

# Atopic Dermatitis – Treatment Response EVALuation and UsEr Satisfaction with Tralokinumab in Standard Clinical Practice (ADValue)

**First published:** 17/12/2025

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000872

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### Study ID

1000000872

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### DARWIN EU® study

No

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### Study countries

Germany

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### Study status

Planned

## Research institutions and networks

## Institutions

Universitätsklinikum des Saarlandes Klinik f.  
Dermatologie, Venerologie und Allergologie

## Contact details

### Study institution contact

Claudia Pföhler [info@uks.eu](mailto:info@uks.eu)

Study contact

[info@uks.eu](mailto:info@uks.eu)

### Primary lead investigator

Claudia Pföhler

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 28/07/2025

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### Study start date

Planned: 16/12/2025

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### Date of final study report

Planned: 31/03/2030

## Sources of funding

- Pharmaceutical company and other private sector

## 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

## Other study registration identification numbers and links

NIS-TRALO-2412

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Evaluation of patient-reported outcomes

Other

**If 'other', further details on the scope of the study**

Efficacy and safety study with no comparator

**Data collection methods:**

Primary data collection

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## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

A non-interventional, non-comparative, prospective, observational study with primary data collection in routine clinical practice.

## Study drug and medical condition

**Medicinal product name**

ADTRALZA

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

TRALOKINUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(D11AH07) tralokinumab

tralokinumab

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## **Medical condition to be studied**

Dermatitis atopic

## Population studied

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

Adolescent (12 years and older) and adult patients with moderate-to-severe AD, eligible for treatment with tralokinumab (new users), during routine clinical care. The decision to start treatment in a patient with tralokinumab was taken before and independently of enrolment in the study.

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### **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly ( $\geq$  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

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 sources (types)

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

[Patient surveys](#)

## 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**

Unknown