

Thrombosis Research Institute Emmanuel Kaye Building Manresa Road Chelsea London SW3 6LR United Kingdom Media Contact Charlotte Shyllon CShyllon@trilondon.ac.uk +44 (0) 7415 858 411

THROMBOSIS RESEARCH INSTITUTE (TRI) TO ANNOUNCE NEW REAL-WORLD INSIGHTS IN ATRIAL FIBRILLATION AT ESC CONGRESS 2018

- Satellite symposium will highlight the breadth of evidence collected since the establishment of the registry in 2009
- An analysis of the comparative effectiveness of oral anticoagulants in everyday practice will be presented
- The economic burden of atrial fibrillation (AF) in nine European countries will be evaluated

Munich, Germany, 16 August 2018 – The latest results from the Global Anticoagulant Registry in the Field – Atrial Fibrillation (GARFIELD-AF) will be presented at the forthcoming ESC Congress 2018, organised by the European Society of Cardiology, to be held in Munich, Germany, from 25th to 29th August.

Data will be presented as posters, oral presentations and at the late breaking science session on clinical registries, exploring a range of areas including the burden attributable to AF in nine European countries, clinicians' prescribing tendencies, and how the quality of stroke prevention has changed over time.

The late breaking science session "Registry Results 2" on Tuesday 28th August, 14:30-15:45, (Centre Stage – The Hub) will see Professors John Camm and Keith Fox present the latest results from the GARFIELD-AF Registry. Professor Camm will highlight significant differences in the risk of mortality in favour of OACs (vs. no OAC) and NOACs (vs. VKAS) even after adjustment for baseline variables. Professor Fox will present findings that challenge the use of combined OAC+AP therapy, particularly among those without a clear indication for AP therapy.

"We are excited to have a strong presence at this year's ESC Congress, as a result of the wealth of new GARFIELD-AF data, which will be presented by some of the leading investigators involved in the registry," said Rt Hon Professor the Lord Ajay K. Kakkar, Professor of Surgery at University College London and Director of the Thrombosis Research Institute (TRI), UK.

GARFIELD-AF is the largest ongoing prospective registry of patients with AF. It is a pioneering, independent outcomes research initiative led by an international steering committee under the auspices of the TRI. It has generated at least 2 years of follow-up data in over 52,000 patients with newly diagnosed AF.

Key results will be unveiled during the TRI Satellite Symposium which will showcase the wealth of evidence collected since the establishment of GARFIELD-AF in 2010.

GARFIELD-AF: New light shed on Atrial Fibrillation and its management

- Satellite Symposium
- Saturday 25th August 2018 from 15.30 17.00 (all times CEST) Room Vienna Village 3

Members of the GARFIELD-AF Steering Committee will present a variety of results, including new insights on the quality of stroke prevention and its clinical effectiveness in routine care, and presentations on the real-world record of change in prescribing practice and outcomes. The new GARFIELD-AF risk score and its online application will also be discussed. The symposium will also include a panel discussion led by Professors Jean-Pierre Bassand (France) and Samuel Z. Goldhaber (USA).

Other key data from GARFIELD-AF will be presented during the following sessions:

Rapid Fire Abstract Session entitled 'Atrial fibrillation - Detection, treatment, outcomes' – (11:00 – 12:30, Sunday 26th August; Location: Agora 2 – Agora)

The effect of non-recommended dosing of non-vitamin K antagonist oral anticoagulants (NOACs) on 1-year mortality in patients with newly diagnosed AF. Results from the GARFIELD-AF registry

Professor John Camm (UK) will highlight the impact of using non-recommended doses of NOACs for stroke prevention in patients with newly diagnosed AF.

Poster Session 3 – (14.00 – 18.00, Sunday 26th August)

Evaluation of the effect of oral anticoagulants on all-cause mortality within 3 months of the diagnosis of atrial fibrillation

Karen Pieper (USA) will reveal significant early mortality in patients with newly diagnosed AF and significant mortality differences in favour of OACs, even after adjustment for 29 baseline variables.

The economic burden attributable to atrial fibrillation in nine European countries
Paolo Cozzolino (Italy) will report that the economic burden of AF, a growing public health
problem, correlates with differences in management between countries.

Poster Session 5 – (14.00 – 18.00, Monday 27th August)

Why do clinicians withhold anticoagulation in patients with atrial fibrillation and CHA₂DS₂-VASc score ≥2?

Dr Deborah Siegal (Canada) will report that guideline-based treatment with oral anticoagulants was associated with better outcomes, results that emphasise the need to better understand decision-making to improve oral anticoagulant prescription rates and outcomes in AF.

Why do clinicians prescribe oral anticoagulation in patients with atrial fibrillation despite a low CHA₂DS₂-VASc score?

Frederik Verbrugge (Belgium) will report on the discrepancy between patient characteristics that predict OAC use in AF patients with a very low CHA₂DS₂-VASc score and factors reported by clinicians that influence their decision-making.

About the GARFIELD-AF registry

GARFIELD-AF is a worldwide observational programme that aims to enhance the breadth and depth of understanding of stroke prevention in atrial fibrillation (AF), ultimately informing strategies to improve patient outcomes, safety and utilisation of healthcare resources.

It offers a unique opportunity to obtain a comprehensive and contemporary description of the spectrum of patients with AF and their management worldwide as they evolve over time. The registry is important in bridging the gap between research and clinical practice, serving to increase awareness of the importance of thrombosis and its treatment.

