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

First published: 08/05/2026

Last updated: 08/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000998

Study ID

1000000998

DARWIN EU® study

Yes

Study countries

- Croatia
- Denmark
- Finland
- Germany

Spain

Sweden

Study description

JAK inhibitor (JAKi) therapy has been gaining popularity for the treatment of several autoimmune conditions, including rheumatoid arthritis, inflammatory bowel disease, and atopic dermatitis. Previous evidence suggests that JAKi use is associated with an increased risk of cardiovascular events, cancer, and opportunistic infections; however, these findings were mainly in rheumatoid arthritis (RA) populations, while evidence is limited for other indications with different demographics by short follow up durations and small sample sizes. Further research is needed to better establish the risks associated with JAKi use, especially for indications where JAKi use was only recently approved.
The current study aims to identify the incidence of new JAKi initiation over time and to characterise new use of JAKi in Europe to inform the feasibility of future safety studies. This is a rerun of a previous study with the same aim, which intends to expand on the countries, as well as the period, covered by the previous report.

Study status

Ongoing

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

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Primary lead investigator

Amy Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/02/2026

Actual: 17/02/2026

Study start date

Planned: 14/04/2026

Actual: 14/04/2026

Date of final study report

Planned: 31/07/2026

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This study will be conducted using six data sources onboarded for DARWIN EU® network of data partners from six European countries.

Main study objective:

1. To estimate the incidence of new JAKi initiation, overall and for each individual JAKi ingredient.
2. To characterise new JAKi initiators for each individual JAKi, overall and stratified by indication.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

JAK inhibitor (abrocitinib, baricitinib, filgotinib, tofacitinib, upadacitinib)

Population studied

Short description of the study population

For treatment initiation incidence estimation (objective 1)

All individuals available in the respective data sources during the study period, with at least 365 days of data visibility, will be included.

Different exclusion criteria will be applied corresponding to each outcome of the JAKi exposure incidence rate analysis (as defined in Section 8.6.2.). For

incidence of first JAKi ever initiation, individuals with any JAKi exposure before index date will be excluded. For incidence of individual JAKi ingredient (abrocitinib/baricitinib/filgotinib/upadacitinib/tofacitinib) initiation, only individuals with respective JAKi exposure before index date will be excluded.
For patients characterisation (objectives 2)
All individuals available in the respective data sources during the study period who newly initiated JAKi and have at least 365 days of data visibility before JAKi initiation will be included. Individuals with specific JAKi exposure before the start of study period will be excluded.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

IQVIA Disease Analyzer Germany

The Valencia Health System Integrated Database

Health Impact - Swedish Population Evidence Enabling Data-linkage

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://github.com/OHDSI/CommonDataModel/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No