

# Non-interventional post-authorization prospective cohort study evaluating the effectiveness of the additional risk minimization measures for filgotinib (Jyseleca®) use in patients with ulcerative colitis: a European multi registry-based study

**First published:** 19/06/2024

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

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/1000000206>

### EU PAS number

EUPAS1000000206

### Study ID

1000000206

## **DARWIN EU® study**

No

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### **Study countries**

☐ Netherlands

☐ Spain

☐ Sweden

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### **Study description**

This longitudinal drug utilization study (DUS) aims to evaluate the effectiveness of the additional risk minimization measures (aRMMs) by assessing how healthcare professionals (HCPs) prescribe filgotinib for the treatment of patients with ulcerative colitis. This non-interventional, post-authorization, prospective, multi-country registry-based cohort study is being conducted based on real-world clinical data derived from 3 European 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

Rachel Weinrib

Study contact

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

### Primary lead investigator

Rachel Weinrib

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 18/01/2023

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### Study start date

Actual: 25/01/2024

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### Date of interim report, if expected

Planned: 31/12/2027

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### Date of final study report

Planned: 29/03/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Alfasigma S.p.A

## Study protocol

[glpg0634-cl-417-protocol-redacted.pdf](#) (5.6 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-417

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

This longitudinal DUS aims to evaluate the effectiveness of the additional risk minimization measures (aRMMs) by assessing how HCPs prescribing filgotinib adhere to the updated filgotinib Summary of Product Characteristics (SmPC) and HCP Guide with a specific focus on aRMMs.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

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**

(L04AF04) filgotinib

filgotinib

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**Medical condition to be studied**

Colitis ulcerative

## Population studied

**Age groups**

Adults (18 to < 65 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**

1500

## Study design details

**Outcomes**

The study will include baseline and follow-up information relevant for the specific aRMM as well as information on the distribution of risk factors indicative of a high risk of major adverse cardiovascular event (MACE), venous thromboembolism (VTE), malignancy, or serious and opportunistic infections.

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**Data analysis plan**

The patients' baseline and follow-up characteristics will be summarized to assess adherence to the aRMMs with a focus on posology, contraindications,

special warnings and precautions, monitoring, as well as the proportion of patients at high risk of major adverse cardiovascular event (MACE), venous thromboembolism (VTE), malignancy, or severe and opportunistic infections. Data will be summarized using univariable descriptive statistical methods. Categorical variables will be summarized by number and percentage of patients in each categorical definition including 95% confidence intervals (CIs). Continuous variables will be summarized descriptively (mean, standard deviation, and median, lower quartile, upper quartile, minimum, maximum, 95% CIs). All statistical analyses will be performed by each registry or its local contracted scientific service provider.

## Data management

### 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

### 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