# Clinical and Economic Outcomes and Treatment Patterns for Non-Valvular Atrial Fibrillation Patients Who Newly Initiated Oral Anticoagulants in the US Medicare Population

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## Administrative details

EU PAS number	
EUPAS25230	
Study ID	
37513	
DARWIN EU® study	
No	
Study countries	
United States	

#### **Study description**

This study will add "real-world" evidence for the comparative risks of stroke/SE, major bleeding, related health care costs, and treatment patterns among elderly NVAF patients who initiated OACs.

#### **Study status**

Finalised

### Research institutions and networks

### Institutions

### Pfizer

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Institution

### Contact details

### **Study institution contact**

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Study contact

Christine.L.Baker@pfizer.com

### Primary lead investigator

Christine L. Baker

**Primary lead investigator** 

## Study timelines

#### Date when funding contract was signed

Actual: 29/07/2017

#### Study start date

Actual: 08/08/2017

#### Date of final study report

Actual: 31/08/2020

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

SIMR\_Pfizer\_Apixaban\_Medicare\_Protocol\_03NOV2017.pdf (583.45 KB)

## 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 topic:**

Human medicinal product

Disease /health condition

#### **Study type:**

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

1. Compare the risk of stroke/SE and major bleeding between NVAF patients who initiated OACs (warfarin, apixaban, rivaroxaban, dabigatran, or edoxaban).2. Compare all-cause and stroke/SE- and major-bleeding-related health care costs among NVAF patients who initiated OACs.3. Compare treatment patterns (discontinuation, switch, and dose) among the cohorts.

## Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Longitudinal retrospective cohort analysis using the US FFS Medicare database

### Study drug and medical condition

#### **Medicinal product name**

**ELIQUIS** 

#### Medical condition to be studied

Atrial fibrillation

Venous thrombosis

## Population studied

#### Short description of the study population

Non-valvular atrial fibrillation (NVAF) patients prescribed an oral anticoagulants (OAC) between 01-Jan-2013 to 31-Dec-2015 (or most recent data available) with continuous health plan enrollment during their baseline period were included in the study. The first Several direct oral anticoagulants (DOAC) pharmacy claim date during the identification period was designated as the index date. The first warfarin prescription date was designated as the index date for patients without any DOAC claim. For the annual prevalence calculation, NVAF patients aged  $\geq$ 65 years with continuous enrollment during each year from 2012 to 2015 were included as the numerator. The Medicare population aged  $\geq$ 65 years with

continuous enrollment during each year from 2012 to 2015 was included as the denominator.

#### Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Special population of interest**

Other

#### Special population of interest, other

Non-valvular atrial fibrillation (NVAF) patients

#### **Estimated number of subjects**

1

## Study design details

#### **Outcomes**

Stroke/SE, Composite clinical outcomes, MB and related cost outcomes

#### Data analysis plan

Descriptives, PSM, Cox Proportional

### **Documents**

#### **Study results**

NVAF Medicare 2015 NI Final study report.pdf (1.01 MB)

#### **Study publications**

Amin A, Keshishian A, Dina O, et al. Comparative clinical outcomes between dire...

## 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**

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### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No