Risk of Malignancy, Major Adverse Cardiovascular Events, and Liver Injury in Patients with Ulcerative Colitis Treated with Mirikizumab versus Other Biologics: A Secondary Database Study in Japan

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Study Planned

Administrative details

EU PAS number

EUPAS1000001009

Study ID

1000001009

DARWIN EU® study

No

Study countries

Japan

Study status

Planned

Contact details

Study institution contact

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Study contact

jpmail_encepp@lilly.com

Primary lead investigator

Jiayi Dong

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/08/2031

Study start date

Planned: 31/08/2031

Date of final study report

Planned: 31/05/2033

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study drug and medical condition

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

MIRIKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC24) mirikizumab

mirikizumab

Population studied

Short description of the study population

Patients with Ulcerative Colitis

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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