

# REACH study: Real-World Evidence study of OM-85 in Adults and Children in China, Italy, and Belgium

**First published:** 06/12/2024

**Last updated:** 20/03/2026

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000316

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### Study ID

1000000316

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### DARWIN EU® study

No

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### Study countries

 Belgium

 China

 Italy

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## **Study description**

This non-interventional study is designed to investigate the effectiveness of OM-85 in the prevention of Respiratory Tract Infection (RTI) episodes and to understand the management of patients with RTI. The objectives will be studied separately in Belgium, Italy and China and will include description and comparison of RTI episodes before and after initiating OM-85 treatment, comparison of RTI episodes in patients initiating OM-85 treatment and in a non-user group, pattern of prescription of OM-85, antibiotics and other concomitant medications of interest, and healthcare resource utilisation.

As primary objectives, the effectiveness of OM-85 is assessed through (1) a before-after design, comparing the rate of RTI episodes before and after initiation of OM-85, and (2) a comparative effectiveness design, comparing the rate of RTI episodes during follow-up between patients who initiated OM-85 and patients who did not initiate OM-85.

The Target Trial Emulation is used as the framework for the design of this non-interventional study.

The study period will start from the date of earliest data availability and end at the date of latest data availability in each of the data sources. The study period will include an inclusion period, a baseline period, an initiation grace period and a follow-up period. The outcomes will be assessed at 3, 6, 9, 12, and 24 months after the initiation grace period, as per data availability.

The overall study population will include patients aged  $\geq 1$  year of age with  $\geq 1$  RTI episodes and no prescriptions of bacterial lysates within 12 months prior to the inclusion (baseline period).

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## **Study status**

Planned

## **Research institutions and networks**

# Institutions

## Parexel International

 United States

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Institution

Non-Pharmaceutical company

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[katja.hakkarainen@parexel.com](mailto:katja.hakkarainen@parexel.com)

### Primary lead investigator

Elani Streja

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 14/06/2024

Actual: 17/06/2024

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**Study start date**

Planned: 16/09/2024

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**Data analysis start date**

Planned: 06/02/2025

Actual: 19/08/2025

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**Date of final study report**

Planned: 05/10/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

OM Pharma

## Study protocol

[Redacted Study Protocol - BV2023-14 - Final Version - 22 Nov 2024.pdf](#) (1.91 MB)

[BV2023-14 Study Protocol v3.0\\_25 March 2025\\_protocol amendment.pdf](#) (1.4 MB)

## 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 topic:**

Disease /health condition

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:**

Secondary use of data

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

The primary objectives are:

- Primary objective 1: RTI rate 12 months before and 12 and 24 months after initiating OM-85: To describe and compare the rate of RTI episodes 12 months before initiating preventive treatment with OM-85 and 12 and 24 months after the initiation.
- Primary objective 2: Comparative effectiveness – rate of RTI episodes during

follow-up at 12 and 24 months: To compare the rate of RTI episodes during the follow-up at 12 and 24 months, in patients initiating preventive treatment with OM-85 and in comparable patients not initiating OM-85 (Standard Of Care/non-user group).

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name, other**

Broncho-vaxom, Ommunal, Broncho Munal, Vaxoral, Paxoral, Others.

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### **Anatomical Therapeutic Chemical (ATC) code**

(J07AX) Other bacterial vaccines

Other bacterial vaccines

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### **Medical condition to be studied**

Respiratory tract infection

## Population studied

### **Short description of the study population**

The overall study population will include patients aged  $\geq 1$  year of age with  $\geq 1$  Respiratory Tract Infection (RTI) episodes and no prescriptions of bacterial

lysates within 12 months prior to the inclusion (baseline period).

Within the overall study population, patients will be categorized to one of the two exposure groups (treatment strategies): patients who initiated OM-85 at the Cohort Entry Date (CED) or within the 30-day initiation grace period, and SOC/non-user group who did not initiate OM-85 at CED or within the 30-day initiation grace period. Subgroup analysis will be considered; if conducted, several subgroups will be defined for subgroup analyses, such as patients with respiratory comorbidities, other selected comorbidities, age, and number of previous RTI episodes in the baseline period.

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### **Age groups**

- **Paediatric Population (< 18 years)**
- **Adult and elderly population ( $\geq 18$  years)**

## **Study design details**

### **Comparators**

The patients who did not initiate OM-85 serve as a SOC/non-user comparator group

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### **Outcomes**

The primary outcome is the rate of RTI episodes.

The secondary and exploratory outcomes are:

- Baseline characteristics (age, sex, Body Mass Index, etc)
- Type and number of previous RTI episodes
- Prescription (dose, pattern of prescribing) of selected comedications, antibiotics
- Comorbidities

- Overall and RTI-specific healthcare resource utilization
- Acute exacerbations of Chronic Obstructive Pulmonary Disease (COPD)/ Chronic Bronchitis (CB) and asthma
- Time from Cohort entry date to first exacerbation of COPD/ CB and asthma

## 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

Inspur (China)

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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**

Unknown