

# GLORIA™-AF REGISTRY PROGRAMME

## EXECUTIVE SUMMARY

- The approval of novel oral anticoagulants has changed prescribing patterns for stroke prevention in atrial fibrillation (AF) worldwide.<sup>1</sup> There is a need to further understand how these novel agents are being used in clinical practice
- GLORIA™-AF will be one of the largest global AF registry programmes, collecting long-term effectiveness and safety data on a range of antithrombotics including warfarin, acetylsalicylic acid (ASA) and novel oral anticoagulants (NOACs) for stroke prevention in atrial fibrillation, as well as clinical outcomes from patients receiving no antithrombotic treatment<sup>2</sup>
- GLORIA™-AF will enrol up to 56,000 patients newly diagnosed with AF at risk of stroke from up to 2,200 sites in nearly 50 countries worldwide, investigating patient characteristics that influence antithrombotic prescribing choice<sup>2</sup>
- The results of GLORIA™-AF are expected to advance current and future AF management

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## The need for effective stroke prevention in atrial fibrillation (AF)

Preventing stroke is the primary goal of treatment in patients with AF for which antithrombotic therapy is essential.<sup>3,4</sup> Vitamin K antagonists (VKAs), like warfarin, have been used for stroke prevention in AF for decades however due to the limitations associated with the treatment, considerable fluctuations in efficacy and safety can occur.<sup>5</sup>

To address the shortcomings of VKAs, several novel oral anticoagulants (NOACs) have been developed.<sup>6</sup> Dabigatran etexilate (Pradaxa®) was the first NOAC to be approved for stroke prevention in AF, and has now been approved in over 100 countries worldwide.<sup>7</sup> Other NOACs are the Factor Xa inhibitors, which include rivaroxaban (first approved in 2011) and apixaban (first approved in 2012), as well as edoxaban (not currently approved for clinical use for the prevention of stroke in AF).<sup>6</sup>

**The introduction of the NOACs has changed prescribing patterns for stroke prevention in AF worldwide.<sup>1</sup> It is therefore vital to understand how these novel treatments are being used in the real-world clinical setting.**

### What is GLORIA™-AF?

GLORIA™-AF (Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation) is a large, multinational, prospective registry programme designed to characterise the treatment of patients newly diagnosed with non-valvular AF at risk of stroke. With up to 56,000 patients planned to be enrolled from up to 2,200 sites in nearly 50 countries, GLORIA™-AF will be one of the largest AF registry programmes currently running worldwide. GLORIA™-AF will provide important real-world information on antithrombotic prescribing patterns and patient outcomes.<sup>2</sup>

#### Why a Registry?



Disease registries are an effective tool to observe the course of a disease and to collect data to evaluate treatment effectiveness and safety, investigate variations in outcomes and to provide insight into factors that affect patient survival.<sup>2</sup>

Real-world data allow the exploration of disease management patterns, treatment safety monitoring and identification of optimisation strategies in clinical practice, which are vital for studying broad patient populations in relation to comorbidities and comedications.<sup>2</sup>

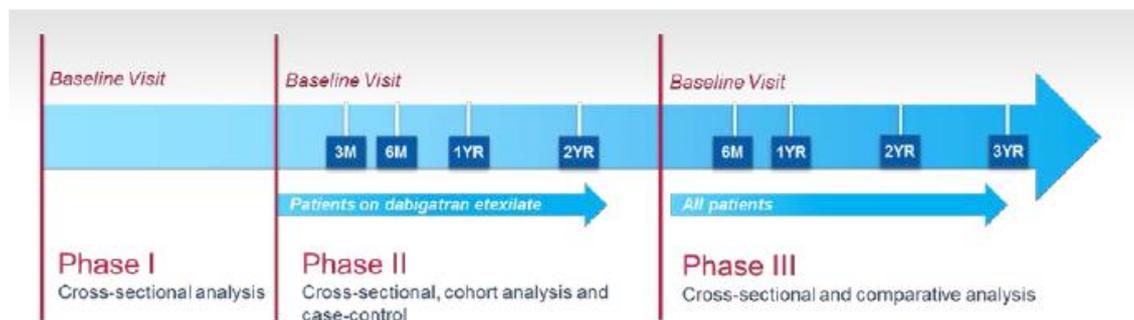
## The GLORIA™-AF Registry Programme Objectives<sup>2</sup>

