

# Non-interventional, post-authorization prospective safety study of filgotinib in patients with moderately to severely active ulcerative colitis: a European multi registry-based study

**First published:** 08/11/2023

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS106566

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### Study ID

108231

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### DARWIN EU® study

No

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### Study countries

 Netherlands

 Spain

## Study description

This study aims to further evaluate the long-term safety (LTS) of filgotinib in the treatment of patients with moderately to severely active ulcerative colitis (UC) under real-world conditions, specifically with respect to important identified and potential risks listed in the Jyseleca® risk management plan (RMP). This non-interventional, post-authorization, prospective, multi-country registry-based safety cohort study is being conducted based on real-world data derived from 3 inflammatory bowel disease (IBD) registries, namely the Nationwide Study on Genetic and Environmental Determinants of Inflammatory Bowel Disease (ENEIDA) Register from Spain (ES), the Initiative on Crohn's and Colitis (ICC) Register from the Netherlands (NL), and the Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG).

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## Study status

Ongoing


## Research institutions and networks


### Institutions


#### RTI Health Solutions (RTI-HS)


 France

 Spain

 Sweden

 United Kingdom

 United Kingdom (Northern Ireland)

 United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution

Not-for-profit

ENCePP partner

## Alfasigma

 Italy

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

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

Institution

Pharmaceutical company

## Networks

ENEIDA (ES), ICC (NL), SWIBREG (SE)

## Contact details

### Study institution contact

Joan Fortuny [jfortuny@rti.org](mailto:jfortuny@rti.org)

Study contact

[jfortuny@rti.org](mailto:jfortuny@rti.org)

## Primary lead investigator

Joan Fortuny

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 18/01/2023

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### Study start date

Actual: 01/05/2023

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### Date of interim report, if expected

Planned: 30/06/2028

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### Date of final study report

Planned: 09/04/2032

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Alfasigma S.p.A

## Study protocol

[glpg0634-cl-413-protocol-redacted.pdf](#) (6.07 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)

## Other study registration identification numbers and links

GLPG0634-CL-413

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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

This study aims to further evaluate the LTS of filgotinib in the treatment of patients with moderately to severely active UC under real-world conditions, specifically with respect to important identified and potential risks listed in the Jyseleca® risk management plan (RMP).

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Medicinal product name

JYSELECA

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

FILGOTINIB MALEATE

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### Anatomical Therapeutic Chemical (ATC) code

(L04AA45) filgotinib

filgotinib

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### Additional medical condition(s)

Moderately to severely active ulcerative colitis

## 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

1200

## Study design details

## **Outcomes**

Estimate incidence rates (IRs) following RMP-listed risks: serious and opportunistic infections, herpes zoster, and primary varicella infection, major adverse cardiovascular events (MACE), venous thromboembolism (VTE), pulmonary embolism (PE), hyperlipidemia, malignancy, nonmelanoma skin cancer (NMSC), gastrointestinal (GI) perforation, fractures and all-cause mortality. Describe patients' baseline characteristics. Estimate IRs of the endpoints in comparator cohorts provided by each registry. Estimate the hazard ratios (HRs) of the identified and potential risks listed above between patients treated with filgotinib (Cohort 1) and comparator Cohort 2, and Cohort 3 assuming sufficient statistical power.

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## **Data analysis plan**

All statistical analyses will be performed by each registry or its local contracted scientific partner. Regular reports adhering to a predefined format will be provided by each registry to the marketing authorization holder (MAH) at 24-month intervals after enrolment is opened to filgotinib-treated patients in the 3 participating countries. The progress reports will be provided as part of the PSUR. The final analysis will be conducted after reaching the end of study period and will summarize descriptive statistics for patients initiating filgotinib as well as for patients in the other cohorts. Depending on adequate statistical power and comparability between the filgotinib cohort and the advanced therapy Cohort 2 and the immunosuppressant/immunomodulator therapy Cohort 3 in relation to their underlying risk of outcome development, comparative analysis between patients exposed to filgotinib and patients in the advanced therapy Cohort 2 and Cohort 3 will be performed in the final analysis.

## **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 source(s), other

- Estudio Nacional en Enfermedad Inflamatoria intestinal sobre Determinantes genéticos y Ambientales (Nationwide study on genetic and environmental determinants of inflammatory bowel disease) (ENEIDA), Spain;
  - Initiative on Crohn's and Colitis (ICC), Netherlands;
  - Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG), Sweden.
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### Data sources (types)

[Disease registry](#)

[Other](#)

## 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