

MEDIA INFORMATION

For immediate release

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Thrombosis Research Institute is to present the latest real-world evidence from three thrombosis registries at ISTH 2019 Congress

- *Insights from the GARFIELD Registries, covering both venous thromboembolism (VTE) and atrial fibrillation (AF), will be presented at a TRI Satellite Symposium*
- *TRI will also showcase 12-month outcomes data from PERCEIVE, a prospective cancer registry recording VTE events*
- *Oral and poster topics will include renal impairment, gender and regional differences in VTE as well as the latest findings from TRI's molecular immunology laboratory*

London, United Kingdom, 3rd July 2019 – For the first time ever, the Thrombosis Research Institute (TRI) will unveil the latest results from three of its global thrombosis registries during the International Society on Thrombosis and Haemostasis Congress 2019, to be held in Melbourne, Australia from July 6th to 10th.

Real-world evidence from the Global Anticoagulant Registry in the FIELD (GARFIELD-VTE and GARFIELD-AF) studies, data from the ProspectivE Registry of Cancer and Events Involving Venous ThromboEmbolism (PERCEIVE) Registry and a the latest findings from TRI's molecular immunology laboratory will be shared during the congress, via a supported Satellite Symposium, five poster presentations, an oral session and on the TRI stand (Number 438).

GARFIELD-VTE is a prospective, multicentre, observational study of patients with acute VTE. The registry has enrolled more than 10,000 patients with deep vein thrombosis and/or pulmonary embolism from 415 sites in 28 countries. The aim of this global registry is to follow patients for at least three years and to observe patients' management according to local practices, recording clinical, patient-reported and economic outcomes.

GARFIELD-AF is the largest global prospective registry of patients with AF. It aims to enhance the breadth and depth of understanding stroke prevention in AF, ultimately informing strategies to improve patient outcomes, safety, and utilisation of healthcare resources. To date, it has generated at least 2 years of follow-up data in over 57,000 patients with newly diagnosed AF.

“While most of the data we unveil during ISTH will be from our GARFIELD-VTE registry, we are in the unparalleled position of being able to further enrich our Satellite Symposium presentations with insights from the GARFIELD-AF registry. This will provide clinicians with a more rounded picture of how these conditions are being managed in the real world globally, to help enhance patient care and outcomes,” said Rt Hon Professor the Lord Ajay K. Kakkar, Director of the Thrombosis Research Institute, UK.

The Satellite Symposium, entitled “Understanding the Outcomes of Anticoagulation: Insights from the GARFIELD Registries” and taking place on Saturday 6th July at 11:30-12:45 in Rooms 219/220, will examine perspectives on provoked versus unprovoked VTE; comparative effectiveness in both AF and VTE, cancer-associated thrombosis in everyday practice and regional differences in VTE, presented by a distinguished speaker panel of clinical leaders.

GARFIELD-VTE data will also be presented during the congress as follows:

The Influence of Renal Impairment on Clinical Outcomes in Venous Thromboembolism Patients Enrolled in GARFIELD-VTE [OC24.1]

- Session – VTE Therapy: Anticoagulants and Bleeding
- Sunday 7th July at 14:45-15:00, Room 203/204

Professor Shinya Goto, School of Medicine, Tokai University, will compare the baseline characteristics and treatment patterns of patients enrolled in GARFIELD-VTE with moderate-to-severe chronic kidney disease (CKD) and patients with normal-to-mild CKD, and explain how VTE patients with CKD are at an increased risk of major adverse outcomes.

Gender-related Differences in Venous Thromboembolism Patients: GARFIELD-VTE [PB0562]

- Poster Session
- Sunday 7th July at 18:30-19:30, Exhibition Hall

Professor Graham Turpie, McMaster University, Canada will explain that despite no differences in anticoagulation treatment at baseline, female VTE patients have an increased risk of bleeding compared to males over 12-months follow up.

Venous Thromboembolism in Asia and Worldwide: Emerging Insights from GARFIELD-VTE [PB1114]

- Poster Session
- Sunday 7th July at 18:30-19:30, Exhibition Hall

Professor Pantep Angchaisuksiri, Department of Medicine, Mahidol University, Thailand, will show that Asian and non-Asian patients have different risk profiles which may contribute to differences in outcomes.

PERCEIVE is a large prospective, non-interventional cancer registry designed to record thromboembolic and cardiovascular events in patients with a newly diagnosed malignancy of the breast, colon and rectum, pancreas, lung, prostate or ovary. This multi-centre, international registry recruited patients from North America, Europe and Asia, allowing comparison of different management strategies and includes up to 11 years follow-up to allow the long-term risk of VTE occurrence to be assessed.

