

# Advancing the Patient Experience in COPD Registry (APEX COPD)

**First published:** 23/04/2019

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

Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/50777>

### EU PAS number

EUPAS29401

### Study ID

50777

### DARWIN EU® study

No

### Study countries

☐ United States

## Study description

The initiative aims to improve primary care for COPD patients. It will bring together electronic medical records with patient reported information and observations, and present this to clinicians in a structured and clinically relevant format at the point of care. This will be achieved using modern technology, including FHIR, electronic patient surveys, and standardized data collection, and will be guided by a network of COPD physicians in primary and secondary care. Impact will be maximised through Research publications regarding treatment effectiveness and associated risk in mild to moderate COPD, reason for therapy switch/escalation and hidden undiagnosed and untreated COPD patients in primary care. A strong network of COPD primary care physicians in the US is driving the initiative and will ensure impact on clinical practice through academic organisations and research outputs.

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## Study status

Planned

# Research institutions and networks

## Institutions

### Optimum Patient Care Australia

☐ Australia

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

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

**Institution**

**Not-for-profit**

# Networks

DARTNet Institute

## Contact details

### Study institution contact

David Price

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: 27/12/2018

Actual: 27/12/2018

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### Study start date

Planned: 01/07/2019

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### Data analysis start date

Planned: 02/09/2019

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## **Date of final study report**

Planned: 29/12/2023

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim, Inc., Optimum Patient Care Ltd.

## 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

Effectiveness study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Quality improvement

**Main study objective:**

Describe and characterise the COPD primary care patient population natural history overall and by different subgroups, and evaluate the comparative clinical, safety and cost effectiveness of current COPD treatments by class of therapy for COPD overall and in specific patient groups/phenotypes, to understand the predictors of response to available COPD treatment options.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Longitudinal registry study

## 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

3000

# Study design details

## Data analysis plan

Describing the natural history of COPD in the US Phenotyping COPD sub-groups

Examining significant predictors of clinical outcomes

## Data management

## ENCePP Seal

## Conflicts of interest of investigators

[Full disclosure statements\\_v1.0\\_14MAR19.pdf](#)(42.55 KB)

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## Composition of steering group and observers

[SC member summary.pdf](#)(94.82 KB)

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## Data sources

## **Data sources (types)**

Disease registry

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