

# Aclidinium Bromide Drug Utilisation Post-Authorisation Safety Studies (DUS): Common Protocol for Aclidinium (DUS1) and Aclidinium/Formoterol Fixed-Dose Combination (DUS2)

**First published:** 15/05/2014

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6559

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### Study ID

39222


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### DARWIN EU® study

No

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### Study countries

 Denmark

 Germany

## **Study description**

Acclidinium bromide is a long-acting antagonist of lung M3 receptors used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. For a post-authorization safety study, a multinational database drug utilisation study (DUS1) in a cohort of new users of acclidinium bromide and new users of other inhaled medications frequently used by patients with COPD will be implemented. DUS2 will begin when the fixed-dose combination of acclidinium bromide/formoterol fumarate becomes available. DUS1/DUS2 objectives are:

- To describe the characteristics and patterns of use of new users of acclidinium bromide (monotherapy or in combination with formoterol) and new users of other COPD medications.
- To evaluate the potential off-label use of acclidinium bromide
- To describe users of acclidinium bromide in subgroups of patients for whom there is missing information in the RMP
- To establish a core cohort of new users of acclidinium bromide for the future evaluation of safety concerns described in the RMP

The study is planned in the Clinical Practice Research Datalink, the German Pharmacoepidemiological Database, and the national health databases in Denmark. DUS1/DUS2 are non-interventional cohort studies of new users of acclidinium bromide (monotherapy or in combination, respectively), tiotropium, LABA, and LABA+ICS who will be characterised 1) at the index date according to prior clinical information and prior and concurrent use of medications and 2) during the year following the index date to assess patterns of use. All available new users of acclidinium bromide or of the fixed-dose combination of acclidinium/formoterol at study initiation in each database will be included. The estimated study target is 1,500-2,000 new users of acclidinium bromide (for DUS1, the fixed-dose combination of acclidinium/formoterol for DUS2) and a sample of 2,000 new users of each comparator in each country-specific database.

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## **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

**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

Multiple centres: 3 centres are involved in the study

### Contact details

#### Study institution contact

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**Study contact**

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**Primary lead investigator**

Cristina Rebordosa

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 02/12/2013

Actual: 10/01/2014

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**Study start date**

Planned: 30/06/2015

Actual: 06/07/2015

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**Data analysis start date**

Planned: 14/07/2015

Actual: 26/08/2015

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**Date of interim report, if expected**

Planned: 31/03/2017

Actual: 18/05/2017

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**Date of final study report**

Planned: 29/05/2020

Actual: 12/03/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Almirall, S.A./AstraZeneca AB

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

D6560R00005 (DUS1 - Eklira), and D6570R00002 (DUS2- Duaklir)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Describe characteristics and patterns of use of new users of acclidinium bromide and other selected COPD treatments, Evaluate potential off-label use of acclidinium bromide, Describe users of acclidinium bromide in subgroups of patients for whom there is missing information in RMP, Establish a core cohort of new users of acclidinium bromide for future evaluation of safety concerns described in RMP

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03AC12) salmeterol

salmeterol  
(R03AC13) formoterol  
formoterol  
(R03AC18) indacaterol  
indacaterol  
(R03AK06) salmeterol and fluticasone  
salmeterol and fluticasone  
(R03AK07) formoterol and budesonide  
formoterol and budesonide  
(R03AK07) formoterol and budesonide  
formoterol and budesonide  
(R03AL05) formoterol and aclidinium bromide  
formoterol and aclidinium bromide  
(R03BB04) tiotropium bromide  
tiotropium bromide  
(R03BB05) aclidinium bromide  
aclidinium bromide  
(R03BB06) glycopyrronium bromide  
glycopyrronium bromide

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### **Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

### **Short description of the study population**

New users of aclidinium bromide (on monotherapy or with concomitant use of formoterol) and new users of other COPD medications will be identified and included in the specific exposure cohort of interest.

## Inclusion Criteria

Patients in the study will be required to meet the following criteria, as ascertained from

each of the automated databases:

- To have at least 1 year of enrolment in the database (DUS1 and DUS2).
- To have not been prescribed aclidinium bromide as monotherapy or with concomitant use of formoterol during the 6 months before the date of first prescription of aclidinium bromide (index date) in DUS1
- To have not been prescribed aclidinium bromide as monotherapy, with concomitant use of formoterol, or as acclidinium/formoterol during the 6 months before the date of first prescription of acclidinium bromide (index date) in DUS2

## Exclusion Criteria

No age restrictions or exclusion criteria will be applied. This will allow for the characterisation of all users of acclidinium bromide and comparator drugs irrespective of the indication for which these medications are used.

Identification of potential off-label use of acclidinium bromide in the paediatric and adult populations is one of the specific objectives of this DUS.

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### **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)
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### **Special population of interest**

Hepatic impaired

Renal impaired

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## Estimated number of subjects

22500

## Study design details

### Data analysis plan

The analysis will be descriptive and implemented in two phases:Phase 1.

Baseline analysis: • Age and sex distribution of users • Proportion of patients with the above listed characteristics, comorbidities, and comedications for up to 1 year before the index date. • Proportion and description of patients with off-label use.Phase 2. Follow-up analysis: • Assessment of relevant comorbidities, pregnancies, and treatment patterns (duration, dose, and switching patterns) during 1 year after the index date.

## Documents

### Study publications

[Rivero-Ferrer E, Witzleb AJ, Olesen M, Plana E, Aguado J, Saigi-Morgui N, Rubin...](#)

[Plana E, Rebordosa C, Aguado J, Thomas S, Garcia-Gil E, Perez-Gutthann S, Caste...](#)

[Rebordosa C, Rubino A, Witzleb AJ, Olesen M, Plana E, Aguado J, Saigi N, Daoud ...](#)

[Rebordosa C, Varas-Lorenzo C, Castellsague J, Plana E, Bui C, Aguado J, Garcia ...](#)

[Rebordosa C, Plana E, Aguado J, Thomas S, Garcia-Gil E, Perez-Gutthann S, Caste...](#)

## 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

German Pharmacoepidemiological Research Database

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### Data source(s), other

National Health Databases Denmark

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No