Safety and Effectiveness of Ocrelizumab under Real World Conditions: a Non-Interventional Post Authorization Safety Study in Patients Diagnosed with Relapsing or Primary Progressive Multiple Sclerosis (CONFIDENCE)

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## Administrative details

#### **EU PAS number**

EUPAS22951

#### Study ID

47489

#### DARWIN EU® study

No

Germany

#### **Study description**

CONFIDENCE is a prospective, multicenter, non-interventional, long-term study collecting primary data in RMS and PPMS patients newly treated during their course of MS therapy with ocrelizumab, or selected MS DMTs (i.e., alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide), in routine clinical practice. To provide robust evidence on the safety and effectiveness profile of ocrelizumab, data from 3000 MS patients treated with ocrelizumab and 767 MS patients treated with other selected MS DMTs from approx. 185 neurological centers and practices in Germany are planned to be included.

#### Study status

Ongoing

## **Contact details**

#### **Study institution contact**

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Study contact

global.clinical\_trial\_registry@roche.com

#### Primary lead investigator

Dr. Sandra Blümich

Primary lead investigator

## Study timelines

#### **Date when funding contract was signed** Actual: 02/02/2018

Study start date Planned: 30/03/2018 Actual: 03/04/2018

Date of final study report Planned: 30/11/2030

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Hoffmann La Roche

# Study protocol

ML39632\_NI-PASS Confidence fv1.0\_2018-01-26\_Redacted.pdf(1.02 MB)

ML39632\_CONFIDENCE\_Protocol\_V6.0\_Redacted.pdf(2.37 MB)

# Regulatory

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

No

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

Not applicable

# Other study registration identification numbers and links

ML39632

## Methodological aspects

Study type

## Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Effectiveness study (incl. comparative)

#### Main study objective:

To assess the long-term safety, with special focus on the occurrence and characterization of uncommon AEs in patients with MS newly exposed to ocrelizumab.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

OCREVUS

#### Medical condition to be studied

Multiple sclerosis

## Population studied

#### Age groups

Adults (18 to < 46 years) Adults (46 to < 65 years) Adults (65 to < 75 years) Adults (75 to < 85 years) Adults (85 years and over)

### Estimated number of subjects

3767

# Study design details

#### Outcomes

Incidence and type of uncommon AEs (i.e. AEs with an incidence rate of at least 0.1% to 1% 1 to 10 out of 1000 patients or less) and death with primary and underlying causes in patients with MS newly exposed to ocrelizumab. - incidence and type of uncommon AEs and death with primary and underlying causes in patients with MS newly exposed to selected MS DMTs other than ocrelizumab -treatment success -proportion of patients with relapses - proportion of patients with CDP -time to onset of CDP and CDI -patient reported

outcomes -incidence of AEs, serious infections, malignancies, mortality rate due to malignancies

#### Data analysis plan

The primary endpoint will be analyzed for each combination of cohort treated with ocrelizumab, MS type and Safety Set. Frequencies of adverse events will be calculated based on MedDRA coding and presented with two-sided 95% Clopper-Pearson intervals. Analogously, the key secondary endpoint will be analyzed for the cohort treated with other DTMs. Effectiveness analyses will be conducted on each combination of cohort, MS type and Full Analysis Set. Secondary, exploratory and other endpoints will be analyzed descriptively. Depending on the endpoint, a logistic, negative binomial, linear or ANCOVA model will be fitted. Time-to-event data will be analyzed with Kaplan-Meier. Other safety analyses will be conducted analogously to the primary endpoint. For safety endpoints time adjusted analyses based on patient years will be performed. To investigate potential channeling effects, a sensitivity analysis of selected endpoints will be performed based on various time spans of patients enrolled.

## 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

#### 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