

# Characteristics of type 2 asthma phenotypes and oral corticosteroid (OCS) use in the International Severe Asthma Registry (ISAR) (STAR)

**First published:** 05/10/2022

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS49201

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### Study ID

50241

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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
  -  Poland
  -  Portugal
  -  Saudi Arabia
  -  Spain
  -  Taiwan
  -  United Arab Emirates
  -  United Kingdom
  -  United States
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## **Study status**

Ongoing

## 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

## 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

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

### Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 11/02/2022

Actual: 11/02/2022

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### Study start date

Planned: 15/11/2022

Actual: 15/11/2022

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**Data analysis start date**

Actual: 12/12/2022

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**Date of interim report, if expected**

Planned: 09/01/2023

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**Date of final study report**

Planned: 30/08/2023

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Regeneron/Sanofi, Optimum Patient Care Global

## 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:**

The main objective is to describe patients aged 18 years or older with GINA 4/5 asthma, enrolled in ISAR, by OCS use and biomarker distribution, Type 2 characteristics and individual biomarkers, prior to biologic initiation. An added objective is to describe those patients with low eosinophilic phenotypes and who have long-term OCS use prior to biologic initiation.

## Study Design

**Non-interventional study design**

Cross-sectional

## 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**

3404

## Study design details

### **Outcomes**

Demographic and clinical characteristics will be described for GINA Steps 4/5 patients with no, intermittent and long-term OCS use. The prevalence of type 2 characteristics, as defined by biomarkers or concomitant type 2 disease, will also be presented. Demographic and clinical characteristics will be described for GINA Steps 4/5 patients with low eosinophilic phenotypes (blood eosinophils <150 cells/microL) and long-term OCS use.

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### **Data analysis plan**

The final sample size will depend on the number of individuals with available data on biomarkers, OCS use and type 2 comorbidities. Analysis will be undertaken in STATA and R. As the study requires descriptive analyses, no inferential statistics will be performed. Continuous variables will be summarised using means, standard deviations, medians and interquartile ranges. Categorical variables will be shown as number and percentage.

## 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 STAR\\_Steering Group and Observers\\_ENCePP.pdf](#) (17.94 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