94	26 - 79
Median	75.00	67.50
Q1-Q3	45.00 - 92.00	53.00 - 78.00
Absolute change after approx. 12 weeks		
n	11	6
Mean (SD)	1.64 (20.348)	11.33 (14.597)
Min-Max	-51 - 21	-15 - 26
Median	7.00	12.50
Q1-Q3	-8.00 - 15.00	9.00 - 23.00
T-Test	t= 0.27 P= 0.795	t= 1.90 P= 0.116
After 24 weeks		
n	10	6
Mean (SD)	75.50 (8.898)	72.83 (15.065)
Min-Max	55 - 88	46 - 87
Median	77.50	78.50
Q1-Q3	72.00 - 78.00	65.00 - 82.00
Absolute change after approx. 24 weeks		
n	10	6
Mean (SD)	10.90 (16.901)	22.33 (14.052)
Min-Max	-14 - 48	5 - 43
Median	10.50	24.00

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Q1-Q3	7.00 - 15.00	9.00 - 29.00
T-Test	t= 2.04 P= 0.072	t= 3.89 P= 0.011

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	30.77 (13.516)	47.14 (17.043)
Min-Max	9 - 60	28 - 75
Median	30.00	45.00
Q1-Q3	25.00 - 38.00	32.00 - 59.00
After 12 weeks		
n	11	6
Mean (SD)	29.64 (25.754)	35.83 (21.198)
Min-Max	6 - 80	21 - 74
Median	25.00	26.00
Q1-Q3	8.00 - 41.00	21.00 - 47.00
Absolute change after approx. 12 weeks		
n	11	6
Mean (SD)	2.18 (22.538)	-6.67 (11.039)
Min-Max	-21 - 53	-15 - 15
Median	-5.00	-9.50
Q1-Q3	-10.00 - 8.00	-14.00 - -7.00
T-Test	t= 0.32 P= 0.755	t= -1.48 P= 0.199
After 24 weeks		
n	10	6
Mean (SD)	20.80 (6.286)	25.50 (15.083)
Min-Max	10 - 30	13 - 54
Median	22.00	19.50
Q1-Q3	16.00 - 25.00	17.00 - 30.00
Absolute change after approx. 24 weeks		
n	10	6
Mean (SD)	-6.10 (12.556)	-17.00 (13.387)
Min-Max	-23 - 16	-43 - -5
Median	-8.00	-13.00

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Q1-Q3	-15.00 - -3.00	-17.00 --11.00
T-Test	t= -1.54 P= 0.159	t= -3.11 P= 0.027

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Baseline		
n	13	7
Mean (SD)	6.92 (8.684)	6.71 (7.675)
Min-Max	0 - 25	0 - 20
Median	4.00	5.00
Q1-Q3	2.00 - 5.00	0.00 - 12.00
After 12 weeks		
n	11	6
Mean (SD)	3.91 (8.006)	2.33 (4.082)
Min-Max	0 - 20	0 - 10
Median	0.00	0.00
Q1-Q3	0.00 - 3.00	0.00 - 4.00
Absolute change after approx. 12 weeks		
n	11	6
Mean (SD)	-3.82 (6.337)	-4.67 (7.339)
Min-Max	-22 - 0	-16 - 0
Median	-2.00	0.00
Q1-Q3	-5.00 - 0.00	-12.00 - 0.00
T-Test	t= -2.00 P= 0.074	t= -1.56 P= 0.180
After 24 weeks		
n	10	6
Mean (SD)	4.60 (7.442)	1.67 (2.066)
Min-Max	0 - 20	0 - 5
Median	0.00	1.00
Q1-Q3	0.00 - 9.00	0.00 - 3.00
Absolute change after approx. 24 weeks		
n	10	6
Mean (SD)	-3.90 (4.606)	-5.33 (7.633)
Min-Max	-16 - 0	-17 - 2
Median	-2.50	-2.50

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.2 Change in total time
5.7.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	<8.5% (N = 13)	>=8.5% (N = 7)
Q1-Q3	-5.00 - -2.00	-12.00 - 0.00
T-Test	t= -2.68 P= 0.025	t= -1.71 P= 0.148

5 Effectiveness (Additional for FGM patients)
5.7 Full Analysis Set - Subgroups - Baseline HbA1c
5.7.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.1 Median target blood glucose and limit value for low glucose
5.8.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	128.6 (10.86)	141.8 (15.59)	145.6 (10.43)	140.0
95% CL	[115.16;142.13]	[129.81;153.77]	[132.65;158.55]	
Min-Max	117.12 - 140	120 - 154	130 - 154	140 - 140
Median	126.1	154.0	150.0	140.0
Q1-Q3	120.0 - 140.0	126.1 - 154.0	140.0 - 154.0	140.0 - 140.0
After 12 weeks				
n	5	7	5	0
Mean (SD)	124.6 (5.87)	130.9 (13.60)	142.0 (10.95)	
95% CL	[117.36;131.94]	[118.30;143.45]	[128.40;155.60]	
Min-Max	117.12 - 130	120 - 150	130 - 150	
Median	126.1	126.1	150.0	
Q1-Q3	120.0 - 130.0	120.0 - 150.0	130.0 - 150.0	
After 24 weeks				
n	5	7	4	0
Mean (SD)	123.6 (10.05)	145.9 (13.88)	140.8 (15.44)	
95% CL	[111.17;136.13]	[133.04;158.71]	[116.19;165.31]	
Min-Max	115 - 140	125 - 154	125 - 154	
Median	120.0	154.0	142.0	
Q1-Q3	117.1 - 126.1	126.1 - 154.0	127.5 - 154.0	

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.1 Median target blood glucose and limit value for low glucose
5.8.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	67.2 (3.80)	70.0 (8.69)	70.0 (0.00)	70.0
95% CL	[62.51; 71.94]	[63.33; 76.69]		
Min-Max	63.064 - 70	60 - 90.091	70 - 70	70 - 70
Median	70.0	70.0	70.0	70.0
Q1-Q3	63.1 - 70.0	70.0 - 70.0	70.0 - 70.0	70.0 - 70.0
After 12 weeks				
n	5	7	5	0
Mean (SD)	73.4 (4.97)	72.9 (9.54)	70.0 (0.00)	
95% CL	[67.18; 79.52]	[64.05; 81.69]		
Min-Max	70 - 81.082	60 - 90.091	70 - 70	
Median	70.0	70.0	70.0	
Q1-Q3	70.0 - 75.7	70.0 - 80.0	70.0 - 70.0	
After 24 weeks				
n	5	7	4	0
Mean (SD)	70.8 (6.47)	71.6 (4.19)	70.0 (0.00)	
95% CL	[62.79; 78.86]	[67.71; 75.46]		
Min-Max	63.064 - 81.082	70 - 81.082	70 - 70	
Median	70.0	70.0	70.0	
Q1-Q3	70.0 - 70.0	70.0 - 70.0	70.0 - 70.0	

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	52.00 (7.382)	50.11 (23.122)	72.00 (6.892)	59.00 ( )
Min-Max	40 - 60	20 - 87	67 - 84	59 - 59
Median	53.00	44.00	70.00	59.00
Q1-Q3	52.00 - 55.00	35.00 - 70.00	68.00 - 71.00	59.00 - 59.00
After 12 weeks				
n	5	7	5	0
Mean (SD)	67.20 (13.971)	52.71 (31.154)	79.40 (13.975)	( )
Min-Max	45 - 79	17 - 94	59 - 93	-
Median	75.00	53.00	78.00	
Q1-Q3	62.00 - 75.00	26.00 - 91.00	75.00 - 92.00	-
Absolute change after approx. 12 weeks				
n	5	7	5	0
Mean (SD)	15.20 (9.338)	-3.86 (24.789)	7.40 (10.455)	( )
Min-Max	5 - 26	-51 - 21	-8 - 21	-
Median	15.00	7.00	9.00	
Q1-Q3	7.00 - 23.00	-15.00 - 15.00	5.00 - 10.00	-
T-Test	t= 3.64 P= 0.022	t= -0.41 P= 0.695	t= 1.58 P= 0.189	t= P=
After 24 weeks				
n	5	7	4	0
Mean (SD)	72.80 (10.710)	75.00 (14.989)	75.75 (3.862)	( )
Min-Max	55 - 82	46 - 88	70 - 78	-
Median	75.00	78.00	77.50	
Q1-Q3	72.00 - 80.00	65.00 - 87.00	73.50 - 78.00	-
Absolute change after approx. 24 weeks				
n	5	7	4	0
Mean (SD)	20.80 (7.596)	18.43 (20.727)	2.50 (11.030)	( )
Min-Max	12 - 29	-10 - 48	-14 - 9	-
Median	20.00	14.00	7.50	

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Q1-Q3	15.00 - 28.00	5.00 - 43.00	-3.50 - 8.50	-
T-Test	t= 6.12 P= 0.004	t= 2.35 P= 0.057	t= 0.45 P= 0.681	t= P=

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	32.60 (6.025)	44.22 (21.312)	26.20 (7.596)	38.00 ( )
Min-Max	25 - 40	9 - 75	14 - 33	38 - 38
Median	35.00	45.00	27.00	38.00
Q1-Q3	28.00 - 35.00	30.00 - 59.00	25.00 - 32.00	38.00 - 38.00
After 12 weeks				
n	5	7	5	0
Mean (SD)	24.00 (6.633)	45.43 (31.198)	20.60 (13.975)	( )
Min-Max	18 - 35	6 - 80	7 - 41	-
Median	21.00	47.00	22.00	
Q1-Q3	21.00 - 25.00	9.00 - 74.00	8.00 - 25.00	-
Absolute change after approx. 12 weeks				
n	5	7	5	0
Mean (SD)	-8.60 (3.507)	7.86 (27.637)	-5.60 (10.213)	( )
Min-Max	-14 - -5	-21 - 53	-19 - 8	-
Median	-7.00	-3.00	-7.00	
Q1-Q3	-10.00 - -7.00	-15.00 - 35.00	-10.00 - 0.00	-
T-Test	t= -5.48 P= 0.005	t= 0.75 P= 0.480	t= -1.23 P= 0.287	t= P=
After 24 weeks				
n	5	7	4	0
Mean (SD)	19.20 (6.535)	24.29 (14.545)	23.75 (4.193)	( )
Min-Max	10 - 26	12 - 54	21 - 30	-
Median	18.00	22.00	22.00	
Q1-Q3	17.00 - 25.00	13.00 - 30.00	21.50 - 26.00	-
Absolute change after approx. 24 weeks				
n	5	7	4	0
Mean (SD)	-13.40 (3.286)	-13.29 (17.481)	-0.75 (11.673)	( )
Min-Max	-17 - -9	-43 - 14	-11 - 16	-
Median	-15.00	-14.00	-4.00	

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Q1-Q3	-15.00 --11.00	-23.00 - -5.00	-8.00 - 6.50	-
T-Test	t= -9.12 P= 0.001	t= -2.01 P= 0.091	t= -0.13 P= 0.906	t= P=

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Baseline				
n	5	9	5	1
Mean (SD)	15.40 (6.768)	5.67 (7.953)	1.80 (2.049)	0.00 ( )
Min-Max	5 - 20	0 - 25	0 - 5	0 - 0
Median	20.00	4.00	2.00	0.00
Q1-Q3	12.00 - 20.00	0.00 - 5.00	0.00 - 2.00	0.00 - 0.00
After 12 weeks				
n	5	7	5	0
Mean (SD)	8.80 (10.354)	1.86 (3.761)	0.00 (0.000)	( )
Min-Max	0 - 20	0 - 10	0 - 0	-
Median	4.00	0.00	0.00	
Q1-Q3	0.00 - 20.00	0.00 - 3.00	0.00 - 0.00	-
Absolute change after approx. 12 weeks				
n	5	7	5	0
Mean (SD)	-6.60 (7.197)	-4.00 (8.083)	-1.80 (2.049)	( )
Min-Max	-16 - 0	-22 - 0	-5 - 0	-
Median	-5.00	0.00	-2.00	
Q1-Q3	-12.00 - 0.00	-4.00 - 0.00	-2.00 - 0.00	-
T-Test	t= -2.05 P= 0.110	t= -1.31 P= 0.238	t= -1.96 P= 0.121	t= P=
After 24 weeks				
n	5	7	4	0
Mean (SD)	8.00 (8.916)	2.00 (3.606)	0.50 (1.000)	( )
Min-Max	0 - 20	0 - 9	0 - 2	-
Median	3.00	0.00	0.00	
Q1-Q3	2.00 - 15.00	0.00 - 5.00	0.00 - 1.00	-
Absolute change after approx. 24 weeks				
n	5	7	4	0
Mean (SD)	-7.40 (6.950)	-3.86 (5.728)	-1.75 (2.872)	( )
Min-Max	-17 - 0	-16 - 0	-5 - 2	-
Median	-5.00	-2.00	-2.00	

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.2 Change in total time
5.8.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	Detemir (N = 5)	Glargin 100 (N = 9)	Glargin 300 (N = 5)	Degludec (N = 1)
Q1-Q3	-12.00 - -3.00	-5.00 - 0.00	-3.50 - 0.00	-
T-Test	t= -2.38 P= 0.076	t= -1.78 P= 0.125	t= -1.22 P= 0.310	t= P=

5 Effectiveness (Additional for FGM patients)
5.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
5.8.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.1 Median target blood glucose and limit value for low glucose
5.9.1.1 Median target blood glucose in mg/dL

Median target blood glucose in mg/dL	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	151.4 (5.26)	132.9 (12.72)
95% CL	[146.57;156.29]	[125.19;140.56]
Min-Max	140 - 154	117.12 - 154
Median	154.0	130.0
Q1-Q3	150.0 - 154.0	120.0 - 140.0
After 12 weeks		
n	6	11
Mean (SD)	140.0 (15.49)	128.1 (8.70)
95% CL	[123.74;156.26]	[122.28;133.97]
Min-Max	120 - 150	117.12 - 150
Median	150.0	130.0
Q1-Q3	120.0 - 150.0	120.0 - 130.0
After 24 weeks		
n	5	11
Mean (SD)	154.0 (0.00)	130.2 (13.50)
95% CL		[121.15;139.28]
Min-Max	154 - 154	115 - 154
Median	154.0	126.1
Q1-Q3	154.0 - 154.0	120.0 - 140.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.1 Median target blood glucose and limit value for low glucose
5.9.1.2 Limit value for low glucose

Limit value for low glucose in mg/dL	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	70.0 (0.00)	68.9 (7.56)
95% CL		[64.37; 73.51]
Min-Max	70 - 70	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	63.1 - 70.0
After 12 weeks		
n	6	11
Mean (SD)	71.7 (4.08)	72.4 (7.70)
95% CL	[67.38; 75.95]	[67.27; 77.61]
Min-Max	70 - 80	60 - 90.091
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 75.7
After 24 weeks		
n	5	11
Mean (SD)	70.0 (0.00)	71.4 (5.22)
95% CL		[67.88; 74.89]
Min-Max	70 - 70	63.064 - 81.082
Median	70.0	70.0
Q1-Q3	70.0 - 70.0	70.0 - 70.0

Glucose in mg/dl = Glucose in mmol/l * 18.0182

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	69.57 (15.999)	49.46 (15.772)
Min-Max	41 - 87	20 - 71
Median	70.00	52.00
Q1-Q3	59.00 - 84.00	40.00 - 60.00
After 12 weeks		
n	6	11
Mean (SD)	65.17 (32.332)	64.64 (20.675)
Min-Max	26 - 94	17 - 92
Median	75.00	75.00
Q1-Q3	28.00 - 93.00	53.00 - 78.00
Absolute change after approx. 12 weeks		
n	6	11
Mean (SD)	-6.17 (25.428)	11.18 (10.815)
Min-Max	-51 - 21	-13 - 26
Median	-0.50	10.00
Q1-Q3	-15.00 - 9.00	5.00 - 21.00
T-Test	t= -0.59 P= 0.578	t= 3.43 P= 0.006
After 24 weeks		
n	5	11
Mean (SD)	73.00 (16.583)	75.18 (8.704)
Min-Max	46 - 88	55 - 87
Median	77.00	78.00
Q1-Q3	70.00 - 84.00	72.00 - 80.00
Absolute change after approx. 24 weeks		
n	5	11
Mean (SD)	0.80 (12.194)	21.73 (13.958)
Min-Max	-14 - 14	7 - 48
Median	5.00	20.00

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.1 Absolute change in the total time in the individual target area in %

Absolute change in total time in individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Q1-Q3	-10.00 - 9.00	9.00 - 29.00
T-Test	t= 0.15 P= 0.890	t= 5.16 P= 0.000

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	28.86 (16.945)	40.62 (15.284)
Min-Max	9 - 59	25 - 75
Median	30.00	35.00
Q1-Q3	14.00 - 38.00	28.00 - 45.00
After 12 weeks		
n	6	11
Mean (SD)	34.83 (32.332)	30.18 (19.281)
Min-Max	6 - 74	8 - 80
Median	25.00	25.00
Q1-Q3	7.00 - 72.00	21.00 - 35.00
Absolute change after approx. 12 weeks		
n	6	11
Mean (SD)	7.50 (25.532)	-5.55 (14.397)
Min-Max	-21 - 53	-19 - 35
Median	2.50	-9.00
Q1-Q3	-7.00 - 15.00	-14.00 - -5.00
T-Test	t= 0.72 P= 0.504	t= -1.28 P= 0.230
After 24 weeks		
n	5	11
Mean (SD)	27.00 (16.583)	20.55 (5.768)
Min-Max	12 - 54	10 - 30
Median	23.00	22.00
Q1-Q3	16.00 - 30.00	17.00 - 25.00
Absolute change after approx. 24 weeks		
n	5	11
Mean (SD)	0.80 (13.405)	-15.18 (10.787)
Min-Max	-14 - 16	-43 - -3
Median	-5.00	-15.00

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.2 Absolute change in total time above individual target area in %

Absolute change in total time above individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Q1-Q3	-7.00 - 14.00	-17.00 - -9.00
T-Test	t= 0.13 P= 0.900	t= -4.67 P= 0.001

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Baseline		
n	7	13
Mean (SD)	1.14 (1.574)	9.92 (8.626)
Min-Max	0 - 4	0 - 25
Median	0.00	5.00
Q1-Q3	0.00 - 2.00	5.00 - 20.00
After 12 weeks		
n	6	11
Mean (SD)	0.00 (0.000)	5.18 (7.935)
Min-Max	0 - 0	0 - 20
Median	0.00	0.00
Q1-Q3	0.00 - 0.00	0.00 - 10.00
Absolute change after approx. 12 weeks		
n	6	11
Mean (SD)	-1.33 (1.633)	-5.64 (7.672)
Min-Max	-4 - 0	-22 - 0
Median	-1.00	-2.00
Q1-Q3	-2.00 - 0.00	-12.00 - 0.00
T-Test	t= -2.00 P= 0.102	t= -2.44 P= 0.035
After 24 weeks		
n	5	11
Mean (SD)	0.00 (0.000)	5.09 (6.804)
Min-Max	0 - 0	0 - 20
Median	0.00	2.00
Q1-Q3	0.00 - 0.00	0.00 - 9.00
Absolute change after approx. 24 weeks		
n	5	11
Mean (SD)	-1.60 (1.673)	-5.73 (6.482)
Min-Max	-4 - 0	-17 - 2
Median	-2.00	-5.00

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.2 Change in total time
5.9.2.3 Absolute change in total time below individual target area in %

Absolute change in total time below individual target area in %	before lunch (N = 7)	before dinner (N = 13)
Q1-Q3	-2.00 - 0.00	-12.00 - 0.00
T-Test	t= -2.14 P= 0.099	t= -2.93 P= 0.015

5 Effectiveness (Additional for FGM patients)
5.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
5.9.3 Absolute and relative change in the number of patients with hypoglycaemic events

NOTE

In FGM events of Hypoglycaemia were documented only for 1 patient
See 4.11.1

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.1 Metformin

Metformin	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	1	0	1
no	18 (26.1%)	5 (25.0%)	13 (26.5%)
yes	51 (73.9%)	15 (75.0%)	36 (73.5%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	1
no	19 (27.5%)	4 (20.0%)	15 (30.6%)
yes	50 (72.5%)	16 (80.0%)	34 (69.4%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	8	4	4
no	22 (35.5%)	4 (25.0%)	18 (39.1%)
yes	40 (64.5%)	12 (75.0%)	28 (60.9%)
Non-missing	62 (100.0%)	16 (100.0%)	46 (100.0%)
After 24 weeks			
Missing	11	3	8
no	20 (33.9%)	4 (23.5%)	16 (38.1%)
yes	39 (66.1%)	13 (76.5%)	26 (61.9%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.2 Sulfonyl urea

Sulfonyl urea	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	2	1	1
no	66 (97.1%)	18 (94.7%)	48 (98.0%)
yes	2 (2.9%)	1 (5.3%)	1 (2.0%)
Non-missing	68 (100.0%)	19 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	3	2	1
no	66 (98.5%)	17 (94.4%)	49 (100.0%)
yes	1 (1.5%)	1 (5.6%)	0 (0.0%)
Non-missing	67 (100.0%)	18 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	11	4	7
no	58 (98.3%)	15 (93.8%)	43 (100.0%)
yes	1 (1.7%)	1 (6.3%)	0 (0.0%)
Non-missing	59 (100.0%)	16 (100.0%)	43 (100.0%)
After 24 weeks			
Missing	11	3	8
no	57 (96.6%)	16 (94.1%)	41 (97.6%)
yes	2 (3.4%)	1 (5.9%)	1 (2.4%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.3 Glinide

Glinide	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	1	0	1
no	66 (95.7%)	17 (85.0%)	49 (100.0%)
yes	3 (4.3%)	3 (15.0%)	0 (0.0%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	1
no	65 (94.2%)	17 (85.0%)	48 (98.0%)
yes	4 (5.8%)	3 (15.0%)	1 (2.0%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	9	4	5
no	60 (98.4%)	15 (93.8%)	45 (100.0%)
yes	1 (1.6%)	1 (6.3%)	0 (0.0%)
Non-missing	61 (100.0%)	16 (100.0%)	45 (100.0%)
After 24 weeks			
Missing	11	3	8
no	58 (98.3%)	16 (94.1%)	42 (100.0%)
yes	1 (1.7%)	1 (5.9%)	0 (0.0%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	1	0	1
no	69 (100.0%)	20 (100.0%)	49 (100.0%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	2	1	1
no	68 (100.0%)	19 (100.0%)	49 (100.0%)
Non-missing	68 (100.0%)	19 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	9	4	5
no	61 (100.0%)	16 (100.0%)	45 (100.0%)
Non-missing	61 (100.0%)	16 (100.0%)	45 (100.0%)
After 24 weeks			
Missing	11	3	8
no	59 (100.0%)	17 (100.0%)	42 (100.0%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.5 Glitazone

Glitazone	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	1	0	1
no	69 (100.0%)	20 (100.0%)	49 (100.0%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	2	1	1
no	68 (100.0%)	19 (100.0%)	49 (100.0%)
Non-missing	68 (100.0%)	19 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	9	4	5
no	61 (100.0%)	16 (100.0%)	45 (100.0%)
Non-missing	61 (100.0%)	16 (100.0%)	45 (100.0%)
After 24 weeks			
Missing	11	3	8
no	59 (100.0%)	17 (100.0%)	42 (100.0%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.6 DPP-4 inhibitor

DPP-4 inhibitor	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
Missing	1	0	1
no	45 (65.2%)	16 (80.0%)	29 (59.2%)
yes	24 (34.8%)	4 (20.0%)	20 (40.8%)
Non-missing	69 (100.0%)	20 (100.0%)	49 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	2	1	1
no	59 (86.8%)	15 (78.9%)	44 (89.8%)
yes	9 (13.2%)	4 (21.1%)	5 (10.2%)
Non-missing	68 (100.0%)	19 (100.0%)	49 (100.0%)
After 12 weeks			
Missing	10	4	6
no	56 (93.3%)	14 (87.5%)	42 (95.5%)
yes	4 (6.7%)	2 (12.5%)	2 (4.5%)
Non-missing	60 (100.0%)	16 (100.0%)	44 (100.0%)
After 24 weeks			
Missing	11	3	8
no	55 (93.2%)	15 (88.2%)	40 (95.2%)
yes	4 (6.8%)	2 (11.8%)	2 (4.8%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.7 SGLT2 inhibitor

SGLT2 inhibitor	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
no	35 (50.0%)	10 (50.0%)	25 (50.0%)
yes	35 (50.0%)	10 (50.0%)	25 (50.0%)
Non-missing	70 (100.0%)	20 (100.0%)	50 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	1	0
no	35 (50.7%)	9 (47.4%)	26 (52.0%)
yes	34 (49.3%)	10 (52.6%)	24 (48.0%)
Non-missing	69 (100.0%)	19 (100.0%)	50 (100.0%)
After 12 weeks			
Missing	8	4	4
no	27 (43.5%)	6 (37.5%)	21 (45.7%)
yes	35 (56.5%)	10 (62.5%)	25 (54.3%)
Non-missing	62 (100.0%)	16 (100.0%)	46 (100.0%)
After 24 weeks			
Missing	12	3	9
no	30 (51.7%)	7 (41.2%)	23 (56.1%)
yes	28 (48.3%)	10 (58.8%)	18 (43.9%)
Non-missing	58 (100.0%)	17 (100.0%)	41 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM - SMBG
6.1.1 Changes in non-insulin concomitant medication
6.1.1.8 Number of additional non-insulin concomitant medication

Number of drugs	FAS (N = 70) N (%)	FGM (N = 20) N (%)	SMBG (N = 50) N (%)
Baseline			
none	3 (4.3%)	1 (5.0%)	2 (4.0%)
one drug	29 (41.4%)	9 (45.0%)	20 (40.0%)
two drugs	28 (40.0%)	6 (30.0%)	22 (44.0%)
three drugs	10 (14.3%)	4 (20.0%)	6 (12.0%)
Non-missing	70 (100.0%)	20 (100.0%)	50 (100.0%)
Baseline - after switch to iGlarLixi			
none	10 (14.3%)	1 (5.0%)	9 (18.0%)
one drug	27 (38.6%)	8 (40.0%)	19 (38.0%)
two drugs	28 (40.0%)	7 (35.0%)	21 (42.0%)
three drugs	5 (7.1%)	4 (20.0%)	1 (2.0%)
Non-missing	70 (100.0%)	20 (100.0%)	50 (100.0%)
After 12 weeks			
Missing	8	4	4
none	12 (19.4%)	1 (6.3%)	11 (23.9%)
one drug	23 (37.1%)	7 (43.8%)	16 (34.8%)
two drugs	23 (37.1%)	5 (31.3%)	18 (39.1%)
three drugs	4 (6.5%)	3 (18.8%)	1 (2.2%)
Non-missing	62 (100.0%)	16 (100.0%)	46 (100.0%)
After 24 weeks			
Missing	11	3	8
none	12 (20.3%)	1 (5.9%)	11 (26.2%)
one drug	24 (40.7%)	8 (47.1%)	16 (38.1%)
two drugs	19 (32.2%)	5 (29.4%)	14 (33.3%)
three drugs	4 (6.8%)	3 (17.6%)	1 (2.4%)
Non-missing	59 (100.0%)	17 (100.0%)	42 (100.0%)

6 Additional assessment parameters
6.1 Full Analysis Set - FGM
6.1.2 Change of the FGM system

Change of the FGM system	FAS (N = 70) N (%)	FGM (N = 20) N (%)
Baseline		
Missing	70	20
After 12 weeks		
Missing	50	0
yes	1 (5.0%)	1 (5.0%)
no	19 (95.0%)	19 (95.0%)
Non-missing	20 (100.0%)	20 (100.0%)
After 24 weeks		
Missing	50	1
no	19 (95.0%)	19 (100.0%)
Non-missing	19 (95.0%)	19 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.1 Metformin

Metformin	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	0
no	9 (33.3%)	9 (21.4%)
yes	18 (66.7%)	33 (78.6%)
Non-missing	27 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	0
no	11 (40.7%)	8 (19.0%)
yes	16 (59.3%)	34 (81.0%)
Non-missing	27 (100.0%)	42 (100.0%)
After 12 weeks		
Missing	5	3
no	9 (39.1%)	13 (33.3%)
yes	14 (60.9%)	26 (66.7%)
Non-missing	23 (100.0%)	39 (100.0%)
After 24 weeks		
Missing	7	4
no	7 (33.3%)	13 (34.2%)
yes	14 (66.7%)	25 (65.8%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.2 Sulfonyl urea

Sulfonyl urea	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	1
no	25 (92.6%)	41 (100.0%)
yes	2 (7.4%)	0 (0.0%)
Non-missing	27 (100.0%)	41 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	2
no	26 (96.3%)	40 (100.0%)
yes	1 (3.7%)	0 (0.0%)
Non-missing	27 (100.0%)	40 (100.0%)
After 12 weeks		
Missing	6	5
no	21 (95.5%)	37 (100.0%)
yes	1 (4.5%)	0 (0.0%)
Non-missing	22 (100.0%)	37 (100.0%)
After 24 weeks		
Missing	7	4
no	19 (90.5%)	38 (100.0%)
yes	2 (9.5%)	0 (0.0%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.3 Glinide

Glinide	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	0
no	25 (92.6%)	41 (97.6%)
yes	2 (7.4%)	1 (2.4%)
Non-missing	27 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	0
no	25 (92.6%)	40 (95.2%)
yes	2 (7.4%)	2 (4.8%)
Non-missing	27 (100.0%)	42 (100.0%)
After 12 weeks		
Missing	5	4
no	22 (95.7%)	38 (100.0%)
yes	1 (4.3%)	0 (0.0%)
Non-missing	23 (100.0%)	38 (100.0%)
After 24 weeks		
Missing	7	4
no	20 (95.2%)	38 (100.0%)
yes	1 (4.8%)	0 (0.0%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	0
no	27 (100.0%)	42 (100.0%)
Non-missing	27 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	27 (100.0%)	41 (100.0%)
Non-missing	27 (100.0%)	41 (100.0%)
After 12 weeks		
Missing	5	4
no	23 (100.0%)	38 (100.0%)
Non-missing	23 (100.0%)	38 (100.0%)
After 24 weeks		
Missing	7	4
no	21 (100.0%)	38 (100.0%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.5 Glitazone

Glitazone	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	0
no	27 (100.0%)	42 (100.0%)
Non-missing	27 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	27 (100.0%)	41 (100.0%)
Non-missing	27 (100.0%)	41 (100.0%)
After 12 weeks		
Missing	5	4
no	23 (100.0%)	38 (100.0%)
Non-missing	23 (100.0%)	38 (100.0%)
After 24 weeks		
Missing	7	4
no	21 (100.0%)	38 (100.0%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.6 DPP-4 inhibitor

DPP-4 inhibitor	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	1	0
no	17 (63.0%)	28 (66.7%)
yes	10 (37.0%)	14 (33.3%)
Non-missing	27 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	24 (88.9%)	35 (85.4%)
yes	3 (11.1%)	6 (14.6%)
Non-missing	27 (100.0%)	41 (100.0%)
After 12 weeks		
Missing	5	5
no	22 (95.7%)	34 (91.9%)
yes	1 (4.3%)	3 (8.1%)
Non-missing	23 (100.0%)	37 (100.0%)
After 24 weeks		
Missing	7	4
no	20 (95.2%)	35 (92.1%)
yes	1 (4.8%)	3 (7.9%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.7 SGLT2 inhibitor

SGLT2 inhibitor	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
no	17 (60.7%)	18 (42.9%)
yes	11 (39.3%)	24 (57.1%)
Non-missing	28 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	18 (64.3%)	17 (41.5%)
yes	10 (35.7%)	24 (58.5%)
Non-missing	28 (100.0%)	41 (100.0%)
After 12 weeks		
Missing	5	3
no	13 (56.5%)	14 (35.9%)
yes	10 (43.5%)	25 (64.1%)
Non-missing	23 (100.0%)	39 (100.0%)
After 24 weeks		
Missing	8	4
no	13 (65.0%)	17 (44.7%)
yes	7 (35.0%)	21 (55.3%)
Non-missing	20 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.1 Changes in non-insulin concomitant medication
6.2.1.8 Number of additional non-insulin concomitant medication

Number of drugs	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
none	2 (7.1%)	1 (2.4%)
one drug	14 (50.0%)	15 (35.7%)
two drugs	7 (25.0%)	21 (50.0%)
three drugs	5 (17.9%)	5 (11.9%)
Non-missing	28 (100.0%)	42 (100.0%)
Baseline - after switch to iGlarLixi		
none	8 (28.6%)	2 (4.8%)
one drug	11 (39.3%)	16 (38.1%)
two drugs	6 (21.4%)	22 (52.4%)
three drugs	3 (10.7%)	2 (4.8%)
Non-missing	28 (100.0%)	42 (100.0%)
After 12 weeks		
Missing	5	3
none	5 (21.7%)	7 (17.9%)
one drug	11 (47.8%)	12 (30.8%)
two drugs	5 (21.7%)	18 (46.2%)
three drugs	2 (8.7%)	2 (5.1%)
Non-missing	23 (100.0%)	39 (100.0%)
After 24 weeks		
Missing	7	4
none	4 (19.0%)	8 (21.1%)
one drug	11 (52.4%)	13 (34.2%)
two drugs	4 (19.0%)	15 (39.5%)
three drugs	2 (9.5%)	2 (5.3%)
Non-missing	21 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.2 Full Analysis Set - Subgroups - Gender
6.2.2 Change of the FGM system

Change of the FGM system	Female (N = 28) N (%)	Male (N = 42) N (%)
Baseline		
Missing	28	42
After 12 weeks		
Missing	20	30
yes	0 (0.0%)	1 (8.3%)
no	8 (100.0%)	11 (91.7%)
Non-missing	8 (100.0%)	12 (100.0%)
After 24 weeks		
Missing	19	31
no	8 (88.9%)	11 (100.0%)
Non-missing	8 (88.9%)	11 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.1 Metformin

Metformin	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	0	1
no	7 (29.2%)	2 (8.3%)	9 (42.9%)
yes	17 (70.8%)	22 (91.7%)	12 (57.1%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	7 (29.2%)	4 (16.7%)	8 (38.1%)
yes	17 (70.8%)	20 (83.3%)	13 (61.9%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	4	1	3
no	6 (30.0%)	5 (21.7%)	11 (57.9%)
yes	14 (70.0%)	18 (78.3%)	8 (42.1%)
Non-missing	20 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	4	2	5
no	6 (30.0%)	4 (18.2%)	10 (58.8%)
yes	14 (70.0%)	18 (81.8%)	7 (41.2%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.2 Sulfonyl urea

Sulfonyl urea	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	1	1
no	23 (95.8%)	22 (95.7%)	21 (100.0%)
yes	1 (4.2%)	1 (4.3%)	0 (0.0%)
Non-missing	24 (100.0%)	23 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	1	1
no	23 (100.0%)	22 (95.7%)	21 (100.0%)
yes	0 (0.0%)	1 (4.3%)	0 (0.0%)
Non-missing	23 (100.0%)	23 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	5	2	4
no	19 (100.0%)	21 (95.5%)	18 (100.0%)
yes	0 (0.0%)	1 (4.5%)	0 (0.0%)
Non-missing	19 (100.0%)	22 (100.0%)	18 (100.0%)
After 24 weeks			
Missing	4	2	5
no	19 (95.0%)	21 (95.5%)	17 (100.0%)
yes	1 (5.0%)	1 (4.5%)	0 (0.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.3 Glinide

Glinide	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	0	1
no	22 (91.7%)	23 (95.8%)	21 (100.0%)
yes	2 (8.3%)	1 (4.2%)	0 (0.0%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	22 (91.7%)	23 (95.8%)	20 (95.2%)
yes	2 (8.3%)	1 (4.2%)	1 (4.8%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	5	1	3
no	19 (100.0%)	22 (95.7%)	19 (100.0%)
yes	0 (0.0%)	1 (4.3%)	0 (0.0%)
Non-missing	19 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	4	2	5
no	20 (100.0%)	21 (95.5%)	17 (100.0%)
yes	0 (0.0%)	1 (4.5%)	0 (0.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	0	1
no	24 (100.0%)	24 (100.0%)	21 (100.0%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	1
no	23 (100.0%)	24 (100.0%)	21 (100.0%)
Non-missing	23 (100.0%)	24 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	5	1	3
no	19 (100.0%)	23 (100.0%)	19 (100.0%)
Non-missing	19 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	4	2	5
no	20 (100.0%)	22 (100.0%)	17 (100.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.5 Glitazone

Glitazone	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	0	1
no	24 (100.0%)	24 (100.0%)	21 (100.0%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	1
no	23 (100.0%)	24 (100.0%)	21 (100.0%)
Non-missing	23 (100.0%)	24 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	5	1	3
no	19 (100.0%)	23 (100.0%)	19 (100.0%)
Non-missing	19 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	4	2	5
no	20 (100.0%)	22 (100.0%)	17 (100.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.6 DPP-4 inhibitor

DPP-4 inhibitor	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	0	0	1
no	20 (83.3%)	15 (62.5%)	10 (47.6%)
yes	4 (16.7%)	9 (37.5%)	11 (52.4%)
Non-missing	24 (100.0%)	24 (100.0%)	21 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	1
no	22 (95.7%)	18 (75.0%)	19 (90.5%)
yes	1 (4.3%)	6 (25.0%)	2 (9.5%)
Non-missing	23 (100.0%)	24 (100.0%)	21 (100.0%)
After 12 weeks			
Missing	5	1	4
no	18 (94.7%)	21 (91.3%)	17 (94.4%)
yes	1 (5.3%)	2 (8.7%)	1 (5.6%)
Non-missing	19 (100.0%)	23 (100.0%)	18 (100.0%)
After 24 weeks			
Missing	4	2	5
no	19 (95.0%)	19 (86.4%)	17 (100.0%)
yes	1 (5.0%)	3 (13.6%)	0 (0.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.7 SGLT2 inhibitor

SGLT2 inhibitor	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
no	12 (50.0%)	10 (41.7%)	13 (59.1%)
yes	12 (50.0%)	14 (58.3%)	9 (40.9%)
Non-missing	24 (100.0%)	24 (100.0%)	22 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	1	0	0
no	11 (47.8%)	11 (45.8%)	13 (59.1%)
yes	12 (52.2%)	13 (54.2%)	9 (40.9%)
Non-missing	23 (100.0%)	24 (100.0%)	22 (100.0%)
After 12 weeks			
Missing	4	1	3
no	7 (35.0%)	9 (39.1%)	11 (57.9%)
yes	13 (65.0%)	14 (60.9%)	8 (42.1%)
Non-missing	20 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	5	2	5
no	8 (42.1%)	12 (54.5%)	10 (58.8%)
yes	11 (57.9%)	10 (45.5%)	7 (41.2%)
Non-missing	19 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.1 Changes in non-insulin concomitant medication
6.3.1.8 Number of additional non-insulin concomitant medication

Number of drugs	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
none	1 (4.2%)	0 (0.0%)	2 (9.1%)
one drug	12 (50.0%)	7 (29.2%)	10 (45.5%)
two drugs	9 (37.5%)	11 (45.8%)	8 (36.4%)
three drugs	2 (8.3%)	6 (25.0%)	2 (9.1%)
Non-missing	24 (100.0%)	24 (100.0%)	22 (100.0%)
Baseline - after switch to iGlarLixi			
none	4 (16.7%)	1 (4.2%)	5 (22.7%)
one drug	9 (37.5%)	9 (37.5%)	9 (40.9%)
two drugs	10 (41.7%)	10 (41.7%)	8 (36.4%)
three drugs	1 (4.2%)	4 (16.7%)	0 (0.0%)
Non-missing	24 (100.0%)	24 (100.0%)	22 (100.0%)
After 12 weeks			
Missing	4	1	3
none	3 (15.0%)	2 (8.7%)	7 (36.8%)
one drug	7 (35.0%)	9 (39.1%)	7 (36.8%)
two drugs	9 (45.0%)	9 (39.1%)	5 (26.3%)
three drugs	1 (5.0%)	3 (13.0%)	0 (0.0%)
Non-missing	20 (100.0%)	23 (100.0%)	19 (100.0%)
After 24 weeks			
Missing	4	2	5
none	3 (15.0%)	2 (9.1%)	7 (41.2%)
one drug	8 (40.0%)	10 (45.5%)	6 (35.3%)
two drugs	8 (40.0%)	7 (31.8%)	4 (23.5%)
three drugs	1 (5.0%)	3 (13.6%)	0 (0.0%)
Non-missing	20 (100.0%)	22 (100.0%)	17 (100.0%)

6 Additional assessment parameters
6.3 Full Analysis Set - Subgroups - Age groups
6.3.2 Change of the FGM system

Change of the FGM system	<= 60 years (N = 24) N (%)	>60 - <70 years (N = 24) N (%)	>=70 years (N = 22) N (%)
Baseline			
Missing	24	24	22
After 12 weeks			
Missing	13	17	20
yes	0 (0.0%)	0 (0.0%)	1 (50.0%)
no	11 (100.0%)	7 (100.0%)	1 (50.0%)
Non-missing	11 (100.0%)	7 (100.0%)	2 (100.0%)
After 24 weeks			
Missing	13	17	20
no	11 (100.0%)	7 (100.0%)	1 (50.0%)
Non-missing	11 (100.0%)	7 (100.0%)	1 (50.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.1 Metformin

