

# Evidence in real world for Trixeo® Aerosphere™ Initiation in COPD (ENARXI)

**First published:** 27/09/2023

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS106900

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### Study ID

106901

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

The main aim of the study is to describe the characteristics of COPD patients when Trixeo® Aerosphere™ is initiated, based on data from the THIN® and Colibri databases. Secondary objectives are: - To describe from THIN®

database data the rate of appropriate initiation of Trixeo® Aerosphere™ according to: - The Transparency Commission (CT) (18); - SPLF 2021 (5) and GOLD 2021 (4) recommendations. - To describe from THIN® database data the distribution of blood eosinophil count in patients initiating Trixeo® Aerosphere™. - To describe the characteristics of COPD patients initiating treatment with Trixeo® Aerosphere™ using data from the Colibri-BPCO cohort to compare the results obtained with THIN® data and supplement them with patients seen mainly by hospital and private lung specialists and potentially more severe.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Cegedim Health Data (CHD)

 France

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**Institution**

Other

ENCePP partner

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

Adrien Coriat

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 01/07/2021

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**Study start date**

Actual: 01/09/2021

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**Date of final study report**

Planned: 31/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Regulatory

## Was the study required by a regulatory body?

Yes

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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:**

Drug utilisation

#### **Main study objective:**

The main aim of the study is to describe the characteristics of COPD patients when Trixeo® Aerosphere™ is initiated, based on data from the THIN® database.

## 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**

600

## Study design details

### **Data analysis plan**

No hypotheses will be tested and no assumptions will be made in this analysis. Continuous variables will be described using mean and standard deviation for parametric variables, median and interquartile range for non-parametric variables. Ordinal, binomial and categorical variables will be described using numbers and proportions.

## 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)

THIN® (The Health Improvement Network®)

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### Data source(s), other

Colibri

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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