

# Evaluation of autonomy and care experience in multiple sclerosis when initiating subcutaneous ocrelizumab

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|----------------------------------------|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>27/01/2026   | <b>Recruitment status</b><br>Recruiting              | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>27/01/2026 | <b>Overall study status</b><br>Ongoing               | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>04/02/2026       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Multiple sclerosis (MS) can significantly impact a patient's autonomy and quality of life. This study, called PEACE, observes patients with Relapsing-Remitting MS (RRMS) who are starting a new treatment formulation: ocrelizumab injected subcutaneously (under the skin). The main aim is to understand how this treatment affects patients' satisfaction, autonomy, and daily symptoms in a real-world setting.

### Who can participate?

Patients aged 18 years and over diagnosed with RRMS in France for whom their doctor has decided to prescribe subcutaneous ocrelizumab.

### What does the study involve?

Participants will follow their standard medical care. In addition, they will complete questionnaires on a smartphone or computer about their quality of life, symptoms, and treatment satisfaction before their first injection and then every 6 months for 2 years.

### What are the possible benefits and risks of participating?

As this is an observational study where patients receive standard care prescribed by their doctor, there are no additional medical risks associated with the study itself. There is no direct benefit, but participation helps improve understanding of MS treatments.

### Where is the study run from?

Roche (France)

### When is the study starting and how long is it expected to run for?

February 2026 to February 2029

### Who is funding the study?

Roche (France)

Who is the main contact?  
Dr David Pau, david.pau@roche.com

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## Additional identifiers

## Study information

**Scientific Title**

Patient Evaluation of Autonomy and Care Experience in multiple sclerosis when initiating ocrelizumab SC in real-world settings: the PEACE study

**Acronym**

PEACE

**Study objectives**

The primary objective is to describe the evolution of Health-Related Quality of Life (HRQoL) in patients initiating ocrelizumab SC, specifically assessing treatment satisfaction, autonomy, symptoms, and general health state.

Secondary objectives include comparing HRQoL over time, describing clinical effectiveness (disability progression, inflammatory activity), and assessing safety/tolerability in real-world conditions.

**Ethics approval required**

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**Ethics approval(s)**

Approved 20/01/2026, Comité de Protection des Personnes Ouest VI (CPP) (CHU Morvan 2 avenue Foch Bâtiment 1, Brest, 29200, France; +33 (0)230338064; cpp.ouest6@chu-brest.fr), ref: 25.03134.000445

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study type(s)**

## **Health condition(s) or problem(s) studied**

Relapsing-remitting multiple sclerosis (RRMS)

## **Interventions**

Adult patients with RRMS initiating ocrelizumab SC (920 mg) as part of their routine clinical care will be observed for 24 months. Data will be collected via electronic Case Report Forms (eCRF) and Patient Reported Outcomes (ePROs). Clinical data and questionnaires are collected at baseline (Day 0) and at 6, 12, 18, and 24 months post-initiation. The study observes two cohorts: patients switching from other therapies (Cohort A) and treatment-naïve patients (Cohort B).

## **Intervention Type**

Biological/Vaccine

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Ocrelizumab

## **Primary outcome(s)**

1. Autonomy measured using the Multiple Sclerosis Autonomy Scale (MSAS) at baseline, 6, 12, 18 and 24 months
2. Multiple sclerosis symptoms measured using the SymptoMScreen score at baseline, 6, 12, 18 and 24 months
3. Health state measured using the EQ-5D-5L health state score at baseline, 6, 12, 18 and 24 months
4. Treatment satisfaction measured using the Treatment Satisfaction Questionnaire for Medication (TSQM) at baseline, 6, 12, 18 and 24 months

## **Key secondary outcome(s)**

## **Completion date**

28/02/2029

## **Eligibility**

**Key inclusion criteria**

1. Diagnosis of RRMS according to the 2017 or 2024 revised McDonald criteria
2. Age 18 years or older
3. Initiation of ocrelizumab SC planned by the healthcare professional (either as a switch from specific prior therapies or in treatment-naïve patients)
4. Physically and cognitively able to complete the study questionnaires and tests
5. Possession of a smartphone, tablet, or computer with an internet connection
6. Non-opposition to participation and data processing

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

120 Years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Administration of ocrelizumab SC not in accordance with the standard of care or the current Summary of Product Characteristics (SmPC).
2. Patient under guardianship or judicial protection.

**Date of first enrolment**

09/02/2026

**Date of final enrolment**

01/02/2027

**Locations****Countries of recruitment**

France

**Sponsor information****Organisation**

Roche (France)

**ROR**

<https://ror.org/01mqmer16>

## **Funder(s)**

### **Funder type**

### **Funder Name**

Roche France

### **Alternative Name(s)**

Roche

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

France

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

Upon study completion and publication, qualified researchers may request access to individual patient level clinical data. Request will have to be send to: [data\\_sharing.france@roche.com](mailto:data_sharing.france@roche.com)

### **IPD sharing plan summary**

Available on request