# An Observational Post-Authorization Safety Study (PASS) of MOVENTIG® (Naloxegol) Drug Utilization in Selected European Populations

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# Administrative details

### **PURI**

https://redirect.ema.europa.eu/resource/17818

#### **EU PAS number**

**EUPAS12598** 

### Study ID

17818

### **DARWIN EU® study**

No

### **Study countries**

Germany

Norway

Sweden

**United Kingdom** 

### Study description

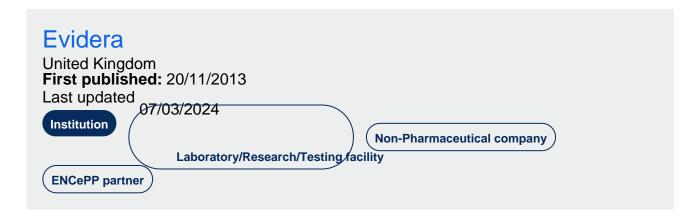
This is a drug utilization study that uses observational data from multiple countries. The study utilizes a retrospective new users cohort (patients newly prescribed naloxegol) study design in each of the countries.

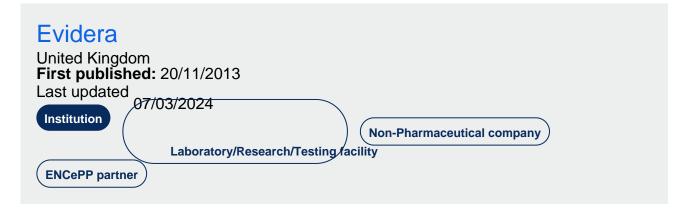
### Study status

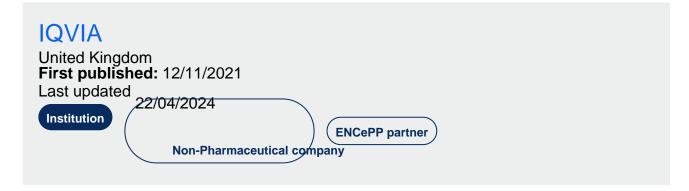
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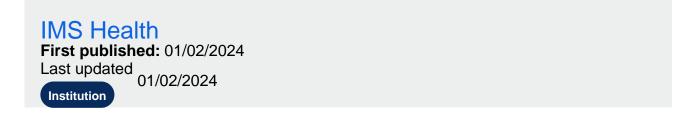
# Research institution and networks

### Institutions









# Contact details

### **Study institution contact**

Javier Cid

Study contact

javier.cid@evidera.com

**Primary lead investigator** 

Javier Cid

Primary lead investigator

# Study timelines

### Date when funding contract was signed

Actual:

13/10/2015

### Study start date

Actual:

01/12/2015

### Date of final study report

Actual:

15/07/2021

# Sources of funding

· Pharmaceutical company and other private sector

# More details on funding

Kyowa Kirin

# Study protocol

D3820R00006 CSP - PRAC 01212015 final.pdf(331.4 KB)

D3820R00006 CSP - PRAC 01212015 final\_ppd OK.pdf(335.3 KB)

# Regulatory

Yes

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

EU RMP category 3 (required)

# Methodological aspects

# Study type list

### Study topic:

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

### **Data collection methods:**

Secondary data collection

### Main study objective:

-To describe the characteristics of patients prescribed naloxegol at time of first prescription (demographics, targeted comorbidities, targeted comedications, provider characteristics, indication characteristics). -To describe any of the following treatment patterns: Discontinuation, Switching, Augmentation, Restart the prescription of naloxegol after temporary discontinuation, Change in dosing

# Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

# Study drug and medical condition

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

# Population studied

### Short description of the study population

The study population included new users of naloxegol (individuals newly prescribed naloxegol) in real-world practice reported from the selected European countries. Inclusion criteria:

- 1. The patient has at least 1 prescription of naloxegol in his/her medical record anytime during the study period.
- 2. The patient has at least 12 months of computerized records prior to the first prescription of naloxegol (index date).

### Exclusion criteria

No exclusion criteria will be applied.

### 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

Pregnant women

Renal impaired

### **Estimated number of subjects**

17254

# Study design details

### **Outcomes**

Treatment outcomes: - Discontinuation: no prescription of naloxegol in the period of twice the number of days of supply of the last prescription following its expiry date - Switching from naloxegol to other drug(s) potentially used by patients with opioid induced constipation (OIC) - Augmentation with other drugs potentially used by patients with OIC - Restart after temporary discontinuation

### Data analysis plan

All analyses for this study are descriptive and performed in each of the study countries separately, and if possible overall for all patients combined. Summary statistics (ie, mean,

standard deviation, median, minimum, and maximum) are presented for continuous variables and number and proportion/percentage are presented for categorical ones. The number and proportion of patients with missing data are reported for each of the variables of interest. The 95% confidence interval (CI) for the proportion of patients having a specific characteristic are presented using the Wilson Score method. Time to events are described using estimates (eg, median) and 95% CI based on the Kaplan-Meier method. Sensitivity analyses are conducted by also describing treatment discontinuation considering a shorter allowable gap. Exploratory analyses of potential predictors of length of naloxegol use are conducted using appropriate methodology (eg, Cox regression analysis)

### **Documents**

### Study results

Naloxegol DU Report\_Final\_V1.0\_clean\_15July2021\_Abstract.pdf(517.48 KB)

# Data management

### Data sources

### Data source(s)

National Prescribed Drugs Register / Läkemedelsregistret THIN® (The Health Improvement Network®)

### Data source(s), other

**NorPD** 

### Data sources (types)

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