# An Observational/Non-interventional Evaluation of Subject Outcomes for Type 2 Diabetes Mellitus (T2DM) Subjects Prescribed Dipeptidyl Peptidase-4 Inhibitors (DPP4i), Sodium-glucose Cotransporter-2 Inhibitors (SGLT2i) or Sulphonylureas (SUs) at First Intensification

**First published:** 27/03/2019

**Last updated:** 25/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS28930

**Study ID**

38608

**DARWIN EU® study**

No

**Study countries**

☐ United Kingdom

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**Study description**

This is an observational, non-interventional, retrospective cohort study of patients with T2DM. This study will evaluate the change in patient’s hemoglobin A1c (HbA1c) level from baseline at 6- and 12-months when a second drug is added to a patient’s treatment regimen using data from real-world clinical practice. To determine the impact of baseline HbA1c level on outcomes, data will be analysed by treatment and by strata defined by patient’s baseline HbA1c levels. Patients diagnosed with T2DM between 01 January 2002 and 31 December 2017 with a prescription for metformin followed by addition of dipeptidyl peptidase-4 inhibitors (DPP4i), sodium-glucose cotransporter-2 inhibitors (SGLT2i) or sulphonylureas (SU) will be observed with results being reported separately for each of these three groups. Retrospective data for each patient will be extracted for a 6-month pre-index period and up to 15-years of follow-up. Index date is defined as the date of intensification of therapy. Data will be available for inclusion in the study across the period from 01 January 2001 to 31 December 2017. Data will be collected up to death, loss to follow-up or end of study period, whichever occurs first. The study will use electronic primary care medical records contained within the Clinical Practices Research Datalink (CPRD) GOLD dataset from primary care sites within the United Kingdom (UK). The overall duration of the study is approximately 6 months.

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**Study status**

Finalised

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Marc Evans

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/03/2019

Actual: 01/03/2019

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**Study start date**

Planned: 01/11/2019

Actual: 01/11/2019

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**Data analysis start date**

Planned: 15/11/2019

Actual: 15/11/2019

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**Date of interim report, if expected**

Planned: 31/12/2019

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**Date of final study report**

Planned: 31/12/2019

Actual: 31/12/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## 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:**

Disease /health condition

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective is to estimate the change in HbA1c post-baseline (that is addition of an SU, DPP-4i or SGLT2i to metformin) stratified by baseline HbA1c, at Months 6 and 12.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

**Short description of the study population**

Adult patients with Type 2 diabetes mellitus (T2DM) on the CPRD GOLD database between 01 January 2002 to 31 December 2017.

**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)

**Special population of interest**

Other

**Special population of interest, other**

Type 2 diabetes mellitus patients

**Estimated number of subjects**

40000

## Study design details

**Outcomes**

There is one primary outcome which evaluates HbA1c change from baseline to Months 6 and 12. The secondary outcomes include: evaluation of change from baseline in body weight at Months 6 and 12, discontinuation rates at Months 6 and 12 post-baseline, treatment intensification at Months 6 and 12 post-baseline, mean medicines possession ratio (MRP) across medication, medication persistence, urinary tract infection (UTI) rates, hypoglycaemic episode counts and rates of adverse events.

**Data analysis plan**

Mixed-effects regression modelling will be used to test for significant differences in changes in HbA1c levels from baseline at 6 and 12 months for 3 different medications. Models will be fitted to data to adjust for the effect of observed covariates including:demographic, clinical factors, other prescriptions, comorbidities and centre effects. Appropriate regression techniques will be used in accordance with the assumed distribution of outcome variable. Descriptive statistics will be used to characterise patterns and interrelationships between different factors. If appropriate, models of rates will be estimated using survival analysis,and binary outcomes will be estimated using logistic or probit regression. Transformation of outcome, or alternatives such as Poisson and negative binomial regression may be used in case of non-normally distributed outcomes. Akaike's Information Criteria may be used to inform variable inclusion.

## Documents

**Study results**

T2DM-5002 - ENCEPP Results.pdf (647.64 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

**Data source(s), other**

CPRD

**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**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

## Data characterisation conducted

No