

# A post-authorisation safety study (PASS) to describe real-world safety and effectiveness of NUCALA (mepolizumab) in paediatric eosinophilic granulomatosis with polyangiitis (EGPA) patients in Europe (218065)

**First published:** 03/11/2022

**Last updated:** 30/10/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS49460

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### Study ID

49461

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### DARWIN EU® study

No

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### Study countries

-  France
  -  Germany
  -  Italy
  -  Spain
  -  United Kingdom
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### Study description

This multinational, multi-site, case-series will aim to collect data on real-world safety and effectiveness of up to 24 months after the initiation of mepolizumab treatment in paediatric EGPA patients in Europe. In addition, demographic and relevant medical history data will be collected up to 12 months prior to the first dose of mepolizumab.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

**GlaxoSmithKline (GSK)**

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

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

**Institution**

### Contact details

### **Study institution contact**

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### **Primary lead investigator**

GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

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

Actual: 18/10/2021

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### **Study start date**

Planned: 04/06/2024

Actual: 07/02/2024

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

Planned: 12/08/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK

# Study protocol

[49466.pdf](#) (1.29 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 topic:**

Human medicinal product

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##### **Study type:**

Non-interventional study

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

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of this study is to describe the real-world safety of mepolizumab treatment in paediatric EGPA patients aged 6 to 17 years in terms of AEs, SAEs, pregnancy exposures and medical device incidents.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Case-series

## Study drug and medical condition

**Medicinal product name**

NUCALA

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

MEPOLIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(R03DX09) mepolizumab

mepolizumab

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**Medical condition to be studied**

## Population studied

### Age groups

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
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### Estimated number of subjects

10

## Study design details

### Data analysis plan

Data from this study will be described per patient as a case series, as the sample size will be insufficient to perform statistical analyses or summarise across patients.

## 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)**

Other

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### **Data sources (types), other**

medical records

## **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