

# A study to evaluate the performance of a continuous glucose monitoring device in people with diabetes

<b>Submission date</b> 15/09/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/09/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/08/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diabetes is a disease that occurs when the blood sugar, also called blood glucose, is too high. The continuous glucose monitoring (CGM) device is intended for continuous measurement of glucose levels in people with diabetes (PwD) over the entire CGM run time in a non-clinical setting. This device will measure the glucose level in the fluid found in the spaces around cells (interstitial fluid) present under the skin (subcutaneous). A small measuring sensor will be applied into the subcutaneous fatty tissue and will remain there over the entire duration of the study. After application, the sensor will be paired with the respective CGM application (app) on the smartphones which will prompt the participant at regular intervals to enter the collected values of self-monitoring of blood glucose (SMBG) in the app. The main purpose of the study is to determine the performance, accuracy, safety and usability of a CGM device in measuring the glucose levels in PwD.

### Who can participate?

Participants with type 1 or insulin-dependent type 2 diabetes mellitus aged at least 18 years.

### What does the study involve?

Participants will have to be a part of this study for a maximum of 22 days, not including the screening visit. The study will have four parts:

1. Screening period wherein participants will be informed about investigational devices and the study, and they will undergo various tests to determine if they are eligible to participate in the study.
2. Device application: Eligible participants will have the investigational devices (CGM Sensor) applied to their arms and will receive respective instructions. Participants will be provided with a study smartphone with the CGM mobile app installed and paired with the CGM sensors. Participants will also measure their SMBG values using a blood glucose (BG) meter with test strips, control solution and a device used to obtain samples of blood for glucose testing (lancing device). A participant diary and a participant card for the duration of the study will also be provided.
3. Sampling days (inpatient): The participants will spend several sampling days at the study site.

For comparison measurements, SMBG measurements will be taken with a commercially available BG meter.

4. Routine days (out-patient): Participants will be asked to perform SMBG measurements during routine days. The participants will be asked to use a diary to document physical activity, showering, bathing, any problems that occurred or any other noticeable observation.

5. Follow-up: After sensor removal, all participants will be followed up for any side effects.

What are the possible benefits and risks of participating?

Participation in this study is purely for research purposes and the participants may have no direct clinical benefits from participating in the study. Participants will be adequately compensated for participating in this study.

Participants may have side effects from the device or procedures used in this study. Side effects can be mild to severe and can vary from person to person.

Risks associated with the CGM device: Bleeding, allergic reaction, damage of muscle tissue or mark on the skin due to the device at the site of application, skin irritations, itching or painful skin condition where fluid fills a space between layers of skin (blistering), a harmful effect from very small quantities of a chemical called cobalt in the small tube called cannula in the sensor.

Risk associated with data handling: There is a rare possibility of photos with potentially participant-identifying skin features, e.g., scars, tattoos.

Where is the study run from?

F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?

January 2023 to November 2023

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

global-roche-genentech-trials@gene.com

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Contact details**

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## Additional identifiers

**Protocol serial number**

## Study information

### Scientific Title

Medical device study to evaluate the performance of a continuous glucose monitoring device by comparing device-generated data with capillary blood glucose comparison values in people with diabetes over a 14-day wearing period

### Study objectives

The main purpose of the study is to determine the performance of a continuous glucose monitoring (CGM) solution.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. approved 08/03/2023, Ethik-Kommission der Landesärztekammer Baden-Wuerttemberg (Ethics Committee of the State Medical Association of Baden-Wuerttemberg) (Liebknechtstr. 33, Stuttgart, 70565, Germany; +49 (0)711 76989-964; ethikkommission@laek-bw.de), ref: MDR-2023-002

2. approved 19/04/2023, Ethikkommission der Medizinischen Universität Graz (Ethics Committee of the Medical University of Graz) (Neue Stiftingtalstr. 6, Graz, 8010, Austria; +43 (0)316 385-13928; ethikkommission@medunigraz.at), ref: 35-240 ex 22/23

### Study design

Open-label single-arm prospective non-randomized multi-center study

### Primary study design

Observational

### Study type(s)

Diagnostic, Safety, Efficacy

### Health condition(s) or problem(s) studied

Diabetes mellitus

### Interventions

Participants will have three CGM sensors applied in both upper arms for continuous measurement of glucose levels in the subcutaneous interstitial fluid. CGM sensors will be paired with a CGM mobile application. Participants will have to enter the self-monitoring of blood glucose (SMBG) values in the CGM app. Participants will use their usual regimen prescribed by their treating physician to manage their diabetes.

Participants will have to be a part of this study for a maximum of 22 days, not including the screening visit. The study will have four parts:

1. Screening period wherein participants will be informed about investigational devices and the study, and they will undergo various tests to determine if they are eligible to participate in the study.

2. Device application: Eligible participants will have the investigational devices (CGM Sensor) applied to their arms and will receive respective instructions. Participants will be provided with a study smartphone with the CGM mobile app installed and paired with the CGM sensors. Participants will also measure their SMBG values using a blood glucose (BG) meter with test strips, control solution and a device used to obtain samples of blood for glucose testing (lancing device). A participant diary and a participant card for the duration of the study will also be provided.

