# Hospital Readmissions Among Nonvalvular Atrial Fibrillation Patients Treated with Oral Anticoagulants in the U.S.

**First published:** 13/08/2018

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS25238

**Study ID**

37527

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The study will address the following primary research question: What is the frequency of readmission for major bleeding (MB) within 1 month after an index hospitalization for NVAF patients treated with apixaban, dabigatran, rivaroxaban, or warfarin?

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Pfizer

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

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**Institution**

# Contact details


**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Christine L. Baker

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 09/03/2018

**Study start date**
Actual: 01/08/2018

**Date of final study report**
Actual: 27/07/2020

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

# Study protocol

PremierDB_Hospital_OAC_AF_Readmission_Protocol_v9.pdf (635.99 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Other

**If ‘other’, further details on the scope of the study**

Major Bleeding

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of the study is to evaluate and compare 1-month MB-related readmission rates of hospitalized NVAF patients treated with dabigatran, rivaroxaban, or warfarin vs. apixaban.

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medicinal product name**

ELIQUIS

# Population studied

**Short description of the study population**

Adult patients (age ≥18 years) hospitalized for NVAF, based on a primary or secondary discharge diagnosis code indicating NVAF, were identified from the Premier
Hospital database between January 1, 2013 and June 30, 2017. Patients who received apixaban, dabigatran, rivaroxaban, or warfarin during any time of the hospitalization (from admission to discharge) were identified and grouped into study cohorts based on the oral anticoagulant (OAC) initiated. The first of such NVAF hospitalizations were defined as the index hospitalization. Patients with more than one type of OAC drug usage during the index hospitalizations were excluded so that patients can be exclusively assigned into each of the OAC patient cohorts.

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**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)

**Special population of interest**

Other

**Special population of interest, other**

Non valvular atrial fibrillation patients

**Estimated number of subjects**

1

## Study design details

**Outcomes**

MB-related Readmission, All-cause Readmission, Stroke-related Readmission

**Data analysis plan**

Means ± standard deviations, and medians will be provided for continuous variables. Numbers and percentages will be provided for dichotomous and polychotomous variables. Bivariate comparisons of baseline patient and hospital characteristics and readmission measurements will be provided, with appropriate tests (e.g. ANOVA test, chi-square test) used based on the distribution of the measure. A propensity score matching (PSM) 1:1 technique will be used to control for confounders when comparing each of the OAC cohorts vs. the apixaban cohort. A logistic regression analysis will be carried out on the matched patient cohorts to further evaluate the potential impact of treatment with the different OACs vs. treatment with apixaban on 1-month MB-related and all-cause readmissions.

## Documents

**Study results**

Approved NVAF Premier NI Final Study Report.docx.pdf (2.73 MB)

# 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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No