

# Definition and validation of algorithms for the identification of specific clinical markers of multiple sclerosis using SNDS data (DIONISOS)

**First published:** 12/07/2023

**Last updated:** 15/03/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS104596

---

### Study ID

104597

---

### DARWIN EU® study

No

---

### Study countries

 France

---

### Study description

Multiple sclerosis (MS) is an incapacitating, progressive, chronic neurological disorder that involves a selective, chronic inflammation and demyelination of the central nervous system. The severity of the disease varies from mildly forms to severe disabilities within a few years. Relapsing-remitting MS forms (RRMS) are the most common, and are characterized by the presence of relapses without disability progression between relapses. A complex algorithm for identifying MS relapses has been developed using SNDS data SNDS, and has been validated within the database using the sequence of patient care consumption in the SNDS. This is an original method that would benefit from external validation using clinical data. In this context, a validation study comparing clinical data of MS patients registered in the OFSEP database between 2010 and 2019 linked to the SNDS via probabilistic matching will be performed. The main objective is to evaluate and improve the diagnostic performance of an MS relapse identification algorithm developed from SNDS data using OFSEP clinical data linked to SNDS data as an external data source. Secondary objectives are to: - Develop and validate an SNDS algorithm to identify the level of MS-related motor disability and its evolution, - Develop and validate an SNDS algorithm to identify the level of disability specific to sphincter impairment and its evolution.

---

## **Study status**

Planned

## Research institutions and networks

### Institutions

University of Bordeaux



France

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

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

**Institution**

**Educational Institution**

## Contact details

### Study institution contact

Laure Carcaillon-Bentata [plateforme.bpe@u-bordeaux.fr](mailto:plateforme.bpe@u-bordeaux.fr)

**Study contact**

[plateforme.bpe@u-bordeaux.fr](mailto:plateforme.bpe@u-bordeaux.fr)

### Primary lead investigator

Laure Carcaillon-Bentata

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 23/03/2023

---

### Study start date

Planned: 15/09/2023

---

### Date of final study report

Planned: 31/12/2023

## Sources of funding

- Other

## More details on funding

Health Data Hub

## Regulatory

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

No

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

---

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

Other

#### **If 'other', further details on the scope of the study**

Algorithms validation

**Main study objective:**

The main objective is to evaluate and improve the diagnostic performance of an MS relapse identification algorithm developed from SNDS data using OFSEP clinical data linked to SNDS data as an external data source.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**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)

---

**Estimated number of subjects**

4500

## Study design details

## Data analysis plan

The statistical analysis will be performed using the SAS software (latest current version), following a detailed statistical analysis plan. The following analyses will be performed: - a description of patient selection, - a description of initial patient characteristics, - for each algorithm (relapses, motor disability, disability specific to sphincter impairment): an estimate of the algorithm's sensitivity and diagnostic performance

## 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), other

SNDS database France, OFSEP database France

---

### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Other](#)

---

### Data sources (types), other

Exposure registry

## 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