

# An Active Surveillance, Post Authorization Safety Study (PASS) of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Interest among Patients Treated with Tofacitinib for Moderately to Severely Active Rheumatoid Arthritis (RA) within the Swedish, Population based, Anti Rheumatic Treatment in Sweden (ARTIS) register. (Safety of tofacitinib in ARTIS)

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

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

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/49403>

### EU PAS number

EUPAS31157

### Study ID

49403

### DARWIN EU® study

No

### Study countries

Sweden

## Study description

Rationale and Background: 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 milligrams (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 safety events 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 included in the ARTIS register. Research Question: What are the rates of safety events of special interest in RA patients treated with tofacitinib and among RA patients treated with other advanced targeted therapies?

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## Study status

Ongoing

# Research institution and networks

## Institutions

**Pfizer**

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Institution

## Contact details

### Study institution contact

Shahar Shmuel

Study contact

[shahar.shmuel@pfizer.com](mailto:shahar.shmuel@pfizer.com)

### Primary lead investigator

Andrea Leapley

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual:

28/05/2018

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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

[A3921314 Final Non-Interventional Protocol, 20 August 2019.doc.pdf](#)(2.12 MB)

[A3921314\\_PROTOCOL- ARTIS PASS \\_V4.0\\_22FEB2023.pdf](#)(581.11 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 estimate the rates of serious infections, malignancy, CV and other safety events of interest among patients with RA in Sweden who initiate tofacitinib. Rates will also be estimated among RA patients who initiate biologic DMARDs (bDMARDs), bDMARD and targeted synthetic DMARD (tsDMARD) naïve RA patients, and the general population to provide context for tofacitinib rates.

## 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**

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**

344

## Study design details

## Data analysis plan

descriptive summaries of baseline variables and crude rates of safety event of interest included in ARTIS. An interim and final analysis of endpoints will describe the rates of events overall with supplemental linked data. Pending feasibility, comparative, adjusted analyses that control for sex, age, year of treatment start, treatment history, disease severity, comorbidities, and other potential confounders will be performed for a final report

## Documents

### Study, other information

[A3921314\\_PROTOCOL VERSION 3.0\\_14Feb2022.pdf](#)(864.22 KB)

## Data management

### Data sources

#### Data source(s)

National Prescribed Drugs Register / Läkemedelsregistret

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#### Data source(s), other

The Swedish prescribed drug register

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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