

# AF In Real practice on Management of oral Anticoagulation (AFIRMA 4.0)

**First published:** 15/07/2020

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36330

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### Study ID

50344

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### DARWIN EU® study

No

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### Study countries

Spain

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### Study description

Options for anticoagulation have been expanding steadily over the past few decades, providing a greater number of oral anticoagulant (OAC) agents for prevention and management of thromboembolic disease. In addition to the

standard treatment with vitamin K antagonists (VKA) (i.e. warfarin and acenocumarol), new oral anticoagulants (non-vitamin K antagonist oral anticoagulants, NOACs) that directly target the activity of thrombin inhibitor (dabigatran) and the factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban) have recently revolutionized thromboprophylaxis for stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF). Appropriate use of these agents requires knowledge of their individual characteristics, risks, and benefits. Thus, advantages and disadvantages of each agent must be individualized to the patient and clinical setting. NOACs are the preferred choice in those NVAF populations with increased risks of both thromboembolic and bleeding events. However, the proper use of NOACs requires a careful approach to many practical aspects. In this context, we propose to use SAVANA, an innovating data-driven system based on Natural Language Processing (NLP) and big data techniques, designed to analyse unstructured data contained in electronic medical files from NVAF patients who were prescribed OACs (apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol and warfarin). The study period will be from January 2014 through December 2018 (or most recent data available). The study will occur over three phases: an initial one describing patient characteristics and treatment pathways, the second one with a description of the minor bleeding events and comparative analysis between treatments, and a third one describing stroke/SE and major bleedings and a comparative analysis between treatments.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

# Hospital Arnau de Vilanova de Valencia (HAV)

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

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

Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Susana Fernandez de Cabo

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 13/07/2020

Actual: 23/07/2020

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### Study start date

Planned: 15/09/2020

Actual: 17/09/2020

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

Planned: 30/11/2023

Actual: 30/11/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

PFIZER

## Study protocol

[Versión redactada Protocolo AFIRMA 4.0.pdf \(25.43 KB\)](#)

## 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

## Other study registration identification numbers and links

B0661131/PFI-API-2019-01

## Methodological aspects

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

To perform a study of NVAf patients based on real-world data through the reuse of electronic health records (EHRs)

**Main study objective:**

The overall objective is to perform a study of NVAf patients based on real-world data through the reuse of electronic health records (EHRs). This approach avoids missing valuable information, and reduces biases normally present in this type of studies.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

APIXABAN

DABIGATRAN ETEXILATE

RIVAROXABAN

EDOXABAN

WARFARIN

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

Atrial fibrillation

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### **Additional medical condition(s)**

STROKESYSTEMIC EMBOLISMMAJOR AND MINOR BLEEDING EVENTS

## 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**

60000

## Study design details

### **Outcomes**

To describe the demographic and clinical characteristics, including comorbidities, for OAC patients who were prescribed apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol or warfarin, • To describe treatment pathways, and report annual incidence rates of stroke/SE, major and minor bleedings for patients receiving OACs • To compare the rates of stroke/SE,

major and minor bleedings and evaluated comparative rates across various subgroups among NVAf patients receiving OACs • To describe bleeding and stroke-related health care resource utilization in the study populations

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### **Data analysis plan**

The methodology of this study is based on SAVANA, a data-driven system based on NLP and big data techniques, designed to analyse unstructured data contained in the electronic medical files. Eligible patients will be assigned to one of the OAC cohort (apixaban, dabigatran, rivaroxaban, edoxaban, warfarin, or acenocumarol). One-to-one propensity score matching (PSM) will be conducted between NOACs and acenocumarol and between the NOACs. As well as overall NOACs versus VKA (acenocumarol and warfarin). Patients will be matched 1:1 in each data set based on the propensity scores generated.

## Documents

### **Study results**

[B0661131\\_AFIRMA FINAL STUDY REPORT\\_13OCT2023-comprimido.pdf](#) (3.97 MB)

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## 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**

Electronic healthcare records of NVAF patients treated with OACs from the available centers in Spain Spain

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**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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**Data sources (types), other**

Electronic healthcare records of NVAF patients treated with OACs from the available centers in Spain

## 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