

# A Retrospective Cohort Study to Assess the Long-Term Safety of Baricitinib Compared with Other Therapies Used in the Treatment of Adults with Moderate to Severe Rheumatoid Arthritis in the Course of Routine Clinical Care (I4V-MC-B004)

**First published:** 03/04/2019

**Last updated:** 15/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS25145

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### Study ID

30229

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### DARWIN EU® study

No

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### Study countries

### **Study description**

\*Note, this study was terminated, and the attached final abbreviated report contains descriptive information up until time of termination. The goal of this study is to monitor the incidence and nature of key serious infections, MACE, VTE, and malignancies amongst patients exposed long term to baricitinib compared to patients treated long-term with bDMARDs or cDMARDs. This goal will be achieved through the following specific objectives: 1) To assess and compare the risk 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 similar patients with RA with long-term exposure to other indicated medications. 2) To describe the incidence rates of the following individual outcomes: lymphoma, herpes zoster, opportunistic infections such as tuberculosis, Candida, and PML, rhabdomyolysis, myelosuppression (agranulocytosis), hyperlipidaemia (hypercholesterolaemia, hypertriglyceridaemia), gastrointestinal perforations, and evidence of drug-induced liver injury. A secondary objective is to describe the incidence of the above outcomes in very elderly patients (aged  $\geq 75$  years old).

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### **Study status**

Finalised

## Research institutions and networks

# Institutions

## HealthCore

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

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Institution

## Contact details

### Study institution contact

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

Study contact

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

### Primary lead investigator

Claudia Salinas

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/03/2019

Actual: 25/03/2019

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### Study start date

Planned: 30/06/2023

Actual: 14/10/2019

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### **Date of interim report, if expected**

Planned: 31/03/2027

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

Planned: 30/06/2030

Actual: 19/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[B004 Pass Version 1.0 Dec2018\\_Redacted.pdf](#) (9.95 MB)

## 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:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The goal of this study is to monitor the incidence and nature of key serious infections, MACE, VTE, and malignancies amongst patients exposed long-term to baricitinib compared to patients treated long-term with bDMARDs or cDMARDs.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

OLUMIANT

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**Medical condition to be studied**

Rheumatoid arthritis

## 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**

12000

## Study design details

### **Outcomes**

1. Primary outcomes to be evaluated in comparative analyses: serious infections and opportunistic infections, major adverse cardiovascular events (MACE), malignancies, and venous thromboembolism. 2. Primary outcomes for descriptive analyses: lymphoma, herpes zoster, opportunistic infections, rhabdomyolysis, myelosuppression (agranulocytosis), hyperlipidemia, GI perforations, and liver injury.

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### **Data analysis plan**

Risk of each aggregate primary outcome will be compared between patients with rheumatoid arthritis (RA) treated with baricitinib and similar patients treated with (a) bDMARDs and (b) cDMARDs. Hazard ratios will be calculated based on Cox proportional hazard regression as a measure of the association between baricitinib and each comparative outcome. Propensity scores will be used to address imbalance of potential confounding factors across groups that might otherwise lead to confounding bias. Sensitivity analyses of malignancy will examine the effect of duration of baricitinib exposure and use of different latency windows. For MACE, sensitivity analyses will investigate an intent-to-

treat approach. Recurrent events, such as for infections, will also be explored. Overall incidence rates and rates over time will be calculated separately for comparative, aggregate outcomes (primary outcomes #1 above) and less common outcomes (primary outcomes #2).

## Documents

### Study results

[LY300914 B004 Non-interventional PASS Final Study Report.pdf](#) (663.37 KB)

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## 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 sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## 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