# Drug utilisation studies using data mapped to the OMOP Common Data Model: a proof of concept study assessing respiratory drug use in patients with asthma or COPD

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS41726

**Study ID**

42388

**DARWIN EU® study**

No

**Study countries**

- ☐ Netherlands
- ☐ United Kingdom
- ☐ United States

**Study description**

The use of healthcare data, generated through the delivery of normal clinical care is increasingly being proposed as a source of evidence to support not only drug development and regulatory decision-making but also to understand the physiology and pathogenesis of diseases. Use of multiple electronic health care databases is important not only to increase sample size but also to investigate country specific differences, differences by type of databases (e.g. primary vs. secondary care) or to replicate findings. One of the challenges however are the differences between the databases with regard to the underlying structures and semantic mapping. A common data model could help harmonise healthcare data across multiple data sets and provide a mechanism to allow the conduct of multi-database, international studies. The European Health Data and Evidence Network (EHDEN) project (https://www.ehden.eu/) is an international project supported by the Innovative Medicines Initiative (IMI) aiming to standardize health care data to the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) and to develop and implement tools to facilitate research on large electronic health care databases. One of the objectives of the EHDEN project is to test existing methodologies but also to develop new methodologies and analytical tools to conduct (pharmaco)epidemiological research using electronic health care databases mapped to the OMOP CDM. To investigate the validity and functionality of this approach, we want to conduct a drug-utilisation study using EHR data. As proof of concept study we want to conduct a drug utilisation studies on respiratory drug use in patients with asthma and chronic obstructive pulmonary disease (COPD). This research is important and relevant as asthma and COPD are prevalent conditions, primarily treated in primary care.

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**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Erasmus Medical Centre Rotterdam

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

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

Institution

### Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

### NDORMS Oxford - UK

## Contact details

**Study institution contact**

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**Primary lead investigator**

Katia Verhamme

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/11/2018

Actual: 01/11/2018

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**Study start date**

Planned: 01/01/2010

Actual: 01/01/2010

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**Data analysis start date**

Planned: 01/11/2021

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**Date of final study report**

Planned: 01/01/2022

## Sources of funding

- EU institutional research programme

## More details on funding

IMI - EHDEN

# Study protocol

DUS_asthmaCOPD_full protocol_2july2021.pdf (763.4 KB)

# 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:**

Drug utilisation

**Main study objective:**

By means of a drug utilisation study we want to investigate: • The frequency of respiratory drug use in terms of prevalence and incidence of use • Treatment pathways in particular treatment step-up and treatment step-down • To investigate switching between respiratory drugs • To investigate treatment

adherence

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03D) OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

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**Medical condition to be studied**

Asthma

Chronic obstructive pulmonary disease

## Population studied

**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)

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**Estimated number of subjects**

1000000

## Study design details

**Data analysis plan**

1/ Drug use will be assessed per respiratory class as a whole presented as prevalent and incident drug use. For prevalent drug use, the nominator consists of all patients with at least one day of exposure to the drug of interest in the calendar year. The denominator consists of all patients contributing at least one day of observation time in that calendar year. For the incidence drug use calculation, the nominator consists of the number of incident users in the year. 2/ This study will describe the treatment pathways of patients diagnosed with asthma, COPD or ACO. The analysis will calculate the aggregate summary statistics for each diagnosis cohort to determine the treatment pathway for each of the respiratory drugs in the study. 3/ Adherence will be assessed using 2 measures of adherence namely the medication possession ratio (MPR) and the proportion days covered (PDC).

# 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)**

Clinical Practice Research Datalink

Integrated Primary Care Information (IPCI)

**Data source(s), other**

CPRD, IPCI

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

**CDM website**

https://www.ohdsi.org/Data-standardization/

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No