# Investigating risk of cancer with Sodium-glucose cotransporter 2 inhibitors: a Case/Non-Case Study in the WHO Global Pharmacovigilance Database Vigibase

**First published:** 03/09/2024

**Last updated:** 03/09/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000311

**Study ID**

1000000311

**DARWIN EU® study**

No

**Study countries**

France

**Study description**

Disproportionnality analysis using the WHO global database Vigibase.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Toulouse University Hospital

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

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

**Institution**

# Contact details


**Study institution contact**

Paul Gautier pgautier95@gmail.com

**Study contact**

pgautier95@gmail.com

**Primary lead investigator**

Paul Gautier 0009-0008-9934-8432

**Primary lead investigator**

**ORCID number:**

0009-0008-9934-8432

# Study timelines

**Date when funding contract was signed**

Planned: 01/02/2024

Actual: 01/02/2024

---

**Study start date**

Planned: 01/02/2024

Actual: 01/02/2024

---

**Data analysis start date**

Planned: 01/03/2024

Actual: 01/03/2024

---

**Date of final study report**

Planned: 01/07/2024

Actual: 01/07/2024

# Regulatory

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

No

---

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

Not applicable

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Study design:**

Disproportionnality analysis on the WHO global database Vigibase.

**Main study objective:**

Exploratory analysis in the WHO's global pharmacovigilance database, Vigibase, to search for main cancers risk signals associated with the use of SGLT-2i.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Case non-case design (disproportionnality analysis)

## Study drug and medical condition

**Medicinal product name**

DAPAGLIFLOZIN

**Medicinal product name, other**

Canagliflozin, Empagliflozin

---

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

CANAGLIFLOZIN

DAPAGLIFLOZIN

EMPAGLIFLOZIN

---

**Anatomical Therapeutic Chemical (ATC) code**

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

(A10BK01) dapagliflozin

dapagliflozin

(A10BK02) canagliflozin

canagliflozin

(A10BK03) empagliflozin

empagliflozin

---

**Additional medical condition(s)**

Cancer

# Population studied

**Short description of the study population**

Adults > 18 years old exposed to SGLT-2i or other oral antidiabetic drugs (GLP1 analogues and DPP4 inhibitors) in Vigibase between 2014 and 2023

---

**Age groups**

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

## Study design details

**Setting**

All ICSR between 01/01/2014 and 31/12/2023 were included. Patients 18 years old or older will be included. Cases are each subtype of cancer and non cases are all other ICSRs of the database. Exposed patients are ICSR with SGLT-2i (empagliflozin, dapagliflozin, canagliflozin) as suspected drug, controls are ICSR with GLP-1 analogues or DPP4 inhibitors as suspected drug.

---

**Comparators**

Patients exposed to GLP-1 analogues or DPP4 inhibitors

---

**Outcomes**

Reprorting Odds Ratios for cancers (overall) and each cancer taken individually.

---

**Data analysis plan**

The characteristics of the subjects in both groups will be described using frequencies and percentages. The disproportionality in cancer reporting between the exposed and non-exposed groups will be analyzed by calculating the Reporting Odds Ratio (ROR) through logistic regression with adjustments for age, sex, reporting country, and co-prescriptions with carcinogenic risk. The signal will be considered significant if the lower bound of the 95% confidence interval (CI95%) is greater than 1.

# 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), other**

WHO global pharmacovigilance database Vigibase

**Data sources (types)**

Spontaneous reports of suspected adverse drug reactions

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No