

# A Retrospective Database Study to Evaluate Rates of Influenza and Related Diagnoses between Patients Treated with Tofacitinib and Other Systemic Therapies within Cohorts of RA, PsA, and UC Patients: A Post-Authorization Safety Study of Tofacitinib

**First published:** 16/02/2021

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/50329>

### EU PAS number

EUPAS39242

### Study ID

50329

### DARWIN EU® study

No

### Study countries

United States

### Study description

Patients with immune-mediated diseases such as rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ulcerative colitis (UC) are known to have an increased risk of infections compared to the general population. As such, it is important to assess the safety of

tofacitinib and other treatments in this patient population. The research questions addressed by this study is: what are the rates of influenza and influenza like illness, including associated morbidity and death, among persons prescribed tofacitinib or other systemic treatments among groups of patients with RA, PsA and UC? The objectives for this study are: (1) to describe demographics and clinical characteristics of RA, PsA, and UC patient cohorts overall and within each treatment group and (2) to describe the frequency, incidence rates and clinical outcomes of influenza infections and influenza-like illness and their complications in patients receiving tofacitinib and other systemic therapies within RA, PsA and UC cohorts, stratified by age (<65 and 65 and older). This is a retrospective records-based cohort study involving secondary analysis of Optum Electronic Health Record databases in the United States consisting of longitudinal health information about patients derived from participating healthcare provider organizations.

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### Study status

Finalised

## Research institution and networks

### Institutions

**Pfizer**

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Institution

## Contact details

### Study institution contact

David Barnes

Study contact

[David.Barnes@pfizer.com](mailto:David.Barnes@pfizer.com)

### Primary lead investigator

Owens Edie

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:  
26/01/2021  
Actual:  
26/01/2021

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### **Study start date**

Planned:  
15/02/2021  
Actual:  
15/02/2021

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### **Data analysis start date**

Planned:  
15/02/2021  
Actual:  
15/02/2021

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### **Date of final study report**

Planned:  
31/01/2023  
Actual:  
11/02/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[FINAL A3921383 Non-Interventional Protocol Study 01 December 2020.pdf\(1.86 MB\)](#)

[A3921383 Non-Interventional Protocol Study Amendment 1 \(CLEAN\) 29 October 2021\\_Redacted.pdf\(3.09 MB\)](#)

## 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 topic:**

Human medicinal product  
Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)  
Safety study (incl. comparative)

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**Data collection methods:**

Secondary data collection

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**Main study objective:**

To describe the rates of influenza and influenza like illness, including associated morbidity and mortality, among persons prescribed Xeljanz or other systemic therapies among cohorts of patients with RA, PsA and UC

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Retrospective record-based study

## Study drug and medical condition

**Name of medicine**

Xeljanz

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**Medical condition to be studied**

Rheumatoid arthritis  
Psoriatic arthropathy  
Colitis ulcerative

## Population studied

**Short description of the study population**

Patients aged 18 years or older diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC) received treatment with tofacitinib and other systemic therapies identified from the Optum database for the study period of 1 June 2014 through 31 May 2019.

Inclusion criteria:

1. Age ≥18 years at index date.
2. Evidence of at least 1 inpatient diagnosis code or 2 outpatient diagnosis codes 7-365 days apart for RA, PsA, or UC.
3. Evidence of initiation for at least 1 approved systemic treatment (tofacitinib, JAKi, TNFi, non-TNFi, csDMARD) for the corresponding identified indication.
4. At least 180 days of continuous enrollment in prior to index date.

Exclusion criteria:

1. Evidence of >1 indications of interest during the whole study period.
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**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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**Special population of interest**

Other

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**Special population of interest, other**

Patients with rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis

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**Estimated number of subjects**

199697

## Study design details

## Outcomes

To describe demographics, comorbidities and clinical characteristics of RA, PsA, and UC patient. To describe the frequency, incidence rates and clinical outcomes of influenza infections and influenza like illness and their complications.

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## Data analysis plan

Baseline demographics, comorbidities and clinical characteristics will be analyzed using baseline data for RA, PsA and UC patients, then stratified by index treatment and age. The frequency and incidence rates for influenza and influenza like illness among patients treated for RA, PsA, and UC in subsets of patients defined by different index treatments will be provided, the frequency of influenza complications, drug use around influenza diagnosis, influenza-related hospitalization and mortality among these patients will also be provided. By influenza season analysis will be performed when applicable.

## Documents

### Study results

[A3921383 Non Interventional Study Report Abstract 10 February 2023\\_Redacted.pdf](#)  
(287.26 KB)

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### Study report

[A3921383 Non Interventional Study Report 10 February 2023\\_Redacted.pdf](#)(8.19 MB)

## Data management

## Data sources

### 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