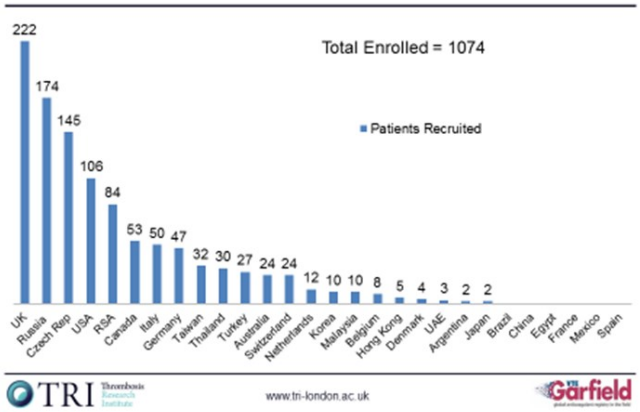
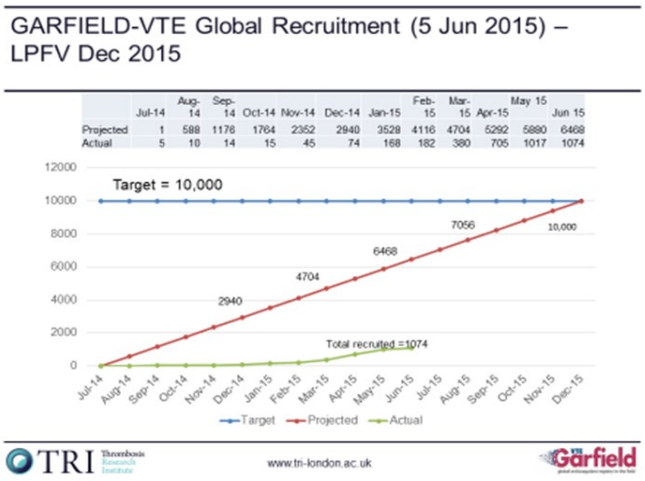
National Coordinating Investigators Newsletter No. 2

June, 2015

Dear National Coordinating Investigators,

Welcome to the second edition of the Garfield VTE Newsletter. As of the first week in June, we have recruited 1074 patients globally.

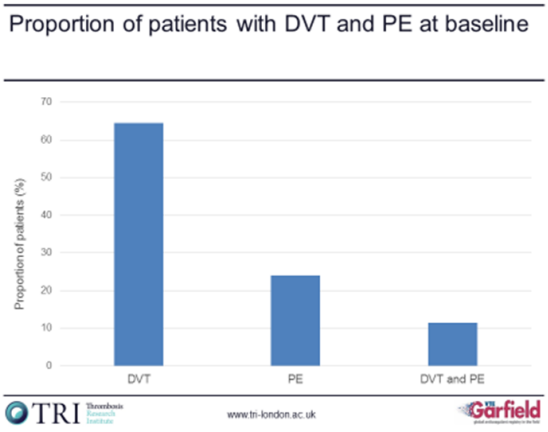




We are pleased to share with you the preliminary baseline results on patient characteristics, planned treatment, prior treatment and risk factors for the first 1,000 patients:

Global News and Announcements

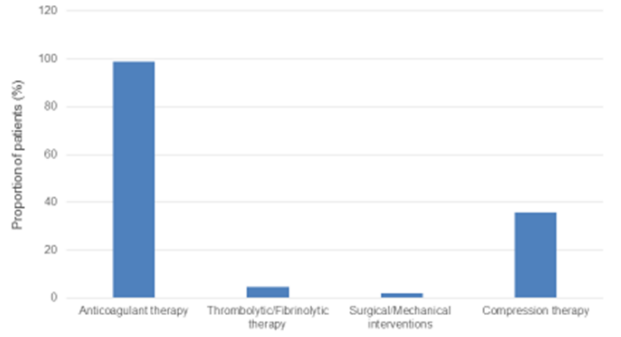
- The first publication on the Garfield VTE study is planned for the first quarter of 2016 and we hope to include as many patients as we can in the analysis. In order to have meaningful results from each country, we will need to have **at least cohort 1 completed by December 2015**. Your help in encouraging the sites in your country to achieve this will be much appreciated.
- Some countries have already started to organise local meetings by teleconference to identify barriers to enrolment. We will be contacting you shortly to discuss the feasibility and logistics of these local meetings in your country. In addition, as summer is approaching in most countries, many site personnel are planning their summer vacation. Please remind the sites to ensure that there is sufficient cover at the sites to ensure that enrolment is not adversely impacted during these few months.



