

An active surveillance, post-authorization safety study (PASS) of serious infection, malignancy, cardiovascular and other safety events of interest among patients treated with tofacitinib for moderately to severely active rheumatoid arthritis within the British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA) (Safety of tofacitinib in BSRBR-RA)

**First published:** 05/09/2019

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

**EU PAS number**

EUPAS31126

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**Study ID**

49434

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## **DARWIN EU® study**

No

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### **Study countries**

 United Kingdom

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### **Study description**

Tofacitinib is a potent, selective inhibitor of the Janus kinase (JAK) family of kinases with a high degree of selectivity relative to other kinases in the human genome. Tofacitinib was approved in the European Union (EU) in March 2017 at a dose of 5 mg administered twice daily (BID) for the treatment of adult patients with moderately to severely active RA who have responded inadequately to, or who are intolerant to, one or more disease modifying antirheumatic drugs (DMARDs). To enable assessment of adverse outcomes of special interest including rare events and endpoints with long latency periods, Pfizer will implement a post approval, active surveillance study of tofacitinib exposed patients using actively collected prospective data in BSRBR RA. Research question: Research Question: What are the rates of safety events of special interest in RA patients treated with tofacitinib in relation to other new advanced targeted therapies?

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### **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**

[michelle.iannacone@pfizer.com](mailto:michelle.iannacone@pfizer.com)

### Primary lead investigator

Andrea Leapley

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 08/05/2018

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### Study start date

Actual: 01/09/2019

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### Date of interim report, if expected

Planned: 14/03/2021

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### Date of final study report

Planned: 14/08/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921312\\_PROTOCOL\\_BSRBR\\_PASS\\_v1.0 20 August 2019.doc.pdf](#) (2.02 MB)

[A3921312\\_PROTOCOL VERSION 3.0\\_14Feb2022.pdf](#) (526.64 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)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To evaluate the rates of serious infections, malignancy, cardiovascular, and other specified outcomes among patients with RA in a United Kingdom (UK) based register who initiate tofacitinib. Rates will also be estimated among RA patients who initiate other tumour necrosis factor inhibitor (TNFi) drugs (ie, patients receiving Humira (adalimumab), Enbrel (etanercept), or Remicade (infliximab))

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

[XELJANZ](#)

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**Medical condition to be studied**

Rheumatoid arthritis

## 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**

500

## Study design details

### **Data analysis plan**

The initial analyses will consist of descriptive comparisons of baseline status and crude event rates between the different cohorts. The final analysis of endpoints will provide the rates of events overall and in subgroups defined by baseline characteristics. Pending feasibility, rates of malignancy, serious infection, CV and other event rates will be compared between tofacitinib treated RA patients and the comparator cohorts using methods that adjust for sex, age, year of treatment start, treatment history, disease severity, comorbidities, and other potential confounders.

## 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)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

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### Data source(s), other

BSRBR - Rheumatic and Musculoskeletal conditions

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### Data sources (types)

[Disease registry](#)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

## 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