Evaluating the Effectiveness of Eliquis® Additional Risk Minimization Measures in Kingdom of Saudi Arabia.

First published: 21/05/2025

Last updated: 19/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000270

Study ID

1000000270

DARWIN EU® study

No

Study countries

☐ Saudi Arabia

Study description

Eliquis® (apixaban) is a reversible and highly potent inhibitor of factor Xa with rapid absorption, a 12-hour half-life, and 25% renal excretion.
It has been co-developed by Bristol-Myers Squibb and Pfizer as an anticoagulant and antithrombotic agent in non-valvular atrial fibrillation (NVAF) and venous thromboembolic events (VTE).
Apixaban was approved in 2014 by the Saudi Food and Drug Authority (SFDA) and the three approved indications include:

• Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors.
• Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.
• Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.

Saudi Arabia reported medication errors related with the use of direct oral anticoagulant in clinical practice and highlighted the need for risk prevention and reduction strategies to enhance safety associated with anticoagulant use.

As directed by the SFDA, the Marketing Authorization Holder (MAH) agreed to provide educational materials as part of additional risk minimization measures (aRMMs), targeting all healthcare professionals (HCPs) who are expected to prescribe/use Eliquis® for any of the approved indications.

This study, therefore, is intended to assess whether implementation of the RM tools has led to effective understanding and reinforcement of key safety messages outlined in the Summary of Product Characteristics (SmPC) and Package Leaflet.
The MAH has committed to do this using a survey-based approach. The survey will be comprised of questions aimed at assessing the success of RM tool

implementation:

- Utilization of the RM tools
- Knowledge and comprehension of the RM tool key safety messages
- Self-declared behaviors (including hypothetical risk-based scenarios).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

IQVIA Saudi Arabia Limited

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/10/2023

Study start date

Planned: 01/06/2025

Actual: 14/07/2025

Date of final study report

Planned: 30/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Saudi Limited 100% Funding

Study protocol

B0661194_Non-Interventional Study Protocol (Clean)_V1_16MAY2025_Redacted.pdf (2.54 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

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

Study design:

This will be a cross-sectional non-interventional PASS to evaluate the effectiveness of RM tools for Eliquis® in the KSA.

The study objectives will be accomplished by means of a cross-sectional survey among HCPs who prescribe and/or dispense Eliquis® in the KSA.

Main study objective:

The primary objective of this study will be to:

1. Assess HCPs' knowledge of RM tools (i.e., Prescriber Guide and Patient Alert Card) with regards to the bleeding risk associated with Eliquis® treatment.

The secondary objectives of this study are to:

1. Assess utilization of Eliquis® RM tools (i.e., Prescriber Guide and Patient Alert Card) by HCPs.
2. Assess HCPs' self- declared behavior with regards to the specific guidance related to the prevention and management of bleeding associated with Eliquis® treatment.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

ELIQUIS

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

APIXABAN

Anatomical Therapeutic Chemical (ATC) code

(B01AF02) apixaban

apixaban

Medical condition to be studied

Venous thrombosis

Population studied

Short description of the study population

HCPs will be considered for participation in the study if they prescribe/dispense Eliquis® for any of the three currently approved indications, including the following subgroups:

• Cardiologists (including allied specialties, e.g., angiologists, electrophysiologists)
• General practitioners/internal medicine physicians
• Other HCPs (e.g., pharmacists).

Estimated number of subjects

20

Study design details

Setting

At the time of protocol writing, approximately 85 HCPs were prescribing/dispensing Eliquis® in KSA and around 73 of these have received the RM tools in-person and 12 by email.

Given this relatively small pool of HCPs, an empirical sample size of 20 HCPs is proposed. Data will be collected during the data collection period of approximately 4-6 months.

The HCPs must meet all of the following criteria to be eligible for inclusion in the survey:

1. Involved in the treatment of at least one patient with Eliquis® within the last 12 months
2. Willing to participate in the self-administered HCP survey by providing voluntary consent to participate in this survey conducted in the KSA

The HCPs meeting any of the following criteria will not be included in the study:

1. Employed in full time research or hospital administration (i.e., non-practicing physicians)
2. Employment by Pfizer, Inc or any research organization/vendor contracted by Pfizer to administer the survey.

HCPs recruitment and survey will be conducted by the following process:

• HCPs will be invited to participate in the survey by email and/or phone. An email invitation will include a web link directing to a webtool named ‘Decipher’, where the survey questionnaire will be available.

• If the HCPs agree to participate in the survey, they can access the survey and the instructions for the web questionnaire by clicking on the web link included in the email.

• If the web questionnaire is not completed in the first attempt, HCPs will

receive a reminder email and/or phone (first reminder) 1 week after the initial invitation.
• If the web questionnaire remains incomplete, a second reminder will be sent about 2 weeks after the initial invitation.
• If the web questionnaire still remains incomplete, a third (and final) reminder will be sent 3 weeks after the initial invitation.

An HCP will be considered unreachable if he/she has been contacted up to 3 times without an answer.

Outcomes

The primary endpoint is:

1. The proportion of targeted HCPs who responds to the knowledge-related questions in agreement with the RM tools for Eliquis®.

The secondary endpoints are:

1. The proportion of targeted HCPs using Eliquis® for any approved indication who have utilized the RM tools.
2. The proportion of targeted HCPs whose responses to the practice-related questions, self-declared behavior, are in agreement with the RM tools.

Data analysis plan

The statistical analysis will be conducted using the SAS® software V9.4 (SAS Institute North Carolina, USA), or R version 3.6 or higher on Windows™.

All the analyses will be descriptive. Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, and median, Q1, Q3, minimum and maximum. Categorical variables will be

described as the total number and relative percentage per category.

In case of multiple-choice questions, the frequency of each option provided by the HCPs will be reported as the total number and relative percentage per category. Different combinations of the answers provided (if any) will not be considered.

Wilson CIs of 95% will be evaluated on the overall result.

The participation rate will be analyzed overall for HCPs.

The proportion of correct and desirable answers to the selected questions asked in the questionnaire will be expressed for HCPs who provide answers to those questions (the missing data will not be counted as a denominator in proportions). Success indicators by objectives will be presented for HCPs.

1. Primary analysis: The general statistical considerations described above will be applied to quantitative and qualitative variables. The number of missing data will be indicated. Missing values are expected to be few and distributed at random. Since there is no applicable method unanimously accepted, there will be no replacement or imputation of missing data.9 Confidence interval of 95% will be evaluated for endpoint variables.

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP).

2. Analysis of participation rate: the following different cases will be distinguished

- HCPs who do not participate (R)
- HCPs with partially answered questionnaires (P)

• Failed screening (F)
• HCPs with completed questionnaire (C)
• Contacted HCPs
• HCPs who agree to participate

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

A web-based, cross-sectional, structured self-administered questionnaire will be used to collect survey data from the HCPs.
The questionnaires will have a disclaimer and consent at the beginning.
They are designed to collect information on the eligibility and demographics of the HCPs.
Depending on the answers to the screening questions, survey participation could either be terminated or continued.

Data sources (types)

Non-interventional study

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

Not applicable