

# PCSCVM003617/ A Real-World Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries

**First published:** 14/06/2022

**Last updated:** 03/06/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS47585

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### Study ID

47809

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### DARWIN EU® study

No

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### Study countries

☐ Belgium

☐ Italy

☐ Spain

☐ United Kingdom

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Johnson & Johnson**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Lu Wang

**Primary lead investigator**

## Study timelines

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

Planned: 08/06/2022

Actual: 08/06/2022

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### **Study start date**

Planned: 31/03/2023

Actual: 07/03/2023

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### **Date of final study report**

Planned: 30/06/2024

Actual: 04/06/2024

## Sources of funding

- Other

## More details on funding

Janssen R&D

## Study protocol

[21Oct2024-REDACTED\\_Protocol-FD-PCSCVM003617-EUPAS47585.pdf](#) (2.6 MB)

## Regulatory

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

Yes

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

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

The primary objectives of this study are to describe the time-trend of canagliflozin utilization in patients with T1DM using real-world databases in European countries with high cumulative exposure, including the UK, Spain, Italy, and Belgium.

### Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Qualitative study including document analysis and qualitative interviews

## Study drug and medical condition

**Medicinal product name**

INVOKANA

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**Study drug International non-proprietary name (INN) or common name**

CANAGLIFLOZIN

METFORMIN

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**Anatomical Therapeutic Chemical (ATC) code**

(A10BK02) canagliflozin

canagliflozin

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**Medical condition to be studied**

Type 1 diabetes mellitus

Type 2 diabetes mellitus

## Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
  - Adults (85 years and over)
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## Estimated number of subjects

14249

## Study design details

### Data analysis plan

Analysis will be conducted within each database. The utilization pattern of canagliflozin in patients with type 1 diabetes mellitus (T1DM) will be described, with continuous variables summarized using mean  $\pm$  standard deviation, median, and interquartile range and categorical variables summarized using counts and proportions.

The unadjusted prevalence (number of canagliflozin users who are patients with T1DM divided by total number of all existing canagliflozin users) and incidence (number of new canagliflozin users who are patients with T1DM divided by the number of all new users) of patients with T1DM in canagliflozin users will be calculated by year as well as overall.

The linear trends of annual prevalence and incidence over the study period will be tested using a general linear regression model or the Joinpoint regression model if potential nonlinear trends are observed.

Individual database-specific estimates will be combined per country as well as overall through meta-analysis.

## Documents

### Study results

[REDACTED\\_CSR-Body-PCSCVM003617-1301642\\_1373227.pdf](#) (714.04 KB)

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## Data management

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)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

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### Data source(s), other

IQVIA Inc Belgium, IQVIA Inc Italy, IQVIA Inc Spain

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No