# Multinational database cohort study to assess RMP specified safety outcomes in association with indacaterol/glycopyrronium bromide in Europe

**First published:** 28/10/2014

**Last updated:** 02/04/2024

Study | Finalised

## Administrative details

**EU PAS number**

EUPAS7674

**Study ID**

37308

**DARWIN EU® study**

No

**Study countries**

Denmark

Italy

Netherlands

Spain

United Kingdom

**Study description**

Multinational database cohort study to assess RMP-specified safety outcomes in association with indacaterol/glycopyrronium bromide in Europe

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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

Institution

### Health Search, Italian College of General Practicioners

Italy

**First published:** 02/03/2010

**Last updated:** 20/08/2024

Institution | Educational Institution | Other

## Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

**First published:** 20/07/2021

**Last updated:** 20/10/2026

Institution | Educational Institution

## SIDIAP Jordi Gol Spain

# Networks

## EU-ADR Alliance

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

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

Network

# Contact details

**Study institution contact**

Clinical Disclosure Office Novartis
Trialandresults.registry@novartis.com

**Study contact**

Trialandresults.registry@novartis.com

**Primary lead investigator**

Clinical Disclosure Officer Novartis

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 17/12/2013

**Study start date**

Actual: 01/11/2013

**Data analysis start date**

Planned: 03/11/2014

**Date of interim report, if expected**

Planned: 20/02/2015

**Date of final study report**

Planned: 28/12/2018

Actual: 03/12/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharma AG

## Study protocol

QVA149A2402-v02--protocol_redacted.pdf (1.67 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)

## Other study registration identification numbers and links

CQVA149A2402

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

**Main study objective:**

To assess the incidence rates and relative risks of selected endpoints in association with QVA149 exposure in a broader, real-world COPD population.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

INDACATEROL

GLYCOPYRRONIUM BROMIDE

**Anatomical Therapeutic Chemical (ATC) code**

(R03AL04) indacaterol and glycopyrronium bromide

indacaterol and glycopyrronium bromide

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**Medical condition to be studied**

Chronic obstructive pulmonary disease

# Population studied

**Short description of the study population**

Population of patients ≥40 years of age with at least one year of valid database history and a recorded diagnosis of COPD. Valid database history means that there is at least one year of database history for a patient. This means that the patient was registered with the GP since at least one year but also that the GP is providing data to the database for at least one year as well. For all patients an eligibility date will first be defined, which is the latest of the following dates: reaching 40 years of age, having one year of data in the database and having fulfilled the criteria for a diagnosis of COPD. Diagnoses of COPD may be searched in the entire available prior history of a patient.

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**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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**Special population of interest**

Other

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**Special population of interest, other**

Chronic obstructive pulmonary disease (COPD) patients

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**Estimated number of subjects**

6.000

# Study design details

**Outcomes**

Primary endpoints of interest are 1) Major cardiovascular events (myocardial infarction (MI) stroke, hospitalizations due to acute coronary syndrome orheart failure), 2) Ischemic heart disease including MI and angina pectoris, 3) cerebrovascular events (ischemic stroke, hemorrhagic stroke and (TIA)), 4) Cardiac arrhythmias (atrial fibrillation/flutter and ventricular arrhythmia, The secondary endpoints of interest are 1) (Narrow-angle) Glaucoma, 2) Bladderobstruction/urinary retention/incident BPH, 3) Diabetes Mellitus, 4) Bronchospasmand 5) all-cause mortality

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**Data analysis plan**

Cox regression will be used to estimate both crude and adjusted relative risks (expressed as hazard ratios HRs with 95% CIs), allowing for time-varying exposures.All analyses will be performed for each database separately. Effect estimates will be pooled across the databases, using a random effects approach. In addition, a pooled mega-analysis will be done by combining the data sources on a patient-level and adjusting for the database.As secondary analysis, subsequent episodes, with or without treatment, will be taken into account. The anchor drug will be used as reference category, HRs of the events will be estimated for all other treatment categories compared to this reference. In addition, a sensitivity analysis will be conducted only considering the first treatment episode during follow-up in patients naïve to both QVA149 and all

comparator drugs.Specific patient groups will be studied via stratified analysis on age, gender,underlying CV co-morbidity and COPD severi

## Documents

**Study results**

qva149a2402--legacy-clinical-study-report-redacted_Part1.pdf (6.99 MB)

**Study report**

qva149a2402--legacy-clinical-study-report-redacted_Part2.pdf (5.97 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 source(s)**

THIN® (The Health Improvement Network®)

Health Search/IQVIA Health Longitudinal Patient Database

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

**Data source(s), other**

Aarhus University Prescription Database (DK)

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

# 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