

# JCV Antibody Program in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with Tysabri: STRATIFY-2

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

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

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/48119>

---

### **EU PAS number**

EUPAS28923

---

### **Study ID**

48119

---

### **DARWIN EU® study**

No

---

## Study countries

United States

---

## Study description

The primary objective of this study is to demonstrate that the incidence of progressive multifocal Leukoencephalopathy (PML) in natalizumab-treated participants who do not have detectable antibodies to John Cunningham virus (JCV) (antibody negative) is lower than in participants who have detectable antibodies to JCV (antibody positive). The secondary objectives of this study are to: Estimate the incidence of PML in natalizumab-treated participants who are anti-JCV antibody negative and anti-JCV antibody positive, based on a meta-analysis of data obtained from this study and other data sources, Define the prevalence of anti-JCV antibody in relapsing multiple sclerosis (MS) participants receiving natalizumab within the TYSABRI Outreach: United Commitment to Health (TOUCH) Prescribing Program, Determine changes in anti-JCV antibody status over time.

---

## 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

Study contact

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

### Primary lead investigator

Study Director Biogen

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 12/02/2010

---

### Study start date

Actual: 31/03/2010

---

### Date of final study report

Actual: 01/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

## Study protocol

## 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

101JC402,NCT01070836

<https://clinicaltrials.gov/ct2/show/NCT01070836?term=101jc402&rank=1>

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

---

#### **Study type:**

Non-interventional study

---

**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The primary objective of this study is to demonstrate that the incidence of progressive multifocal Leukoencephalopathy (PML) in natalizumab-treated participants who do not have detectable antibodies to John Cunningham virus (JCV) (antibody negative) is lower than in participants who have detectable antibodies to JCV (antibody positive).

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Observational, longitudinal

## Study drug and medical condition

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

NATALIZUMAB

---

## **Medical condition to be studied**

Multiple sclerosis

## **Population studied**

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

The study involved the US patients with relapsing multiple sclerosis receiving commercial Tysabri. Patients may participate in other clinical studies sponsored by Biogen Idec or Elan, however, if the anti-JCV antibody test is included in another study, they should withdraw from STRATIFY-2.

The incidence of progressive multifocal leukoencephalopathy in Tysabri-treated patients was also analysed.

Inclusion criteria:

- All patients who are enrolled and have provided at least one serum sample will be included in the analysis

---

### **Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**

Patients with progressive multifocal leukoencephalopathy

---

### **Estimated number of subjects**

35895

## **Study design details**

### **Outcomes**

- Demonstrate that the incidence of PML in natalizumab-treated participants who do not have detectable antibodies to JC virus (JCV) (antibody negative) is lower than in patients who have detectable antibodies to JCV (antibody positive),
  - Estimate the incidence of PML in natalizumab-treated participants who are anti-JCV antibody negative and anti-JCV antibody positive
  - Define the prevalence of anti-JCV antibody in relapsing MS participants receiving natalizumab within the TOUCH Prescribing Program
  - Determine changes in anti-JCV antibody status over time
- 

### **Data analysis plan**

All appropriate background data will be summarized by presenting frequency distribution and/or basic summary statistics. The incidence of PML in patients testing anti-JCV antibody positive and in those testing, negative will be presented separately and compared using a 1-sided Fisher's Exact Test. The percentage of patients who have tested anti-JCV antibody positive will be presented for those receiving Tysabri in the TOUCH Prescribing Program and for those who are interested in or are considering beginning Tysabri treatment. In addition, the percentage of patients who have anti-JCV antibody status changes from negative to positive over time will be presented. The data from this study will be analyzed separately and in combination with the data from the STRATIFY-1 study (Biogen Idec study 101JC401).

## **Documents**

## Study results

[101JC402 CSR Synopsis V1 Section 2 Final 01Dec2016\\_\\_Redacted.pdf\(296.2 KB\)](#)

---

## 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