

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

**First published:** 10/08/2018

**Last updated:** 06/10/2020

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/37513>

### EU PAS number

EUPAS25230

### Study ID

37513

### DARWIN EU® study

No

## Study countries

☐ United States

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## 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.

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Pfizer**

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

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

**Institution**

## Contact details

### Study institution contact

Christine L. Baker

**Study contact**

[Christine.L.Baker@pfizer.com](mailto: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

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### Study start date

Actual: 08/08/2017

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### 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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

Longitudinal retrospective cohort analysis using the US FFS Medicare database

## Study drug and medical condition

### **Name of medicine**

ELIQUIS

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### **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.

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### **Age groups**

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Non-valvular atrial fibrillation (NVAF) patients

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### **Estimated number of subjects**

1

## **Study design details**

### **Outcomes**

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

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## Data analysis plan

Descriptives, PSM, Cox Proportional

## Documents

### Study results

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

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### Study publications

[Amin A, Keshishian A, Dina O, et al. Comparative clinical outcomes between dire...](#)

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## Data management

## 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