Post-authorisation Safety (PAS)
Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038)

**First published:** 17/07/2015 **Last updated:** 06/09/2024





## Administrative details

**EU PAS number** 

**EUPAS10316** 

Study ID

107565

**DARWIN EU® study** 

Study countries
Belgium
Czechia
Germany
Hungary
Italy
☐ Netherlands
Poland
Spain
United Kingdom
United States

## **Study description**

The study will address the research question of whether the incidence rates of cardiovascular (CV) and cerebrovascular events differ for new users of umeclidinium bromide/vilanterol trifenatate (UMEC/VI) combination or umeclidinium bromide (UMEC) compared with tiotropium in patients diagnosed with Chronic Obstructive Pulmonary Disease (COPD).

### **Study status**

Finalised

## Research institutions and networks

## Institutions

## Quintiles

First published: 01/02/2024

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



Real World Solutions, IQVIA
☐ Netherlands
United Kingdom (Northern Ireland)
First published: 28/04/2011
Last updated: 22/03/2024
Institution Other ENCePP partner

## Contact details

## **Study institution contact**

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

## Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

# Study timelines

### Date when funding contract was signed

Planned: 01/05/2015 Actual: 01/05/2015

### Study start date

Planned: 02/02/2016 Actual: 02/02/2016

### **Date of final study report**

Planned: 10/11/2023 Actual: 21/12/2023

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

GlaxoSmithKline

# Study protocol

gsk-201038-protocol-redact.pdf (1.29 MB)

gsk-201038-protocol-amend4-redact.pdf (1.52 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

## Study type

# Study type list

### Study type:

Non-interventional study

### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Effectiveness study (incl. comparative)

### Main study objective:

The primary objectives are: 1. To demonstrate non-inferiority of UMEC/VI combination and UMEC to tiotropium for risk of myocardial infarction (MI), stroke, heart failure or sudden cardiac death based on analysis to time to first event. 2. To quantify incidence rate and frequency of MI, stroke, heart failure or sudden cardiac death for new users of UMEC/VI combination, UMEC, and tiotropium.

## Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

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

TIOTROPIUM BROMIDE MONOHYDRATE

**UMECLIDINIUM BROMIDE** 

VILANTEROL TRIFENATATE

#### 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)

### **Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

## **Estimated number of subjects**

7214

# Study design details

#### **Outcomes**

Safety outcomes reported will include MI, stroke and new onset, or acute worsening/decompensation heart failure, sudden cardiac death, serious pneumonia/serious LRTI events, all-cause mortality, CV mortality and non-CV mortality, haemorrhagic stroke and ischaemic stroke, hospitalisation for heart failure, SAEs, all serious CV AESIs and all drug related AEs. Treatment effectiveness outcomes recorded will include persistence with initiated medications, moderate/severe COPD exacerbations (requiring treatment with one or more of the following: antibiotics, systemic steroids, hospitalisation) and health care utilisation: all cause and COPD-related.

#### Data analysis plan

The analysis will compare new users of UMEC/VI with new users of tiotropium, and new users of UMEC with new users of tiotropium. These new treatments may be added on to existing therapies. Analyses will be based on the time to the first event of stroke, MI and heart failure individually and non-inferiority will be considered to be demonstrated if the upper bound of the 95% confidence interval around the hazard ratio is 2.0 or less. If the lower bound is greater than 1.0, non-inferiority will not be assumed.

## **Documents**

## Study report

Clinical Study Report Anonymized 29 Jan 2024.pdf (2.88 MB)

## 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