

# A real-world observational study of treatment patterns and outcomes for patients with neuromyelitis optica spectrum disorders (NMOSD) treated with inebilizumab (UPLIZNA) in Europe

**First published:** 25/03/2024

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000084

### Study ID

1000000084

### DARWIN EU® study

No

### Study countries

☐ France

☐ Germany

- ☐ Italy
  - ☐ Netherlands
  - ☐ Spain
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## **Study description**

The overall research questions for this study are: 1) What are the demographic, clinical, and treatment characteristics of a population of patients who initiate inebilizumab in real-world practice? 2) What are inebilizumab treatment patterns in the first 12 months following treatment initiation? 3) What is the incidence of adverse events of special interest (AESI) in the first 12 months following treatment initiation?

Specific objectives are:

- To describe demographic, clinical and treatment characteristics of patients at the time of first inebilizumab treatment
- To describe inebilizumab treatment patterns in the first 12 months following treatment initiation in terms of dosing, duration of treatment, frequency of drug discontinuation, switching, and use of add-on therapies
- To quantify the incidence of AESI, including serious infections, opportunistic infections, hepatitis B reactivations, serious infusion related reactions, and malignancies.

Analyses will be performed in the overall study population and in sub-groups of special interest: patients concomitantly receiving other immunosuppressive agents and patients aged >65 years at index date.

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## **Study status**

Planned

## **Research institutions and networks**

## Institutions

### Global Database Studies, IQVIA

- ☐ Czechia
- ☐ Finland
- ☐ Germany
- ☐ Slovakia
- ☐ Spain

**First published:** 17/01/2011

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**Institution**

**Other**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

### Primary lead investigator

Ana Cristina Santos

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 17/08/2022

Actual: 17/08/2022

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**Study start date**

Planned: 30/04/2024

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**Date of final study report**

Planned: 31/12/2028

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

[HZNP-UPL-402 Protocol\\_v2.0\\_clean\\_17Feb2023\\_redacted.pdf](#)(1.08 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)

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

A non-interventional multi-center cohort study of patients initiating inebilizumab conducted with secondary data sources in France, Germany, Italy, the Netherlands, and Spain.

**Main study objective:**

This study aims to characterize patients who initiate inebilizumab, describe treatment patterns and incidence of adverse events of special interest (AESI) in the first 12 months following treatment initiation.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

UPLIZNA

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

INEBILIZUMAB

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

(L04AA47) inebilizumab

inebilizumab

(L04AG10) inebilizumab

inebilizumab

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## **Medical condition to be studied**

Neuromyelitis optica spectrum disorder

# Population studied

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

The study population will be identified in national healthcare administrative databases, claim databases and disease-specific registries and will include adult (18 years old or more at the index date) female and male patients diagnosed with NMOSD and initiating inebilizumab during the study period.

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## **Age groups**

Adult and elderly population ( $\geq 18$  years)

Adults (18 to  $< 65$  years)

Adults (18 to  $< 46$  years)

Adults (46 to  $< 65$  years)

Elderly ( $\geq 65$  years)

Adults (65 to  $< 75$  years)

Adults (75 to  $< 85$  years)

Adults (85 years and over)

## 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)

Système National des Données de Santé (French national health system main database)

PHARMO Data Network

The Information System for Research in Primary Care (SIDIAP)

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### Data source(s), other

Observatoire Français de la Sclérose en Plaques (OFSEP)

Gesetzliche Krankenversicherung (GKV)

Registro Italiano Sclerosi Multipla e Patologie Correlate (RISM)

## 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