

Cohort study to estimate incidence of pneumonia in users of Trelegy 100 or multiple inhaler triple therapy among patients with chronic obstructive pulmonary disease using health insurance claims data provided by Medical Data Vision Co., Ltd. in Japan (212606)

**First published:** 04/01/2022

**Last updated:** 17/09/2025

Study

Finalised

## Administrative details

**EU PAS number**

EUPAS44882

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**Study ID**

48198

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**DARWIN EU® study**

No

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## Study countries

Japan

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## Study status

Finalised

# Research institutions and networks

## Institutions

### GlaxoSmithKline (GSK)

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

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

Institution

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor [Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 31/03/2022

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## **Study start date**

Planned: 29/04/2022

Actual: 20/04/2022

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## **Date of final study report**

Planned: 29/08/2024

Actual: 30/07/2024

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

GSK

# Study protocol

[gsk-212606-protocol-orig-redact.pdf](#) (1.19 MB)

# Regulatory

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

Yes

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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

Compare the occurrence of hospitalization due to community-acquired pneumonia (CAP) among patients with COPD who were incident users of Trelegy 100 or MITT.

Hazard ratio (HR) will be calculated to investigate if the risk of CAP in Trelegy 100 group is not higher than a certain level ( $HR > 3$ ) compared to MITT group.

### Study Design

**Non-interventional study design**

Cohort

### Study drug and medical condition

**Medicinal product name**

TRELEGY ELLIPTA

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**Study drug International non-proprietary name (INN) or common name**

FLUTICASONE FUROATE

UMECLIDINIUM

VILANTEROL

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**Anatomical Therapeutic Chemical (ATC) code**

(R03AL08) vilanterol, umeclidinium bromide and fluticasone furoate

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**Medical condition to be studied**

Chronic obstructive pulmonary disease

Pneumonia

## 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**

4000

## Study design details

## Outcomes

Community-acquired pneumonia (CAP)

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## Data analysis plan

Risk estimation

## Documents

### Study report

[Study Report Anonymised 22 Jan 2025.pdf](#) (303.86 KB)

## 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)

[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