

# International Severe Asthma Registry (ISAR)

**First published:** 23/04/2018

**Last updated:** 27/11/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS23651

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### Study ID

47596

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### DARWIN EU® study

No

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### Study countries

- ☐ Argentina
- ☐ Australia
- ☐ Belgium
- ☐ Brazil
- ☐ Bulgaria
- ☐ Canada
- ☐ Colombia

- ☐ Denmark
  - ☐ Ecuador
  - ☐ Estonia
  - ☐ France
  - ☐ Greece
  - ☐ India
  - ☐ Ireland
  - ☐ Italy
  - ☐ Japan
  - ☐ Korea, Republic of
  - ☐ Kuwait
  - ☐ Mexico
  - ☐ Norway
  - ☐ Poland
  - ☐ Portugal
  - ☐ Saudi Arabia
  - ☐ Singapore
  - ☐ Spain
  - ☐ Taiwan
  - ☐ United Arab Emirates
  - ☐ United Kingdom
  - ☐ United States
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### **Study description**

The international Severe Asthma Registry (ISAR) is a multi-country, multicenter, observational initiative to gather de-identified longitudinal real-life data, for patients with severe asthma from over 29 countries.

The purpose of the registry is to provide a mechanism to store data to enable greater power to answer key research questions in severe asthma across the collaborating countries.

The key feature of the International Severe Asthma Registry will be a standardised annualised recording of:

- A key set of severe asthma related data points
- Selected enhanced data points for optional additional data collection
- Standardised coding for data point variables and
- Standardised response options

Due to its innovative approach with comprehensive data collection, the registry will have a core component where the key variables will be collected via eCRFs creating a large web-based registry platform in which more specific studies addressing particular objectives can be accommodated.

The details of the sub-studies will be finalised and shared.

The sub-studies will be conducted in subsamples of patients from the registry and the countries may choose whether or not to participate in new sub-studies without jeopardizing their status as ISAR participants.

Significant changes in the protocol and new sub-studies will be reviewed by those entities prior to initiation.

All patients enrolled in the ISAR platform will be followed-up annually during routine clinical visits for a total duration of up to seven years.

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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:** 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: 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 final study report

Actual: 14/08/2020

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPC Global

## Study protocol

[OR00617\\_ISAR Registry Protocol\\_V1.2\\_11 April 2018.pdf](#)(479.34 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

Describe and characterise the severe asthma patient population natural history overall where appropriate and by different subgroups (e.g. by age, sex, etc) Facilitate the phenotyping and endotyping of patients with severe asthma and to describe these groups by the burden of illness, disease management patterns and clinical evolution in these patient populations in an international setting.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Registry Study, multi-country, multicentre, observational initiative which will retrospectively and prospectively collect data regarding severe asthma patients

## Study drug and medical condition

## **Medical condition to be studied**

Asthma

## **Population studied**

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

Patients receiving care at severe asthma secondary and tertiary care centres in each participating country in accordance with local regulatory/ethical requirements.

#### **Inclusion Criteria**

- Patients 18 years or older
  - Patients in receiving treatment according to GINA Step 5 or uncontrolled in 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

34394

## Study design details

### Data analysis plan

Describing the natural history of severe asthma  
Phenotyping severe asthma sub-groups  
Examining significant predictors of clinical outcomes

## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

[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