

# Long-Term Surveillance of Ocrelizumab Treated Patients With Multiple Sclerosis (MANUSCRIPT Study)

**First published:** 28/02/2019

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS28619

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### Study ID

31380

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### DARWIN EU® study

No

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### Study countries

 Australia

 Denmark

 France

 Germany

 Italy

 Sweden

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### Study description

This longitudinal observational study is part of the European Union (E.U.) risk management plan and is designed to further assess the long-term safety profile of ocrelizumab in the real world setting. The study will provide safety data for a 10 year period after ocrelizumab launch, specifically targeting the rate of SAEs, including serious infections and malignancies.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

[F. Hoffmann-La Roche](#)

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**Institution**

## Contact details

### Study institution contact

David Wormser [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**

David Wormser

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Actual: 01/06/2017

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### **Study start date**

Planned: 01/08/2019

Actual: 15/07/2019

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### **Data analysis start date**

Planned: 14/04/2028

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### **Date of final study report**

Planned: 31/01/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche

# Study protocol

[Protocol BA39730 ocrelizumab Final v1\\_approved\\_Redacted.pdf](#) (1.86 MB)

[Prot BA39730 ocrelizumab v1, Published\\_Redacted.pdf](#) (1.87 MB)

## 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

BA39730

## 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:**

The research question is to assess and characterize the long-term safety data from the use of ocrelizumab in patients with MS (overall and by MS type).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

OCRELIZUMAB

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**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)
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### **Estimated number of subjects**

0

## Study design details

### **Outcomes**

The primary objective is to estimate (overall and by MS type) the event rates of serious adverse events (SAEs), including malignancy and serious infections, following ocrelizumab treatment in patients with MS.

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### **Data analysis plan**

Data will be analyzed every 6 months. The number of safety events and unadjusted incidence rates with 95% confidence intervals will be provided for each treatment group, ocrelizumab and other DMTs, for each data source. For malignancy and Progressive multifocal leukoencephalopathy (PML), an ever-exposed model will be applied that includes all person-time observed since the first drug dose in the study until censorship. For all other SAEs a time-on-drug approach will be used. For analyses of death, both approaches will be used. Comparison between ocrelizumab and other DMTs, at year 4, 6, 8, and end of the study, will be based on a Cox proportional-hazards regression model adjusted for important covariates and probability of treatment with ocrelizumab.

## 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 source(s), other**

Multiple Sclerosis Documentation System 3D (MSDS3D) Germany, The Big MS Data (BMSD) Group, a collaboration of MS registries, France, Italy, Sweden Denmark, International registry MSBase Australia

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### **Data sources (types)**

[Disease registry](#)

## 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