Apixaban

B0661131 NON-INTERVENTIONAL STUDY REDACTED PROTOCOL

Title	***AF I**n **R**eal practice on **M**anagement of oral **A**nticoagulation– **AFIRMA 4.0***
Protocol number	*B0661131*
Active substance	*Oral anticoagulants (OACs)*
Medicinal product	*Apixaban, rivaroxaban, edoxaban, dabigatran, warfarin, and acenocumarol.*
Product reference	*Apixaban*
Country(-ies) of study	*Spain.*
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1. RATIONALE AND BACKGROUND

Options for anticoagulation have been expanding steadily over the past few decades, providing a greater number of oral anticoagulant (OAC) agents for prevention and management of thromboembolic disease. In addition to the standard treatment with vitamin K antagonists (VKA) (i.e. warfarin and acenocumarol), new oral anticoagulants (non-vitamin K antagonist oral anticoagulants, NOACs) that directly target the activity of thrombin inhibitor (dabigatran) and the factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban) have recently revolutionized thromboprophylaxis for stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF). Appropriate use of these agents requires knowledge of their individual characteristics, risks, and benefits. Thus, advantages and disadvantages of each agent must be individualized to the patient and clinical setting.

NOACs are the preferred choice in those NVAF populations with increased risks of both thromboembolic and bleeding events. However, the proper use of NOACs requires a careful approach to many practical aspects.

In this context, we propose to use SAVANA, an innovating data-driven system based on Natural Language Processing (NLP) and big data techniques, designed to analyse unstructured data contained in electronic medical files from NVAF patients who were prescribed OACs (apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol and warfarin).

2. RESEARCH QUESTION AND OBJECTIVES

PRIMARY:

To describe the demographic and clinical characteristics, including comorbidities, for OAC patients who were prescribed apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol or warfarin.

SECONDARY:

- To describe treatment pathways, and report annual incidence rates of stroke/SE, major and minor bleedings for patients receiving OACs
- To compare the rates of stroke/SE, major and minor bleedings and evaluated comparative rates across various subgroups among NVAF patients receiving OACs
- To describe bleeding and stroke-related health care resource utilization in the study populations

The study will occur over three phases: an initial one describing patient characteristics and treatment pathways; the second one with a description of the minor bleeding events and comparative analysis between treatments; and a third one describing stroke/SE and major bleedings and a comparative analysis between treatments.

3. SETTING

The study period will be from January 2014 through December 2018 (or most recent data available).

4. POPULATION

All adult patients with a diagnosis of NVAF who were prescribed an OACs (apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol and warfarin).