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

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## Administrative details

EU PAS number	
EUPAS47585	
Study ID	
47809	
DARWIN EU® study	
No	
Study countries	
Belgium	
Italy	
Spain Spain	

United Ki	ngdom
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### **Study status**

**Finalised** 

## Research institutions and networks

### Institutions

## Johnson & Johnson

First published: 01/02/2024

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Institution

## Contact details

### **Study institution contact**

Lu Wang RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

## **Primary lead investigator**

Lu Wang

**Primary lead investigator** 

## Study timelines

### Date when funding contract was signed

Planned: 08/06/2022 Actual: 08/06/2022

### Study start date

Planned: 31/03/2023 Actual: 07/03/2023

### **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

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

## Methodological aspects

## Study type

## Study type list

### **Study topic:**

Human medicinal product

### **Study type:**

Non-interventional study

### 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

### Non-interventional study design, other

Qualitative study including document analysis and qualitative interviews

## Study drug and medical condition

#### Name of medicine

INVOKANA

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

**CANAGLIFLOZIN** 

**METFORMIN** 

### **Anatomical Therapeutic Chemical (ATC) code**

(A10BK02) canagliflozin

canagliflozin

#### 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)

#### **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 ±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)

## 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)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

#### Data source(s), other

IQVIA Inc Belgium, IQVIA Inc Italy, IQVIA Inc Spain

### Data sources (types)

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

### **CDM** mapping

No

## Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

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	,,,,			JVI	, , ,

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No