

# Characteristics and Treatment Patterns of Patients with Chronic Obstructive Pulmonary Disease (COPD), Initiating Tio+Olo or Other Maintenance Therapies in the US and the UK: A Retrospective Claims Database Study.

**First published:** 25/10/2019

**Last updated:** 14/07/2021

Study

Planned

## Administrative details

### EU PAS number

EUPAS31940

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### Study ID

31941


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

 United States

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## **Study description**

Chronic obstructive pulmonary disease (COPD) is a common disease characterized by airway obstruction confirmed by spirometry, often including small airway obstruction and emphysema. For patients who are diagnosed with COPD, maintenance treatments often include bronchodilators, primarily long-acting muscarinic antagonists (LAMA), long-acting beta agonists (LABA), and inhaled corticosteroids (ICS) alone or in combination with each other and corticosteroids. Sp(t)iolto® Respimat®, a LAMA+LABA combination, was approved in May 21, 2015 in the US and July 1, 2015 in the EU (marketed as Stiolto in the US and Spiolto in the EU, referred to here as Tio+Olo). Selective prescribing according to patient characteristics, known as channeling, can lead to bias in comparative studies where drugs with similar therapeutic indications are prescribed to groups of patients with prognostic differences. Claimed advantages of a new drug may be distorted if they are channeled to patients with special pre-existing morbidity, with the consequence that disease states can be incorrectly attributed to use of the drug. Therefore, it is important to identify clinical and socio-demographic characteristics of patients who initiate each treatment as opposed to other available maintenance treatments in COPD patients.

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## **Study status**

Planned

## **Research institutions and networks**

### **Institutions**

## Aetion

 Spain

**First published:** 24/11/2022

**Last updated:** 16/07/2024

**Institution**

**Other**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Jukka Montonen

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 26/02/2019

Actual: 26/02/2019

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### Study start date

Planned: 15/11/2019

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

Planned: 30/04/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

The primary objectives of the study are to use US and UK data to describe the characteristics of COPD patients according to various demographic, lifestyle, clinical, and medication use at the time of diagnosis, at the time of initiation of first maintenance therapy and at the time of initiation of second maintenance therapy

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**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**

350000

## Study design details

### **Outcomes**

Patient characteristics, include various demographic, lifestyle, clinical, and medication characteristics will be reported at three points in time: 1) COPD claim confirming diagnosis date (Cohort Entry Date), 2) Date of initiation of first maintenance therapy (1st Treatment Index Date), overall and stratified by therapy category, 3)

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### **Data analysis plan**

- All covariates will be reported as mean (SD) and/or median (IQR) for continuous variables and counts and frequency (%) for categorical variables.

## 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

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### Data source(s), other

CPRD

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## 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