

# Uveitis in chronic inflammatory conditions and ulcerative colitis-related pyoderma gangrenosum and axial spondylarthritis: an observational study of patients receiving advanced therapies in the United States

**First published:** 18/01/2024

**Last updated:** 19/08/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107604

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### Study ID

199002

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### DARWIN EU® study

No

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### Study countries

 United States

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## **Study description**

Tofacitinib is a Janus kinase (JAK) inhibitor approved for 5 indications in the US(United States): adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), adults with moderately to severely active ulcerative colitis (UC), adults with active ankylosing spondylitis (also known as radiographic axSpA). Data on tofacitinib clinical efficacy in anterior uveitis (AU) from the clinical trial program across all the indications, and pyoderma gangrenosum (PG) and axial spondylarthritis (axSpA) in the UC clinical trial program, is very limited due to study design, inclusion criteria, and baseline characteristics of the different study populations, which would not allow to perform a post-hoc analysis for these outcomes. In the last years, however, several case reports and small observational studies have highlighted the potential beneficial use of JAK inhibitors (including tofacitinib) in treating uveitis as an extra-musculoskeletal or extra-intestinal manifestations, such as AU, PG, and axSpA. In addition, there is an ongoing phase 3 trial assessing the clinical effectiveness of another JAK inhibitor, baricitinib, in JIA-associated uveitis. This non-interventional study aims to provide data on the comparative clinical effectiveness of advanced therapies on incidence of AU among several chronic inflammatory conditions (UC, PsA and axSpA) as well as incidence of PG and axSpA in patients with UC. The results are intended to provide useful information to healthcare professionals and patients in real-world clinical decision making on treatment choice for patients with these conditions.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

Pfizer

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Institution

Komodo Health

## Contact details

### Study institution contact

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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: 11/11/2023

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### Study start date

Planned: 31/01/2024

Actual: 01/08/2024

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### **Data analysis start date**

Planned: 15/04/2024

Actual: 31/12/2024

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### **Date of final study report**

Planned: 01/06/2025

Actual: 13/08/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921444\\_NIS\\_protocol\\_Cross\\_indication\\_uveitis\\_\\_EIM\\_12Jan2024.pdf](#) (5.6 MB)

[A3921444\\_NIS\\_Protocol\\_V2.0\\_31-May-2024.pdf](#) (211.32 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 topic:**

Disease /health condition

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

**Main study objective:**

This non-interventional study aims to provide data on the comparative clinical effectiveness of advanced therapies on incidence of uveitis among several chronic inflammatory conditions, as well as incidence of pyoderma gangrenosum and axial spondylarthritis in patients with ulcerative colitis (UC).

### Study Design

**Non-interventional study design**

Cohort

### Study drug and medical condition

**Medicinal product name**

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**

Axial spondyloarthritis

Colitis ulcerative

Psoriatic arthropathy

## Population studied

**Short description of the study population**

All individuals meeting study entry criteria will be included in the analysis.

Estimated number of patients will be updated 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)

## Study design details

**Outcomes**

To estimate the distributions of demographic and clinical characteristics among patients with inflammatory conditions on tofacitinib and other advanced treatments. To estimate crude incidence rates and hazard ratios of anterior uveitis among patients with inflammatory conditions, and pyoderma gangrenosum and axial spondylarthritis in UC patients on tofacitinib and other treatments. To examine the stratified incidence rates and adjusted hazard ratios of anterior uveitis and pyoderma gangrenosum by previous history of uveitis and pyoderma gangrenosum, respectively.

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### **Data analysis plan**

Number of events, person-years at risk, and crude incidences will be calculated for each outcome. IRs for select safety events will be calculated with person-time at risk starting on the index date and ending on the date of a censoring event: 1) death, 2) end of study period, 3) the event of interest, 4) treatment switch, 5) treatment discontinuation (+ 90 days), or 6) end of enrollment in the database. IRs per 100 person-years will be calculated based on the number of new events divided by the sum of the duration of patient exposures from the index date to censoring date during the risk period. Hazard ratios will be estimated using an inverse probability (IP) weighted Cox proportional hazards model with time since treatment start as timescale. IP weighting will be used to control for potential confounding variables at baseline, and selected based on a priori knowledge and statistical properties of the cohorts under study.

## Documents

### **Study report**

[A3921444 Non-Interventional-Low-Interventional Study Type 1 Study Report\\_Redacted.pdf](#) (567.61 KB)

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**

Komodo Health United States

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## 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