

# Mavacamten Real-World Safety: a post-authorisation multi-national, long-term, observational study in patients with obstructive Hypertrophic Cardiomyopathy (oHCM) in the real-world setting in Europe (CV027-013)

**First published:** 03/01/2024

**Last updated:** 05/02/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS108178

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### Study ID

108179


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### DARWIN EU® study

No

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### Study countries

 Denmark

 France

 Germany

 Sweden

 United Kingdom

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## Study description

The aim of this study is to evaluate the risk of clinically important cardiovascular safety-related outcomes among adult patients with symptomatic oHCM receiving mavacamten compared to non-mavacamten oHCM treatment in a real-world setting in Europe.

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## Study status

Planned

## Research institutions and networks

### Institutions


#### Bristol-Myers Squibb (BMS)

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

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

**Institution**

#### IQVIA

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Transparency and Disclosure Lead [ctt.group@bms.com](mailto:ctt.group@bms.com)

**Study contact**

[ctt.group@bms.com](mailto:ctt.group@bms.com)

### Primary lead investigator

Sophie Shen

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 30/06/2024

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### Study start date

Planned: 31/03/2026

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### Data analysis start date

Planned: 31/03/2026

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### Date of final study report

Planned: 31/12/2034

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bristol-Myers Squibb

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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

The main objective of this study is to estimate the incidence rates of heart failure (HF) associated with exposure to mavacamten and with exposure to non-mavacamten oHCM treatment, among adult patients with symptomatic oHCM and to estimate the risk of HF associated with exposure to mavacamten compared with non-mavacamten oHCM treatment, among adult patients with symptomatic oHCM.

## Study Design

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

Cohort

## Study drug and medical condition

### **Medicinal product name**

CAMZYOS

## 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**

3648

## Study design details

## Outcomes

Incidence rate (IR) of Heart Failure (HF) Risk of HF, HF with systolic dysfunction  
Hospitalisation due to HF Non-fatal myocardial infarction (MI) Non-fatal stroke  
Arrhythmia Hospitalisation for arrhythmia Atrial fibrillation Atrial flutter  
Ventricular tachycardia Implanted cardioverter defibrillator therapy 3-point  
MACE 4-point MACE eMACE Cardiovascular mortality All-cause mortality

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## Data analysis plan

Data analysis will be performed separately for each registry or database, using statistical packages SAS® Version 9.4 or higher (SAS Institute, Cary, NC, USA) or R (Version 3.5.0 or above), as appropriate.

In the study reports, study results will be presented separately for each registry or database, as appropriate, per data availability.

The complete study results for all registries/databases, including descriptive, comparative, exploratory, and sensitivity analyses, as well as the meta-analysis results (if feasible) will be provided in the final report.

A full description of the analytical approach, data derivations, category definitions, analyses and presentation of the study results will be detailed in the SAP.

The SAP will be finalised prior to the conduct of the study analyses.

## 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), other**

Register of Hypertrophic Cardiomyopathy (REMY) France, Translational Registry for Cardiomyopathies (TORCH) Germany, Statutory Health Insurance (SHI) Claims Germany, Clinical Practice Research Datalink (CPRD) Aurum United Kingdom, Danish National Health and Socioeconomic registries Denmark

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

## 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