

# The Characterization and Comparison of Eosinophilic and Non-eosinophilic Phenotypes of Severe Asthma

**First published:** 12/09/2019

**Last updated:** 26/02/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS31355

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### Study ID

32956


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### DARWIN EU® study

No


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### Study countries

 Bulgaria

 Canada

 Greece

 Ireland

-  Italy
  -  Japan
  -  Korea, Republic of
  -  Kuwait
  -  Spain
  -  United Kingdom
  -  United States
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## **Study description**

This cross-sectional study design is the first step to better understand and assess the presence of eosinophilic and non-eosinophilic asthma phenotypes using known constructs of severe asthma epidemiology. Firstly, most likely non-eosinophilic asthma patients will be identified followed by discerning eosinophilic asthma patients with most likely versus likely degrees of confidence. The characteristics of eosinophilic and non-eosinophilic phenotypes will be compared to a benchmark (published results from a similar study population). Data for this study will be sourced from the International Severe Asthma Registry (ISAR). Parallel analyses using a primary care observational database, the Optimum Patient Care Research Database (OPCRD), will be conducted for providing a benchmark for comparison.

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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

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### Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/04/2018

Actual: 30/04/2018

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### Study start date

Planned: 31/08/2018

Actual: 15/10/2018

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### **Data analysis start date**

Planned: 01/03/2019

Actual: 15/03/2019

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

Planned: 31/01/2020

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPCG

## 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:**

Disease epidemiology

**Main study objective:**

To describe and compare the demographic and clinical features of eosinophilic and non-eosinophilic asthma phenotypes in a cohort of adult patients with severe asthma To investigate the unique clusters of asthma phenotypes in the international severe asthma registry

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

5000

## Study design details

### **Outcomes**

Description and comparison of demographic and clinical features of the eosinophilic versus non-eosinophilic phenotypes of severe asthma, Unique clusters of severe asthma phenotypes in the international severe asthma registry (ISAR)

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### **Data analysis plan**

Firstly, most likely non-eosinophilic asthma patients will be identified followed by discerning eosinophilic asthma patients with most likely vs likely degree of confidence. Descriptive statistics will be provided for continuous and categorical variables accordingly. Summary statistics will be produced for variables measured on the interval or ratio scale, including sample size, mean and SD and categorical variables including range and the percentage by category. A benchmark for each descriptive statistic will be calculated using OPCR data. Characteristics of groups will be compared via contingency tables and group difference will be tested for statistical significance. Data reduction methods will be used to validate the expected clusters of eosinophilic phenotype and/or to investigate the unique cluster present in the ISAR cohort. Univariate distributions for patient characteristics and clinical characteristics will be described for four identified phenotypes.

## 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)

Optimum Patient Care Research Database

International Severe Asthma Registry

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### Data sources (types)

[Disease registry](#)

## 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