

# Onset of asthma in severe asthma patients (PATH)

**First published:** 15/04/2021

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS40583

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### Study ID

43405


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### DARWIN EU® study

No

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### Study countries

 Bulgaria

 Canada

 Greece

 Italy

 Korea, Republic of

 Kuwait



Spain



United Kingdom



United States

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## Study description

This study aim is to describe and compare the demographic and clinical features of early-onset vs late-onset asthma phenotypes in an international cohort of adult patients with severe asthma. The primary objectives are: ● To describe the distribution of age of asthma onset in the international severe asthma registry cohort ● To define and validate the most appropriate age cut-off to delineate age-of-onset groups ● To describe and compare the demographic and clinical characteristics of the early-onset vs late-onset asthma phenotypes in adult patients with severe asthma The secondary objective is to evaluate possible geographical differences in early-onset and late-onset asthma phenotypes in severe asthma population. Data will be sourced from the International Severe Asthma Registry (ISAR). Anonymized person-level data from 9 countries will be used for this analysis. ISAR has governance provided by the ISAR scientific steering committee, The Anonymous Data Ethics Protocols and Transparency (ADEPT) committee, an independent body of experts and regulators commissioned by the Respiratory Effectiveness Group (REG).

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## Study status

Ongoing

## Research institutions and networks

### Institutions

## Optimum Patient Care (OPC)

 United Kingdom

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


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

**Institution**

**Not-for-profit**

## Networks

### Optimum Patient Care (OPC) Network

 United Kingdom (Northern Ireland)


**First published:** 26/09/2015


**Last updated:** 16/06/2025


**Network**

**ENCePP partner**


### Respiratory Effectiveness Group (REG)


 Belgium

 Denmark


 France

 Germany

 Greece


 Hungary

 Italy

 Netherlands

 Spain

 Sweden

 United Kingdom

**First published:** 07/07/2021

**Last updated:** 04/06/2024

Network

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[dprice@opri.sg](mailto:dprice@opri.sg)

### Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 19/05/2018

Actual: 19/05/2018

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### Study start date

Planned: 01/09/2019

Actual: 16/01/2020

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### **Data analysis start date**

Planned: 01/11/2019

Actual: 18/03/2021

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

Planned: 01/12/2021

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPC Global

## 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

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

The study aims to describe and compare the demographic and clinical features of early-onset vs late-onset asthma phenotypes in an international cohort of adult patients with severe asthma.

### Study Design

**Non-interventional study design**

Cross-sectional

### Study drug and medical condition

**Medical condition to be studied**

Asthma

### 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**

2000

# Study design details

## **Outcomes**

The primary outcome is to describe the distribution of age of asthma onset in the international severe asthma cohort, define and validate the most appropriate age cut-off to delineate age-of-onset groups and to describe and compare the demographic and clinical characteristics of the early-onset vs late-onset asthma phenotypes in adult patients with severe asthma. The secondary outcome is to evaluate possible geographical differences in early-onset and late-onset asthma phenotypes in a severe asthma population.

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## **Data analysis plan**

To define age cut-off, the study will explore the potential cut-offs through various methods including ROC curve analysis and best fitted model (highest area under the curve). Baseline characteristics will be reported for early-onset and late-onset asthma groups with continuous variables summarised using descriptive statistics, the frequency and percentages of observed levels will be reported for categorical variables, and tables will be annotated with the total population size. Characteristics of groups will be compared via contingency

tables and group difference will be tested for statistical significance via chi-square tests for comparison of counts. Moreover, t-test or one-way analysis of variance (ANOVA) will be applied to compare means across groups. Demographic or clinical constructs will be compared between early-onset vs late-onset severe asthma phenotype groups.

## 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.

#### **Composition of steering group and observers**

[OPCG-1823\\_PATH\\_EnCEPP\\_Advisory Project Group.pdf](#) (90.17 KB)

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## Data sources

#### **Data source(s)**

International Severe Asthma Registry

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#### **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