Project Team at TRI

Gloria Kayani (Chief Operating Officer), Pearl Kho (Global Project Manager), Richard Coles (Regional Project Manager, Americas, Asia), Elizabeth Demmisse (Regional Project Manager, EMEA), Sofia Fernandez (Research Coordinator, UK, France, Spain), Luz Angela Gomez (Clinical Trial Administrator).

Planned treatment



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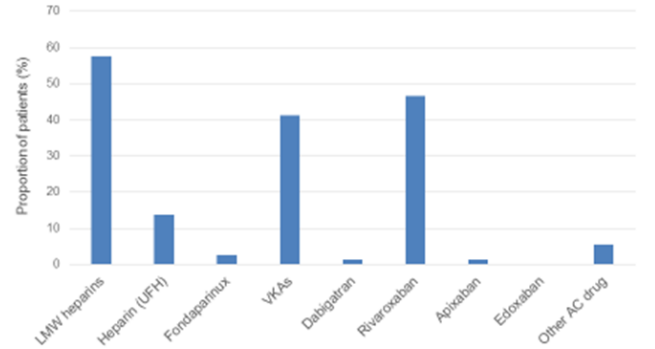
Treatment at baseline



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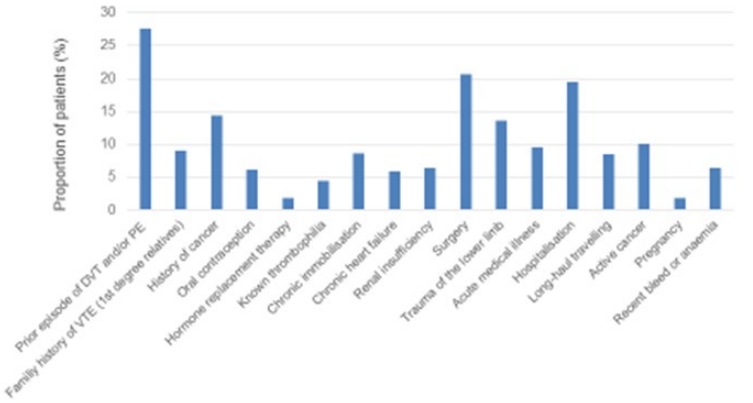
Risk factors for VTE (568 patients had at least one risk factor)



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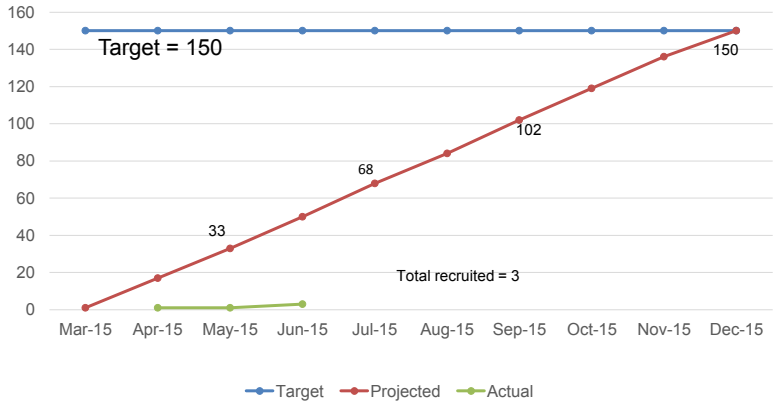
GARFIELD-VTE – Recruitment in UAE



TRI Thrombosis Research Institute www.tri-london.ac.uk VTE Garfield global anticoagulant registry in the field

Site Recruitment

PI	Site #	SIV	Projection during IMVs	Actual Enrolment per SVR	Actual Enrolment per EDC
Mustafa, Bisher	UAE0266	17-Mar-15	30	3	3
Singh, Rupesh	UAE0267	09-Jun-15	7	0	0
AlOmairi, Munther	UAE8109	TBS			

Site Regulatory Start-up

PI Name	Account Name	Estimated Date of Submission	Date of Submission	Meeting Date (Projected)	Meeting Date (Actual)	Estimated Date of Approval	Date of Approval	Last Site Contract Fully Executed	SIV Date
M. Esheiba, Ehab	Gulf Medical University Hospital	05/Mar/2015	01/Mar/2015	13/May/2015		28/May/2015		14/Apr/2015	
Al Ghoul, Ashraf	Mafraq Hospital	01/Jun/2015		25/Jun/2015		02/Jul/2015			

Clarification of Inclusion and Exclusion Criteria:

(1) Patients who have a short life expectancy, for example, less than 6 months should be excluded
(2) Patients who have been treated for previous AF rather than VTE should be excluded

Study Timelines

Global recruitment is currently behind target, all efforts should be made to ensure that at least Cohort 1 is completed by December

Electronic Data Capture System (Clinpal)

On-line tutorial will be available in July to familiarise users with the system

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