

# Exploring different composite definitions of responders and non-responders to biologic treatment for severe asthma (FULL BEAM)

**First published:** 24/03/2023

**Last updated:** 02/07/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS104132

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### Study ID

104133

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### DARWIN EU® study


No

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### Study countries

 Argentina

 Australia

 Bulgaria

 Canada

-  Colombia
  -  Denmark
  -  Greece
  -  India
  -  Ireland
  -  Italy
  -  Japan
  -  Korea, Republic of
  -  Kuwait
  -  Mexico
  -  Poland
  -  Portugal
  -  Saudi Arabia
  -  Taiwan
  -  United Arab Emirates
  -  United Kingdom
  -  United States
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## **Study status**

Planned

## Research institutions and networks

### Institutions

Observational & Pragmatic Research Institute Pte  
(OPRI)

 United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### Study institution contact

David Price [dprice@opri.sg](mailto:dprice@opri.sg)

**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: 01/03/2022

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### Study start date

Planned: 02/05/2022

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### Date of interim report, if expected

Planned: 30/12/2022

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## **Date of final study report**

Planned: 30/04/2023

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPRI Pte Ltd

## 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 type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

1) Define the study population To describe pre-biologic demographic, clinical and functional characteristics of patients initiating biologics, overall and by biologic class 2) Quantify levels of response and characterize patients by levels of response To operationally assess levels of response to biologics (from non-response to highest level of response) in individual domains

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Registry-based cohort study

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

## **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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## **Estimated number of subjects**

4000

# Study design details

## **Outcomes**

Clinical remission and response to treatment. While clinical remission will be assessed in all patients irrespective of their status pre-biologic initiation, response can only be assessed in patients impaired when initiating the treatment. Impairment will be defined for each domain independently as: 1) exacerbations:  $\geq 2$  exacerbations in the year preceding biologic initiation, 2) long-term OCS use

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## **Data analysis plan**

Objective 1 aims at describing the study population used in objectives 2 and 3. To this end, the pre-biologic asthma-related outcomes will first be described individually and in composite variables. For individual asthma-related outcomes, both continuous and categorical variables will be used. The distributions will be compared between initiated biologic class using t-tests, Kruskal Wallis tests, or Person's Chi-squared tests as appropriate. The proportion of patients responding to biologics as defined in section 5 will be computed overall and by biologic classes, for each individual domain and

composite definition of response. Patient characteristics will be described by levels of response using means, standard deviations, medians and interquartile ranges for continuous variables and numbers and percentages for categorical variables.

## 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.

### Composition of steering group and observers

[ISAR FULL BEAM Steering Group & Observers.pdf](#) (17.92 KB)

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## Data sources

### Data source(s)

International Severe Asthma Registry

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### Data sources (types)

[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