

# ANALYSIS OF TREATMENT PATTERNS WITH DISEASE MODIFYING THERAPIES (DMTs) AMONG PATIENTS WITH MULTIPLE SCLEROSIS

**First published:** 11/07/2022

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Study

Planned

## Administrative details

### EU PAS number

EUPAS48105

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### Study ID

48106

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### DARWIN EU® study

No

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### Study countries

 Italy

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### Study status

Planned

## Research institutions and networks

## Institutions

### University of Pisa

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

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

**Institution**

### Center for Public Health Research (CESP), University of Milan Bicocca

 Italy

**First published:** 09/03/2015

**Last updated:** 11/05/2026

**Institution**

**Educational Institution**

**ENCePP partner**

## Contact details

### Study institution contact

Ersilia Lucenteforte [ersilia.lucenteforte@unipi.it](mailto:ersilia.lucenteforte@unipi.it)

**Study contact**

[ersilia.lucenteforte@unipi.it](mailto:ersilia.lucenteforte@unipi.it)

### Primary lead investigator

Ersilia Lucenteforte

Primary lead investigator

## Study timelines

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

Planned: 01/03/2022

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### **Study start date**

Planned: 01/09/2022

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

Planned: 31/07/2023

## Sources of funding

- Other

## More details on funding

University

## Study protocol

[Multiple\\_Sclerosis\\_treatment\\_DU\\_07\\_07\\_2022.pdf](#) (1.79 MB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

#### **Main study objective:**

- To estimate the population-based yearly prevalence, incidence, and consumption of disease modifying therapies (DMTs), - To describe the treatment patterns of DMTs in Multiple sclerosis patients, - To estimate the impact of demographic and clinical characteristics on the relationship between DMTs specific exposure and treatment patterns (i.e. switches, interruptions, and drug discontinuations)

## Study Design

#### **Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L03AX13) glatiramer acetate

glatiramer acetate

(L04AA31) teriflunomide

teriflunomide

(L04AX07) dimethyl fumarate

dimethyl fumarate

(L04AA27) fingolimod

fingolimod

(L04AA23) natalizumab

natalizumab

(L04AA36) ocrelizumab

ocrelizumab

(L04AA34) alemtuzumab

alemtuzumab

(L01BB04) cladribine

cladribine

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## **Medical condition to be studied**

Multiple sclerosis

## **Population studied**

### **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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### **Estimated number of subjects**

3000

## Study design details

### **Outcomes**

- Prevalence, incidence, and consumption of disease modifying therapies (DMTs) in the study period, - Treatment patterns during follow-up: continuers, discontinuers, interrupters, switchers and mixed users.

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### **Data analysis plan**

- Incidence, prevalence, and consumption of DMTs use will be estimated yearly during the study period. - Subjects will be grouped according to the first DMT dispensed in the study period. Then, each subject will be defined according to their treatment patterns observed during the follow-up. Finally, demographic, and clinical characteristics at the index date, as well as treatment patterns observed during the follow-up, will be summarized through standard descriptive statistic for each drug group. - For each DMT new user, treatment patterns during the entire follow-up will be plotted by using the Sankey diagram. - Recurrent events models and time-varying variables will be used to estimate the impact of the demographic and clinical covariates on the relationship between DMTs specific exposure and study outcomes (discontinuation and switch/interruption). Results will be expressed as Hazard Ratio (HR) with 95%

CI.

## 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 source(s)

ARS Toscana

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### 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

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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