

# Rheumatologist and Dermatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant (baricitinib), a JAK1/2 inhibitor (I4V-MC-B025)

**First published:** 04/10/2021

**Last updated:** 12/08/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS43239

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### Study ID

43240

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### DARWIN EU® study

No

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### Study countries

France

Germany

United Kingdom

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### Study description

This study will assess:

a) effectiveness of the updated baricitinib healthcare professional (HCP) educational materials and Patient Alert Card among dermatologists and rheumatologists and

b) the effectiveness of a Direct Healthcare Professional Communication (DHPC) distributed to dermatologists and rheumatologists.

This study was updated as a result of the Article 20 referral for JAKi, the protocol was endorsed by PRAC.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

### Contact details

### **Study institution contact**

Kristin Meyers meyers\_kristin\_joy@lilly.com

Study contact

[meyers\\_kristin\\_joy@lilly.com](mailto:meyers_kristin_joy@lilly.com)

### **Primary lead investigator**

Kristin Meyers

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 15/09/2021

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### **Study start date**

Planned: 31/03/2024

Actual: 27/03/2024

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

Planned: 30/09/2025

Actual: 27/03/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[LY3009104 B025\(b\) NI PASS Protocol\\_Redacted.pdf](#) (493.76 KB)

## Regulatory

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

Yes

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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

#### **Study design:**

This study uses a multi-national, observational cross-sectional design.

**Main study objective:**

- 1) assess effectiveness of updated HCP Educational Materials and PAC among dermatologists and rheumatologists. Key risk messages within these materials include those pertaining to pregnancy, infections, lipids, VTE, MACE, malignancy and dosing.
- 2) The effectiveness of a DHPC distributed to dermatologists and rheumatologists.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

OLUMIANT

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

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**

400

## Study design details

### **Outcomes**

The proportion of HCPs who demonstrate understanding of the important safety information in HCP Educational Materials and in the DHPC.

We will also report proportion who report communication of important safety information to their patients prescribed baricitinib for the first time and the proportion who distribute the PAC to patients prescribed baricitinib for the first time.

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### **Data analysis plan**

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for responses to questions that address the survey objectives (i.e. excluding demographic questions).

Survey data will be analysed overall, and stratified by country, prescriber status (has previously prescribed baricitinib or has not previously prescribed baricitinib), and by number of patients treated.

## Documents

### **Study report**

[LY3009104 B025 Non-interventional PASS Final Study Report Version 1 \(4\).pdf](#)  
(3.79 MB)

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), other**

Data for this study will be collected through a survey of dermatologists.

## 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