

# Voluntary PASS non interventional study: Retrospective Observational Study of VKA and Novel Oral Anticoagulants in Patients with Non-valvular Atrial Fibrillation:

**First published:** 21/12/2015

**Last updated:** 31/01/2017

Study

Planned

## Administrative details

### EU PAS number

EUPAS11897

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### Study ID

17533


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### DARWIN EU® study

No

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### Study countries

 Japan

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### Study description

The four novel oral anticoagulants (NOACs) were available in Japan for reduction of the risk of stroke and systemic embolism (SE) among patients with NVAF: edoxaban in September 2014, apixaban in February, 2013, rivaroxaban in April 2012, and dabigatran etexilate in March 2011. Despite the evidence on efficacy and safety of these NOACs from RCTs, little is known about how they perform in real-world clinical practice settings. This study will assess the following- baseline demographics and clinical characteristics of NVAF patients prescribed apixaban, rivaroxaban, dabigatran or warfarin, treatment patterns of anticoagulant therapy, rates of occurrence of a bleeding event, and healthcare resource use. Edoxaban is excluded from this study because of limited sample size.

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## Study status

Planned

## Research institutions and networks

### Institutions

Crecon

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Ruslan Horblyuk ruslan.horblyuk@pfizer.com

Study contact

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**Primary lead investigator**

Ruslan Horblyuk

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/10/2015

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**Study start date**

Planned: 23/12/2015

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**Date of final study report**

Planned: 30/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer-Japan

## Study protocol

## 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:**

Other

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

Observational cohort Study

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

To Compare the incidence of major bleeding events among NVAf patients newly initiated with apixaban versus each other OACs for 1 year after initiation of each OAC.

## Study Design

## **Non-interventional study design**

Cohort

Other

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

A retrospective observational cohort study of NVAF patients treated for the prevention of stroke with OACs after NVAF diagnosis using large insurance claims data.

# Study drug and medical condition

## **Medicinal product name**

ELIQUIS

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## **Medical condition to be studied**

Atrial fibrillation

# 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**

30000

# Study design details

## Outcomes

Incidence of major bleeding will be compared between apixaban and warfarin. Incidence of and time to any bleeding among NVAF patients treated with apixaban, which are compared with other NOACs or warfarin. A rate of discontinuation and time to discontinuation of each OAC. Health-care resource utilization.

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## Data analysis plan

Baseline patient demographics information and healthcare resource utilization will be compared among the apixaban, rivaroxaban, dabigatran and warfarin cohorts by using chi-square test (categorical variables) and ANOVA with a post-hoc test (numerous variables). COX proportional hazard regression analysis will be used to compare the incidence of post treatment major bleeding among four OAC groups. Discontinuation of or switching from an index OAC will be compared among four OACs by using COX proportional hazard regression analysis.

## 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)**

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