

# DARWIN EU® - Characterising the use of JAK inhibitors in Europe: a Drug Utilisation Study

**First published:** 19/12/2024

**Last updated:** 15/05/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000424

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### Study ID

1000000424

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### DARWIN EU® study

Yes


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### Study countries

 Finland

 Germany

 Netherlands

 Norway

## **Study description**

Janus kinase inhibitor (JAKi) therapy has been gaining popularity for the treatment of several autoimmune conditions, including rheumatoid arthritis, inflammatory bowel disease, and atopic dermatitis.

The first JAKi, tofacitinib, was approved by the European Medicines Agency (EMA) for the management of rheumatoid arthritis in 2017.

An FDA-requested study (the Oral Rheumatoid Arthritis Trial (ORAL) Surveillance trial) showed a higher risk of major adverse cardiovascular events (MACE), cancer and adjudicated opportunistic infection with tofacitinib compared to tumour necrosis factor (TNF) inhibitors in patients aged 50 years or older with at least one cardiovascular risk factor.

Further research has been conducted on the safety profile of JAKi for other indications, including psoriatic arthritis, ulcerative colitis and atopic dermatitis. It was shown that risk of venous thrombotic events of JAKi users was similar to placebo users in patients with atopic dermatitis and ulcerative colitis.

Incidence of adverse events, including herpes zoster infection and thrombotic events, remained similar with longer follow-up up to two years in psoriatic arthritis patients with JAKi. However, especially in these newer indications, the available evidence has been limited by short duration of follow-up and limited sample size.

The current study aims to identify the incidence of new JAKi use over time, and to characterise new users of JAKi in Europe to inform the feasibility of future safety studies.

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## **Study status**

Finalised

## **Research institutions and networks**

## Institutions

### Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

 Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024


**Institution**

**Educational Institution**


**ENCePP partner**


## Networks


### Data Analysis and Real World Interrogation Network (DARWIN EU®)

 Belgium

 Croatia


 Denmark


 Estonia

 Finland


 France


 Germany

 Greece

 Hungary


 Italy


 Netherlands

 Norway

 Portugal

 Spain

 Sweden

 United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

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Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Amy Lam

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 06/02/2024

Actual: 06/02/2024

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### Study start date

Planned: 13/12/2024

Actual: 13/12/2024

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

Planned: 30/04/2025

Actual: 22/04/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_P3-C1-001\\_Protocol\\_JAKi\\_V3.pdf](#) (885.06 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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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 topic, other:**

JAK inhibitors

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

- Population level cohort study (objective 1)
- New user cohort study (objectives 2)

**Main study objective:**

1. To estimate the incidence of new JAKi use, overall and for each individual JAKi ingredient.
2. To characterise new JAKi users and treatment for each individual JAKi ingredient, over all indications and stratified by indication.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(L01EJ) Janus-associated kinase (JAK) inhibitors

Janus-associated kinase (JAK) inhibitors

(L04AF) Janus-associated kinase (JAK) inhibitors

Janus-associated kinase (JAK) inhibitors

## Population studied

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

The population level cohort study will include all subjects available in the selected databases from 1st January 2017 until the most recent data lock of their respective databases, with at least 365 days of data visibility.

The patient level cohort study will include all JAKi new users from the 1st January 2017 until the most recent data lock of their respective databases, with at least 365 days of data visibility.

## Documents

### **Study report**

[DARWIN EU\\_Report\\_P3-C1-001\\_JAKi\\_V2.pdf](#) (2.68 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 source(s)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Norwegian Health Registers

The Valencia Health System Integrated Database

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### Data source(s), other

FINOMOP-HILMO

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

### CDM Mappings

### CDM name

OMOP

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### CDM website

<https://www.ohdsi.org/Data-standardization/>

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### CDM version

<https://ohdsi.github.io/CommonDataModel/index.html>

## 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**

Unknown