

An observational study utilising data from the US Tysabri TOUCH programme and select EU MS Registries to estimate the risk of progressive multifocal leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabri

**First published:** 23/01/2018

**Last updated:** 24/02/2025

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/48270>

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### EU PAS number

EUPAS19800

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**Study ID**48270

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**DARWIN EU® study**No

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**Study countries**☐ United States

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**Study description**

The primary purpose of this study is to estimate the incidence of progressive multifocal leucoencephalopathy (PML) among patients who switched to Tysabri from disease modifying therapies (DMTs), including newer DMTs (including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs (interferon beta and glatiramer acetate). Researchers will also look to estimate the incidence of other serious opportunistic infections among patients who switch to Tysabri from newer DMTs (including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs (interferon beta and glatiramer acetate)

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**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**

Planned: 01/12/2016

Actual: 05/12/2016

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### **Study start date**

Planned: 24/01/2018

Actual: 01/06/2017

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

Planned: 31/12/2024

Actual: 16/09/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

## Study protocol

[101MS411 Protocol V2 Final 26Jan2022\\_Redacted.pdf](#) (1.09 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

101MS411, Clinicaltrials.gov ID: NCT03399981, Clinicaltrials.gov

URL: <https://clinicaltrials.gov/ct2/show/NCT03399981?id=101ms411&rank=1>

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To estimate the incidence of progressive multifocal leucoencephalopathy(PML) among patients who switched to Tysabri from disease modifying therapies(DMTs), including newer DMTs(including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs(interferon beta and glatiramer acetate)

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Patient Registry Study

## Study drug and medical condition

**Name of medicine**

TYSABRI

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

NATALIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AG03) natalizumab

natalizumab

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**Medical condition to be studied**

Progressive multifocal leukoencephalopathy

Multiple sclerosis

## Population studied

**Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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)

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**Estimated number of subjects**

80327

## Study design details

## Outcomes

To estimate the incidence of progressive multifocal leucoencephalopathy (PML) among patients who switched to Tysabri from disease modifying therapies (DMTs) and to estimate the incidence of other serious opportunistic infections among patients who switch to Tysabri from newer DMTs and the established DMTs.

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## Data analysis plan

Risk Estimation

## Documents

### Study report

[101MS411 CSR Synopsis V1 PASS Final 16Sep2024\\_Redacted.pdf](#) (541.13 KB)

## Data management

## Data sources

### Data sources (types)

[Disease registry](#)

## 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