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.

Study status

Planned

Research institutions and networks

Institutions

Optimum Patient Care Australia

Australia

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Institution | Not-for-profit

Networks

DARTNet Institute

Contact details

Study institution contact

David Price

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/12/2018

Actual: 27/12/2018

Study start date

Planned: 01/07/2019

Data analysis start date

Planned: 02/09/2019

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

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)

Composition of steering group and observers

SC member summary.pdf(94.82 KB)

Data sources

Data sources (types)

Disease registry

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No