# A prospective, non-interventional, multi-country cohort study of the effectiveness and safety of filgotinib in adult patients with moderately to severely active ulcerative colitis (GALOCEAN)

**First published:** 11/04/2023

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

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS50214

**Study ID**

105477

**DARWIN EU® study**

No

**Study countries**

- [ ] Austria
- [ ] Belgium

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

**Study description**

To describe the effectiveness, treatment patterns, quality of life, and safety of patients with moderately or severely active ulcerative colitis treated with filgotinib in a real-world setting

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Alfasigma

- [ ] Italy

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

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Institution | Pharmaceutical company

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Monia Zignani

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Actual: 31/05/2022

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**Study start date**

Actual: 12/06/2023

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**Date of final study report**

Planned: 31/12/2027

# 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

# 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 describe the real-world clinical treatment persistence in adult patients with moderately or severely active UC treated with filgotinib for approximately 52 weeks in routine clinical practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

FILGOTINIB MALEATE

**Medical condition to be studied**

Colitis ulcerative

# 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)

**Estimated number of subjects**

600

# Study design details

**Outcomes**

Treatment persistence rate at week 52, Treatment persistence rate at weeks 10 and 24, Clinical response rate, Clinical remission rate, change from baseline in Health-Related Quality of Life (HRQoL) as measured by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), Urgency Numeric Rating Scale (NRS), and Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F), rate of AE and SAE during 52 weeks

**Data analysis plan**

In general, data analysis will be descriptive and use summary statistics. Continuous variables will include the number of patients (N), mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum, together with the number of missing values. Categorical variables will include numbers and percentages, with missing values as separate category. Descriptive summary statistics will be conducted for all effectiveness measurements, as well as baseline characteristics, demographics, medical and treatment histories, HRU, AEs, and HRQoL. More advanced analysis (e.g. time-to-event, change from baseline) may also be conducted.

# Data management

## 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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No