# DARWIN EU® -Drug utilisation of salbutamol products for inhalation and therapeutic alternative inhalation products

**First published:** 03/12/2024

**Last updated:** 27/05/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000403

**Study ID**

1000000403

**DARWIN EU® study**

Yes

**Study countries**

- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands

Spain

United Kingdom

**Study description**

Salbutamol is essential for managing asthma and chronic obstructive pulmonary disease (COPD) due to its rapid bronchodilation effects. The rising prevalence of these conditions in Europe, driven by aging populations and worsening air quality, has led to increased demand for salbutamol, especially in urban areas. A shortage would severely impact patient care, leading to challenges in managing acute symptoms and increased strain on alternative therapies, which are not as effective for immediate relief.

The aim of the study is to understand if salbutamol (inhaled formulation) use has been increasing over the last few years in Europe which will in turn inform a potential risk of shortage. And secondly to understand the impact of the shortage of salbutamol inhaled formulations on therapeutic alternative inhalation products. This exercise falls under preparedness and prevention activities.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024

Institution | Educational Institution | ENCePP partner

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Marzyeh Amini

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/10/2024

Actual: 01/10/2024

### Study start date

Planned: 01/10/2024

Actual: 01/10/2024

### Date of final study report

Planned: 31/01/2025

## Sources of funding

- EMA

## Study protocol

DARWIN EU_Protocol_P3-C1-016_DUS_Salbutamol_V3.pdf(787.64 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

A cohort study will be conducted using routinely collected health data from 7 databases. The study will comprise two consecutive parts:

• A population-level cohort study

• Patient-level characterisation study

**Main study objective:**

1. To describe the overall (i.e. all drug formulations combined) rate of prescribing inhaled salbutamol (irrespective of type of formulation) by calendar time (month, year). Monthly prescribing rates will be provided by database and healthcare setting (inpatient/outpatient).
2. To describe the rate of prescribing inhaled salbutamol by type of formulation and calendar time (year, month). Monthly prescribing rates will be provided by database and healthcare setting.
3. To describe the rate of prescribing other inhaled alternatives and oral salbutamol by calendar time (month, year). Monthly prescribing rates will be provided by database and healthcare setting.
4. To describe characteristics of individuals treated with inhaled salbutamol in terms of indication of use, sex and age (in age categories) stratified by formulation and provided by database and healthcare setting.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03AC02) salbutamol

salbutamol

## Population studied

**Short description of the study population**

The study cohort will include all individuals registered in the database between 1st of January 2015 and the most recent available data, with at least 365 days of data visibility prior to becoming eligible for study inclusion. This requirement of at least 365 days of prior data history will not hold for children <1 year of age.

## Study design details

**Setting**

This study will use routinely collected health data from 7 databases in the DARWIN EU® network of data partners from 6 European countries. All databases were previously mapped to the OMOP CDM.

# 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 (CPRD) GOLD

Danish Health Data Registries

Institut Municipal d'Assistència Sanitària Information System

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

The Information System for Research in Primary Care (SIDIAP)

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

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**CDM website**

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

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**CDM version**

https://ohdsi.github.io/CommonDataModel/index.html

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown