

# A Cross-sectional Study to Evaluate the Effectiveness of the Colobreathe Risk Minimisation Educational Programme Among Healthcare Professionals and Patients

**First published:** 12/01/2016

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12030

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### Study ID

34147

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### DARWIN EU® study

No

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### Study countries


 Austria

 Denmark

 France

 Germany

 Netherlands

 United Kingdom

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## **Study description**

Colobreathe, authorised in Europe in 2012 through a centralized procedure, is indicated for the management of chronic pulmonary infections due to *P. aeruginosa* in patients with CF aged 6 years and older. Colobreathe was approved with a requirement for additional risk minimisation measures, specifically, that healthcare professionals (HCPs) and patients are provided with educational material containing information on the need to comply with treatment, instructions on how to use the product (capsules and Turbospin inhaler device), and information on side effects. Educational material has been developed and disseminated in Europe to inform HCPs and patients of important information on the safe use of Colobreathe. This study is being conducted to assess the effectiveness of the educational material among HCPs who prescribe or administer, and patients who use, Colobreathe in Europe. The proposed study utilises a cross-sectional survey study design.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

Teva B.V.

## Contact details

### Study institution contact

Madison Terri [terri.madison@iconplc.com](mailto:terri.madison@iconplc.com)

Study contact

[terri.madison@iconplc.com](mailto:terri.madison@iconplc.com)

### Primary lead investigator

Terri Madison

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 25/06/2015

Actual: 26/10/2015

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### Study start date

Planned: 16/09/2016

Actual: 28/09/2016

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### Data analysis start date

Planned: 03/04/2018

Actual: 25/04/2018

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### Date of final study report

Planned: 31/08/2018

Actual: 02/08/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Forest Laboratories UK Limited, Teva B.V.

## Regulatory

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

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The overall objective of this study is to evaluate process indicators of the effectiveness of the risk minimisation educational material implemented in the EU for Colobreathe, specifically, knowledge rates, and measures of distribution and use of, the Colobreathe RMM educational material.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

COLOBREATHE

## Population studied

**Short description of the study population**

Healthcare professionals (HCPs) who have prescribed or administered Colobreathe within the 12 months prior to completing the survey, and patients (or their caregivers) who have received Colobreathe within the 6 months prior to completing the survey.

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## **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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**

300

## **Study design details**

### **Outcomes**

Knowledge rates of information included in the Colobreathe RMM educational material. Measures of distribution and use of the Colobreathe RMM educational material.

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### **Data analysis plan**

The primary analysis population will include all HCPs and patients/caregivers who have completed the survey. The primary criteria are the respondents' knowledge rates across each of the key risk minimisation educational messages for Colobreathe. Other criteria are measures of distribution and use of educational material. Knowledge rates for each of the key risk minimisation educational messages for Colobreathe will be calculated with 95% two-sided CI. Knowledge rates may also be reported by relevant subgroups such as country and recruitment method.

## **Documents**

## Study publications

[Kaplan S, Patino O, Rainville C, Madison T. Assessment of Colistimethate Sodium...](#)

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## 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](#)

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### Data sources (types), other

Cross-sectional survey study conducted in HCPs who have prescribed or administered Colobreathe within the 12 months prior to completing the survey, and in patients (or their caregivers) who have received Colobreathe within the 6 months prior to completing the survey

## 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**

Unknown