

Dear Members of the National Coordinators Council,

Welcome to the 6th version of the Garfield-VTE Newsletter. As of 26 February, we have recruited 5900 patients, of which 900 are in Cohort 2. Thank you for all your help in encouraging our sites in their recruitment. In the last newsletter, we informed you that we hope to start the analysis of the baseline data in March and was aiming to have clean and completed baseline data for Cohort 1 by the end of February. A great amount of effort has been put in by all the sites and as of today, we have 4,888 completed baseline CRF. We hope that more baseline CRF will be completed in the next few days so that we can include more patients in the publication.

Overall Study Status at a Glance:

No. of patients recruited (actual/planned) :
5900/10,000

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

No. of sites initiated: 381

No. of recruiting sites: 342

Global News and Announcements

Updates to Clinpal. Several changes have been made to the EDC system in order to enhance the experience of site users. These include the following:

- Ability to search for a patient or a site
- Clear indication of opened and closed queries and messages in the dashboard
- Study coordinators are able to see and resolve all queries
- The status of the patients can be found in the dashboard
- Patients can be deactivated by data management with approval from the principal investigator or his or her delegate

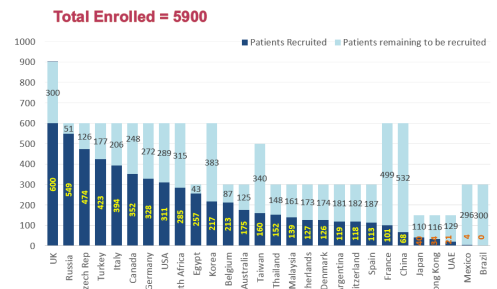
Investigators Meetings : An investigator meeting was held in London on 20 February for the European sites and another one was held in China for the sites in China on 27 February. Two additional meetings will be held in the coming month, one in Japan (17 March) and another in Hong Kong (19 March) for the sites in Asia Pacific.

Publications: A publication on the methods of the study is being prepared and plans are in place to submit this at the end of March, once it has been approved by the publication committee.

GARFIELD-VTE Global Recruitment– Cohort 2



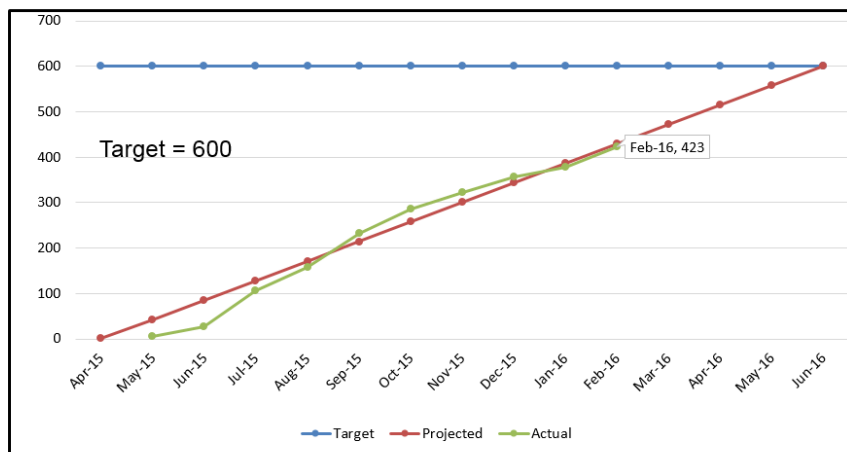
Global Enrolment : By Country (Target vs Actual Recruitment Cohort 1 and 2)



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).

GARFIELD-VTE – Recruitment in Turkey



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Country Highlights

Sites selected	
EC submissions completed	18
EC/Regulatory approvals in place	18
Clinical Trial Agreements fully executed	18
Site Initiation Visits completed	18
Patients enrolled	423
Patients expected to date	430



Site Regulatory Start-up

PI Name	Country	Site #	SIV	Projection during IMVs n	Expected Enrolment to date	Actual Enrolment per EDC
Aksoy, Ahmet	Turkey	TUR0246	10-Jun-2015	30	17	29
Adademir, Taylan	Turkey	TUR0247	21-May-2015	60	34	44
Battaloglu, Bektas	Turkey	TUR0248	12-May-2015	30	17	17
Dogan, Emre	Turkey	TUR0250	21-May-2015	60	34	46
Gur, Ozcan	Turkey	TUR0251	14-May-2015	40	23	31
Gurbuz, Orcun	Turkey	TUR0252	11-May-2015	20	12	12
Hasanoglu, Hatice	Turkey	TUR0253	1-Jun-2015	30	17	24
Hashas, Erman	Turkey	TUR0254	26-May-2015	40	23	38
Isbir, Selim	Turkey	TUR0255	28-May-2015	20	11	3
Kanko, Muhip	Turkey	TUR0256	29-Apr-2015	40	24	33
Karaarslan, Kemal	Turkey	TUR0257	26-May-2015	10	6	10
Kiris, Ilker	Turkey	TUR0258	30-Apr-2015	20	12	11
Kubat, Emre	Turkey	TUR0259	15-May-2015	20	12	13
Oguz Karahan <i>Mavitas, Binalli</i>	Turkey	TUR0260	27-Apr-2015	30	18	24
Oto, Oztekin	Turkey	TUR0261	6-May-2015	15	9	7
Ozkan Aktogu, Serir	Turkey	TUR0262	25-May-2015	40	23	38
Savas, Ismail	Turkey	TUR0263	3-Apr-2015	15	9	12
Turker, Hatice	Turkey	TUR0264	13-May-2015	40	23	31

