

# Post Marketing Safety Surveillance of Baricitinib in Three European Registries (I4V-MC-B012)

**First published:** 17/12/2018

**Last updated:** 31/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS25142

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### Study ID

25143

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### DARWIN EU® study

No

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### Study countries

 Germany

 Sweden

 United Kingdom

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## Study description

The objectives of this study are:(1) To monitor the incidence rate and profile of the following aggregate outcomes: serious infections (including herpes zoster) and opportunistic infections (including tuberculosis, Candida infections, and progressive multifocal leukoencephalopathy PML), major adverse cardiovascular events (MACE), malignancies (including lymphoma and typically virus-induced malignancies, such as cervical and many oropharyngeal cancers), and venous thromboembolism (VTE) among patients with long-term exposure to baricitinib compared to patients with long-term exposure to other medications indicated for moderate-to-severe RA, as possible given the data available in the BSRBR, RABBIT and ARTIS registries.(2) To describe the occurrence of the following individual outcomes: lymphoma, herpes zoster, opportunistic infections, rhabdomyolysis, agranulocytosis, PML, gastrointestinal perforations, and evidence of drug-induced liver injury, as possible given the data available in the BSRBR, RABBIT, and ARTIS registries.

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Eli Lilly and Company**

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

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

**Institution**

## Contact details

### Study institution contact

Salinas Claudia [claudia.salinas@lilly.com](mailto:claudia.salinas@lilly.com)

Study contact

[claudia.salinas@lilly.com](mailto:claudia.salinas@lilly.com)

### Primary lead investigator

Salinas Claudia

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 12/05/2017

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### Study start date

Actual: 12/05/2017

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### Date of final study report

Planned: 31/03/2024

Actual: 19/03/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[B012 PASS Version 1.0 Nov2018\\_Redacted.pdf](#) (604.46 KB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

To monitor the incidence rate and profile of the following aggregate outcomes serious infections and opportunistic infections, MACE, malignancies, and VTE among patients with long-term exposure to baricitinib compared to patients with long-term exposure to other medications for moderate to severe RA. Also to monitor the occurrence of more rare individual outcomes.

## Study Design

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

Cohort

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

BARICITINIB

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

(L04AA37) baricitinib

baricitinib

## Population studied

### **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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### **Estimated number of subjects**

2500

## Study design details

### **Outcomes**

Primary outcomes: -serious infections (including herpes zoster) and opportunistic infections (including TB, Candida infections, and PML).-MACE-Malignancies (including lymphoma and typically virus-induced malignancies such as cervical and many oropharyngeal cancers)-venous thromboembolism  
Secondary outcomes: -rhabdomyolysis-arganulocytosis-PML-gastrointestinal perforations-drug induced liver injury

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### **Data analysis plan**

Analysis of BSRBR, RABBIT, and ARTIS data is under the control of each individual registry and will not (with the exception of ARTIS) include input from Lilly. In general, each registry will provide incidence rates and outcomes and a final comparative report.

## Documents

### **Study report**

[LY3009104 B012 NI PASS Final Study Report\\_ENCePP\\_Redacted.pdf](#) (4.31 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)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

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### Data sources (types)

[Disease registry](#)

[Other](#)

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### 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