

# A Multicenter, Open-Label Safety Study of Natalizumab administered to Subjects with Relapsing Forms of Multiple Sclerosis who participated in STRATA

**First published:** 28/03/2019

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28992

---

### Study ID

36709

---

### DARWIN EU® study

No

---

### Study countries

 Belgium

---

### Study description

The primary objective for this study is long-term safety (incidence and pattern of serious adverse events) in subjects receiving natalizumab. The secondary objective is to evaluate the long-term efficacy of natalizumab in delaying the progression of disability, reducing the frequency of relapses, decreasing the disease activity observed by magnetic resonance imaging (MRI), and the evaluation of the quality of life and cognitive function in patients on treatment with natalizumab for more than 8 years.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Biogen

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

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

Institution

Multiple centres: 4 centres are involved in the study

## Contact details

### **Study institution contact**

Study Director Biogen [ctr@biogen.com](mailto:ctr@biogen.com)

Study contact

[ctr@biogen.com](mailto:ctr@biogen.com)

### **Primary lead investigator**

Study Director Biogen

Primary lead investigator

## Study timelines

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

Actual: 08/10/2014

---

### **Study start date**

Actual: 10/12/2014

---

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

Actual: 05/03/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

# Study protocol

BEL-TYS-14-

[10675\\_Tysabri\\_Protocol\\_11Aug14\\_final6811801528117131664\\_Redacted.pdf](#)

(2.35 MB)

## Regulatory

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

No

---

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

Non-EU RMP only

## Other study registration identification numbers and links

BEL-TYS-14-106752014-003669-97 <https://www.clinicaltrialsregister.eu/ctr-search/search?query=bel-tys-14-10675>

## Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

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

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The primary objective for this study is long-term safety (incidence and pattern of SAEs) in patients receiving natalizumab. The primary objective is to evaluate the safety of natalizumab in patients with Relapsing Forms of Multiple Sclerosis who were included in STRATA and did not meet reimbursement criteria upon termination of STRATA.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Prospective, non-interventional, multicenter, open label long-term safety study

## Study drug and medical condition

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

NATALIZUMAB

---

### **Medical condition to be studied**

Relapsing-remitting multiple sclerosis

## **Population studied**

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

Patients with relapsing-remitting Multiple sclerosis (MS) who participated in STRATA, had stable disease for at least 7 years during STRATA, and did not meet reimbursement criteria for Tysabri® in Belgium, upon termination of the STRATA study.

Inclusion Criteria:

1. Had the ability to understand the purpose and risks of the study and provided signed and dated informed consent and any authorizations required by local law in accordance with national and local subject privacy regulations.
2. Had participated in the STRATA study, had stable disease and did not meet reimbursement criteria for natalizumab (Tysabri®) in Belgium, upon termination of the STRATA study.
3. Were  $\geq 18$  years old.
4. Patients of child bearing potential had to practice effective contraception during the study and be able to continue contraception for 3 months after their last infusion.

Exclusion Criteria:

1. Patients participating in STRATA who were in line with current Belgian reimbursement criteria when they started in one of the feeder studies (Affirm or Sentinel).
2. Patients with any significant change in clinical status that, in the

opinion of the Investigator, would have made them unsuitable to participate in this study. The Investigator had to review the patient's medical fitness for participation and consider any diseases that would have precluded treatment.

3. Patients that were unwilling or unable to comply with study requirements, or were deemed unsuitable for study participation as determined by the Investigator. 4. Female patients who were considering becoming pregnant while in the study.

5. Female patients of childbearing potential who were not using the appropriate contraception as determined by the Investigator.

6. Female patients who were currently pregnant or breastfeeding.

7. Any prescheduled elective procedure during the study period that, in the opinion of the Investigator, would have interfered with study parameters.

8. Any other condition, clinical finding, or reason that, in

---

### **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)
- 

### **Special population of interest**

Other

---

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

Multiple sclerosis patients

---

### **Estimated number of subjects**

10

## **Study design details**

## Outcomes

- The primary endpoint of the open label study is the incidence of AEs and SAEs.
- Disability progression
- MS disease activity
- JCV status
- Frequent MRI monitoring
- Quality of life measurement by EQ-5D
- Cognitive evaluation by Symbol Digit Modalities Test (SDMT)

---

## Data analysis plan

The purpose of this study is to evaluate the safety and efficacy of natalizumab in patients with Relapsing Forms of Multiple Sclerosis who were included in STRATA and did not meet reimbursement criteria upon termination of STRATA. The study will also evaluate the long-term effectiveness of natalizumab in delaying the progression of disability, reducing the frequency of relapses, and MRI activity during long-term treatment with natalizumab. Quality of Life measurements and cognitive evaluations will be measured on a 6-monthly basis.

## Documents

### Study results

[BEL-TYS-14-10675\\_CSR Synopsis\\_10 Aug 2020.pdf](#) (400.95 KB)

---

## 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