

# Claims Database Study of Utilization Patterns of Dimethyl Fumarate in Germany

**First published:** 13/10/2017

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/29058>

---

### EU PAS number

EUPAS21305

---

### Study ID

29058

---

### DARWIN EU® study

No

---

### Study countries

Germany

---

## Study description

The primary objective of this study is to estimate the proportion of DMF use that is prescribed "on-label" versus "off-label". The secondary objectives are: To describe the demographic characteristics and medical history of DMF users, To describe prescription drug history and concomitant medication use of DMF users, To describe the duration of therapy in participants newly initiating DMF treatment, To describe the medical specialties of DMF prescribers.

---

## 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: 06/10/2014

Actual: 15/10/2014

---

### **Study start date**

Actual: 01/09/2013

---

### **Data analysis start date**

Actual: 31/12/2016

---

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

Planned: 02/10/2017

Actual: 20/10/2017

## 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?**

Yes

---

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

109MS409

NCT02969304<https://clinicaltrials.gov/ct2/show/NCT02969304?term=NCT02969304&rank>

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

---

#### **Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

The primary objective of this study is to estimate the proportion of DMF use that is prescribed “on-label” versus “off-label”.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Retrospective analysis of a research database

## Study drug and medical condition

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

DIMETHYL FUMARATE

---

**Medical condition to be studied**

Multiple sclerosis

## Population studied

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

All patients who were users of dimethyl fumarate (DMF) in the post launch study period were retrieved from the database.

Patients were included in the study if they satisfied the following eligibility criteria:

1. Treatment initiation with DMF on or after 1 March 2014 without a previous prescription for DMF in the 6 months prior to the index date
- 

### **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**

Multiple sclerosis patients

---

### **Estimated number of subjects**

500

## **Study design details**

## **Outcomes**

Proportion of dimethyl fumarate use that is prescribed "on-label" versus "off-label" in Germany. Demographic characteristics of dimethyl fumarate (DMF) users, Prescription drug history of DMF users, duration of therapy in participants newly initiating DMF treatment, number of medical specialists prescribing DMF as identified according to specialty-specific billing codes at outpatient visits, medical history of DMF users, concomitant medication use of DMF users.

---

## **Data analysis plan**

This study is strictly descriptive (i.e. no hypothesis testing is being conducted). Demographic characteristics, concomitant medication, medication history, time on DMF and specialty of prescribing physician will be analysed separately by "on-label" or "off-label" use. All statistical analyses will be reported in a descriptive manner. Continuous data will be described by their mean, standard deviation, median, minimum, and maximum. Categorical data will be described by absolute and relative frequencies. A detailed description of the statistical analysis will be provided in the statistical analysis plan.

## **Documents**

### **Study results**

[109MS409\\_ EUPASResultsPacket\\_Redacted.pdf](#)(259.01 KB)

---

## **Data management**

## **Data sources**

## **Data sources (types)**

Administrative healthcare records (e.g., claims)

## 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**

Unknown