

# Venous Thromboembolism Treatment (VOLT)

**First published:** 29/05/2019

**Last updated:** 14/06/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS29910

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### Study ID

47198

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### DARWIN EU® study

No

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### Study countries

- ☐ Finland
  - ☐ Norway
  - ☐ Sweden
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### Study description

A retrospective, observational study of patients prescribed an OAC following a VTE event after the 1 January 2013 or the marketing date of NOACs in each country, whichever occurs last, using nationwide registries from multiple Nordic countries (Sweden, Norway, and Finland).

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### PPD Evidera

- ☐ Sweden
- ☐ United Kingdom
- ☐ United States

**First published:** 20/11/2013

**Last updated:** 22/09/2025

**Institution**

**Laboratory/Research/Testing facility**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Jenkins Aaron Rupesh.Subash@pfizer.com

#### Study contact

[Rupesh.Subash@pfizer.com](mailto:Rupesh.Subash@pfizer.com)

#### Primary lead investigator

Jenkins Aaron

#### Primary lead investigator

## Study timelines

#### Date when funding contract was signed

Planned: 03/05/2018

Actual: 03/05/2018

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#### Study start date

Planned: 01/07/2019

Actual: 02/12/2019

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#### Date of final study report

Planned: 30/06/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

BMS/Pfizer

## 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

## Other study registration identification numbers and links

B0661132

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

Phase I involves a descriptive assessment of patient characteristics and treatment patterns in each country as well as detailed power calculations. If the study is adequately powered for comparative analyses, it will proceed to Phase II. Phase II involves analyses of comparative effectiveness and safety, utilising

warfarin as the comparator.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

This is a retrospective, observational, nationwide cohort study using administrative registry data.

## Study drug and medical condition

### **Medicinal product name**

ELIQUIS

LIXIANA

PRADAXA

XARELTO

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

WARFARIN

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### **Medical condition to be studied**

Deep vein thrombosis

Pulmonary embolism

## Population studied

## 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

20000

# Study design details

## Outcomes

Primary efficacy, Recurrent VTE Primary safety, Major Bleeding, Treatment interruption, Complete treatment discontinuation, Treatment switching, Treatment persistence, GI bleeding, intracranial haemorrhage, other bleeding, health care resource utilisation

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## Data analysis plan

Phase I of this study would be descriptive in nature, including the number, percentage of patients who discontinue, interrupt, and switch treatment. Patient characteristics will be summarised using numbers and percentages for categorical values and descriptive statistics (mean, SD, median, minimum, maximum and IQR) for continuous. Descriptive analyses will also be performed for specific subgroups. Phase II involves comparative safety and effectiveness analyses, which for this study includes a number of clinical endpoints (recurrent VTE, major bleeding, overall and by site (GI, ICH, other sites) and health care resource utilisation.

## 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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### Data source(s), other

The Swedish prescribed drug register, NorPD

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## 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