Metformin	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	1
no	7 (38.9%)	11 (21.6%)
yes	11 (61.1%)	40 (78.4%)
Non-missing	18 (100.0%)	51 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	6 (33.3%)	13 (25.5%)
yes	12 (66.7%)	38 (74.5%)
Non-missing	18 (100.0%)	51 (100.0%)
After 12 weeks		
Missing	4	4
no	6 (42.9%)	16 (33.3%)
yes	8 (57.1%)	32 (66.7%)
Non-missing	14 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	4
no	5 (45.5%)	15 (31.3%)
yes	6 (54.5%)	33 (68.8%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.2 Sulfonyl urea

Sulfonyl urea	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	2
no	18 (100.0%)	48 (96.0%)
yes	0 (0.0%)	2 (4.0%)
Non-missing	18 (100.0%)	50 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	3
no	18 (100.0%)	48 (98.0%)
yes	0 (0.0%)	1 (2.0%)
Non-missing	18 (100.0%)	49 (100.0%)
After 12 weeks		
Missing	5	6
no	13 (100.0%)	45 (97.8%)
yes	0 (0.0%)	1 (2.2%)
Non-missing	13 (100.0%)	46 (100.0%)
After 24 weeks		
Missing	7	4
no	11 (100.0%)	46 (95.8%)
yes	0 (0.0%)	2 (4.2%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.3 Glinide

Glinide	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	1
no	18 (100.0%)	48 (94.1%)
yes	0 (0.0%)	3 (5.9%)
Non-missing	18 (100.0%)	51 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	18 (100.0%)	47 (92.2%)
yes	0 (0.0%)	4 (7.8%)
Non-missing	18 (100.0%)	51 (100.0%)
After 12 weeks		
Missing	5	4
no	13 (100.0%)	47 (97.9%)
yes	0 (0.0%)	1 (2.1%)
Non-missing	13 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	4
no	11 (100.0%)	47 (97.9%)
yes	0 (0.0%)	1 (2.1%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	1
no	18 (100.0%)	51 (100.0%)
Non-missing	18 (100.0%)	51 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	2
no	18 (100.0%)	50 (100.0%)
Non-missing	18 (100.0%)	50 (100.0%)
After 12 weeks		
Missing	5	4
no	13 (100.0%)	48 (100.0%)
Non-missing	13 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	4
no	11 (100.0%)	48 (100.0%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.5 Glitazone

Glitazone	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	1
no	18 (100.0%)	51 (100.0%)
Non-missing	18 (100.0%)	51 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	2
no	18 (100.0%)	50 (100.0%)
Non-missing	18 (100.0%)	50 (100.0%)
After 12 weeks		
Missing	5	4
no	13 (100.0%)	48 (100.0%)
Non-missing	13 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	4
no	11 (100.0%)	48 (100.0%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.6 DPP-4 inhibitor

DPP-4 inhibitor	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	0	1
no	8 (44.4%)	37 (72.5%)
yes	10 (55.6%)	14 (27.5%)
Non-missing	18 (100.0%)	51 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	2
no	15 (83.3%)	44 (88.0%)
yes	3 (16.7%)	6 (12.0%)
Non-missing	18 (100.0%)	50 (100.0%)
After 12 weeks		
Missing	5	5
no	13 (100.0%)	43 (91.5%)
yes	0 (0.0%)	4 (8.5%)
Non-missing	13 (100.0%)	47 (100.0%)
After 24 weeks		
Missing	7	4
no	10 (90.9%)	45 (93.8%)
yes	1 (9.1%)	3 (6.3%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.7 SGLT2 inhibitor

SGLT2 inhibitor	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
no	7 (38.9%)	28 (53.8%)
yes	11 (61.1%)	24 (46.2%)
Non-missing	18 (100.0%)	52 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	7 (38.9%)	28 (54.9%)
yes	11 (61.1%)	23 (45.1%)
Non-missing	18 (100.0%)	51 (100.0%)
After 12 weeks		
Missing	4	4
no	4 (28.6%)	23 (47.9%)
yes	10 (71.4%)	25 (52.1%)
Non-missing	14 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	5
no	4 (36.4%)	26 (55.3%)
yes	7 (63.6%)	21 (44.7%)
Non-missing	11 (100.0%)	47 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.1 Changes in non-insulin concomitant medication
6.4.1.8 Number of additional non-insulin concomitant medication

Number of drugs	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
none	0 (0.0%)	3 (5.8%)
one drug	7 (38.9%)	22 (42.3%)
two drugs	8 (44.4%)	20 (38.5%)
three drugs	3 (16.7%)	7 (13.5%)
Non-missing	18 (100.0%)	52 (100.0%)
Baseline - after switch to iGlarLixi		
none	3 (16.7%)	7 (13.5%)
one drug	5 (27.8%)	22 (42.3%)
two drugs	9 (50.0%)	19 (36.5%)
three drugs	1 (5.6%)	4 (7.7%)
Non-missing	18 (100.0%)	52 (100.0%)
After 12 weeks		
Missing	4	4
none	3 (21.4%)	9 (18.8%)
one drug	4 (28.6%)	19 (39.6%)
two drugs	7 (50.0%)	16 (33.3%)
three drugs	0 (0.0%)	4 (8.3%)
Non-missing	14 (100.0%)	48 (100.0%)
After 24 weeks		
Missing	7	4
none	2 (18.2%)	10 (20.8%)
one drug	4 (36.4%)	20 (41.7%)
two drugs	5 (45.5%)	14 (29.2%)
three drugs	0 (0.0%)	4 (8.3%)
Non-missing	11 (100.0%)	48 (100.0%)

6 Additional assessment parameters
6.4 Full Analysis Set - Subgroups - Body Mass Index
6.4.2 Change of the FGM system

Change of the FGM system	<30 kg/m² (N = 18) N (%)	>=30 kg/m² (N = 52) N (%)
Baseline		
Missing	18	52
After 12 weeks		
Missing	14	36
yes	0 (0.0%)	1 (6.3%)
no	4 (100.0%)	15 (93.8%)
Non-missing	4 (100.0%)	16 (100.0%)
After 24 weeks		
Missing	13	37
no	4 (80.0%)	15 (100.0%)
Non-missing	4 (80.0%)	15 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.1 Metformin

Metformin	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	9 (52.9%)	6 (15.4%)
yes	8 (47.1%)	33 (84.6%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
no	9 (52.9%)	7 (17.9%)
yes	8 (47.1%)	32 (82.1%)
Non-missing	17 (100.0%)	39 (100.0%)
After 12 weeks		
Missing	2	6
no	9 (60.0%)	8 (24.2%)
yes	6 (40.0%)	25 (75.8%)
Non-missing	15 (100.0%)	33 (100.0%)
After 24 weeks		
Missing	5	6
no	7 (58.3%)	8 (24.2%)
yes	5 (41.7%)	25 (75.8%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.2 Sulfonyl urea

Sulfonyl urea	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Missing	0	1
no	17 (100.0%)	36 (94.7%)
yes	0 (0.0%)	2 (5.3%)
Non-missing	17 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	2
no	17 (100.0%)	36 (97.3%)
yes	0 (0.0%)	1 (2.7%)
Non-missing	17 (100.0%)	37 (100.0%)
After 12 weeks		
Missing	3	7
no	14 (100.0%)	31 (96.9%)
yes	0 (0.0%)	1 (3.1%)
Non-missing	14 (100.0%)	32 (100.0%)
After 24 weeks		
Missing	5	6
no	12 (100.0%)	31 (93.9%)
yes	0 (0.0%)	2 (6.1%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.3 Glinide

Glinide	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	17 (100.0%)	36 (92.3%)
yes	0 (0.0%)	3 (7.7%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
no	16 (94.1%)	36 (92.3%)
yes	1 (5.9%)	3 (7.7%)
Non-missing	17 (100.0%)	39 (100.0%)
After 12 weeks		
Missing	2	7
no	15 (100.0%)	31 (96.9%)
yes	0 (0.0%)	1 (3.1%)
Non-missing	15 (100.0%)	32 (100.0%)
After 24 weeks		
Missing	5	6
no	12 (100.0%)	32 (97.0%)
yes	0 (0.0%)	1 (3.0%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	17 (100.0%)	39 (100.0%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	17 (100.0%)	38 (100.0%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Missing	2	7
no	15 (100.0%)	32 (100.0%)
Non-missing	15 (100.0%)	32 (100.0%)
After 24 weeks		
Missing	5	6
no	12 (100.0%)	33 (100.0%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.5 Glitazone

Glitazone	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	17 (100.0%)	39 (100.0%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	17 (100.0%)	38 (100.0%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Missing	2	7
no	15 (100.0%)	32 (100.0%)
Non-missing	15 (100.0%)	32 (100.0%)
After 24 weeks		
Missing	5	6
no	12 (100.0%)	33 (100.0%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.6 DPP-4 inhibitor

DPP-4 inhibitor	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	8 (47.1%)	28 (71.8%)
yes	9 (52.9%)	11 (28.2%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	16 (94.1%)	33 (86.8%)
yes	1 (5.9%)	5 (13.2%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Missing	2	7
no	14 (93.3%)	31 (96.9%)
yes	1 (6.7%)	1 (3.1%)
Non-missing	15 (100.0%)	32 (100.0%)
After 24 weeks		
Missing	5	6
no	12 (100.0%)	32 (97.0%)
yes	0 (0.0%)	1 (3.0%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.7 SGLT2 inhibitor

SGLT2 inhibitor	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
no	7 (41.2%)	22 (56.4%)
yes	10 (58.8%)	17 (43.6%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	8 (47.1%)	21 (55.3%)
yes	9 (52.9%)	17 (44.7%)
Non-missing	17 (100.0%)	38 (100.0%)
After 12 weeks		
Missing	2	6
no	7 (46.7%)	16 (48.5%)
yes	8 (53.3%)	17 (51.5%)
Non-missing	15 (100.0%)	33 (100.0%)
After 24 weeks		
Missing	5	6
no	7 (58.3%)	19 (57.6%)
yes	5 (41.7%)	14 (42.4%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.1 Changes in non-insulin concomitant medication
6.5.1.8 Number of additional non-insulin concomitant medication

Number of drugs	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
none	2 (11.8%)	0 (0.0%)
one drug	6 (35.3%)	17 (43.6%)
two drugs	6 (35.3%)	17 (43.6%)
three drugs	3 (17.6%)	5 (12.8%)
Non-missing	17 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi		
none	4 (23.5%)	5 (12.8%)
one drug	7 (41.2%)	14 (35.9%)
two drugs	6 (35.3%)	16 (41.0%)
three drugs	0 (0.0%)	4 (10.3%)
Non-missing	17 (100.0%)	39 (100.0%)
After 12 weeks		
Missing	2	6
none	4 (26.7%)	6 (18.2%)
one drug	7 (46.7%)	11 (33.3%)
two drugs	4 (26.7%)	14 (42.4%)
three drugs	0 (0.0%)	2 (6.1%)
Non-missing	15 (100.0%)	33 (100.0%)
After 24 weeks		
Missing	5	6
none	4 (33.3%)	6 (18.2%)
one drug	6 (50.0%)	13 (39.4%)
two drugs	2 (16.7%)	12 (36.4%)
three drugs	0 (0.0%)	2 (6.1%)
Non-missing	12 (100.0%)	33 (100.0%)

6 Additional assessment parameters
6.5 Full Analysis Set - Subgroups - Renal function
6.5.2 Change of the FGM system

Change of the FGM system	<=60 ml/min/1.73 m² (N = 17) N (%)	>60 ml/min/1.73 m² (N = 39) N (%)
Baseline		
Missing	17	39
After 12 weeks		
Missing	14	24
yes	0 (0.0%)	1 (6.7%)
no	3 (100.0%)	14 (93.3%)
Non-missing	3 (100.0%)	15 (100.0%)
After 24 weeks		
Missing	13	25
no	3 (75.0%)	14 (100.0%)
Non-missing	3 (75.0%)	14 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.1 Metformin

Metformin	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	1
no	2 (28.6%)	7 (33.3%)	8 (21.1%)
yes	5 (71.4%)	14 (66.7%)	30 (78.9%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	5 (71.4%)	5 (23.8%)	8 (21.1%)
yes	2 (28.6%)	16 (76.2%)	30 (78.9%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
After 12 weeks			
Missing	1	6	0
no	4 (66.7%)	4 (26.7%)	12 (30.8%)
yes	2 (33.3%)	11 (73.3%)	27 (69.2%)
Non-missing	6 (100.0%)	15 (100.0%)	39 (100.0%)
After 24 weeks			
Missing	2	7	1
no	3 (60.0%)	3 (21.4%)	12 (31.6%)
yes	2 (40.0%)	11 (78.6%)	26 (68.4%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.2 Sulfonyl urea

Sulfonyl urea	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	2
no	7 (100.0%)	20 (95.2%)	36 (97.3%)
yes	0 (0.0%)	1 (4.8%)	1 (2.7%)
Non-missing	7 (100.0%)	21 (100.0%)	37 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	2
no	7 (100.0%)	20 (100.0%)	36 (97.3%)
yes	0 (0.0%)	0 (0.0%)	1 (2.7%)
Non-missing	7 (100.0%)	20 (100.0%)	37 (100.0%)
After 12 weeks			
Missing	2	6	2
no	5 (100.0%)	15 (100.0%)	36 (97.3%)
yes	0 (0.0%)	0 (0.0%)	1 (2.7%)
Non-missing	5 (100.0%)	15 (100.0%)	37 (100.0%)
After 24 weeks			
Missing	2	7	1
no	5 (100.0%)	13 (92.9%)	37 (97.4%)
yes	0 (0.0%)	1 (7.1%)	1 (2.6%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.3 Glinide

Glinide	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	1
no	7 (100.0%)	20 (95.2%)	37 (97.4%)
yes	0 (0.0%)	1 (4.8%)	1 (2.6%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	7 (100.0%)	20 (95.2%)	37 (97.4%)
yes	0 (0.0%)	1 (4.8%)	1 (2.6%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
After 12 weeks			
Missing	1	6	1
no	6 (100.0%)	15 (100.0%)	37 (97.4%)
yes	0 (0.0%)	0 (0.0%)	1 (2.6%)
Non-missing	6 (100.0%)	15 (100.0%)	38 (100.0%)
After 24 weeks			
Missing	2	7	1
no	5 (100.0%)	14 (100.0%)	37 (97.4%)
yes	0 (0.0%)	0 (0.0%)	1 (2.6%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	1
no	7 (100.0%)	21 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	1
no	7 (100.0%)	20 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	20 (100.0%)	38 (100.0%)
After 12 weeks			
Missing	1	6	1
no	6 (100.0%)	15 (100.0%)	38 (100.0%)
Non-missing	6 (100.0%)	15 (100.0%)	38 (100.0%)
After 24 weeks			
Missing	2	7	1
no	5 (100.0%)	14 (100.0%)	38 (100.0%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.5 Glitazone

Glitazone	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	1
no	7 (100.0%)	21 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	1
no	7 (100.0%)	20 (100.0%)	38 (100.0%)
Non-missing	7 (100.0%)	20 (100.0%)	38 (100.0%)
After 12 weeks			
Missing	1	6	1
no	6 (100.0%)	15 (100.0%)	38 (100.0%)
Non-missing	6 (100.0%)	15 (100.0%)	38 (100.0%)
After 24 weeks			
Missing	2	7	1
no	5 (100.0%)	14 (100.0%)	38 (100.0%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.6 DPP-4 inhibitor

DPP-4 inhibitor	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	0	0	1
no	3 (42.9%)	14 (66.7%)	27 (71.1%)
yes	4 (57.1%)	7 (33.3%)	11 (28.9%)
Non-missing	7 (100.0%)	21 (100.0%)	38 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	1
no	7 (100.0%)	18 (90.0%)	31 (81.6%)
yes	0 (0.0%)	2 (10.0%)	7 (18.4%)
Non-missing	7 (100.0%)	20 (100.0%)	38 (100.0%)
After 12 weeks			
Missing	1	6	2
no	6 (100.0%)	14 (93.3%)	35 (94.6%)
yes	0 (0.0%)	1 (6.7%)	2 (5.4%)
Non-missing	6 (100.0%)	15 (100.0%)	37 (100.0%)
After 24 weeks			
Missing	2	7	1
no	5 (100.0%)	13 (92.9%)	35 (92.1%)
yes	0 (0.0%)	1 (7.1%)	3 (7.9%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.7 SGLT2 inhibitor

SGLT2 inhibitor	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
no	5 (71.4%)	15 (71.4%)	12 (30.8%)
yes	2 (28.6%)	6 (28.6%)	27 (69.2%)
Non-missing	7 (100.0%)	21 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	0
no	5 (71.4%)	14 (70.0%)	13 (33.3%)
yes	2 (28.6%)	6 (30.0%)	26 (66.7%)
Non-missing	7 (100.0%)	20 (100.0%)	39 (100.0%)
After 12 weeks			
Missing	1	6	0
no	4 (66.7%)	8 (53.3%)	13 (33.3%)
yes	2 (33.3%)	7 (46.7%)	26 (66.7%)
Non-missing	6 (100.0%)	15 (100.0%)	39 (100.0%)
After 24 weeks			
Missing	2	8	1
no	4 (80.0%)	7 (53.8%)	17 (44.7%)
yes	1 (20.0%)	6 (46.2%)	21 (55.3%)
Non-missing	5 (100.0%)	13 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.1 Changes in non-insulin concomitant medication
6.6.1.8 Number of additional non-insulin concomitant medication

Number of drugs	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
none	0 (0.0%)	1 (4.8%)	2 (5.1%)
one drug	5 (71.4%)	12 (57.1%)	11 (28.2%)
two drugs	0 (0.0%)	7 (33.3%)	19 (48.7%)
three drugs	2 (28.6%)	1 (4.8%)	7 (17.9%)
Non-missing	7 (100.0%)	21 (100.0%)	39 (100.0%)
Baseline - after switch to iGlarLixi			
none	3 (42.9%)	4 (19.0%)	3 (7.7%)
one drug	4 (57.1%)	9 (42.9%)	12 (30.8%)
two drugs	0 (0.0%)	8 (38.1%)	19 (48.7%)
three drugs	0 (0.0%)	0 (0.0%)	5 (12.8%)
Non-missing	7 (100.0%)	21 (100.0%)	39 (100.0%)
After 12 weeks			
Missing	1	6	0
none	2 (33.3%)	3 (20.0%)	6 (15.4%)
one drug	4 (66.7%)	6 (40.0%)	12 (30.8%)
two drugs	0 (0.0%)	5 (33.3%)	18 (46.2%)
three drugs	0 (0.0%)	1 (6.7%)	3 (7.7%)
Non-missing	6 (100.0%)	15 (100.0%)	39 (100.0%)
After 24 weeks			
Missing	2	7	1
none	2 (40.0%)	2 (14.3%)	6 (15.8%)
one drug	3 (60.0%)	6 (42.9%)	15 (39.5%)
two drugs	0 (0.0%)	5 (35.7%)	14 (36.8%)
three drugs	0 (0.0%)	1 (7.1%)	3 (7.9%)
Non-missing	5 (100.0%)	14 (100.0%)	38 (100.0%)

6 Additional assessment parameters
6.6 Full Analysis Set - Subgroups - Duration of diabetes
6.6.2 Change of the FGM system

Change of the FGM system	up to 5 years (N = 7) N (%)	5 to 10 years (N = 21) N (%)	over 10 years (N = 39) N (%)
Baseline			
Missing	7	21	39
After 12 weeks			
Missing	6	14	28
yes	0 (0.0%)	0 (0.0%)	1 (9.1%)
no	1 (100.0%)	7 (100.0%)	10 (90.9%)
Non-missing	1 (100.0%)	7 (100.0%)	11 (100.0%)
After 24 weeks			
Missing	6	13	29
no	1 (100.0%)	7 (87.5%)	10 (100.0%)
Non-missing	1 (100.0%)	7 (87.5%)	10 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.1 Metformin

Metformin	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	1	0
no	8 (21.6%)	10 (31.3%)
yes	29 (78.4%)	22 (68.8%)
Non-missing	37 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	0
no	10 (27.0%)	9 (28.1%)
yes	27 (73.0%)	23 (71.9%)
Non-missing	37 (100.0%)	32 (100.0%)
After 12 weeks		
Missing	4	4
no	12 (35.3%)	10 (35.7%)
yes	22 (64.7%)	18 (64.3%)
Non-missing	34 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	12 (37.5%)	8 (29.6%)
yes	20 (62.5%)	19 (70.4%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.2 Sulfonyl urea

Sulfonyl urea	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	2	0
no	35 (97.2%)	31 (96.9%)
yes	1 (2.8%)	1 (3.1%)
Non-missing	36 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	2	1
no	35 (97.2%)	31 (100.0%)
yes	1 (2.8%)	0 (0.0%)
Non-missing	36 (100.0%)	31 (100.0%)
After 12 weeks		
Missing	7	4
no	30 (96.8%)	28 (100.0%)
yes	1 (3.2%)	0 (0.0%)
Non-missing	31 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	31 (96.9%)	26 (96.3%)
yes	1 (3.1%)	1 (3.7%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.3 Glinide

Glinide	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	1	0
no	36 (97.3%)	30 (93.8%)
yes	1 (2.7%)	2 (6.3%)
Non-missing	37 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	0
no	35 (94.6%)	30 (93.8%)
yes	2 (5.4%)	2 (6.3%)
Non-missing	37 (100.0%)	32 (100.0%)
After 12 weeks		
Missing	5	4
no	33 (100.0%)	27 (96.4%)
yes	0 (0.0%)	1 (3.6%)
Non-missing	33 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	32 (100.0%)	26 (96.3%)
yes	0 (0.0%)	1 (3.7%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	1	0
no	37 (100.0%)	32 (100.0%)
Non-missing	37 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	37 (100.0%)	31 (100.0%)
Non-missing	37 (100.0%)	31 (100.0%)
After 12 weeks		
Missing	5	4
no	33 (100.0%)	28 (100.0%)
Non-missing	33 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	32 (100.0%)	27 (100.0%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.5 Glitazone

Glitazone	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	1	0
no	37 (100.0%)	32 (100.0%)
Non-missing	37 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	37 (100.0%)	31 (100.0%)
Non-missing	37 (100.0%)	31 (100.0%)
After 12 weeks		
Missing	5	4
no	33 (100.0%)	28 (100.0%)
Non-missing	33 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	32 (100.0%)	27 (100.0%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.6 DPP-4 inhibitor

DPP-4 inhibitor	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	1	0
no	25 (67.6%)	20 (62.5%)
yes	12 (32.4%)	12 (37.5%)
Non-missing	37 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	1	1
no	34 (91.9%)	25 (80.6%)
yes	3 (8.1%)	6 (19.4%)
Non-missing	37 (100.0%)	31 (100.0%)
After 12 weeks		
Missing	6	4
no	30 (93.8%)	26 (92.9%)
yes	2 (6.3%)	2 (7.1%)
Non-missing	32 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
no	31 (96.9%)	24 (88.9%)
yes	1 (3.1%)	3 (11.1%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.7 SGLT2 inhibitor

SGLT2 inhibitor	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
no	19 (50.0%)	16 (50.0%)
yes	19 (50.0%)	16 (50.0%)
Non-missing	38 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
Missing	0	1
no	20 (52.6%)	15 (48.4%)
yes	18 (47.4%)	16 (51.6%)
Non-missing	38 (100.0%)	31 (100.0%)
After 12 weeks		
Missing	4	4
no	16 (47.1%)	11 (39.3%)
yes	18 (52.9%)	17 (60.7%)
Non-missing	34 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	7	5
no	17 (54.8%)	13 (48.1%)
yes	14 (45.2%)	14 (51.9%)
Non-missing	31 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.1 Changes in non-insulin concomitant medication
6.7.1.8 Number of additional non-insulin concomitant medication

Number of drugs	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
none	2 (5.3%)	1 (3.1%)
one drug	16 (42.1%)	13 (40.6%)
two drugs	14 (36.8%)	14 (43.8%)
three drugs	6 (15.8%)	4 (12.5%)
Non-missing	38 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi		
none	4 (10.5%)	6 (18.8%)
one drug	19 (50.0%)	8 (25.0%)
two drugs	13 (34.2%)	15 (46.9%)
three drugs	2 (5.3%)	3 (9.4%)
Non-missing	38 (100.0%)	32 (100.0%)
After 12 weeks		
Missing	4	4
none	5 (14.7%)	7 (25.0%)
one drug	16 (47.1%)	7 (25.0%)
two drugs	12 (35.3%)	11 (39.3%)
three drugs	1 (2.9%)	3 (10.7%)
Non-missing	34 (100.0%)	28 (100.0%)
After 24 weeks		
Missing	6	5
none	7 (21.9%)	5 (18.5%)
one drug	15 (46.9%)	9 (33.3%)
two drugs	9 (28.1%)	10 (37.0%)
three drugs	1 (3.1%)	3 (11.1%)
Non-missing	32 (100.0%)	27 (100.0%)

6 Additional assessment parameters
6.7 Full Analysis Set - Subgroups - Baseline HbA1c
6.7.2 Change of the FGM system

Change of the FGM system	<8.5% (N = 38) N (%)	>=8.5% (N = 32) N (%)
Baseline		
Missing	38	32
After 12 weeks		
Missing	25	25
yes	1 (7.7%)	0 (0.0%)
no	12 (92.3%)	7 (100.0%)
Non-missing	13 (100.0%)	7 (100.0%)
After 24 weeks		
Missing	26	24
no	12 (100.0%)	7 (87.5%)
Non-missing	12 (100.0%)	7 (87.5%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.1 Metformin

Metformin	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	1	0	0
no	1 (9.1%)	7 (30.4%)	9 (31.0%)	1 (16.7%)
yes	10 (90.9%)	16 (69.6%)	20 (69.0%)	5 (83.3%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	1	0	0
no	3 (27.3%)	5 (21.7%)	9 (31.0%)	2 (33.3%)
yes	8 (72.7%)	18 (78.3%)	20 (69.0%)	4 (66.7%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	2	2	2
no	3 (33.3%)	7 (31.8%)	10 (37.0%)	2 (50.0%)
yes	6 (66.7%)	15 (68.2%)	17 (63.0%)	2 (50.0%)
Non-missing	9 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	2 (25.0%)	5 (25.0%)	10 (37.0%)	3 (75.0%)
yes	6 (75.0%)	15 (75.0%)	17 (63.0%)	1 (25.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.2 Sulfonyl urea

Sulfonyl urea	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	2	0	0
no	10 (90.9%)	21 (95.5%)	29 (100.0%)	6 (100.0%)
yes	1 (9.1%)	1 (4.5%)	0 (0.0%)	0 (0.0%)
Non-missing	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	3	0	0
no	10 (90.9%)	21 (100.0%)	29 (100.0%)	6 (100.0%)
yes	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-missing	11 (100.0%)	21 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	3	3	3	2
no	7 (87.5%)	21 (100.0%)	26 (100.0%)	4 (100.0%)
yes	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-missing	8 (100.0%)	21 (100.0%)	26 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	7 (87.5%)	19 (95.0%)	27 (100.0%)	4 (100.0%)
yes	1 (12.5%)	1 (5.0%)	0 (0.0%)	0 (0.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.3 Glinide

Glinide	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	1	0	0
no	9 (81.8%)	22 (95.7%)	29 (100.0%)	6 (100.0%)
yes	2 (18.2%)	1 (4.3%)	0 (0.0%)	0 (0.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	1	0	0
no	9 (81.8%)	22 (95.7%)	28 (96.6%)	6 (100.0%)
yes	2 (18.2%)	1 (4.3%)	1 (3.4%)	0 (0.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	3	2	2
no	8 (88.9%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
yes	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-missing	9 (100.0%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	7 (87.5%)	20 (100.0%)	27 (100.0%)	4 (100.0%)
yes	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	1	0	0
no	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	2	0	0
no	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	3	2	2
no	9 (100.0%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
Non-missing	9 (100.0%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.5 Glitazone

Glitazone	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	1	0	0
no	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	2	0	0
no	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
Non-missing	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	3	2	2
no	9 (100.0%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
Non-missing	9 (100.0%)	21 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.6 DPP-4 inhibitor

DPP-4 inhibitor	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	0	1	0	0
no	8 (72.7%)	17 (73.9%)	17 (58.6%)	3 (50.0%)
yes	3 (27.3%)	6 (26.1%)	12 (41.4%)	3 (50.0%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	2	0	0
no	9 (81.8%)	19 (86.4%)	25 (86.2%)	6 (100.0%)
yes	2 (18.2%)	3 (13.6%)	4 (13.8%)	0 (0.0%)
Non-missing	11 (100.0%)	22 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	3	3	2
no	8 (88.9%)	20 (95.2%)	24 (92.3%)	4 (100.0%)
yes	1 (11.1%)	1 (4.8%)	2 (7.7%)	0 (0.0%)
Non-missing	9 (100.0%)	21 (100.0%)	26 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
no	7 (87.5%)	19 (95.0%)	25 (92.6%)	4 (100.0%)
yes	1 (12.5%)	1 (5.0%)	2 (7.4%)	0 (0.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.7 SGLT2 inhibitor

SGLT2 inhibitor	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
no	7 (63.6%)	13 (54.2%)	13 (44.8%)	2 (33.3%)
yes	4 (36.4%)	11 (45.8%)	16 (55.2%)	4 (66.7%)
Non-missing	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
Missing	0	1	0	0
no	7 (63.6%)	12 (52.2%)	14 (48.3%)	2 (33.3%)
yes	4 (36.4%)	11 (47.8%)	15 (51.7%)	4 (66.7%)
Non-missing	11 (100.0%)	23 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	2	2	2
no	4 (44.4%)	10 (45.5%)	12 (44.4%)	1 (25.0%)
yes	5 (55.6%)	12 (54.5%)	15 (55.6%)	3 (75.0%)
Non-missing	9 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	5	2	2
no	4 (50.0%)	10 (52.6%)	15 (55.6%)	1 (25.0%)
yes	4 (50.0%)	9 (47.4%)	12 (44.4%)	3 (75.0%)
Non-missing	8 (100.0%)	19 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.1 Changes in non-insulin concomitant medication
6.8.1.8 Number of additional non-insulin concomitant medication

Number of drugs	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
none	1 (9.1%)	1 (4.2%)	1 (3.4%)	0 (0.0%)
one drug	3 (27.3%)	13 (54.2%)	11 (37.9%)	2 (33.3%)
two drugs	4 (36.4%)	8 (33.3%)	14 (48.3%)	2 (33.3%)
three drugs	3 (27.3%)	2 (8.3%)	3 (10.3%)	2 (33.3%)
Non-missing	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
Baseline - after switch to iGlarLixi				
none	2 (18.2%)	3 (12.5%)	5 (17.2%)	0 (0.0%)
one drug	3 (27.3%)	10 (41.7%)	10 (34.5%)	4 (66.7%)
two drugs	4 (36.4%)	10 (41.7%)	12 (41.4%)	2 (33.3%)
three drugs	2 (18.2%)	1 (4.2%)	2 (6.9%)	0 (0.0%)
Non-missing	11 (100.0%)	24 (100.0%)	29 (100.0%)	6 (100.0%)
After 12 weeks				
Missing	2	2	2	2
none	2 (22.2%)	4 (18.2%)	6 (22.2%)	0 (0.0%)
one drug	2 (22.2%)	9 (40.9%)	9 (33.3%)	3 (75.0%)
two drugs	3 (33.3%)	8 (36.4%)	11 (40.7%)	1 (25.0%)
three drugs	2 (22.2%)	1 (4.5%)	1 (3.7%)	0 (0.0%)
Non-missing	9 (100.0%)	22 (100.0%)	27 (100.0%)	4 (100.0%)
After 24 weeks				
Missing	3	4	2	2
none	2 (25.0%)	2 (10.0%)	7 (25.9%)	1 (25.0%)
one drug	1 (12.5%)	11 (55.0%)	10 (37.0%)	2 (50.0%)
two drugs	3 (37.5%)	6 (30.0%)	9 (33.3%)	1 (25.0%)
three drugs	2 (25.0%)	1 (5.0%)	1 (3.7%)	0 (0.0%)
Non-missing	8 (100.0%)	20 (100.0%)	27 (100.0%)	4 (100.0%)

6 Additional assessment parameters
6.8 Full Analysis Set - Subgroups - Previous basal insulin therapy
6.8.2 Change of the FGM system

Change of the FGM system	Detemir (N = 11) N (%)	Glargin 100 (N = 24) N (%)	Glargin 300 (N = 29) N (%)	Degludec (N = 6) N (%)
Baseline				
Missing	11	24	29	6
After 12 weeks				
Missing	6	15	24	5
yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
no	5 (100.0%)	9 (100.0%)	5 (100.0%)	0 (0.0%)
Non-missing	5 (100.0%)	9 (100.0%)	5 (100.0%)	1 (100.0%)
After 24 weeks				
Missing	6	14	24	6
no	5 (100.0%)	9 (90.0%)	5 (100.0%)	0 (0.0%)
Non-missing	5 (100.0%)	9 (90.0%)	5 (100.0%)	0 (0.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.1 Metformin

Metformin	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	9 (32.1%)	3 (33.3%)	6 (18.8%)
yes	19 (67.9%)	6 (66.7%)	26 (81.3%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
no	10 (35.7%)	3 (33.3%)	6 (18.8%)
yes	18 (64.3%)	6 (66.7%)	26 (81.3%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
After 12 weeks			
Missing	4	0	4
no	10 (41.7%)	3 (33.3%)	8 (28.6%)
yes	14 (58.3%)	6 (66.7%)	20 (71.4%)
Non-missing	24 (100.0%)	9 (100.0%)	28 (100.0%)
After 24 weeks			
Missing	5	0	6
no	10 (43.5%)	3 (33.3%)	6 (23.1%)
yes	13 (56.5%)	6 (66.7%)	20 (76.9%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.2 Sulfonyl urea

Sulfonyl urea	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Missing	0	1	0
no	27 (96.4%)	8 (100.0%)	31 (96.9%)
yes	1 (3.6%)	0 (0.0%)	1 (3.1%)
Non-missing	28 (100.0%)	8 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	1	1
no	28 (100.0%)	8 (100.0%)	30 (96.8%)
yes	0 (0.0%)	0 (0.0%)	1 (3.2%)
Non-missing	28 (100.0%)	8 (100.0%)	31 (100.0%)
After 12 weeks			
Missing	5	0	6
no	23 (100.0%)	9 (100.0%)	25 (96.2%)
yes	0 (0.0%)	0 (0.0%)	1 (3.8%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)
After 24 weeks			
Missing	5	0	6
no	22 (95.7%)	9 (100.0%)	25 (96.2%)
yes	1 (4.3%)	0 (0.0%)	1 (3.8%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.3 Glinide

Glinide	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	28 (100.0%)	9 (100.0%)	29 (90.6%)
yes	0 (0.0%)	0 (0.0%)	3 (9.4%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
no	28 (100.0%)	9 (100.0%)	28 (87.5%)
yes	0 (0.0%)	0 (0.0%)	4 (12.5%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
After 12 weeks			
Missing	4	0	5
no	24 (100.0%)	9 (100.0%)	26 (96.3%)
yes	0 (0.0%)	0 (0.0%)	1 (3.7%)
Non-missing	24 (100.0%)	9 (100.0%)	27 (100.0%)
After 24 weeks			
Missing	5	0	6
no	23 (100.0%)	9 (100.0%)	25 (96.2%)
yes	0 (0.0%)	0 (0.0%)	1 (3.8%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.4 Alpha-glucosidase inhibitor

Alpha-glucosidase inhibitor	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	28 (100.0%)	9 (100.0%)	32 (100.0%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	28 (100.0%)	9 (100.0%)	31 (100.0%)
Non-missing	28 (100.0%)	9 (100.0%)	31 (100.0%)
After 12 weeks			
Missing	4	0	5
no	24 (100.0%)	9 (100.0%)	27 (100.0%)
Non-missing	24 (100.0%)	9 (100.0%)	27 (100.0%)
After 24 weeks			
Missing	5	0	6
no	23 (100.0%)	9 (100.0%)	26 (100.0%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.5 Glitazone

Glitazone	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	28 (100.0%)	9 (100.0%)	32 (100.0%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	28 (100.0%)	9 (100.0%)	31 (100.0%)
Non-missing	28 (100.0%)	9 (100.0%)	31 (100.0%)
After 12 weeks			
Missing	4	0	5
no	24 (100.0%)	9 (100.0%)	27 (100.0%)
Non-missing	24 (100.0%)	9 (100.0%)	27 (100.0%)
After 24 weeks			
Missing	5	0	6
no	23 (100.0%)	9 (100.0%)	26 (100.0%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.6 DPP-4 inhibitor

DPP-4 inhibitor	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	19 (67.9%)	9 (100.0%)	17 (53.1%)
yes	9 (32.1%)	0 (0.0%)	15 (46.9%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	28 (100.0%)	9 (100.0%)	22 (71.0%)
yes	0 (0.0%)	0 (0.0%)	9 (29.0%)
Non-missing	28 (100.0%)	9 (100.0%)	31 (100.0%)
After 12 weeks			
Missing	5	0	5
no	23 (100.0%)	9 (100.0%)	23 (85.2%)
yes	0 (0.0%)	0 (0.0%)	4 (14.8%)
Non-missing	23 (100.0%)	9 (100.0%)	27 (100.0%)
After 24 weeks			
Missing	5	0	6
no	23 (100.0%)	9 (100.0%)	22 (84.6%)
yes	0 (0.0%)	0 (0.0%)	4 (15.4%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.7 SGLT2 inhibitor

SGLT2 inhibitor	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
no	15 (53.6%)	4 (44.4%)	16 (50.0%)
yes	13 (46.4%)	5 (55.6%)	16 (50.0%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
Missing	0	0	1
no	16 (57.1%)	4 (44.4%)	15 (48.4%)
yes	12 (42.9%)	5 (55.6%)	16 (51.6%)
Non-missing	28 (100.0%)	9 (100.0%)	31 (100.0%)
After 12 weeks			
Missing	4	0	4
no	12 (50.0%)	4 (44.4%)	11 (39.3%)
yes	12 (50.0%)	5 (55.6%)	17 (60.7%)
Non-missing	24 (100.0%)	9 (100.0%)	28 (100.0%)
After 24 weeks			
Missing	6	0	6
no	13 (59.1%)	4 (44.4%)	13 (50.0%)
yes	9 (40.9%)	5 (55.6%)	13 (50.0%)
Non-missing	22 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.1 Changes in non-insulin concomitant medication
6.9.1.8 Number of additional non-insulin concomitant medication

Number of drugs	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
none	2 (7.1%)	1 (11.1%)	0 (0.0%)
one drug	13 (46.4%)	5 (55.6%)	10 (31.3%)
two drugs	10 (35.7%)	3 (33.3%)	15 (46.9%)
three drugs	3 (10.7%)	0 (0.0%)	7 (21.9%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
Baseline - after switch to iGlarLixi			
none	7 (25.0%)	1 (11.1%)	2 (6.3%)
one drug	12 (42.9%)	5 (55.6%)	9 (28.1%)
two drugs	9 (32.1%)	3 (33.3%)	16 (50.0%)
three drugs	0 (0.0%)	0 (0.0%)	5 (15.6%)
Non-missing	28 (100.0%)	9 (100.0%)	32 (100.0%)
After 12 weeks			
Missing	4	0	4
none	7 (29.2%)	1 (11.1%)	4 (14.3%)
one drug	8 (33.3%)	5 (55.6%)	9 (32.1%)
two drugs	9 (37.5%)	3 (33.3%)	11 (39.3%)
three drugs	0 (0.0%)	0 (0.0%)	4 (14.3%)
Non-missing	24 (100.0%)	9 (100.0%)	28 (100.0%)
After 24 weeks			
Missing	5	0	6
none	7 (30.4%)	1 (11.1%)	4 (15.4%)
one drug	9 (39.1%)	5 (55.6%)	9 (34.6%)
two drugs	7 (30.4%)	3 (33.3%)	9 (34.6%)
three drugs	0 (0.0%)	0 (0.0%)	4 (15.4%)
Non-missing	23 (100.0%)	9 (100.0%)	26 (100.0%)

6 Additional assessment parameters
6.9 Full Analysis Set - Subgroups - Time of iGlarLixi administration
6.9.2 Change of the FGM system

Change of the FGM system	before breakfast (N = 28) N (%)	before lunch (N = 9) N (%)	before dinner (N = 32) N (%)
Baseline			
Missing	28	9	32
After 12 weeks			
Missing	28	2	19
yes	0 (0.0%)	1 (14.3%)	0 (0.0%)
no	0 (0.0%)	6 (85.7%)	13 (100.0%)
Non-missing	0 (0.0%)	7 (100.0%)	13 (100.0%)
After 24 weeks			
Missing	28	3	18
no	0 (0.0%)	6 (100.0%)	13 (92.9%)
Non-missing	0 (0.0%)	6 (100.0%)	13 (92.9%)

7 Safety
7.1 Incidence of adverse events
Safety Analysis Set (SAS)

	SAS (N = 89) N (%)
Number of patients	
with at least one adverse event (AE)[2]	39 (43.8%)
with at least one serious adverse event (SAE)[2]	1 (1.1%)
with at least one related adverse drug reaction (ADR)	12 (13.5%)
Events - as reported[1]	
adverse events (AE)[2]	61
serious adverse events (SAE)[2]	1
adverse drug reactions (ADR)	23

[1] Same event as reported (term) counted once per patient
No serious adverse drug reactions (SADR) and adverse events of special interest (AESI) were documented
[2] Includes patients documented with Product Name = NO STUDY DRUG GIVEN:
Patient [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted]

7 Safety
7.2 Adverse events as reported
Safety Analysis Set (SAS)

	SAS (N = 89) N (%)
AE - as reported	
45 IU Suliqua with no AE	1 (1.1%)
Diarrhea	1 (1.1%)
Hypoglcemic event	1 (1.1%)
Hypoglycaemie during sports	1 (1.1%)
Hypoglycemia	2 (2.2%)
Hypoglycemia 23 mg/dl	1 (1.1%)
Hypoglycemia 27 mg/dl	1 (1.1%)
Hypoglycemia Hypoglycemia 60 mg/dl	1 (1.1%)
Hypoglycemic event	1 (1.1%)
Hypos twice level below 30 mg/dl, once 60/	1 (1.1%)
Low blood glucose during sports	2 (2.2%)
Off label use	2 (2.2%)
Off label use Beginning dose was 35	1 (1.1%)
Past complications due to Diabetes mellitus (long-term complications)	1 (1.1%)
Recurrent hypoglycemia	1 (1.1%)
Start of iGlarLixi therapy with 50 dose steps, with no reported adverse event	1 (1.1%)
Worsening of triglyceride levels (436 mg/dl)	1 (1.1%)
diabetic nephropathy	2 (2.2%)
diabetic neuropathy	4 (4.5%)
diarrhea	1 (1.1%)
dose steps per day are <30	1 (1.1%)
elevated value for aspartate aminotransferase/glutamic oxaloacetic transaminase (2.17 µmol/sL)	1 (1.1%)
hypoglycemia	6 (6.7%)
hypoglycemia during sports	1 (1.1%)
hypoglycemia during walking	1 (1.1%)
hypoglycemia with blood glucose < 54 mg/dl	1 (1.1%)
hypoglycemic event under Lantus/Insuman basal therapy	3 (3.4%)
hypoglycemic event under Suliqua therapy	2 (2.2%)
hypoglycemic event under Toujeo therapy	3 (3.4%)
iGlarLixi therapy with 26 dose steps per day	1 (1.1%)
iGlarLixi therapy with 45 dose steps (30 in the morning and 15 in the evening)	1 (1.1%)
nausea	2 (2.2%)
nocturnal hypoglycemia with blood glucose < 54 mg/dl/ hypoglycemia with blood glucose < 54 mg/dl	1 (1.1%)
off label use	1 (1.1%)

Events are counted as reported
Same event as reported (term) counted once per patient
Includes patients documented with Product Name = NO STUDY DRUG GIVEN:
Patient [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted]

7 Safety
7.2 Adverse events as reported
Safety Analysis Set (SAS)

	SAS (N = 89) N (%)
off label use with no reported adverse event	1 (1.1%)
only increase of the dose with no AE	1 (1.1%)
only increased the dose initial from 30 IU to 34 IU	1 (1.1%)
patient received treatment with Suliqua, at a dose of 34 (frequency-1), subcutaneously for Diabetes, with no adverse event	1 (1.1%)
start of iGlarLixi therapy with 32 dose steps per day with no adverse event	1 (1.1%)
start of iGlarLixi therapy with 40 dose steps per day with no AE	1 (1.1%)
start of iGlarLixi therapy with 60 dose steps per day with no adverse event	1 (1.1%)
triglycerides 413 mg/dl	1 (1.1%)
two events with low glucose value within the period from 15MAR2021 to 29MAR2021	1 (1.1%)

Events are counted as reported
Same event as reported (term) counted once per patient
Includes patients documented with Product Name = NO STUDY DRUG GIVEN:
Patient [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted]

7 Safety
7.3 Adverse events by MedDRA system organ class and preferred term (MedDRA 25.0)
Safety Analysis Set (SAS)

SOC PT	SAS (N = 89) N (%)
Eye disorders	1 (1.1%)
Diabetic retinopathy	1 (1.1%)
Gastrointestinal disorders	4 (4.5%)
Diarrhoea	2 (2.2%)
Nausea	2 (2.2%)
Injury, poisoning and procedural complications	14 (15.7%)
Inappropriate schedule of product administration	1 (1.1%)
Off label use	14 (15.7%)
Investigations	6 (6.7%)
Aspartate aminotransferase increased	1 (1.1%)
Blood glucose decreased	3 (3.4%)
Blood triglycerides increased	2 (2.2%)
Metabolism and nutrition disorders	16 (18.0%)
Hypoglycaemia	16 (18.0%)
Nervous system disorders	4 (4.5%)
Diabetic neuropathy	4 (4.5%)
Renal and urinary disorders	2 (2.2%)
Diabetic nephropathy	2 (2.2%)

Patients with at least one adverse event of the corresponding category (Multiple answers possible)
Same SOC counted once per patient, same PT counted once per patient.
Includes patients (events) documented with Product Name = NO STUDY DRUG GIVEN:
Patient [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted]

7 Safety
7.4 Serious adverse events by MedDRA system organ class and preferred term (MedDRA 25.0)
Safety Analysis Set (SAS)

SOC PT	SAS (N = 89) N (%)
Eye disorders	1 (1.1%)
Diabetic retinopathy	1 (1.1%)

Patients with at least one SAE of the corresponding category (Multiple answers possible)

7 Safety
7.5 Adverse drug reactions by MedDRA system organ class and preferred term (MedDRA 25.0)
Safety Analysis Set (SAS)

SOC PT	SAS (N = 89) N (%)
Gastrointestinal disorders	4 (4.5%)
Diarrhoea	2 (2.2%)
Nausea	2 (2.2%)
Injury, poisoning and procedural complications	5 (5.6%)
Off label use	5 (5.6%)
Metabolism and nutrition disorders	6 (6.7%)
Hypoglycaemia	6 (6.7%)
Nervous system disorders	1 (1.1%)
Diabetic neuropathy	1 (1.1%)

Patients with at least one ADR of the corresponding category (Multiple answers possible)
Same SOC counted once per patient, same PT counted once per patient.

