Treatment of T2DM Patients in Germany receiving Empagliflozin: A retrospective RWE Study Description of Treatment and Population Characteristics of Type 2 Diabetic Patients in Germany receiving Empagliflozin: A retrospective Real-World Evidence (RWE) study based on German registries DPV&DIVE

First published: 11/11/2026

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001187

Study ID

1000001187

DARWIN EU® study

No

Study countries

Germany

Study description

Description of the real-life treatment of adult patients with type-2 diabetes mellitus (T2DM) receiving Empagliflozin, comparing the characteristics of patients starting Empagliflozin in three time intervals

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maximilian Gabler

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/07/2019

Study start date

Actual: 16/09/2019

Data analysis start date

Actual: 01/03/2014

Date of final study report

Actual: 31/12/2019

Study protocol

1245-0198_CTP_final-rule_Redacted.pdf (424.3 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

1245-0198

NCT04098575

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective non-interventional cross-sectional study

Main study objective:

Description of the real-life treatment of adult patients with T2DM receiving empagliflozin, comparing the characteristics of patients starting empagliflozin in three time intervals:

- The first analysis will include the patients receiving Empagliflozin before the EMPA-REG-OUTCOME study was published (time until mid-Sept. 2015; “Cohort 1”).
- The second analysis will include patients receiving Empagliflozin starting from the EMPA-REG-OUTCOME study being published until CV Label Change (time from mid-Sept. 2015-mid-Jan. 2017; “Cohort 2”).
- The third analysis will include all patients receiving Empagliflozin starting from mid-Jan. 2017 until last available data cut (“Cohort 3").

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

JARDIANCE

SYNJARDY

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

EMPAGLIFLOZIN

Population studied

Short description of the study population

Type 2 Diabetic Patients in Germany receiving Empagliflozin

Estimated number of subjects

7.900

Study design details

Setting

Real-world data from German patient registries

Outcomes

Primary outcomes

- Previous occurrence (percentages) of

o Typical CV comorbidities:

- MI
- Stroke
- CAD
- PAD
- CHF (form (HFrEF/ HFpEF)

o Other typical diabetes complications:

- Neuropathy
- Nephropathy / Renal function (eGFR, micro-/ macroalbuminuria)
- Diabetic foot syndrome
- Retinopathy (background and proliferative)
- Antidiabetic and cardiovascular co-medication (lipid-lowering agents, RAAS blockers, other antihypertensives, beta blockers, diuretics, antiplatelets and anticoagulants)

Secondary outcomes

- Age(<65; 65 – <75; 75 – 80 , >80)
- Gender
- Weight [kg]
- Height [cm]
- HbA1c [% or mmol/ mol], FPG (available in subgroup only)
- Duration of diabetes (time since diagnosis)
- Previous glucose-lowering treatment
- Dosage of empagliflozin (10mg vs 25mg) (available in subgroup only)
- Participation in Disease Management Programme (DMP) Type 2 Diabetes (from DPV registry)
- Hospitalizations (from DPV registry)

Data analysis plan

Variables will be assessed in half-yearly periods after index date (date of first prescription of empagliflozin), for total study population and separated by study cohort.

Anonymized data from the DIVE and the DPV registries will be combined; nonparametric descriptive analyses will be used. Group comparison will be based on Wilcoxon rank sum test (continuous variables) and X^2-test for binary/categorial values. Analysis will be implemented using SAS 9.4. Complete case analysis will be used.

Analysis will be done by an experienced biostatistician with detailed knowledge of the DIVE and the DPV registries. A second independent programmer will check the generated SAS code for inconsistencies. The medical team will evaluate the results from a clinical background to ensure plausibility. Quality assurance and control will be the responsibility of the medical team.

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 sources (types)

Disease registry

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

Unknown