# Evaluation of pregnancy and infant outcomes in Mayzent patients using PRegnancy outcomes Intensive Monitoring (PRIM) data – The Mayzent-PRIM study

**First published:** 21/03/2022

**Last updated:** 23/04/2024

Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/49696

**EU PAS number**

EUPAS45875

**Study ID**

49696

**DARWIN EU® study**

No

**Study countries**

Switzerland

**Study description**

The Mayzent PRIM study is a secondary use of data, non-interventional study (NIS) based on Novartis' pharmacovigilance (PV) system leveraging data collected via PRIM using a set of targeted checklists with structured follow-up on pregnancies spontaneously reported to the Novartis global safety database (Argus). Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

**Last updated:** 01/02/2024

Institution

# Contact details

**Study institution contact**

Novartis Clinical Disclosure Officer

Study contact

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**Primary lead investigator**

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 15/02/2019

Actual: 15/02/2019

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**Study start date**
Planned: 25/03/2022

Actual: 25/03/2022

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**Data analysis start date**
Planned: 25/03/2031

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**Date of interim report, if expected**
Planned: 03/06/2023

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**Date of final study report**
Planned: 03/06/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharmaceuticals

## Study protocol

BAF312A2411 protocol V1.0_Redacted.pdf(824.61 KB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

CBAF312A2411

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To estimate the proportion of major congenital malformations associated with exposure to siponimod immediately before (up to 10 days before LMP) and during pregnancy among (i) live births and (ii) live births, stillbirths, and termination of pregnancy for fetal anomaly (TOPFA).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

SIPONIMOD

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**Medical condition to be studied**

Multiple sclerosis

Pregnancy

Congenital anomaly

Foetal malformation

Stillbirth

Abortion spontaneous

Exposure during pregnancy

Drug exposure before pregnancy

## Population studied

**Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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**Special population of interest**

Pregnant women

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**Estimated number of subjects**

500

## Study design details

**Outcomes**

Major congenital malformation, To estimate the proportion of minor malformations, pregnancy outcomes, overall malformations, physical and cognitive development and serious infections in infants up to one year of age

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**Data analysis plan**

A statistical analysis plan (SAP) detailing the analysis to be conducted will be developed prior to the first data lock point. Annual interim reports will be provided as described in the Milestones section below. The primary Mayzent-

PRIM analysis cohort will constitute of the prospectively reported pregnancies associated with maternal exposure during pregnancy or up to 10 days before LMP. Since retrospective cases may be subject to reporting biases but still be informative, these will be analyzed and reported separately. Note that comparison with external background data will only be performed for the primary cohort, due to the high risk of bias for retrospective reports. Data analysis will include the estimation of proportion and 95% confidence intervals (CI) of malformations and specific pregnancy and infant outcomes. The proportion of congenital malformations will be calculated amongst (i) live births, and (ii) live births, stillbirths, and TOPFA.

# Data management

## Data sources

**Data source(s), other**

Novartis global safety database Switzerland

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**Data sources (types)**

Spontaneous reports of suspected adverse drug reactions

## 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