# Drug Utilisation Study for Olodaterol

First published: 24/01/2017

**Last updated:** 14/06/2024





## Administrative details

<b>EU PAS number</b>		
EUPAS17386		
Study ID		
33210		
DARWIN EU® study		
No		
Study countries		
Denmark		
France		
Netherlands		

## **Study description**

Boehringer Ingelheim GmbH (BI) developed olodaterol, an inhaled long-acting beta2-agonist (LABA), for the indication of chronic obstructive pulmonary

disease (COPD). Because the use of LABAs has been associated with increased morbidity and mortality in patients with asthma, the health authorities requested the conduct of a post-approval drug utilisation study to assess potential off-label use of olodaterol in asthma and to characterise the use of olodaterol in clinical practice. The single agent indacaterol, the only other marketed LABA authorised in clinical practice for COPD but not for asthma, will also be assessed. Study objectives include the following: (1) Quantify the frequency of off-label use of olodaterol and indacaterol among new users of these medications, and (2) Describe the baseline characteristics of new users of olodaterol and indacaterol. This cross-sectional study will use information among new users of olodaterol or indacaterol collected in the following healthcare databases: the PHARMO Database Network in the Netherlands, the National Registers in Denmark, and the IMS Health Information Solutions (IMS) Real-World Evidence (RWE) Longitudinal Patient Database (LPD) in France. The source population is all subjects enrolled in the selected study databases at the date olodaterol became available in each database's country. The study groups are those subjects from the source population who receive a first dispensing for single-agent formulations of olodaterol for the primary objective or indacaterol for the secondary objective and have at least 12 months of continuous enrolment in the study databases. The study will describe the number and proportion of new users by indication and potential off-label use and according to medical history and use of co-medications.

## Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)			
France			
Spain			
Sweden			
United Kingdom			
United Kingdom (Northern Ireland)			
United States			
First published: 21/04/2010			
<b>Last updated:</b> 13/03/2025			
Institution Not-for-profit ENCePP partner			
Real World Evidence Solutions, IMS Health			
☐ France			
First published: 06/09/2011			
<b>Last updated:</b> 20/08/2024			
Institution Other			
Aarhus University & Aarhus University Hospital			
DEPARTMENT OF CLINICAL EPIDEMIOLOGY			
☐ Denmark			
First published: 20/07/2021			
<b>Last updated:</b> 02/04/2024			

# The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

□ Netherlands

**First published:** 07/01/2022

Last updated: 24/07/2024

Institution

Laboratory/Research/Testing facility

**ENCePP** partner

## Contact details

### **Study institution contact**

Alicia Gilsenan agilsenan@rti.org

Study contact

agilsenan@rti.org

## Primary lead investigator

Alicia Gilsenan

**Primary lead investigator** 

## Study timelines

Date when funding contract was signed

Planned: 18/08/2015

Actual: 18/08/2015

#### Study start date

Planned: 01/02/2017 Actual: 12/01/2017

#### **Data analysis start date**

Planned: 08/02/2017

#### Date of interim report, if expected

Planned: 01/09/2017 Actual: 23/08/2017

#### Date of final study report

Planned: 30/09/2018 Actual: 03/09/2018

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Boehringer Ingelheim International GmbH

# Study protocol

Olodaterol DUS Protocol\_Redacted.pdf (605.23 KB)

# Regulatory

## Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

# Methodological aspects

# Study type

# Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

## Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

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

Secondary use of data

## Main study objective:

To quantify the frequency of off-label use of olodaterol among new users of these olodaterol and indacaterol (i.e. the proportion of new users who do not have COPD) and to describe the baseline characteristics of new users of olodaterol.

# Study Design

#### Non-interventional study design

Cross-sectional

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(R03AC18) indacaterol indacaterol (R03AC19) olodaterol olodaterol

#### Medical condition to be studied

Chronic obstructive pulmonary disease

# Population studied

#### Short description of the study population

All subjects enrolled in the selected study databases at the date olodaterol became available in each database's country. The study groups are those subjects from the source population who receive a first dispensing for single-agent formulations of olodaterol for the primary objective or indacaterol for the secondary objective and have at least 12 months of continuous enrolment in

#### Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days – 23 months)

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**

20000

# Study design details

#### **Outcomes**

The primary outcome is the prevalence of off-label prescribing among new users of olodaterol. The secondary outcome is the prevalence of off-label prescribing among new users of indacaterol.

#### **Data analysis plan**

Statistical analyses will be descriptive in nature. Descriptive statistics will include the absolute and relative number of subjects, mean, median, standard deviation, and range for continuous variables. Statistical inference will not be performed (e.g. no P values will be generated). Where appropriate, two-sided 95% confidence intervals will be presented. All analyses will be conducted

separately in each study database and will be further analysed separately by new users of olodaterol and by new users of indacaterol, further stratified by treatment-naïve subjects and switchers. In the French IMS RWE LPD, data will be analysed separately for the panel of general practitioners and for the panel of pulmonologists. Analysis for each report (i.e. interim and final) will include data on all patients starting treatment with olodaterol or indacaterol from the start of such treatment up to the latest available data.

## **Documents**

#### Study results

1222\_53\_Olodaterol DUS\_Final Report\_Final\_20Aug2018\_clean\_Abstract (pages 6 to 13)\_Redacted.pdf (234.13 KB)

#### **Study publications**

Rebordosa, C., Houben, E., Laugesen, K. et al. No Evidence of Off-label Use of ... Rebordosa C, Houben E, Laugesen K, Asmar J, Montonen JT, Aguado J, et al. Utili...

# 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)

Danish registries (access/analysis)

PHARMO Data Network

Longitudinal Patient Data - France

#### Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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**

No