

# Demographic and Clinical Characteristics of Severe Asthma Patients Worldwide

**First published:** 03/10/2018

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/27888>

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### EU PAS number

EUPAS25489

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### Study ID

27888

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### DARWIN EU® study

No

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### Study countries

Australia

Italy

Korea, Republic of

United Kingdom

United States

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### **Study description**

This study aims to inform the asthma scientific community of the demographic and clinical characteristics of severe asthma patients seen at severe asthma centres across the globe. This will help drive the next key research questions to be asked at the country, region, and international level. This is a cross-sectional study to describe the severe asthma population, utilising data from the International Severe Asthma Registry (ISAR) to descriptively illustrate differences and similarities of demographic and clinical attributes of severe asthma patients globally. The study will include adult severe asthma patients receiving treatment according to the Global Initiative of Asthma (GINA) Step 5 or uncontrolled on GINA Step 4. Descriptive statistics will be summarized for demographic factors and clinical characteristics, including medical history, healthcare resource utilisation, blood test measurements, fractional exhaled nitric oxide (FeNO) test, comorbidities and medication use categories.

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### **Study status**

Finalised

## 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:** 14/08/2024

**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: 01/05/2017

Actual: 15/05/2017

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### Study start date

Planned: 01/11/2017

Actual: 16/04/2018

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### Date of interim report, if expected

Planned: 15/10/2018

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

Planned: 31/12/2018

Actual: 31/01/2019

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPC Global

## Study protocol

[ISAR\\_global reseach topic protocol 2017 20180905 v0.4.pdf\(350.75 KB\)](#)

## 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:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of this study is to describe the global severe asthma population using aggregate demographic and clinical measures such as healthcare resource utilisation, blood test measurements, comorbidities, etc. The secondary objective is to descriptively compare the distribution of demographic and clinical attributes of severe asthma patients across sub-populations (regions/countries)

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Historical study describing the baseline data of a cohort of severe asthma patients

## Study drug and medical condition

## **Medical condition to be studied**

Asthma

## Population studied

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

Severe asthma patients aged 18 years or older who received treatment according to GINA step 5 or uncontrolled at Step 4. Uncontrolled is defined as having severe asthma symptoms or frequent exacerbations.

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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Asthma patients

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### **Estimated number of subjects**

4990

## Study design details

## **Outcomes**

Demographic and clinical characteristics of the global severe asthma population, Descriptive comparison of baseline and clinical characteristics of severe asthma population across countries

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## **Data analysis plan**

Descriptive statistics will be computed for all demographics and clinical variables for the patient population as categorical variables, and count and percentage of non-missing observations will be reported for each category. Country or region (group) comparison will be examined with contingency tables. Frequencies and 95% confidence intervals will be shown for each characteristic and group difference will be tested for statistical significance via chi-square test for comparison of counts. Statistical significance will be defined as  $p < 0.05$ .

## Documents

### **Study results**

[ISAR global report 2017\\_final\\_updated\\_24.01.2019\\_ENCePP.pdf](#) (1.35 MB)

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## Data management

## Data sources

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

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**

Unknown