

# A Retrospective, Multi-Center, Observational Study to Assess the Effect of Tecfidera® Delayed-Release Capsules on Lymphocyte Subsets in Subjects with Relapsing Forms of Multiple Sclerosis (REALIZE)

**First published:** 24/10/2016

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9336

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### Study ID

29107

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### DARWIN EU® study

No

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### Study countries

## Study description

The primary objective of the study is to retrospectively investigate changes in lymphocyte counts and lymphocyte subtypes, with a focus on CD4+ and CD8+ T cells, in participants on Tecfidera therapy for at least 6 months. The secondary objective is to investigate changes in lymphocyte subtypes other than CD4+ and CD8+ T cells.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Biogen](#)

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

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

**Institution**

[Multiple centres: 10 centres are involved in the study](#)

## Contact details

### **Study institution contact**

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

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: 27/03/2015

Actual: 27/01/2015

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### **Study start date**

Planned: 01/07/2015

Actual: 21/07/2015

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### **Data analysis start date**

Actual: 19/04/2016

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

Planned: 14/11/2016

Actual: 25/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

## Study protocol

[109MS419 Protocol V2 Final 03Dec2015\\_Redacted.pdf](#) (618.42 KB)

## Regulatory

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

No

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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

109MS419/NCT02519413: <https://clinicaltrials.gov/ct2/show/NCT02519413>

## 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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of the study is to retrospectively investigate changes in lymphocyte counts and lymphocyte subtypes, with a focus on CD4+ and CD8+ T cells, in participants on Tecfidera therapy for at least 6 months.

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Retrospective, observational study

## Study drug and medical condition

**Medicinal product name**

TECFIDERA

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**Medical condition to be studied**

Multiple sclerosis

## Population studied

**Short description of the study population**

Adult patients with relapsing forms of MS who were receiving or received Tecfidera for at least 6 months in routine clinical practice.

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**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)
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**Special population of interest**

Other

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**Special population of interest, other**

Multiple sclerosis patients

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**Estimated number of subjects**

483

## Study design details

## Outcomes

- Estimated absolute lymphocyte count (ALC) change from baseline following Tecfidera initiation
- Estimated CD4+ count change from baseline following Tecfidera initiation
- Estimated CD8+ count change from baseline following Tecfidera initiation
- Raw absolute counts for leukocyte, lymphocyte, CD4+/CD8+ ratio following Tecfidera initiation
- Raw absolute counts for additional lymphocyte subsets (other than CD4+ and CD8+)
- Change from baseline for leukocyte, lymphocyte, CD4+/CD8+ ratio following Tecfidera initiation
- Change from baseline for additional lymphocyte subsets (other than CD4+ and CD8+) following Tecfidera initiation

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## Data analysis plan

For the primary analysis changes from baseline in Lymphocyte, CD4, and CD8 counts will be analyzed separately using a repeated measures mixed effects model (RMMM). In addition descriptive statistics will be presented for at 6 and 12 Months for absolute values, the change and percent change from baseline. Kaplan-Meier curves will estimate the time to pre-determined lymphocyte counts following the start of Tecfidera therapy. An analysis of covariance and logistic regression models will be evaluated to determine potential predictors of low lymphocyte counts. Descriptive statistics will be used to summarize lymphocyte counts and subsets post discontinuation. Similar analyses will be performed for the additional lymphocyte subsets and CD4/CD8 ratio. The association between opportunistic and serious infections and WBC, lymphocytes, CD4 as well as CD8 counts will be evaluated with a Fisher's exact and Barnard's exact test.

## Documents

### Study results

[109MS419 CSR Synopsis\\_Redacted.pdf](#) (93.07 KB)

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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

Retrospective medical chart abstraction This retrospective chart review study aims to investigate the effect of Tecfidera on lymphocytes and lymphocyte subsets, to observe lymphocyte recovery following Tecfidera discontinuation, and to assess the incidence of opportunistic infections, serious infections, and MS relapses

## 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**

Unknown