

# A multicenter evaluation of the treatment persistence of advanced therapies (Biological disease-modifying agents and Targeted synthetic Disease Modifying Anti-Rheumatic Drugs) in the treatment of rheumatoid arthritis (RA): A Real World Evidence (RWE) study from India

**First published:** 27/10/2023

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS103727

### Study ID

107874

### DARWIN EU® study

No

## Study countries

☐ India

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## Study description

This multicenter prospective study of patient charts evaluates treatment persistence, time until drug discontinuation (drug survival), effectiveness and safety of advanced therapies in Rheumatoid arthritis patients.

Patients will be enrolled in this study if they were diagnosed with Rheumatoid arthritis and are eligible for treatment with biological or targeted synthetic Disease Modifying Anti-Rheumatic Drugs as per the routine clinical practice.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

Pfizer

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

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Institution

Centre for Rheumatic Diseases and Regenerative  
Clinical Medicine

Mumbai Arthritis Clinic and Research Center  
Institute of Post-Graduate Medical Education and  
Research  
Kalinga Institute of Medical Sciences (KIMS)  
Optima Arthritis and Rheumatology Clinic  
Stanley Medical College  
Shanti Wellness Care  
Sri Deepti Rheumatology Center  
A B Rheumatology Centre  
Center for Rheumatic Diseases  
Max Super Specialty Hospital  
Kokilaben Dhirubhai Ambani Hospital & Medical  
Research Institution  
Krishna Institute of Medical Sciences Ltd.  
Amrita Institute of Medical Sciences & Research  
Centre  
Artemis Hospital  
Institute of Postgraduate Medical Education &  
Research

# Networks

Insignia

## Contact details

### Study institution contact

Amod Madhav Tilak amodmadhav.tilak@pfizer.com

Study contact

[amodmadhav.tilak@pfizer.com](mailto:amodmadhav.tilak@pfizer.com)

### Primary lead investigator

Hala Sayed

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 19/12/2022

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### Study start date

Planned: 15/06/2024

Actual: 25/09/2024

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### Data analysis start date

Planned: 15/06/2026

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## Date of final study report

Planned: 15/05/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921433 Non-Interventional Study Protocol\\_Amendment 1\\_\(clean\)\\_Version 2.0\\_26JAN2024\)\\_Redacted.pdf\(4.75 MB\)](#)

## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

This is a multicenter prospective study conducted in India to evaluate treatment persistence and drug survival on advanced therapies in rheumatoid arthritis.

All assessments described in this protocol are performed as part of normal clinical practice for the patient population.

**Main study objective:**

Treatment persistence and drug survival in patients on the advanced therapies for rheumatoid arthritis.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

XELJANZ

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

TOFACITINIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA29) tofacitinib

tofacitinib

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**Medical condition to be studied**

Rheumatoid arthritis

## Population studied

**Short description of the study population**

Adult patients aged 18 years and over, diagnosed with rheumatoid arthritis eligible for to start treatment with advanced therapies (biological and targeted synthetic disease modifying anti-rheumatic drugs).

Patients who have started treatment with disease modifying anti-rheumatic drugs for longer than 3 months cannot be included in this study.

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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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## **Estimated number of subjects**

225

## **Study design details**

### **Setting**

The patients would be enrolled based on the inclusion and exclusion criteria. The treatment regimen will be as per treating physician (investigators) decision. Routine clinical and diagnostic evaluations will be as per standard practice guidelines, irrespective of whether the patient is participating in the study or not.

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### **Comparators**

NA

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### **Outcomes**

The percentage of patients in each class, achieving 1 year survival will be calculated. 100% of the study population considered as all patients who entered the study.

Effectiveness parameters, as the change in Disease activity score 28, Health Assessment Questionnaire disability index and psoriatic arthritis disease activity scores from baseline to the end of the study.

Number of adverse events while on treatment during the study inclusion.

Disease factors or other determinants for treatment switch and time to first and subsequent switch to advanced therapies.

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### **Data analysis plan**

In the statistical analysis plan the clinical profile of the patients will be summarized by mean  $\pm$  Standard Deviation and frequency (%) respectively.

Demographic parameters will be reported by suitable measure of average like



mean or median if continuous otherwise frequency and percentage.

Median drug survival/ drug persistency will be compared across demographic parameters and external validity will be assessed by log-rank test.

Mean  $\pm$  Standard of the score efficacy parameters will also be reported and compared across demographic parameters, external validity will be tested by independent t-test and ANOVA or Mann-Whitney and Kruskal Wallis test.

Adverse event and severity of advance event will also be compared if many across demographic parameters by percentage with 95% confidence interval.

## 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)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### Data sources (types), other

Routine primary care patient files

## 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**

Not applicable