7 Safety
7.6 Serious adverse drug reactions by MedDRA system organ class and preferred term
Safety Analysis Set (SAS)

NOTE

Not applicable
No serious adverse drug reactions were documented

7 Safety
7.7 Adverse events of special interest by MedDRA system organ class and preferred term
Safety Analysis Set (SAS)

NOTE

Not applicable
No adverse event of special interest were documented

BEOBACHTUNGSPLAN

NICHT-INTERVENTIONELLE STUDIE

Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle durch Therapieintensivierung mit iGlarLixi im Suliqua®-(30-60)-Pen in der täglichen Praxis bei PatientInnen mit Typ-2-Diabetes, deren Blutzucker unter Basalinsulin und oraler antidiabetischer Therapie (BOT) nicht ausreichend kontrolliert ist

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WIRKSTOFF: Insulin glargin/Lixisenatid (iGlarLixi)

PRÄPARAT: Suliqua®

STUDIENNUMMER: OBS16751

STUDIENNAME: CHANCE

Die Studie wird durchgeführt von:

Sanofi-Aventis Deutschland GmbH
Brüningstr. 50
65929 Frankfurt am Main
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Versionsnummer: 1.0			
Datum:	01-Jul-2020	Gesamtzahl der Seiten:	57

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1 ZUSAMMENFASSUNG

PRÄPARAT: Suliqua® 30-60 (Fixkombination aus Insulin glargin 100 E/ml und Lixisenatid 33 µg/ml, iGlarLixi) **STUDIEN-Nr.:** OBS16751	
TITEL	Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle durch Therapieintensivierung mit iGlarLixi im Suliqua®-(30-60)-Pen in der täglichen Praxis bei PatientInnen mit Typ-2-Diabetes, deren Blutzucker unter Basalinsulin und oraler antidiabetischer Therapie (BOT) nicht ausreichend kontrolliert ist
ORT	Praxen in ganz Deutschland
VORSITZENDER DES WISSENSCHAFTLICHEN AUSSCHUSSES	[redacted]
STUDIENZIEL(E)	Ziel dieser Nicht-Interventionellen Studie ist es, die Effektivität und Sicherheit von iGlarLixi bei PatientInnen mit Typ-2-Diabetes im klinischen Alltag zu untersuchen, die aufgrund unzureichender glykämscher Kontrolle unter Basalinsulin in Kombination mit oralen Antidiabetika (OAD) von ihren ÄrztInnen auf iGlarLixi umgestellt werden. **Primäre Zielsetzung** Dokumentation der Veränderung des HbA_{1c} durch die Behandlung mit iGlarLixi im klinischen Alltag. **Sekundäre Zielsetzung(en)** Dokumentation der glykämischen Variabilität durch die Behandlung mit iGlarLixi sowie der Verträglichkeit von iGlarLixi im klinischen Alltag.
STUDIENDESIGN UND DAUER	Multizentrisch, prospektiv, Nicht-Interventionell in Bezug auf die Behandlungsstrategie. Beobachtungsdauer ca. 24 Wochen mit einer Zwischenvisite nach ca. 12 Wochen.
STUDIENPOPULATION	Erwachsene PatientInnen (≥ 18 Jahre zum Zeitpunkt der Unterzeichnung der Einwilligungserklärung) mit Typ-2-Diabetes und unzureichender glykämischer Kontrolle, die mit einem Basalinsulin in Kombination mit OAD (BOT) behandelt werden und bereit sind, Glukosemessungen in Form eines 7-Punkte-Tagesprofils durchzuführen, oder bereits ein FGM-System zur kontinuierlichen Glukosemessung verwenden.

	Selektionskriterien <u>für</u> die Dokumentation eines/r PatientIn • Erwachsene PatientInnen mit Typ-2-Diabetes mellitus • Seit mind. 6 Monaten in Behandlung mit OAD und einem Basalinsulin ohne prandiales Insulin und ohne GLP-1-Rezeptoragonisten • HbA_{1c} 7,5 % bis 10,0 % (Befund aus den letzten 3 Monaten) • Vorliegen einer Basalinsulin-Vortherapie, die stabil zwischen 30-60 Einheiten pro Tag liegt • Umstellung auf iGlarLixi erfolgt im Zeitraum zwischen 14 Tage vor der Eingangsdokumentation bis 7 Tage nach der Eingangsdokumentation • Entscheidung des/der behandelnden Arztes/Ärztin, unabhängig von der Aufnahme in die Studie das bisherige Basalinsulin durch iGlarLixi zu ersetzen • Fähigkeit und Bereitschaft, Messungen für ein 7-Punkte-Glukose-Tagesprofil mit einem Glukometer durchzuführen, ODER Selbstmanagement des Blutzuckers anhand eines FGM-Systems seit mindestens 3 Monaten • FGM-PatientInnen sollten nur eingeschlossen werden wenn: o mind. 70 % erfasste Sensordaten aus den FGM-Tagesprofilen der letzten ca. 14 Tage (max. 3 Wochen) vor Umstellung auf iGlarLixi vorhanden sind (1) o keine Änderung des verwendeten FGM-Herstellers während der Studiendauer geplant ist; ein Wechsel zu einem Gerät des gleichen Herstellers (z. B. zur neuesten Gerätegeneration) ist möglich o Kalibrierung des FGM-Systems gewährleistet ist gemäß den Herstellerangaben • Unterschriebene Einverständniserklärung liegt vor Studienbeginn vor **Selektionskriterien <u>gegen</u> die Dokumentation eines/r PatientIn** • Typ-1-Diabetes mellitus • Gegenanzeigen zur Behandlung mit iGlarLixi laut Fachinformation

	• Basalinsulindosis < 30 oder > 60 Einheiten pro Tag • Teilnahme an einer klinischen Prüfung • Geplante oder bestehende Schwangerschaft, Krebserkrankungen, Drogen- oder Alkoholmissbrauch, Demenz bzw. allgemeines Unvermögen, die Inhalte der Beobachtungsstudie zu verstehen **Erwartete PatientInnen-Zahl:** 250 **Erwartete Anzahl an teilnehmenden Zentren:** 100
AUSWAHLMODALITÄTEN	**Auswahl der teilnehmenden ÄrztInnen** Die Nicht-Interventionelle Studie (NIS) wird durch die Mitarbeiter von Sanofi (Deutschland) bei AllgemeinärztInnen/PraktikerInnen/InternistInnen, DiabetologInnen oder in Praxen mit diabetologischem Schwerpunkt gemäß den lokalen Anforderungen zur Durchführung einer NIS platziert. Die teilnehmenden ÄrztInnen sind mit der Software der FGM-Systeme vertraut und verwenden diese bereits in Ihrer täglichen Praxis zur Auswertung der FGM-Daten. **Auswahl der PatientInnen** Typ-2-DiabtespatientInnen, bei denen der/die behandelnde Arzt/Ärztin die Entscheidung zur Umstellung des Basalinsulins auf iGlarLixi unabhängig von der Nicht-Interventionellen Studie unter Berücksichtigung der Vorgaben der iGlarLixi Fachinformation (2) getroffen hat. Die PatientInnen müssen in der Lage sein, anhand von Blutzuckerselbstmessungen die iGlarLixi-Dosis entsprechend des Nüchternblutzucker-Ziels anzupassen (eine Dosis-Titration durchzuführen).
ENDPUNKTE	**Primärer Endpunkt** Absolute Änderung des HbA_{1c} (%) unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Ende der Dokumentation nach ca. 24 Wochen. **Sekundäre Endpunkte** • Relative Änderung des HbA_{1c} (%) • Absolute und relative Änderung des Nüchternblutzuckers (mg/dl bzw. mmol/l) • Anteil an PatientInnen, die den individuellen HbA_{1c}-Zielwert erreichen (%)

	• Anteil an PatientInnen, die einen Nüchternblutzucker ≤ 110 mg/dl bzw. 6,1 mmol/l erreichen (%) • Absolute und relative Änderung der Glukose im 7-Punkte-Glukose-Tagesprofil (mg/dl bzw. mmol/l) • Absolute und relative Änderung der iGlarLixi-Dosis (Dosisschritte/Tag) • Absolute und relative Änderung des Körpergewichts (kg) • Absolute Änderung des Body-Mass-Index (kg/m²) • Hypoglykämie-Inzidenz und Hypoglykämie-Raten (symptomatische, bestätigte [< 70 mg/dl und ≥ 54 mg/dl bzw. < 3,9 mmol/l und ≥ 3,0 mmol/l, < 54 mg/dl bzw. < 3,0 mmol/l], schwere, nächtliche (während der Schlafzeit der PatientInnen [ca. 22-6 Uhr] und schwere nächtliche), dokumentiert im Zeitraum von ca. 12 Wochen vor Studieneinschluss im Vergleich zum Zeitraum von der Eingangsdokumentation (Dokumentation 1) bis zur Dokumentation 2 (nach ca. 12 Wochen) und von Dokumentation 2 bis zur Abschlussdokumentation (Dokumentation 3; nach ca. 24 Wochen) • Absolute und relative Änderung der Glukose gemessen am Median (mg/dl) • Absolute Änderung der Therapiezufriedenheit (DTSQs und DTSQc) Zusätzlich für FGM-PatientInnen: • Medianer Zielwert des Blutzuckers und Grenzwert für niedrige Glukose (mg/dl bzw. mmol/l) • Absolute Änderung der Gesamtzeit im individuellen Zielbereich in % • Absolute Änderung der Gesamtzeit in % über dem individuellen Zielbereich • Absolute Änderung der Gesamtzeit in % unter dem individuellen Zielbereich • Absolute und relative Änderung der Anzahl der PatientInnen mit hypoglykämischen Ereignissen und der Anzahl an Ereignissen pro PatientIn (dokumentierte Hypoglykämien während der 14-tägigen FGM-Messung vor Studieneinschluss im Vergleich zur 14-tägigen FGM-Messung vor

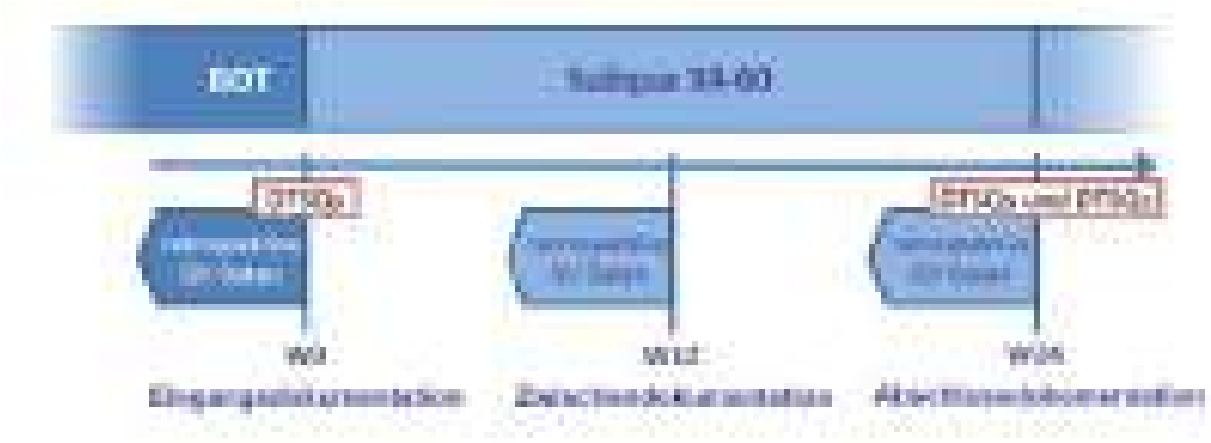
	Dokumentation 2 (nach ca. 12 Wochen) und zur 14-tägigen FGM-Messung vor der Abschluss-dokumentation (Dokumentation 3; nach ca. 24 Wochen)). Alle Endpunkte werden für PatientInnen, die ein FGM-Gerät verwenden, zusätzlich zur Gesamtpopulation analysiert.
GESAMMELTE HAUPTDATEN	Datenerhebung wird zu den Zeitpunkten Woche 0 (Eingangsdokumentation (Dokumentation 1)), ca. 4 und ca. 8 Wochen (monatliche Dokumentation 1.1 und 1.2) ca. 12 Wochen (Dokumentation 2), ca. 16 und ca. 20 Wochen (monatliche Dokumentation 2.1 und 2.2) und ca. 24 Wochen (Abschlussdokumentation (Dokumentation 3)) nach Umstellung auf iGlarLixi durchgeführt. Hauptdaten sind dabei die HbA_{1c}-Werte und mittels 7-Punkte-Glukose-Tagesprofil oder FGM erfassten Daten des Glukoseverlaufs vor und ca. 12 bzw. ca. 24 Wochen nach Beginn der Therapie mit iGlarLixi. Vor der Umstellung des Basalinsulins auf iGlarLixi und ca. 12 bzw. ca. 24 Wochen nach der Umstellung werden die mittels FGM-Systems erfassten Hauptdaten der jeweils letzten ca. 14 Tage (max. 3 Wochen vor Dokumentationszeitpunkt) dokumentiert. Zusätzlich werden folgende Daten erhoben: • Fragebogen für teilnehmende/n Ärztin/Arzt • Überprüfung der Dokumentationskriterien • Grund für die Therapieentscheidung, auf iGlarLixi umzustellen • PatientInnen-Charakteristika (Alter, Geschlecht, Größe, Gewicht, Blutdruck) • Diabetes mellitus Vorgeschichte (Diabetesdauer, aktuelle Medikation (Basalinsulin und OAD) und deren Dosis, Komplikationen) • Vorliegen von Retinopathie, Neuropathie, Nephropathie, diabetischem Fußsyndrom, kardiovaskulären Erkrankungen, festgehalten in den Krankenakten der PatientInnen • Lipidsenkende Medikation und blutdrucksenkende Medikation • Individueller HbA_{1c}-Zielwert • Laborwerte – sofern vorhanden – (Nüchternblutzucker [NBZ], Aspartat-Aminotransferase [AST]- und Alanin-Aminotransferase [ALT]-Werte, Gesamtcholesterin, Low

	Density Lipoprotein [LDL], High Density Lipoprotein [HDL], Triglyzeride, geschätzte glomeruläre Filtrationsrate [eGFR], Kreatinin) • Erfassung der glykämischen Variabilität aus 7-Punkte-Glukose-Tagesprofil oder Erhebung der glykämischen Variabilität aus FGM (Glukosemedian, Glukosevariablität gemessen als Standardabweichung, Zeit im Zielbereich [TIR], Zeit oberhalb des Zielbereichs [TAR], Zeit unterhalb des Zielbereichs [TBR]) • Therapie mit iGlarLixi (Datum des Therapiebeginns, Startdosis, Zeitpunkt der Injektion und monatlich aktuelle iGlarLixi-Dosis, Anzahl der Dosisänderungen in den letzten 4 Wochen und aktueller selbstgemessener Nüchternblutzuckerwert) • FGM-System o genaue Gerätebezeichnung o erfasste Hauptdaten, mindestens 70 % erfasste Sensordaten aus den letzten ca. 14 Tage (max. 3 Wochen) vor Umstellung auf iGlarLixi • Unerwünschte Ereignisse, insb. Hypoglykämien, Übelkeit, Durchfall und Erbrechen • Änderung der antidiabetischen Therapie • Änderung des Gerätes zur Bestimmung der glykämischen Variabilität • Fragebogen zur Therapiezufriedenheit (mittels DTSQs und DTSQc) • Dokumentation der Gründe für einen Therapieabbruch
STATISTISCHE METHODIK	**Stichprobenberechnung** Es wird erwartet, dass von der Stichprobengröße von 250 PatientInnen etwa 60 %, d. h. 150 PatientInnen, hinsichtlich Wirksamkeit auswertbar sein werden. Diese relativ hohe Abbruchquote ist eine konservative Schätzung aus den vorangegangenen RWE-Studien, die in Deutschland bereits durchgeführt wurden. Die Stichprobengröße wurde anhand der folgenden Annahmen abgeschätzt, die teilweise von einer Publikation zum Einsatz von iGlarLixi bei PatientInnen mit Typ-2-Diabetes abgeleitet wurden (3): Eine Analyse von 150 PatientInnen wird mit einer 90 %-igen Power einen klinisch relevanten Unterschied des HbA_{1c} von 0,4 % feststellen (im Vergleich der Eingangsdokumentation zur Abschlussdokumentation), wobei eine

	Standardabweichung der Differenzen von 1,5 % angenommen wird und ein gepaarter t-Test mit einem zweiseitigen Signifikanzniveau von 0,05 zum Einsatz kommt. Für die Sicherheitsanalyse werden alle PatientInnen eingeschlossen, die mindestens eine Dosis der Studienmedikation erhalten haben. Bei 250 PatientInnen beträgt die Wahrscheinlichkeit 95,0 %, in dieser Studie mindestens ein „seltenes“ Ereignis zu beobachten, welches mit einer Wahrscheinlichkeit von 0,01 in dieser PatientInnenpopulation auftritt. **Primäranalyse** Basierend auf der Normalverteilungsannahme wird das 95 %-Konfidenzintervall für den geschätzten Parameter, die absolute Änderung des HbA_{1c} (%) unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Ende der Dokumentation nach ca. 24 Wochen, berechnet. Mithilfe des t-Tests für verbundene Stichproben wird darüber hinaus überprüft, ob eine von Null verschiedene Differenz vorliegt. Zusätzlich werden die Wechselwirkungen der Parameter durch eine Varianzanalyse untersucht. Des Weiteren kommen Methoden zur Berücksichtigung fehlender Daten zur Anwendung (z.B. MMRM-Modell). **Sekundäranalyse** Das 95 %-Konfidenzintervall wird mithilfe von exakten Methoden, z. B. der Blyth-Still-Castella-Methode, ermittelt.
GESCHÄTZTE STUDIENDAUER	Beobachtungsdauer: ca. 24 Wochen Erster Dokumentationszeitpunkt des/r ersten PatientIn: 09/2020 Aufnahme von PatientInnen zur Dokumentation: 09/2020 bis 06/2021 Letzter Dokumentationspunkt des/r letzten PatientIn: 12/2021

2 FLUSSDIAGRAMM

2.1 GRAPHISCHES STUDIENDESIGN



Legende: BOT, basalunterstützte orale Therapie
DTSQs, Diabetes Treatment Satisfaction Questionnaire (Status)
DTSQc, Diabetes Treatment Satisfaction Questionnaire (Change)
GV, glykämische Variabilität
W, Woche

2.2 FLUSSDIAGRAMM DER STUDIE

	Eingangs-dokumentation (Dokumentation 1)	Monatliche Dokumentation (Zwischen-erfassung)	**Zwischen-dokumentation** (Dokumentation 2)	Monatliche Dokumentation (Zwischen-erfassung)	**Abschluss-dokumentation** (Dokumentation 3)
Zeitpunkt (Woche)	0 (Beginn Beobachtung)	ca. 4 ca. 8	ca. 12	ca. 16 ca. 20	ca. 24 (Abschluss)
Arztfragebogen	X				
Selektionskriterien	X				
PatientInnen-Charakteristika	X				
Einwilligungs- / Datenschutzerklärung	X				
Demographische Daten	X				
Größe	X				
Gewicht	X		X		X
Krankengeschichte inkl. Diabetes mellitus	X				
Aktuelle Begleiterkrankungen	X				
Individueller HbA_{1c} Zielwert	X				

Medikamentenanamnese	X				
Aktuelle Medikation	X		X		X
Daten iGlarLixi- Anpassung	X	X	X	X	X
iGlarLixi-Dosis	X	X	X	X	X
Glykämische Variabilität (7-Punkte-Blutzucker-Tages-profil oder FGM)	X		X		X
Laborwerte inkl. HbA_{1c}	X		X		X
Nüchternblutzucker (Patientenmessung)	X	X	X	X	X
Therapiezufriedenheit (DTSQs und DTSQc)	X (nur DTSQs)				X (DTSQs und DTSQc)
Unerwünschte Ereignisse	X		X		X

3 INHALTSVERZEICHNIS

4 ABKÜRZUNGSLISTE

ALT	Alanin-Aminotransferase
AST	Aspartat-Aminotransferase
BMI	Body Mass Index
BOT	basalunterstützte orale Therapie
CGM	Kontinuierliche Glukosemessung in Echtzeit (real-time continuous glucose monitoring, rtCGM)
CRF	Prüfbogen (Case Report Form)
CRO	Clinical Research Organisation
DMP	Datenmanagementplan
DSGVO	Datenschutz-Grundverordnung
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DTSQc	Diabetes Treatment Satisfaction Questionnaire - Change
DTSQs	Diabetes Treatment Satisfaction Questionnaire - Status
DVP	Datenvalidierungsplan
e-CRF	elektronischer Prüfbogen (Case Report Form)
eGFR	geschätzte glomeruläre Filtrationsrate (estimated glomerular filtration rate)
FAS	Full Analysis Set
FGM	Flash Glucose Monitoring oder periodisch abgelesene kontinuierliche Glukosemessung (**i**ntermittend **c**ontinuous **g**lucose **m**onitoring, iCGM)
GLP-1	Glucagon-like-peptide-1
GLP-1-RA	GLP-1-Rezeptoragonist
GV	glykämische Variabilität
HbA_{1c}	Glykohämoglobin A_{1c}
HDL	High-density Lipoprotein

iCGM	periodisch abgelesene kontinuierliche interstitielle Glukosemessung (intermittently viewed continuous glucose monitoring)
LDL	Low-density Lipoprotein
MDR	Medical Device Regulation
MMRM	Mixed Model for Repeated Measures
NBZ	Nüchternblutzucker
NIS	Nicht-Interventionelle Studie
OAD	orale Antidiabetika
PPG	post-prandiale Glukose
PTC	Produkt-technische Reklamation (Product Technical Complaints)
rtCGM	kontinuierliche interstitielle Glukosemessung in Echtzeit (real time continuous glucose monitoring)
RWE	Real-World-Evidence
SAP	statistischer Analyseplan
SAS	Safety Analysis Set
SGLT2i	Natrium-Glukose-Cotransporter-2-Inhibitor
SmPC	Summary of Product Characteristics
SUE	schwerwiegendes unerwünschtes Ereignis
T2DM	Typ-2 Diabetes mellitus
TAR	time above range
TBR	time below range
TIR	time in range
UE	unerwünschtes Ereignis
UESI	unerwünschtes Ereignis von speziellem Interesse
VFA	Verband forschender Arzneimittelhersteller

5 EINLEITUNG UND BEGRÜNDUNG

5.1 HINTERGRUND

Der Blutzucker bei Typ-2 Diabetes mellitus (T2DM) erreicht erwünschte Zielbereiche oftmals nicht und eine unzureichende oder verspätete Therapieanpassung erhöht das Risiko für Langzeitkomplikationen (4). Diese Beobachtung der sogenannten Therapieresistenz ist nicht beschränkt auf den Einsatz von oralen Antidiabetika (OAD) und deren Kombinationen, sondern wurde auch bei PatientInnen, die bereits eine Basalinsulintherapie erhalten, beobachtet (5). Mauricio et al. untersuchten in einer retrospektiven, longitudinalen Analyse elektronischer medizinischer Aufzeichnungen aus 5 europäischen Ländern und den USA die Daten von mehr als 40.000 PatientInnen mit T2DM, die eine Basalinsulingabe mit oder ohne orale Antidiabetika erhielten. Lediglich 20,9 % der PatientInnen erreichten einen Glykohämoglobin A_{1c} (HbA_{1c}-) Wert unterhalb von 7 % innerhalb von 3 Monaten und 27,8 % innerhalb von 24 Monaten nach Initiierung des Basalinsulins (5).

Leitlinien raten in dieser Situation eindeutig zu einer Intensivierung der basalunterstützten oralen Therapie (BOT) (6). Eine Therapieintensivierung ist unter anderem möglich durch den zusätzlichen Einsatz von Glucagon-like-peptide-1-(GLP-1-) Rezeptoragonisten. Der GLP-1-Rezeptor ist Zielrezeptor für das endogene Inkretinhormon GLP-1. Dieses steigert glukoseabhängig die Insulinsekretion der pankreatischen Betazellen und unterdrückt parallel die Glukagonfreisetzung aus den Alphazellen (7). Lixisenatid vermag die Insulinsekretion zu stimulieren, allerdings nur bei hohen Blutzuckerwerten und nicht bei einer Normoglykämie. Damit wird das Risiko für Hypoglykämien begrenzt. Zusätzlich wird die Magenentleerung verlangsamt. Mit Insulin glargin 100 E/ml steht ein langwirksames Humaninsulin-Analogon mit gleichmäßiger Retardwirkung über 24 Stunden zur Verfügung (8).

In Suliqua® 30-60 (iGlarLixi) wurden diese zwei Wirkstoffe mit synergistischen Wirkprinzipien kombiniert. Insulin glargin 100 E/ml (Gla-100) wirkt als Basalinsulinanalogon insbesondere auf die Nüchternglukosewerte bei weniger nächtlichen Hypoglykämien vs. NPH-Insulin (9) und der GLP-1-Rezeptoragonist (GLP-1-RA) Lixisenatid auf die postprandialen Glukosewerte (10-13).

Der komplementäre Effekt von Lixisenatid und Basalinsulin, appliziert als separate Injektionen, konnte bereits im klinischen Studienprogramm zu Lixisenatid GetGoal gezeigt werden (11-13). In die GetGoal Duo2- Studie wurden übergewichtige PatientInnen mit unzureichender glykämischer Kontrolle trotz Kombination eines Basalinsulins mit 1-3 OAD eingeschlossen (14). Es konnte gezeigt werden, dass sich die glykämische Kontrolle unter Lixisenatid zusätzlich zu Gla-100 mit oder ohne Metformin deutlich verbesserte. Außerdem kam es zu weniger Hypoglykämien und Gewichtsabnahme im Vergleich zu prandialem Insulin zusätzlich zu Gla-100, appliziert als Basal-plus- oder Basal-Bolus-Schema, wo Hypoglykämien häufiger auftraten und eine Gewichtszunahme beobachtet wurde. Allerdings wurden mehr gastrointestinale Nebenwirkungen unter der Kombination mit Lixisenatid beobachtet (14). GLP-1-RA bringen alle ein erhöhtes Risiko für gastrointestinale Nebenwirkungen mit sich (15).

In der offenen, randomisierten, parallel-Gruppen-kontrollierten Phase III-Studie LixiLan-L wurde bei 736 PatientInnen mit T2DM mit unzureichender glykämischer Kontrolle unter BOT der Einsatz

von iGlarLixi mit Gla-100 (beides zusätzlich zu Metformin) verglichen (3). Es konnte gezeigt werden, dass im Vergleich zu Gla-100 ein größerer Anteil der iGlarLixi-behandelten PatientInnen einen $HbA_{1c} < 7$ % erreichten. Darüber hinaus gab es positive Effekte auf das Körpergewicht, kein erhöhtes Hypoglykämie-Risiko und wenig gastrointestinale Nebenwirkungen unter der fixen Kombination iGlarLixi.

iGlarLixi wurde im Januar 2017 in der Europäischen Union zugelassen in den Dosierungskombinationen iGlarLixi 10-40 (Insulin glargin 100 Einheiten/ml plus Lixisenatid 50 µg/ml) in einem Fertigpen, der 10-40 Dosisschritte ermöglicht, sowie iGlarLixi 30-60 (Insulin glargin 100 Einheiten/ml plus Lixisenatid 33 µg/ml) in einem Fertigpen mit 30-60 Dosisschritten. Nach Einigung über die Preisgestaltung im Juli 2019 ist seit Januar 2020 der Fertigpen iGlarLixi 30-60 (Insulin glargin 100 Einheiten/ml plus Lixisenatid 33 µg/ml) auf dem deutschen Arzneimittelmarkt verfügbar und stellt die aktuell einzige in Deutschland erhältliche fixe Kombination aus einem Basalinsulin und einem GLP-1-RA dar.

Damit gibt es bislang keine Effektivitäts- und Sicherheits-Untersuchungen bezüglich einer Therapie-Intensivierung mit iGlarLixi 30-60 in der klinischen Praxis in Deutschland. CHANCE ermöglicht, als Nicht-Interventionelle Studie, spezifische Einblicke in die Charakteristika von T2DM-PatientInnen mit unzureichender glykämischer Kontrolle unter einer BOT und liefert Ergebnisse zur Effektivität und Sicherheit der Therapieumstellung auf iGlarLixi mit ≥ 30 Dosisschritten. Gemäß der Fachinformation von iGlarLixi beträgt die Tageshöchstdosis 60 Einheiten Insulin glargin und 20 µg Lixisenatid, entsprechend 60 Dosisschritten (2).

Zur Beurteilung der glykämischen Kontrolle wurde der HbA_{1c}-Wert zum Goldstandard etabliert, nachdem in der DCCT (Diabetes Control and Complications Trial) eine starke Assoziation zwischen HbA_{1c}-Werten und dem Risiko chronischer diabetischer vaskulärer Komplikationen gezeigt werden konnte (16). Der HbA_{1c}-Wert vermag die durchschnittliche Glukose der letzten Wochen darzustellen, allerdings liefert er keine Erkenntnisse hinsichtlich Hyper- und Hypoglykämien, glykämischer Variabilität (GV) und dem täglichen glykämischen Profil der DiabetespatientInnen (17). Die GV ist ein Schlüsselfaktor mit Einfluss auf die Lebensqualität, sowie mikro- und makrovaskuläre Ereignisse (17-19).

Heute können PatientInnen ihren Blutzuckerspiegel auch mit Hilfe von Geräten zur kontinuierlichen Glukosemessung ermitteln. Dabei unterscheidet man zwischen Geräten, die periodisch ausgelesen werden (FGM, intermittent CGM, und Geräten, die die Glukosewerte in Echtzeit auswerten (CGM, real time CGM) (20). Während bei Typ-1-DiabetespatientInnen der Gebrauch von real time CGM und intermittent scanning CGM/FGM etabliert ist, ist dies noch relativ ungewöhnlich bei PatientInnen mit T2DM. Dennoch erkennen auch T2DM-PatientInnen mit einer BOT FGM als innovative Möglichkeit zur Verbesserung ihrer glykämischen Kontrolle an. In der Konsequenz erhöht sich der Gebrauch von FGM-Geräten bei T2DM-PatientInnen mit BOT. Es konnte gezeigt werden, dass die Visualisierung der GV und deren Verbesserung durch Anpassung der antidiabetischen Therapie eine überzeugende Möglichkeit zur Verbesserung der Therapietreue, PatientInnen-Selbstmotivation, sowie Zielerreichung in der klinischen Praxis sowohl für PatientInnen als auch für ÄrztInnen darstellt.

Primäres Ziel der Studie ist die Sammlung von Daten bezüglich der glykämischen Kontrolle von T2DM-PatientInnen, deren Therapie, nach Versagen einer BOT, auf iGlarLixi umgestellt wurde.

Die Effektivität wird primär beurteilt durch die Veränderung des HbA_{1c}-Werts. Zusätzlich werden Daten zur GV ermittelt durch Verwendung eines 7-Punkte-Glukose-Tagesprofils und/oder eines FGM-Profils. Für PatientInnen, deren Diabetes unter einer BOT nicht ausreichend kontrolliert ist, und die die Einschlusskriterien erfüllen, wird im Vorfeld eine Bewertung der GV (7-Punkte-Glukose-Tagesprofil an einem Tag vor W0) oder ein 14-Tage-Auszug der FGM-Messung vorgenommen, bevor die BOT nach der von der Teilnahme an der Studie unabhängigen Entscheidung des/der Arztes/Ärztin umgestellt wird. Nach ca. 12 und ca. 24 Wochen wird die GV erneut dokumentiert.

5.2 BEGRÜNDUNG

Mit Suliqua® 30-60 (Insulin glargin 100 E/ml plus Lixisenatid 33 µ/ml) ist eine Kombination aus einem Langzeit-Insulinanalogon und einem GLP-1-RA für die Behandlung in Kombination mit Metformin und mit oder ohne SGLT2i (Natrium-Glukose-Cotransporter-2-Inhibitor) für PatientInnen mit T2DM, bei denen mittels Diät und Bewegung und einer Kombinationsbehandlung aus Metformin alleine oder mit anderen oralen Antidiabetika und Basalinsulin keine ausreichende Kontrolle des Blutzuckers erreicht werden konnte, zugelassen und verfügbar.

Mit der vorliegenden Nicht-Interventionellen Studie (NIS) sollen Erkenntnisse gewonnen werden, wie die glykämische Kontrolle beim routinemäßigen Einsatz von iGlarLixi im Praxisalltag aussieht. Damit soll der Nutzen für T2DM-PatientInnen dargestellt, sowie potenzielle unerwünschte Nebenwirkungen beim Einsatz in der alltäglichen Praxis in Deutschland erkannt werden.

Zu diesem Zweck werden PatientInnen mit T2DM und unzureichender glykämischer Kontrolle unter einer BOT dokumentiert, die sich in der ambulanten Behandlung befinden. Die Entscheidung zur iGlarLixi-Therapie liegt im Ermessen des/der behandelnden Arztes/Ärztin, beruht auf der Suliqua®-Fachinformation und wurde unabhängig von der Teilnahme an der Studie gefällt.

Um die Auswirkungen der Therapieänderung auf die glykämische Kontrolle zu dokumentieren, werden zum einen Veränderungen des HbA_{1c} und Daten zur GV, letztere entweder mittels 7-Punkte-Glukose-Tagesprofil oder FGM, vor iGlarLixi-Initiierung und nach ca. 12 und ca. 24 Wochen erhoben. Ziel dieser NIS ist es, die Effektivität und Sicherheit der Umstellung auf iGlarLixi bei T2DM-PatientInnen unter Praxisbedingungen zu dokumentieren.

6 STUDIENZIELE

Ziel dieser Nicht-Interventionellen Studie ist es, die Effektivität und Sicherheit von iGlarLixi bei PatientInnen mit T2DM im klinischen Alltag zu untersuchen, die aufgrund unzureichender glykämischer Kontrolle mit einem Basalinsulin von ihren ÄrztInnen auf iGlarLixi umgestellt werden.

6.1 PRIMÄR

Primäres Ziel ist die Dokumentation der absoluten Veränderung des HbA_{1c} (%) durch die Behandlung mit iGlarLixi im klinischen Alltag ca. 12 und ca. 24 Wochen nach dem Wechsel von einer bestehenden BOT.

6.2 SEKUNDÄR

Sekundäre Ziele sind die Dokumentation der Veränderungen weiterer glykämischer Parameter, insbesondere der glykämischen Variabilität, durch die Behandlung mit iGlarLixi sowie die Dokumentation der Verträglichkeit von iGlarLixi im klinischen Alltag. Die sekundären Ziele umfassen:

- Relative Änderung des HbA_{1c} (%)
- Absolute und relative Änderung des selbstgemessenen Nüchternblutzuckers (NBZ) (mg/dl bzw. mmol/l)*
- Anteil an PatientInnen, die den individuellen HbA_{1c}-Zielwert erreichen (%)
- Anteil an PatientInnen, die einen Nüchternblutzucker ≤ 110 mg/dl bzw. ≤ 6,1 mmol/l erreichen (%)
- Absolute und relative Änderung der Glukose im 7-Punkte-Glukose-Tagesprofil (mg/dl bzw. mmol/l)
- Absolute und relative Änderung der iGlarLixi-Dosis (Dosisschritte/Tag)*
- Absolute und relative Änderung des Körpergewichts (kg)
- Absolute Änderung des BMI (kg/m^2)
- Absolute und relative Änderung des Medianwertes der Glukose (mg/dl)
- Inzidenz und Rate von Hypoglykämien** (dokumentierte Hypoglykämien innerhalb der letzten ca. 12 Wochen vor Studieneinschluss im Vergleich zu den letzten 12 Wochen vor Dokumentation 2 (nach ca. 12 Wochen) und den letzten 12 Wochen vor der Abschlussdokumentation (nach ca. 24 Wochen))

- Änderung der Therapiezufriedenheit mittels des DTSQs und DTSQc***

  *Diese Änderungen werden zusätzlich zu Dokumentation 1, 2 und 3 monatlich dokumentiert nach Umstellung auf iGlarLixi.

