# COMPARABILITY OF POPULATION DEFINITIONS WITHIN & BETWEEN GLOBAL DATABASES - DEVELOPING TOOLS FOR OBSERVATIONAL RESEARCH (ACO Population Definitions)

First published: 15/07/2016

Last updated: 02/07/2024





# Administrative details

EU PAS number	
EUPAS13959	
Study ID	
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31039	
DARWIN EU® study	
No	
Study countries	
Korea, Democratic People's Republic of	
Netherlands	

Poland		
Spain		
United Kingdom		

#### Study description

This initial phase—the focus of this study—intends to compare prevalence and agreement rates for the different ACO definitions between different national and international databases. As such, simple ACO definitions will be used to ensure they can be operationalized across a number of databases. As each database used will be specific to a patient population and (in most cases) to one country of origin, use of multiple databases affords a unique opportunity to examine the sensitivity of findings to how populations were included in different databases. Future phases of the REG ACO Working Group's research programme will go on to characterize the different ACO populations from a clinical perspective (cross sectionally and historically) and to explore potential differential treatment outcomes associated with the different definitions. It is expected to be considerable variation in characterization approaches in the follow-on clinical characterisation and outcome evaluation phases (owing to differences in available variables and the requirement to use a range of proxy measures in order to optimise approaches within each database). As such, this work will be treated as a separate second study phase

#### **Study status**

Finalised

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

University of Groningen Netherlands, University
Hospital Vall d'Hebron Spain, Adelphi Real World
UK, Primary Care Majorca Department Spain,
OPCRD UK

## **Networks**

Respiratory Effectiveness Group (REG)
Belgium
Denmark
France
Germany
☐ Greece
Hungary

Italy
Netherlands
Spain
Sweden
United Kingdom
First published: 07/07/2021
Last updated: 04/06/2024
Network ENCePP partner

## Contact details

## **Study institution contact**

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Study contact

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## **Primary lead investigator**

Jerry Krishnan

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 31/08/2016

Actual: 31/08/2016

#### Study start date

Planned: 31/10/2016

Actual: 31/10/2016

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

Planned: 31/08/2017 Actual: 31/08/2018

# Sources of funding

Other

## More details on funding

Respiratory Effectiveness Group

# 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 topic:**

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

To inform standardised methods for future ACO observational research, the study aims to: test various smoking-related ACO population definitions (based on previous evidence), evaluating their respective prevalence and agreement (i) within and (ii) between a number of national and international research quality databases

## Study Design

## Non-interventional study design

Other

## Non-interventional study design, other

Observational, historical database study

# Study drug and medical condition

#### Medical condition to be studied

Chronic obstructive pulmonary disease

**Asthma** 

Asthma-chronic obstructive pulmonary disease overlap syndrome

# Population studied

#### Short description of the study population

Chronic obstructive pulmonary disease, Asthma, and Asthma-chronic obstructive pulmonary disease overlap syndrome patients

#### Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**

50000

# Study design details

#### Outcomes

The primary outcomes of the study are the prevalence of subpopulations B and C, relative to A within each of the parent population series (COPD, ACOS,

Asthma, Control) and the agreement within each database between the most selective subpopulations' definitions within each parent series (i.e. subpopulation C) and between different databases

#### **Data analysis plan**

Evaluation of:1. Outcome 1 (total number of patients) will require absolute count of patient numbers.2. Outcome 2 (population prevalence) will require evaluation of the percent prevalence within different Parent Series.3. Outcomes 3 & 4 (agreement across different population definitions: 1C vs 2C vs 3C vs 4C) will use the kappa statistic (k) or suitable alternatives (e.g. Chi-squared)

## **Documents**

#### **Study publications**

Krishnan JA, Nibber A, Chisholm A, Price D, Bateman ED, Bjermer L, van Boven JF...

# 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)

The Information System for Research in Primary Care (SIDIAP)

Optimum Patient Care Research Database

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

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

## 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**

Unknown