

# Non-interventional study on Edoxaban treatment in routine clinical practice for patients with non valvular atrial fibrillation (ETNA-AF-Europe)

**First published:** 19/05/2015

**Last updated:** 10/08/2017

Study

Ongoing

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/20482>

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### **EU PAS number**

EUPAS8896

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### **Study ID**

20482

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### **DARWIN EU® study**

No

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## Study countries

- Austria
  - Belgium
  - France
  - Germany
  - Ireland
  - Italy
  - Luxembourg
  - Netherlands
  - Portugal
  - Spain
  - Switzerland
  - United Kingdom
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## Study description

Edoxaban has recently been approved by the European Medicines Agency EMA for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, as well as for the treatment of adult patients with venous thromboembolism and the prevention of recurrent venous thromboembolism. In order to understand the risks and benefits of Edoxaban use in a real-world clinical setting, Daiichi-Sankyo proposed this post-authorization safety study (PASS) to gain insight into the safety (bleeding, liver adverse events, and other drug related adverse events) of Edoxaban use in non-preselected patients with non-valvular atrial fibrillation (NVAF). Real world evidence data of routine clinical practice use of Edoxaban up to 4 years will be collected in 13100 patients, treated by specialized as well as non-specialized physicians in hospitals and office based centres.

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## Study status

Ongoing

## Research institutions and networks

## Institutions

University of Birmingham

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

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

Institution

School of Clinical and Experimental Medicine

The total number of planned centres is 1500.

Europe

## Contact details

### Study institution contact

Tessa Schliephacke

Study contact

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### Primary lead investigator

Tessa Schliephacke

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 30/11/2014

Actual: 30/11/2014

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**Study start date**

Planned: 01/08/2015

Actual: 14/08/2015

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**Data analysis start date**

Planned: 01/10/2021

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**Date of interim report, if expected**

Planned: 01/04/2019

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**Date of final study report**

Planned: 31/12/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Daiichi Sankyo Europe GmbH

## Regulatory

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

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

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

Patient reported outcome

#### **Main study objective:**

The primary objective of this study is to collect real-world safety data on bleeding events, drug related adverse events in AF patients treated with Edoxaban up to 4 years. Furthermore, subgroup analyses will be performed in predefined patient populations, such as patients with renal or hepatic impairment.

## Study Design

## **Non-interventional study design**

Other

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

Non-interventional post-authorisation safety study

## Study drug and medical condition

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

EDOXABAN TOSYLATE

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### **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)

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### **Special population of interest**

Renal impaired

Hepatic impaired

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### **Estimated number of subjects**

13100

## Study design details

## **Outcomes**

Major bleeding events including intracranial haemorrhage, fatal bleeding events, clinically relevant non-major bleeding events, stroke, systemic embolic events, cardiovascular (CV) events leading to hospitalisation, CV mortality, all-cause mortality Suspected Edoxaban related adverse events, To assess the effect of Edoxaban on patient relevant outcomes as strokes, systemic embolic events, major cardiovascular events, hospitalisations related to cardiovascular condition, persistence to therapy, patient/physician reported outcome, health care utilization and resource use

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## **Data analysis plan**

Details of the data analysis strategy will be fully described in a Statistical Analysis Plan (SAP). Briefly, all collected variables will be used in the statistical analysis. Binary, categorical, and ordinal parameters will be summarised by means of absolute and percentage numbers within the various categories. Numerical data will be summarised by means of standard statistics. In addition, adequate graphs (eg bar charts, box-whisker plots) may be presented. Kaplan-Meier plots will be generated where applicable to characterize the risk over time for each outcome. The purpose of all analyses will not be confirmatory but purely descriptive/exploratory.

## **Data management**

### **Data sources**

#### **Data sources (types)**

[Non-interventional study](#)

Other

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**Data sources (types), other**

Prospective patient-based data collection

## 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