International Severe Asthma Registry (ISAR)

First published: 23/04/2018

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS23651

Study ID

47596

DARWIN EU® study

No

Study countries

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

- Denmark
- Ecuador
- Estonia
- Germany
- Greece
- Hungary
- India
- Ireland
- Italy
- Japan
- Korea, Republic of
- Kuwait
- Mexico
- Netherlands
- Norway
- Poland
- Portugal
- Saudi Arabia
- Singapore
- Spain
- Taiwan
- United Arab Emirates
- United Kingdom
- United States

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 31 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 eight years.

For each year of the ISAR Extension (2024-2026), a quality improvement goal is prioritized and approved by the ISAR Steering Committee. ISAR provides countries with tools (e.g., ISAR REDCap Cloud data capture system, instant patient care reports and QISAR dashboards) that help facilitate practice change.

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

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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

Study start date
Planned: 01/11/2017

Actual: 16/04/2018

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)

ISAR Extension Protocol_ v2.1.pdf (708.8 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 topic:

Disease /health condition

Study type:

Non-interventional study

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

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 describe these groups by the burden of illness, disease management patterns and clinical evolution in these patient populations in an international setting. Assess the real-life effectiveness of severe asthma treatments.

Study Design

Non-interventional study design

Other

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

38527

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

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 sources (types)

Disease registry

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No