# AERIAL®: Changes in health and functional status in patients with COPD during therapy with Spiolto® Respimat®

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## Administrative details

**Study description** 

EU PAS number	
EUPAS18745	
Study ID	
34041	
DARWIN EU® study	
No	
Study countries	
Germany	

The objective of this NIS is to measure changes in health status including functional status using CCQ scores in COPD patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

#### **Study status**

Finalised

## Research institutions and networks

## **Institutions**

## Boehringer Ingelheim

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Institution

Multiple centres: 144 centres are involved in the study

## Contact details

## Study institution contact

Andrea Marseille info@boehringer-ingelheim.com

Study contact

#### **Primary lead investigator**

## Adrian Gillissen

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Planned: 18/10/2016 Actual: 18/10/2016

#### Study start date

Planned: 30/04/2017 Actual: 26/05/2017

#### Data analysis start date

Planned: 31/08/2018 Actual: 24/05/2019

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

Planned: 31/12/2018 Actual: 18/12/2019

## Sources of funding

Pharmaceutical company and other private sector

# More details on funding

# 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:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

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

Primary data collection

#### Main study objective:

The objective of this NIS is to measure changes in health status including functional status using CCQ scores in COPD patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine, other

Spiolto Respimat

#### Medical condition to be studied

Chronic obstructive pulmonary disease

# Population studied

#### Short description of the study population

Chronic obstructive pulmonary disease (COPD) patients receiving treatment with Spiolto® Respimat® after approximately 6 weeks in routine clinical practice.

#### 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)

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

Other

#### Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

#### **Estimated number of subjects**

1300

# Study design details

#### **Outcomes**

Primary objective: Assess proportion of patients achieving "therapeutic success" (= 0.4 point decrease in the CCQ score between baseline and approximately week 6), Secondary objectives: Assessment of changes in CCQ and CCQ-4, patient's general condition at visit 1 (baseline and at visit 2 (approx. 6 weeks after visit 1), patient satisfaction with Spiolto® Respimat®, willingness to continue treatment with Spiolto® Respimat® at visit 2 as proxy for adherence

#### **Data analysis plan**

For the primary outcome, the proportion of patients with CCQ therapeutic success will be presented together with the 95% confidence interval.Patient's

general condition (PGE) at visit 1 and visit 2, patient satisfaction and willingness to continue treatment at visit 2 as categorical variables will be analyzed as tabulations of frequencies. Change from Visit 1 to Visit 2 in the CCQ and CCQ-4 score as continuous outcome will be analyzed with

N/mean/SD/min/median/max.Subgroup analysis for maintenance naïve patients and the ones already treated at baseline with long acting bronchodilators (LABA only, LAMA only) or LABA + ICS will be performed for the primary outcome, if such subgroups include >20% of all patients.Subgroup analyses will be performed by GOLD spirometric classifications (2 vs. 3 vs. 4) and GOLD patient groups (B vs. C/D and B vs. C vs. D) for the primary outcome and changes in CCQ and CCQ-4 for the secondary outcome

## 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 sources (types)

Other

## Data sources (types), other

Prospective patient-based data collection

# 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