

# Study to evaluate the safety, performance and ease of use of a continuous glucose monitoring (CGM) solution in everyday life for people with diabetes

<b>Submission date</b> 24/05/2025	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/06/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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 frequent measurement of glucose levels in people with diabetes (PWD). 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 glucose-measuring sensor will be inserted into the subcutaneous fatty tissue and will remain there over the entire duration of the study. After application, the CGM device will be paired with a CGM application (app) on a smartphone. The main purpose of the study is to determine the safety, performance and ease of use of a CGM solution in measuring the glucose levels in PWD.

### Who can participate?

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

### What does the study involve?

Subjects will have to be a part of this study for a maximum of 22 days, not including screening visit. The study will have 4 parts:

1. Screening period of 28 days wherein subjects will be informed about the CGM device and the study, and they will undergo various tests to determine if they are eligible to participate in the study.
2. Device application: On Day 1, eligible subjects insert a CGM device into their arm. Subjects will be provided with a study smartphone with a CGM mobile app installed. The CGM device will be paired with the CGM mobile app.
3. Sampling Days (in-patient): The subjects will spend 3 sampling days at the study site. For comparison measurements, self-monitoring of blood glucose (SMBG) values will be taken with a commercially available BG meter.
4. Routine Days (out-patient): Subjects will be asked to perform SMBG measurements during routine days.

5. Follow up: After sensor removal on Day 15, all subjects will be followed up for any side effects up to Day 22.

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?

Roche Diabetes Care GmbH (Germany)

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

March 2025 to September 2025

Who is funding the study?

Roche Diabetes Care GmbH (Germany)

Who is the main contact?

Katrin Mueller, [katrin.mueller.km3@roche.com](mailto:katrin.mueller.km3@roche.com)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Katrin Mueller

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

RD007379

## Study information

**Scientific Title**

Medical device study to evaluate the safety, performance and usability of a CGM solution in people with type 1 and type 2 diabetes under real-life conditions for a wear-time of 14 days

**Study objectives**

The main purpose of the study is to determine the safety, performance and usability of a CGM solution.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 16/05/2025, Ethik-Kommission der Landesärztekammer Baden-Wuerttemberg (Liebknechtstr. 33, Stuttgart, 70565, Germany; +49 711 76989-19; ethikkommission@laek-bw.de), ref: MDR-2025-007-ff

**Study design**

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

**Primary study design**

Observational

**Study type(s)**

Diagnostic, Efficacy, Safety

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

Diabetes mellitus

**Interventions**

Subjects will insert a CGM device in the upper arm for continuous measurement of glucose levels in the subcutaneous interstitial fluid. The CGM sensor will be paired with a mobile application for monitoring of glucose information. Throughout the study, subjects are required to frequently measure their SMBG values. Subjects will continue to follow their regular diabetes management regimen as prescribed by their treating physician.

**Intervention Type**

Device

**Phase**

Not Applicable

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

CGM Solution

### **Primary outcome(s)**

Performance of the CGM solution assessed as the overall mean absolute relative difference (MARD) based on paired capillary blood glucose values on multiple days up to Day 14

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

1. Performance of the CGM solution assessed as the MARD for different glucose levels/ranges and rate of changes based on paired capillary blood glucose values on multiple days up to Day 14
2. Performance of the CGM solution assessed as the MARD per CGM sensor batch based on paired capillary blood glucose values on multiple days up to Day 14
3. Performance of the CGM solution assessed as an agreement rate based on paired capillary blood glucose values expressed as percentage falling within  $\pm 20/20$  and  $\pm 40/40$  (mg/dL <100 mg/dL,  $\% \geq 100$  mg/dL) on multiple days from Day 1 up to Day 14
4. Consensus error grid (CEG) assessed up to Day 14
5. Lag time of the CGM sensor assessed up to Day 14
6. Failure rate of CGM solution and sensor survival rate up to Day 14
7. 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 up to Day 22
8. Usability of the CGM solution assessed using a questionnaire for the subjects on Day 15

### **Completion date**

25/09/2025

## **Eligibility**

### **Key inclusion criteria**

1. Diabetes mellitus type 1 or type 2 diagnosed at least 12 months prior to screening
2. If applicable, acceptance to inject insulin or wearing an insulin pump infusion set minimum 7.5 centimetre (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**

76

### **Key exclusion criteria**

1. Serious acute or chronic concomitant disease or an anamnesis which might, in the opinion of the investigator, pose a risk to the participant
2. Severe diabetes related complications
3. Significantly impaired awareness of hypoglycemia
4. Severe hypoglycemia which required the help of another person or resulting in seizure or loss of consciousness in the three months prior to enrolment
5. Acute illness or abnormality interfering with clinical study procedures
6. HbA1c <6.5% / 48 millimoles per mole (mmol/mol), unless achieved by using an insulin pump or automated insulin delivery (AID) system, and HbA1c >9.5 % / 80.3 mmol/mol
7. Hematocrit greater than 10% below the lower limit of normal
8. History of adhesive incompatibility and/or other contact allergies
9. Skin alterations at the application sites (e.g., psoriasis vulgaris, scars, lipodystrophy)
10. 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), within 2 weeks prior to planned application of the study devices and during the course of the clinical study
11. Intake of ascorbic acid (>500 mg total daily dose); methyldopa or supplements with gentisic acid within two days prior to CGM application and during the course of the study

**Date of first enrolment**

03/07/2025

**Date of final enrolment**

07/08/2025

## Locations

**Countries of recruitment**

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**

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Mannheim

Germany

68167

# Sponsor information

## Organisation

Roche Diabetes Care GmbH

## Funder(s)

### Funder type

Industry

### Funder Name

Roche Diabetes Care GmbH

# 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 subject-level data not being a regulatory requirement.

## IPD sharing plan summary

Not expected to be made available