

# COSIMO Cancer associated thrombosis - patient reported outcomes with rivaroxaban. A non-interventional study on patients changing to Xarelto® for treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in patients with active cancer

**First published:** 19/04/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12608

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### Study ID

33638

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### DARWIN EU® study

No

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## Study countries

-  Australia
  -  Belgium
  -  Canada
  -  Denmark
  -  France
  -  Germany
  -  Italy
  -  Netherlands
  -  Spain
  -  United Kingdom
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## Study description

This study aims to collect patient reported outcomes and assess treatment satisfaction in active cancer patients treated with rivaroxaban for VTE (venous thromboembolism).

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Site in Germany](#)

Multiple centres: 100 centres are involved in the study

## Contact details

### Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

### Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 02/03/2016

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### Study start date

Planned: 31/10/2016

Actual: 10/10/2016

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### Date of final study report

Planned: 10/02/2020

Actual: 10/02/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[18137\\_Study Protocol\\_v1.2\\_2018-02-01.pdf](#) (821.87 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## 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:**

Drug utilisation  
Other

**If 'other', further details on the scope of the study**

Patient reported outcomes

**Data collection methods:**

Primary data collection

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**Main study objective:**

To assess patient reported treatment satisfaction with regard to the Anti-Clot Treatment Scale (ACTS) burden score for the use of rivaroxaban for treatment of acute deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in patients with active cancer changing to this therapy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(B01AF01) rivaroxaban

rivaroxaban

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## **Medical condition to be studied**

Venous thrombosis

Pulmonary embolism

## **Population studied**

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

Female and male patients with active cancer and a diagnosis of DVT/ and/or PE were enrolled after the decision to start treatment with rivaroxaban has been made by the investigator.

Inclusion criteria was as follow:

1. Adult female and male patients with active cancer other than fully treated basal-cell or squamous-cell carcinoma of the skin (active cancer defined as the diagnosis or treatment of cancer in the previous < 6 months or recurrent or metastatic cancer)
2. Patients that have been treated with standard of care anticoagulation (LMWH/VKA) for treatment of DVT and/ or PE (index VTE event), and/ or prevention of recurrent DVT and PE for at least 4 weeks prior to inclusion in the study
3. Patients for whom the decision was made to start rivaroxaban for treatment of DVT and/ or PE, and/ or prevention of recurrent DVT and PE
4. Patients with Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2 (See Annex 3. For ECOG score details)

5. Patients who were willing to participate in this study (signed informed consent)

6. Patients who were available for follow-up with a life expectancy > 6 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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### **Special population of interest**

Other

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### **Special population of interest, other**

Cancer patients

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### **Estimated number of subjects**

500

## **Study design details**

### **Outcomes**

- Treatment satisfaction burden score Anti-Clot Treatment Scale (ACTS), - Preferences regarding the attributes of the anticoagulation medication options LMWH, VKA, rivaroxaban using DCE Survey- Change of ACTS score over time- Patient's quality of life using the FACIT-Fatigue questionnaire - Type of index VTE (venous thromboembolism) Event(for more secondary outcome measures please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov))

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## Data analysis plan

All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles and maximum). Continuous variables will be described by absolute value and as change from baseline per analysis time point, if applicable. The analyses for ACTS (Anti-Clot Treatment Scale) will be performed for the population which includes patients whose ACTS score at the time point for the target analysis, i.e. week 4, or months 3 and 6, is available. Other analyses will be performed for the population which includes patients receiving at least one dose of rivaroxaban. All details including calculated variables and proposed format and content of tables will be described in the Statistical Analysis Plan (SAP). SAP will be finalized before study database lock.

## Documents

### Study results

[18137\\_study abstract.pdf](#) (640.99 KB)

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### Study report

[18137\\_final study report.pdf](#) (6.15 MB)

## 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

Prospective patient-based data collection

## 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