# Oral Anticoagulant Use in Patients with Non Valvular Atrial Fibrillation: Analysis of Electronic Medical Record Data

**First published:** 03/02/2017

**Last updated:** 03/02/2017

Study Planned

## Administrative details

**EU PAS number**

EUPAS17684

**Study ID**

17685

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

This retrospective cohort study will involve adult NVAF patients treated with an oral anti-coagulant (OAC). Key study outcomes include safety and effectiveness endpoints.

**Study status**

Planned

## Research institutions and networks

### Institutions

#### Boston Health Economics

**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**

Masseria Cristina

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 01/10/2017

**Study start date**
Planned: 20/01/2017

**Data analysis start date**
Planned: 17/02/2017

**Date of interim report, if expected**
Planned: 28/02/2017

**Date of final study report**
Planned: 24/03/2017

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Pfizer, Inc.

# Regulatory

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

No

**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:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

Investigation of safety and effectiveness outcomes for NVAF patients taking OACs.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ELIQUIS

XARELTO

PRADAXA

**Medicinal product name, other**

Coumadin

**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)

**Estimated number of subjects**

20000

## Study design details

**Outcomes**

Bleeding, stroke, embolism

**Data analysis plan**

Propensity score matching will be conducted. Standard statistical measures will be calculated (e.g. mean, median, mode) along with hazard ratios.

# 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

**Data sources (types), other**

Humedica EMR

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No