  **Definition und Unterteilung hypoglykämischer Ereignisse. Hypoglykämien werden als symptomatische Hypoglykämien sowie als bestätigte Hypoglykämien in drei Levels unterteilt und erfasst (21):
  - Level 1: Selbstgemessener Blutzuckerwert < 70 mg/dl (< 3,9 mmol/l) und ≥ 54 mg/dl (≥ 3,0 mmol/l)
  - Level 2: Selbstgemessener Blutzuckerwert < 54 mg/dl (< 3,0 mmol/l); klinisch signifikante Hypoglykämie
  - Level 3: Schweres hypoglykämisches Ereignis, charakterisiert durch eine beeinträchtigte geistige und/oder körperliche Verfassung, die Fremdhilfe erfordert

  - Nächtliche Hypoglykämie: Hypoglykämie, die während der regulären Schlafenszeit des/r PatientIn stattfindet (ca. 22 Uhr bis 6 Uhr)

  ***DTSQ: Fragebogen zur Zufriedenheit mit der Diabetes-Behandlung:

  Es gibt 2 verschiedene Formen dieses Fragebogens, DTSQs und DTSQc. Beide beinhalten 8 Fragen, die auf einer 7-Punkte-Skala die Diabetes-Therapiezufriedenheit erfassen sollen. Es gibt zum einen die „Status“-Version des Fragebogens (DTSQs). Dieser wird hier bei der Eingangs- und Abschlussdokumentation genutzt. Die „Change“-Version (DTSQc) wird lediglich zur Abschlussdokumentation verwendet. Der DTSQs ist als Erhebungsinstrument primär zur Darstellung eines Zustandes (nicht einer Veränderung), der DTSQc zur Darstellung einer Veränderung geeignet.

<u>Zusätzlich für FGM-PatientInnen:</u>

- Medianer Zielwert des Blutzuckers und Grenzwert für niedrige Glukose (mg/dl bzw. mmol/l)

- Absolute Änderung der Gesamtzeit im individuellen Zielbereich in %

- Absolute Änderung der Gesamtzeit in % über individuellem Zielbereich

- Absolute Änderung der Gesamtzeit in % unter individuellem Zielbereich

- Absolute und relative Änderung der Anzahl der PatientInnen mit hypoglykämischen Ereignissen entsprechend Level 1** und der Anzahl an Ereignissen pro PatientIn (dokumentierte Hypoglykämien innerhalb der 14-tägigen FGM-Auswertung vor Studieneinschluss im Vergleich zur 14-tägigen FGM-Auswertung vor Dokumentation 2 (nach ca. 12 Wochen) und zur 14-tägigen FGM-Auswertung vor der Abschlussdokumentation (nach ca. 24 Wochen))

Alle Endpunkte werden für PatientInnen, die ein FGM-Gerät verwenden, zusätzlich zur Gesamtpopulation analysiert.

7 STUDIENDESIGN

7.1 BESCHREIBUNG DES STUDIENDESIGNS

Die vorliegende Studie ist eine nationale, multizentrische, hinsichtlich der therapeutischen Vorgehensweise nicht- interventionelle, prospektive Studie. Sie hat zum Ziel, Informationen über die Effektivität und potenzielle Nebenwirkungen einer Behandlung von T2DM-PatientInnen mit iGlarLixi, die mit einer vorangegangenen BOT kein ausreichende glykämische Kontrolle erreichen konnten, zu sammeln. Das Studiendesign spiegelt die Lebenssituation dieser PatientInnen unter Alltagsbedingungen wider.

Die Entscheidung für die Initiierung der iGlarLixi-Therapie wird vom/von der behandelnden Arzt/Ärztin unabhängig von der Teilnahme an dieser Beobachtungsstudie getroffen.

Die Studie dokumentiert PatientInnen mit T2DM, die bei AllgemeinärztInnen/PraktikerInnen/ InternistInnen, DiabetologInnen oder in Praxen mit diabetologischem Schwerpunkt betreut werden. Es besteht keine Pflicht für den/die einzelne/n Arzt/Ärztin, sukzessive PatientInnen einzuschließen.

Die Besuche werden in Übereinstimmung mit der klinischen Praxis vereinbart. Ziel ist es, die Daten für die Studienendpunkte nach ca. 12- bzw. ca. 24-wöchiger Therapie mit iGlarLixi zu erfassen. Daten der monatlichen Dokumentation nach ca. 4, ca. 8, ca. 16 und ca. 20 Wochen können durch den/die PatientIn mittels PatientInnen-Tagebuch dokumentiert werden oder optional telefonisch durch die betreuende Praxis erfragt werden. Die Daten sind im eCRF bei dem nächsten Besuch in der betreuenden Praxis zu erfassen.

7.2 DAUER DER STUDIENTEILNAHME FÜR JEDE/N PATIENTIN

Die Daten der an dieser NIS teilnehmenden PatientInnen werden über den Beobachtungszeitraum von ca. 24 Wochen dokumentiert. Die Datenerhebung erfolgt zu Beginn der Studie beim Einschluss des/r PatientIn (Eingangsdokumentation [Dokumentation 1], Woche 0), nach ca. 4 und ca. 8 Wochen (monatliche Dokumentationen 1.1 und 1.2), nach ca. 12 Wochen (Dokumentation 2), nach ca. 16 und ca. 20 Wochen (monatliche Dokumentationen 2.1 und 2.2) und am Ende des Beobachtungszeitraumes nach ca. 24 Wochen (Abschlussdokumentation [Dokumentation 3]).

Während des Beobachtungszeitraumes erfolgt die Betreuung, d.h. Ärztetermine, Untersuchung und Laborkontrollen, gemäß der üblichen Praxis des/der jeweiligen Arztes/Ärztin.

Die Gesamtstudiendauer vom Einschluss des/r ersten PatientIn bis zum Abschluss der Dokumentation des/r letzten PatientIn beträgt 15 Monate.

7.3 EVALUIERUNGSKRITERIEN

<u>Hauptevaluierungskriterien:</u>

Hauptevaluierungskriterium ist die absolute Änderung des HbA_{1c} in % unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 Wochen bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Abschluss der Dokumentation nach ca. 24 Wochen.

Sekundäre Evaluierungskriterien:

- Relative Änderung des HbA_{1c} (%) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung des selbstgemessenen Nüchternblutzuckers (NBZ) (mg/dl bzw. mmol/l)* bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Anteil an PatientInnen, die den individuellen HbA_{1c}-Zielwert innerhalb Woche 0-12, 13-24 und 0-24 erreichen (%)
- Anteil an PatientInnen, die einen Nüchternblutzucker ≤ 110 mg/dl bzw. ≤ 6,1 mmol/l innerhalb Woche 0-12, 13-24 und 0-24 erreichen (%)
- Absolute und relative Änderung der Glukose im 7-Punkte-Glukose-Tagesprofil (mg/dl bzw. mmol/l) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung der iGlarLixi-Dosis (Dosisschritte/Tag)* bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Häufigkeit von Dosisänderungen in den letzten 4 Wochen*
- Absolute und relative Änderung des Körpergewichts (kg) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung des BMI (kg/m^2) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung des Medianwertes der Glukose (mg/dl bzw. mmol/l) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Inzidenz und Rate von Hypoglykämien** (dokumentierte Hypoglykämien innerhalb der letzten ca. 12 Wochen vor Studieneinschluss im Vergleich zu den letzten 12 Wochen vor Dokumentation 2 (nach ca. 12 Wochen) und den letzten 12 Wochen vor der Abschlussdokumentation (nach ca. 24 Wochen))
- Inzidenz unerwünschter Ereignisse bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung der Therapiezufriedenheit mittels des DTSQs und DTSQc bis ca. 24 Wochen nach Behandlungsbeginn***

  *Diese Änderungen werden zusätzlich zu Dokumentation 1, 2 und 3 monatlich dokumentiert nach Umstellung auf iGlarLixi.

**Definition und Unterteilung hypoglykämischer Ereignisse. Hypoglykämien werden als symptomatische Hypoglykämien sowie als bestätigte Hypoglykämien in drei Levels unterteilt und erfasst (21):

- Level 1: Selbstgemessener Blutzuckerwert < 70 mg/dl (< 3,9 mmol/l) und ≥ 54 mg/dl (≥ 3,0 mmol/l)
- Level 2: Selbstgemessener Blutzuckerwert < 54 mg/dl (< 3,0 mmol/l); klinisch signifikante Hypoglykämie
- Level 3: Schweres hypoglykämisches Ereignis, charakterisiert durch eine beeinträchtigte geistige und/oder körperliche Verfassung, die Fremdhilfe erfordert

- Nächtliche Hypoglykämie: Hypoglykämie, die während der regulären Schlafenszeit des/r PatientIn stattfindet (ca. 22 Uhr bis 6 Uhr)

***DTSQ: Fragebogen zur Zufriedenheit mit der Diabetes-Behandlung:

Es gibt 2 verschiedene Formen dieses Fragebogens DTSQsund DTSQc. Beide beinhalten 8 Fragen, die auf einer 7-Punkte-Skala die Diabetes-Therapiezufriedenheit erfassen sollen. Es gibt zum einen die „Status"-Version des Fragebogens (DTSQs). Dieser wird hier bei der Eingangs- und Abschlussdokumentation genutzt. Die „Change"-Version (DTSQc) wird lediglich zur Abschlussdokumentation verwendet. Der DTSQs ist als Erhebungsinstrument primär zur Darstellung eines Zustandes (nicht einer Veränderung), der DTSQc zur Darstellung einer Veränderung geeignet.

<u>Zusätzlich für FGM-PatientInnen:</u>

- Medianer Zielwert des Blutzuckers und Grenzwert für niedrige Glukose (mg/dl bzw. mmol/l)

- Absolute Änderung der Gesamtzeit im individuellen Zielbereich in % ca. 12 und ca. 24 Wochen nach Behandlungsbeginn

- Absolute Änderung der Gesamtzeit in % über individuellem Zielbereich ca. 12 und ca. 24 Wochen nach Behandlungsbeginn

- Absolute Änderung der Gesamtzeit in % unter individuellem Zielbereich ca. 12 und ca. 24 Wochen nach Behandlungsbeginn

- Absolute und relative Änderung der Anzahl der PatientInnen mit hypoglykämischen Ereignissen entsprechend Level 1** und der Anzahl an Ereignissen pro PatientIn (dokumentierte Hypoglykämien innerhalb der 14-tägigen FGM-Messung vor Studieneinschluss im Vergleich zur 14-tägigen FGM-Messung vor Dokumentation 2 (nach ca. 12 Wochen) und zur 14-tägigen FGM-Auswertung vor der Abschlussdokumentation (nach ca. 24 Wochen))

  Alle Endpunkte werden für PatientInnen die ein FGM-Gerät verwenden, zusätzlich zur Gesamtpopulation analysiert.

**Definition und Unterteilung hypoglykämischer Ereignisse:
Hypoglykämien werden als symptomatische Hypoglykämien sowie als bestätigte Hypoglykämien in drei Levels unterteilt und erfasst (21):

- Level 1: Selbstgemessener Blutzuckerwert < 70 mg/dl (< 3,9 mmol/l) und ≥ 54 mg/dl (≥ 3,0 mmol/l)
- Level 2: Selbstgemessener Blutzuckerwert < 54 mg/dl (< 3,0 mmol/l); klinisch signifikante Hypoglykämie
- Level 3: Schweres hypoglykämisches Ereignis, charakterisiert durch eine beeinträchtigte geistige und/oder körperliche Verfassung, die Fremdhilfe erfordert

- Nächtliche Hypoglykämie: Hypoglykämie, die während der regulären Schlafenszeit des/r PatientIn stattfindet (ca. 22 Uhr bis 6 Uhr)

Weitere Evaluierungskriterien:

- Änderungen der sonstigen Diabetestherapie
- Änderung des FGM-Systems oder Gerätes zur Bestimmung des 7-Punkte-Glukose-Tagesprofils (Glukometer)
- Weitere explorative Auswertungen

Subgruppenanalysen werden für ausgewählte Variablen durchgeführt nach

- Geschlecht
- Alter (Verteilung in 3 annähernd gleichgroße Gruppen nach Datenlage)
- Body Mass Index (BMI) (< 30 kg/m² und ≥ 30 kg/m²)
- Nierenfunktion (eGFR ≤ 60 ml/min/1,73 m², > 60 ml/min/1,73 m²)
- Diabetesdauer (bis 5 Jahre, 5 bis 10 Jahre, über 10 Jahre)
- Eingangs-HbA_{1c} (< 8,5 %, ≥ 8,5 %)
- Vorherige Basalinsulintherapie
- Zeitpunkt der iGlarLixi-Gabe (vor dem Frühstück, vor dem Mittagsessen, vor dem Abendessen)

8 AUSWAHL DER PATIENTINNEN

8.1 STICHPROBENGRÖSSE

Es ist geplant, 250 PatientInnen in 100 Zentren in Deutschland zu dokumentieren.

8.2 KRITERIEN FÜR DIE DOKUMENTATION EINES/R PATIENTIN

Alle folgenden Selektionskriterien müssen erfüllt sein:

- Erwachsene PatientInnen mit Typ-2 Diabetes mellitus
- Seit mindestens 6 Monaten in Behandlung mit OAD und einem Basalinsulin ohne prandiales Insulin und ohne GLP1-RA.
- HbA_{1c} 7,5 % bis 10,0 % (Befund aus den letzten 3 Monaten)
- Vorliegen einer Basalinsulin-Vortherapie, die stabil zwischen 30-60 Einheiten pro Tag liegt.
- Umstellung auf iGlarLixi erfolgt im Zeitraum zwischen 14 Tage vor der Eingangsdokumentation bis 7 Tage nach der Eingangsdokumentation.
- Entscheidung des/der behandelnden Arztes/Ärztin, unabhängig von der Aufnahme in die Studie, das bisherige Basalinsulin durch iGlarLixi zu ersetzen.
- Fähigkeit und Bereitschaft, 7-Punkte-Glukose-Tagesprofil-Messungen mit einem Glukometer ODER Selbstmanagement anhand eines FGM-Systems durchzuführen. FGM-PatientInnen sollten nur eingeschlossen werden, wenn:
  - mindestens 70 % erfasste Sensordaten aus den FGM-Tagesprofilen der letzten ca. 14 Tage (max. 3 Wochen) vor Umstellung auf iGlarLixi vorhanden sind.
  - keine Änderung des verwendeten FGM-Herstellers während der Studiendauer geplant ist; ein Wechsel zu einem Gerät des gleichen Herstellers (z.B. zur neuesten Gerätegeneration) ist möglich.
  - Kalibrierung des FGM-Systems gewährleistet ist gemäß den Herstellerangaben.
- Vom/n PatientIn und Arzt/Ärztin unterschriebene Einverständniserklärung.

8.3 KRITERIEN GEGEN DIE DOKUMENTATION EINES/R PATIENTIN

- Diabetes mellitus Typ 1
- Gegenanzeigen zur Behandlung mit iGlarLixi laut Fachinformation
- Teilnahme an einer klinischen Prüfung

- Geplante oder bestehende Schwangerschaft, Krebserkrankungen, Drogen- oder Alkoholmissbrauch, Demenz bzw. allgemeines Unvermögen, den Inhalt der Beobachtungsstudie zu verstehen

- Tägliche Basalinsulin-Dosis < 30 Einheiten oder > 60 Einheiten

8.4 AUSWAHLMODALITÄTEN

Die ÄrztInnen sind frei in der Auswahl der teilnehmenden PatientInnen nach den oben genannten Kriterien für bzw. gegen die Dokumentation eines/r PatientIn („Studienpopulation“). Dabei muss der/die Arzt/Ärztin die Entscheidung für die Therapie mit iGlarLixi bereits vor Initiierung und vollkommen unabhängig von einer möglichen Teilnahme an der vorliegenden NIS getroffen haben.

9 AUSWAHL DER TEILNEHMENDEN ÄRZTE

Die NIS wird bei ÄrztInnen in Deutschland durchgeführt, die bei ihren PatientInnen iGlarLixi zur Therapie des Diabetes mellitus Typ 2 einsetzen.

Die NIS wird durch die Mitarbeiter der Sanofi-Aventis Deutschland GmbH gemäß den lokalen Anforderungen zur Durchführung einer NIS vorgestellt und gestartet.

10 BEHANDLUNGEN

Die Verschreibung von Therapien ist alleinige Verantwortung des/der teilnehmenden Arztes/Ärztin.

PatientInnen, die in die Studie aufgenommen werden, werden aus den PatientInnen ausgewählt, denen der/die teilnehmende Arzt/Ärztin unabhängig von ihrem Eintritt in die Studie iGlarLixi verschreiben möchte.

Der/Die teilnehmende Arzt/Ärztin muss für Informationen zur verordneten Behandlung die Zusammenfassung der Merkmale des Arzneimittels (Fachinformation) konsultieren.

In dieser NIS werden nur PatientInnen mit Erfahrung in der Durchführung von 7-Punkte-Glukose-Tagesprofil-Messungen mit einem Glukometer oder mit Erfahrung im Blutzucker-Selbstmanagement anhand des eigenen FGM-Systems eingeschlossen. Es werden keine Vorgaben zum Glukometer- oder FGM-Modell gemacht. Für die Zeit, in der der/die PatientIn an der Studie teilnimmt, soll kein Wechsel des Gerätes geplant sein. Ein Wechsel zu einem Gerät des gleichen Herstellers (z. B. zur neuesten Gerätegeneration) ist möglich.

11 DATENSAMMLUNG

11.1 ZEITPLAN FÜR DIE DATENSAMMLUNG

Es wird kein festes Schema für die Dokumentation der Daten gegeben. Die Termine richten sich nach der klinischen Praxis, wobei die Datenerfassung zu den Zeitpunkten Woche 0, sowie nach ca. 4, ca. 8, ca. 12, ca. 16, ca. 20 und ca. 24 Wochen nach Einstellung auf iGlarLixi stattfinden soll. Empfohlen wird keine längere Abweichung als ± 3 Wochen zu den angegebenen Zeitpunkten.

11.2 DEFINITION DER QUELLDATEN

Bei den erfassten Daten handelt es sich mit Ausnahme des Fragebogens zur Lebensqualität nur um Daten, die im Rahmen der praktischen routinemäßigen Versorgung der PatientInnen erhoben werden.

11.3 GESAMMELTE DATEN

11.3.1 PatientInnen-Daten

Eine Übersicht über die zu sammelnden Daten und die Zeitpunkte findet sich auch im graphischen Studiendesign und im Flowchart auf den Seiten 11 und 12.

Eingangsdokumentation zum Beobachtungsbeginn (Dokumentation 1), Woche 0
(Soweit routinemäßig erhoben bzw. letzter verfügbarer Wert)

- PatientInnen-Charakteristika: Geburtsjahr, Geschlecht, Größe, Gewicht, Blutdruck
- Grund für die Therapieentscheidung für iGlarLixi
- Diabetes mellitus Vorgeschichte (anamnestische Angaben, Dauer, Komplikationen)
- Aktuelle Basalinsulintherapie (inklusive Dauer und letzte Dosierung vor der Umstellung)
- Aktuelle antidiabetische orale Therapie
- Dokumentation von Retinopathie, Neuropathie, Nephropathie, diabetischem Fußsyndrom, kardiovaskulären Erkrankungen, festgehalten in den Krankenakten der PatientInnen
- Lipidsenkende Medikation und blutdrucksenkende Medikation
- Individueller HbA_{1c}-Zielwert
- Aktueller selbstgemessener NBZ (Glukometer, wenn vorhanden, oder aus FGM)
- Laborwerte (letzter verfügbarer Wert innerhalb der letzten 6 Monate):
    - HbA_{1c} (Wert innerhalb der letzten 3 Monate)

  - sofern verfügbar (letzte verfügbare Werte innerhalb der letzten 6 Monate): NBZ, AST und ALT-Werte, Gesamtcholesterin, LDL, HDL, Triglyzeride, eGFR, Kreatinin

- Erfassung der glykämischen Variabilität aus 7-Punkte-Glukose-Tagesprofil oder Erhebung der glykämischen Variabilität aus FGM (Glukosemedian, Variabilität gemessen als Standardabweichung, Time in range (TIR), Time above range (TAR), time below range (TBR))
- Therapiestart mit iGlarLixi (Datum, Dosierung, Grund für Umstellung, Zeitpunkt der Injektion) und Änderung der antidiabetischen Begleitmedikation
- FGM-System:
  - genaue Gerätebezeichnung
  - erfasste Hauptdaten, mindestens 70 % erfasste Sensordaten aus den letzten ca. 14 Tagen (max. 3 Wochen) vor Umstellung auf iGlarLixi
- Unerwünschte Wirkungen inklusive hypoglykämischer Ereignisse (innerhalb der letzten 12 Wochen)
- PatientInnen-Fragebogen zur Therapiezufriedenheit (DTSQs)

Monatliche Dokumentation ca. 4, 8, 16 und 20 Wochen nach Umstellung auf iGlarLixi (z.B. im PatientInnen-Tagebuch oder durch telefonische Befragung)

- Aktuelle Therapie mit iGlarLixi (Dosierung; Häufigkeit von Dosisänderungen in den vorangegangenen 4 Wochen)
- Aktueller selbstgemessener NBZ (Glukometer, wenn vorhanden oder aus FGM)

Zwischendokumentation (Dokumentation 2), ca. 12 Wochen nach Umstellung auf iGlarLixi:

- Aktuelle Therapie mit iGlarLixi (Dosierung; Häufigkeit von Dosisänderungen in den vorangegangenen 4 Wochen)
- Aktuelle sonstige antidiabetische Begleitmedikation
- Weitere aktuelle Medikation
- Gewicht
- Aktueller selbstgemessener NBZ (Glukometer, wenn vorhanden, oder aus FGM)
- Laborwerte:
  - HbA_{1c}
  - NBZ, AST- und ALT-Werte, Gesamtcholesterin, LDL, HDL, Triglyzeride, eGFR, Kreatinin
- Erfassung der glykämischen Variabilität aus 7-Punkte-Glukose-Tagesprofil oder Erhebung der glykämischen Variabilität aus FGM (Glukosemedian, glykämische Variabilität, TIR, TAR, TBR)
- FGM-System:

  - erfasste Hauptdaten, mindestens 70 % erfasste Sensordaten aus den letzten ca. 14 Tagen (max. 3 Wochen) vor der Zwischendokumentation
- Änderung des Gerätes zur 7-Punkte-Glukose-Tagesprofilbestimmung bzw. des FGM-Systems
- Unerwünschte Wirkungen inklusive hypoglykämischer Ereignisse (innerhalb der letzten 12 Wochen)

Abschlussdokumentation (Dokumentation 3), ca. 24 Wochen nach Umstellung auf iGlarLixi:

- Aktuelle Therapie mit iGlarLixi (Dosierung; Häufigkeit von Dosisänderungen in den vorangegangenen 4 Wochen) und Nicht-Insulin Begleitmedikation
- Aktuelle sonstige antidiabetische Begleitmedikation
- Weitere aktuelle Medikation
- Gewicht
- Aktueller selbstgemessener NBZ (Glukometer, wenn vorhanden oder aus FGM) Laborwerte:
  - HbA_{1c}
  - NBZ, AST- und ALT-Werte, Gesamtcholesterin, LDL, HDL, Triglyzeride, eGFR, Kreatinin
- Erfassung der glykämischen Variabilität aus 7-Punkte-Glukose-Tagesprofil oder Erhebung der glykämischen Variabilität aus FGM (Glukosemedian, glykämische Variabilität, TIR, TAR, TBR)
- FGM-System:
  - erfasste Hauptdaten, mindestens 70 % erfasste Sensordaten aus den letzten ca. 14 Tagen (max. 3 Wochen) vor der Abschlussdokumentation
- Änderung des Gerätes zur 7-Punkte-Glukose-Tagesprofilbestimmung bzw. des FGM-Systems
- Unerwünschte Wirkungen inklusive hypoglykämischer Ereignisse (innerhalb der letzten 12 Wochen)
- PatientInnen-Fragebögen zur Therapiezufriedenheit (DTSQs und DTSQc)

11.3.2 Fragebogen des/r teilnehmenden Arztes/Ärztin

Vom/Von der teilnehmenden Arzt/Ärztin werden folgende freiwillige Angaben erhoben:

- Fachrichtung des/der Arztes/Ärztin
- Größe der Praxis (Anzahl der PatientInnen (Scheine) pro Quartal)
- Art der Einrichtung (z.B. Gemeinschafts-) Praxis)
- Lage der Einrichtung
- KV-Gebiet

11.4 LOGISTISCHER ASPEKT

Die NIS wird durch MitarbeiterInnen der Sanofi-Aventis Deutschland GmbH gemäß den VFA-Empfehlungen zur Durchführung einer NIS (22) platziert. Dabei wird der/die teilnehmende Arzt/Ärztin über die Ziele, Hintergründe und die Verfahrensweise der Beobachtungsstudie informiert. Bei Fragen steht die Projektleitung der Sanofi-Aventis Deutschland GmbH zur Verfügung.

Jedes teilnehmende Zentrum erhält eine Mappe mit folgenden Unterlagen:

- NIS-Vertrag
- Beobachtungsplan
- Patienten-Tracking-Liste
- PatientInnen-Informationen (für den/die PatientIn) und PatientInnen-Einverständniserklärung (in zweifacher Ausführung, jeweils eine für den/die Patient/In und eine für den/die Arzt/Ärztin). Die dem/der Arzt/Ärztin vorliegende Ausführung der PatientInnen-Einverständniserklärung hat dieser für 25 Jahre zu archivieren.
- PatientInnen-Tagebuch (für den/die PatientIn)
- Diabetesspezifischer Fragebogen zur Therapiezufriedenheit des/r PatientIn (2x DTSQs und 1x DTSQc)
- Ethikberatungsergebnis der für den wissenschaftlichen Leiter zuständigen Ethikkommission
- Fachinformation iGlarLixi
- Anleitung und Zugang zum e-CRF
- (S)UE-Berichtsbögen
- Qualitätsmangel (PTC)-Bogen

Alle PatientInnen, die an der Studie teilnehmen, werden in die PatientInnen-Identifikationsliste eingetragen, die vom/von der Arzt/Ärztin selbstständig zu erstellen ist. Diese Liste hat der/die Arzt/Ärztin für 25 Jahre zu archivieren.

12 DATENMANAGEMENT

12.1 DATENSAMMLUNG, VALIDIERUNG UND QUALITÄTSKONTROLLE DER DATEN BEI SANOFI

Die Datensammlung erfolgt mittels e-CRF (elektronischer Dokumentationsbogen).

Die elektronische Datenverarbeitung durch Sanofi kann zu zusätzlichen Anfragen führen, die der/die teilnehmende Arzt/Ärztin verpflichtet ist zu beantworten, indem er die betreffenden Daten bestätigt oder modifiziert.

Datensammlungs- und Validierungsverfahren werden in geeigneten Betriebsunterlagen wie z. B. im Datenmanagementplan (DMP) und Datenvalidierungsplan (DVP) detailliert behandelt.

12.2 MONITORING UND DATENQUALITÄTSKONTROLLE AM STUDIENORT

Der/Die behandelnde Arzt/Ärztin erklärt per Vertragsunterschrift sein/ihr Einverständnis, alle Daten für den Auftraggeber zum Zwecke einer Überprüfung zugänglich zu machen. Die Datenqualitätskontrolle (am Standort) erfolgt auf Studienortebene, und zwar in 5 % der aktiven teilnehmenden Zentren, die nach dem Zufallsprinzip ausgewählt wurden.

13 VORGEHEN BEI UND MELDUNG VON UNERWÜNSCHTEN EREIGNISSEN/UNERWÜNSCHTEN REAKTIONEN

Alle unerwünschten Ereignisse, unabhängig von ihrem Schweregrad oder vom kausalen Zusammenhang mit iGlarLixi, müssen ab der Unterzeichnung der Einverständniserklärung bis zum im Beobachtungsplan festgelegten Ende der Studie bei jedem/r PatientIn vom/von der teilnehmenden Arzt/Ärztin erfasst und AKP GmbH gemeldet werden.

13.1 SICHERHEITSANWEISUNGEN

Sämtliche unerwünschte Ereignisse werden unter Berücksichtigung aller geltenden Vorschriften behandelt und gemeldet.

13.1.1 Definitionen von unerwünschten Ereignissen (UEs), schwerwiegenden unerwünschten Ereignissen (SUEs), unerwünschten Arzneimittelwirkungen (UAW) und unerwünschten Medizinproduktwirkungen (UMW)

Diese NIS ist im Sinne der gesetzlichen Regelungen eine sogenannte systematische Datenerhebung zu unserem Arzneimittel iGlarLixi. Deshalb müssen in dieser Studie grundsätzlich unerwünschte Ereignisse, unabhängig von ihrem Bezug zum Produkt, dokumentiert werden, die von der Unterzeichnung des Formblattes zur Einverständniserklärung durch die PatientInnen bis zum im Beobachtungsplan festgelegten Studienende für die PatientInnen auftreten oder nachträglich mit der Teilnahme an dieser Studie in Zusammenhang gebracht werden (Prospektive Phase der Studie). Zusätzlich sind auch alle Hypoglykämien, die in den 12 Wochen vor Studieneinschluss unter Therapie mit einem Sanofi-Insulin aufgetreten sind wie ein unerwünschtes Ereignis zu dokumentieren (Retrospektive Phase).

Sämtliche unerwünschten Ereignisse müssen vom/von der Arzt/Ärztin dokumentiert werden und form- und fristgerecht (siehe Kapitel 13.1.3) an die zuständige CRO AKP GmbH weitergeleitet werden.

Ein **unerwünschtes Ereignis** ist jeder ungünstige medizinische Vorfall, der bei einem/einer mit einem Arzneimittel behandelten PatientIn oder an einer klinischen Studie teilnehmenden PatientIn auftritt und bei dem nicht notwendigerweise ein kausaler Zusammenhang mit einer Behandlung bestehen muss. Hierzu gehören auch atypische Heilungsverläufe, Miss- oder Fehlgebrauch, Anwendung außerhalb der Zulassung, Abhängigkeit, Ausbleiben der erwarteten Wirksamkeit oder Funktion, Verdacht der Infektionsübertragung durch ein Arzneimittel oder Medizinprodukt, berufs- oder umweltbedingte Exposition, unerwartet positive Heilungsverläufe und vermutete Wechselwirkungen mit anderen Produkten. Im Falle von abnormen Laborwerten entscheidet der/die Arzt/Ärztin über die medizinische Relevanz des Laborergebnisses für den/die betroffene/n PatientIn und somit, ob dieser abnorme Laborwert als unerwünschtes Ereignis bei dem/der PatientIn zu werten und dokumentieren ist oder nicht.

Ein **schwerwiegendes unerwünschtes Ereignis** ist jeder ungünstige medizinische Vorfall, der bei jeder beliebigen Dosis:

- den Tod zur Folge hat oder
- lebensbedrohlich ist oder
  Hinweis: Der Begriff „lebensbedrohlich“ in der Definition von „schwerwiegend“ bezieht sich auf ein Ereignis, bei dem sich der/die PatientIn zum Zeitpunkt des Ereignisses in Lebensgefahr befand; er bezieht sich nicht auf ein Ereignis, welches hypothetisch den Tod hätte verursachen können, falls es von schwerwiegenderer Natur gewesen wäre.
- einen stationären Krankenhausaufenthalt notwendig macht oder verlängert oder
- eine bleibende oder schwerwiegende Behinderung/Erwerbsunfähigkeit nach sich zieht oder
- eine kongenitale Anomalie/ein Geburtsfehler ist oder
- ein medizinisch schwerwiegendes Ereignis ist:
  - Verdacht auf Übertragung eines Infektionserregers; dies ist jeder Verdacht auf Übertragung eines Infektionserregers über ein medizinisches Produkt (z. B. Produktverunreinigung)
- eine Intervention erforderlich machte, um einen schwerwiegenden Verlauf (dauerhafte Beeinträchtigung oder Schädigung, einen tödlichen Ausgang oder einen Krankenhausaufenthalt) zu verhindern.

Eine medizinische und wissenschaftliche Beurteilung muss eingeholt werden, um entscheiden zu können, ob eine beschleunigte Meldung in anderen Situationen angemessen ist, wie im Fall von wichtigen medizinischen Ereignissen, die nicht unmittelbar lebensbedrohlich sind oder nicht mit dem Tod oder einem Klinikaufenthalt enden, die jedoch den/die PatientIn gefährden könnten oder zur Abwehr eines der anderen in vorstehender Definition aufgeführten Ausgänge erforderlich sein könnten.

13.1.2 Weitere sicherheitsrelevante Ereignisse

Überdosierung:

Jeder Fall einer versehentlichen oder bewussten Überdosierung, auch ohne Vorliegen eines UEs (asymptomatisch), muss wie ein unerwünschtes Ereignis dokumentiert und an den dafür vorgesehenen Stellen des e-CRF vermerkt werden. Für die Weiterleitung gelten die in Kap. 13.1.3 beschriebenen Regeln. Im Fall einer Überdosierung muss der/die PatientIn so lange überwacht werden, wie der/die teilnehmende Arzt/Ärztin dies für notwendig erachtet. Es müssen geeignete symptombedingte Maßnahmen ergriffen werden.

Fehlgebrauch:

Situationen, in denen das Arzneimittel absichtlich und unsachgemäß verwendet wird sind zu dokumentieren

Missbrauch:

Anhaltender oder sporadischer, vorsätzlicher exzessiver Gebrauch eines Arzneimittels, das mit schädlichen physischen oder psychischen Wirkungen einhergeht, ist zu dokumentieren.

Berufliche Exposition:

Exposition gegenüber einem Arzneimittel, die sich aus der beruflichen Tätigkeit ergibt, ist zu dokumentieren.

Schwangerschaft:

iGlarLixi darf während der Schwangerschaft nicht angewendet werden. Tierexperimentelle Studien mit Lixisenatid haben eine Reproduktionstoxizität gezeigt. Weitere Details dazu entnehmen Sie bitte der Fachinformation von iGlarLixi.
Kommt es bei einer Patientin oder bei der weiblichen Partnerin eines männlichen Patienten, der einem medizinischen Produkt von Sanofi ausgesetzt wurde, zu einer Schwangerschaft, so ist dies sofort wie ein unerwünschtes Ereignis zu dokumentieren und an den entsprechenden Stellen des e-CRF zu vermerken. Für die Weiterleitung gelten die in Kap. 13.1.3 beschriebenen Regeln.

Vorkommnis mit Medizinprodukten:

Ein Vorkommnis bei einem Medizinprodukt bedeutet eine Funktionsstörung, einen Ausfall, eine Änderung der Merkmale, der Leistung, eine unsachgemäße Kennzeichnung oder Gebrauchsanweisung, die unmittelbar oder mittelbar zum Tod bzw. zu einer schwerwiegenden Verschlechterung des Gesundheitszustands eines/r PatientIn, eines/r Anwenders/Anwenderin oder einer anderen Person geführt hat, geführt haben könnte oder führen könnte. Vorkommnisse mit Medizinprodukten sind wie unerwünschte Ereignisse zu dokumentieren (UE-Bericht).

Vorkommnisdefinition gemäß EU MDR (Medical Device Regulation, ab 26.05.2020)
„Vorkommnis“ bezeichnet eine Fehlfunktion oder Verschlechterung der Eigenschaften oder Leistung eines bereits auf dem Markt bereitgestellten Produkts, einschließlich Anwendungsfehlern aufgrund ergonomischer Merkmale, sowie eine Unzulänglichkeit der vom Hersteller bereitgestellten Informationen oder eine unerwünschte Nebenwirkung;
„Schwerwiegendes Vorkommnis“ bezeichnet ein Vorkommnis, das direkt oder indirekt eine der nachstehenden Folgen hatte, hätte haben können oder haben könnte: a) den Tod eines/r PatientIn, Anwenders/Anwenderin oder einer anderen Person, b) die vorübergehende oder dauerhafte schwerwiegende Verschlechterung des Gesundheitszustands eines/r PatientIn, Anwenders/Anwenderin oder anderer Personen, c) eine schwerwiegende Gefahr für die öffentliche Gesundheit.

Medikationsfehler:

Ein Medikationsfehler ist ein unbeabsichtigter Fehler, der bei der Verschreibung, Abgabe, Lagerung, Vorbereitung oder Verabreichung einer Behandlung passieren kann und der zu einem Schaden für den Patienten führen kann oder das Potenzial dazu hat. Medikationsfehler sind mit und ohne Auftreten eines unerwünschten Ereignisses zu dokumentieren.

Anwendungen außerhalb der Zulassung (Off-label use):

Anwendungen, die nicht durch die Zulassung abgedeckt sind, sind mit oder ohne unerwünschtes Ereignis, zu dokumentieren.

Hypersensitivitätsreaktionen:

Sämtliche Hypersensitivitätsreaktionen (z.B. Ausschlag, Reaktionen an der Einstichstelle, etc), die im Zusammenhang mit der Behandlung mit iGlarLixi aufgetreten sind, sind auf dem dafür vorgesehenen Formblatt zu dokumentieren.

13.1.3 Pflichten des/der teilnehmenden Arztes/Ärztin in Bezug auf Sicherheitsberichte

Erfassung unerwünschter Ereignisse

Sämtliche unerwünschte Ereignisse (s. Definition 13.1.1) und weitere sicherheitsrelevante Ereignisse (s. Definition 13.1.2) müssen, unabhängig von ihrem kausalen Zusammenhang mit iGlarLixi, von der Unterzeichnung der Einverständniserklärung bis zum Ende der Studie (wie für jede/n PatientIn im Beobachtungsplan definiert) im Fall schwerwiegender UEs **unverzüglich** (innerhalb eines Arbeitstages nach Bekanntwerden) und im Fall nichtschwerwiegender UEs innerhalb von 30 Kalendertagen nach Bekanntwerden auf der (den) entsprechenden Seite(n) des e-CRFs vermerkt werden, wie nachstehend erläutert.

Meldung von unerwünschten Ereignissen

Schwerwiegende unerwünschte Ereignisse

- EINGABE (innerhalb eines Arbeitstages) der Informationen zum Ereignis in die entsprechenden Eingabemasken des e-CRFs; nach der Freigabe durch den/die teilnehmende/n Arzt/Ärztin im e-CRF oder nach einer voreingestellten Wartezeit sendet das System die Benachrichtigung automatisch an den/die RepräsentantIn von AKP GmbH.
- ÜBERMITTLUNG (vorzugsweise per Fax oder E-Mail) der Kopien aller durchgeführten Untersuchungen mit Angabe der Termine, an denen diese Untersuchungen durchgeführt wurden, an AKP GmbH, deren Name, Faxnummer und E-Mail-Adresse auf der ersten Seite dieses Beobachtungsplans aufgeführt sind. Es ist sicherzustellen, dass die Identität des/r PatientIn geschützt bleibt und die studienbezogenen Identifikationsmerkmale des/r PatientIn auf jeder Kopie von Quelldokumenten, die an AKP GmbH übermittelt wird, ordnungsgemäß angeführt sind. Laborbefunde müssen auch die Normbereiche des jeweiligen Labors enthalten.
- Alle weiteren Datenaktualisierungen müssen im e-CRF ordnungsgemäß aufgezeichnet werden und weitere Dokumente sowie zusätzliche Informationen (zu Labordaten, Begleitmedikation, PatientInnen-Status, etc.) müssen innerhalb eines Arbeitstages nach Bekanntwerden an AKP GmbH gesendet werden (per Fax oder E-Mail). Zusätzlich müssen sämtliche Anstrengungen unternommen werden, um jedes lebensbedrohliche oder tödliche schwerwiegende UE innerhalb von einer Woche (7 Tage) nach der Erstmeldung näher zu dokumentieren.

Es wird ein Backup-Plan (siehe S.42) verwendet (und dabei auf die Papierform zurückgegriffen) für den Fall, dass das e-CRF-System nicht funktioniert.

Nicht-schwerwiegende unerwünschte Ereignisse

- EINGABE (innerhalb von 30 Kalendertagen) der Informationen zum UE in die entsprechenden Eingabemasken des e-CRFs; nach der Freigabe durch den/die teilnehmende/n Arzt/Ärztin im e-CRF oder nach einer voreingestellten Wartezeit sendet das System die Benachrichtigung automatisch an AKP GmbH.
- Übermittlung (vorzugsweise per E-Mail, notfalls per Fax) der Kopien aller durchgeführten Untersuchungen mit Angabe der Termine, an denen diese Untersuchungen durchgeführt wurden, an AKP GmbH, deren Name, Faxnummer und EMail-Adresse auf der ersten Seite dieses Beobachtungsplans aufgeführt sind. Es ist sicherzustellen, dass die Identität des/r PatientIn geschützt bleibt und die studienbezogenen Identifikationsmerkmale des/r PatientIn auf jeder Kopie von Quelldokumenten, die an AKP GmbH übermittelt wird, ordnungsgemäß angeführt sind. Laborbefunde müssen auch die Normbereiche des jeweiligen Labors enthalten.
- Alle weiteren Datenaktualisierungen müssen im e-CRF ordnungsgemäß aufgezeichnet werden und weitere Dokumente sowie zusätzliche Informationen (zu Labordaten, Begleitmedikation, PatientInnen-Status, etc.) müssen innerhalb eines Arbeitstages nach Bekanntwerden an AKP GmbH gesendet werden (per Fax oder E-Mail). Zusätzlich müssen sämtliche Anstrengungen unternommen werden, um jedes lebensbedrohliche oder tödliche schwerwiegende UE innerhalb von einer Woche (7 Tage) nach der Erstmeldung näher zu dokumentieren.

