# Utilisation of dulaglutide in European countries: A cross-sectional, multi-country and multi-source drug utilisation study using electronic health record databases (H9X-MC-B010)

**First published:** 14/06/2016

**Last updated:** 02/11/2020

Study | Finalised

## Administrative details

**EU PAS number**

EUPAS13783

**Study ID**

37875

**DARWIN EU® study**

No

**Study countries**

France

Germany

Spain

Sweden

United Kingdom

**Study description**

This study describes the frequency of dulaglutide use in different groups of patients in European countries, including the characterization of use by demographics, main comorbidities and comedications, overall and in subgroups of interest, including patients with specific diseases, children and adolescents, the elderly, and pregnant and breastfeeding women. Additionally, medication errors and off-label use will be described among patients using dulaglutide.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Real World Evidence Solutions, IMS Health

France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

Institution | Other

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Ayad Ali

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 15/12/2014

Actual: 15/12/2014

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**Study start date**

Planned: 13/06/2016

Actual: 13/06/2016

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**Date of final study report**

Planned: 16/12/2019

Actual: 14/11/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

H9X-MC-B010_EU-PAS-Registered.pdf (1.48 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

To describe the frequency of dulaglutide use in overall patients, and in subgroups of interest, including patients with severe renal failure, hepatic disease, heart failure, severe gastrointestinal disease, children and adolescents, elderly patients (75+ years), and pregnant and breastfeeding women. Additionally, to describe utilization in patients with medication errors and off-label use.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

**Short description of the study population**

The study population included all patients receiving dulaglutide prescriptions in the outpatient setting in the selected databases of five European target countries (i.e. France, Germany, Spain, Sweden, and the UK). The eligible patients were those for whom treatment with dulaglutide was initiated during the observation period in each wave of the study for patients having at least 6 months of available continuous history prior to the date of the first dulaglutide prescription (i.e. baseline period). There were no exclusion criteria applied in this study.

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**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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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**Special population of interest**

Renal impaired

Hepatic impaired

Pregnant women

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**Estimated number of subjects**

1.000

# Study design details

**Outcomes**

To describe the frequency of off-label use among each of the subgroups of interest.

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**Data analysis plan**

Descriptive statistics will be used including univariate analysis.

## Documents

**Study results**

B010_Final_Report_Dulaglutide_PASS_DUS_FINAL_10.28.19_Redacted.pdf (4.42 MB)

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# 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

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

**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