# 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 RCV NIS)

**First published:** 18/03/2016

**Last updated:** 12/12/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS12864

**Study ID**

13460

**DARWIN EU® study**

No

**Study countries**

- [ ] Austria
- [ ] Bulgaria
- [ ] Croatia
- [ ] Czechia
- [ ] Hungary
- [ ] Israel
- [ ] Romania
- [ ] Russian Federation
- [ ] Slovakia
- [ ] Slovenia
- [ ] Switzerland

**Study description**

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 weeks.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.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Boehringer Ingelheim

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Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Ingelheim Boehringer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 13/05/2015

Actual: 13/05/2015

**Study start date**

Planned: 19/04/2016

Actual: 11/04/2016

**Date of final study report**

Planned: 30/06/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim RCV GmbH & Co KG

## 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

**Study type:**

Non-interventional study

**Scope of the study:**

Evaluation of patient-reported outcomes

**Data collection methods:**

Primary data collection

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**Study design:**

Open-label observational study conducted in 6 countries, including COPD patients receiving treatment with Spiolto® Respimat®

**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 weeks.

## Study drug and medical condition

**Medicinal product name**

SPIOLTO RESPIMAT

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**Anatomical Therapeutic Chemical (ATC) code**

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

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**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**Short description of the study population**

The following inclusion criteria were defined:

- Written informed consent prior to participation
- Female and male patients ≥ 40 years of age
- Patients diagnosed with COPD and requiring long-acting dual bronchodilation (LAMA + LABA) treatment according to approved Spiolto® Respimat® SmPC and COPD GOLD Strategy Document recommendation

Patients fulfilling any of the following exclusion criteria were excluded from study participation:

- Patients with contraindications according to Spiolto® Respimat® SmPC
- Patients who have been treated with a LABA/LAMA combination (free and fixed dose) in the previous 6 weeks
- Patients continuing LABA-ICS treatment should not be additionally treated with Spiolto® Respimat® in order to avoid a double dosing of long-acting beta-agonists
- Patients for whom further follow-up is not possible at the enrolling site during the planned study period of approx. 6 weeks
- Pregnancy and lactation
- Patients currently listed for lung transplantation
- Current participation in any clinical trial or any other non-interventional study of a drug or device

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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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**Estimated number of subjects**

7000

# Study design details

**Setting**

Between August 2016 and November 2017, 68 investigation sites in 6 countries (Belgium, Denmark, Luxembourg, the Netherlands, Portugal, Sweden), mainly office based pulmonologists and general practitioners,
participated in this NIS. The first patient was screened on 08 November 2016 and the last patient was
screened on 28 September 2017. Last patient out (LPO) was on 14 December 2017. In total, 132 patients of the planned 1200 patients were screened in 30 investigational sites. Patient enrolment was discontinued prematurely due to recruitment failure.

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**Outcomes**

Primary outcomes:“Therapeutic success” at visit 2 (10-point increase in the PF-10 score between visit 1 and visit 2). Secondary outcomes:- Changes in the PF-10 score from visit 1 to visit 2- General condition of the patient, evaluated by the physician (PGE score) at visit 1 and visit 2.- Patient satisfaction with Spiolto Respimat at visit 2.

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**Data analysis plan**

For the primary outcome, the proportion of patients with therapeutic success will be presented together with the 95% confidence interval. The patient’s general condition (PGE) at visit 1 and visit 2, mMRC at visit 1 and patient satisfaction at visit 2 are categorical variables so they will be analyzed as tabulations of frequencies. Change from visit 1 to visit 2 in the PF-10 score is a continuous outcome, so it 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 more than 20% of all patients.Subgroup analyses will be performed by GOLD spirometric classifications (2 vs. 3/4) and GOLD patient groups (B vs. C/D and B vs. C, vs. D) for the primary outcome and changes in PF-10 for the secondary outcome.

## Documents

**Study results**

1237-0045_Synopsis.pdf (413.61 KB)

# 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