

# Assessment of off-label use of baricitinib in the paediatric population (Paediatric use of baricitinib)

**First published:** 26/06/2019

**Last updated:** 22/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS24371

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### Study ID

44308

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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### Study description

Rationale and background: Baricitinib is approved in Europe for the treatment of rheumatoid arthritis (RA) in adults. Although the potential for off-label use in paediatric patients is considered low, baricitinib has not yet been studied in children and adolescents and hence its use in this population is classified as a safety concern (missing information) in the EU-Risk Management Plan for baricitinib. Lilly has proposed this study in order to provide a more systematic evaluation of use in children and adolescents in Europe. Understanding the proportion of baricitinib prescribing that is off-label to children and adolescents will help quantitate the level of this safety concern. Research question and objectives: This study's primary objective is to evaluate the proportion of baricitinib prescribing that occurs off-label in paediatric patients (defined as less than 18 years of age). As a secondary objective, if paediatric use is  $\geq 5$  patients, this study aims to describe paediatric patients who receive a prescription for baricitinib in terms of total number of patients, demographics (age and sex) and select baseline diagnoses codes. Study design: This observational study will use a descriptive cohort design to characterize off-label prescribing of baricitinib in United Kingdom (UK) paediatric patients. Population: The setting is general care practices within the UK, limited to the practices that contribute to the Clinical Practice Research Datalink (CPRD). Patients will be retrospectively selected from the CPRD (both GOLD and Aurum) based on first occurrence of baricitinib within the database from April 2017 (date of baricitinib launch in the UK) to June 2020.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

# Eli Lilly and Company

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Institution

## Contact details

### Study institution contact

Schroeder Krista [schroeder\\_krista\\_marie@lilly.com](mailto:schroeder_krista_marie@lilly.com)

Study contact

[schroeder\\_krista\\_marie@lilly.com](mailto:schroeder_krista_marie@lilly.com)

### Primary lead investigator

Schroeder Krista

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/06/2018

Actual: 30/06/2018

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### Study start date

Planned: 01/10/2019

Actual: 29/08/2019

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## **Date of final study report**

Planned: 31/03/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## 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

Drug utilisation

**Main study objective:**

This study's primary objective is to evaluate the proportion of baricitinib prescribing that occurs off-label in paediatric patients (defined as less than 18 years of age).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

OLUMIANT

## Population studied

**Age groups**

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**

50

## Study design details

### **Data analysis plan**

A descriptive approach will be used to answer the study research questions. Specifically, the total number of identified baricitinib-prescribed patients and the proportion of these patients who are younger than 18 years at index will be reported. The paediatric subgroups will be further described in terms of age (mean/standard deviation, median/ interquartile range and age categories: 0 to 5 years, 6 to 10 years, 11 to 14 years and 15 to 17 years), sex, and diagnoses (read codes) received during the 1-year pre-index (including the index day).

## 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)**

Clinical Practice Research Datalink

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**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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