

# 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:** 09/08/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/49461>

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### 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

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: 25/04/2031

## 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 type:**

Non-interventional study

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

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

**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

**Name of medicine**

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**

Eosinophilic granulomatosis with polyangiitis

## 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

### Data sources

#### **Data sources (types)**

[Other](#)

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

Prospective patient-based data collection

## 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