

# Ocrelizumab Pregnancy Registry

**First published:** 10/09/2019

**Last updated:** 21/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS31342

---

### Study ID

35186

---

### DARWIN EU® study

No

---

### Study countries

☐ Germany

☐ United States

---

### Study description

This is a prospective observational registry that will collect primary data from 290 pregnant women with multiple sclerosis (MS) from the United States and Germany, who have been exposed to ocrelizumab during the 6 months prior to

their last menstrual period (LMP) or at any time during pregnancy, and 290 pregnant women who have not been exposed to ocrelizumab.

Frequency of exposed pregnancy outcomes will be compared with the unexposed group and with available background prevalence from external comparators, namely the Metropolitan Atlanta Congenital Defects Program(MACDP) and the European Surveillance of Congenital Anomalies (EUROCAT).

---

## Study status

Finalised

## Research institutions and networks

### Institutions

**F. Hoffmann-La Roche**

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

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

**Institution**

**1 centre Germany, 2 centres United States**

## Contact details

### Study institution contact

Erwan Muros [global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

Study contact

[global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

### Primary lead investigator

Erwan Muros

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/08/2018

---

### Study start date

Planned: 07/10/2019

Actual: 04/11/2019

---

### Date of final study report

Planned: 26/04/2031

Actual: 11/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Roche

# Study protocol

[Prot WA40063 OCREVUS v1\\_Redacted.pdf](#) (2.1 MB)

[Prot WA40063 ocrelizumab v2\\_Redacted.pdf](#) (1.18 MB)

## Regulatory

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

Yes

---

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

Not applicable

## Other study registration identification numbers and links

WA40063

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The main objective of the study is to assess and characterize frequency of maternal, fetal, and infant outcomes among women with MS exposed to ocrelizumab during the 6 months before the estimated date of conception or at any time during pregnancy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

OCRELIZUMAB

---

**Anatomical Therapeutic Chemical (ATC) code**

(L04AG08) ocrelizumab

ocrelizumab

---

**Medical condition to be studied**

Multiple sclerosis

## 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)

Adults (46 to < 65 years)

---

## **Special population of interest**

Pregnant women

---

## **Estimated number of subjects**

455

# Study design details

## **Outcomes**

- Frequency of selected adverse pregnancy outcomes - Frequency of selected adverse fetal/neonatal/infant outcomes - Compare the maternal, fetal, and infant outcomes with unexposed comparator

---

## **Data analysis plan**

Descriptive statistics will be used to summarize the findings, specifically, overall frequency (prevalence, 95% CI) of selected adverse pregnancy outcomes will be calculated, as well as frequencies of specific outcomes.

Prevalence and associated 95% CIs will also be calculated for selected adverse fetal, neonatal, and infant outcomes at birth and through at least the first year of life of infants from pregnancies in women with MS exposed to ocrelizumab. The comparison to ocrelizumab-exposed women to the internal unexposed comparator will be performed using risk ratios (95% CIs) unadjusted and adjusted to relevant covariates, if sufficient number of outcomes are available.

# Documents

## Study results

[Final CSR, Study WA40063, , Published Output-1\\_Redacted.pdf](#) (400.98 KB)

---

## 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)

[Disease registry](#)

[Other](#)

---

### Data sources (types), other

Prospective patient-based data collection

## 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