

Type 1 Diabetes Mellitus Type 2 Diabetes Mellitus

## A French Study to Evaluate the Usefulness of Implantable Continuous Glucose Monitoring (CGM) Sensor to Improve Glycemic Control in Participants With Diabetes Mellitus.

**Trial Status**  
Completed

**Trial Runs In**  
1 Countries

**Trial Identifier**  
NCT03445065 RD003329

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

### ***Trial Summary:***

This study will be conducted in France and will evaluate the usefulness of using a long-term subcutaneously inserted continuous glucose monitoring (CGM) sensor (the Eversense XL CGM System) to improve glycemic control in patients with either Type 1 or Type 2 diabetes mellitus under insulin therapy. Participants will be enrolled into one of two cohorts (Cohorts 1 and 2). Cohort 1 will be focused on participants with Type 1 or Type 2 diabetes with hemoglobin A1C (HbA1c) >8%. Cohort 2 will be focused on participants with Type 1 diabetes spending more than 1.5 hours per day with mean glucose <70 mg/dL, including excursions below 54 mg/dL, for at least 28 days. Within each cohort, participants will be randomized in a 2:1 ratio to one of two groups: the Enabled and Control groups, respectively. The Enabled group will be trained to use the CGM system, whereas the Control group will continue with their usual glucose monitoring system (self-monitoring of blood glucose [SMBG] or flash glucose monitoring [FGM]).

**Hoffmann-La Roche**  
Sponsor

**N/A**  
Phase

**NCT03445065 RD003329**  
Trial Identifiers

### ***Eligibility Criteria:***

**Gender**  
All

**Age**  
≥ 18 Years

**Healthy Volunteers**  
No