National Coordinating Investigators Newsletter No. 1

VTE Garfield
global anticoagulant registry in the field

May, 2015

Dear National Coordinating Investigators,

Welcome to the first newsletter for the Garfield VTE study. We currently have 28 countries from North America, Latin America, Asia, Australia, Africa, Europe and Middle East. The target is to recruit 10,000 patients.

Overall Study Status At A Glance:

No. of patients recruited (actual/planned) : 786/10,000
No. of sites selected (actual/planned): 418/505
No. of sites initiated: 194

Global News and Announcements

Welcome to Professors Marie-Antoinette Sevestre and Dr Sherif Sholkamy who have joined as national coordinating investigators (NCI) for France and Egypt respectively.

Congratulations to the United Kingdom for recruiting the highest number of patients (184) for the study.

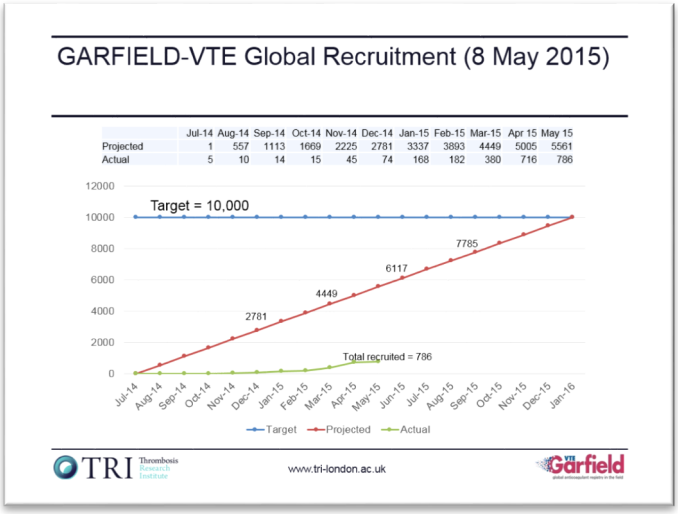
Regular communications from Thrombosis Research Institute (TRI)

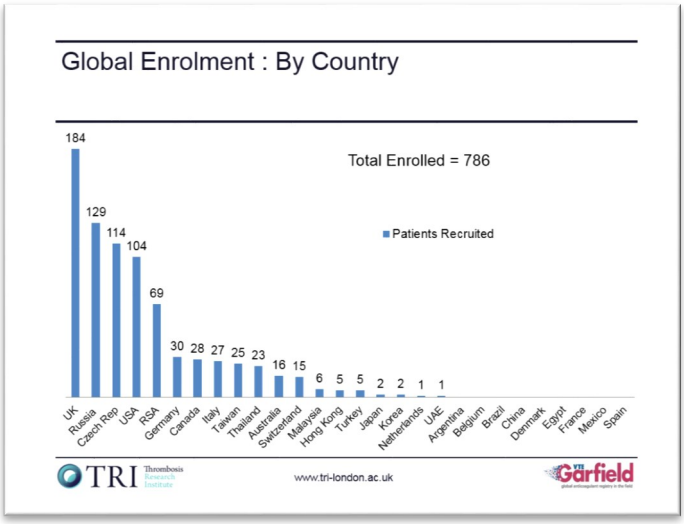
In addition to the monthly newsletter which you will receive at the end of each month, TRI would like to initiate regular calls with you in order to keep you updated on the progress of the study and for us to address any local issues which are of concerns to you. You will be contacted by members of the project team shortly.

Project Team at TRI

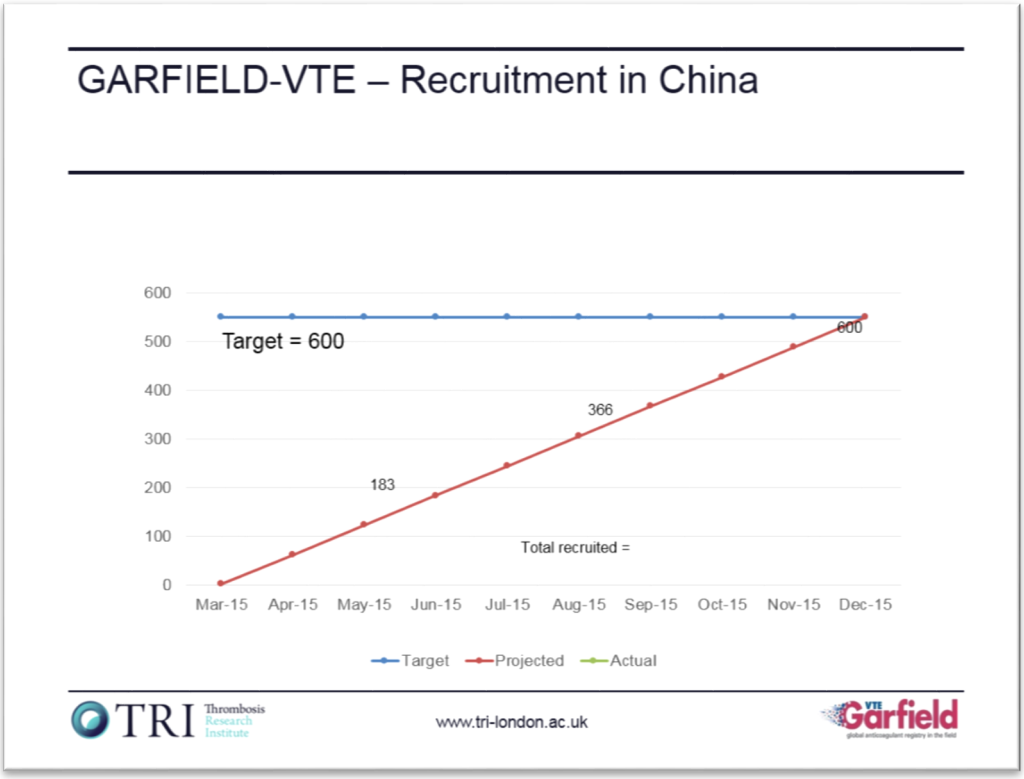
Gloria Kayani (Chief Operating Officer), Pearl Kho (Global Project Manager), Richard Coles (Regional Project Manager, Americas, Asia), Elizabeth Demmisse (Regional Project Manager, EMEA), Sofia Fernandez (Research Coordinator, UK, France, Spain), Luz Angela Gomez (Clinical Trial Administrator).