Es wird ein Backup-Plan (siehe S. 42) verwendet (und dabei auf die Papierform zurückgegriffen) für den Fall, dass das e-CRF-System nicht funktioniert.

Backup-Plan für den Fall, dass das e-CRF System nicht funktioniert

- Sollte wegen einer technischen Störung eine fristgerechte Weiterleitung mittels e-CRF nicht möglich sein, so müssen die unerwünschten Ereignisse (s. Definition 13.1.1) und weiteren sicherheitsrelevanten Ereignisse (s. Definition 13.1.2) mit Angabe der PatientInnen-Nummer und der Mappennummer unverzüglich (spätestens jedoch innerhalb von einem Arbeitstag) unter Verwendung der mit den Studienunterlagen zur Verfügung gestellten Dokumentationsbögen-Kopiervorlagen per E-Mail oder Fax an die CRO AKP GmbH übermittelt werden.
- Für den Fall, dass die Berichtsweiterleitung weder per e-CRF noch per E-Mail oder Fax möglich ist, kann die Übermittlung notfalls auch telefonisch an die CRO AKP GmbH erfolgen.

Nachträgliche Korrekturen im e-CRF

Korrekturen müssen binnen eines Arbeitstages nach Bekanntwerden im e-CRF durchgeführt werden. Bei Korrekturen an zusätzlichen Informationen, für die keine Dokumentationsfelder im e-CRF vorhanden sind, müssen diese Informationen binnen eines Arbeitstages per E-Mail oder Fax an die CRO AKP GmbH geschickt werden. Es muss darauf geachtet werden, dass Studienname und

PatientInnen-Identifikationsnummer sowie ein Vermerk „Aktualisierung“ oder „Korrektur“ enthalten sind. Das e-CRF enthält eine feldbezogene Änderungshistorie.

13.2 SICHERHEITSRELEVANTE BEOBACHTUNGEN

Der/Die teilnehmende Arzt/Ärztin muss alle geeigneten Maßnahmen ergreifen, um die Sicherheit der PatientInnen entsprechend der gängigen Praxis zu gewährleisten.

Im Fall eines unerwünschten Ereignisses muss der/die PatientIn nachbeobachtet werden, bis eine klinische Besserung eingetreten ist und die Laborwerte sich wieder normalisiert haben oder bis sich sein Zustand stabilisiert hat. Das kann bedeuten, dass die Nachbeobachtung auch dann weiter fortgesetzt werden muss, nachdem der/die PatientIn die Studie verlassen hat.

Im Fall von schwerwiegenden unerwünschten Ereignissen, die dem/der teilnehmenden Arzt/Ärztin zu einem beliebigen Zeitpunkt nach dem Ende der Studienteilnahme des/der betroffenen PatientIn zur Kenntnis gebracht werden und die der/die teilnehmende Arzt/Ärztin mit der Teilnahme des/der PatientIn an dieser Studie in Verbindung bringt, muss er/sie dies der AKP GmbH melden.

13.3 UMGANG MIT DATEN AUS DEN PATIENTINNENFRAGEBÖGEN

Die auf den PatientInnenfragebögen von der/dem PatientIn dokumentierten Daten werden im Studienbericht separat ausgewertet und dokumentiert. Befindet sich auf einem PatientInfragebogen ein handschriftlicher Zusatzkommentar der/des PatientIn, der ein UE oder unerwünschte Medizinproduktwirkung beschreibt, wird dieses entsprechend erfasst und ausgewertet. Sollten sich während des Arzt/Ärztin-PatientIn-Gesprächs und / oder der Durchsicht des von der/dem PatientIn ausgefüllten PatientInfragebogens für den/die Arzt/Ärztin Hinweise auf ein UE / UAW / UESI / unerwünschte Medizinproduktwirkung ergeben, so muss der/die Arzt/Ärztin dies in der betreffenden Maske des eCRF dokumentieren. Für die Weiterleitung gelten die in Kap. 13.1.3 beschriebenen Regeln.

13.4 UNERWÜNSCHTE EREIGNISSE VON SPEZIELLEM INTERESSE (UESI)

Bei einem unerwünschten Ereignis von speziellem Interesse (UESI) handelt es sich um ein Ereignis, das unter wissenschaftlichen oder medizinischen Gesichtspunkten produkt- oder programmspezifisch ist und für das ein weiterführendes Monitoring und eine rasche Mitteilung seitens des/der behandelnden Arztes/Ärztin erforderlich sind. Solche unerwünschten Ereignisse erfordern in der Regel eine sorgfältige Dokumentation und Untersuchung, um sie zu charakterisieren. UESIs werden im e-CRF vom/von der Arzt/Ärztin unverzüglich (d. h. innerhalb eines Arbeitstages) dokumentiert. Im e-CRF befindet sich eine entsprechende Abfrage, ob es sich bei dem dokumentierten UE um ein UESI handelt. Bei dieser Abfrage ist das zutreffende UESI anzukreuzen und die damit verbundene Spezialeingabemaske auszufüllen. Für die Weiterleitung gelten die in Kap. 13.1.3 beschriebenen Regeln.

UESIs

- Schwangerschaft einer Studienteilnehmerin (ebenso Schwangerschaft bei einer weiblichen Partnerin eines männlichen an einer Studie mit Sanofi-Produkten beteiligten

Studienteilnehmers): Sobald eine Schwangerschaft wie auch in Kap. 13.1.2 bzw. Kap. 13.1.3 beschrieben, dokumentiert und weitergeleitet wurde, wird ein Datenerhebungsformular zur Schwangerschaft an den/die MitteilerIn / behandelnde/n Arzt/Ärztin ausgegeben, damit sichergestellt ist, dass zusätzliche Informationen bezüglich des Ausgangs der Schwangerschaft gesammelt werden. Falls die betroffene Frau sich weigert, Informationen über die Schwangerschaft und deren Ausgang zur Verfügung zu stellen, wird diese Information mit Hilfe des Datenerhebungsformulars zur Schwangerschaft/Arzneimittelexposition von Sanofi erfasst (Pregnancy / Drug Exposure via Parent Data Collection Form; Version Number: 6.0; Effective Date: 25-May-2020).

13.5 VERMUTETE QUALITÄTSMÄNGEL (PTC: PRODUCT TECHNICAL COMPLAINTS)

Ein **Qualitätsmangel** ist jeder Bericht, der auf einen Mangel eines Produktes (Arzneimittel, Medizinprodukt, Kosmetikum oder Lebensmittel) hinsichtlich seiner Identität, Qualität, Funktionsweise, Zuverlässigkeit, Sicherheit, Wirksamkeit, Gebrauchsinformation bzw. deren Inhalt hinweist.

Vermutete Qualitätsmängel zu Produkten der Sanofi-Gruppe können in Zusammenhang mit einem UE und ohne ein UE gemeldet werden. Alle Fälle müssen ebenfalls erfasst und im PTC-Bogen dokumentiert werden. Besteht der Verdacht, dass der vermutete Qualitätsmangel ein UE verursacht hat, ist das unerwünschte Ereignis zusätzlich auf dem unerwünschten Ereignis-Bereich im e-CRF zu dokumentieren. Die Weiterleitung von PTC-Einzelfällen mit und ohne unerwünschtes Ereignis erfolgt per E-Mail (s. Namen und Adressen, AKP GmbH).

13.6 PFLICHTEN VON SANOFI

Während des Verlaufs der Studie wird Sanofi den zuständigen Gesundheitsbehörden alle Fälle melden, die den Kriterien für eine umgehende Meldung gemäß den lokalen und globalen Vorschriften entsprechen.

Der Sponsor wird alle während der Dauer der Studie von ihm gemachten sicherheitsrelevanten Beobachtungen im Studienbericht vermerken.

14 STATISTISCHE ÜBERLEGUNGEN

14.1 BESTIMMUNG DER STICHPROBENGRÖSSE

Da es sich um eine nicht-konfirmatorische Beobachtungsstudie handelt und vorher keine zu prüfenden Hypothesen aufgestellt wurden, wird keine formale Stichprobenumfangs- bzw. Powerberechnung durchgeführt, sondern lediglich eine nicht-formale Begründung des Stichprobenumfangs gegeben.

Statistische Power- und Fallzahlbegründung
Es wird erwartet, dass von der Stichprobengröße von 250 PatientInnen etwa 60 %, d. h. 150 PatientInnen, hinsichtlich Wirksamkeit auswertbar sein werden. Diese relativ hohe Abbruchquote ist eine konservative Schätzung aus den vorangegangenen RWE-Studien, die in Deutschland bereits durchgeführt wurden.

Wirksamkeit

Die Stichprobengröße wurde anhand der folgenden Annahmen abgeschätzt, die teilweise von einer Publikation zum Einsatz von iGlarLixi bei PatientInnen mit T2DM abgeleitet wurden (3):
Eine Analyse von 150 PatientInnen wird mit einer 90 %-igen Power einen klinisch relevanten Unterschied des HbA_{1c} von 0,4 % feststellen (im Vergleich der Eingangsdokumentation zur Abschlussdokumentation), wobei eine Standardabweichung der Differenzen von 1,5 % vorausgesetzt und ein gepaarter t-Test mit einem zweiseitigen Signifikanzniveau von 0,05 angewendet wird.

Sicherheit

Für die Sicherheitsanalyse werden alle PatientInnen eingeschlossen, die mindestens eine Dosis der Studienmedikation erhalten haben. Bei 250 PatientInnen beträgt die Wahrscheinlichkeit 95,0 %, in dieser Studie mindestens ein „seltenes“ Ereignis zu beobachten, welches mit einer Wahrscheinlichkeit von 0,01 in dieser PatientInnen-Population auftritt.

14.2 DISPOSITION DER PATIENTINNEN

Patienten, die der behandelnde Arzt als geeignet für diese Beobachtungsstudie bewertet, werden in die Patienten-Tracking-Liste eingetragen. Nimmt ein Patient aus dieser Liste nicht an der Studie teil, so wird der Grund dafür eingetragen.

Alle PatientInnen, die an der Studie teilnehmen, werden in die PatientInnen-Identifikationsliste eingetragen.

Die Disposition der PatientInnen (eingeschlossen, Abschluss der einzelnen Besuchstermine, Abbruch, etc.) werden zusammengefasst.

14.3 ANALYSEPOPULATIONEN

Zur Analyse des Hauptkriteriums wird das Full Analysis Set (FAS) als Subset des Sicherheits-/Safety-Analysis-Set (SAS) herangezogen. Dieses enthält alle PatientInnen, für die ausreichend Daten für die Auswertung des Hauptkriteriums vorliegen und die alle Selektionskriterien für die Dokumentation, aber kein Selektionskriterium gegen die Dokumentation erfüllen.

Der modifizierte FAS-Datensatz umfasst alle PatientInnen mit mindestens einem Basis- und einem Nachkontrollwert für den primären Endpunkt.

Das SAS umfasst alle eingeschlossenen PatientInnen, die mindestens einmal in der Nicht-Interventionellen Studie eine Dosis von iGlarLixi (Suliqua® 30-60) bekommen haben.

14.4 STATISTISCHE METHODEN

Dieser Abschnitt enthält genaue Angaben zur Vorbereitung des endgültigen statistischen Analyseplans (SAP), der vor dem Datenbankschluss zu erstellen ist. Alle Abweichungen, die gegenüber den Angaben im Statistikabschnitt auftreten, müssen im endgültigen SAP identifiziert und dokumentiert werden.

Anhand des vorher festgelegten SAP werden die Daten analysiert und die Ergebnisse in einem Abschlussbericht tabellarisch und graphisch aufbereitet. Alle erhobenen Daten werden deskriptiv ausgewertet und haben rein explorativen Charakter. Es werden für kontinuierliche / stetige Variablen die Anzahl der PatientInnen, Mittelwert, Standardabweichung, Median, Minimum, Maximum sowie ausgewählte Perzentile, für kategorielle Variablen Häufigkeiten, prozentuale Häufigkeiten und wenn erforderlich adjustierte prozentuale Häufigkeiten bestimmt. Für geschätzte Parameter werden geeignete 95 %-Konfidenzintervalle berechnet.

Die Auswertungen werden auch für vorab definierte Subgruppen vorgenommen.

14.4.1 Analysevariablen

Primärer Endpunkt:

Absolute Änderung des HbA_{1c} (%) unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Ende der Dokumentation nach ca. 24 Wochen.

Sekundäre Endpunkte:

- Relative Änderung des HbA_{1c} (%) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung des selbstgemessenen Nüchternblutzuckers (mg/dl bzw. mmol/l)* bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn

- Anteil an PatientInnen, die den individuellen HbA_{1c}-Zielwert innerhalb Woche 0-12, 13-24 und 0-24 erreichen (%)
- Anteil an PatientInnen, die einen Nüchternblutzucker ≤ 110 mg/dl bzw. ≤ 6,1 mmol/l innerhalb Woche 0-12, 13-24 und 0-24 erreichen (%)
- Absolute und relative Änderung der Glukose im 7-Punkte-Glukose-Tagesprofil (mg/dl bzw. mmol/l) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung der iGlarLixi-Dosis (Dosisschritte pro Tag)* bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Häufigkeit von Dosisänderungen in den letzten 4 Wochen*
- Absolute und relative Änderung des Körpergewichts (kg) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung des BMI (kg/m²) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung des Medianwertes der Glukose (mg/dl bzw. mmol/l) bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Inzidenz und Rate von Hypoglykämien** (dokumentierte Hypoglykämien innerhalb der letzten ca. 12 Wochen vor Studieneinschluss im Vergleich zu den letzten 12 Wochen vor Dokumentation 2 (nach ca. 12 Wochen) und den letzten 12 Wochen vor der Abschlussdokumentation (nach ca. 24 Wochen))
- Inzidenz unerwünschter Ereignisse bis ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung der Therapiezufriedenheit (mittels DTSQs und DTSQc) bis ca. 24 Wochen nach Behandlungsbeginn

*Diese Änderungen werden zusätzlich zu den Dokumentationen 1, 2 und 3 monatlich durch den Patienten dokumentiert nach Umstellung auf iGlarLixi.

Zusätzlich für FGM PatientInnen:

- Medianer Zielwert des Blutzuckers und Grenzwert für niedrige Glukose
- Absolute Änderung der Gesamtzeit im individuellen Zielbereich in % ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung der Gesamtzeit in % über individuellem Zielbereich ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute Änderung der Gesamtzeit in % unter individuellem Zielbereich ca. 12 und ca. 24 Wochen nach Behandlungsbeginn
- Absolute und relative Änderung der Anzahl der PatientInnen mit hypoglykämischen Ereignissen und der Anzahl an Ereignissen pro PatientIn (dokumentierte Hypoglykämien innerhalb der 14-tägigen FGM-Messung vor Studieneinschluss im Vergleich zur 14-tägigen FGM-Messung vor Dokumentation 2 (nach ca. 12 Wochen) und der 14-tägigen FGM-Messung vor der Abschlussdokumentation (nach ca. 24 Wochen))

14.4.1.1 Hauptkriterien

Das Hauptevaluierungskriterium ist die absolute Änderung des HbA_{1c} (%) unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Ende der Dokumentation nach ca. 24 Wochen.

14.4.1.2 Sonstige Kriterien

n/a

14.4.1.3 Primäranalyse

Basierend auf der Normalverteilungsannahme wird das 95 %-Konfidenzintervall für den geschätzten Parameter, die absolute Änderung des HbA_{1c} (%) unter iGlarLixi vom Beobachtungsbeginn bis zur Visite nach ca. 12 bzw. ca. 24 Wochen, sowie zwischen der Visite nach ca. 12 Wochen und dem Ende der Dokumentation nach ca. 24 Wochen, berechnet.

Mithilfe des t-Tests für verbundene Stichproben wird darüber hinaus überprüft, ob eine von Null verschiedene Differenz vorliegt.
Zusätzlich werden die Wechselwirkungen der Parameter durch eine Varianzanalyse untersucht. Des Weiteren kommen Methoden zur Berücksichtigung fehlender Daten zur Anwendung (z.B. MMRM-Modell).

14.4.1.4 Sekundäre Analyse

Das 95 %-Konfidenzintervall wird mithilfe von exakten Methoden, z. B. der Blyth-Still-Castella-Methode, ermittelt.

14.5 ZWISCHENANALYSE

Für diese Beobachtungsstudie ist eine Zwischenanalyse nach ca. 12 Wochen oder 50 PatientInnen geplant.

15 AUFGABEN UND VERANTWORTLICHKEITEN

15.1 VERANTWORTLICHKEITEN DER STUDIENAUSSCHÜSSE

Ein Studienkomitee wird nicht eingesetzt, die Nicht-Interventionelle Studie hat jedoch einen wissenschaftlichen Leiter. Der wissenschaftliche Leiter berät den Auftraggeber bei der Konzeption und Durchführung des Projektes sowie bei der Erstellung der Publikation(en) nach Vorliegen der Ergebnisse.

15.2 VERANTWORTLICHKEITEN DER TEILNEHMENDEN ÄRZTE

Der/Die teilnehmende Arzt/Ärztin wird die Studie gemäß den Bestimmungen dieses Beobachtungsplans in Übereinstimmung mit den örtlichen Vorschriften und internationalen Richtlinien durchführen.

Der/Die teilnehmende Arzt/Ärztin ist zuständig für:

- Die Einholung der schriftlichen Einverständniserklärung der PatientInnen vor deren Einschluss in die Studie
- Das Ausfüllen des e-CRFs und die Erfassung sämtlicher studienrelevanten Daten. Der/Die teilnehmende Arzt/Ärztin stellt sicher, dass die im e-CRF enthaltenen Informationen präzise und exakt sind.

Der/Die teilnehmende Arzt/Ärztin oder eine vom/von der teilnehmenden Arzt/Ärztin bestimmte Person, die dem/der teilnehmenden Arzt/Ärztin gegenüber verantwortlich ist, muss den/die PatientIn in vollem Umfang über sämtliche Aspekte der Studie einschließlich der schriftlichen Information unterrichten. Alle PatientInnen müssen in einer ihnen verständlichen Sprache und Wortwahl so umfassend wie möglich über die Studie informiert werden.

- Vor der Teilnahme eines/r PatientIn an der Studie muss dieser persönlich oder sein gesetzlicher Vertreter den Namen des/r PatientIn und das Datum in die schriftliche Einverständniserklärung einfügen und diese unterzeichnen. Anschließend muss die Person, die das Aufklärungsgespräch zur Einverständniserklärung geführt hat, diese ebenfalls unterzeichnen. Der/die PatientIn erhält eine Kopie der unterzeichneten und datierten schriftlichen Einverständniserklärung. **Ein weiteres Exemplar verbleibt beim/bei der Arzt/Ärztin und wird von diesem mindestens 25 Jahre aufbewahrt.** Der/die PatientIn wird darauf hingewiesen, dass er/sie seine/ihre Teilnahme jederzeit widerrufen kann, ohne dass ihm/ihr hieraus Nachteile entstehen.

Die Einverständniserklärung und das Informationsblatt, die vom/von der teilnehmenden Arzt/Ärztin zur Einholung des Einverständnisses des/r PatientIn verwendet werden, müssen von Sanofi vor der Einreichung bei der zuständigen Ethikkommission (IRB/IEC) für eine zustimmende Bewertung überprüft und genehmigt werden.

15.3 VERANTWORTLICHKEITEN VON SANOFI

Sanofi ist dafür verantwortlich, alle angemessenen Schritte zu ergreifen und angemessene Ressourcen bereitzustellen, um die ordnungsgemäße Durchführung der Studie sicherzustellen.
Sanofi ist verantwortlich für:

- Lokale Einreichung(en) entsprechend den Datenschutzvorschriften
- Sonstige lokale Einreichung(en).

15.4 VERANTWORTLICHKEITEN DES AUFTRAGSFORSCHUNGSINSTITUTS (CRO)

Das Auftragsforschungsinstitut stellt sicher, dass die Weitergabe der UE/SUE- und PTC-Meldungen an den Sanofi-Kontakt des jeweiligen Landes unverzüglich (spätestens jedoch innerhalb von 24 Stunden) für die Dauer der NIS permanent gewährleistet ist.

Das Auftragsforschungsinstitut führt bei 5 % der teilnehmenden Zentren die Besuche zur Qualitätssicherung in den Praxen durch.

Ferner erstellt das Auftragsforschungsinstitut den statistischen Analyseplan, den Datenmanagementplan, inklusive eines Datenvalidierungsplans und verantwortet die Datenanalyse und Erstellung des Abschlussberichts.

16 ETHISCHE STANDARDS UND REGULIERUNGSNORMEN

16.1 ETHISCHE PRINZIPIEN

Diese Studie wird in Übereinstimmung mit den Grundsätzen der Deklaration von Helsinki, beschlossen auf der 18. Generalversammlung des Weltärztebundes (Helsinki, 1964), sowie allen nachfolgenden Änderungen durchgeführt.

16.2 GESETZE UND VORSCHRIFTEN

Diese Studie wird gemäß den Richtlinien der Guten Epidemiologischen Praxis durchgeführt (23).

Jedes Teilnehmerland muss auf lokaler Ebene sicherstellen, dass alle für die Zulassung erforderlichen Vorschriften eingehalten werden (z. B. IRB/IEC), einschließlich lokaler Datenschutzbestimmungen.

17 ADMINISTRATIVE VORGABEN

17.1 AUFBEWAHRUNG VON AUFZEICHNUNGEN AN STUDIENORTEN

Der/Die teilnehmende Arzt/Ärztin wird alles Notwendige für die Aufbewahrung der Studiendokumentation bis zum Ende der Studie veranlassen. Zusätzlich wird der/die teilnehmende Arzt/Ärztin alle örtlichen Vorschriften/Empfehlungen in Bezug auf die Aufbewahrung von PatientInnen-Daten einhalten.

Es wird empfohlen, dass der/die teilnehmende Arzt/Ärztin die Studiendokumente in Übereinstimmung mit den weiteren Normen und/oder lokalen Gesetzen nach Abschluss oder Abbruch der Studie 25 Jahre lang aufbewahrt, sofern im Vertrag des/der teilnehmenden Arztes/Ärztin nichts anderes vorgegeben ist.

Dennoch sind im Fall einer längeren Aufbewahrungsfrist stets geltende gesetzliche Bestimmungen zu berücksichtigen.

17.2 VERTRAULICHKEIT

Alle Materialien, Informationen (mündlich oder schriftlich) und unveröffentlichten Dokumente, die dem teilnehmenden Arzt zur Verfügung gestellt werden (oder im Auftrag von Sanofi durchgeführte Handlungen), einschließlich des vorliegenden Beobachtungsplans und des Dokumentationsbogens (e-CRF), sind alleiniges Eigentum von Sanofi.

Diese Materialien oder Informationen (sowohl teilweise als auch im Ganzen) dürfen von den teilnehmenden ÄrztInnen oder anderen Mitgliedern seines Teams ohne das vorherige formelle schriftliche Einverständnis von Sanofi nicht an unbefugte Personen weitergegeben werden.

Der/Die teilnehmende Arzt/Ärztin muss sämtliche Informationen, die er/sie während der Studie erhalten, erworben oder abgeleitet hat, vertraulich behandeln und alle erforderlichen Schritte unternehmen, dass diese Vertraulichkeit gewahrt bleibt, mit Ausnahme ihrer Weitergabe zu Informationszwecken wie vom Gesetzgeber gefordert.

17.3 DATENSCHUTZ

Alle erhobenen personenbezogenen Daten mit Bezug zu an der Studie beteiligten Teilnehmern, teilnehmende ÄrztInnen oder sonstigen Personen, die gegebenenfalls in die Datenbanken des Sponsors eingetragen werden, werden unter Einhaltung aller geltenden Gesetze und Vorschriften, einschließlich der Datenschutz-Grundverordnung (DSGVO), behandelt.

Die erhobenen Daten müssen in Bezug zu den Zwecken, für die sie erhoben werden, angemessen und relevant und dürfen diesbezüglich nicht unverhältnismäßig sein. Jede Datenkategorie muss ausreichend begründet sein und mit dem Studienziel in Einklang stehen.

Den TeilnehmerInnen wird vom Sponsor eine eindeutige Identifikationsnummer zugewiesen. Alle TeilnehmerInnen- Aufzeichnungen oder -Datensätze, die an den Sponsor übermittelt werden,

enthalten nur die Identifikationsnummer; die Namen der Teilnehmer oder Informationen, anhand derer die Teilnehmer identifiziert werden könnten, werden nicht übermittelt.

Der/Die TeilnehmerIn muss darüber informiert werden, dass seine/ihre personenbezogenen studienbezogenen Daten vom Sponsor in Übereinstimmung mit den örtlichen Datenschutzgesetzen verwendet werden. Der Offenlegungsgrad muss dem/der TeilnehmerIn ebenfalls erklärt werden.

Der/Die TeilnehmerIn muss darüber informiert werden, dass seine/ihre medizinischen Unterlagen von Auditoren der klinischen Qualitätssicherung oder anderen vom Sponsor ernannten autorisierten Mitarbeitern, von den zuständigen IRB-/IEC-Mitgliedern und von Inspektoren der Genehmigungsbehörden geprüft werden können.

Bei der Archivierung oder Verarbeitung personenbezogener Daten, die sich auf den/die teilnehmende/n Arzt/Ärztin und/oder die TeilnehmerInnen beziehen, muss der Sponsor alle angemessenen Maßnahmen ergreifen, um diese Daten vor Zugriff durch unbefugte Dritte zu schützen und einen derartigen Zugriff zu verhindern.

17.4 SANOFI AUDITS UND INSPEKTIONEN DURCH GENEHMIGUNGSBEHÖRDEN BEI SANOFI

Der/die teilnehmende Arzt/Ärztin erklärt sich damit einverstanden, den Auditoren von Sanofi/den Inspektoren der zuständigen Behörden zu Überprüfungszwecken direkten Zugang zu seinen/ihren Studienunterlagen zu gewähren, wobei diese Personen der beruflichen Schweigepflicht unterliegen und somit keine Informationen, anhand derer eine Person identifiziert werden könnte, und keine personenbezogenen medizinischen Informationen weitergeben werden.

Der/die teilnehmende Arzt/Ärztin wird bei der Abwicklung der Audits und der Inspektionen jegliche Unterstützung gewähren und Zugang zu sämtlichen Einrichtungen, Daten und Dokumenten gewähren.

Die Vertraulichkeit der überprüften Daten und der Schutz der PatientInnen müssen während dieser Inspektionen gewahrt bleiben.

Alle Ergebnisse und Informationen, die im Rahmen der behördlichen Inspektionen erzeugt werden, werden vom/von der teilnehmenden Arzt/Ärztin an Sanofi weitergeleitet.

Der/die teilnehmende Arzt/Ärztin muss von Sanofi geforderte, angemessene Korrekturmaßnahmen ergreifen, um alle bei den Audits oder Inspektionen festgestellten Mängel zu beheben.

17.5 VORZEITIGER ABBRUCH DER STUDIE ODER VORZEITIGE SCHLIESSUNG EINES STUDIENSTANDORTES

Sanofi kann jederzeit und aus jedwedem Grund entscheiden, die Studie abzubrechen. Der/Die beteiligte teilnehmende Arzt/Ärztin wird schriftlich über die Entscheidung in Kenntnis gesetzt.

Wenn der/die teilnehmende Arzt/Ärztin entscheidet, aus der Studie auszuscheiden, muss er/sie Sanofi seiner-/ihrerseits ebenso schriftlich darüber informieren.

Falls dies laut örtlichen Bestimmungen vorgeschrieben ist, ist die Ethikkommission/sind die Ethikkommissionen (IRB/IEC) und die zuständigen Behörden zu informieren.

17.6 EIGENTUMSRECHT UND VERWENDUNG VON DATEN UND STUDIENERGEBNISSEN

Eine Verwendung der Daten ist ohne die Genehmigung von Sanofi nicht zulässig.

Das wissenschaftliche Komitee hat in vollem Umfang Zugriff auf die endgültigen Daten, zum Zweck einer entsprechenden akademischen Analyse und Meldung der Studienergebnisse.

17.7 PUBLIKATIONEN

Alle teilnehmenden ÄrztInnen und Komiteemitglieder geben dem wissenschaftlichen Leiter alle Befugnisse für die Erstpräsentation und/oder die Erstveröffentlichung der Ergebnisse. Vor der Erstveröffentlichung ist keine andere Veröffentlichung gestattet. Jede spätere Präsentation oder Veröffentlichung (gilt auch für Unterstudien) durch eine/n StudienteilnehmerIn muss vom wissenschaftlichen Komitee genehmigt werden und auf die Studie und die Erstveröffentlichung verweisen.

Die endgültige Entscheidung über die Veröffentlichung von Manuskripten/Zusammenfassungen/Präsentationen trifft der wissenschaftliche Leiter nach vorheriger Mitteilung an den Sponsor, wobei dieser eine interne Überprüfung vornehmen und Anmerkungen machen kann.

Alle Manuskripte/Zusammenfassungen/Präsentationen müssen dem Sponsor mindestens fünfundvierzig (45) Kalendertage vor der Einreichung zur Veröffentlichung vorgelegt werden, um eine interne Begutachtung zu ermöglichen. Der Sponsor kann verlangen, dass der Name des Sponsors und/oder die Namen von einem/r oder mehreren seiner MitarbeiterInnen in einer solchen Veröffentlichung erscheinen beziehungsweise nicht erscheinen dürfen.

Der Sponsor kann die Publikation oder die Mitteilung zum Schutz der Vertraulichkeit oder zum Schutz beliebiger darin enthaltener Informationen für einen begrenzten Zeitraum hinauszögern.

18 ÄNDERUNGEN AM BEOBACHTUNGSPLAN

Jede Änderung des Beobachtungsplans wird in einer schriftlichen Änderung aufgezeichnet, die vom/von der teilnehmenden Arzt/Ärztin unterzeichnet wird. Eine Änderung des Beobachtungsplans kann gemäß den örtlichen Vorschriften unter Umständen behördliche Einreichungen (z. B. beim IRB/IEC) erforderlich machen.

19 LITERATURHINWEISE

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Stempel Arztpraxis bzw. Ärztliche Einrichtung

SANOFI

Patienten-Information und -Einwilligung zur Teilnahme an folgender Beobachtungsstudie

Titel: Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle durch Therapieintensivierung mit iGlarLixi im Suliqua®-(30-60)-Pen in der täglichen Praxis bei PatientInnen mit Typ-2-Diabetes, deren Blutzucker unter Basalinsulin und oraler antidiabetischer Therapie (BOT) nicht ausreichend kontrolliert ist

Präparat (Wirkstoff): Suliqua® (Insulin glargin/Lixisenatid (iGlarLixi))
Studiennummer: OBS16751
Studienname: CHANCE

Beobachtungsplan V1.0 vom 01.07.2020

Patienten-Nummer: _____

Behandelnder Arzt: _____

Telefon: _____

Exemplar für den Patienten / die Patientin

1. Einleitung

Sehr geehrte Patientin, sehr geehrter Patient,
mit dieser Patienteninformation wollen wir Sie über die Möglichkeit informieren, an der oben genannten Beobachtungsstudie zur Behandlung des Diabetes mellitus Typ 2 teilzunehmen.

Ihr behandelnder Arzt / Ihre behandelnde Ärztin hat festgestellt, dass Sie die Kriterien erfüllen, um an dieser von der Sanofi-Aventis Deutschland GmbH durchgeführten Beobachtungsstudie teilzunehmen. Ihre Teilnahme ist vollkommen freiwillig. Sie können jederzeit aus der Beobachtungsstudie ausscheiden, ohne irgendwelche Nachteile zu haben oder Ihnen zustehende Leistungen einzubüßen.

Sie können der Teilnahme nur zustimmen, wenn Sie die nachfolgenden Erläuterungen zu den Studienmaßnahmen gelesen und verstanden haben. Nehmen Sie sich Zeit, Ihrem behandelnden Arzt / Ihrer behandelnden Ärztin alle Ihre Fragen zu stellen.

2. Zweck der Studie

Es handelt sich um eine Beobachtungsstudie, die durchgeführt wird, um Informationen über die Behandlung mit Suliqua® (Insulin glargin/Lixisenatid (iGlarLixi)) bei Patientinnen und Patienten mit Diabetes mellitus Typ 2 in der täglichen Praxis zu sammeln. In dieser Studienform (Beobachtungsstudie) beruht Ihre Behandlung auf der von Ihnen gemeinsam mit Ihrem behandelnden Arzt / Ihrer behandelnden Ärztin getroffenen Entscheidung. Unabhängig von Ihrer eventuellen Teilnahme an dieser Beobachtungsstudie wurde Ihnen Suliqua® als Teil der üblichen Behandlung Ihres Diabetes mellitus Typ 2 verschrieben. Diese Beobachtungsstudie wird Ihre Behandlung in keiner Weise festlegen oder verändern. Sofern Sie sich zur Teilnahme entschließen, werden Informationen über Sie, Ihre Erkrankung und den Behandlungsverlauf Ihres Diabetes mellitus Typ 2 gesammelt.

Suliqua® wird als Ergänzung zu Diät und Bewegung zusätzlich zu Metformin mit oder ohne SGLT-2-Inhibitoren zur Behandlung von erwachsenen Patienten mit unzureichend kontrolliertem Diabetes mellitus Typ 2 zur Verbesserung der Blutzuckerkontrolle angewendet.

Ziel dieser Nicht-Interventionellen Studie ist es, die Effektivität und Sicherheit von iGlarLixi bei Patientinnen und Patienten mit Typ 2 Diabetes im klinischen Alltag zu untersuchen, die aufgrund unzureichender glykämischer Kontrolle unter Basalinsulin in Kombination mit oralen Antidiabetika (OAD) von Ihrem Arzt / Ihrer Ärztin auf Suliqua® umgestellt wurden.

Es handelt sich nicht um die Erprobung eines neuen Arzneimittelwirkstoffs. Suliqua® ist ein von der EMA (European Medicines Agency / Europäische Arzneimittel-Agentur) und BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) in Deutschland zugelassenes Medikament. Auftraggeber dieser Beobachtungsstudie ist die Sanofi-Aventis Deutschland GmbH.

3. Beschreibung der Studie

In diese Beobachtungsstudie sollen ungefähr 250 Patienten aus Deutschland aufgenommen werden. Alle Patienten, die an dieser Beobachtungsstudie teilnehmen, werden genauso wie Sie mit Suliqua® behandelt. Der Behandlungsverlauf aller teilnehmenden Patienten wird über eine Dauer von max. 6 Monaten nach Beginn der Behandlung mit Suliqua® beobachtet.

Sie haben selbst keinen direkten Nutzen aus der Teilnahme an dieser Beobachtungsstudie, da Ihre Behandlung durch die Studienteilnahme nicht beeinflusst wird. Sie helfen uns aber durch Ihre Teilnahme, mehr Erkenntnisse über die Behandlung von Diabetes mellitus Typ 2-Patienten mit Suliqua® zu gewinnen, z. B. Anwendung und Verträglichkeit von Suliqua® im Praxisalltag. Diese Erkenntnisse tragen möglicherweise zu einer weiteren Verbesserung der Behandlung von Diabetes mellitus Typ 2-Patienten in der Zukunft bei.

4. Erhobene Daten

Um an dieser Beobachtungsstudie teilnehmen zu können, müssen Sie und Ihr Arzt weder die Behandlung ändern noch werden zusätzliche Verfahren oder Tests verlangt. Es werden keine besonderen Besuchstermine im Rahmen der Beobachtungsstudie erforderlich. Sie werden Ihren Arzt zu den gewohnten Zeitpunkten für die normale Versorgung Ihrer Krankheit aufsuchen, und es werden die üblichen Behandlungsverfahren bzw. Tests durchgeführt. Wenn Sie allerdings einer Studienteilnahme zugestimmt haben, werden beim Aufnahmetermin folgende Angaben aus der Krankenakte entnommen: *Alter, Geschlecht, Größe, Gewicht, Blutdruck, Diabetes mellitus Vorgeschichte inkl. Diabetesdauer und aktueller Diabetes-Medikation, Begleiterkrankungen, aktuelle Medikation, unerwünschte Ereignisse wie z. B. Hypoglykämien, Grund für die Umstellung auf Suliqua®, sofern vorhanden einige Laborwerte, die ohnehin erhoben werden (AST- und ALT-Werte (Aminotransferasen (Leberwerte)), eGFR (geschätzte glomeruläre Filtrationsrate, Kreatinin (Nierenfunktion)), Gesamtcholesterin, LDL, HDL, Triglyzeride (Blutfettwerte), NBZ (Nüchternblutzucker), HbA_{1c} (Langzeitblutzucker)), Ihr HbA_{1c}-Zielwert, die Glykämische Variabilität (7-Punkte-Blutzucker-Tagesprofil oder FGM (FGM = Flash Glucose Monitoring)), Ihr aktueller selbstgemessener Nüchternblutzucker (per Glukometer oder FGM), Angaben zum FGM-System sowie Ihre mittels FGM-Blutzuckermessung selbst gemessenen Blutzuckerwerte der letzten 14 Tage vor Umstellung auf Suliqua®.*

Im Verlauf der Studie werden zusätzlich nach ca. 12 Wochen (Zwischendokumentation) und ca. 24 Wochen (Abschlussdokumentation) folgende Daten dokumentiert: *Gewicht, aktuelle Medikation, Daten zur Suliqua®-Therapie, Suliqua®-Dosis und ggf. Suliqua®-Dosisanpassung , Laborwerte (sofern vorhanden – wie oben), unerwünschte Ereignisse, Glykämische Variabilität (7-Punkte-Blutzucker-Tagesprofil oder FGM), unerwünschte Ereignisse, Ihr selbstgemessener Nüchternblutzucker (per Glukometer oder FGM), Angaben zum Glukometer/FGM-System sowie Ihre mittels FGM-Blutzuckermessung gemessenen Blutzuckerwerte der letzten 14 Tage vor der Zwischen- bzw. Abschlussdokumentation (ca. 12 bzw. ca. 24 Wochen nach Umstellung auf Suliqua®).*

Außerdem werden bei den monatlichen Dokumentationen nach ca. 4, ca. 8, ca. 16 und ca. 20 Wochen noch folgende Daten dokumentiert (sofern erfolgt): *evtl. Anpassung der Suliqua® Dosierung, momentane Suliqua® Dosierung sowie Ihr selbstgemessener Nüchternblutzucker.*

Zusätzlich werden Sie gebeten, einen (zu Beginn der Studie) bzw. zwei Fragebögen (am Ende der Studie) zu Ihrer Therapiezufriedenheit auszufüllen.

Die nachfolgende Tabelle zeigt Ihnen noch einmal im Überblick, welche Gesundheitsdaten, sofern sie von Ihrem behandelnden Arzt erhoben wurden, im weiteren Verlauf Ihrer Behandlung und der 6-monatigen Beobachtungsdauer der Studie aus Ihrer Krankenakte entnommen werden.

	Eingangs-dokumentation (Dokumentation 1)	Monatliche Dokumentation (Zwischenerfassung)	Zwischen-dokumentation (Dokumentation 2)	Monatliche Dokumentation (Zwischenerfassung)	Abschluss-dokumentation (Dokumentation 3)
Zeitpunkt (Woche)	0 (Beginn Beobachtung)	ca. 4 ca. 8	ca. 12	ca. 16 ca. 20	ca. 24 (Abschluss)
Arztfragebogen	X				
Selektionskriterien	X				
PatientInnen-Charakteristika	X				
Einwilligungs- / Datenschutzerklärung	X				
Demographische Daten	X				
Größe	X				
Gewicht	X		X		X
Krankengeschichte inkl. Diabetes mellitus	X				
Aktuelle Begleit-erkrankungen	X				
Individueller HbA_{1c} Zielwert	X				
Medikamenten-anamnese	X				
Aktuelle Medikation	X		X		X
Daten iGlarLixi-Anpassung	X	X	X	X	X
iGlarLixi-Dosis	X	X	X	X	X
Glykämische Variabilität (7-Punkte-Blutzucker-Tagesprofil oder FGM)	X		X		X
Laborwerte inkl. HbA_{1c}	X		X		X
Nüchternblutzucker (Patientenmessung)	X	X	X	X	X
Patientenfragebögen zur Therapiezufrieden-heit (DTSQs und DTSQc)	X (nur DTSQs)				X (DTSQs und DTSQc)
Unerwünschte Ereignisse	X		X		X

5. Schwangerschaft

Bisher liegen keine Erfahrungen mit der Anwendung von Präparat bei Schwangeren vor.

ANMERKUNG FÜR MÄNNER
Wenn Sie während der Beobachtungsstudie oder innerhalb von bis zu 3 Monaten, nachdem Sie die letzte Dosis des Sanofi-Medikaments erhalten haben, ein Kind zeugen, müssen Sie den teilnehmenden Arzt innerhalb von 24 Stunden nach Bestätigung der Schwangerschaft benachrichtigen. Die Durchführungen in dem folgenden Absatz sind freiwillig:

Sofern Ihre Partnerin zustimmt, ihren behandelnden Arzt (z. B. den Gynäkologen) von der Schweigepflicht zu entbinden, werden nach den behördlichen Regeln und unter Ein-haltung der örtlichen Bestimmungen und der Datenschutzgesetze Daten über die Schwangerschaft Ihrer Partnerin, ihr Ergebnis und die Entwicklung des Kindes erhoben. Möglicherweise sind darüber hinaus noch Nachuntersuchungen des Babys bis mindestens ein Jahr nach der Geburt erforderlich, da nicht auszuschließen ist, dass mögliche Veränderungen zum Zeitpunkt der Geburt noch nicht erkennbar sind.

