Assessment of the effectiveness of risk minimisation measures set up for new safety information for Efient® (Prasugrel): a multinational survey among physicians to evaluate their knowledge and consideration of the new safety warning for Prasugrel in four European countries (H7T-MC-B021)

First published: 16/04/2014 Last updated: 29/03/2024





### Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/15799

#### **EU PAS number**

EUPAS6355

### Study ID

15799

#### **DARWIN EU® study**

No

#### Study countries

France Germany Netherlands United Kingdom

### Study description

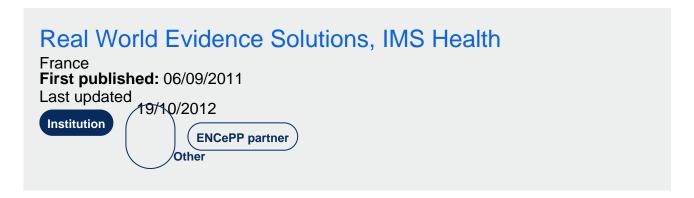
The research question is whether the new safety information included in the risk minimisation measures (Direct Healthcare Professional Communication (DHPC), international congress and journal publication) were effective in:• educating Healthcare Professionals (HCPs) about the increased bleeding risk when pre-treating with a loading dose of Efient® (prasugrel) prior to diagnostic coronary angiography in UA/NSTEMI patients, and• influencing their consideration of this risk when prescribing a loading dose of Efient® (prasugrel).

### **Study status**

Finalised

### Research institution and networks

### Institutions



### Contact details

Study institution contact Claudia Salinas

Study contact

claudia.salinas@lilly.com

Primary lead investigator

Toussi Massoud

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 20/12/2013 Actual: 20/12/2013

### Study start date

Planned: 02/06/2014 Actual: 10/06/2014

### Data analysis start date

Planned: 05/08/2014 Actual: 19/08/2014

### Date of final study report

Planned: 12/12/2014 Actual: 05/01/2015

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company and Daiichi Sankyo Company

## Study protocol

B021 RMiP PASS Protocol.pdf(628.84 KB)

# Regulatory

Was the study required by a regulatory body? Yes

Is the study required by a Risk Management Plan (RMP)? EU RMP category 3 (required)

# Methodological aspects

### 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:

Primary data collection

#### Main study objective:

To evaluate the proportion of targeted physicians who are knowledgeable of the new safety warning about Prasugrel.

# Study Design

### Non-interventional study design

Cross-sectional

# Study drug and medical condition

#### Name of medicine, other

**Effient** 

#### Medical condition to be studied

Acute coronary syndrome

## Population studied

### Short description of the study population

Physicians, prescribers, or potential prescribers, of Efient® (prasugrel); Specialists of any of those targeted for the Direct Healthcare Professional Communication (DHPC): cardiologists in all countries; physicians working in emergency departments, according to country specificities (cardiologists, emergency physicians, and physicians working in first aid).

### 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)

### Estimated number of subjects

442

## Study design details

#### **Outcomes**

To evaluate the proportion of targeted physicians who are knowledgeable of the new safety warning about prasugrel. To evaluate whether the physicians will consider the safety warning when prescribing Efient® (prasugrel).

### Data analysis plan

The statistical analysis will be conducted using the SAS®softwareV9.3 on Windows™ (SAS Institute, North Carolina, USA).Statistical results of the four countries will be presented in the same report, overall, by country and physician's specialty.Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, median, Q1, Q3, minimum and maximum.Categorical variables will be described as the total number and relative percentage per category. These will be the percentage per category.Confidence intervals of 95% will be calculated, when relevant.

### Data management

### Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional survey

## Use of a Common Data Model (CDM)

**CDM** mapping

Nο

# Data quality specifications

### Check conformance Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

Unknown