

# Patient real-world clinical, neurological, tolerability, and safety outcomes for Tecfidera® and Rebif®: A retrospective study (PROTRACT)

**First published:** 03/03/2016

**Last updated:** 23/10/2018

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12652

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### Study ID

26260

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### DARWIN EU® study

No

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### Study countries

Canada

United States

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## Study description

The purpose of this study is to evaluate the proportion of patients who demonstrate no medical need to discontinue therapy among DMT-naïve patients with relapsing forms of multiple sclerosis after 1 year of treatment with Rebif 44 mcg tid or with Tecfidera 240 mg bid based on real-world data.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Real World Evidence Solutions, IMS Health

France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

**Institution**

Other

## Contact details

### Study institution contact

Gabriele Haas [gahaas@de.imshealth.com](mailto:gahaas@de.imshealth.com)

**Study contact**

[gahaas@de.imshealth.com](mailto:gahaas@de.imshealth.com)

### Primary lead investigator

Gabriele Haas

Primary lead investigator

## Study timelines

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

Planned: 31/08/2015

Actual: 27/10/2015

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### **Study start date**

Planned: 18/02/2016

Actual: 02/03/2016

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

Planned: 30/04/2017

Actual: 20/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

EMD Serono

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective is to evaluate the proportion of patients who demonstrate no medical need to discontinue therapy among Disease Modifying Therapy (DMT)-naïve patients with relapsing forms of Multiple Sclerosis (MS) after 1 year of treatment with Rebif 44 mcg tiw or with Tecfidera 240 mg bid.

## Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Medicinal product name**

REBIF

TECFIDERA

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## **Medical condition to be studied**

Relapsing-remitting multiple sclerosis

# Population studied

## **Short description of the study population**

Patients who demonstrate no medical need to discontinue therapy among DMT-naïve patients with relapsing forms of multiple sclerosis after 1 year of treatment with Rebif 44 mcg tiw or with Tecfidera 240 mg bid.

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## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Relapsing-remitting multiple sclerosis patients

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## Estimated number of subjects

500

## Study design details

### Outcomes

The primary outcome is "No medical need to discontinue therapy" defined as:1. No Evidence of Disease Activity (NEDA-2): A composite measure of (1) absence of relapses AND (2) no new or enlarging T2 or T1 gadolinium-enhancing lesions on Magnetic Resonance Imaging over the follow-up period.2. No discontinuation due to disease activity, tolerability, or adverse events during the follow-up, Evaluation of:1. Clinical and/or neurological differences (e.g. relapses, neurological lesions) between the two treatment groups.2. Proportion of individuals within each treatment group who discontinued treatment due to tolerability- to adverse events- to disease activity

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### Data analysis plan

observational, retrospective, longitudinal cohort study to assess effectiveness in the real world

## 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

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### **Data sources (types), other**

Medical chart review- Retrospective data is collected through an eCRF.

## 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