

# Anticoagulant treatment patterns and outcomes among venous thrombosis patients in France: a retrospective cohort analysis using SNDS database

**First published:** 18/06/2020

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS35888

### Study ID

50097

### DARWIN EU® study

No

### Study countries

☐ France

### Study description

A retrospective cohort study to describe anticoagulant (AC) treatment patterns and health outcomes in patients with venous thromboembolism (VTE), using the French national health data system (SNDS).

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Evidence and Access/Analytica Laser, Certara

☐ France

☐ United Kingdom (Northern Ireland)

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**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[ruth.mokgokong@pfizer.com](mailto:ruth.mokgokong@pfizer.com)

### Primary lead investigator

Ruth Mokgokong

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 05/07/2019

Actual: 05/07/2019

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### **Study start date**

Planned: 30/09/2020

Actual: 31/07/2020

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### **Data analysis start date**

Actual: 30/09/2020

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### **Date of final study report**

Planned: 28/02/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer/BMS

## 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 type:**

Non-interventional study

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#### **Scope of the study:**

Effectiveness study (incl. comparative)

#### **Main study objective:**

To describe anticoagulant treatment patterns and outcomes in patients with venous thromboembolism (VTE), using the French national health data system (SNDS), in two phases. Phase 1 involves descriptive analyses of patients' characteristics and treatment patterns for VTE patients, with and without active cancer. Phase 2 involves comparative effectiveness and safety analyses (only if powered)

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

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

WARFARIN

ACENOCOUMAROL

FLUINDIONE

HEPARIN

LOW MOLECULAR WEIGHT HEPARIN CALCIUM

LOW MOLECULAR WEIGHT HEPARIN SODIUM

FONDAPARINUX

ARGATROBAN

APIXABAN

RIVAROXABAN

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

Venous thrombosis

## 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

24000

## Study design details

### Outcomes

Primary efficacy, Recurrent VTE Primary safety, Major Bleeding, Treatment discontinuation, Treatment switching

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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, 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 analyses, which for this study includes a number of clinical endpoints (recurrent VTE, major bleeding). Subgroup analyses are also planned.

## 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**

SNDS France

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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