An Active Surveillance, Post-Authorization Study to Characterize the Safety of Tofacitinib in Patients With Moderately to Severely Active Ulcerative Colitis in the Real-World Setting Using Data From the United Registries for Clinical Assessment and Research (UR-CARE) in the European Union (EU)

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Last updated: 24/03/2026

Study Planned

Administrative details

EU PAS number

EUPAS103632

Study ID

103633

DARWIN EU® study

No

Study countries

Belgium
Bulgaria
Croatia
France
Greece
Netherlands
Poland
Romania
Slovenia
Spain

Study description

Tofacitinib, an inhibitor of the Janus kinase (JAK) family of kinases, was approved in the European Union (EU) in July 2018 at a dose of 5 mg twice daily or 10 mg twice daily for the treatment of adults with moderate-to-severe ulcerative colitis (UC), who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. Malignancy excluding non-melanoma skin cancer (NMSC) is an important potential risk and venous thromboembolism (VTE) is an important identified risk associated with the use of tofacitinib, and follow-up of large cohorts of patients over a long period is needed to evaluate the risks of these safety events, as well as other potential safety events of interest, that may be associated with tofacitinib treatment. Pfizer will implement a post-approval, active surveillance study of tofacitinib-exposed and unexposed patients using actively collected prospective data included in the UR-CARE platform.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Networks

United Registries for Clinical Assessment and Research (UR-CARE)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2020

Actual: 18/11/2020

Study start date
Planned: 31/01/2024

Date of interim report, if expected
Planned: 31/08/2024

Date of final study report
Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921352_TOFACITINIB UC PASS PROTOCOL_V4.0_ 27FEB2023.pdf (605.65 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a 7-year active cohort study of adult UC patients aged ≥18 years treated with tofacitinib compared to patients receiving alternative treatment or no treatment. The study will use secondary data collected in the UR-CARE

platform.

Main study objective:

What are the incidence rates of safety events of interest in adult ulcerative colitis (UC) patients aged ?18 years treated with tofacitinib in routine clinical care, as compared to the incidence rates in UC patients treated with other approved systemic agents, and UC patients naïve to biologics and immunomodulators/immunosuppressants (hereafter referred to as immunosuppressants)?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XELJANZ

Anatomical Therapeutic Chemical (ATC) code

(L04AF01) tofacitinib

tofacitinib

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

The study population will include adult UC patients aged ≥18 years enrolled in UR-CARE who are initiating treatment with tofacitinib (Cohort 1) from 01 July 2018 (date of approval of tofacitinib for UC patients in the EU) through 31 March 2025.

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

500

Study design details

Setting

The UR-CARE platform is set up for daily care use (i.e. individual sites may upload patient information directly onto the UR-CARE platform) and contains medical records, including identifying data, of patients from multiple EU and non-EU countries.

Comparators

The study will also include the following comparator cohorts: Cohort 2: UC patients who
initiate biologics, with/without concurrent

immunomodulators/immunosuppressants, stratified on TNFi/non-TNFi use and number of previous biologic treatments; Cohort 3: UC patients who initiate immunomodulators/immunosuppressants without concurrent biologics; Cohort 4: UC patients naïve to both biologics and immunomodulators/immunosuppressants.

Outcomes

Estimate the incidence rates of malignancy and VTE (deep venous thrombosis DVT and pulmonary embolism PE) among adult UC patients years who initiate tofacitinib in the course of routine clinical care, as well as the incidence rates in UC patients treated with other approved systemic agents such as biologics and immunosuppressants, and in UC patients naïve to biologics and immunosuppressants, Estimate incidence rates of other safety events among adult UC patients who initiate tofacitinib in the course of routine clinical care, in UC patients treated with other approved systemic agents, and in comparator cohorts. Estimate incidence rates of primary and secondary safety events of interest stratified by tofacitinib dose.

Data analysis plan

Baseline demographic and clinical characteristics for each cohort, including proportion of patients with ?1 VTE risk factors will be described. For all the safety events of interest, descriptive statistics, counts and proportions, unadjusted cumulative incidence proportions, and crude incidence rates (i.e. number of events per person-years) and age/sex standardized incidence rates with associated 2-sided 95% confidence intervals will be calculated as appropriate. The estimated incidence rates will be based on survival analysis of time to first event based on an index date defined for each cohort with appropriate censoring rules applied for those who do not experience an event by end of follow-up period.

Documents

Abstract of study report

A3921352_PROGRESS REPORT_16FEB2026.pdf (566.98 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

United Registries for Clinical Assessment and Research (UR-CARE) Austria

Data sources (types)

Disease registry

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