

# Exacerbation history in COPD patients prior to diagnosis and subsequent treatment and outcomes

**First published:** 06/07/2023

**Last updated:** 14/03/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS105737

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### Study ID

105870

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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### Study description

This is a historical cohort study of patients in the year prior to and the year following the patients initial COPD diagnosis. The index date will be the patients first COPD diagnosis. Patients will be followed for one year prior and one year following their initial COPD diagnosis.

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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.org](mailto:dprice@opri.org)

Study contact

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

## Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 16/06/2023

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### Study start date

Planned: 10/07/2023

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### Data analysis start date

Planned: 24/07/2023

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### Date of interim report, if expected

Planned: 25/08/2023

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### Date of final study report

Planned: 29/09/2023

## Sources of funding

- Other

## More details on funding

OPRI

## 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

**Other study registration identification numbers and links**

OPRI 2306

**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:**

To describe the number of exacerbations in the year prior to first COPD diagnosis, the patient's characteristics at time of diagnosis, and the treatments and number of exacerbations by severity in the year following diagnosis

**Study Design**

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Medical condition to be studied**

Chronic obstructive pulmonary disease

# 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**

70000

# Study design details

## **Outcomes**

The number of exacerbations following initial COPD diagnosis by severity, frequency and initial treatment

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## **Data analysis plan**

Incident rate ratios will be calculated for any exacerbation/severe exacerbations and initial treatment following the index date.

## 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)**

Optimum Patient Care Research Database

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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