

# Comparative Assessment of VTE and Other Risks among Patients with Rheumatoid Arthritis treated with Baricitinib versus Tumor Necrosis Factor Inhibitors: A Multi-database Observational Cohort Study

**First published:** 17/12/2020

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32271

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### Study ID

32272

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### DARWIN EU® study


No

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### Study countries

 France

 Sweden

 United Kingdom

 United States

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## Study description

This study aims to evaluate the safety of patients with RA treated with baricitinib. This aim will be achieved using postmarketing data from multiple sources and through the following objectives, to be addressed by a meta-analysis of analytic results across individual data sources: Primary Objective: To compare the risk of VTE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. Secondary Objectives: • To compare the risk of MACE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. • To compare the risk of incident serious infection among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi. • To describe the risk of tuberculosis (TB) requiring hospitalization among patients with RA treated with baricitinib.

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Aetion**

 Spain

**First published:** 24/11/2022

**Last updated:** 16/07/2024

Institution

Other

ENCePP partner

Eli Lilly and Company

Eli Lilly and Company

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

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

Institution

## Contact details

### Study institution contact

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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: 12/03/2019

Actual: 12/03/2019

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### **Study start date**

Planned: 24/01/2020

Actual: 24/01/2020

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

Planned: 31/03/2021

Actual: 30/06/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[B023 05 Protocol\(d\).pdf](#) (856.46 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)?**

Not applicable

## 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:**

Primary Objective: To compare the risk of VTE among patients with RA treated with baricitinib with the risk among similar patients treated with TNFi.

## 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**

6000

## Study design details

### **Outcomes**

Venous thromboembolism, - MACE - incident serious infection - tuberculosis requiring hospitalization

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### **Data analysis plan**

The risk of each respective outcome will be calculated using Cox proportional hazards regression for patients with rheumatoid arthritis treated with baricitinib compared to those treated with TNFi. Results from each data source will be combined using meta-analysis.

## Documents

### **Study results**

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 1 of 6.pdf](#)  
(2.11 MB)

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### **Study report**

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 2 of 6.pdf](#)  
(9.51 MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 3 of 6.pdf](#)

(6.11 MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 4 of 6.pdf](#) (9.5

MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 5 of 6.pdf](#) (9.5

MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 6 of 6.pdf](#)

(4.27 MB)

### **Study, other information**

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 6 of 6.pdf](#)

(4.27 MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 5 of 6.pdf](#) (9.5

MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 4 of 6.pdf](#) (9.5

MB)

[Non interventional PASS B023 Final Study Report\\_Redacted\\_Part 3 of 6.pdf](#)

(6.11 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)**

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

German Pharmacoepidemiological Research Database

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**Data source(s), other**

Pharmetrics Plus United States, Humana United States, Aetna United States,

Corrona RA Registry United States, Corrona RA Registry Japan

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**Data sources (types)**

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

[Disease registry](#)

[Drug dispensing/prescription data](#)

## 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