

# A pan-European registry-based observational study of abrocitinib and conventional systemic therapies in moderate and severe atopic dermatitis (Dream to TREAT AD)

**First published:** 12/01/2024

**Last updated:** 10/03/2025

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/199009>

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### **EU PAS number**

EUPAS108468

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### **Study ID**

199009

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### **DARWIN EU® study**

No

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### Study countries

- Denmark
  - Germany
  - Ireland
  - Netherlands
  - United Kingdom
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### Study description

This observational study will seek to characterise the profile of abrocitinib and conventional systemic treatment patients with moderate and severe atopic dermatitis in clinical practice in Europe through the involvement of 5 registries in Germany, Netherlands, UK, Ireland and Denmark. It will aim to describe the short- and long-term effectiveness of abrocitinib and conventional systemic therapies in a three-year follow-up period through the aggregated data analysis.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### St John's Institute of Dermatology

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

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

Institution

Multiple centres: 5; Amsterdam UMC, Amsterdam, Netherlands, Bispebjerg Hospital, Copenhagen, Denmark, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany, Medical School Hannover, Hannover, Germany, Technical University Dresden, Dresden, Germany, University College Dublin, Dublin, Ireland, St John's Institute of Dermatology, St Thomas' Hospital, London, UK

## Networks

European TREATment of ATopic eczema registry Taskforce (TREAT) (European TREAT Registry Taskforce)

- Denmark
- France
- Germany
- Italy
- Netherlands
- Portugal
- Spain
- Sweden
- United Kingdom

**First published:** 12/10/2018

**Last updated:** 20/08/2024

Network

## Contact details

### Study institution contact

Flohr Carsten

Study contact

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### Primary lead investigator

Flohr Carsten

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/01/2023

Actual: 10/05/2023

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### Study start date

Planned: 02/01/2023

Actual: 02/01/2023

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### Date of final study report

Planned: 01/06/2026

Actual: 09/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## 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 topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To describe abrocitinib and conventional systemic therapy patients' demographic details, AD diagnosis, comorbidities, prior and concomitant AD therapies and AD severity, initially separately for the study registers but then also in aggregated form.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational patient registries

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(D11AH08) abrocitinib

abrocitinib

(H02AB06) prednisolone

prednisolone

(L04AD01) ciclosporin

ciclosporin

(L04AX03) methotrexate

methotrexate

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### **Medical condition to be studied**

Dermatitis atopic

## Population studied

### **Short description of the study population**

200 abrocitinib patients and 200 patients on conventional systemics  
(methotrexate, ciclosporin, prednisolone)

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### **Age groups**

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**

400

## Study design details

## Outcomes

Baseline disease severity measured with physician- and patient-reported outcomes (o EASI, vIGA-AD (where available), POEM,PP-NRS, (C)DLQI ,demographic characteristics of the cohort, number of past systemic eczema treatments, age of eczema onset, pattern of prescription of systemic eczema treatment of interest at baseline, change in disease severity with physician- (EASI, vIGA-AD) and patient-reported outcomes (POEM, PP-NRS, CDLQI/DLQI) from baseline at week 4, 16 and subsequent visits (every 3-6 months) up to month 36 in patients treated with abrocitinib and conventional systemics stratified by line of AD treatment and concomitant AD therapy use.

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## Data analysis plan

Statistical assessments will be performed to describe study outcomes, using descriptive statistics, relative risks and/or odds ratios, 95% CI, P-values, or modelling where appropriate.

In the aggregated data analyses, incremental increases in the patient population size during the three year follow up period will be described in interim and final analyses.

For individual register dataset analyses, descriptive statistics will be provided separately, using a jointly developed standardized template.

For the aggregated data analyses, the following will be performed:

- Summary statistics will be presented for observed values of continuous endpoints at the baseline period, at each follow-up visit during the observation, and the changes from the baseline period.
- For further details on the data analyses, see the SAP.

## Data management

### Data sources



**Data source(s)**

German Atopic Dermatitis Registry TREATgermany

The UK-Irish Atopic Eczema Systemic Therapy Register

TREAT NL/BE registry (TREATment of Atopic eczema, the Netherlands and Belgium)

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**Data source(s), other**

TREAT NL/BE, A-STAR Ireland, A-STAR UK, SCRATCH Denmark

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**Data sources (types)**

[Disease registry](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings****CDM name (other)**

Study-specific harmonised dataset

**CDM name**

OMOP

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**CDM website**

<https://www.ohdsi.org/Data-standardization/>

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## 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