Assessment of physical functioning and handling of Spiolto® Respimat® in patients with chronic obstructive pulmonary disease (COPD) requiring long-acting dual bronchodilation in routine clinical practice (OTIVACTO)

First published: 13/12/2016 Last updated: 02/04/2024





### Administrative details

#### **EU PAS number**

**EUPAS16629** 

Study ID

16933

**DARWIN EU® study** 

No

**Study countries** 

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### **Study description**

Reduced physical activity resulting in deconditioning and restricted physical functioning is a common constraint of patients with moderate to very severe COPD. Clinical studies investigating treatment with Spiolto® Respimat® and its single components have shown significant improvements in exercise capacity in patients with COPD.Real-world data on the effects of a fixed-dose combination (LABA+LAMA) therapy with tiotropium and olodaterol administered in a single device, in COPD patients who need treatment with two long-acting bronchodilators, is not available.)

#### **Study status**

Planned

### Research institutions and networks

### Institutions

### Boehringer Ingelheim

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Institution

### Contact details

**Study institution contact** 

# Ingelheim Boehringer MEDICABIITALIA@boehringeringelheim.com

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## **Primary lead investigator** Ingelheim Boehringer

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 13/02/2017

### Study start date

Planned: 20/02/2017

#### Data analysis start date

Planned: 27/02/2017

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

Planned: 30/06/2018

## 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 type:**

Non-interventional study

#### Scope of the study:

Other

### If 'other', further details on the scope of the study

Measure changes in physical function

### Main study objective:

The primary objective of the study is to measure changes in physical functioning - serving as a surrogate for physical activity and exercise capacity - in COPD patients being treated with Spiolto® Respimat® after approximately 6

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine, other

**SPIOLTO** 

### Study drug International non-proprietary name (INN) or common name

**TIOTROPIUM** 

**OLODATEROL** 

#### Medical condition to be studied

Chronic obstructive pulmonary disease

# Population studied

#### **Age groups**

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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

## Study design details

#### **Outcomes**

The primary objective is to evaluate the Physical Functioning based on Physical Functioning Questionnaire (PF-10)scores which consists of 10 questions evaluating the extent of experienced restrictions while conducting usual activities at visit 1 and at visit 2 with Spiolto® Respimat. The secondary objective is to evaluate the patient's general condition (physician's evaluation) at visit 1 (= baseline visit at the start of the study) and at visit 2 (= final visit approx. 6 weeks after visit 1), as well as patient satisfaction with Spiolto® Respimat® at visit 2.

#### Data analysis plan

All patients who have received at least one dose of Spiolto® Respimat® will be included in the analysis, this is the treated set. All analyses will be performed on the treated set (as-treated analysis). If patients have missing values for an outcome, those patients will be excluded for that outcome's analysis. The assessment will be carried out using SAS® software. The statistical characteristics presented in the end-of-text tables will be N / mean / SD / min / median / max for continuous variables. Tabulations of relative and absolute frequencies will be presented for categorical variables. Incidence rates and 95% CI will be given when appropriate

## 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