

# Xarelto (Rivaroxaban) Risk Minimisation Plan Evaluation: Patient and Physician Knowledge of Key Safety Messages

**First published:** 12/06/2013

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3911

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### Study ID

40441

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### DARWIN EU® study

No

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### Study countries

- ☐ France
  - ☐ Germany
  - ☐ Spain
  - ☐ United Kingdom
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## Study description

This cross-sectional epidemiologic study will measure physician and patient awareness and understanding of the key messages in the Xarelto prescriber guide and Xarelto patient alert card.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

**Multiple centres:** 50 centres are involved in the study

## Contact details

### Study institution contact

Elizabeth B. Andrews eandrews@rti.org

Study contact

[eandrews@rti.org](mailto:eandrews@rti.org)

### Primary lead investigator

Elizabeth B. Andrews

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 16/12/2011

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### Study start date

Planned: 15/09/2014

Actual: 15/09/2014

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### Date of final study report

Planned: 10/06/2020

Actual: 18/06/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[16167\\_Xarelto\\_Protocol\\_Risk Minimization Study\\_Final\\_28Nov2011.pdf](#)(1.66 MB)

[16167\\_Protocol\\_V4\\_Wave II\\_redacted.pdf](#)(1.69 MB)

## 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)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this cross-sectional epidemiologic study is to measure physician and patient awareness and understanding of the key messages in the prescriber guide and patient alert card.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

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

RIVAROXABAN

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**Anatomical Therapeutic Chemical (ATC) code**

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

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## **Medical condition to be studied**

Anticoagulant therapy

## **Population studied**

### **Short description of the study population**

Physicians and patients with recent rivaroxaban experience.

Physicians were eligible to participate if they had prescribed rivaroxaban in the past 6 months for one of the indications of interest.

Patients were eligible if they had taken rivaroxaban within the last 3 months for one of the indications of interest.

Patients will be identified through selection of a diverse set of medical practices across the five targeted countries. To be eligible for the study, the patients must meet all of the following criteria:

1. Patient has taken rivaroxaban within the last 3 months for prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (SPAF) or treatment of DVT and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.
2. Patient is aged 18 years or older.
3. Patient is able to understand and complete the consent form and patient questionnaire.
4. Patient can read and understand the native language of the country in which the study is being conducted.
5. Patient has not participated in a clinical trial for a treatment to prevent blood clots in the past 12 months.

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### **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**

5000

## Study design details

### **Outcomes**

1) Knowledge and understanding among physicians regarding key safety information contained in the prescriber guide assessed by web-based questionnaire. 2) Knowledge and understanding of patients regarding the key safety information contained in the patient alert card assessed by paper-based questionnaire.

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### **Data analysis plan**

Analyses will include detailed review of responses to individual questions as well as potential summary measure across logical grouping of response items. Physician results will be stratified by country, speciality, and other logical variables. Patient results will be stratified by country and other logical variables, potentially including a measure of the knowledge level of their physician. A detailed analysis plan describing methods of analysis and presentation, as well as table shells, will be developed prior to starting analysis of data.

## Documents

### **Study results**

[16167\\_EU PAS Abstract\\_Redacted\\_V 1.0\\_2020-06-09.pdf](#)(223.79 KB)

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### **Study report**

[16167\\_Clinical Study Report\\_Wave III\\_redacted\\_V 1.0\\_2020-06-09.pdf](#)(1.94 MB)

[16167\\_Clinical Study Report\\_Wave II\\_redacted\\_V 1.0\\_2018-05-24.pdf](#)(3.67 MB)

[16167\\_Clinical Study Report\\_Wave I\\_redacted\\_V 1.0\\_2015-10-16.pdf](#)(9.48 MB)

[16167\\_progress report.pdf](#)(119.93 KB)

[RTI EUPAS3911 - Summary Interim Report.pdf](#)(88.78 KB)

### **Study, other information**

[16167\\_Protocol\\_V2\\_Wave I\\_redacted.pdf](#)(4.07 MB)

[16167\\_Clinical Study Report\\_Wave II\\_redacted\\_V 1.0\\_2018-05-24.pdf](#)(3.67 MB)

[16167\\_Clinical Study Report\\_Wave I\\_redacted\\_V 1.0\\_2015-10-16.pdf](#)(9.48 MB)

[16167\\_progress report.pdf](#)(119.93 KB)

[RTI EUPAS3911 - Summary Interim Report.pdf](#)(88.78 KB)

## 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

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### **Data sources (types), other**

Cross-sectional survey to patients and physicians

## 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