Alle Informationen werden entsprechend den nationalen Vorschriften und unter Einhaltung der Datenschutzgesetze erhoben.

ANMERKUNG FÜR FRAUEN
Wenn Sie während der Studienteilnahme oder innerhalb von 3 Monaten nach Ihrer letzten Dosis des Sanofi-Medikaments erfahren oder vermuten, dass Sie schwanger sind, müssen Sie Ihren teilnehmenden Arzt innerhalb von 24 Stunden nach der medizinischen Bestätigung Ihrer Schwangerschaft informieren.

Nach den behördlichen Regeln und unter Einhaltung der örtlichen Bestimmungen und der Datenschutzgesetze werden Daten über Ihre Schwangerschaft, deren Ergebnis und die Entwicklung des Kindes erhoben.

Möglicherweise sind darüber hinaus noch Nachuntersuchungen des Babys bis mindestens ein Jahr nach der Geburt erforderlich, da nicht auszuschließen ist, dass mögliche Veränderungen zum Zeitpunkt der Geburt noch nicht erkennbar sind.

Alle Informationen werden entsprechend den nationalen Vorschriften und unter Einhaltung der Datenschutzgesetze erhoben.

6. Alternative Verfahren oder Behandlungsmöglichkeiten

Ihre Teilnahme an der Beobachtungsstudie hat keinen Einfluss auf die Therapieentscheidung, die Sie bzw. Ihr behandelnder Arzt getroffen haben. Wenn Sie Fragen zu alternativen Therapiemethoden haben, besprechen Sie diese bitte mit Ihrem behandelnden Arzt. Sie können gemeinsam mit Ihrem Arzt entscheiden, welcher Behandlungsweg für Sie der geeignetste ist.

7. Verwendung und Schutz von personenbezogenen Daten

Während der Beobachtungsstudie werden medizinische Befunde und persönliche Informationen von Ihnen durch Ihren behandelnden Arzt erhoben und in der Arztpraxis / Ärztlichen Einrichtung in Ihrer persönlichen Akte niedergeschrieben oder elektronisch gespeichert. Zugriff auf diese personenbezogenen Daten und medizinischen Befunde hat ausschließlich Ihr behandelnder Arzt und seine / ihre Mitarbeiter.

Das Arzneimittelgesetz enthält nähere Vorgaben für den erforderlichen Umfang der Einwilligung in die Datenerhebung und -verwendung. **Einzelheiten, insbesondere zur Möglichkeit eines Widerrufs, entnehmen Sie bitte der Einwilligungserklärung, die im Anschluss an diese Patienteninformation abgedruckt ist.**

8. Pflichten des Patienten während der Teilnahme

Wenn Sie einverstanden sind, an dieser Studie teilzunehmen, sind Sie verpflichtet, Fragen über alle medizinischen oder physischen Ereignisse, die Sie während der Behandlung mit Suliqua® feststellen, zu ihrem gesundheitlichen Zustand und zu Therapien die Sie erhalten, wenn notwendig auch über Fragebögen zu beantworten.

9. Beendigung der Studienteilnahme

Ihre Teilnahme an dieser Beobachtungsstudie ist vollkommen **freiwillig**.

Sie können jederzeit vor und nach Beginn der im Zusammenhang mit dieser Beobachtungsstudie erfolgenden Datenerhebung Ihre Meinung ändern und Ihre Zustimmung zur Teilnahme, auch ohne Angabe von Gründen, **widerrufen**. Wenn Sie sich entscheiden, nicht oder nicht mehr an dieser Erhebung teilzunehmen, beeinträchtigt diese Entscheidung keinesfalls Ihre Beziehung zu Ihrem Arzt. Für Ihre weitere ärztliche Versorgung entstehen hierdurch keine Nachteile.

Im Fall eines Widerrufs Ihrer Einwilligung, an der Beobachtungsstudie teilzunehmen, wird Ihr behandelnder Arzt Sie fragen, ob Ihre bis zu diesem Zeitpunkt bereits gespeicherten Daten weiterhin verwendet werden dürfen, weil die Daten wichtig sind, um

- Wirkungen des angewendeten Arzneimittels festzustellen,
- sicherzustellen, dass Ihre schutzwürdigen Interessen nicht beeinträchtigt werden.

Die von Ihnen vorhandenen Daten werden lediglich in anonymisierter Form weiterverarbeitet. Das heißt, ein Rückschluss auf Ihre Person ist nicht möglich. Weitere Daten werden nicht erhoben.

Falls dies aber von Ihnen gewünscht wird, werden die bei Ihnen erhobenen und noch über die Pseudonymisierungsnummer identifizierbaren Daten gelöscht.

Stempel Arztpraxis bzw. Ärztliche Einrichtung

Datenschutz-Einwilligungserklärung

Patienten-Nummer: _____

Behandelnder Arzt: _____

Telefon: _____

Studiennummer: OB16751
Studienname: CHANCE

Titel: Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle bei PatientInnen mit T2D, die nicht ausreichend kontrolliert sind unter Basalinsulin und oraler antidiabetischer Therapie (BOT) und eine Therapieintensivierung mit Suliqua® in der täglichen Praxis benötigen

Präparat (Wirkstoff): Suliqua® (Insulin glargin/Lixisenatid (iGlarLixi)

Mir ist bekannt, dass zum Zwecke dieser Nicht-Interventionellen Studie personenbezogene Daten (Name, Vorname, Geburtsdatum, Geschlecht, Adresse, Telefonnummer), insbesondere auch Gesundheitsdaten (siehe Punkt 4 der Patienteninformation) über mich verarbeitet werden sollen.
Die Verarbeitung dieser Daten erfolgt nach den gesetzlichen Bestimmungen und setzt gemäß Art. 6 Abs. 1 lit. a), Art. 9 Abs. 2 lit. a) der Datenschutzgrundverordnung (DSGVO) meine **folgende freiwillige Einwilligungserklärung** voraus:

1. Ich erkläre mich damit **einverstanden**, dass im Rahmen dieser Nicht-Interventionellen Studie die oben genannten personenbezogenen Daten, insbesondere auch Gesundheitsdaten über mich erhoben und in Papierform sowie auf elektronischen Datenträgern bei dem mich behandelnden Arzt aufgezeichnet werden. Zugriff auf diese personenbezogenen Daten, insbesondere Gesundheitsdaten hat nur das mit meiner Behandlung befasste Personal meines behandelnden Arztes.

2. Ich erkläre mich damit **einverstanden**, dass aus diesen erhobenen personenbezogenen Daten, insbesondere Gesundheitsdaten die für die Nicht-Interventionelle Studie relevanten Daten zusätzlich in pseudonymisierter (verschlüsselter) Form gespeichert werden. Pseudonymisiert bedeutet, dass keine Angaben von Namen oder Initialen verwendet werden, sondern nur ein Nummern- und / oder Buchstabencode und das Geburtsjahr / Alter.

3. Ich bin damit **einverstanden**, dass diese pseudonymisierten personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten weitergegeben werden:
   a. an den Sponsor und von diesem beauftragte Stellen zum Zwecke der wissenschaftlichen Auswertung:
      Beauftragte Stelle zum Datenmanagement:
      - Arbeitskreis Klinische Prüfungen, PD Dr. med. Seiler GmbH (AKP) GmbH, Munzinger Str. 10, 79111 Freiburg Deutschland
      Beauftragte Stelle zur Bearbeitung der Sicherheitsmeldungen:
      - [redacted]
      - [redacted]
   b. im Falle unerwünschter Ereignisse: an den Sponsor und die zuständige Bundesoberbehörde (*in Deutschland: das Bundesinstitut für Arzneimittel und Medizinprodukte BfArM*), von dieser an die Europäische Datenbank und an internationale Überwachungsbehörden.
   c. zum Zwecke der Erstellung des Sicherheitsberichts: an den nationalen oder internationalen Zulassungsinhaber des mit dieser Nicht-Interventionellen Studie beobachteten Arzneimittels sowie an die globale Einheit für Pharmakovigilanz des Sanofi-Konzerns und dessen beauftragte Stelle: [redacted] die mit der Erstellung des international verwendeten Sicherheitsberichts für dieses Arzneimittel befasst ist.

4. Sofern meine personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten darüber hinaus ebenfalls in Länder übermittelt werden, in denen die Datenschutzanforderungen nach den dort geltenden rechtlichen Bestimmungen niedriger sind als in der Europäischen Union, unternimmt der Sponsor alle notwendigen Maßnahmen, um einen gleichwertigen Schutz meiner personenbezogenen Daten, insbesondere meiner Gesundheitsdaten gemäß den Datenschutzstandards der Europäischen Union herzustellen.

   Folgende Maßnahmen kommen insbesondere in Betracht:
   a. Verbindliche interne Datenschutzvorschriften (Binding Corporate Rules) (Art. 46 Abs. 2 lit. b), Art. 47 DSGVO) und
   b. Standarddatenschutzklauseln der Kommission oder einer Aufsichtsbehörde (Art. 46 Abs. 2 lit. c) und d) DSGVO) bzw. Standardvertragsklauseln gem. Art. 46 Abs. 5 DSGVO i.V.m. Art. 26 Abs. 2 der Richtlinie 95/46/EG.

   Der Sponsor erklärt, dass er verbindliche interne Datenschutzvorschriften (Binding Corporate Rules) für die konzerninterne Verarbeitung personenbezogener Daten implementiert hat. Diese kann ich unter folgendem Link abrufen:
   „www.sanofi.com/-/media/project/one-sanofi-web/websites/global/sanofi-com/home/common/docs/download-center/binding_corporate_rules_list_of_sanofi_affiliates_having_signed_the_bcr_janvier_2017.pdf"

   Mit beauftragten und zur Verschwiegenheit verpflichteten Dritten außerhalb der Europäischen Union schließen Gesellschaften innerhalb des Sanofi-Konzerns entsprechende datenschutzkonforme Vereinbarungen (Standarddatenschutzklauseln).

   Das Vorstehende ist dann nicht erforderlich, wenn die Datenübermittlung in ein Drittland erfolgt, für das ein Angemessenheitsbeschluss der EU-Kommission besteht.

5. Ich erkläre mich damit **einverstanden**, dass Beauftragte des Sponsors in meine bei dem behandelnden Arzt vorhandenen personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten, Einsicht nehmen können, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der Nicht-Interventionellen Studie notwendig ist. **Für diese Maßnahme entbinde ich den behandelnden Arzt von der ärztlichen Schweigepflicht.**

6. Ich bin damit **einverstanden**, dass meine personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten nach Beendigung oder Abbruch der Nicht-Interventionellen Studie 25 Jahre durch meinen behandelnden Arzt aufbewahrt werden. Danach werden meine personenbezogenen Daten gelöscht, soweit nicht gesetzliche Aufbewahrungsfristen entgegenstehen.

7. Ich wurde darüber **informiert**, dass ich das Recht habe, jederzeit meine Einwilligung in die im Rahmen der Nicht-Interventionellen Studie erfolgende Datenverarbeitung **mit Wirkung für die Zukunft zu widerrufen** und dass dies keinerlei Einfluss auf meine weitere Behandlung oder medizinische Versorgung hat.

8. Ich habe das Recht, jederzeit **Auskunft** nach Art. 15 DSGVO über die über mich gespeicherten personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten zu erhalten sowie eine kostenlose Kopie meiner gespeicherten personenbezogenen Daten, insbesondere Gesundheitsdaten anzufordern und kann gegebenenfalls eine **Berichtigung** entsprechend Art. 16 DSGVO verlangen.

9. Ich habe das Recht, dass meine mich betreffenden personenbezogenen Daten, insbesondere auch meine Gesundheitsdaten unverzüglich **gelöscht** werden, sofern einer der folgenden Gründe zutrifft:
   a. Die personenbezogenen Daten sind für die Zwecke, für die sie erhoben oder auf sonstige Weise verarbeitet wurden, nicht mehr notwendig;
   b. Die personenbezogenen Daten wurden unrechtmäßig verarbeitet.

   Ich wurde darüber informiert, dass ich keinen Anspruch auf Löschung habe, soweit meine Daten für die wissenschaftliche Forschung erforderlich sind und die Löschung voraussichtlich die Verwirklichung der Ziele dieser Verarbeitung unmöglich macht oder ernsthaft beeinträchtigt,
   oder
   die Verarbeitung zur Geltendmachung, Ausübung oder Verteidigung von Rechtsansprüchen erforderlich ist.

10. Ich habe das Recht, die mich betreffenden personenbezogenen Daten, die ich im Rahmen dieser Nicht-Interventionellen Studie bereitgestellt habe, in einem strukturierten, gängigen und maschinenlesbaren Format zu erhalten und diese Daten einem anderen Verantwortlichen ohne Behinderung zu übermitteln, sofern die Verarbeitung mithilfe automatisierter Verfahren erfolgt. Bei der Ausübung meines Rechts auf **Datenübertragbarkeit** gemäß Art. 20 DSGVO habe ich das Recht, zu erwirken, dass die personenbezogenen Daten direkt von einem Verantwortlichen einem anderen Verantwortlichen übermittelt werden, soweit dies technisch machbar ist. Die Ausübung des Rechts auf Datenübertragbarkeit lässt das Recht auf Löschen der Daten unberührt. Dieses Recht gilt nicht für eine Verarbeitung, die für die Wahrnehmung einer Aufgabe erforderlich ist, die im öffentlichen Interesse liegt oder in Ausübung öffentlicher Gewalt erfolgt, die dem Verantwortlichen übertragen wurde. Das Recht gemäß Absatz 2 darf die Rechte und Freiheiten anderer Personen nicht beeinträchtigen.

Die von mir erhobenen Daten stellen möglicherweise bei dem Verantwortlichen ein Betriebsgeheimnis/Geschäftsgeheimnis dar. Ich bin darüber informiert, dass die Ausübung des Rechts auf Datenübertragbarkeit in diesem Fall in die Rechte des Verantwortlichen eingreifen würde und deshalb von mir nicht ausgeübt werden kann.

Zur Geltendmachung der vorgenannten Rechte siehe Ziffer 13.

11. Ich bin darüber **informiert**, dass allen Empfängern, denen meine personenbezogenen Daten, insbesondere meine Gesundheitsdaten offengelegt wurden, jede Berichtigung oder Löschung der personenbezogenen Daten oder eine Einschränkung der Verarbeitung mitgeteilt wird, es sei denn, dies erweist sich als unmöglich oder ist mit einem unverhältnismäßigen Aufwand verbunden. Der Verantwortliche unterrichtet mich über diese Empfänger, wenn ich dies verlange.

12. **„Verantwortliche"** im Sinne der Datenschutzgrundverordnung für diese Beobachtungsstudie sowie die Datenverarbeitung sind sowohl
    a. der behandelnde Arzt (Kontaktdaten – siehe 1. Seite) als auch
    b. der Sponsor der Beobachtungsstudie Sanofi-Aventis Deutschland GmbH, Brüningstr. 50, 65926 Frankfurt; Kontaktdaten der für die Klinische Forschung zuständigen Abteilung des Sponsors: Sanofi-Aventis Deutschland GmbH, Potsdamer Str. 8, 10785 Berlin).

    als **gemeinsam Verantwortliche im Sinne des Art 26 DSGVO**. Dies bedeutet, dass beide Verantwortliche verantwortlich gem. Art. 4 Ziffer 7 DSGVO sind, die Verantwortlichkeiten im Innenverhältnis jedoch aufgeteilt haben. Der Sponsor als Auftraggeber der Beobachtungsstudie legt durch Gestaltung der Anwendungsbeobachtung primär den Zweck der Verarbeitung der pseudonymisierten Daten der Teilnehmer fest und der behandelnden Arzt die Mittel der Verarbeitung der Rohdaten als auch alleinverantwortlich auf Basis der Rohdaten die Entscheidungen bezüglich des Ein- und Ausschlusses der Teilnehmer. Die beiden verantwortlichen haben insoweit eine Vereinbarung gemäß Art. 26 DSGVO getroffen, die die Verantwortlichkeiten untereinander regelt. Die wesentlichen Informationen werden Ihnen durch Ihren Arzt auf Anfrage zur Verfügung gestellt.

13. Ich bin darüber **informiert** worden, dass **mein behandelnder Arzt mein erster Ansprechpartner für datenschutzrechtliche Anfragen ist** und ich mich im Regelfall an den behandelnden Arzt bzw. seinen Datenschutzbeauftragten wenden sollte, denn allein der behandelnde Arzt bzw. sein Datenschutzbeauftragter kann auf Grund des Pseudonymisierungsprozesses in Nicht-Interventionellen Studien vollumfänglich auf meine Daten zugreifen bzw. entsprechende Auskünfte geben. Dem Datenschutzbeauftragten des Sponsors stehen im Zweifel die zur Erteilung von Auskünften über personenbezogene Daten erforderlichen Informationen nicht zur Verfügung. Aus diesem Grund übernimmt Ihr behandelnder Arzt die Erfüllung Ihrer Rechte gemäß vorstehender Ziffern 7 – 10.

Exemplar für den Patienten / die Patientin

14. In Fragen zu Datenverarbeitungsprozessen steht mir
    a. der behandelnde Arzt oder ggf. sein **Datenschutzbeauftragter**

    _____

    Kontaktdaten des Datenschutzbeauftragten
    bzw.
    b. der **Datenschutzbeauftragte des Sponsors**
    [redacted]
    Telefon: [redacted]
    gerne zur Verfügung.

15. Ich bin darüber **informiert** worden, dass ich mich an die Datenschutzbehörden wenden kann, wenn ich Bedenken hinsichtlich des Umgangs mit meinen personenbezogenen Daten, insbesondere meinen Gesundheitsdaten habe. Zuständig ist der jeweils zuständige Landesdatenschutzbeauftragte des Bundeslandes, indem der behandelnde Arzt bzw. der Sponsor ansässig ist. Die Kontaktdaten kann ich unter
    https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html einsehen.
    Die Kontaktdaten der Datenschutzbehörde für den Sponsor lauten:
    Der Hessische Datenschutzbeauftragte; Gustav-Stresemann-Ring 1; 65189 Wiesbaden;
    E-Mail: Poststelle@datenschutz.hessen.de; Telefon: 0611 / 1408 - 0
    Gerne stellen aber auch der behandelnde Arzt oder der Sponsor die entsprechenden Kontaktdaten zur Verfügung.
    Ich bin auch darüber informiert, dass ich mich auch an jede weitere Datenschutzaufsichtsbehörde in der Europäischen Union wenden kann.

Ich habe vorstehende Informationen gelesen und verstanden und willige freiwillig entsprechend der vorstehenden Erklärungen in die Verarbeitung meiner personenbezogenen Daten, insbesondere meiner Gesundheitsdaten mit meiner Unterschrift ein:

_____

Name des Patienten in Druckbuchstaben

_____ _____

Datum Unterschrift des **Patienten**

Ich habe das Aufklärungsgespräch geführt und die Einwilligung des Patienten eingeholt.

_____

Name des informierenden Arztes / der informierenden Ärztin

_____ _____

Datum Unterschrift des informierenden Artes / der informierenden Ärztin

STATISTICAL ANALYSIS PLAN

A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood glucose is not adequately controlled on basal insulin and oral antidiabetic therapy (BOT) – CHANCE

STUDY NUMBER: OBS16751

STUDY NAME: CHANCE

COMPOUND: Insulin glargine/lixisenatide (iGlarLixi; Suliqua®)

STATISTICIAN: [redacted]

DATE OF ISSUE: 11-September-2022

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Author

29.09.2022
Date

[redacted] (Statistician)

Review

28.09.2022
Date

[redacted]
Medical Operations
Sanofi-Aventis Deutschland GmbH

Approval

15.09.2022
Date

[redacted]
Winicker Norimed, Biostatistician

29.09.2022
Date

[redacted]
Clinical Project Leader
Sanofi-Aventis Deutschland GmbH

TABLE OF CONTENTS

List of abbreviations and definition of terms

Initials	Explanation
ADR	Adverse drug reaction
AE	Adverse event
AESI	Adverse event of special interest
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BMI	Body mass index
BOT	Basal insulin supported oral therapy
CGM	Real-time continuous glucose monitoring (rtCGM)
CRF	Case Report Form
CRO	Clinical Research Organisation
DMP	Data Management Plan
DTSQc	Diabetes Treatment Satisfaction Questionnaire – Change
DTSQs	Diabetes Treatment Satisfaction Questionnaire – Status
DVP	Data Validation Plan
eCRF	Electronic Case Report Form
eGFR	Estimated glomerular filtration rate
FAS	Full analysis set
FBG	Fasting blood glucose
FGM	Flash Glucose Monitoring or intermittend [*sic:* **i**ntermittent] **c**ontinuous **g**lucose **m**onitoring (iCGM)
GDPR	General Data Protection Regulation
GLP-1	Glucagon-like peptide-1
GLP-1 RA	GLP-1 receptor agonist
GV	Glycaemic variability
HbA_{1c}	Glycohaemoglobin A_{1c}

HDL	High-density lipoprotein
iCGM	Intermittently viewed continuous glucose monitoring
KV	Kassenärztliche Vereinigung
LDL	Low-density lipoprotein
mFAS	modified Full analysis set
MDR	Medical Device Regulation
MMRM	Mixed model for repeated measures
NIS	Non-interventional study
OAD	Oral antidiabetic drugs
PPG	Post-prandial glucose
PTC	Product technical complaints
rtCGM	real-time continuous glucose monitoring
RWE	Real-world evidence
SADR	Serious adverse drug reaction
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SAS	Safety analysis set
SGLT2i	Sodium-glucose cotransporter 2 inhibitor
SMBG	Self-measured blood glucose
SmPC	Summary of Product Characteristics
T2DM	Type 2 Diabetes mellitus
TAR	Time above range
TBR	Time below range
TIR	Time in range
VFA	Association of Research-Based Pharmaceutical Companies [*Verband forschender Arzneimittelhersteller*]

1 OVERVIEW AND STUDY PLAN

This Statistical Analysis Plan (SAP) provides a comprehensive and detailed description of strategy and statistical technique to be used to realize the analysis of data for the observational study CHANCE (OBS16751).

The document has been developed regarding to:

- the respective observation protocol version 1.0, 01-Jul-2020
- template for standardized evaluation of a non-interventional study version 3.0, Aug-2010 (7a, 7b)

1.1 STUDY DESIGN

This study is a national, multicentre, non-interventional in terms of therapeutic approach, prospective study (NIS). It aims to collect information on the effectiveness and potential side effects of treatment of type 2 diabetes mellitus (T2DM) patients with iGlarLixi who could not achieve adequate glycaemic control with a previous basal insulin supported oral therapy (BOT). The study design reflects the living situation of these patients under everyday conditions.

The decision to initiate iGlarLixi therapy has been made by the treating physician independently of participation in this observational study.

The study documents patients with T2DM who are supervised by general practitioners/internal practitioners, diabetologists or in practices with a diabetological focus. There is no obligation for the individual physician to include successive patients.

Visits will be scheduled in accordance with clinical practice. The objective is to collect the data for the study endpoints after approx. 12 and approx. 24 weeks of therapy with iGlarLixi. Data for the monthly documentation after approx. 4, approx. 8, approx. 16 and approx. 20 weeks can be documented by the patient using the patient diary or optionally requested by the treating practice via telephone. Data are to be collected in the electronic case report form (eCRF) at the next visit to the treating practice.

- Duration of observation: Approx. 24 weeks per patient.

During the observation period, care is provided, i.e. medical appointments, examinations and l bor tor tests, ccording to the h sici n s usual practice.

<u>The NIS includes patients with</u>

All of the following selection criteria must be met:

- Adult patients with type 2 diabetes mellitus
- In treatment with OADs and a basal insulin without prandial insulin and without GLP-1 RA for at least 6 months.
- HbA_{1c} 7.5% to 10.0% (findings from the last 3 months)

- Presence of prior basal insulin therapy that is stable between 30-60 units per day.
- Switching to iGlarLixi takes place between 14 days before the initial documentation and 7 days after the initial documentation.
- Decision of the treating physician to replace the previous basal insulin with iGlarLixi regardless of the enrolment in the study
- Ability and willingness to perform 7-point glucose daily profile measurements using a glucometer (self-measured blood glucose [SMBG]) OR self-management using a flash glucose monitoring (FGM) system. FGM patients should only be included if:
  - at least 70% of recorded sensor data from the FGM daily profiles of the last approx. 14 days (max. 3 weeks) are available before switching to iGlarLixi.
  - no change of the FGM system manufacturer used during the study period is planned; however, a switch to a device of the same manufacturer (e.g. the latest device generation) is possible.
  - calibration of the FGM s stem is gu r nteed ccording to the m nu cturer s specifications.
- Informed consent signed by the patient and the physician.

And none the following selection criteria have to be met:

- Type 1 diabetes mellitus
- Contraindications to treatment with iGlarLixi according to the Summary of Product Characteristics (SmPC)
- Participation in a clinical trial
- Planned or existing pregnancy, cancer, drug or alcohol abuse, dementia, or general inability to understand the content of the observational study
- Daily basal insulin dose <30 units or >60 units

The physicians are free to select patients according to the above-mentioned criteria for or against the document tion o tient tud o ul tion . n the rocess, the doctor must h e lre d made the decision for the therapy with iGlarLixi before initiation and completely independently from possible participation in this NIS.

It is planned to document and analyse about 250 patients from about 100 sites in Germany.

1.2 OBJECTIVES

The aim of the observational study is to receive new insights regarding effectiveness under daily routine conditions and possible adverse events of iGarLixi in patients with T2DM, who are switched to iGlarLixi by their doctors due to insufficient glycaemic control under basal insulin in combination with oral antidiabetic drugs (OAD).

1.2.1 Primary objectives

Descriptive analysis of the change of HbA_{1c} due to treatment with iGlarLixi in everyday clinical practice:

Absolute change in HbA_{1c} (%) under iGlarLixi from the start of observation (baseline) to the visit after approx. 12 and approx. 24 weeks, as well as between the visit after approx. 12 weeks and the end of the documentation after approx. 24 weeks

1.2.2 Secondary objectives

Documentation of changes in other glycaemic parameters, in particular glycemic variability and the safety due to treatment with iGlarLixi in everyday clinical practice:

- Relative change in HbA_{1c} (%) from baseline to approx. 12 and approx. 24 weeks, respectively, after the start of treatment
- Absolute and relative change from baseline in self-measured fasting blood glucose (FBG) (mg/dL or mmol/L)* to approximately 12 and 24 weeks, respectively, after the start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)
- Proportion of patients who achieve the individual HbA_{1c} target value within weeks 0–12, 13–24 nd 0 4, respectively (%)
- Proportion of patients achieving FBG ≤110 mg/dL or ≤6.1 mmol/L within weeks 0–12, 13–24, and 0–24, respectively (%)
- Absolute and relative change in glucose in the 7-point daily SMBG profile (mg/dL or mmol/L) from baseline to approximately 12 and 24 weeks, respectively, after start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)
- Absolute and relative change in iGlarLixi dose (dose steps/day)* from start of treatment to approximately 12 and 24 weeks, respectively, after treatment initiation
- Frequency of dose adjustments in the past 4 weeks*
- Absolute and relative change in body weight (kg) from baseline to approx. 12 and approx. 24 weeks, respectively, after start of treatment
- Absolute change in BMI (kg/m^2) from baseline to approximately 12 and 24 weeks, respectively, after start of treatment
- Absolute and relative change in median glucose level (mg/dL or mmol/L) from baseline to

approximately 12 and 24 weeks, respectively after start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)

- Incidence and rate of hypoglycaemic episodes** (documented hypoglycaemic episodes within the last approx. 12 weeks prior to study inclusion compared to the last 12 weeks prior to documentation 2 (after approx. 12 weeks) and the last 12 weeks prior to the final documentation (after approx. 24 weeks), respectively)
- Incidence of adverse events from baseline to approx. 12 and approx. 24 weeks after the start of treatment, respectively
- Absolute change in treatment satisfaction using the DTSQs at baseline and DTSQs and DTSQc approximately 24 weeks after the start of treatment ***

* These changes are documented monthly after switching to iGlarLixi in addition to documentation 1, 2 and 3.

** Definition and subdivision of hypoglycaemic events. Hypoglycaemic episodes are divided into three levels and recorded as symptomatic hypoglycaemic episodes as well as confirmed hypoglycaemic episodes

- Level 1: SMBG <70 mg/dL (<3.9 mmol/L nd ≥54 mg/dL ≥3.0 mmol/L)
- Level 2: SMBG <54 mg/dL (<3.0 mmol/L); clinically significant hypoglycaemia
- Level 3: Severe hypoglycaemic event characterised by impaired mental and/or physical condition requiring outside assistance
- octurn l h ogl c emi ogl c emi th t occurs during the tient s regul r sleeping period (approx. 10 p.m. to 6 a.m.)

*** DTSQ: Diabetes Treatment Satisfaction Questionnaire:

There are 2 different forms: the DTSQs and DTSQc questionnaire. Both contain 8 questions designed to measure diabetes treatment satisfaction on a 7- oint sc le. here is t tus version of the questionnaire (DTSQs). This is used here for the initial and final documentation. he h nge ersion (DTSQc) is used for final documentation only. The DTSQs are used as a survey instrument primarily to represent a state (not a change), and the DTSQc is suitable for the presentation of a change.

<u>Additional for FGM patients:</u>

- Median target blood glucose and limit value for low glucose (mg/dL or mmol/L; values in mmol/L are converted to mg/dL for statistical analysis)
- Absolute change in the total time in the individual target range in % from baseline to approx. 12 and approx. 24 weeks after start of treatment, respectively
- Absolute change in total time in % above the individual target range from baseline to approx. 12 and approx. 24 weeks after start of treatment, respectively

- Absolute change in total time in % below the individual target range from baseline to approx. 12 and approx. 24 weeks after start of treatment, respectively
- Absolute and relative change in the number of patients with at least one hypoglycaemic event by subdivision of complications of hypoglycaemic events ** and the number of events per patient (documented hypoglycaemic episodes within the 14-day FGM measurement before study inclusion compared to the 14-day FGM measurement before documentation 2 (after approx. 12 weeks) and the 14-day FGM evaluation before the final documentation (after approx. 24 weeks), respectively)

  All endpoints will be analysed for patients using an FGM device in addition to the total population.

  ** Definition and subdivision of hypoglycaemic events:
  Hypoglycaemic episodes are divided into three levels and recorded as symptomatic hypoglycaemic episodes as well as confirmed hypoglycaemic episodes:

  - Level 1: Self-measured blood glucose <70 mg/dL (<3.9 mmol/L nd ≥54 mg/dL ≥3.0 mmol/L)
  - Level 2: Self-measured blood glucose <54 mg/dL (<3.0 mmol/L); clinically significant hypoglycaemia
  - Level 3: Hypoglycaemia with symptoms and the glucose value is not known
  - Level 4: Severe hypoglycaemic event characterised by impaired mental and/or physical condition requiring outside assistance
  - Nocturnal h ogl c emi ogl c emi th t occurs during the tient s regul r sleeping period (approx. 10 p.m. to 6 a.m.)

Additional evaluation criteria:

- Number of patients with change in non-insulin concomitant medication
- Change of the manufacturer of the FGM system
- Additional explorative assessments - if post-hoc necessary

<u>Subgroup analyses are carried out for selected variables according to</u>

- Gender
- Age (divided in 3 groups of approximately the same size according to the data available)
- od ss nde <30 g/m nd ≥30 g/m

- en l unction e ≤60 ml/min/1.73 m , >60 ml/min/1.73 m²)
- Duration of diabetes (up to 5 years, 5 to 10 years, over 10 years)
- Baseline HbA_{1c} < .5 , ≥ .5
- Previous basal insulin therapy
- Time of iGlarLixi administration (before breakfast, before lunch, before dinner)

1.3 DETERMINATION OF SAMPLE SIZE

As this is a non-confirmatory observational study, and no previous hypotheses were specified for confirmation, no formal random sampling or power calculations are carried out, but merely an informal justification of the number of random samples is given.

Statistical power and case number justification
It is expected that approximately 60%, i.e. 150 patients, of the sample size of 250 patients will be evaluable for efficacy. This relatively high drop-out rate is a conservative estimate from previous RWE studies that have already been carried out in Germany.

Efficacy
The sample size was estimated based on the following assumptions, which were partly derived from a publication on the use of iGlarLixi in patients with T2DM (3):

An analysis of 150 patients will detect a clinically relevant difference in HbA_{1c} of 0.4% (comparing the initial documentation and the final documentation) with a power of 90%, whereby a standard deviation of the differences of 1.5% is assumed, and a paired t-test with a two-sided significance level of 0.05 is used.

Safety
All patients who received at least one dose of the study medication will be included in the safety n l sis. ith 50 tients, the rob bilit is 95.0 o obser ing t le st one r re e ent in this study, which occurs with a probability of 0.01 in this patient population.

1.4 STUDY PLAN

Data collection is at the times week 0 (baseline documentation (documentation 1)), approx. 4 and approx. 8 weeks (monthly documentation 1.1 and 1.2) approx. 12 weeks (documentation 2), approx. 16 and approx. 20 weeks (monthly documentation 2.1 and 2.2) and approx. 24 weeks (final documentation (documentation 3)), respectively, after switching to iGlarLixi. The therapeutic decision for Suliqua® must be taken in advance and with no influence by participation in the study.

1.5 MODIFICATIONS FROM THE PROTOCOL

Not applicable.

1.6 MODIFICATIONS FROM THE APPROVED STATISTICAL ANALYSIS PLAN

Not applicable.

2 COLLECTED DATA

There will be no fixed scheme for the documentation of data. The visits will be based on clinical practice with data collection at week 0, and approx. 4, approx. 8, approx. 12, approx. 16, approx. 20, and approx. 24 weeks, respectively, after switching to iGlarLixi. No deviation longer than ± 3 weeks from the specified times is recommended.

2.1 PHYSICIAN QUESTIONNAIRE

Physician questionnaires are completed by the participating physicians in German language.

In the physician questionnaire, data collected on physicians are (voluntary information):

- Physician speciality
- Size of practice (number of patients (certificates) per quarter)
- Type of facility (e.g. (joint) practice)
- Facility location
- KV area

2.2 SCREENING LOG

Not applicable.

2.3 PATIENT DATA

Case Report Forms (CRFs) are completed by the sites in German language.

(AEs and SAEs were also recorded in the eCRF (SANOFI - Individual Safety Information Documentation Form) and transmitted to Sanofi for further processing. After final data reconciliation, SANOFI provides the final and coded (MedDRA) pharmacovigilance dataset for analyses)

Initial documentation at the start of the treatment (documentation 1), week 0
(if routinely recorded or the last available value)

- Meeting of selection criteria
- Patient characteristics: Year of birth, gender, height, BMI, weight, blood pressure
- Individual HbA_{1c} target value
- History of diabetes mellitus (year or period of initial diagnosis)

- Occurrence and number of events of Previous complications from diabetes mellitus by type of complication

  a) Hypoglycaemi with glucose < 70 mg/dl nd ≥ 54 mg/dl,

  b) hypoglycaemia with glucose < 54 mg/dl,

  c) hypoglycaemia with symptomatology and the Glucose value is not known,

  d) severe hypoglycaemia, which is characterized by an impaired mental and/or physical condition that requires outside assistance) evaluated by overall occurrence and number of events,

  as well as nocturnal occurrence and number of events

- Late complications as diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, diabetic foot syndrome or lower limb amputation due to diabetic foot syndrome
- Concomitant diseases as arterial hypertension, coronary heart disease, peripheral arterial occlusive disease, renal failure, history of myocardial infarction, stroke (ischemic, hemorrhagic) in the history
- Lipid-lowering medication and antihypertensive medication
- Current basal insulin therapy (including duration and last dose before switch, time point of injection)
- Non-insulin concomitant medication (before switch)
- Current self-measured FBG (glucometer if available or from FGM)
- Recording of glycaemic variability from FGM profiles and 7-point glucose daily profile (Glucometer) - measured before switching to iGlarLixi - presenting median values
- FGM system:
  - Exact device description
- Collected main data, at least 70% of recorded sensor data from the last approx. 14 days (max. 3 weeks) prior to the switch to iGlarLixiLaboratory values HbA_{1c} (value within the last 3 months)
- if available (last available values within the last 6 months): FBG, AST and ALT values, total cholesterol, LDL, HDL, triglycerides, eGFR, creatinine
- Start of therapy with iGlarLixi (date, dosage, reason for switch, time of injection) and changeover in concomitant antidiabetic medication
- Patient questionnaire on treatment satisfaction (DTSQs)

Monthly documentation approx. 4, 8, 16 and 20 weeks after switching to iGlarLixi (e.g. in the patient diary or by telephone interview)

- Current therapy with iGlarLixi (dosage; frequency of dose changes in the previous 4 weeks, time of injection)
- Current self-measured FBG (glucometer, if available or from FGM)

Intermediate documentation (documentation 2), approx. 12 weeks after switching to iGlarLixi:

- Current therapy with iGlarLixi (dosage; frequency of dose changes in the previous 4 weeks, time of injection)
- Discontinuation of therapy with iGlarLixi (reason for discontinuation and subsequent diabetes therapy
- Non-insulin concomitant medication
- Weight
- Current self-measured FBG (glucometer if available or from FGM)
- Laboratory values (last available value within the last 3 months)
    - HbA_{1c}
    - FBG, AST and ALT, total cholesterol, LDL, HDL, triglycerides, eGFR, creatinine
- Recording of glycaemic variability from 7-point glucose daily profile or collection of glycaemic variability from FGM (glucose median, glycaemic variability, TIR, TAR, TBR)
- FGM system:
    - Collected main data, at least 70% of recorded sensor data from the last approx. 14 days (max. 3 weeks) before the interim documentation
    - Change of the FGM system
- Adverse events including hypoglycaemic events (hypoglycaemia within the last 12 weeks) and other events such as gastrointestinal side effects (vomiting, nausea, diarrhoea) and other side effects

Final documentation (documentation 3), approx. 24 weeks after switching to iGlarLixi:

- Current therapy with iGlarLixi (dosage; frequency of dose changes in the previous 4 weeks, time of injection)
- Discontinuation of therapy with iGlarLixi (reason for discontinuation and subsequent diabetes therapy
- Non-insulin concomitant medication
- Weight
- Current self-measured FBG (glucometer if available or from FGM)
- Laboratory values:
    - HbA_{1c}
    - FBG, AST and ALT, total cholesterol, LDL, HDL, triglycerides, eGFR, creatinine
- Recording of glycaemic variability from 7-point glucose daily profile or collection of glycaemic variability from FGM (glucose median, glycaemic variability, TIR, TAR, TBR)
- FGM system:
    - Collected main data, at least 70% of recorded sensor data from the last approx. 14 days (max. 3 weeks) before the final documentation
    - Change of the the FGM system
- Adverse events including hypoglycaemic events (hypoglycaemia within the last 12 weeks) and other events such as gastrointestinal side effects (vomiting, nausea, diarrhoea) and other side effects
- Patient questionnaires on treatment satisfaction (DTSQs and DTSQc)

3 GENERAL STATISTICAL APPROACH

The statistical analysis of all data collected is descriptive.

Continuous (quantitative) variables will be summarized by descriptive statistics:

- Number of patients (n),
- Mean and standard deviation (SD),
- 1% percentile,
- 99% percentile,
- Median,
- 1st and 3rd quartile (Q1 and Q3)
- Minimum
- Maximum

Categorical variables

- Frequencies (n), where n is the actual number of patients with data within a category for the particular summary statistic which should always be less than or equal to the total number N of patients
- Percent frequencies (%= n/N*100)
- If necessary, adjusted frequency distributions will also be provided considering only patients with non-missing data (% = n/Nnonmiss*100).

Appropriate 95% confidence intervals (CIs) will be calculated for estimated parameters.

Analyses will also be performed for predefined subgroups.

All statistical analyses are exploratory in nature.

Number of decimal places (DP):

- for minimum, maximum the same number of DPs as for raw data
- for mean, median, SD, 95%-CIs, 1% and 99% percentiles, Q1 and Q3 one more DP as for raw data
- percentages: 1 DP
  - In case of need, if small incidences or particularly large numbers of cases are of particular importance, more DPs are used.

4 ANALYSIS OF PHYSICIAN QUESTIONNAIRE

4.1 ANALYSIS VARIABLES

All variables listed in Section 2.1 will be considered.

4.2 ANALYSIS POPULATION

The physician questionnaire will be evaluated once per participating physician, irrespective of how many physicians from a site participated in the study.

