VALIDATION STUDY PROTOCOL (OP0007) FOR THE EUROPEAN NON-INTERVENTIONAL POST- AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS CARDIOVASCULAR EVENTS OF MYOCARDIAL INFARCTION AND STROKE AND ALL-CAUSE MORTALITY FOR ROMOSOZUMAB BY THE EU-ADR ALLIANCE (OP0004) AND EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSOZUMAB BY THE EU-ADR ALLIANCE (OP0006)

First published: 08/10/2020

Last updated: 19/06/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS36734

Study ID

37819

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain

Study description

The objective of this study is to determine the completeness and diagnostic validity of the following outcomes, which will be evaluated in the 2 European non-interventional post-authorisation safety studies (PASS) of romosozumab: 1. cardiovascular death, 2. myocardial infarction, 3. Stroke, 4. serious infection. Outcomes will be identified based on predefined code lists, which were adapted according to the relevant coding system for the respective database. Validation algorithms are defined individually for each specific outcome. In addition, the validation procedures, e.g. manual free text evaluation, will depend on the specific characteristics of the individual databases (primary care and claims databases). Validation of the outcomes of interest will be conducted for databases where previous validation demonstrated insufficient positive predictive values (PPVs) <75% (all-case validation), or where validation has not yet been performed (sample validation of 250 cases).

Study status

Ongoing

Research institutions and networks

Institutions

UCB Biopharma SRL

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | 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

Teamit Institute

Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

Networks

EU-ADR Alliance

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Clinical Trial Registries and Results | Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results | Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2020

Actual: 30/09/2020

Study start date

Planned: 01/10/2020

Actual: 01/10/2020

Data analysis start date

Planned: 30/09/2026

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SRL

Study protocol

op0007-protocol-final-Redacted.pdf(2.5 MB)

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 type:

Not applicable

If ‘other’, further details on the scope of the study

Validation of real-world data

Main study objective:

The objective of this study is to determine the completeness and diagnostic validity of the following outcomes, which will be evaluated in the 2 European non-interventional PASS of romosozumab: 1. cardiovascular death, 2. myocardial infarction, 3. Stroke, 4. serious infection.

Study drug and medical condition

Name of medicine

EVENITY

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

ROMOSOZUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX) Other drugs affecting bone structure and mineralization

Other drugs affecting bone structure and mineralization

Medical condition to be studied

Osteoporosis postmenopausal

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

250

Study design details

Outcomes

Validation of 4 main outcomes in 2 PASS studies

Data analysis plan

In patients eligible for each of 2 PASS studies, outcomes will be identified based on predefined code lists, which were adapted according to the relevant coding system for the respective databases. All validations (either sample or all-case validations) will be based on free text review of the individual cases. Primary care charts and any related documents (e.g. specialist letters, referrals) will be reviewed by clinically trained validators blinded to exposure. The algorithms for the validation of each of 4 outcomes is provided. Adaptations and specifications to the algorithm may be required to adapt the algorithm to database-specific needs.

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)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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