# TOP: Tysabri® Observational Program

**First published:** 29/03/2019

**Last updated:** 17/04/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS28580

**Study ID**

46161

**DARWIN EU® study**

No

**Study countries**

- [ ] Argentina
- [ ] Australia
- [ ] Belgium
- [ ] Canada
- [ ] Czechia
- [ ] Finland
- [ ] France

- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Mexico
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Slovakia
- [ ] Spain
- [ ] United Kingdom

**Study description**

The primary objective of this study is to assess the long-term safety and impact on disease activity and progression of natalizumab in participants with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Biogen

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

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

Institution

# Contact details

**Study institution contact**

Study Director Biogen ctrr@biogen.com

**Study contact**

ctrr@biogen.com

**Primary lead investigator**

Study Director Biogen

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Actual: 19/02/2007

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**Study start date**

Actual: 29/06/2007

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**Date of final study report**

Planned: 31/10/2024

Actual: 11/11/2024

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Biogen

# Study protocol

IMA-06-02 Protocol V9 Final 28NOV2022_Redacted.pdf(368.12 KB)

# Regulatory

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

No

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

IMA-06-02, NCT00493298

Link to Clinicaltrials.gov

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

**Main study objective:**

The primary objective of this study is to assess the long-term safety and impact on disease activity and progression of natalizumab in participants with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

TYSABRI

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

NATALIZUMAB

**Anatomical Therapeutic Chemical (ATC) code**

(L04AG03) natalizumab

natalizumab

**Medical condition to be studied**

Relapsing-remitting multiple sclerosis

## Population studied

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

**Estimated number of subjects**

6620

## Study design details

**Outcomes**

• Number of participants with serious adverse events (SAE)

• Annualized Relapse Rate (ARR)

• Time to first relapse

• Percentage of subjects with relapse

• Percentage of subjects with disability progression

• Percentage of subjects that reach Expanded Disability Status Score (EDSS) milestones

• Percentage of subjects whose EDSS worsened, stabilized or improved
• Evaluation of baseline disease characteristics
• Evaluation of short-term disease outcomes

**Data analysis plan**

All data will be summarized by presenting the frequency distributions for discrete endpoints and summary statistics (i.e. mean, standard deviation, median, and range) for continuous endpoints.

## Documents

**Study report**

IMA-06-02 CSR Synopsis Closeout Full V1 PASS Final 11Nov2024_Redacted.pdf (326.86 KB)

IMA-06-02 PASS CSR Synopsis Closeout Full V2 Final 03Mar2025__Redacted.pdf (421.87 KB)

# Data management

## 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