National Coordinating Investigators Newsletter No. 5

VTE Garfield
global anticoagulant registry in the field

January , 2016

Dear Members of the National Coordinators Council,

Cohort 1 is now complete ! Entry of data to be completed and query free by 15 February 2016 in preparation for the publication of the baseline paper. We would like to thank you all for your contributions in achieving this important milestone. Thank you for your continued support, your invaluable input and above all for encouraging all our investigators in their recruitment. We hope that recruitment into Cohort 2 will be as successful. Your help will be much appreciated. **Based on the number of patients we have for Cohort 1 in the database on the 21st Jan, the target recruitment in your country for Cohort 2 is:**

Overall Study Status at a Glance:

No. of patients recruited (actual/planned) : 5025/10,000

No. of sites selected (actual/planned): 476/490

No. of sites initiated: 369

No. of recruiting sites: 322

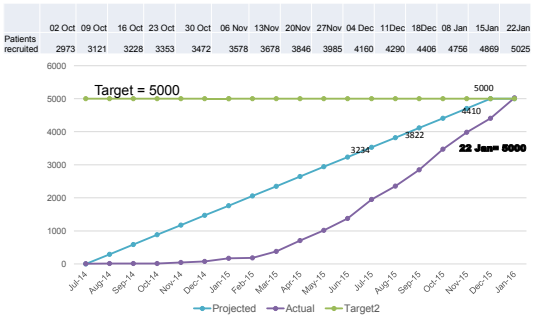
Global News and Announcements

Updates to Clinpal are being planned to include new fields to capture additional data. These are currently being finalised with the steering committee. Further information will be circulated in the next newsletter.

- A successful **Investigators Meeting** for UAE, Egypt and Turkey was held on 23 January in Dubai.
- **Forthcoming Investigators Meetings** in the planning phase are:
  - ◊ **Europe** Investigators Meeting - 20 Feb (London)
  - ◊ **China** Investigators Meeting -27 Feb (Shanghai)
  - ◊ **Japan** Investigators Meeting— 17 Mar (Tokyo)
  - ◊ **Asia Pacific/Australia** Investigators Meeting—19 Mar (Hong Kong)

In order for the meeting to be a success, please encourage all the investigators in your country to participate so that we can have a constructive and meaningful meeting. A Protocol **Questions and Answers** document will be updated fol-lowing our discussions at the Ambassador meeting and will be distributed to you shortly.

GARFIELD-VTE Global Recruitment (22 Jan 2016) – Cohort 1



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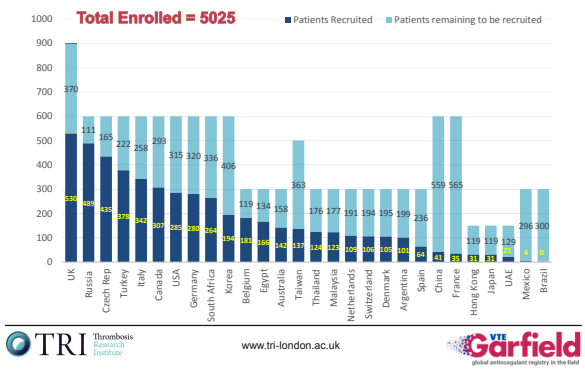
Global Enrolment : By Country (Actual and Target Recruitment)



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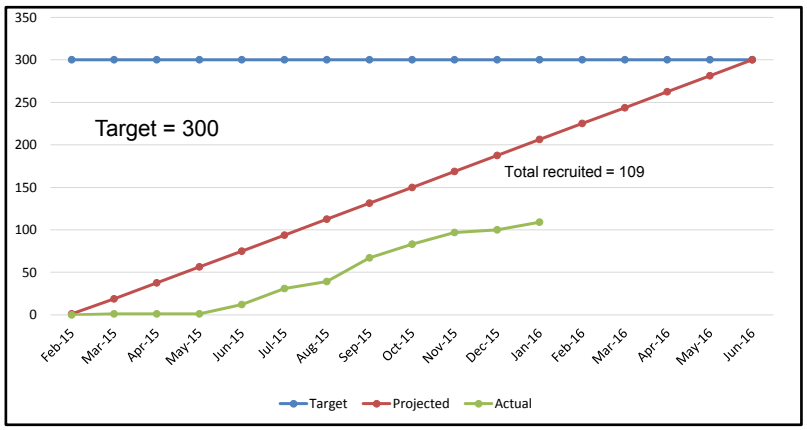
Project Team at TRI

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

TRI Thrombosis Research Institute

GARFIELD-VTE – Recruitment in Netherlands



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Country Highlights

Sites selected	
EC submissions completed	10
EC/Regulatory approvals in place	10
Clinical Trial Agreements fully executed	10
Site Initiation Visit calls completed	10
Patients enrolled	109
Patients expected to date	206

Site Regulatory Start-up

PI Name	Country	Site #	SIV	Projection during IMVs n	Expected Enrolment to date	Actual Enrol-ment per EDC
Bax, W.A.	Nether-	NLD0082	6-Mar-2015	1	12	9
Boomars, Karin	Nether-	NLD0083	11-Mar-2015	1	6	3
Dees, Ad	Nether-	NLD0084	25-Feb-2015	2	21	22
Donders, Servaas	Nether-	NLD0085	2-Sep-2015	3	15	1
Erdkamp, Frans	Nether-	NLD0086	1-Apr-2015	3	30	15
Middeldorp, Saskia	Nether-	NLD0087	9-Apr-2015	4	36	24
Ten Cate, Hugo	Nether-	NLD0088	30-Mar-2015	1	10	6
Tick, Lidwine	Nether-	NLD0089	8-Apr-2015	1	10	10
Gerdes, Victor	Nether-	NLD0231	24-Feb-2015	2	24	17
Loualidi, Ab	Nether-lands	NLD0359	25-Sep-15	3	13	0