

# Cardiopulmonary risk model for patients with chronic obstructive pulmonary disease

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

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS105272

### Study ID

105273

### DARWIN EU® study

No

### Study countries

United Kingdom

### Study description

An observational, historical cohort study to construct a risk model that predicts major cardiopulmonary events amongst patients with chronic obstructive pulmonary disease using the OPCRD database

## 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**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

David Price

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 05/10/2022

Actual: 05/10/2022

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## **Study start date**

Planned: 21/10/2022

Actual: 21/10/2022

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## **Date of final study report**

Planned: 31/07/2023

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

AstraZeneca

# 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To construct a risk model that predicts major cardiopulmonary events (MACRE) in patients with chronic obstructive pulmonary disease (COPD)

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

Myocardial infarction

Cardiac failure

## 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**

131581

## Study design details

### **Outcomes**

The outcome will be MACRE, which is a composite of any of the following:

- First heart failure hospitalization after the index date,
- First diagnosis or hospitalization for myocardial infarction, or occurrence of coronary revascularization after the index date,
- First severe COPD exacerbation, defined by COPD-related hospitalizations, after the index date, and
- Non-cancer-related mortality.

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### **Data analysis plan**

A predictive model will be constructed for the outcome (MACRE) using Fine-Gray competing risk regression, with cancer-related mortality as the only competing event. The hold-out method will be used, with a randomly selected 80% of the cohort being the development dataset and the remainder 20% being the validation dataset. Elastic net will be used for variable selection and regularization. Discrimination of the resultant model will be evaluated within the derivation cohort using Harrell's C-index. Calibration will be assessed quantitatively using the Greenwood-Nam-D'Agostino test and/or the Brier score, as well qualitatively as using an overlaid plot of the predicted and observed (Kaplan-Meier) freedom from the composite outcome for each quintile as

grouped by the predicted risk. Prognostic value of the predicted risks generated by the resultant model will be additionally evaluated by means of survival analysis.

## 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