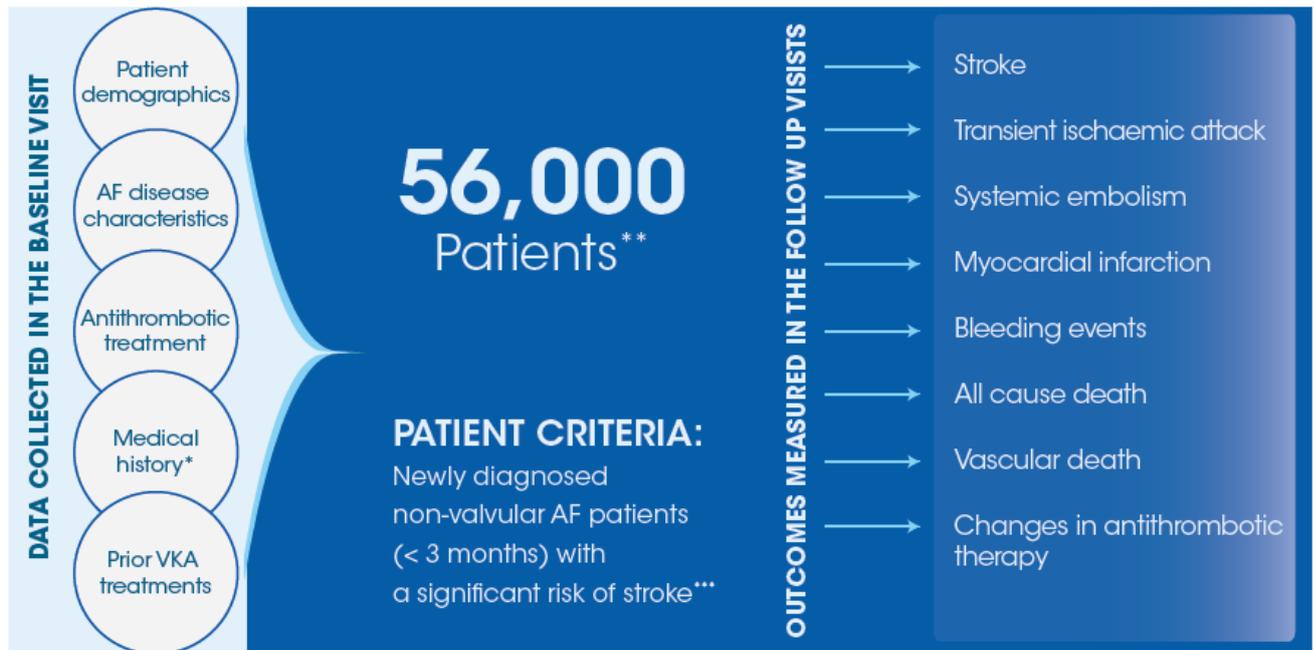
1. Characterise patients newly diagnosed with non-valvular atrial fibrillation at risk for stroke on a global level
2. Define study patterns, predictors and outcomes of different treatment regimes for stroke prevention in non-valvular atrial fibrillation
3. Collect data on the safety and effectiveness of antithrombotic treatments, such as the long time standard of care vitamin K antagonist i.e. warfarin, and novel oral anticoagulant Pradaxa®

## Phases of the GLORIA™-AF Registry Programme

The novel three-phase design of the GLORIA™-AF Registry Programme includes propensity scoring to ensure that there are no significant differences in baseline patient characteristics between treatment groups that might bias the results. Furthermore, useful information will be collected to assess changes in prescribing patterns of antithrombotic therapies over time and across different regions of the world. The knowledge gained from the registry programme will advance the management of AF in clinical practice.<sup>1</sup>

- Phase I** Undertaken to collect information on antithrombotic prescribing patterns prior to the approval of NOACs in many countries worldwide, enrolling patients from May 2011 to January 2013<sup>1</sup>
- Phase II** Began after the approval of the first novel oral anticoagulant Pradaxa® in November 2011 and collects data on the safety of the treatment as well as the baseline characteristics of patients treated with Pradaxa® or warfarin<sup>1</sup>
- Phase III** Starts when there is sufficient overlap of patient characteristics between Pradaxa® and warfarin treatment groups. Phase III will follow patients for three years to evaluate the effectiveness and safety of Pradaxa® versus warfarin using patient outcome data. Information regarding the overall safety and effectiveness of other antithrombotic treatments will also be collected<sup>1</sup>





\*Medical history includes: history of thromboembolic disease, history of cardiovascular disease, history of bleeding events, and concomitant medications, key variables needed to assess patients risk scores (CHADS<sub>2</sub>, CHA<sub>2</sub>DS<sub>2</sub>-VASc HAS BLED)

\*\*Not all patients will have follow up visits

\*\*\*As characterised by a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of at least 1

## GLORIA™-AF – A Global Registry Programme

The GLORIA™-AF Registry Programme will be undertaken in nearly 50 countries, enrolling up to 56,000 AF patients from up to 2,200 sites worldwide.<sup>1</sup>

Patients will be grouped into five regions:

- Asia
- Europe
- North America
- Latin America
- Africa/Middle East

 Countries participating in the GLORIA™-AF Registry Program



To mirror the real-world setting, GLORIA™-AF will involve a range of clinical settings including general practices, specialist offices, community hospitals, university hospitals, outpatient care centres and anticoagulation clinics.<sup>1</sup>

## References

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2. GLORIA-AF Registry website. <https://www.gloria-af.com/public/about-objectives.html> Last accessed October 2014.
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6. Camm AJ. *et al.* 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. *Eur Heart J.* 2012;**33**(21):2719-47.
7. Boehringer Ingelheim data on file.