# CLinical oUtcomes before and after biologic treatMent by bIologic class, by iNdividuAl biologic, and by subgroups of baseliNe characTeristics (LUMINANT)

**First published:** 12/11/2021
**Last updated:** 23/04/2024

Study  Planned

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/50332

**EU PAS number**
EUPAS44027

**Study ID**
50332

**DARWIN EU® study**
No

**Study countries**
Argentina
Australia
Bulgaria
Canada
Colombia
Denmark
Greece
India
Ireland
Italy

Japan
Korea, Republic of
Kuwait
Mexico
Portugal
Saudi Arabia
Spain
Taiwan
United Arab Emirates
United Kingdom
United States

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**Study status**
Planned

# Research institution 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
08/08/2023

**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**

## David Price

Study contact

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**Primary lead investigator**

## David Price

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned:
01/04/2021

**Study start date**
Planned:
01/04/2021

**Data analysis start date**
Planned:
01/11/2021

**Date of final study report**
Planned:
31/05/2023

# Sources of funding

- Other

- Pharmaceutical company and other private sector

# More details on funding

AstraZeneca, OPC Global

# 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 type:**
Non-interventional study

**Scope of the study:**
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology
Effectiveness study (incl. comparative)

**Main study objective:**
To describe the ISAR cohort who initiate biologic treatment and examine clinical outcomes
at 12 months by biologic class, and subgroups of patients, and compare these to those not
initiated on biologic medications

## Study Design

**Non-interventional study design**
Other

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**Non-interventional study design, other**
Registry-based longitudinal 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**
11000

# Study design details

**Outcomes**
Asthma exacerbations, asthma control, oral corticosteroid use and dose, healthcare
utilisation, lung function, Inflammatory markers, asthma symptoms, lung function

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**Data analysis plan**
Overall and by subset groups (type of biologics, individual biologics, and baseline
characteristics), descriptive statistics for Section 5.1 Demographic Variables (Table 2) and
Section 5.2 Clinical Variables (Table 3) will be provided for continuous and categorical
variables accordingly: Descriptive statistics for the overall population and by subgroup of
interest: •For variables measured on the interval or ratio scale, summary statistics
produced will be: Sample size (n), Percentage nonmissing, Mean, Standard deviation,
Range (minimum-maximum), Median •Inter-quantile range (25th and 75th percentile) •For
categorical variable the summary statistics will include: Sample size (n) •Range (if
applicable) •Count and percentage by category (distribution) •Characteristics of study
groups will be compared and tested for statistical significance via McNemar's tests for
comparison of counts data, t-test, or one-way analysis of variance (ANOVA) for continuous
variables.

# Data management

# ENCePP Seal

**Composition of steering group and observers**
Project Steering Committee Member_LUMINANT.pdf(39.01 KB)

# 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