4.3 STATISTICAL METHODS

All analysis variables will be described by frequency tables:

Description of the participating physicians by frequency tables:

- Number of participating physicians (n)
- Number of physicians who answered the questionnaire (n, % of all physicians)
- Specialization of the physician (n, % answered)
- Size of the practice (number of patients (certificates) per quarter) (n, % answered)
- Type of institution (e.g. individual practice, group practice, practice community) (n, % answered)
- Location of the institution (n, % answered)
- KV area of the institution (n, % answered)

Frequencies (n), *where n is the actual number of physicians with data within a category for the particular summary statistic*

Percent based on the number of participating physicians. ***(% all physicians**= n/N total number of participating physicians * 100)*

Percent based on the number of physicians who answered the questionnaire. ***(%answered**= n/N physicians who answered the questionnaire * 100)*

- Number and percent of patients per specialty (%= n/N total number patients * 100)

5 ANALYSIS OF PATIENT DATA

5.1 ANALYSIS VARIABLES

5.1.1 Baseline variables

The following demographics, anamnestic and baseline characteristics will be analysed:

- Patient characteristics: age (year of informed consent – year of birth), gender, height, BMI, weight, blood pressure
- Individual HbA_{1c} target value
- History of diabetes mellitus (year or period of initial diagnosis)
- Occurrence and number of events of previous complications from diabetes mellitus by type of complication

  a) Hypoglycaemi with glucose < 70 mg/dl nd ≥ 54 mg/dl,

  b) Hypoglycaemia with glucose < 54 mg/dl,

  c) Hypoglycaemia with symptomatology and the Glucose value is not known,

  d) severe hypoglycaemia, which is characterized by an impaired mental and/or physical condition that requires outside assistance) evaluated by overall occurrence and number of events,

  as well as nocturnal occurrence and number of events
- Late complications as diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, diabetic foot syndrome or lower limb amputation due to diabetic foot syndrome
- Concomitant diseases as arterial hypertension, coronary heart disease, peripheral arterial occlusive disease, renal failure, history of myocardial infarction, stroke (ischemic, hemorrhagic) in the history
- Lipid-lowering medication and antihypertensive medication
- Non-insulin concomitant medication (prior to switch)
- Current self-measured FBG (glucometer if available or from FGM)
- Recording of glycaemic variability from FGM profiles and 7-point glucose daily profile (Glucometer) - measured before switching to iGlarLixi - presenting median values
- FGM system:
  - Exact device description

  - Collected main data, at least 70% of recorded sensor data from the last approx. 14 days (max. 3 weeks) prior to the switch to iGlarLixi

- Adverse events including hypoglycaemic events (hypoglycaemia within the last 12 weeks)
- Laboratory values:
  - HbA_{1c} (value within the last 3 months)
  - if available (last available values within the last 6 months): FBG, AST and ALT values, total cholesterol, LDL, HDL, triglycerides, eGFR, creatinine
- Start of therapy with iGlarLixi (date, dosage, reason for switch, time of injection) and changeover in concomitant antidiabetic medication
- Patient questionnaire on treatment satisfaction (DTSQs)

The analysis will be according to the general approach and 95%-CI according to Wald will be calculated (procedure freq).

5.1.2 Main evaluation variable(s)

Primary analysis includes:

- Absolute change in HbA_{1c} (%) under iGlarLixi from the start of treatment to the visit after approx. 12 weeks
- Absolute change in HbA_{1c} (%) under iGlarLixi from the start of treatment to the visit after approx. 24 weeks
- Absolute change in HbA_{1c} (%) under iGlarLixi between the visit after approx. 12 weeks and the end of the documentation after approx. 24 weeks

5.1.3 Secondary evaluation variable(s)

Secondary efficacy parameters include:

- Relative change in HbA_{1c} (%) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment
- Absolute and relative change in fasting blood glucose (mg/dl or mmol/l) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)
- Proportion of patients who achieve the individual HbA_{1c} target value within week 0-12, 13-24 and 0-24 (%)

- Proportion of patients who achieve a fasting blood glucose ≤110 mg/dl or 6.1 mmol/l within week 0-12, 13-24 and 0-24 (%)

- Absolute and relative change in glucose in the 7-point daily glucose profile (mg/dl or mmol/l) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)

- Absolute and relative change in iGlarLixi dose (dose steps/day)* up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment

- Frequency of dose changes in the last 4 weeks *

- Absolute and relative change in body weight (kg) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment

- Absolute change in body mass index (kg/m²) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment

- Absolute and relative change in the median value of glucose (mg/dl or mmol/l) up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment (values in mmol/L are converted to mg/dL for statistical analysis)

- Incidence and rate of hypoglycaemia ** (documented hypoglycaemia within the last approx. 12 weeks before study inclusion compared to the last 12 weeks before documentation 2 (after approx. 12 weeks) and the last 12 weeks before the final documentation (after approx. 24 weeks))

- Incidence of adverse events up to approx. 12 and approx. 24 weeks, respectively, after the start of treatment

- Status of treatment satisfaction (DTSQs) at baseline and after approx. 24 weeks and change of treatment satisfaction (DTSQc) after approx. 24 weeks of treatment ***

* These changes are documented monthly in addition to documentation 1, 2 and 3 after the switch to iGlarLixi.

** Definition and subdivision of hypoglycaemic events. Hypoglycaemia is classified as symptomatic hypoglycaemia and confirmed hypoglycaemia in three levels and recorded (Observational plan - Bibliography: 21):

o Level 1: Self-measured blood glucose lue <70 mg/dl <3.9 mmol/l nd ≥54 mg/dl ≥3.0 mmol/l)

o Level 2: Self-measured blood glucose value <54 mg/dl (<3.0 mmol/l); clinically significant hypoglycaemia

o Level 3: Severe hypoglycaemic event, characterized by an impaired mental and/or physical condition that requires outside help

o Nocturnal hypoglycaemia: Hypoglycaemia that occurs during the patient's regular bedtime (approx. 10 p.m. to 6 a.m.)

*** DTSQ: Questionnaire on satisfaction with diabetes treatment:

There are 2 different forms of this questionnaire DTSQs and DTSQc. Both contain 8 questions that are intended to measure diabetes therapy satisfaction on a 7-point scale. On the one hand, there is the st tus ersion o the uestionn ire s . his is used here or the initi l nd final documentation. The "Change" version (DTSQc) is only used for final documentation. As a survey instrument, the DTSQs is primarily suitable for the representation of a condition (not a change), the DTSQc for the representation of a change.

Additional for FGM patients:

- Median target blood glucose and limit value for low glucose (mg/dl or mmol/l). Values in mmol/L are converted to mg/dL for statistical analysis.
- Absolute change in the total time in the individual target area in % approx. 12 and approx. 24 weeks, respectively, after the start of treatment
- Absolute change in the total time in % over the individual target range approx. 12 and approx. 24 weeks, respectively, after the start of treatment
- Absolute change in the total time in% below the individual target range approx. 12 and approx. 24 weeks, respectively, after the start of treatment
- Absolute and relative change in the number of patients with hypoglycaemic events and the number of events per patient (documented hypoglycaemia during the 14-day FGM measurement before inclusion in the study compared to the 14-day FGM measurement before documentation 2 (after approx. 12 weeks) and for the 14-day FGM measurement before the final documentation (Documentation 3; after approx. 24 weeks)).

All endpoints are analysed for patients using an FGM device in addition to the total population.

** Definition and subdivision of hypoglycaemic events. Hypoglycaemia is classified as symptomatic hypoglycaemia and confirmed hypoglycaemia in three levels and recorded:

o Level 1: Self-measured blood glucose lue <70 mg/dl <3.9 mmol/l nd ≥54 mg/dl ≥3.0 mmol/l)

o Level 2: Self-measured blood glucose value <54 mg/dl (<3.0 mmol/l); clinically significant hypoglycaemia

o Level 3: Severe hypoglycaemic event, characterized by an impaired mental and / or physical condition that requires outside help

o Nocturnal hypoglycaemia: Hypoglycaemia that occurs during the patient's regular bedtime (approx. 10 p.m. to 6 a.m.)

Additional assessment parameters include:

- Number of patients with change in non-insulin concomitant medication

- Measurement of glycemic variability on base of the FGM system or the 7-point daily glucose profile (glucometer)

5.1.4 Safety variable(s)

Safety parameters are:

- Incidence of AEs
- Incidence of SAEs
- Incidence of ADRs
- Incidence of SADRs
- Incidence of AESI

5.2 ANALYSIS POPULATION(S)

5.2.1 All patients enrolled (ALL)

Patients that meet all selection criteria for the documentation, but no selection criterion against the documentation. Evaluation of disposition of patients will be done on base of all patients enrolled.

5.2.2 Safety Analysis Set (SAS)

The safety analysis set (SAS) includes all patients who received at least one dose of iGlarLixi (Suliqua® 30-60) during the non-interventional study.

5.2.3 Full Analysis Set (FAS)

The Full Analysis Set (FAS) will be used to analyse the main evaluation variable. The FAS is defined as a subset of the Safety Analysis Set (SAS) and includes all patients for whom all the following criteria are fulfilled:

- Written informed consent (date of consent reported)
- All inclusion criteria fulfilled and not any exclusion criterion met
- At least one dose of iGlarLixi (Suliqua® 30-60) during the non-interventional study
- Sufficient data exist for the assessment of the main criterion (primary endpoint): HBA_{1c} documented at baseline and at least once after baseline.

This is compliant with the mFAS population defined in the observation plan.

5.2.4 Patients using an FGM device (FGM)

All endpoints will be analysed for patients using an FGM device in addition to the FAS.

5.3 STATISTICAL METHODS

All analysis variables will be described according to the methods defined in Section 3 for the description of continuous and categorical variables.

5.3.1 Disposition of patients

An overview will be provided for duration of the study presenting the dates of first patient, which was included in and of last patient ended the study.

5.3.2 Analyses of baseline characteristics

Demographics and baseline characteristics will be analysed for the FAS and, in addition, for the SAS, if the difference between FAS and the respective set is 5% or more.

5.3.3 Analyses of evaluation variables

5.3.3.1 Analysis of main evaluation variable(s)

Main evaluation parameters will be analysed for the FAS. Based on the assumed normal distribution, the 95% confidence interval for the estimated parameter, the absolute change in HbA_{1c} (%) with iGlarLixi from the start of the treatment up to the visit after approx. 12 or approx. 24 weeks, respectively, is calculated as well as between the visit after approx. 12 weeks and the end of the documentation after approx. 24 weeks.

The t-test for connected samples will also be used to check if the true difference is different from zero.

Subgroup analyses: see section 5.3.66.

5.3.3.2 Analyses of secondary evaluation variables

The secondary parameters will be analysed for the FAS and FGM. Frequency distributions (n, %) will be provided (see 5.1.3). Exact (Clopper-Pearson) 95% CI will be provided for this response rates.

For continuous variables the 95% confidence interval for the mean is calculated on base of an assumed normal distribution.

Subgroup analyses: see section 5.3.66.

5.3.4 Analysis of Safety

Safety parameters will be analysed for the SAS. Data from the pharmacovigilance database will be used for analyses of AEs, SAEs, ADRs, SADRs and AESI.

Adverse Events

An **adverse event** (AE) is any untoward medical occurrence in a patient which does not necessarily have to have a causal relationship with the medical product.

Frequency distributions (absolute and relative) for patients with AEs by MedDRA preferred term and system organ class will be provided.

Serious Adverse Events

A serious adverse event is any untoward medical occurrence that at any dose:

- Results in death or;
- Is life-threatening; or
  ote he term li e-thre tening in the de inition o serious re ers to n e ent, in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
- Requires inpatient hospitalization or prolongation of existing hospitalization or;
- Results in persistent or significant disability/incapacity to work or;
- Is a congenital anomaly/birth defect
- In case of clinically relevant events associated with a medical product, also the following
- must be seen as severe:
  o Suspected transmission of pathogens; any suspected transmission of pathogens via a medical device (e.g., product contamination);
  o Necessity of an intervention to prevent permanent impairment or damage (through devices)

Frequency distributions (absolute and relative) for patients with SAEs by MedDRA preferred term and system organ class will be provided.

In addition, frequency distributions (absolute and relative) for patients with fatal AEs by MedDRA preferred term and system organ class will be provided as well as a data listing of all fatal AEs.

Adverse Drug Reactions

An **adverse drug reaction** (ADR) is a harmful and unintended reaction to a product. Reaction to a product means that a causal relationship between a product and an adverse event is at least a plausible possibility, e.g., the relationship cannot be excluded.

Frequency distributions (absolute and relative) for patients with ADRs by MedDRA preferred term and system organ class will be provided.

Serious Adverse Drug Reactions

A **severe adverse drug reaction** (SADR) is an ADR of an aforementioned severity grade (see definition under severe adverse event).

Frequency distributions (absolute and relative) for patients with SADRs by MedDRA preferred term and system organ class will be provided.

Adverse Events of Special Interest

An **adverse event of special interest** (AESI) is a subset of special AEs, i.e.:

Overdose:

All cases of accidental or deliberate overdose, even if there is no adverse event (asymptomatic), must be documented as an adverse event and noted in the appropriate places in the electronic case report form (eCRF). The reporting rules described in Chapter 13.1.3 in the observation plan apply. In the event of an overdose, the patient must be monitored as long as the participating physician considers this necessary. Suitable, symptom-related measures must be taken.

Misuse:

Situations in which the medicinal product is used intentionally and improperly must be documented.

Abuse:

Persistent or sporadic, intentional excessive use of a drug that is associated with harmful physical or psychological effects must be documented.

Occupational exposure:

Exposure to a medicinal product resulting from the professional activity must be documented.

Pregnancy:

iGlarLixi may not be used during pregnancy. Animal studies with lixisenatide have demonstrated reproductive toxicity. Please refer to the Summary of Product Characteristics of iGlarLixi for further details.

If a female patient or female partner of a male patient who was exposed to a medical product from Sanofi becomes pregnant, this must then be documented immediately as an adverse event and noted in the appropriate places in the eCRF. The reporting rules described in Chapter 13.1.3 in the observation plan apply.

Medication errors:

A medication error is an unintended mistake that can happen with the prescription, delivery, storage, preparation or administration of a treatment and which can lead to harm to the patient or has the potential for this. Medication errors must be documented with and without occurrence of an adverse event.

Applications outside of the licensed approval (off-label use):

Applications that are not covered by approval are to be documented even with or without an adverse event.

Hypersensitivity reactions:

All hypersensitivity reactions (e.g. rash, reactions at the injection site, etc.) that occurred in connection with treatment with iGlarLixi are to be documented on the form provided for this.

Incidents *in* conjunction with a Medical Device (according to EU MDR)

ent denotes m l unction or deterior tion o the ro erties or er orm nce o roduct already provided on the market, including application errors due to ergonomic features, as well as an inadequacy of the information provided by the manufacturer or an adverse side effect.

erious e ent me ns n e ent th t h d, or could h e h d, directl or indirectl , one of the following consequences: a) the death of a patient, user, or another person, b) the temporary or permanent worsening of the health status of a patient, user, or another person, c) a serious danger to public health.

Frequency distributions (absolute and relative) for patients with SADRs by MedDRA preferred term and system organ class will be provided.

5.3.5 Analysis of other parameters

n.a.

5.3.6 Subgroup analyses

Analyses will be performed for the following subgroups by:

- Gender
- Age (divided in 3 groups of approximately the same size according to the data available)
- od ss nde <30 g/m nd ≥30 g/m
- en l unction e ≤60 ml/min/1.73 m , >60 ml/min/1.73 m²)

- Duration of diabetes (up to 5 years, 5 to 10 years, over 10 years)
- Baseline HbA_{1c} < .5 , ≥ .5
- Previous basal insulin therapy (Insulin detemir, Insulin glargin 100 E/ml, Insulin glargin 300 E/ml, Insulin degludec 100/200 E/ml, NPH Insulin, other)
- Time of iGlarLixi administration (before breakfast, before lunch, before dinner)

6 ANALYSIS OF BASELINE PATIENT DATA

Not applicable.

7 ANALYSIS OF PATIENT DATA AT FOLLOW-UP

Not applicable.

8 FINAL ANALYSIS OF PATIENT DATA

Not applicable.

9 DATA HANDLING CONVENTIONS

There will be no fixed scheme for the documentation of data. The dates depend on the clinical practice. In any case, a comprehensive data collection should occur after approximately 0, 4, 8, 12 and 24 weeks. The data is collected by means of patient documentation sheets and a physician sheet.

9.1 DATA HANDLING CONVENTIONS FOR PHYSICIAN QUESTIONNAIRE

To be completed by the physician (voluntary information).

9.2 DATA HANDLING CONVENTIONS FOR PATIENT DATA

The data collected constitutes exclusively of data collected within the practical routine care of the patients.

The data documented by the patient on the patient questionnaire is evaluated and documented separately in the study report. If there is a handwritten additional comment by the patient on a patient questionnaire describing an AE or undesirable medical device effect, this is recorded and evaluated accordingly. If during the doctor-patient conversation and / or the review of the patient questionnaire completed by the patient, the doctor reveals indications of an AE / ADR / AESI / undesirable medical device effect, the doctor must document this in the relevant mask of the eCRF. The rules for forwarding are described in Chap. 13.1.3 of the observational plan.

Obviously wrong data

Values out of plausibility ranges will be excluded from analyses. The following plausibility ranges are defined:

- HbA_{1c}: 3-20%
- Blood glucose values (7-point profile): 30-600 mg/dL, 1.6-33.3 mmol/L
- Triglycerides: 50-600 mg/dL, 0.5-6.9 mmol/L
- HDL-Cholesterol: 10-400 mg/dL, 0.2-10.4 mmol/L
- LDL-Cholesterol: 10-400 mg/dL, 0.2-10.4 mmol/L
- Total cholesterol: 20-500 mg/dL, 0.5-13.0 mmol/L
- Height (cm): 100-220
- Weight (kg): 35-300
- Systolic blood pressure (mmHg): 50 - 290
- Diastolic blood pressure (mmHg): 30 - 140

9.3 DATA HANDLING CONVENTIONS FOR PATIENT REPORTED OUTCOMES

Completed PROs (DTSQs and DTSQc) could be uploaded to the eCRF by study personnel at the study site or faxed to the CRO AKP.

Submitted PROs were double-entered by AKP into the designated forms in the eCRF (these forms were locked to study personnel at the center).

Following the double data entry, data reconciliation between first and second entry was performed.

9.4 MISSING DATA

Unless described explicitly in the text above, missing values will be treated as such and will not be imputed in any way.

9.5 DEFINITION OF REGIONS

Not applicable.

9.6 WINDOWS FOR TIME POINTS

Not applicable.

9.7 STATISTICAL TECHNICAL ISSUES

Not applicable.

10 INTERIM ANALYSIS

For this observational study, an interim analysis was planned after approx. 12 weeks or 50 patients. No interim analysis was performed.

11 SOFTWARE DOCUMENTATION

All statistical analyses will be generated using SAS version 9.4 or higher.

12 LIST OF APPENDICES

Appendix name	Title
Appendix A:	List of Planned Outputs

13 REFERENCES

APPENDIX A: LIST OF PLANNED OUTPUTS

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
1	**Physician Questionnaire**		
1.1	Speciality of the physician – categorical n (xxx.x%)	ALL	no
1.2	Size of the practice (number of patients (certificates) per quarter	ALL	no
1.3	Type of institution (e.g. community, practice)	ALL	no
1.4	Location of the institution	ALL	no
1.5	KV area of the institution	ALL	no
1.6	Number of patients per speciality	ALL	no
2	**Disposition and Baseline characteristics**		
2.1	Analysis populations and patient disposition	ALL, FAS, SAS	no
2.1.1	Patients excluded from analysis - Violation of at least one inclusion criterion - Violation of at least one exclusion criterion - Other reason for exclusion from analysis population – categorical n (xxx.x%)	ALL	no
2.1.2	Individual listing of patients excluded - details	ALL	no
2.1.3	Number of patients available at each visit	ALL	no
2.2	Demographic data and baseline characteristics - age - continuous and categorical - gender - categorical - height - continuous - weight - continuous - BMI - continuous - blood pressure - continuous	FAS, SAS*	yes (FAS)
2.3	Medical history	FAS	yes (FAS)
2.3.1	History of diabetes mellitus	FAS	yes (FAS)
2.3.1.1	Period of initial diagnosis – categorical	FAS	yes (FAS)
2.3.1.2	Hypoglycaemi with glucose < 70 mg/dl nd ≥ 54 mg/dl Events total/nocturnal - categorical number of events - continuous	FAS	yes (FAS)
2.3.1.3	Hypoglycaemia with glucose < 54 mg/dl Events total/nocturnal - categorical number of events - continuous	FAS	yes (FAS)

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
2.3.1.4	Hypoglycaemia with symptomatology and the Glucose value is not known Events total/nocturnal - categorical number of events – continuous	FAS	yes (FAS)
2.3.1.5	Severe hypoglycaemia, which is characterized by an impaired mental and/or physical condition that requires outside assistance Events total/nocturnal - categorical number of events – continuous	FAS	yes (FAS)
2.3.2	Current basal insulin therapy (including duration and last dose before switch) - medication - categorical - number of insulin injections – continuous - duration of medication - continous - time of injection – categorical - last dose [units/day] - continous	FAS	yes (FAS)
2.3.3	Current anti-diabetic oral therapy Type of medication - categorical	FAS	yes (FAS)
2.3.4	Late complications - diabetic retinopathy - diabetic neuropathy - diabetic nephropathy - diabetic foot syndrome or lower - limb amputation due to diabetic foot syndrome event (categorical) and since years (continuous)	FAS	yes (FAS)
2.3.5	Concomitant diseases as - arterial hypertension - coronary heart disease - peripheral arterial occlusive disease - renal failure - history of myocardial infarction - stroke (ischemic, hemorrhagic) in the history	FAS	yes (FAS)
2.3.6	Lipid lowering medication and antihypertensive medication - medication - categorical - start of treatment – categorical	FAS	yes (FAS)
2.4	Individual HbA_{1c} target value - continuous	FAS	yes (FAS)
2.5	Current self-measured FBG (glucometer, if available, or from FGM) - Median target area - continuous - Median blood sugar – continuous	FAS	yes (FAS)

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
2.6.1	HbA_{1c} (value within the last 3 months) - continuous	FAS	yes (FAS)
2.6.2	Last available values within the last 6 months of eGFR, Creatinine, AST, ALT, Fasting plasmaglucose, Total cholesterol, LDL cholesterol, HDL cholesterol, Triglycerides - continuous	FAS	yes (FAS)
2.6.3	Acquisition of the glycemic variability from the 7-point glucose daily profile or survey of the glycemic variability from FGM (glucose median, variability measured as standard deviation, time in range (TIR), time above range (TAR), time below range (TBR)) - summary statistics evaluated separately for FGM, Glucometer and overall	FAS	yes (FAS)
2.7	Start therapy with iGlarLixi - reason for switch - categorical n (xxx.x%) - Number of iGlarLixi dose steps - categorical - Time of injection - categorical - change of the concomitant antidiabetic medication - categorical	FAS	yes (FAS)
2.8	Patient questionnaires on therapy satisfaction (DTSQs) – continuous	FAS	yes (FAS)
3	**Effectiveness (primary)**		
3.1	Absolute change in HbA_{1c} (%) under iGlarLixi from the start of treatment to the visit after approx. 12 weeks - continuous Summary statistics and test according to MT1	FAS, FGM	yes (FAS)
3.2	Absolute change in HbA_{1c} (%) under iGlarLixi from the start of treatment to the visit after approx. 24 weeks - continuous Summary statistics and test according to MT1	FAS, FGM	yes (FAS)
3.3	Absolute change in HbA_{1c} (%) under iGlarLixi between the visit after approx. 12 weeks and the end of the documentation after approx. 24 weeks - continuous Summary statistics and test according to MT1	FAS, FGM	yes (FAS)

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
4	**Effectiveness (secondary)**		
4.1.1	Relative change in HbA_{1c} (%) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.1.2	Relative change in HbA_{1c} (%) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.2.1	Absolute and relative change in fasting blood glucose (mg/dl) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.2.2	Absolute and relative change in fasting blood glucose (mg/dl) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.3.1	Proportion of patients who achieve the individual HbA_{1c} target value within week 0-12, 13-24 and 0-24 (%) - categorial	FAS, FGM	yes (FAS)
4.3.2	Time until achievement of the individual HbA1c target value was documented first time - time course graphics according to Kaplan-Meier	FAS, FGM	yes (FAS)
4.3.3	Minimal time staying below the individual HbA1c target value - continuous	FAS, FGM	yes (FAS)
4.4	Proportion of patients who achieve a fasting blood glucose ≤110 mg/dl or 6.1 mmol/l within week 0-12, 13-24 and 0-24 (%) - categorial	FAS, FGM	yes (FAS)
4.5.1	Absolute and relative change in glucose in the 7-point glucose daily profile (mg/dl) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.5.2	Absolute and relative change in glucose in the 7-point glucose daily profile (mg/dl) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.6.1	Absolute and relative change in iGlarLixi dose (dose steps/day) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
4.6.2	Absolute and relative change in iGlarLixi dose (dose steps/day) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.6.3	Frequency of dose changes in the last 4 weeks (monthly) - categorial	FAS, FGM	yes (FAS)
4.7.1	Absolute values of fasting glucose level measured by patient every 4 weeks up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.7.2	Absolute and relative change of fasting glucose level measured by patient every 4 weeks up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.8.1	Absolute and relative change in body weight (kg) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.8.2	Absolute and relative change in body weight (kg) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.9.1	Absolute change in body mass index (kg/m²) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.9.2	Absolute change in body mass index (kg/m²) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.10.1	Absolute and relative change in the median value of glucose (mg/dl) up to approx. 12 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.10.2	Absolute and relative change in the median value of glucose (mg/dl) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
4.11	Incidence and rate of hypoglycaemia (documented hypoglycaemia within the last approx. 12 weeks before study inclusion	FAS, FGM	yes (FAS)

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
	compared to the last 12 weeks before documentation 2 (after approx. 12 weeks) and the last 12 weeks before the final documentation (after approx. 24 weeks)) - categorial		
4.12	Absolute values in therapy satisfaction (DTSQs and DTSQc) up to approx. 24 weeks after the start of treatment - continuous	FAS, FGM	yes (FAS)
5	**Effectiveness (Additional for FGM patients)**		
5.1	Median target blood glucose and limit value for low glucose (mg/dl) - continuous	FAS = FGM	yes (FAS)
5.2.1	Absolute change in the total time in the individual target area in% approx. 12 and approx. 24 weeks after the start of treatment - continuous	FAS = FGM	yes (FAS)
5.2.2	Absolute change in the total time in % over the individual target range approx. 12 and approx. 24 weeks after the start of treatment - continuous	FAS = FGM	yes (FAS)
5.2.3	Absolute change in the total time in% below the individual target range approx. 12 and approx. 24 weeks after the start of treatment - continuous	FAS = FGM	yes (FAS)
5.4	Absolute and relative change in the number of patients with hypoglycaemic events according to level 1** and the number of events per patient (documented hypoglycaemia during the 14-day FGM measurement before inclusion in the study compared to the 14-day FGM measurement before documentation 2 (after approx. 12 weeks) and for the 14-day FGM measurement before the final documentation (Documentation 3; after approx. 24 weeks)) - continuous - categorial	FAS = FGM	yes (FAS)
6	**Additional assessment parameters**		

Output No	Output Title	Analysis Population * output created if difference in number of patients compared to FAS >=5%	Presented for Subgroups
6.1	Changes in other diabetes therapy - categorial	FAS, FGM	yes (FAS)
6.2	Change of the FGM system or device for determining the 7-point daily glucose profile (glucometer) - categorial	FAS, FGM	yes (FAS)
7	**Safety**		
7.1	AE by MedDRA system organ class and preferred term	SAS	no
7.2	Incidence of AE - categorial	SAS	no
7.3	SAE by MedDRA system organ class and preferred term	SAS	no
7.4	ADRs by MedDRA system organ class and preferred term	SAS	no
7.5	SADRs by MedDRA system organ class and preferred term	SAS	no
7.6	AESIs by MedDRA system organ class and preferred term	SAS	no

eCRF Layout

Version 1.0

01.07.2020

NIS CHANCE (OBS16751)

Inhaltsverzeichnis

1 Arztfragebogen

Frage	Antwortmöglichkeit
Fachrichtung des/r Arztes/Ärztin	❍ Praktische/r Ärztin/Arzt ❍ AllgemeinmedizinerIn ❍ InternistIn ❍ DiabetologIn ❍ Andere
Art der Einrichtung	❍ Niedergelassen ❍ Medizinisches Versorgungszentrum ❍ Andere
Anzahl der PatientInnen (Scheine) pro Quartal angeben	_____ (4-stellig)
Lage der Einrichtung	❍ Großstadt (> 100.000 Einwohner) ❍ Mittelstadt (20.001-100.000 Einwohner) ❍ Kleinstadt (5.001-20.000 Einwohner) ❍ Ländlich (< 5.000 Einwohner)
KV-Gebiet	❍ Baden Württemberg ❍ Bayern ❍ Berlin ❍ Brandenburg ❍ Bremen ❍ Hamburg ❍ Hessen ❍ Meckl.-Vorpommern ❍ Niedersachsen ❍ Nordrhein ❍ Rheinland-Pfalz ❍ Saarland ❍ Sachsen ❍ Sachsen-Anhalt ❍ Schleswig-Holstein ❍ Thüringen ❍ Westfalen-Lippe

2 PatientInnenselektion

2.1 Selektionskriterien für die Dokumentation eines/r PatientIn

#	Kriterien	Antwort	
1	Diabetes mellitus Typ 2	❍ Ja	❍ Nein
2	Seit mind. 6 Monaten in Behandlung mit OAD und einem Basalinsulin ohne prandiales Insulin und ohne GLP-1-Rezeptoragonisten	❍ Ja	❍ Nein
3	HbA_{1c} 7,5 % bis 10,0 % (58 bis 86 mmol/mol) (Befund innerhalb der letzten 3 Monate)	❍ Ja	❍ Nein
4	lter ≥ 1 hre (zum Zeitpunkt der Signatur der Einwilligungserklärung)	❍ Ja	❍ Nein
5	Vorliegen einer Basalinsulin-Vortherapie, die stabil zwischen 30-60 Einheiten/Tag liegt	❍ Ja	❍ Nein
6	Umstellung auf iGlarLixi erfolgt im Zeitraum zwischen 14 Tage vor der Eingangsdokumentation bis 7 Tage nach der Eingangsdokumentation	❍ Ja	❍ Nein
7	Entscheidung des/der behandelnden Arztes/Ärztin, unabhängig von der Aufnahme in die Studie das bisherige Basalinsulin durch iGlarLixi zu ersetzen	❍ Ja	❍ Nein
8	Fähigkeit und Bereitschaft des/der PatientIn 7-Punkte-Glukose-Tagesprofil-Messungen mit einem Glukometer durchzuführen ODER Selbstmanagement anhand eines FGM-Systems seit mindestens 3 Monaten	❍ Ja	❍ Nein
8.1	**Nur auszufüllen, falls ein FGM verwendet wird.** FGM-PatientInnen sollten nur eingeschlossen werden, wenn: o mind. 70 % auswertbare Daten aus den FGM-Tagesprofilen der letzten ca. 14 Tage (max. 3 Wochen) vor Umstellung auf iGlarLixi vorhanden sind. o Keine Änderung des verwendeten FGM-Herstellers während der Studiendauer geplant ist. Ein Wechsel zu einem Gerät des gleichen Herstellers (z.B. zur neuesten Gerätegeneration) ist möglich.	❍ Ja	❍ Nein

	o Kalibrierung des FGM-Systems gewährleistet ist gemäß den Herstellerangaben.	
9	Unterschriebene Einverständniserklärung liegt **vor** Studienbeginn vor	❍ Ja ❍ Nein

Der Patient/die Patientin **MUSS ALLE** der folgenden Kriterien **erfüllen**:

2.2 Selektionskriterien gegen die Dokumentation eines/r PatientIn

Der/Die PatientIn **DARF KEINES** der folgenden Kriterien **erfüllen**:

#	Kriterien	Antwort
1	Teilnahme an einer klinischen Prüfung	❍ Ja ❍ Nein
2	Diabetes mellitus Typ 1	❍ Ja ❍ Nein
3	Gegenanzeigen zur Behandlung mit iGlarLixi laut Fachinformation	❍ Ja ❍ Nein
4	Basalinsulin < 30 oder > 60 Einheiten pro Tag	❍ Ja ❍ Nein
5	Geplante Schwangerschaft oder bestehende Schwangerschaft, Krebserkrankung, Drogen- oder Alkoholmissbrauch, Demenz bzw. allgemeines Unvermögen, den Inhalt der Beobachtungsstudie zu verstehen	❍ Ja ❍ Nein

3 Eingangsdokumentation (Dokumentation 1)

Frage	Antwort
Datum, an dem die **Untersuchung des/r PatientIn** stattgefunden hat	____ / ____ / _____ (TT / MM / JJJJ)

3.1 Einverständniserklärung

Frage	Antwort
Datum, an dem die **Einverständniserklärung vom/von der PatientIn unterschrieben wurde**	____ / ____ / _____ (TT / MM / JJJJ)

3.2 Umstellung auf iGlarLixi

Frage	Antwort
Datum der **Umstellung auf iGlarLixi**	____ / ____ / _____ (TT / MM / JJJJ)

3.3 Individueller HbA_{1c}-Zielwert

Frage	Antwort
Individueller HbA_{1c}-Zielwert ≤	_____ ❍ % / ❍ mmol/mol

3.4 Demographie und Körpermaße

Frage	Antwort
Geburtsjahr	_____ (JJJJ)
Alter	_____ (JJ) [bitte automatisch berechnen]
Geschlecht	❍ Männlich ❍ Weiblich ❍ Divers
Größe	_____ cm
Gewicht	_____ kg
BMI	_____ (kg/m²) [bitte automatisch berechnen]
Blutdruck	_____ / _____ mmHg (systolisch / diastolisch)

3.5 Krankengeschichte

3.5.1 Diagnose Diabetes mellitus Typ 2

Frage	Antwort
Jahr der Erstdiagnose	_____ (JJJJ) ❍ unbekannt [falls dieses gekreuzt wird bitte folgendes dem Arzt anzeigen]: ❍ bis 5 Jahre ❍ 5 bis 10 Jahre ❍ über 10 Jahre ❍ weiß ich nicht

3.5.2 Bisherige Komplikationen durch Diabetes mellitus

Akutkomplikationen der letzten 12 Wochen vor Studieneinschluss

#	Komplikation	Auftreten	Anzahl der Ereignisse in den letzten 3 Monaten
1	Hypoglykämie mit Glukosewert < 70 mg/dl; < 3,9 mmol/l und ≥ 54 mg/dl; ≥ 3,0 mmol/l	❍ Nein ❍ Ja	_____

	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
2	Hypoglykämie mit Glukosewert < 54 mg/d; < 3,0 mmol/l	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
3	Hypoglykämie mit Symptomatik und der Glukosewert ist nicht bekannt	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
4	Schwere Hypoglykämie, das heißt charakterisiert durch eine beeinträchtigte geistige und/oder körperliche Verfassung, die Fremdhilfe erfordert.	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____

Spätkomplikationen

#	Komplikation	Auftreten	Start Jahr
1	Diabetische Retinopathie	❍ Nein ❍ Ja ❍ unbekannt	_____ (JJJJ)
2	Diabetische Neuropathie	❍ Nein ❍ Ja ❍ unbekannt	_____ (JJJJ)
3	Diabetische Nephropathie	❍ Nein ❍ Ja ❍ unbekannt	_____ (JJJJ)
4	Diabetisches Fußsyndrom	❍ Nein ❍ Ja ❍ unbekannt	_____ (JJJJ)
5	Amputation der unteren Gliedmaßen aufgrund des diabetischen Fußsyndroms	❍ Nein ❍ Ja ❍ unbekannt	_____ (JJJJ)

3.5.3 Begleiterkrankungen

#	Erkrankungen	Auftreten
1	Arterielle Hypertonie	❍ Nein ❍ Ja ❍ unbekannt
2	Koronare Herzerkrankung	❍ Nein ❍ Ja ❍ unbekannt
3	Periphere arterielle Verschlusskrankheit	❍ Nein ❍ Ja ❍ unbekannt
4	Niereninsuffizienz	❍ Nein ❍ Ja ❍ unbekannt
5	Herzinfarkt in der Anamnese	❍ Nein ❍ Ja ❍ unbekannt
6	Schlaganfall (ischämisch, hämorrhagisch) in der Anamnese	❍ Nein ❍ Ja ❍ unbekannt

3.5.4 Lipidsenkende Begleitmedikation

#	Medikament (Wirkstoff)	Antwort	Seit wann
1	**Statine**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
2	**Fibrate**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
3	**Colestyramin**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
4	**Ezetimib**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
5	**PCSK9-Hemmer**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
6	**Omega-3-Fettsäuren**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)

3.5.5 Blutdrucksenkende Begleitmedikation

#	Medikament (Wirkstoff)	Antwort	Seit wann
1	**ACE-Hemmer**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
2	**AT_1R-Hemmer** (Sartane)	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
3	**Thiazide**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
4	**Betablocker**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)
5	**Calciumantagonisten**	❍ Ja ❍ Nein ❍ unbekannt	_____ (JJJJ)

3.6 Letzte anti-diabetische Medikation vor Umstellung

3.6.1 Letztes Basalinsulin vor der Umstellung auf iGlarLixi

Frage	Antwort
Medikation (Handelsname)	Drop-down: ❍ Insulin detemir (Levemir®) ❍ Insulin glargin 100 E/ml (Lantus®, Abasaglar®) ❍ Insulin glargin 300 E/ml (Toujeo®) ❍ Insulin degludec 100/200 E/ml (Tresiba® 100/200) ❍ NPH Insulin (Protaphane®, Insulatard® Human, Huminsulin® basal, Insuman® basal, Berlinsulin® basal) ❍ Anderes: _____
Beginn der Therapie	____ / _____ (MM / JJJJ)

	❍ unbekannt
Einheiten	_____ pro Tag
Anzahl der Insulininjektionen	_____ pro Tag
Zeitpunkt der Injektion	❍ morgens ❍ mittags ❍ abends ❍ vor dem Zubettgehen ❍ unbekannt

3.6.2 Nicht-Insulin Begleitmedikation

#	Frage	Antwort
1	Metformin	❍ Nein ❍ Ja
2	Sulfonylharnstoff	❍ Nein ❍ Ja
3	Glinid	❍ Nein ❍ Ja
4	Alpha-Glukosidase-Hemmer	❍ Nein ❍ Ja
5	Glitazon	❍ Nein ❍ Ja
6	DPP-4-Hemmer	❍ Nein ❍ Ja
7	SGLT2-Hemmer	❍ Nein ❍ Ja

3.7 Glykämische Variabilität **(vor Umstellung auf iGlarLixi)**

3.7.1 FGM-Gerät (ca. 14-Tage-Mittelwerte)

Verfügbarkeit mindestens 70 % auswertbare Daten aus den FGM-Tagesprofilen der letzten ca. 14 Tage (max. 3 Wochen) **vor** Umstellung auf iGlarLixi muss gewährleistet sein. **Bitte sicherstellen, dass die Grenzwerte im Gerät und der Arztsoftware übereinstimmen.**

Frage	**Antwort**
	Hersteller, Gerät
❍ **Abbott,** Freestyle Libre 2 FGM	❍ Anderes: (bitte Gerät benennen)
Messzeitraum vor Umstellung auf iGlarLixi	Beginn: ____ / ____ / _____ (TT / MM / JJJJ) Ende: ____ / ____ / _____ (TT / MM / JJJJ)
mindestens 70 % **erfasste Sensordaten** des FGMs der letzten ca. 14 Tage (max. 3 Wochen) vor Umstellung auf iGlarLixi	❍ ja ❍ nein Wenn **nein**: PatientIn bitte nicht als StudienteilnehmerIn dokumentieren.
Medianer Zielwert des BZ	_____ ❍ mg/dl / ❍ mmol/l
Grenzwert niedrige Glukose	_____ ❍ mg/dl / ❍ mmol/l
Glukosedurchschnitt (Medianwert des BZ)	_____ ❍ mg/dl / ❍ mmol/l
Individueller Zielbereich des Patienten	von_____ ❍ mg/dl / ❍ mmol/l bis_____ ❍ mg/dl / ❍ mmol/l
% über Zielbereich	_____ %
% im Zielbereich	_____ %
% unter Zielbereich	_____ %
Ereignisse mit niedrigem Glukosewert	_____
Durchschnittliche Dauer	_____ min

3.7.2 7-Punkte-Glukose-Tagesprofil bestimmt mit Glukometer

Messungen finden statt vor der Umstellung auf iGlarLixi

7-Punkte-Glukose-Tagesprofil	
Datum der Messung	____ / ____ / _____ (TT / MM / JJJJ)
Vor dem Frühstück	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Frühstück	_____ ❍ mg/dl / ❍ mmol/l
Vor dem Mittagessen	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Mittagessen	_____ ❍ mg/dl / ❍ mmol/l
Vor dem Abendessen	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Abendessen	_____ ❍ mg/dl / ❍ mmol/l
Schlafenszeit	_____ ❍ mg/dl / ❍ mmol/l

3.8 Laborwerte (**vor Umstellung auf iGlarLixi)**

#	Laborwert	Ergebnis	Einheit	Datum
Letzter Wert **innerhalb der letzten 3 Monate** (Pflichtwert)				
1	HbA_{1c}	_____	❍ % ❍ mmol/mol	____ / ____ / _____ (TT/MM/JJJJ)
Letzte Werte innerhalb der letzten 6 Monate (sofern verfügbar)				
2	eGFR	_____	ml/min/1,73m²	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
3	Kreatinin	_____	❍ mg/dl ❍ µmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
4	AST (GOT)	_____	❍ U/l ❍ µmol/sL	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
5	ALT (GPT)	_____	❍ U/l ❍ µmol/sL	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
6	Nüchtern-Plasmaglukose	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
7	Gesamtcholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
8	LDL-Cholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
9	HDL-Cholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
10	Triglyzeride	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar

3.9 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Frage	Antwort
Datum, an dem der Wert gemessen wurde	____ / ____ / _____ (TT / MM / JJJJ)
Ergebnis	_____ ❍ mg/dl / ❍ mmol/l ❍ Wert nicht verfügbar

3.10 Anti-diabetische Medikation bei und nach Umstellung auf iGlarLixi

3.10.1 iGlarLixi

Frage	Antwort
Grund für Umstellung auf iGlarLixi: *Mehrfachnennungen möglich*	Verbesserung der glykämischen Kontrolle, insbesondere: ❍ des HbA_{1c}-Wertes ❍ des Nüchternblutzuckers ❍ des postprandialen Blutzuckers ❍ Verminderung der Hypoglykämierate ❍ Verbesserung der Glukosevariabilität ❍ Verbesserung der TIR (time in range) ❍ bisher hohe Dosierung des Basalinsulins (Verringerung der Dosis wird angestrebt) ❍ Umstellung des Injektionszeitpunktes ❍ Präferenz für iGlarLixi-Pen ❍ einfache Handhabung der Fixkombination ❍ Wunsch des Patienten (persönliche Gründe) ❍ Sonstige
Falls 'Sonstige', bitte spezifizieren:	
Beginn der Therapie mit iGlarLixi	____ / ____ / _____ (TT / MM / JJJJ)
Anzahl der iGlarLixi Dosisschritte	_____ pro Tag
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen

3.10.2 Nicht-Insulin-Begleitmedikation

Frage	Antwort
Veränderung in der Therapie im Vergleich zu **vor** Umstellung auf iGlarLixi?	❍ Nein ❍ Ja
Wenn **JA,** aktuelle Medikation:	
Metformin	❍ Nein ❍ Ja
Sulfonylharnstoff	❍ Nein ❍ Ja
Glinid	❍ Nein ❍ Ja
Alpha-Glucosidase-Hemmer	❍ Nein ❍ Ja
Glitazon	❍ Nein ❍ Ja
DPP-4-Hemmer	❍ Nein ❍ Ja
SGLT2-Hemmer	❍ Nein ❍ Ja

3.11 Therapiezufriedenheit DTSQs

Die folgenden Fragen des diabetesspezifischen Fragebogens zur Therapiezufriedenheit des/r PatientIn (DTSQs) beziehen sich auf die Behandlung (einschließlich ihrer Therapie mit Insulin, Tabletten und / oder Diät) und die Erfahrungen des/r PatientIn während der letzten Wochen.
Bitte lassen Sie den/die PatientIn den Fragebogen ausfüllen.

