

# Nation-wide health resource consumption and costs associated with mepolizumab (Nucala): a French SNDS database study (Resala)

**First published:** 06/01/2021

**Last updated:** 14/03/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS38868

---

### Study ID

38869

---

### DARWIN EU® study

No

---

### Study countries

 France

---

### Study description

Currently, no study has addressed real-life data describing changes in health resource consumption and related costs attributable to mepolizumab treatment. The aim of the current study is to fill this knowledge gap by performing an exhaustive extraction of data for patients receiving mepolizumab in the French single-payer health care system. The change in real-life health-resource usage and costs observed for these patients would provide the first evidence that mepolizumab is changing the care landscape for eligible severe asthma patients. The overall objectives of this study are: (i) using the SNDS French national database, to identify a representative, nation-wide population of patients treated with mepolizumab with a follow-up period of at least 12 months, (ii) to describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment and (iii) to estimate the change in associated costs for the first year of treatment. These initial data will additionally serve as a basis for the design of longer-term studies.

---

### **Study status**

Planned

## Research institutions and networks

### Institutions

#### Plateforme A3TOS

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

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

**Institution**

## Contact details

### **Study institution contact**

Carey Suehs careysuehs@protonmail.com

Study contact

[careysuehs@protonmail.com](mailto:careysuehs@protonmail.com)

### **Primary lead investigator**

Nicolas Molinari

Primary lead investigator

## Study timelines

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

Planned: 31/08/2020

Actual: 31/08/2020

---

### **Study start date**

Planned: 01/02/2021

---

### **Data analysis start date**

Planned: 01/02/2021

---

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

Planned: 30/06/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK

## Study protocol

[Resala\\_protocol\\_2020-05-14\\_for\\_public\\_release.pdf](#) (478.12 KB)

## Regulatory

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

No

---

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

Not applicable

## Other study registration identification numbers and links

<https://osf.io/zg3us/,,NCT04550780>

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Main study objective:**

(i) using the SNDS French national database, to identify a representative, nation-wide population of patients treated with mepolizumab with a follow-up period of at least 12 months, (ii) to describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment and (iii) to estimate the change in associated costs for the first year of treatment.

## Study drug and medical condition

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

MEPOLIZUMAB

---

**Medical condition to be studied**

Asthma

---

**Additional medical condition(s)**

We will be extracting data for all persons prescribed Mepolizumab.

## Population studied

**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)
- 

### **Estimated number of subjects**

2813

## Study design details

### **Outcomes**

- To estimate the change in associated costs for the first year of treatment

Total health care costs for the year preceding the initiation of mepolizumab, as well as for the year after.

- To describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment

Cumulative estimates for health resource use and associated costs for the year preceding the initiation of mepolizumab, as well as for the year after.

- To further characterize rates of change in health resource usage and/or costs in subpopulations of interest
- 

### **Data analysis plan**

Differences between the two study periods will be presented with their 95% confidence intervals, as well as significance testing for paired data. Changes in total costs with time will also be visually presented using mean cumulative function step curves. The cost rate curve (ie the slope of the mean cumulative cost curve) will be determined by a 28-day sliding window for the

demonstration of changes in the speed of accumulating costs. Mean cumulative functions describing the difference between baseline and exposure periods can be computed. For the latter, the elapsed time at which the 95% confidence interval no longer contains zero indicates differences in cumulative costs. Similarly, mean cumulative functions for events of interest (specific health resource usages or associated costs found to differ before versus after T0) can be computed.

## 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 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**

No