# A Long-Term, Observational Study within the Corrona Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting

**First published:** 28/06/2019

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS30314

**Study ID**

34556

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The goal of the study is to characterize the safety of tofacitinib (all approved formulations) in ulcerative colitis (UC) patients in the post-approval setting. The primary outcome of interest is malignancy, excluding non-melanoma skin (NMSC).

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Pfizer

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

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Institution

# 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**
Actual: 07/03/2019

**Study start date**
Planned: 30/06/2019

Actual: 30/06/2019

**Date of interim report, if expected**
Planned: 30/06/2024

**Date of final study report**
Planned: 31/12/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

Final_Protocol_A3921329_Tofacitinib UC Corrona PASS_6.5.2019_REDACTED.pdf

(928.31 KB)

FINAL_Protocol_A3921329_Tofacitinib UC Corrona PASS_1.24.2020_REDACTED.pdf (690.08 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

A3921329

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The primary objective is to assess the incidence of malignancy, excluding non-melanoma skin cancer (NMSC), in adult UC patients exposed to tofacitinib (all approved formulations) in the course of routine clinical care compared to other medications approved to treat UC.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**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

**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**

6.858

# Study design details

**Outcomes**

Malignancy, excluding non-melanoma skin cancer (NMSC) in adult UC patients exposed to tofacitinib (all approved formulations) in the course of routine clinical care compared to other medications approved to treat UC, NMSC, opportunistic infections, major adverse cardiac events, thromboembolic events (deep venous thrombosis and pulmonary embolism), hepatic events (serious or requiring liver biopsy), serious infections, herpes zoster, progressive multifocal leukoencephalopathy, gastrointestinal perforations, surgery for UC and all-cause mortality

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**Data analysis plan**

Counts and proportions, unadjusted cumulative incidence proportions, unadjusted incidence rates (number of events/person-years) and associated two-sided 95% confidence intervals will be calculated as appropriate and compared between groups for all safety outcomes. Pending data availability, subgroup analyses (disease severity, tofacitinib dose, prior treatment group and/or comorbidity status) may be performed. The primary summary of reporting rates of events will be based on survival analysis of time to first event based on an index date defined for each population with appropriate censoring rules applied for those who do not experience an event by end of follow-up period. Rates will be expressed as events/100 person-years of follow-up. A Cox regression model will be estimated to analyze time to first event for each safety outcome and compare rates of events between the tofacitinib study population and two defined comparator groups (biologics and immunosuppressant groups).

# 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 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