

# A prospective, non-interventional study of the effectiveness, safety, and health related outcomes in patients with moderate to severe active rheumatoid arthritis receiving filgotinib (FILOSOPHY)

**First published:** 14/04/2021

**Last updated:** 05/09/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS39767

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### Study ID

48323

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### DARWIN EU® study

No

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### Study countries

 Belgium

 Germany

 Italy

 Netherlands

 Spain

 United Kingdom

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## Study description

To describe the effectiveness, safety, and patient-reported outcomes in patients with moderate to severe active rheumatoid arthritis receiving filgotinib in real-world setting.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Alfasigma

 Italy

**First published:** 30/08/2024

**Last updated:** 30/08/2024

**Institution**

**Pharmaceutical company**

## Contact details

### Study institution contact

Monia Zignani Monia.Zignani@alfasigma.com

Study contact

[Monia.Zignani@alfasigma.com](mailto:Monia.Zignani@alfasigma.com)

### Primary lead investigator

Monia Zignani

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 06/04/2021

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### Study start date

Actual: 11/05/2021

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### Date of final study report

Planned: 30/06/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Alfasigma S.p.A

## Regulatory

## Was the study required by a regulatory body?

No

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

Not applicable

## Other study registration identification numbers and links

ClinicalTrials.gov Identifier: <https://clinicaltrials.gov/ct2/show/NCT04871919>

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### **Main study objective:**

To evaluate the treatment persistence rate at 24 months, defined as the rate of patients continuing to receive filgotinib 24 months from treatment initiation.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

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

FILGOTINIB MALEATE

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### **Medical condition to be studied**

Rheumatoid arthritis

## 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**

1304

## Study design details

### **Outcomes**

Treatment persistence rates at 24 months, Throughout the study: rates of AE and SAE during 24 months, patients' assessment of pain (Pain VAS), patients' assessment of fatigue (FACIT-F score), patients' assessment of work productivity (WPAI-RA), disease activity (DAS28CRP and/or CDAI), medication adherence (CQR19 and CQR5), patients' assessment of Rheumatoid Arthritis Impact of Disease (RAID).

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### **Data analysis plan**

In general, for continuous variables, descriptive summary statistics will be provided including number of patients (N), mean, standard deviation (SD), minimum, median, and maximum, together with the number of missing values. Categorical variables will be summarized with counts and percentages, with missing values as separate category. Incidence rates and 95% confidence intervals (CIs) will be provided. Demographics and baseline characteristics will be summarized using descriptive statistics.

## 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**

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