Evaluation of the effectiveness of Eliquis® (apixaban) risk minimization tools in European

First published: 29/07/2015

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10443

Study ID

19658

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France

- [ ] Germany
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Assessment of the risk minimization tools for Eliquis®

Study status

Finalised

Research institutions and networks

Institutions

Drug safety, Risk management & regulatory Practice, Pope Woodhead & Associates (PWA)

- [ ] United Kingdom

First published: 22/03/2010

Last updated: 07/03/2024

Institution | Educational Institution | Non-Pharmaceutical company | ENCePP partner

Networks

PopeWoodhead Associates

Contact details

Study institution contact

Sophie Shen sophie.shen@bms.com

Study contact

sophie.shen@bms.com

Primary lead investigator

Sophie Shen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/04/2014

Study start date

Planned: 26/08/2015

Actual: 26/08/2015

Data analysis start date

Actual: 26/08/2016

Date of interim report, if expected

Planned: 28/11/2016

Date of final study report
Planned: 26/05/2017

Actual: 24/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb, Pfizer

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 type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to evaluate the effectiveness of the Eliquis Prescriber Guide and Patient Alert Card in terms of knowledge of the important identified risk of bleeding associated with Eliquis treatment communicated by the RM tools.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

ELIQUIS

Population studied

Short description of the study population

Health care professionals (HCPs) using and adult patients receiving Eliquis® (apixaban).

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

576

Study design details

Outcomes

The proportions of HCPs using Eliquis and patients treated with Eliquis with knowledge of the important identified risk of bleeding associated with Eliquis treatment. (1) The proportions of HCPs using Eliquis and patients treated with Eliquis who have received the RM tools, (2) The proportions of HCPs using Eliquis and patients treated with Eliquis who have utilized the RM tools, and the extent of tool usage, and (3) The levels and distributions of behavior questionnaire results for HCPs and patients.

Data analysis plan

Descriptive analyses of the data will be conducted. HCP data will be presented by country, indication, specialty, HCP type, practice setting, regular vs. occasional treatment with Eliquis, RM tool users vs. non-users, and in total.

Patient data will be presented by country, indication, duration of exposure, usage vs. non-usage of the Patient Alert Card, number of previous anticoagulant treatments prescribed, and in total.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown