# Prospective observational study of Fremanezumab (Ajovy™) effectiveness in chronic and episodic migraine patients in clinical routine: FINESSE study

**First published:** 08/12/2021

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS44606

**Study ID**

48417

**DARWIN EU® study**

No

**Study countries**

- ☐ Austria
- ☐ Germany

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Ludwig-Maximilians-University Munich

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

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**Institution**

## Contact details

**Study institution contact**

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**Primary lead investigator**

Xenia Hamann

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 03/09/2019

**Study start date**
Planned: 18/11/2019

Actual: 18/11/2019

**Date of final study report**
Planned: 31/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva GmbH

## 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

Paul-Ehrlich-Institut (PEI) NIS-number 506

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

To evaluate the effectiveness of fremanezumab administered in adult patients with chronic migraine (CM) or episodic migraine (EM) who have at least 4 migraine days per month, including the proportion of patients reaching at least 50% reduction in the monthly average number of migraine days, during the 6-month period after the first dose of fremanezumab, in real-world clinical practice.

## Study drug and medical condition

**Medical condition to be studied**

Migraine

## Population studied

**Age groups**

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)

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**Estimated number of subjects**

1000

## Study design details

**Outcomes**

The proportion of patients reaching at least 50% reduction in the monthly average number of migraine days during the 6-month period after the first dose of fremanezumab. Please refer to study protocol section 5.3.2. (Primary and Secondary Endpoints).

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**Data analysis plan**

All treatment period timepoints will be defined in relation to each patient’s first dose of fremanezumab, regardless of their time of enrollment. All outcomes will be reported using summary statistics. No sensitivity analyses are planned. Interim analyses are planned.

# 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

**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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No