GARFIELD-AF recruited patients with newly diagnosed nonvalvular AF and at least one risk factor for stroke. A total of 57,262 patients were recruited from over 1000 centres in 35 countries worldwide, including the Americas, Europe, Africa and Asia-Pacific, over five sequential cohorts. Follow-up is over a minimum of 2 years and up to 8 years after diagnosis, to create a comprehensive database of treatment decisions and outcomes in everyday clinical practice.

GARFIELD-AF is a pioneering, independent academic research initiative led by an international steering committee under the auspices of the TRI, London, UK.

Contemporary understanding of AF is based on data gathered in controlled clinical trials. Whilst essential for evaluating the efficacy and safety of new treatments, these trials are not representative of everyday clinical practice and, hence, uncertainty persists about the real-life burden and management of this disease. GARFIELD-AF seeks to provide insights into the impact of anticoagulant therapy on thromboembolic and bleeding complications seen in this patient population. It will provide a better understanding of the potential opportunities for improving care and clinical outcomes amongst a representative and diverse group of patients and across distinctive populations. This should help physicians and healthcare systems to appropriately adopt innovation to ensure the best outcomes for patients and populations.

The registry started in December 2009. Four key design features of the GARFIELD-AF protocol ensure a comprehensive and representative description of AF; these are:

- Five sequential cohorts of prospective, newly diagnosed patients, facilitating comparisons of discrete time periods and describing the evolution of treatments and outcomes;
- Investigator sites that are selected randomly within carefully assigned national AF care setting distributions, ensuring that the enrolled patient population is representative;
- Enrolment of consecutive eligible patients regardless of therapy to eliminate potential selection bias;
- Follow-up data captured for a minimum of 2 and up to 8 years after diagnosis, to create
 a comprehensive database of treatment decisions and outcomes in everyday clinical
 practice.

Included patients must have been diagnosed with non-valvular AF within the previous 6 weeks and have at least one risk factor for stroke; as such, they are potential candidates for anticoagulant therapy to prevent blood clots leading to stroke. It is left to the investigator to identify a patient's stroke risk factor(s), which need not be restricted to those included in established risk scores. Patients are included whether or not they receive anticoagulant therapy,

so that the merit of current and future treatment strategies can be properly understood in relation to patients' individual risk profiles.

The GARFIELD-AF registry is funded by an unrestricted research grant from Bayer AG, Berlin, Germany.

For more information, visit our website: www.garfieldregistry.org

The burden of AF

Up to 2% of the global population has AF,¹ including around 8.8 million people in Europe² and 5–6.1 million in the United States.³ It is estimated that its prevalence will at least double by 2050 as the global population ages.³ AF is associated with a five-fold increase in stroke risk, and one out of five strokes is attributed to this arrhythmia.¹ Ischaemic strokes related to AF are often fatal, and those patients who survive are left more frequently and more severely disabled and have a greater risk of recurrence than patients with other causes of stroke.¹ Hence, the risk of mortality from AF-associated stroke is doubled and the cost of care is 50% higher.¹

AF occurs when parts of the atria emit uncoordinated electrical signals. This causes the chambers to pump too quickly and irregularly, not allowing blood to be pumped out completely.⁴ As a result, blood may pool, clot and lead to thrombosis, which is the number one cardiovascular killer in the world.⁵ If a blood clot leaves the left atrium, it could potentially lodge in an artery in other parts of the body, including the brain. A blood clot in an artery in the brain leads to a stroke; 92% of fatal strokes are caused by thrombosis.⁵ Stroke is a major cause of death and long-term disability worldwide – each year, 6.5 million people die⁶ and 5 million are left permanently disabled.⁷ People with AF also are at high risk for heart failure, chronic fatigue and other heart rhythm problems.⁸

About the TRI

The TRI is dedicated to bringing new solutions to patients for the detection, prevention and treatment of blood clots. The TRI's goal is to advance the science of real-world enquiry so that the value of real-world data is realised and becomes a critical link in the chain of evidence. Our pioneering research programme, across medical disciplines and across the world, continues to provide breakthrough solutions in thrombosis.

For more information, visit: http://www.tri-london.ac.uk/.

###

Camm A J, Kirchhof P, et al. Guidelines for the management of atrial fibrillation: The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). Eur Heart J 2010; 31(19):2369-429.

Krijthe B P, Kunst A, et al. Projections on the number of individuals with atrial fibrillation in the European Union, from 2000 to 2060. Eur Heart J 2013; 34:2746-51.

Colilla S, Crow A, Petkun W, et al. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol 2013; 112(8):1142-7.

^{4.} National Heart, Lung, and Blood Institute. What is Atrial Fibrillation? Available at: http://www.nhlbi.nih.gov/health/health-topics/topics/af/_ [Last accessed: 10 August

World Thrombosis Day. Know Thrombosis. Available at: http://www.worldthrombosisday.org/issue/thrombosis/. [Last accessed: 10 August 2018].

^{6.} World Stroke Organization. World Stroke Campaign. Available at: http://www.worldstrokecampaign.org/. [Last accessed: 10 August 2018].

World Stroke Organization. World Stroke Campaign. Available at: http://www.worldstrokecampaign.org/_Last accessed: 10 August 2016.
 Stroke Centre. Stroke Statistics. Available at: http://www.strokecenter.org/patients/about-stroke/stroke-statistics/_[Last accessed: 10 August 2018]

American Heart Association. Why Atrial Fibrillation (AF or AFib) Matters. Available at: http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Why-Atrial-Fibrillation-AF-or-AFib-Matters_UCM_423776_Article.jsp. [Last accessed: 10 August 2018].