

# ENLIGHTEN: Assessment of quality improvement in the International Severe Asthma Registry

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000510

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### Study ID

1000000510

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### DARWIN EU® study


No

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### Study countries

 Argentina

 Belgium

 Brazil

 Bulgaria

-  Canada
  -  Colombia
  -  Denmark
  -  Estonia
  -  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**

A prospective cohort study using data on eligible adults with severe asthma in ISAR (International Severe Asthma Registry). We will investigate how data quality and clinical practice in ISAR has changed over time using a combination of joinpoint regression, interrupted time-series and time-to-event analyses.

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## **Study status**

Planned

## Contact details

### Study institution contact

David Price d.price@opri.sg

Study contact

[d.price@opri.sg](mailto:d.price@opri.sg)

### Primary lead investigator

David Price 0000-0002-9728-9992

Primary lead investigator

### ORCID number:

0000-0002-9728-9992

## Study timelines

### Date when funding contract was signed

Planned: 11/11/2023

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### Study start date

Planned: 01/02/2025

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### Data analysis start date

Planned: 01/02/2025

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### Date of interim report, if expected

Planned: 22/12/2025

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### Date of final study report

Planned: 15/12/2026

## Sources of funding

- Other

## More details on funding

Joint funding from AstraZeneca and Optimum Patient Care Global

## Study protocol

[ENLIGHTEN\\_Protocol\\_Final\\_25.02.05\\_clean.pdf](#) (719.62 KB)

[ISAR\\_ENLIGHTEN I\\_Protocol\\_25.10.08\\_clean.pdf](#) (833.44 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:**

Other

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**Study topic, other:**

Investigation of data quality and clinical practice over time in patients with severe asthma

**Study type:**

Non-interventional study

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**Scope of the study:**

Validation of study variables (exposure outcome covariate)

**Data collection methods:**

Primary data collection

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**Study design:**

Prospective cohort study using the International Severe Asthma Registry (ISAR)

**Main study objective:**

To investigate data quality (completeness) and clinical practice (long-term oral corticosteroid use and severity of asthma when starting biologics) over time in the International Severe Asthma Registry

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

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

This study uses data on eligible patients with severe asthma contributing to the ISAR programme from those countries that have consented for their data to be used for research.

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### **Age groups**

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
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### **Special population of interest**

Other

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

People living with severe asthma

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### **Estimated number of subjects**

95568

## **Study design details**

### **Setting**

This is a prospective cohort study using the International Severe Asthma Registry, a global collaborative initiative to gather anonymous, longitudinal, real-life data for patients with severe asthma. ISAR provides a rich source of data for studies of symptoms, treatments and patient outcomes in people with asthma. A consistent goal of the ISAR is to improve data quality, which involves constant re-evaluation of existing data and how it might be enhanced.

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## **Comparators**

N/A

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## **Outcomes**

- (1) Patients meeting 90% and 100% data quality standards
  - (2) Completeness of variables in ISAR
  - (3) Long-term oral corticosteroid use
  - (4) Biologic initiation
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## **Data analysis plan**

The analysis will use a combination of joinpoint regression (log-linear model and the weighted Bayesian Information Criterion (BIC) test with a parametric method), interrupted time-series approaches (creation of splines at fixed timepoints when changes are expected to occur) and time-to-event analyses (Kaplan-Meier and flexible parametric approaches) to evaluate differential time in discontinuing/reducing LTOCS by calendar year and asthma severity indicators and initiating biologics by calendar year.

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## **Summary results**

Findings from this study will be presented at the Respiratory Effectiveness Group (REG)

in March 2025. A report will be finalised by December 2025 and the work will be submitted to a peer-reviewed journal in December 2026.

**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)

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