3. Sampling days (inpatient): The participants will spend several sampling days at the study site. For comparison measurements, SMBG measurements will be taken with a commercially available BG meter.

4. Routine days (out-patient): Participants will be asked to perform SMBG measurements during routine days. The participants will be asked to use a diary to document physical activity, showering, bathing, any problems that occurred or any other noticeable observation.

5. Follow-up: After sensor removal, all participants will be followed up for any side effects.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

CGM Device

## **Primary outcome(s)**

1. Performance of the CGM sensor assessed as an agreement rate of >83% falling within  $\pm 20$  milligrams per decilitre (mg/dL) (<100 mg/dL) and  $\pm 20\%$  ( $\geq 100$  mg/dL) of paired capillary blood glucose values measured using SMBG measurements on multiple days up to Day 14

## **Key secondary outcome(s)**

1. Performance of the CGM sensor assessed as an agreement rate between paired CGM and SMBG values expressed as percentage falling within  $\pm 15/15$ ,  $\pm 20/20$ ,  $\pm 30/30$ ,  $\pm 40/40$  (mg/dL <100 mg/dL, %  $\geq 100$  mg/dL) for different glucose levels/ranges and for periods with stable and dynamic blood glucose levels measured using pairwise comparison on multiple days from Day 1 up to Day 14

2. Overall mean absolute relative difference (MARD) measured based on SMBG values across all CGM sensors, different glucose levels/ranges and for periods with stable and dynamic blood glucose levels from Day 1 up to Day 14

3. Availability of valid glucose values transmitted using CGM sensors measured from Day 1 up to Day 14

4. Consensus error grid (CEG) assessed based on the CGM sensor wear time up to Day 14

5. Comparison between the performance of two CGM sensors assessed as paired absolute relative difference (PAR) in one participant over 10 and 14 days

6. Classification of application pain measured using Numeric Pain Scale (NRS) on Day 1

7. Classification of bleeding after application measured on a scale of "no, mild, moderate, or severe" assessed on Day 1

8. Failure rate of investigational devices reported using device deficiency report from Day 1 up to Day 22

9. Number of adverse events (AEs), serious AEs (SAEs) adverse device effects (ADEs)/serious ADEs (SADEs) reported in accordance with Regulation (EU) 2017/745 on medical devices from Day 1 up to Day 22

10. Usability of the investigational device assessed using questionnaires for participants and the health care professionals (HCPs) on Day 1 and Day 15

**Completion date**

16/11/2023

**Eligibility**

**Key inclusion criteria**

1. Diabetes mellitus type 1 or type 2 with insulin therapy diagnosed at least 12 months prior to screening
2. Participants using automated insulin delivery (AID) systems: Willingness to stop its algorithm during the course of the Sampling Days (SDs)
3. Acceptance to inject insulin or wearing an insulin pump infusion set minimum of 7.5 centimeter (cm) away from the CGM Sensor application site

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

48

**Key exclusion criteria**

1. Potential participant older than 45 years with all three cardiovascular risks factors (smoker, arterial hypertension, glycated haemoglobin (HbA1c) >9.0%)
2. Serious acute or chronic concomitant disease or an anamnesis which might, in the opinion of the investigator, pose a risk to the participant
3. Severe diabetes related complications
4. Significantly impaired awareness of hypoglycemia
5. Severe hypoglycemia resulting in seizure or loss of consciousness in the three months prior to screening
6. HbA1c >9.5% / 80.3 millimoles per mole (mmol/mol)
7. Hematocrit greater than 10% below the lower limit of normal at screening
8. History of adhesive incompatibility and/or allergy
9. Skin alterations at the insertion sites (e.g., psoriasis vulgaris, scars, lipodystrophy)
10. History of frequent catheter abscesses in the past year associated with insulin pump therapy, as per investigator's discretion
11. Chronic use of steroids in adrenal suppressive doses, other immuno-modulatory medication

or chemotherapy

12. Anticoagulant treatment and platelet inhibition (with the exception of acetylsalicylic acid, daily dose rate <300 mg), phenprocoumon (e.g., marcumar), novel oral anticoagulants for atrial fibrillation (NOAK) (e.g., dabigatran, rivaroxaban)

**Date of first enrolment**

22/09/2023

**Date of final enrolment**

16/11/2023

## **Locations**

**Countries of recruitment**

Austria

Germany

**Study participating centre**

**Institute for Diabetes Technology (IfDT)**

Lise-Meitner-Str. 8/2

Ulm

Germany

89081

**Study participating centre**

**CRS Clinical Research Services Mannheim GmbH**

Grenadierstr. 1

Mannheim

Germany

68167

**Study participating centre**

**Medical University Graz**

Auenbruggerplatz 15

Graz

Austria

8036

## **Sponsor information**

**Organisation**

F. Hoffmann-La Roche Ltd

## Funder(s)

### Funder type

Industry

### Funder Name

F. Hoffmann-La Roche

### Alternative Name(s)

Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Switzerland

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/08/2024	29/08/2024	Yes	No