Global Recruitment





TRI Thrombosis Research Institute



Country Highlights

- 16 sites selected
- 12 EC submissions completed
- 5 EC approvals in place
- 0 Clinical Trial Agreements fully executed
- 0 Site Initiation Visit calls completed
- Quintiles to organise teleconference between NCIs to discuss:
  - Site selection
  - Recruitment

Site Recruitment

PI	Country	Site #	SIV	Projection during IMVs	Expected Enrolment to date	Actual Enrolment per SVR	Actual Enrolment per EDC
Jiang, Weihong	China	CHN0151	NA	NA		0	0
Jing, Zhicheng	China	CHN0152	NA	NA		0	0
Li, Zhikui	China	CHN0164	NA	NA		0	0
Liu, Bing	China	CHN0166	NA	NA		0	0
PI name	China	TBD	NA	NA		0	0
Sun, Sheng Hua	China	CHN0186	NA	NA		0	0
Sun, Yihong	China	CHN0187	NA	NA		0	0
Wang, Haofu	China	CHN0195	NA	NA		0	0
Wang, Shenming	China	CHN0196	NA	NA		0	0
Wang, Yongjun	China	CHN0197	NA	NA		0	0
Yang, Jinghua	China	CHN0204	NA	NA		0	0
Yang, Yuanhua	China	CHN0205	NA	NA		0	0
Yang, Zhenwen	China	CHN0206	NA	NA		0	0
Yang, Zhongqi	China	CHN0207	NA	NA		0	0
Yuan, Zuyi	China	CHN0214	NA	NA		0	0
Zhang, Jiwei	China	CHN0215	NA	NA		0	0
Zhang, Lei	China	CHN0216	NA	NA		0	0
Zhang, Weihua	China	CHN0217	NA	NA		0	0
Zhu, Hong	China	CHN0218	NA	NA		0	0
Li, Yiqing	China	CHN0226	NA	NA		0	0

Site Regulatory Start-up

Site #	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
CHN0205	Yang, Yuanhua	Beijing Chao Yang Hospital	08/May/2015		22/May/2015		28/May/2015			
CHN0218	Zhu, Hong	Peking University Third Hospital	14/May/2015		21/May/2015		28/May/2015			
CHN0214	Yuan, Zuyi	First Affiliated Hospital of Xi'an Jiaotong University	15/May/2015		29/May/2015		26/Jun/2015			
CHN0151	Jiang, Weihong	The Third Xiangya Hospital of Central South University	08/May/2015	27/Apr/2015	22/May/2015		29/May/2015			
CHN0152	Jing, Zhicheng	Fuwai Hospital	30/Apr/2015	10/Apr/2015	29/May/2015		05/Jun/2015			
CHN0226	Li, Yiqing	Wuhan Union Hospital	10/Apr/2015	10/Apr/2015	08/May/2015		15/May/2015	04/May/2015		
CHN0186	Sun, Sheng Hua	The Third Xiangya Hospital of Central South University	08/May/2015	24/Apr/2015	22/May/2015		29/May/2015			

Site #	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 Exe-	SIV Date
CHN0187	Sun, Yihong	Peking University Peoples Hospital	12/Aug/2014	12/Aug/2014	31/Mar/2015	31/ Mar/2015	10/Apr/2015	02/Apr/2015		
CHN0195	Wang, Haofu	The Affiliated Hospital of Medical College Qingdao University	17/Apr/2015	16/Apr/2015	29/ May/2015		12/Jun/2015			
CHN0196	Wang, Shenming	The First Affiliated Hospital, Sun Yat-sen University	23/Jan/2015	27/Jan/2015	17/Mar/2015	17/ Mar/2015	24/Mar/2015	26/Mar/2015		
CHN0204	Yang, Jinghua	Beijing Anzhen Hospital	27/Mar/2015	27/Mar/2015	16/Apr/2015	16/Apr/2015	30/Apr/2015			
CHN0206	Yang, Zhenwen	Tianjin Medical University General Hospital	09/Mar/2015	10/Mar/2015	30/Apr/2015	26/ Mar/2015	08/May/2015	27/Mar/2015		
CHN0207	Yang, Zhongqi	First Affiliated Hospital of Guangzhou University of TMC	27/Apr/2015	27/Apr/2015	05/ May/2015	05/ May/2015	19/May/2015			
CHN0216	Zhang, Lei	The 1st Affiliated hospital of Hebei Medical University	23/Mar/2015	23/Mar/2015	27/Mar/2015	27/ Mar/2015	06/Apr/2015	30/Mar/2015		
CHN0217	Zhang, Weihua	The First Hospital of Jilin University	30/Apr/2015	10/Apr/2015	15/Jun/2015		25/Jun/2015			