

# Risk of Safety Events Among Patients with UC and PsA Treated with Tofacitinib and Other Advanced Treatments in the United States

**First published:** 19/04/2023

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Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/105306>

### EU PAS number

EUPAS103443

### Study ID

105306

### DARWIN EU® study

No

### Study countries

United States

### Study description

This non-interventional study aims to provide additional information about incidence rates for specific safety outcomes in ulcerative colitis and psoriatic arthritis populations in routine clinical practice in the United States.

### Study status

Ongoing

## Research institution and networks

# Institutions

**Pfizer**

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Institution

## 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

Planned:

28/10/2022

Actual:

28/10/2022

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### Study start date

Planned:

31/03/2023

Actual:

19/04/2023

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### Date of final study report

Planned:

30/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921431 Non-Interventional Study Protocol v1.0 \(PASS\)\\_22 February 2023\\_Redacted.pdf\(1005.83 KB\)](#)

[A3921431 Non-Interventional Study Protocol v2.0 22Nov2023 Redacted.pdf\(204.84 KB\)](#)

## 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:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Other

**If 'other', further details on the scope of the study**

Incidence rates of select safety outcomes

**Main study objective:**

This non-interventional study aims to provide additional insights into incidence rates of select safety outcomes in ulcerative colitis and Psoriatic arthritis populations using active comparator groups in routine clinical practice in the United States.

## Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

### Name of medicine

Xeljanz

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### Medical condition to be studied

Colitis ulcerative

Psoriatic arthropathy

## 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

1

## Study design details

### Outcomes

Primary outcomes in this study include incidence rates in patients on tofacitinib and other forms of advanced treatment of the following safety events: major adverse cardiovascular events, venous thromboembolic disease (defined as deep vein thrombosis and pulmonary embolism), malignancy (excluding non-melanoma skin cancer) and serious infections.

Estimates of safety events will be stratified by the following factors: 1. Age: younger than 50 years or at least 50 years and older 2. Age: younger than 65 years or at least 65 years and older 3. Systemic glucocorticoid use at baseline 4. Previous biologic or other advanced

treatment used prior to baseline 5. History of major adverse cardiovascular events or venous thromboembolic diseases

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### **Data analysis plan**

This is a descriptive analyses. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan. Baseline demographic and clinical characteristics will be tabulated among the two cohorts of patients (ulcerative colitis and Psoriatic arthritis), and each exposure category within the disease cohorts. Incidence rates 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. Statistical methods for propensity score matching will be detailed in the statistical analysis plan. Hazard rates will be estimated using an inverse probability weighted Cox proportional hazards model with time since treatment start as timescale.

## Documents

### **Study, other information**

[A3921431 Non Interventional PASS ABSTRACT 22Feb2023\\_Redacted.pdf](#)(323.73 KB)

## Data management

### Data sources

#### **Data source(s), other**

Optum's Clinformatics United States, Komodo Health United States

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

[Administrative data \(e.g. claims\)](#)

## 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