# SATisfaction and adherence to COPD treatment

**First published:** 27/05/2016

**Last updated:** 17/12/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS13605

**Study ID**

13606

**DARWIN EU® study**

No

**Study countries**

☐ Italy

**Study description**

The present study will explore the patients' satisfaction to COPD medical treatment (i.e. pharmacological and not pharmacological treatment) in a clinical real-world setting and how the satisfaction for medical treatment is related to

clinical parameters, quality of life, illness perception and treatment adherence evolution. Moreover health care resource consumption will be observed during the observation period.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Boehringer Ingelheim

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

# Contact details

**Study institution contact**

Ingelheim Boehringer MEDICABIITALIA@boehringer-ingelheim.com

**Study contact**

MEDICABIITALIA@boehringer-ingelheim.com

**Primary lead investigator**

Ingelheim Boehringer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 08/09/2015

Actual: 08/09/2015

---

**Study start date**
Planned: 25/11/2015

Actual: 25/11/2015

---

**Date of final study report**
Planned: 31/12/2017

Actual: 30/08/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer-Ingelheim

## Study protocol

1237-0051_protocol_redacted.pdf (715.6 KB)

## 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:**

Disease /health condition

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Evaluation of patient-reported outcomes

Healthcare resource utilisation

Other

**If ‘other’, further details on the scope of the study**

Disease awareness and treatment satisfaction

**Data collection methods:**

Primary data collection

**Study design:**

Multi-center, non-interventional (observational), prospective cohort study based mainly on newly-collected data.

**Main study objective:**

To describe the patients’ satisfaction to COPD medical treatments (by means of the TSQM9) during a 12-month observation period (namely, at enrolment, and after 6 and 12 months) in real- world setting

## 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 (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

**Estimated number of subjects**

400

## Study design details

**Setting**

20 Italian Pneumology Centres.

**Outcomes**

Patient Reported Outcomes Questionnaires/scales (filled in by patient or the investigator): Treatment Satisfaction Questionnaire, 9 items (TSQM-9), Brief Illness Perception Questionnaire (B-IPQ), COPD Assessment Test (CAT), Modified Medical Research Council Dyspnea Scale (MMRC), Morisky Medication-Taking Adherence Scale, Awareness structured interview (COPD awareness questionnaire).

**Data analysis plan**

Descriptive analysis will be means, medians, quantiles, proportions (with their respective 95% confidence intervals and SE when relevant) and contingency tables according to the nature of the variables. As a dispersion measurement the standard deviation and the interquartile range will be calculated.The statistical analysis will be done on all evaluable patients i.e. patients who enter the study without inclusion-exclusion criteria violations and with at least one TSQM-9 domain score (effectiveness, convenience and global satisfaction) calculated. Patients with missing values will not be excluded from the analysis, their data will not be replaced, frequency of missing data will be given for all analyzed variables. Lost to follow up patients will be analyzed until their last available visit.

## Documents

**Study results**

1237-0051_Synopsis.pdf (282.42 KB)

**Study publications**

https://pubmed.ncbi.nlm.nih.gov/31760881/

# 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