A Post-Authorisation Safety Study of the Utilisation and Prescribing Patterns of Xeljanz® (tofacitinib) in the European Union Using Secondary Data Sources

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Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS46910

Study ID

47492

DARWIN EU® study

No

Study countries

Germany

Hungary

Netherlands

Sweden

Study description

Tofacitinib citrate (Xeljanz®) is an oral Janus kinase inhibitor approved by the European Commission (EC) for the treatment of adults with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC). To minimise important potential and identified risks associated with the use of tofacitinib, the Marketing Authorisation Holder (MAH) implemented additional risk minimisation measures (aRMMs). This protocol describes a drug utilisation study to assess prescribing patterns of tofacitinib and whether there is evidence that prescribers are following the screening and monitoring recommendations and limitations for use included in the aRMM materials for patients prescribed tofacitinib, as well as any potential off-label use of tofacitinib, contraindicated use, and use with concomitant medications not compatible with tofacitinib. Additionally, as a result of the 2019 benefit-risk reassessment requested by the EC pursuant to Article 20 of Regulation (EC) No 726/2004, as well as the 2021 signal evaluation procedure, the MAH will evaluate healthcare professionals' compliance with the new Pharmacovigilance Risk Assessment Committee (PRAC) recommendations and limitations for use implemented after the 2019 Article 20 referral to minimise the risk of venous thromboembolism (VTE), use in elderly patients aged ≥65 years, and mortality, and after the signal evaluation procedure to assess use in patients with cardiovascular (CV) risk factors and use in patients with malignancy risk factors.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/07/2017

Study start date

Planned: 30/09/2022

Actual: 22/03/2023

Date of interim report, if expected
Planned: 31/08/2023

Date of final study report
Planned: 31/10/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A3921321 Protocol 11 Feb 2022.pdf (1.54 MB)

A3921321_PROTOCOL- EU DUS_V5.0_11FEB2022.pdf (1.8 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

A3921321

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To determine whether there evidence that prescribers in the European Union (EU) are compliant with the recommendations and limitations for use described in the tofacitinib additional risk minimisation measures (aRMM) materials?

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA29) tofacitinib

tofacitinib

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- 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)

Estimated number of subjects

1200

Study design details

Outcomes

1. Describe the characteristics of patients treated with tofacitinib, stratified by study country and indication, in terms of demographics and comorbidities and prior and current medication use. 2. Evaluate prescribers’ adherence to the tofacitinib aRMMs. 1. Describe prescribing patterns over time. 2. Describe changes in the utilisation of tofacitinib following the updated recommendations and limitations for use implemented after the 2019 Article 20 referral and the 2021 signal evaluation procedure.

Data analysis plan

The primary analyses will be conducted per approved indication per country, unless otherwise specified. Data will not be pooled across countries due to heterogeneity in: how the data are recorded in each database, local data protection laws, and prescribing and coding practices. Results will be provided as descriptive statistics, no comparative statistical analyses will be conducted.

Categorical variables will be reported using frequency distributions. Ordinal variables will be reported using frequency distributions, means, standard deviations (SD), minimums, 25th percentiles, medians, 75th percentiles, and maximums, unless otherwise specified. Continuous variables will be reported using means, SDs, minimums, 25th percentiles, medians, 75th percentiles, and maximums, unless otherwise specified. Missing values will be reported as missing and no imputation will be undertaken. Results will be summarized in tables and figures in Microsoft® Excel and/or Word format.

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

PHARMO Data Network

Data source(s), other

Gesetzliche Krankenversicherung (GKV) claims Germany, National Health Insurance Fund Administration (NHIFA) Hungary

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Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

National patient registers (Sweden)

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

No