

# Association between exposure to GLP-1 receptor agonists and risk of suicide-related and self-harm-related events

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000052

### Study ID

1000000052

### DARWIN EU® study

No

### Study countries

☐ United Kingdom

### Study description

Cohort study aimed at investigating the association between GLP-1 receptor agonists and increased risk of suicide-related and self-injury-related events.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

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Institution

### Contact details

#### Study institution contact

Maria Clara Restrepo-Méndez [RWE@ema.europa.eu](mailto:RWE@ema.europa.eu)

Study contact

[RWE@ema.europa.eu](mailto:RWE@ema.europa.eu)

#### Primary lead investigator

Andrei Barbulescu

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 15/08/2023

Actual: 15/08/2023

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## **Study start date**

Planned: 15/09/2023

Actual: 15/09/2023

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## **Data analysis start date**

Planned: 27/09/2023

Actual: 27/09/2023

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## **Date of final study report**

Planned: 08/11/2023

Actual: 14/11/2023

# Sources of funding

- EMA

# Study protocol

[FINAL\\_Protocol - Suicidal ideation and GLP1a\\_v1.6.pdf](#) (1011.55 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Main study objective:**

Is the use of GLP-1 receptor agonists associated with an increased risk of suicide-related and self-harm-related events when compared to patients who are prescribed SGLT-2 inhibitors among T2DM patients?

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

### **Medical condition to be studied**

Suicidal ideation

Self-injurious ideation

Suicide attempt

Completed suicide

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### **Additional medical condition(s)**

Self-injury/self-harm

## **Population studied**

### **Short description of the study population**

The population eligible for the study will consist of patients:

- registered with a GP-practice covered by IQVIA™ Medical research data (IMRD),
- who initiated treatment with GLP-1 receptor agonists or SGLT-2 inhibitors (new users) during the study period,
- who had not used GLP-1 receptor agonists or SGLT-2 inhibitors before index-date (i.e., date of index treatment initiation and the start of follow-up in the study),
- with at least one year (365 days) of recorded medical history prior to index-date,
- with at least one diagnosis of T2DM before index-date,
- with no history of suicide-related or self-harm-related events prior to index-date,
- who have been treated with biguanides (e.g., metformin, which is considered first-line antidiabetic treatment according to NICE guidelines (NICE, 2022))

before index-date.

No exclusion will be applied according to age.

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## **Age groups**

# Documents

## **Study report**

[Final study report\\_Suicidal ideation and GLP1.pdf](#) (4.35 MB)

## Data management

# ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

## **Data source(s)**

IQVIA Medical Research Data - OMOP

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Yes

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## Data characterisation

### **Data characterisation conducted**

Yes