

# Addressing the burden of respiratory disease in General Practice: A real-life implementation study focusing on high risk asthma and COPD patients

**First published:** 27/11/2020

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Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/38200>

### EU PAS number

EUPAS38199

### Study ID

38200

### DARWIN EU® study

No

## Study countries

☐ Australia

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## Study description

To identify high-risk asthma and COPD patients and reduce subsequent avoidable hospitalisations through a focused approach on the prevention of frequent disease flare-ups (exacerbations) and improved management of chronic and complex health conditions, associated with preventable factors.

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## Study status

Planned

# Research institutions and networks

## Institutions

### Woolcock Institute of Medical Research

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Networks

### Optimum Patient Care (OPC) Network

☐ United Kingdom (Northern Ireland)

**First published:** 26/09/2015

**Last updated:** 14/08/2024

**Network**

**ENCePP partner**

## Contact details

### **Study institution contact**

Sinthia Bosnic-Anticevich

**Study contact**

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### **Primary lead investigator**

Sinthia Bosnic-Anticevich

**Primary lead investigator**

## Study timelines

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

Planned: 16/11/2020

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### **Study start date**

Planned: 01/02/2021

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### **Date of final study report**

Planned: 28/02/2023

## Sources of funding

- Pharmaceutical company and other private sector
- Other

## More details on funding

GSK, Observational Pragmatic Research Institute

## 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:**

Not applicable

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To identify patients with a COPD and/or asthma diagnosis at high risk of exacerbation utilising technology to support improved disease management by primary care providers and reduce the high-cost burden of respiratory events on the health care system by preventing otherwise avoidable hospitalisations.

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

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**

2748

## Study design details

## Outcomes

For asthma exacerbations, a 20% reduction in exacerbations is anticipated. For COPD exacerbations, a 20% reduction in exacerbations is anticipated. Time to first, and rate of, asthma-related crisis events for at-risk patients. The percentage of all registered asthma patients with an asthma-related crisis event, their rate of, and time to, first asthma-related crisis events.

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## Data analysis plan

The OPC Clinical Audit consists of an electronic clinical audit using secure and confidential patient data from GP sites. Patients with asthma and/or COPD including a screen for undiagnosed COPD will be included. Patient-reported outcomes will be collected for identified high-risk asthma and COPD patients. A list of patients at risk of exacerbation or that have undiagnosed COPD will be generated (re-identified) and invited to the study as part of the Audit Group. A face-to-face review of the re-identified high-risk patients with the practice nurse followed up with a consultation with the GP utilising clinical decision support advice from OPC.

## Data management

### ENCePP Seal

#### Composition of steering group and observers

[Sinthia Bosnic-Anticevich\\_CV.pdf](#)(602.04 KB)

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## Data sources

**Data source(s)**

Optimum Patient Care Research Database

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**Data source(s), other**

Optimum Patient Care Research Database (OPCRD)

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## 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