# Incidence rates of Cutaneous T-Cell Lymphomas (CTCL) among patients with atopic dermatitis (AD)

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# Administrative details

**Study description** 

EU PAS number	
EUPAS50516	
Study ID	
50517	
DARWIN EU® study	
No	
Study countries	
Germany	
United Kingdom	

This is a cohort study describing population incidence rates of cutaneous T-cell lymphomas (CTCL), patient-level incidence rates of CTCL following diagnosis of atopic dermatitis (AD), and patient-level incidence rates of CTCL following treatment for severe AD. The study population was the general population in the UK and patients visiting general practices in Germany.

### **Study status**

Finalised

### Research institutions and networks

### Institutions

### **European Medicines Agency (EMA)**

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Institution

### Contact details

### Study institution contact

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Study contact

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### **Primary lead investigator**

Karin Hedenmalm

#### **Primary lead investigator**

# Study timelines

### Date when funding contract was signed

Planned: 31/10/2022

Actual: 31/10/2022

### Study start date

Planned: 31/10/2022

Actual: 31/10/2022

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

Planned: 16/12/2022

Actual: 19/12/2022

# Sources of funding

EMA

# Study protocol

Analysis-Plan-AD and CTCL-Nov 2022-for publication.pdf (1.12 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

# Methodological aspects

# Study type

# Study type list

### **Study topic:**

Disease /health condition

#### Study type:

Non-interventional study

### **Scope of the study:**

Disease epidemiology

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

This study aimed to estimate: i. incidence rates of cutaneous T-cell lymphomas (CTCL) in the general adult population ii. incidence rates of CTCL in adult patients with diagnosis of atopic dermatitis (AD) iii. incidence rates of CTCL in adult patients receiving treatment for severe AD

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

#### Medical condition to be studied

Cutaneous T-cell lymphoma

### Population studied

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

The study focused on general population in the UK and patients visiting general practices in Germany identified from the IMRD databases to determine the incidence rates of primary cutaneous T-cell lymphoma.

### 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)

#### Special population of interest

Other

#### Special population of interest, other

Patients with cutaneous T-cell lymphoma

#### **Estimated number of subjects**

### Study design details

#### **Outcomes**

Cutaneous T-cell lymphomas, Event rates for CTCL in the general population were stratified by sex, age group and year. Event rates among patients with AD were stratified by sex and age

#### Data analysis plan

This is a cohort study describing population incidence rates of cutaneous T-cell lymphomas (CTCL), patient-level incidence rates of CTCL following diagnosis of atopic dermatitis (AD), and patient-level incidence rates of CTCL following treatment for severe AD.

### **Documents**

### **Study results**

FINAL-REPORT-AD and CTCL-Dec2022-for publication.pdf (1.92 MB)

### 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)

IQVIA Disease Analyzer Germany

IQVIA Medical Research Data - OMOP

### **Data sources (types)**

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**