

# Post-Authorisation Safety Study (PASS) to Evaluate the Risk of Malignancies in Patients with Myasthenia Gravis (MG) Treated with Efgartigimod

**First published:** 03/02/2026

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000915

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### Study ID

1000000915

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### DARWIN EU® study

No

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### Study countries

 France

 United Kingdom

 United States

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## Study description

This is a multinational, longitudinal database cohort study which aims to assess the risk of malignancy in patients with MG exposed to at least one dose of efgartigimod compared to MG patients with no record of exposure to efgartigimod by analysing data from three claims databases. The reference cohort will consist of patients with a diagnosis code for MG without efgartigimod exposure but are on any other therapy for the treatment of MG during the study period.

Patients will be followed from study entry to at least 10 years following inclusion in the study.

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## Study status

Planned

## Research institutions and networks

### Institutions

[argenx BV](#)

## Contact details

### Study institution contact

Sabine Coppieters [clinicaltrials@argenx.com](mailto:clinicaltrials@argenx.com)

[Study contact](#)

[clinicaltrials@argenx.com](mailto:clinicaltrials@argenx.com)

### Primary lead investigator

argenx BV

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 08/09/2023

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### Study start date

Planned: 01/09/2026

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### Data analysis start date

Planned: 01/09/2026

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### Date of final study report

Planned: 01/09/2039

## Study protocol

[ARGX-113-PASS-2316-protocol malignancy v1.0 24July2025\\_Redacted.pdf](#) (1.69 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 topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

Post-Authorization Safety Study (PASS)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

This is a non-interventional, longitudinal database cohort post authorisation safety study.

**Main study objective:**

To evaluate the long-term risk of malignancies overall and by type in patients with MG treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the lookback period, in a real-world setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

VYVGART

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

EFGARTIGIMOD ALFA

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA58) efgartigimod alfa

efgartigimod alfa

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**Medical condition to be studied**

Myasthenia gravis

## Population studied

**Short description of the study population**

The study will identify two cohorts from each selected database:

- Efgartigimod Cohort: Patients with an MG diagnosis and who have initiated efgartigimod.
  - Reference Cohort: Patients with an MG diagnosis and who have not initiated efgartigimod but are on any other therapy for the treatment of MG. Immunoglobulins and plasmapheresis are not considered here, as they are usually used for acute management of MG crisis.
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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)
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## **Estimated number of subjects**

4074

## **Study design details**

### **Setting**

The observational study will identify two cohorts from each targeted database:

- Efgartigimod Cohort: Patients with an MG diagnosis and who have initiated efgartigimod.
- Reference Cohort: Patients with an MG diagnosis and who have not initiated efgartigimod but are on any other therapy for the treatment of MG.

Immunoglobulins and plasmapheresis are not considered here, as they are usually used for acute management of MG crisis.

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### **Outcomes**

- Long-term risk of malignancies overall and by type in patients with MG treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the lookback period, in a real-world setting.
- Long-term risk of malignancies overall and by type in MG patients with malignancy history in the lookback period.
- Long-term risk of malignancies by duration of efgartigimod exposure.
- Long-term risk of malignancies in subpopulations with increased risk for malignancy: elderly (age 65 years and older); chronic use (i.e.,  $\geq$ 1 year) of

corticosteroids.

## 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.

## 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