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

First published: 14/03/2025

Last updated: 26/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000510

Study ID

1000000510

DARWIN EU® study

No

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

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.

Study status

Finalised

Contact details

Study institution contact

David Price d.price@opri.sg

Study contact

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

Study start date

Planned: 01/02/2025

Data analysis start date

Planned: 01/02/2025

Date of interim report, if expected

Planned: 22/12/2025

Date of final study report

Planned: 15/12/2026

Actual: 26/10/2026

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Other

Study topic, other:

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Validation of study variables (exposure outcome covariate)

Data collection methods:

Primary data collection

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.

Age groups

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

People living with severe asthma

Estimated number of subjects

95.568

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.

Comparators

N/A

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

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.

Summary results

Conclusion

Overall, these findings provide converging evidence of reduced LTOCS use among countries participating in ISAR’S QI programme following the intervention, and that LTOCS cessation rates accelerated specifically in

temporal association with the programme’s rollout. While improvements in LTOCS cessation rates coincided with the QI programme and accelerated beyond broader trends, causality cannot be ascertained and the influence of both longer standing scientific and practice exchange within the registry and external factors must be considered. ISAR will continue to monitor the consistency of these findings as further data is accrued, building on the findings to date which are already a promising reflection of registry trends in LTOCS use and consistent with the contribution of QI engagement in driving meaningful change in LTOCS prescribing practice.

Documents

Study report

ENLIGHTEN_Study_Report_Final Draft_26.10.26_Clean.pdf (2.47 MB)

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

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No