# Real-world comparative effectiveness of tofacitinib, tumour necrosis factor inhibitors, and interleukin 17 inhibitors among patients with axial spondylarthritis and psoriatic arthritis

**First published:** 15/11/2024

**Last updated:** 19/05/2026

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000226

**Study ID**

1000000226

**DARWIN EU® study**

No

**Study countries**

United States

## Study description

This is a non-interventional, population-based retrospective cohort study of adults (ages ≥18 years of age) with Axial spondylarthritis (AxSpA), and Psoriatic arthritis (PsA) identified through a United States (US) administrative claims database.

This study aims to provide data on the comparative real-world clinical effectiveness of advanced therapies (tofacitinib, TNFi, and IL-17i) as well as their associated costs and resource utilization.

The results are intended to provide useful information to healthcare professionals and patients in clinical decision making for patients with these conditions.

De-identified individual who initiated one of the study treatments will be selected from a database between December 14, 2021, and most recent data available for the AxSpA sample and December 14, 2017, and most recent data available for the PsA sample.

The index date will be defined as the date of initiation (first time use) of one of the selected treatments (ie, tofacitinib, TNFi or IL-17i) within the specified identification period for each sample. Patients will be required to have at least 12 months of continuous enrollment (medical and pharmacy benefits) prior to the index date and at least 6 months after the index date.

Analysis will be replicated for a subset of patients with at least 12 months of continuous enrollment after the index date.

The baseline period will be defined as the 12 months before index date.

Patient’s demographic and clinical characteristics will be characterized at index date or during the baseline period, depending on the study variable. Treatment effectiveness and healthcare resource utilization and costs will be assessed over the 6 and 12 months following the index date.

Persistence on the index treatment will be assessed over the 12 months following the index date.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Pfizer

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

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**Institution**

### Komodo Health

## Contact details

**Study institution contact**

Karina Kauffmann karina.kauffmann@pfizer.com

**Study contact**

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**Primary lead investigator**

Matthew Brouillette

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 05/04/2024

Actual: 05/04/2024

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**Study start date**
Planned: 05/02/2025

Actual: 18/02/2025

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**Date of final study report**
Planned: 30/06/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

A3921446_Protocol_V1_23AUG2024_ REDACTED.pdf (1.1 MB)

A3921446 Protocol_V3.0_10JULY2025_FINAL_Redacted.pdf (916.27 KB)

A3921446 Protocol V 2.0 dated 03 JAN 2025_FINAL_Redacted.pdf (886.66 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)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

This non-interventional study is a population-based retrospective cohort study.

**Main study objective:**

Primary objectives:
1. To compare the proportion of AxSpA patients fulfilling effectiveness criteria within 6 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 6 months of continuous enrollment after index date.
2. To compare the proportion of b/tsDMARD-naïve PsA patients fulfilling effectiveness criteria within 6 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 6 months of continuous enrollment after index date.

Secondary objectives:
1. To compare the proportion of AxSpA patients fulfilling effectiveness criteria within 12 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
2. To compare the proportion of b/tsDMARD-naïve PsA patients fulfilling effectiveness criteria within 12 months after initiating treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
3. Evaluate drug persistence (median time to therapy discontinuation) among AxSpA patients within 12 months of treatment with tofacitinib vs TNFi vs IL-17i among patients with at least 12 months of continuous enrollment after index date.
4. Evaluate drug persistence (median time to therapy discontinuation) among b/tsDMARD-naive PsA patients within 12 months of treatment with tofacitinib vs TNFi vs IL-17i among the sample of patients with at least 12 months of continuous enrollment after index date.
5. Evaluate health care resource utilization and cost data for AxSpA patients within 6 and 12 months of treatment with tofacitinib vs TNFi vs IL-17i among

patients with at least 6 or 12 months of continuous enrollment after index date, respectively.

## Study drug and medical condition

**Medicinal product name**

XELJANZ

**Study drug International non-proprietary name (INN) or common name**

TOFACITINIB

**Medical condition to be studied**

Axial spondyloarthritis

**Additional medical condition(s)**

Psoriatic Arthritis

## Population studied

**Short description of the study population**

Adults (ages ≥18 years of age) with AxSpA or PsA

## Study design details

**Setting**

Komodo Healthcare Map database (Komodo)

**Outcomes**

The number and proportion of patients that satisfy the effectiveness criteria.

Primary Outcome:

- Patients that satisfy all the 8 effectiveness criteria

Secondary Outcome:

- Patients that satisfy each of the effectiveness criterion– pending feasibility

Additional secondary outcomes of this study are persistence, HCRU, and costs. These will be assessed during the follow-up period

# 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**

Komodo's Healthcare Map database

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

## 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**

Unknown