

# A 24-Month Prospective Observational Cohort Study Evaluating Oral Systemic Therapies in the Management of Adult Patients with Atopic Dermatitis in REAL-World Practice (AD-REAL)

**First published:** 29/10/2020

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS37841

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### Study ID

50366

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### DARWIN EU® study

No

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### Study countries

☐ France

☐ Germany

- ☐ Spain
- ☐ United Kingdom
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### Study description

Due to the limited data available on current clinical practice and new treatments entering the market, the study aims to describe treatment patterns of baricitinib and other oral systemic treatments. Therefore, the primary objective of this study is to report descriptively the proportion of patients with all-cause treatment discontinuation at Week 24 after initiation of a new oral systemic treatment at baseline for the baricitinib cohort and the all other oral systemic treatment cohort.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### Syneos Health

☐ United Kingdom

**First published:** 23/04/2015

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

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

### Contact details

### Study institution contact

Catherine Reed reed\_catherine@lilly.com

Study contact

[reed\\_catherine@lilly.com](mailto:reed_catherine@lilly.com)

### Primary lead investigator

Catherine Reed

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 05/11/2020

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### Study start date

Planned: 07/05/2021

Actual: 15/12/2021

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### Date of final study report

Planned: 30/09/2025

## 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?

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### Study type:

Non-interventional study

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#### Scope of the study:

Effectiveness study (incl. comparative)

#### Main study objective:

Post-launch prospective observational study to understand real-world treatment effectiveness over 24 months of AD patients who initiate or switch to a new oral systemic treatment

## Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

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

BARICITINIB

METHOTREXATE

MYCOPHENOLATE MOFETIL

AZATHIOPRINE

CICLOSPORIN

UPADACITINIB

ABROCITINIB

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**Medical condition to be studied**

Dermatitis atopic

## 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**

760

## Study design details

## Outcomes

To report descriptively the proportion of patients with all-cause treatment discontinuation at Week 24 after initiation of a new oral systemic treatment at baseline for (1) the baricitinib cohort and (2) the all other oral systemic treatment cohort, To characterize treatment patterns of oral systemic therapies used in clinical practice

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## Data analysis plan

Kaplan-Meier analysis will be used to analyze the primary endpoint (ie, the proportion of patients discontinuing their initial treatment baricitinib, other oral systemic treatment) at Week 24 for assigned treatment cohorts at baseline.

# Data management

## Data sources

### Data sources (types)

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