

# An Observational Study of Xeljanz® (tofacitinib citrate) and Biologic Rheumatoid Arthritis Treatments to Characterize their General Treatment Patterns, Effectiveness and Safety in a Real-World Taiwanese Population

**First published:** 11/05/2016

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS13431

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### Study ID

48622

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### DARWIN EU® study

No

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### Study countries

☐ Taiwan

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### Study description

Update - administrative updates were needed to the final study report and are addressed in the summary of changed document I have attached. The main objective of this multicenter, prospective, observational comparative effectiveness study in Taiwan is to understand general treatment patterns, effectiveness, and safety of tofacitinib compared to TNFi in a non-restricted population of RA patients in the real-world setting.

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### Study status

Finalised

## Research institutions and networks

### Institutions

**Pfizer**

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

**Last updated:** 01/02/2024

**Institution**

**IQVIA**

☐ United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

Taipei Veterans General Hospital Taipei, Tri-Service General Hospital Taipei, Taichung Veterans General Hospital Taichung City, Kaohsiung Medical University Chung-Ho Memorial Hospital Kaohsiung City, Kaohsiung Veterans General Hospital Kaohsiung City, National Taiwan University Hospital Taipei City, China Medical University Hospital Taichung City

## Contact details

### **Study institution contact**

Edward Kuo [Edward.Kuo@pfizer.com](mailto:Edward.Kuo@pfizer.com)

**Study contact**

[Edward.Kuo@pfizer.com](mailto:Edward.Kuo@pfizer.com)

### **Primary lead investigator**

Edith Owens

**Primary lead investigator**

# Study timelines

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

Planned: 25/12/2015

Actual: 25/12/2015

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## **Study start date**

Planned: 15/04/2016

Actual: 12/08/2016

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## **Date of final study report**

Planned: 30/04/2022

Actual: 01/04/2022

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Pfizer

# Study protocol

[A3921275\\_PROTOCOL\\_V1.0\\_01FEB2016 \(for EU PAS register\).pdf](#) (638.26 KB)

[A3921275 Non-Interventional PROTOCOL Amendment 1 \(clean version 2\) 16](#)

[March 2022\\_Redacted.pdf](#) (1.92 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)?**

Non-EU RMP only

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this multicenter, prospective, observational comparative effectiveness study in Taiwan is to understand general treatment patterns, effectiveness, and safety of tofacitinib compared to TNFi in a non-restricted population of RA patients in the real-world setting.

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Prospective, observational, multicenter, comparative effectiveness study

## Study drug and medical condition

### **Medicinal product name**

ENBREL

HUMIRA

SIMPONI

XELJANZ

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### **Medical condition to be studied**

Rheumatoid arthritis

## Population studied

## **Short description of the study population**

The study involved participants aged 20 years or older who were newly prescribed tofacitinib or a tumor necrosis factor inhibitors (TNFi) for the treatment of rheumatoid arthritis (RA) in Taiwan.

Inclusion criteria:

- Adults over 20 years of age
- The patient had a clinical diagnosis of RA.
- The patient is newly prescribed tofacitinib or a TNFi (ie, Enbrel®, Humira® or Simponi®) for RA at the time of enrollment. Patients switching from one TNFi to another or from one TNFi to tofacitinib will be included as long as they are incident users of a given TNFi or of tofacitinib.
- The patient must have evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study.
- The patient is able to read, write and reply the study questionnaires.

Exclusion criteria:

- The patient is enrolled in any other clinical trial of an investigational product.
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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

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## **Estimated number of subjects**

500

# Study design details

## **Outcomes**

Describe the baseline characteristics of RA patients prescribed tofacitinib or TNFi Enbrel® (etanercept), Humira® (adalimumab), or Simponi® (golimumab) and evaluate whether baseline characteristics of patients treated with tofacitinib are comparable to patients prescribed TNFi within line of therapy. Describe measures of short-term and long-term effectiveness for tofacitinib and TNFi. Describe safety outcomes in patients receiving tofacitinib and TNFi. The safety outcomes of interest Targeted Adverse Events (TAE) include cardiovascular events, hepatitis B and C reactivation, tuberculosis (TB), serious infections, herpes zoster, malignancy, and liver enzyme abnormalities.

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## **Data analysis plan**

Categorical variables will be summarized as proportions with 95% confidence intervals. P-values will be used to compare baseline characteristics of tofacitinib with TNFi. The effectiveness of tofacitinib will be descriptively compared to TNFi by using mixed logistic regression models with dichotomous outcome variables for HAQ-DI, CDAI and DAS-ESR. Propensity scores (PS) may be used to adjust for confounding by indication. The mean and standard deviation of WPAI-RA scores will be summarized at a given time point for each patient.

# Documents

## Study results

[A3921275 Non Interventional Study Report Abstract 25 March 2022.pdf](#) (109.32 KB)

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## Study report

[A3921275 Non Interventional Study Report 25 March 2022\\_Redacted.pdf](#) (2.36 MB)

[A3921275 Non Interventional Study Report Summary of Changes 19Jul2022.pdf](#) (1.24 MB)

## Study, other information

[A3921275 Non Interventional Study Protocol Abstract 16 March 2022.pdf](#) (1.78 MB)

[A3921275 Non Interventional Study Report Summary of Changes 19Jul2022.pdf](#) (1.24 MB)

## 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)

**Data sources (types), other**

Prospective patient-based data collection

## 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