Prospective Registry of Cancer and Events Involving Venous Thromboembolism (PERCEIVE): 12-month outcomes [PB1050]

- Poster Session
- Monday 8th July at 18:00-19:30 AEST, Exhibition Hall

Dr Gloria Petralia will describe the baseline demographics, cancer characteristics and treatment of cancer patients as well as clinical outcomes at 12 months. Furthermore, details on the development of a multivariable model for the prediction of VTE occurrence will be presented.

Finally, data from TRI's thrombosis immunology laboratory research project will be presented as follows:

Efficacy of Immunomodulatory Therapy for Atherosclerosis-role of Tolerance and Protective Antibodies [PB0011]

Immunization with Recombinant Atherogenic Antigen (AHC) Does Not Promote Melanoma Cell-induced Lung Cancer in B6;129s-Ldlrtm1herApobtm2sgy/J mice [PB0009]

- *Poster Session*
- *Sunday 7th July at 18:30-19:30 AEST, Exhibition Hall*

Dr Xinjie Lu will describe the role of tolerance and protective antibodies in the context of immunomodulatory therapy for atherosclerosis. He will display evidence that administration of a multi-antigenic construct can lead to a reduction in plaque growth and lipid accumulation. Furthermore, a separate poster will detail how immunisation with this antigenic construct does not promote melanoma cell-induced lung cancer.

About GARFIELD-VTE

GARFIELD-VTE is a prospective registry describing acute and long-term management and outcomes in 10,874 adult patients with venous thromboembolism (VTE) representative of everyday clinical practice in 28 countries.

It is an international, observational, multicentre study of patients with newly diagnosed VTE. Patients were enrolled from 415 sites from 28 countries worldwide, including the Americas, Europe, Africa and Asia-Pacific. Compared with other ongoing prospective registries in VTE, GARFIELD-VTE has the potential to capture the burden of disease in large-scale populations by employing broad inclusion criteria in widely representative populations of patients with VTE (across a range of clinical settings) and to capture long-term follow-up data in the community as well as the hospital setting.

Contemporary understanding of VTE 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-VTE seeks to provide insights into the impact of anticoagulant therapy on thrombotic 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.

Current treatment regimens in real-life practice seem to be shorter than recommended guidelines¹. GARFIELD-VTE is important in connecting research and clinical practice, serving to increase awareness of the importance and treatment of DVT/PE.

The registry seeks to describe:

- the acute, sub-acute and extended duration of anticoagulation management;
- the clinical and economic outcomes in patients with treated acute VTE in the real-world setting.

The registry started in July 2014. Four key design features of the GARFIELD-VTE protocol ensure a comprehensive and representative description of VTE; these are:

- Two sequential cohorts of prospective, newly diagnosed patients, facilitating comparisons of discrete time periods and describing the evolution of treatments and outcomes;
- Selection of sites representative of national VTE care settings;
- Enrolment of consecutive eligible patients regardless of therapy to eliminate potential selection bias;
- Follow-up data captured for a minimum of 36 months after diagnosis, to create a comprehensive database of treatment decisions and outcomes in everyday clinical practice.

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-VTE registry is supported by an unrestricted educational grant from Bayer AG, Berlin, Germany.

For further information, please visit: www.garfieldregistry.org.

The burden of VTE

VTE occurs when part of a clot formed in a deep vein, for example in the leg (known as deep vein thrombosis, or DVT), is carried to the lung, via the heart, preventing the uptake of oxygen. This is known as a pulmonary embolism (PE), an event which can be rapidly fatal.

The third most common cardiovascular illness after acute coronary syndrome and stroke, VTE is responsible for nearly 800,000 deaths in the Europe and United States each year. This equates to VTE killing one person every 37 seconds in the Western world. In around 90% of fatal cases the embolism is undetected or untreatable. VTE recurrence is likely, making VTE-prevention an essential task for every healthcare system^[i].

Approximately 20% of all VTE cases occur in patients with cancer, and VTE is present in up to 50% of patients with cancer at autopsy^[ii]. The total cost of VTE treatment and management is estimated to be £640 million per year in the United Kingdom ^[iii]. Like its sister registry GARFIELD-AF, GARFIELD-VTE will be vital in improving clinical practice in the coming years.

About TRI

The Thrombosis Research Institute (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. Their 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/>.

References

[i] GARFIELD-VTE Registry. About VTE. Available at <https://vte.garfieldregistry.org/about/about-vte> [Accessed: 1 July 2019]

[ii] Lyman G. Venous Thromboembolism in the Patient with Cancer: Focus on Burden of Disease and Benefits of Thromboprophylaxis. [Cancer. 2011 Apr 1; 117\(7\): 1334–1349.](#)

[iii] Ageno W, McCallum P, Haas S, et al. Clinical characteristics and management of 10,329 patients with a confirmed diagnosis of venous thromboembolism: the GARFIELD-VTE registry. Oral presentation at ISTH Congress 2017.