A global evaluation of the economic impact of time to initiation of biologic treatment of severe asthma patients

First published: 30/10/2024

Last updated: 30/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000332

Study ID

1000000332

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Belgium
- [ ] Bulgaria

- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Estonia
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] Spain
- [ ] Sweden
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study description

This study aims to identify the effect of time to initiation of biologic treatment of severe asthma patients on lifetime cost and disease burden at both global and national levels. The study will proceed through a systematic two-step process: (i) identification of biologic initiation and its clinical implications using the ISAR database and (ii) development of economic models to understand the cost-effectiveness of early versus late or non-initiation.

1. Calculation of national-level estimates:

• Utilise retrospective ISAR and other published data to derive national-level estimates for model parameters and inputs.

2. Development of cumulative national disease burden:

• Utilize a validated economic model22 to generate and estimate scenarios comparing earlier biologic initiation versus later initiation.

3. Cross-country comparison

• Explore factors contributing to observed variation between countries, including differences in healthcare infrastructure, treatment accessibility, or patient demographics.

Study status

Finalised

Research institutions and networks

Institutions

Respiratory Effectiveness Group

Contact details

Study institution contact

Graham Lough graham@regresearchnetwork.org

Study contact

graham@regresearchnetwork.org

Primary lead investigator

Brett McQueen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/10/2024

Actual: 02/10/2024

Study start date
Planned: 30/11/2024

Actual: 02/10/2024

Data analysis start date
Planned: 09/12/2024

Actual: 02/10/2024

Date of interim report, if expected
Planned: 30/04/2025

Actual: 02/10/2024

Date of final study report
Planned: 30/06/2025

Actual: 02/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

REG_Time to Biologics Protocol.pdf(1.14 MB)

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:

Disease /health condition

Study type:

Not applicable

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Economic study

Data collection methods:

No individual level data collected for the purpose of the study

---

Study design:

This study will proceed through a systematic two-step process: (i) identification of biologic initiation and its clinical implications using the ISAR database and (ii) development of economic models to understand the cost-effectiveness of early versus late or non-initiation.

Main study objective:

This study aims to:

1. Evaluate global and national-level cost-effectiveness:

• Assess the cost-effectiveness of initiating biologic treatment early in severe asthma patients at both the global and national level.

• Compare this to delayed initiation, considering direct and indirect costs at a global / country-specific level.

2. Explore cross-country variations:

• Investigate variations in early biologic initiation effectiveness across different countries.

• Identify factors contributing to these variations and potential implications for national healthcare strategies.

3. Quantify cumulative national disease burden:

• Quantify and compare the cumulative disease burden in severe asthma patients at the national level with early biologic initiation versus later initiation.

• Explore long-term health outcomes, including exacerbation rates,

hospitalizations, and quality-adjusted life years (QALYs), tailored to each country's context.

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

The International Severe Asthma Registry (ISAR) contains severe asthma patient information from over 33,000 patients from 29 countries.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

30000

Study design details

Data analysis plan

1. Calculation of national-level estimates:

• Utilise retrospective ISAR and other published data to derive national-level estimates for model parameters and inputs.

2. Development of cumulative national disease burden:

• Utilize a validated economic model22 to generate and estimate scenarios comparing earlier biologic initiation versus later initiation.

3. Cross-country comparison

• Explore factors contributing to observed variation between countries, including differences in healthcare infrastructure, treatment accessibility, or patient demographics.

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)

Population registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown