

Bimekizumab Pregnancy Exposure and Outcome Registry: An OTIS Autoimmune Diseases in Pregnancy Study

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000000968

Study ID

1000000968

DARWIN EU® study

No

Study countries

Canada

United States

Study status

Ongoing

Contact details

Study institution contact

UCB Cares UCBCares@ucb.com

Study contact

UCBCares@ucb.com

Primary lead investigator

Christina Chambers

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2022

Actual: 01/03/2022

Study start date

Planned: 03/10/2024

Actual: 03/10/2024

Date of final study report

Planned: 30/06/2035

Sources of funding

- Pharmaceutical company and other private sector

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)

Other study registration identification numbers and links

PS0036

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Yes

Check completeness

Yes

Check stability

No

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes