

# A network meta-analysis of real-world studies comparing tofacitinib with other advanced therapies in the treatment of moderate-to-severe ulcerative colitis

**First published:** 15/01/2024

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/199008>

### EU PAS number

EUPAS108141

### Study ID

199008

### DARWIN EU® study

No

### Study countries

United States

### Study description

The study is designed as a NMA (network meta-analysis) with the primary objective to compare the effectiveness of tofacitinib with other advanced therapies in real-world studies for the treatment of patients with moderate-to-severe UC (ulcerative colitis). The secondary objective of the study is to compare the safety outcomes as IR assessed through a meta-analysis of tofacitinib and other advanced therapies in real-world studies of patients with moderate-to-severe UC. These analyses will be performed on data collected from studies published in literature in the form of a systematic literature review (SLR) and no patient

enrollment will be done.

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## Study status

Ongoing

## Research institution and networks

### Institutions

**Pfizer**

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

Last updated 01/02/2024

Institution

**ConnectHEOR Limited**

## Contact details

### Study institution contact

Milena Gianfrancesco

Study contact

[Milena.Gianfrancesco@pfizer.com](mailto:Milena.Gianfrancesco@pfizer.com)

### Primary lead investigator

Milena Gianfrancesco

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual:

06/11/2023

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### Study start date

Planned:

17/01/2024

Actual:  
16/01/2024

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### Date of final study report

Planned:  
30/04/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921447\\_Non-Interventional Study Protocol V1.0\\_2Jan2024\\_FINAL -R.pdf\(306.43 KB\)](#)

## 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:**

Not applicable

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**Main study objective:**

To compare the effectiveness and safety of tofacitinib with other advanced therapies in real-world studies for the treatment of patients with moderate-to-severe UC.

## Study drug and medical condition

### Name of medicine

Xeljanz

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

TOFACITINIB CITRATE

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### Medical condition to be studied

Colitis ulcerative

## Population studied

### Short description of the study population

A total of 246 studies will be included in this network meta analysis; the actual number of patients in each study will be determined after data analysis.

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### 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

1

## Study design details

### Outcomes

1. To estimate the difference in the likelihood of achieving a clinically meaningful response, in terms of effectiveness outcomes, between patients treated with tofacitinib compared to other advanced therapies. 2. To estimate the relative risk of serious adverse events (AEs) between patients treated with tofacitinib versus other advanced therapies Are there secondary outcomes?, 1. To estimate the incidence rate (IR) of various AEs, and of mortality, on each therapy.

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## Data analysis plan

In the following, two approaches have been planned to performing the NMA, (i) contrast-based models which perform the synthesis of data on relative treatment effects between study arms, and (ii) arm-based models which perform the synthesis of data on absolute effects across study arms. Both approaches can be applied to estimate an overall pooled relative effect.

# Data management

## Data sources

### Data sources (types)

Other

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### Data sources (types), other

Electronic biomedical literature databases

## 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