A Retrospective Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in European Patients in the Course of Routine Clinical Care (I5Q-MC-B002)

First published: 17/01/2019

Last updated: 17/12/2025

Study | Ongoing

Administrative details

EU PAS number

EUPAS27594

Study ID

36549

DARWIN EU® study

No

Study countries

France

Germany

Italy
Netherlands
Spain
Sweden
United Kingdom

Study description

To evaluate the utilisation and long-term safety of galcanezumab in Europe, in routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 19/12/2025

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 30/03/2026

Institution | Not-for-profit | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 19/12/2025

Institution | Non-Pharmaceutical company | ENCePP partner

Quantify Research

Sweden

First published: 09/07/2020

Last updated: 14/02/2023

Institution | Other | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina,

IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Agenzia regionale di sanità della Toscana (ARS Toscana)

Italy

First published: 01/02/2024

Last updated: 23/03/2026

Institution | EU Institution/Body/Agency | ENCePP partner

University of Basel, in collaboration with the Boston Collaborative Drug Surveillance Program United Kingdom, University Institute for Primary Care Research Jordi Gol and University of Oxford Spain, Agenzia regionale di sanita della Toscana Italy, Quantify Research Sweden

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eline Houben

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/01/2019

Actual: 18/01/2019

Study start date
Planned: 30/06/2020

Actual: 30/06/2020

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

I5Q-MC-B002 Galcanezumab_EU Long Term Safety_Drug Utilization_Protocol_amendment_Redacted.pdf (3.6 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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

An observational, prevalent new-user cohort study using data from various population-based healthcare databases from seven different European countries.

Main study objective:

To evaluate the utilisation and long-term safety of galcanezumab in Europe, in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

GALCANEZUMAB

Anatomical Therapeutic Chemical (ATC) code

(N02CD02) galcanezumab

galcanezumab

Medical condition to be studied

Migraine

Cluster headache

Additional medical condition(s)

serious cardiovascular events, malignancy, and serious hypersensitivity events

Population studied

Short description of the study population

The source population will include all patients with a prescription or dispensing of galcanezumab in the population-based healthcare databases from seven different
European countries including France (FR), Germany (DE), Italy (IT), the Netherlands (NL), Spain
(ES), Sweden (SE) and the United Kingdom (UK).

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)

Estimated number of subjects

100

Study design details

Setting

Seven different European countries including France (FR), Germany (DE), Italy (IT), the Netherlands (NL), Spain
(ES), Sweden (SE) and the United Kingdom (UK).

Comparators

If feasible, based on accrual of target sample size, comparative analyses will be conducted to compare the incidence of serious CV and malignancy events among migraine patients that are new users of galcanezumab with propensity score-matched users of topiramate.

Outcomes

Cardiovascular, malignancy, and serious hypersensitivity.

Data analysis plan

Descriptive analysis

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)

PHARMO Data Network

German Pharmacoepidemiological Research Database

ARS Toscana

Data source(s), other

CPRD, SIDIAP, PHARMO Data Network, GePaRD, ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

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