

# United States Post-Marketing Observational Cardiovascular Safety Study in Patients taking Naloxegol (Naloxegol US Post-Market Requirement CV Safety)

**First published:** 16/03/2017

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS18201

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### Study ID

25981

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

The overall research goal for this study is to provide additional data to characterize the safety of naloxegol in patients aged 18 years and older who do not have a diagnosis of cancer and who are treated with opioids chronically.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### PPD Evidera

- Sweden
- United Kingdom
- United States

**First published:** 20/11/2013

**Last updated:** 22/09/2025

**Institution**

Laboratory/Research/Testing facility

Non-Pharmaceutical company

ENCePP partner

#### HealthCore

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

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

**Institution**

HealthCore United States, Edward Hines Jr. VA  
Hospital United States, Chicago Association for  
Research and Education in Science United States,  
Scott & White Memorial Hospital United States

## Contact details

### Study institution contact

Eric Wittbrodt [SLane@Valinorrx.com](mailto:SLane@Valinorrx.com)

Study contact

[SLane@Valinorrx.com](mailto:SLane@Valinorrx.com)

### Primary lead investigator

Eric Wittbrodt

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 13/10/2015

Actual: 13/10/2015

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### Study start date

Planned: 01/12/2015

Actual: 01/12/2015

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### **Data analysis start date**

Planned: 01/06/2016

Actual: 01/06/2016

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### **Date of interim report, if expected**

Planned: 30/06/2018

Actual: 23/05/2018

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

Planned: 31/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

[D3820R00008-clinical-study-protocol-25Sep2015 Redacted.pdf](#) (465.99 KB)

## 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)

## Other study registration identification numbers and links

D3820R00008

### Methodological aspects

#### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess the relative risk of MACE among naloxegol-treated patients compared with that among patients on prescription non-PAMORA OIC treatment.

#### Study Design

**Non-interventional study design**

Cohort

Case-control

Other

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### **Non-interventional study design, other**

Self-controlled case series

## Study drug and medical condition

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

Moventik

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

Constipation

## 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**

4400

## Study design details

## Outcomes

MACE defined as a composite of myocardial infarction, stroke and cardiovascular death, Individual components of MACE

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## Data analysis plan

The primary effect estimate is the relative incidence of MACE during naloxegol exposure as compared to during comparison drug treatment. The analysis of MACE is based on the Cox proportional hazards model with an indicator for naloxegol versus comparison drug treatment as a predictor, a non-specified baseline hazard with stratification by calendar year of cohort entry, and decile of propensity score. In addition to treatment status, the predictors will include covariates that are not balanced by the propensity scores.

## 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 \(e.g., claims\)](#)

[Electronic healthcare records \(EHR\)](#)

Other

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**Data sources (types), other**

National Death Index

## 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