

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

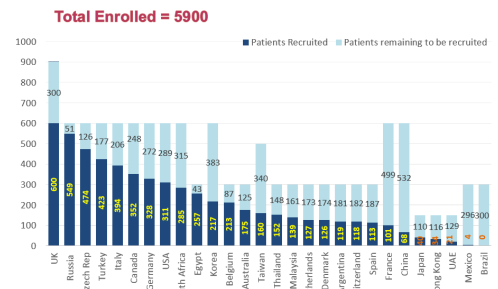
Investigators Meetings : An investigator meeting was held in London on 20 February for the European sites and another one was held in China for the sites in China on 27 February. Two additional meetings will be held in the coming month, one in Japan (17 March) and another in Hong Kong (19 March) for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



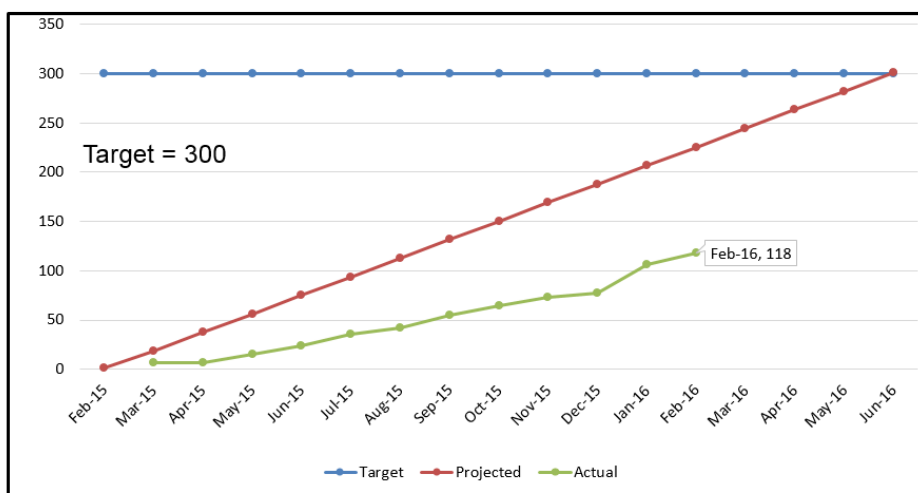
Global Enrolment : By Country (Target vs Actual Recruitment Cohort 1 and 2)



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 Switzerland



www.tri-london.ac.uk



Country Highlights

Sites selected	
EC submissions completed	8
EC/Regulatory approvals in place	8
Clinical Trial Agreements fully executed	8
Site Initiation Visits completed	8
Patients enrolled	118
Patients expected to date	225



Site Regulatory Start-up

PI Name	Country	Site #	SIV	Projection during IMVs n	Expected Enrolment to date	Actual Enrolment per EDC
Bounameaux, Henri	Switzerland	CHE0244	11-Feb-2015	63	41	47
Banyai, Martin	Switzerland	CHE0324	29-May-2015	10	6	10
Canevascini, Reto	Switzerland	CHE0325	13-Aug-2015	10	5	7
Groechenig, Ernst	Switzerland	CHE0326	1-Jul-2015	10	5	10
Jeanneret, Christina	Switzerland	CHE0327	11-Sep-15	10	4	15
Korte, Wolfgang	Switzerland	CHE0328	13-Jul-2015	11	6	0
Staub, Daniel	Switzerland	CHE0329	26-Feb-2015	50	32	22
Amann-Vesti, Beatrice	Switzerland	CHE0367	09-Sep-15	8	4	7

