

# Mirikizumab Pregnancy Registry (I6T-MC-B006)

**First published:** 15/12/2023

**Last updated:** 28/10/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS107688

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### Study ID

107689

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Mirikizumab Pregnancy Registry

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### Study status

Planned

## Research institutions and networks

# Institutions

## Eli Lilly and Company

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Francis Mawanda [mawanda\\_francis@lilly.com](mailto:mawanda_francis@lilly.com)

Study contact

[mawanda\\_francis@lilly.com](mailto:mawanda_francis@lilly.com)

### Primary lead investigator

Francis Mawanda

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 05/12/2023

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### Study start date

Planned: 31/03/2025

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## Date of final study report

Planned: 31/12/2035

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly & Co.

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### Study type:

Non-interventional study

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**Main study objective:**

To estimate the relative birth prevalence of major congenital malformations (up to 12 months) among infants born to women exposed

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

MIRIKIZUMAB

## Population studied

**Age groups**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)
- Adults (18 to < 46 years)

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**Estimated number of subjects**

400

## Study design details

## Outcomes

Major congenital malformations

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## Data analysis plan

Descriptive analyses will be generated for all enrolled women and infants.

## 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 sources (types)

Other

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No