Frage	Antwort
Wurde der DTSQs ausgefüllt?	❍ Nein ❍ Ja
Wie wird der Fragebogen versendet?	❍ im eCRF hochgeladen ❍ per Mail gesendet an: info@akp-freiburg.de ❍ per Fax gesendet an: +49 (0)761 479 4022

3.12 Abschluss der Eingangsdokumentation

Hiermit bestätige ich als behandelnde/r Ärztin/Arzt, dass die Einträge im eCRF vollständig und richtig sind, und mit den Informationen in der Krankenakte des/r PatientIn übereinstimmen.

Alle unerwünschten Ereignisse (UE) gemäß vorliegender Definition (siehe Beobachtungsplan) wurden vollständig dokumentiert.

___ / ___ / ____ _____

[TT / MM / JJJJ] Signatur des/r behandelnden Arztes/Ärztin

3.13 Monatliche Dokumentation

3.13.1 ca. 4 Wochen nach Umstellung auf iGlarLixi

Bitte tragen Sie hier die Werte des vom/von der PatientIn selbst gemessen Nüchtern-Glukosespiegels und die aktuelle Dosis für iGlarLixi ein. Beide Angaben können Sie aus dem PatientInnen-Tagebuch entnehmen oder telefonisch erfragen.

3.13.1.1 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Frage	Antwort
Datum, an dem der Wert gemessen wurde	____ / ____ / _____ (TT / MM / JJJJ)
Ergebnis	_____ ❍ mg/dl / ❍ mmol/l ❍ Wert nicht verfügbar

3.13.1.2 Aktuelle Dosis iGlarLixi

Frage	Antwort
Datum	____ / ____ / _____ (TT / MM / JJJJ)
Anzahl der Dosisschritte iGlarLixi	_____ pro Tag ❍ Wert nicht verfügbar
Anzahl der Dosisänderungen von iGlarLixi (seit letzter Dokumentation vor 4 Wochen)	_____
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen

3.13.2 ca. 8 Wochen nach Umstellung auf iGlarLixi

Bitte tragen Sie hier die Werte des vom/von der PatientIn selbst gemessen Nüchtern-Glukosespiegels und die aktuelle Dosis für iGlarLixi ein. Beide Angaben können Sie aus dem PatientInnen-Tagebuch entnehmen oder telefonisch erfragen.

3.13.2.1 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Frage	Antwort
Datum, an dem der Wert gemessen wurde	____ / ____ / _____ (TT / MM / JJJJ)
Ergebnis	_____ ❍ mg/dl / ❍ mmol/l ❍ Wert nicht verfügbar

3.13.2.2 Aktuelle Dosis iGlarLixi

Frage	Antwort
Datum	____ / ____ / _____ (TT / MM / JJJJ)
Anzahl der Dosisschritte iGlarLixi	_____ pro Tag ❍ Wert nicht verfügbar
Anzahl der Dosisänderungen von iGlarLixi (seit letzter Dokumentation vor 4 Wochen)	_____
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen

4 Zwischendokumentation (Dokumentation 2)

ca. 12 Wochen nach Umstellung auf iGlarLixi

Frage	Antwort
Datum, an dem die **Untersuchung des/r PatientIn** stattgefunden hat	____ / ____ / _____ (TT / MM / JJJJ)

4.1 Gewicht

Frage	Antwort
Gewicht	❍ _____ kg ❍ Wert nicht verfügbar

4.2 Glykämische Variabilität **(ca. 12 Wochen nach Umstellung auf iGlarLixi)**

4.2.1 FGM-Gerät (ca. 14-Tage-Mittelwerte)

Bitte sicherstellen, dass die Grenzwerte im Gerät und der Arztsoftware übereinstimmen.

Frage	Antwort
Wechsel des Herstellers des FGM-Messsystems?	❍ Nein ❍ Ja (wenn ja, bitte für PatientIn alles weiter dokumentieren außer den FGM-Daten)
Messzeitraum	Beginn: ____ / ____ / _____ (TT / MM / JJJJ) Ende: ____ / ____ / _____ (TT / MM / JJJJ)
mindestens 70 % **erfasste Sensordaten** des FGMs der letzten ca. 14 Tage (max. 3 Wochen) ca. 12 Wochen nach Umstellung auf iGlarLixi	❍ ja ❍ nein Wenn **nein**: bitte für PatientIn alles weiter dokumentieren außer den FGM-Daten)
Medianer Zielwert des BZ	_____ ❍ mg/dl / ❍ mmol/l
Grenzwert niedrige Glukose	_____ ❍ mg/dl / ❍ mmol/l
Glukosedurchschnitt (Medianwert des BZ)	_____ ❍ mg/dl / ❍ mmol/l
Individueller Zielbereich des Patienten	von_____ ❍ mg/dl / ❍ mmol/l bis_____ ❍ mg/dl / ❍ mmol/l
Gesamtzeit % über Zielbereich	_____ %
% im Zielbereich	_____ %
% unter Zielbereich	_____ %
Ereignisse mit niedrigem Glukosewert	_____
Durchschnittliche Dauer	_____ min

4.2.2 7-Punkte-Glukose-Tagesprofil bestimmt mit Glukometer

Ca. 12 Wochen nach der Umstellung auf iGlarLixi

7-Punkte-Glukose-Tagesprofil	
Datum der Messung	____ / ____ / _____ (TT / MM / JJJJ)
Vor dem Frühstück	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Frühstück	_____ ❍ mg/dl / ❍ mmol/l
Vor dem Mittagessen	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Mittagessen	_____ ❍ mg/dl / ❍ mmol/l
Vor dem Abendessen	_____ ❍ mg/dl / ❍ mmol/l
2 Stunden nach dem Abendessen	_____ ❍ mg/dl / ❍ mmol/l
Schlafenszeit	_____ ❍ mg/dl / ❍ mmol/l

4.3 Laborwerte

#	Laborwert	Ergebnis	Einheit	Datum
Letzter Wert **innerhalb der letzten 3 Monate** (Pflichtwert)				
1	HbA_{1c}	_____	❍ % ❍ mmol/mol	____ / ____ / _____ (TT/MM/JJJJ)
Letzte Werte innerhalb der letzten 3 Monate (sofern verfügbar)				
2	eGFR	_____	ml/min/1,73m²	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
3	Kreatinin	_____	❍ mg/dl ❍ µmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
4	AST (GOT)	_____	❍ U/l ❍ µmol/sL	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
5	ALT (GPT)	_____	❍ U/l ❍ µmol/sL	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
6	Nüchtern-Plasmaglukose	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
7	Gesamtcholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
8	LDL-Cholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
9	HDL-Cholesterin	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar
10	Triglyzeride	_____	❍ mg/dl ❍ mmol/l	❍____ / ____ / ____ (TT/MM/JJJJ) ❍ Wert nicht verfügbar

4.4 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Siehe **Eingangsdokumentation 3.9**

4.5 Aktuelle Medikation

4.5.1 iGlarLixi

Frage	Antwort
Wird iGlarLixi seit der Eingangsdokumentation durchgängig verwendet?	❍ Ja ❍ Nein
Wenn JA:	
Dosisschritte iGlarLixi	_____ pro Tag
Anzahl der Dosisänderungen von iGlarLixi (seit letzter Dokumentation vor 4 Wochen)	_____
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen
Wenn NEIN: Abbruch der Studie, PatientIn bitte nicht weiter als StudienteilnehmerIn dokumentieren. **Bitte füllen Sie noch die zwei folgenden Fragen aus:**	
a) Warum wurde die Verwendung von iGlarLixi abgebrochen? *Mehrfachnennung möglich*	❍ Unerwünschtes Ereignis (bitte (S)UE-Bogen ausfüllen) ❍ Entscheidung des/r behandelnden Arztes/Ärztin ❍ Wunsch des/r PatientIn ❍ Anderes
Falls 'Anderes', bitte spezifizieren:	_____(bitte ggf. (S)UE-Bogen ausfüllen)
b) Welche Diabetestherapie erhält der/die PatientIn nach Abbruch der Studie?	Drop-down: **Kurzwirksames Insulin:** ❍ Insulin aspart (NovoRapid®) ❍ schnelles Insulin aspart (Fiasp®) ❍ Insulinglulisin (Apidra®)

❍ Insulin lispro 100/200 E/ml (Humalog®, Insulin lispro Sanofi®, Liprolog®)
❍ Normalinsulin (Actrapid®, Huminsulin® normal, Insuman® Rapid, Berlinsulin® H normal)

Kombinationsinsulin (Mischinsulin)
❍ NPH Insulin + Humaninsulin (Actraphane®, Berlinsulin® H 30/70, Insuman Comb® 25, 50, Huminsulin Profil III®)
❍ Insulin aspart +Insulin aspart Protamin (Novomix®)
❍ Insulin lispro + Insulin lispro Protamin (Humalog Mix®)

Basalinsulin:
❍ Insulin detemir (Levemir®)
❍ Insulin glargin 100 E/ml (Lantus®, Abasaglar®)
❍ Insulin degludec 100/200 E/ml (Tresiba® 100/200)
❍ NPH Insulin (Protaphane®, Insulatard® Human, Huminsulin® basal, Insuman® basal, Berlinsulin® basal)

Orale Antidiabetika:
❍ Metformin
❍ Sulfonylharnstoff
❍ Glinid
❍ Alpha-Glukosidase-Hemmer
❍ Glitazon
❍ DPP-4-Hemmer
❍ SGLT2-Hemmer

GLP-1-Rezeptoragonist:
❍ Exenatid (Byetta®)

❍ Liraglutid (Victoza®)

❍ Dulaglutid (Trulicity®)

❍ Semaglutid (Ozempic®)

Andere:

❍ _____

(bitte Medikation hier eintragen)

4.5.2 Nicht-Insulin-Begleitmedikation

Siehe **Nicht-Insulin Begleitmedikation 3.6.2**

4.6 Hypoglykämien

Ca. 12 Wochen nach der Umstellung auf iGlarLixi (seit der Eingangsdokumentation bis zu dieser Dokumentation).

#	Komplikation	Auftreten	Anzahl der Ereignisse
1	Hypoglykämie mit Glukosewert < 70 mg/dl; < 3,9 mmol/l und ≥ 54 mg/dl; ≥ 3,0 mmol/l	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
2	Hypoglykämie mit Glukosewert < 54 mg/d; < 3,0 mmol/l	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
3	Hypoglykämie mit Symptomatik und der Glukosewert ist nicht bekannt	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____
4	Schwere Hypoglykämie, das heißt charakterisiert durch eine beeinträchtigte geistige und/oder körperliche Verfassung, die Fremdhilfe erfordert.	❍ Nein ❍ Ja	_____
	Wenn ja, nächtlich?	❍ Nein ❍ Ja	_____

Bitte dokumentieren Sie alle unerwünschten Ereignisse sowie vermutete Qualitätsmängel, die seit Studienbeginn aufgetreten sind auf dem entsprechenden Meldebogen.

4.7 Weitere unerwünschte Ereignisse

#	Art der Nebenwirkungen		Auftreten
1	Gastrointestinale Nebenwirkungen		❍ Nein ❍ Ja ❍ unbekannt
		Erbrechen	❍ Nein ❍ Ja ❍ unbekannt
		Nausea	❍ Nein ❍ Ja ❍ unbekannt
		Diarrhö	❍ Nein ❍ Ja ❍ unbekannt
2	Sonstige Nebenwirkungen (bitte Art der Nebenwirkung in 2.Spalte eintragen)		❍ Nein ❍ Ja ❍ unbekannt

Bitte dokumentieren Sie alle unerwünschten Ereignisse sowie vermutete Qualitätsmängel, die seit Studienbeginn aufgetreten sind auf dem entsprechenden Meldebogen

4.8 Abschluss der Zwischendokumentation

Hiermit bestätige ich als behandelnde/r Ärztin/Arzt, dass die Einträge im eCRF vollständig und richtig sind, und mit den Informationen in der Krankenakte des/r PatientIn übereinstimmen.

Alle unerwünschten Ereignisse (UE) gemäß vorliegender Definition (siehe Beobachtungsplan) wurden vollständig dokumentiert.

___ / ___ / ____ _____

[TT / MM / JJJJ] Signatur des/r behandelnden Arztes/Ärztin

4.9 Monatliche Dokumentation

4.9.1 ca. 16 Wochen nach Umstellung auf iGlarLixi

Bitte tragen Sie hier die Werte des Nüchtern-Glukosespiegel vom/von der PatientIn gemessen und die aktuelle Dosis für iGlarLixi ein. Beide Angaben können Sie aus dem PatientInnen-Tagebuch entnehmen oder telefonisch erfragen.

4.9.1.1 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Frage	Antwort
Datum, an dem der Wert gemessen wurde	____ / ____ / _____ (TT / MM / JJJJ)
Ergebnis	_____ ❍ mg/dl / ❍ mmol/l ❍ Wert nicht verfügbar

4.9.1.2 Aktuelle Dosis iGlarLixi

Frage	Antwort
Datum	____ / ____ / _____ (TT / MM / JJJJ)
Anzahl der Dosisschritte iGlarLixi	_____ pro Tag ❍ Wert nicht verfügbar
Anzahl der Dosisänderungen von iGlarLixi (seit letzter Dokumentation vor 4 Wochen)	_____
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen

4.9.2 ca. 20 Wochen nach Umstellung auf iGlarLixi

Bitte tragen Sie hier die Werte des Nüchtern-Glukosespiegel vom/von der PatientIn gemessen und die aktuelle Dosis für iGlarLixi ein. Beide Angaben können Sie aus dem PatientInnen-Tagebuch entnehmen oder telefonisch erfragen.

4.9.2.1 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Frage	Antwort
Datum, an dem der Wert gemessen wurde	____ / ____ / _____ (TT / MM / JJJJ)
Ergebnis	_____ ❍ mg/dl / ❍ mmol/l

	❍ Wert nicht verfügbar

4.9.2.2 Aktuelle Dosis iGlarLixi

Frage	Antwort
Datum	____ / ____ / _____ (TT / MM / JJJJ)
Anzahl der Dosisschritte iGlarLixi	_____ pro Tag ❍ Wert nicht verfügbar
Anzahl der Dosisänderungen von iGlarLixi (seit letzter Dokumentation vor 4 Wochen)	_____
Zeitpunkt der Injektion	❍ vor dem Frühstück ❍ vor dem Mittagessen ❍ vor dem Abendessen

5 Abschlussdokumentation (Dokumentation 3)

ca. 24 Wochen nach Umstellung auf iGlarLixi

Frage	Antwort
Datum, an dem die **Untersuchung des/r PatientIn** stattgefunden hat	____ / ____ / _____ (TT / MM / JJJJ)

5.1 Gewicht

Frage	Antwort
Gewicht	_____ kg

5.2 Glykämische Variabilität

Siehe **Zwischendokumentation 4.2**

5.3 Laborwerte

Siehe **Zwischendokumentation 4.3**

5.4 Nüchtern-Glukosespiegel vom/von der PatientIn gemessen

Siehe **Eingangsdokumentation 3.9**

5.5 Aktuelle Medikation

5.5.1 iGlarLixi

Siehe **iGlarLixi 4.5.1**

5.5.2 Nicht-Insulin Begleitmedikation

Siehe **Nicht-Insulin Begleitmedikation 3.6.2**

5.6 Hypoglykämien

Ca. 24 Wochen nach der Umstellung auf iGlarLixi (seit der Zwischendokumentation (Dokumentation 2) bis vor dieser Dokumentation).

Siehe **Hypoglykämie 4.6**

Bitte dokumentieren Sie alle unerwünschten Ereignisse sowie vermutete Qualitätsmängel, die seit Studienbeginn aufgetreten sind, auf dem entsprechenden Meldebogen.

5.7 Weitere unerwünschte Ereignisse

Siehe **Unerwünschte Ereignisse 4.7**

Bitte dokumentieren Sie alle unerwünschten Ereignisse sowie vermutete Qualitätsmängel, die seit Studienbeginn aufgetreten sind, auf dem entsprechenden Meldebogen.

5.8 Therapiezufriedenheit DTSQs und DTSQc

Die folgenden Fragen der diabetesspezifischen Fragebögen zur Therapiezufriedenheit des/r PatientIn (DTSQs und DTSQc) beziehen sich auf die Behandlung (einschließlich Ihrer Therapie mit Insulin, Tabletten und / oder Diät) und die Erfahrungen des/r PatientIn während der letzten Wochen. Bitte lassen Sie den/die PatientIn den Fragebogen ausfüllen.

Frage	Antwort
Wurde der DTSQs ausgefüllt?	❍ Nein ❍ Ja
Wurde der DTSQc ausgefüllt?	❍ Nein ❍ Ja
Wie werden die Fragebögen versendet?	❍ im eCRF hochgeladen ❍ per Mail gesendet an: info@akp-freiburg.de ❍ per Fax gesendet an: +49 (0)761 479 4022

5.9 Abschluss der Abschlussdokumentation

Hiermit bestätige ich als behandelnde/r Ärztin/Arzt, dass die Einträge im eCRF vollständig und richtig sind, und mit den Informationen in der Krankenakte des/r PatientIn übereinstimmen.

Alle unerwünschten Ereignisse (UE) gemäß vorliegender Definition (siehe Beobachtungsplan) wurden vollständig dokumentiert.

___ / ___ / ____ _____

[TT / MM / JJJJ] Signatur des/r behandelnden Arztes/Ärztin

Kopie des Votums/
Kein Original

Sächsische Landesärztekammer
Körperschaft des öffentlichen Rechts

Sächsische Landesärztekammer · PF 100465 · 01074 Dresden

Sanofi-Aventis Deutschland GmbH
[redacted]
Potsdamer Straße 8
10785 Berlin

Dresden, 20. Aug. 2020
Bearbeiten: [redacted]
Aktenzeichen: [redacted]
Telefon: [redacted]
Telefax: [redacted]
E-Mail: [redacted]
Persönliche Termine bitten wir telefonisch abzusprechen

Berufsrechtliche Beratung eines Antrages gemäß § 15 der Berufsordnung der Sächsischen Landesärztekammer

Titel des Forschungsvorhabens: Eine prospektive Beobachtungsstudie zur Beurteilung der glykämischen Kontrolle durch Therapieintensivierung mit iGlarLixi im Suliqua®-(30-60)-Pen in der täglichen Praxis bei PatientInnen mit Typ-2-Diabetes, deren Blutzucker unter Basalinsulin und oraler antidiabetischer Therapie (BOT) nicht ausreichend kontrolliert ist

Sehr geehrte [redacted],

die Ethikkommission der Sächsischen Landesärztekammer hat den o. g. Antrag gemäß § 15 der Berufsordnung der Sächsischen Landesärztekammer in der Sitzung vom 17.08.2020 beraten. Dabei orientiert sie sich an den ICH-GCP-Richtlinien.

Aus Sicht der Ethikkommission bestehen keine ethischen bzw. berufsrechtlichen Bedenken gegen die Teilnahme des folgenden Arztes:

- [redacted]

Die Kommission befürwortet diese Studie und wünscht bei der Durchführung Ihres Forschungsvorhabens viel Erfolg.

Wir weisen vorsorglich daraufhin, dass die Verantwortung für die Studie und ihre Durchführung uneingeschränkt bei den Prüfärzten verbleibt.

Es wird darauf hingewiesen, dass künftige Änderungen der Studie der Ethikkommission anzuzeigen sind und ggf. eine erneute Beratung erforderlich machen.

Das Ergebnis der berufsrechtlichen Beratung und die studienrelevante Korrespondenz sind an alle teilnehmenden Ärzte weiterzuleiten.

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Datenschutzrechtliche Aspekte von Forschungsvorhaben werden durch die Ethikkommission grundsätzlich nur kursorisch geprüft. Diese Bewertung ersetzt mithin nicht die Konsultation des zuständigen betrieblichen oder behördlichen Datenschutzbeauftragten.

Wir bitten um Mitteilung des Endes der Studie und um Vorlage eines zusammenfassenden Abschlussberichtes.

Mit freundlichen Grüßen

[redacted]

Vorsitzender der Ethikkommission

Kopie an k/m 60
WV an :
Postausgang: 21. Aug. 2020
z.d.A. :

Zur Bewertung eingereichte Unterlagen:

Mit Schreiben vom 27.07.2020:

- 01: Ethikantrag: Formale inhaltliche Beschreibung (FIB) für Forschungsvorhaben, die nicht dem AMG unterliegen vom 27.07.2020
- 02: Beobachtungsplan Version 1.0 vom 01.07.2020
- 03: Zusammenfassung (Synopse) des Beobachtungsplans Version 1.0 vom 01.07.2020
- 04: Patienteninformation und -einwilligung Version 1.0 vom 21.07.2020
- 05: Vollmacht wissenschaftlicher Leiter zum Ethik-Antrag [redacted] vom 17.07.2020
- 06: CV wissenschaftlicher Leiter [redacted] vom 15.07.2020
- 07: Kostenübernahmeerklärung vom 16.07.2020
- 08: AWB-Vertrag für niedergelassene Ärzte Version März 2020
- 09: AWB-Vertrag für MVZ Version März 2020
- 10: Darstellung des Aufwandes für die beteiligten Ärzte und eine Begründung für die Angemessenheit der Entschädigung vom 22.07.2020
- 11: Protocol amendment form (PAF) Sponsor signiert vom 16.07.2020
- 12: Protocol amendment form (PAF) [redacted] signiert vom 17.07.2020
- 13: DTSQs - Fragebogen - Muster DE Version vom 18.04.2007
- 14: DTSQc - Fragebogen - Muster DE Version vom 18.04.2007
- 15: Fachinformation Suliqua® vom März 2020
- 16: Patiententagebuch - Ausfüllhilfe Version 1.0 vom 24.07.2020
- 17: Patiententagebuch Version 1.0 vom 16.07.2020

Study report: Principal or coordinating Investigator signature form

SANOFI

Product Code:	*Suliqua*
Study Code / Name:	*OBS16751 / CHANCE*
Study Title:	*A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood sugar is not adequately controlled on basal insulin and oral antidiabetic therapy (BOT)*
Document Type:	☐ Clinical Study Report ☒ Product Observational Study Report ☐ Disease Observational Study Report ☐ Post Authorization Safety Study (PASS) Report
Final draft dated:	04.08.2023

I have read this report and confirm that to the best of my knowledge, it accurately describes the conduct and results of the study.

Investigator	
[redacted]	[redacted] Signature Date:

Study report or synopsis Sponsor approval form for Local Medical studies

SANOFI

Product Code:	Suliqua
Study Code / Name:	OBS16751
Study Title:	A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood sugar is not adequately controlled on basal insulin and oral antidiabetic therapy (BOT)
Document Type: (Tick appropriate box)	☐ Clinical Study Report / ☐ Synopsis ☒ Product Observational Study Report / ☐ Synopsis ☐ Disease Observational Study Report / ☐ Synopsis ☐ Post Authorization Safety Study (PASS) Report / ☐ Synopsis
Name of Sponsor's responsible medical officer (i.e. individual responsible for medical oversight of the report):	[redacted]

THE STUDY REPORT / SYNOPSIS

Final Draft dated 04-08-2023

is APPROVED*.

*Note: to approve the document, the Sponsor's responsible medical officer should ensure that the local PV contact has reviewed the document and comments have been incorporated

Sponsor's responsible medical officer:			
☒ Country GBU (or TA) Medical Head	[redacted]	[redacted] [redacted] *Grund: approved Datum: 11. August 2023 12:11 GMT+2*	
		Signature	Date:

794-P

ADA 2023
June 23–26
San Diego, CA

Effectiveness and Safety of iGlarLixi in People with Type 2 Diabetes (PwT2D), Not at Target on Basal Insulin (BI) and Oral Antidiabetic Therapy (BOT)—Results from the Observational, Prospective Study CHANCE

Tobias Wiesner[1], Martin Pfohl[2], Katrin Pegelow[3], Julia Müller[3], Jochen Seufert[4]

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INTRODUCTION

- In suboptimal controlled PwT2D on a BOT regimen, intensifying to the fixed-ratio combination (FRC) insulin glargine 100 U/mL plus lixisenatide 33 µg/mL (iGlarLixi 100/33) may provide a simple and effective treatment option to improve glycemic control vs BOT[1] or other intensification options like premix insulin[2] or basal-bolus[3] regimens.
- In current guidelines, use of FRCs is recommended.[4,5]
- Efficacy and safety of intensifying from a BOT setting to iGlarLixi was assessed in the phase 3 study LixiLan-L.[1] However, prospective data assessments on translation of these trial results into daily clinical practice are still rare.

OBJECTIVE

The CHANCE‡ study was conducted to assess efficacy and safety of intensifying antiglycemic treatment to iGlarLixi 100/33 in PwT2D, suboptimal controlled on BOT, in daily clinical practice in Germany.

METHODS

- Prospective observational multicenter trial in PwT2D in primary care (general practitioners, internists and diabetologists) all over Germany. PwT2D were enrolled after the physician had decided to intensify an existing BOT to iGlarLixi 100/33 due to suboptimal glycemic control (HbA_{1c} at baseline [BL] 7.5-10%), independent of inclusion of the patient into this study, after informed consent.
- **Primary endpoint:** absolute change in HbA_{1c} (%) from BL until approx. 12 and 24 weeks, respectively.
- **Secondary endpoints**: include changes from BL in FPG, 7-point blood glucose profiles, body weight, iGlarLixi dose and body mass index (BMI), proportion of patients at individualized, prespecified HbA_{1c} and FPG target ≤110 mg/dL, hypoglycemia incidence and rates, BL previous BI doses, and safety after approximately 12 and 24 weeks.
- In addition, a subgroup using flash glucose monitoring (FGM) was evaluated for time in range (TIR), time above range (TAR) and time below range (TBR), respectively.
- Patients with self-measured blood glucose (SMBG) were evaluated for derived TIR (dTIR), dTAR and dTBR.

Figure 1: Study design

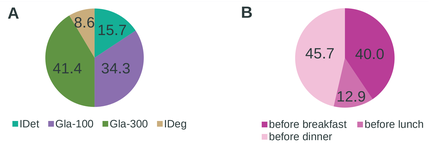
Demographics and baseline characteristics were documented at baseline only. Primary and secondary endpoints were documented at baseline, and after approximately 12 and approximately 24 weeks, respectively. In addition, self-measured fasting plasma glucose and current iGlarLixi dose were documented monthly.

Table 1: Demographics and baseline characteristics

	FAS n = 70	FGM n = 20	SMBG n = 50
Age, years	64.6 (9.5)	60.3 (7.9)	66.4 (9.6)
Male, [n (%)]	42 (60.0)	12 (60.0)	30 (60.0)
Weight, kg	104.3 (22.5)	107.0 (23.1)	103.1 (22.4)
BMI, kg/m²	35.1 (7.2)	35.8 (7.6)	34.8 (7.0)
Duration T2D, years	12.3 (6.7)	14.3 (8.3)	11.6 (6.1)
FPG*, mg/dL	174.3 (44.6)	159.3 (27.3)	180.6 (49.0)
HbA_{1c}, %**	8.5 (0.8)	8.4 (0.8)	8.6 (0.9)
Indiv. target HbA_{1c}, %	6.9 (0.4)	6.9 (0.5)	7.0 (0.3)

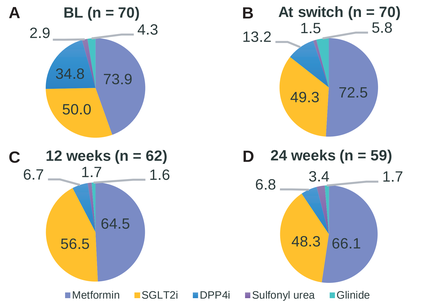
Data are mean (SD), unless otherwise specified. * Self-measured fasting plasma glucose; ** Last value within last 3 months. BMI, body mass index; FAS, full analysis set; FGM, flash glucose monitoring; FPG, fasting plasma glucose; HbA_{1c}, glycated hemoglobin A_{1c}; indiv., individual; SD, standard deviation; SMBG, self-measured blood glucose; T2D, type 2 diabetes.

Figure 2: Previous basal insulin therapy (A) and timepoint of iGlarLixi 100/33 administration (B)



Data are % of full analysis set population (n = 70); one value missing for (B). Gla-100, insulin glargine 100 U/mL; Gla-300, insulin glargine 300 U/mL; IDeg, insulin degludec; IDet, insulin detemir; iGlarLixi 100/33, insulin glargine 100 U/mL + lixisenatide 33 µg/mL.

Figure 3: Oral antidiabetic drug use at BL (A), at switch (B), after 12 weeks (C) and after 24 weeks (D)

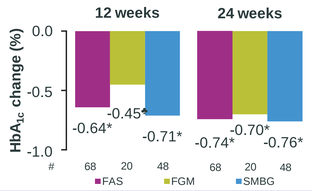


	BL	At switch	12 weeks	24 weeks
No OAD	4.3	14.3	19.4	20.3
1 OAD	41.4	38.6	37.1	40.7
2 OADs	40.0	40.0	37.1	32.2
≥3 OADs	14.3	7.1	6.5	6.8

Figure: percent sum up to > 100% due to ≥ 1 OAD in most patients. **Figure** + **Table**: Data are percent of full analysis set population with data available. BL, baseline; DPP4i, dipeptidyl peptidase 4 inhibitor; OAD, oral antidiabetic drug; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

Figure 4: HbA_{1c} change from baseline

	FAS n = 70	FGM n = 20	SMBG n = 50
Baseline, %	8.5 (0.8)	8.4 (0.8)	8.6 (0.9)
After 12 weeks, %	7.9 (0.8)	8.0 (0.9)	7.9 (0.8)
After 24 weeks, %	7.7 (0.8)	7.8 (0.9)	7.7 (0.7)



Data are mean (SD). p-value calculated for paired t-test. * p < 0.001; ♣ p = 0.005. FAS, full analysis set; FGM, flash glucose monitoring; HbA_{1c}, glycated hemoglobin A_{1c}; SD, standard deviation; SMBG, self-measured blood glucose.

Table 2: Body weight change from baseline

	FAS n = 68	FGM n = 20	SMBG n = 48
After 24 weeks, kg	101.3 (21.6)	102.6 (22.8)	100.8 (21.2)
Weight change‖, kg	-3.0 (-4.8, -1.1)	-4.5 (-7.3, -1.6)	-2.3 (-4.7, -0.0)
p-value	0.002	0.004	0.049

Data are mean (SD), unless otherwise specified. ‖ Data are mean (95% CI). p-value calculated for paired t-test. CI, confidence interval; FAS, full analysis set; FGM, flash glucose monitoring; SD, standard deviation; SMBG, self-measured blood glucose.

Figure 5A: Derived time in range (dTIR) from 7-point blood glucose daily profiles‡

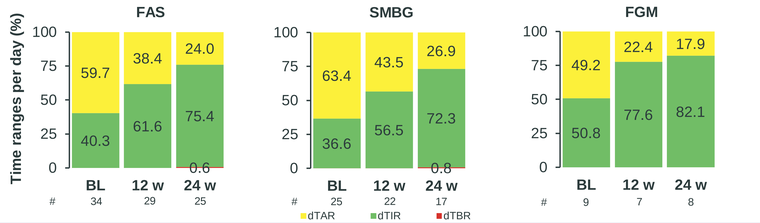
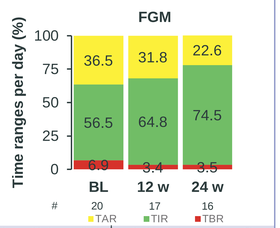


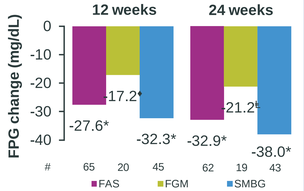
Figure 5B: Time in rangeᵀ (TIR)



Percentage per day of dTIR / dTAR / dTBR = number of SMBGs within 70-180 mg/dL / above 180 mg/dL / below 70 mg/dL devided by number of all SMBGs times 100[6]. # Number of patients with data available. ‡ 7-point blood glucose daily profiles were self-measured; ᵀ derived from FGM measurements. BL, baseline; 12 w, at week 12; 24 w, at week 24; d, derived; FAS, full analysis set; FGM, flash glucose monitoring; SMBG, self-measured blood glucose; TAR, time above range (> 180 mg/dL); TBR, time below range (< 70 mg/dL); TIR, time in range (70-180 mg/dL).

Figure 6: FPG change from baseline

	FAS n = 68	FGM n = 20	SMBG n = 48
Baseline, mg/dL	174.3 (44.6)	159.3 (27.3)	180.6 (49.0)
After 12 weeks, mg/dL	147.1 (36.5)	142.2 (30.5)	149.3 (39.0)
After 24 weeks, mg/dL	141.4 (34.1)	139.0 (26.3)	142.5 (37.2)



Data are mean (SD); values of 3 patients are missing after 12 weeks, values of 5 patients are missing after 24 weeks in groups FAS and SMBG. p-value calculated for paired t-test. * p < 0.001; ♦ p = 0.050; ‡ p = 0.010. FAS, full analysis set; FGM, flash glucose monitoring; FPG, fasting plasma glucose; SD, standard deviation; SMBG, self-measured blood glucose.

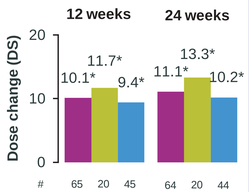
Table 3: Patients at individualized HbA_{1c} target (Tab. 1) and at FPG target ≤110 mg/dL

HbA_{1c} at indiv. target	FAS n = 70	FGM n = 20	SMBG n = 50
0-12 weeks	8 (11.4)	2 (10.0)	6 (12.0)
0-24 weeks	12 (17.1)	4 (20.0)	8 (16.0)
FPG at target ≤110 mg/dL	**FAS n = 70**	**FGM n = 20**	**SMBG n = 50**
0-12 weeks	15 (21.4)	5 (25.0)	10 (20.0)
0-24 weeks	21 (30.0)	5 (25.0)	16 (32.0)

Data are n (%). FAS, full analysis set; FGM, flash glucose monitoring; FPG, fasting plasma glucose; HbA_{1c}, glycated hemoglobin A_{1c}; SMBG, self-measured blood glucose.

Figure 7: iGlarLixi dose change from baseline

	FAS n = 70	FGM n = 20	SMBG n = 50
Baseline, DS	30.0 (0.0)	30.0 (0.0)	30.0 (0.0)
After 12 weeks, DS	40.1 (9.8)	41.7 (9.2)	39.4 (10.0)
After 24 weeks, DS	41.1 (9.5)	43.3 (9.8)	40.2 (9.4)



Data are mean (SD). p-value calculated for paired t-test. * p < 0.001. DS, dose steps: 1 DS = 1 U insulin glargine + 0.33 µg lixisenatide; FAS, full analysis set; FGM, flash glucose monitoring; SD, standard deviation; SMBG, self-measured blood glucose; U, unit.

Table 4: Hypoglycemia events (reported)

ADA level 1	FAS; n = 67	FGM; n = 19	SMBG; n = 48
BL incidence◊, %	4.5 (0.9, 12.5)	5.3 (0.1, 26.0)	4.2 (0.5, 14.3)
BL events PPY	0.58	0.92	0.45
24 w incidence◊, %	3.6 (0.4, 12.3)	-	5.1 (0.6, 17.3)
24 w events PPY	0.52	-	0.73
ADA level 2	**FAS; n = 67**	**FGM; n = 19**	**SMBG; n = 48**
BL incidence◊, %	-	-	-
BL events PPY	-	-	-
24 w incidence◊, %	3.6 (0.4, 12.3)	-	5.1 (0.6, 17.3)
24 w events PPY	0.37	-	0.52

ADA level 1: BG < 70 mg/dL and ≥ 54 mg/dL; ADA level 2: BG < 54 mg/dL. ◊ data are mean (95% CI). 24 w, after 24 weeks (reported for last 12 weeks before); BL, baseline (reported for last 12 weeks before), CI, confidence interval; FAS, full analysis set; FGM, flash glucose monitoring; PPY, per patient year; SMBG, self-measured blood glucose.

RESULTS

- Previous basal insulin dose was [mean (SD)] 38.7 (9.6) U/d (FAS), 40.8 (10.9) U/d (FGM) and 37.8 (8.9) U/d (SMBG). iGlarLixi was started as per European Medicines Agency label for the (30-60) pen at 30 dose steps (DS); dose increased significantly by 11.1 DS after 24 weeks (**Figure 7**)
- HbA_{1c} (**Figure 4**), FPG (**Figure 6**) and body weight (**Table 2**) decreased significantly after 12 and 24 weeks.
- dTIR increased and dTAR decreased, both significantly, after 24 weeks (all p < 0.05; **Figure 5A**). FGM data in a subgroup of patients showed similar patterns for TIR and TAR and a reduction in TBR (p = 0.007; **Figure 5B**).
- Hypoglycemia events did not change significantly and were low in number (**Table 3**). No severe hypoglycemia requiring outside assistance was reported.

DISCUSSION

- Treatment intensification from a BOT regimen to iGlarLixi significantly improved HbA_{1c} and FPG levels, leading to recommended[7] dTIR/TIR > 70% and dTBR/TBR < 4%, respectively, as well as dTAR/TAR around 25%.
- Hypoglycemia were seldom reported, probably due to underreporting, because more hypoglycemic events were seen from FGM readings.
- This is the first study reporting on real world use of iGlarLixi in Germany with 29% of PwT2D using FGM devices. Limitations are its non-randomized, single arm design, which might have led to bias from unknown con-founders and to selection bias.

CONCLUSION

Intensifying antiglycemic treatment from a BOT regimen to iGlarLixi 100/33 in suboptimal controlled PwT2D in daily clinical practice allowed patients to reach glycemic target ranges with no increased hypoglycemia and favorable body weight change.

‡ CHANCE: A prospective observational study to assess glycaemic **C**ontrol by intensifying therapy wit**H** iGlarLixi in the Suliqua® (30-60) pen in d**A**ily practice in patie**N**ts with type 2 diabetes whose blood sugar is not adequately **C**ontrolled on basal insulin and oral antidiabetic th**E**rapy (BOT)

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7. Battelino T, *et al. Diabetes Care* 2019; 42: 1593−603

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DISCLOSURES

TW received honoraria for talks and/or advisory boards and/or consultancy and/or research funding and/or other medical-scientific support from Abbott, Animas, AstraZeneca, Berlin Chemie, Boehringer Ingelheim, Dexcom, Daichii, Amarin, Roche, Merck Sharp Dohme (MSD), Eli Lilly, Novo Nordisk and Sanofi. **MP** received honoraria for advisory boards from Boehringer Ingelheim, Eli Lilly and Sanofi and for lectures from Novartis and Sanofi. **KP** and **JM** are employees of Sanofi and may hold shares and/or stock options in the company. **JS** received honoraria for lectures and/or consultancy and/or research funding from Apitope, Astra Zeneca, Bayer, Berlin Chemie, Boehringer Ingelheim, Bristol Myers Squibb (BMS), Eli Lilly, GI-Dynamics, Glaxo Smith Kline (GSK), Intarcia, Ipsen, Janssen, LifeScan, MedScape, MSD, Novartis, Novo Nordisk, Omniamed, Pfizer, Roche, Sanofi, Servier, Takeda and Ypsomed.

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