

# Defining and Characterizing Responders to Biologic Treatment (BEAM)

**First published:** 26/11/2020

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS38288

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### Study ID

48128

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### DARWIN EU® study

No

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### Study countries

 Argentina

 Bulgaria

 Canada

 Colombia

 Denmark

 Germany

-  Greece
  -  Ireland
  -  Italy
  -  Japan
  -  Korea, Democratic People's Republic of
  -  Kuwait
  -  Mexico
  -  Portugal
  -  Saudi Arabia
  -  Singapore
  -  Spain
  -  Taiwan
  -  United Arab Emirates
  -  United Kingdom
  -  United States
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## **Study description**

This is a registry cohort study in which we will operationally define responders to biologic treatment by clinical endpoints and describe their characteristics overall and per biologic class (anti-IgE and anti-IL5). Initially, response to a biologic therapy will be evaluated based on improvements of single domains including exacerbation rate, cumulative OCS dose, long-term OCS dose, asthma control and lung function from pre- to post-therapy. To avoid duplication of information, response will be examined for the first biologic only. The level of responsiveness will then be assessed based on the overlap of the following four domains: exacerbation rate, long-term OCS use, asthma control and lung function. Data will be sourced from the International Severe Asthma Registry (ISAR).

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## **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**

## 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: 01/03/2020

Actual: 01/03/2020

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### Study start date

Planned: 01/12/2015

Actual: 01/12/2015

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### Data analysis start date

Planned: 01/08/2020

Actual: 01/08/2020

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### Date of interim report, if expected

Planned: 01/11/2020

Actual: 01/11/2020

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### Date of final study report

Planned: 31/05/2022

Actual: 17/06/2022

## Sources of funding

- Other

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, OPC Global

## Study protocol

[OPCG-2001\\_BEAM\\_Protocol\\_FINAL.pdf](#) (1.09 MB)

## 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:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To classify responders to biologic treatment by clinical and functional endpoints and describe their characteristics overall and per biologic drug class.

## 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**

Patients  $\geq 18$  years old who receive treatment according to GINA Step 5 or experience uncontrolled asthma at GINA Step 4 as per the definition of severe

asthma.

Patients who were included in the International Severe Asthma Registry (ISAR) after they had started biologic treatment will not be included in the study unless pre-treatment data is available.

Inclusion criteria:

- Patients 18 years or older, who are receiving treatment according to GINA (2018 Criteria) step 5 or are uncontrolled at step 4. Uncontrolled asthma is defined as having severe asthma symptoms or frequent exacerbations requiring systemic corticosteroids.
- Patients prescribed with anti-IL5/5R, anti-IgE or anti-IL4/IL13 during study period
- Available registry data prior to or on biologic therapy initiation date
- Available registry data from biologic initiation date until a follow-up visit that is closest to a 1-year period (min. 16 weeks) or until date of switching/stopping their first biologic
- Switched/stopped their first biologic before first follow-up visit or before 16 weeks (as nonresponse)

Exclusion criteria:

- Patients who received bronchial thermoplasty
- Patients who are <18 years old
- Patients with a follow-up visit less than 16 weeks after biologic initiation date (without switch/stop)

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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)
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### **Special population of interest**

Other

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

Asthma patients

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### **Estimated number of subjects**

1609

## Study design details

### **Outcomes**

To operationally assess response to biologic therapy by clinical and functional endpoints including exacerbations, systemic corticosteroids, asthma control and lung function. To describe and compare baseline (pre-therapy) demographic, clinical and functional characteristics of response and non-response groups to overall biologic treatment and by biologic class.

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### **Data analysis plan**

We are assessing improvement from at/before biologic initiation to after biologic therapy across 4 main domains of clinical response: Lung function, exacerbation, Long-term OCS, Asthma Control. What classifies as an improvement for each domain has been classified in agreement with published literature (e.g. clinical trials data). Level of response is also ascertained via assessing the number of domains with a positive change that a patient had. Finally, a responder is identified if they show improvement in more than 50% of the clinical response domains from the total of domain they have non-missing

data for.

## 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.

#### **Conflicts of interest of investigators**

[David Price\\_COI.pdf](#) (50.59 KB)

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#### **Composition of steering group and observers**

[BEAM Steering Committee Members.pdf](#) (37.69 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**

Observational initiative with retrospective and prospective 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