

# Utilization patterns, access to healthcare facilities and economic assessment of JAKi drugs used in rheumatoid arthritis patients in Tuscany: the LEONARDO study

**First published:** 13/06/2020

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS35746

---

### Study ID

37637

---

### DARWIN EU® study

No

---

### Study countries

 Italy

---

### Study description

In this study, we will identify new users of JAKi in Tuscany from their approval in the treatment of severe to moderate RA in 2018 to 2019, and describe their utilization of the Regional Healthcare System facilities after treatment initiation, including an economic assessment. Since JAKi are used as second line in patients with moderate to severe RA non-responders to biologic DMARDs, we will provide an estimation over time of the new users of bDMARDs with and without history of access to rheumatoid arthritis wards in Tuscany.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Unit of adverse drug reactions monitoring (UADRM),  
University Hospital of Pisa

 Italy

**First published:** 08/01/2014

**Last updated:** 16/02/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Pisa Scuola Superiore Sant'Anna

## Contact details

### Study institution contact

Marco Tuccori marco.tuccori@gmail.com

Study contact

[marco.tuccori@gmail.com](mailto:marco.tuccori@gmail.com)

### Primary lead investigator

Corrado Blandizzi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/06/2020

Actual: 01/07/2020

---

### Study start date

Planned: 30/06/2020

Actual: 01/07/2020

---

### Data analysis start date

Planned: 06/07/2020

Actual: 10/07/2020

---

### Date of final study report

Planned: 31/07/2020

Actual: 16/10/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Galapagos NV

## Study protocol

[Study protocol \(ENCEPP REGISTRY\).pdf](#) (846.63 KB)

## Regulatory

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

No

---

### **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

---

**Main study objective:**

to identify and describe new users of JAKi in Tuscany from 2018 (year of approval in the treatment of severe to moderate RA) to 2019, and describe their utilization of the Regional Healthcare System facilities after treatment initiation, including an economic assessment

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AA29) tofacitinib

tofacitinib

(L04AA37) baricitinib

baricitinib

## Population studied

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

In order to answer the research questions (RQ), we created three different study cohorts, as described in detail below.

For the RQ-1 and RQ-2, patients were identified by the first dispensation of a JAKi from January 1st, 2018 to December 31st, 2019. Cohort entry was defined by the first dispensation of a JAKi. We excluded patients with less than 10 years of records in the look back period, history of cancer or use of anti-cancer drugs in the look back period, as well as those aged  $\leq 18$  at the index date.

For the RQ-3 and RQ-4, patients were identified by the first dispensation of a JAKi from January 1 st, 2018 to June 30th, 2019. Cohort entry was defined by the first prescription of JAKi. Only patients with at least six months of observation after cohort entry were included. We excluded patients with less than 10 years of records in the look back period, history of cancer or use of anti-cancer drugs in the look back period, as well as those aged  $\leq 18$  at index date.

In both the above analyses, patient observation was censored at the end of the study period, loss to follow-up, or death whichever came first.

For the RQ-5, patients were identified by the first prescription of a bDMARD from January 1st, 2014 to December 31st, 2019. Cohort entry was defined by the date of the first prescription of a bDMARD. We included patients with at least one visit in a Tuscan rheumatology ward in the year preceding the cohort entry. We excluded patients with less than 1 year of look back period.

---

## **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)
-

## Special population of interest

Immunocompromised

---

## Estimated number of subjects

200

## Study design details

### Data analysis plan

Descriptive analysis (count, percentages)

## Documents

### Study results

[Final report Leonardo \(+ annexes\).pdf](#) (1.88 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.

### Signed checklist for study protocols

[ENCePPChecklistfor StudyProtocols \(signed\).pdf](#) (3.32 MB)

---

## Data sources

**Data source(s)**

ARS Toscana

---

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

## 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