

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

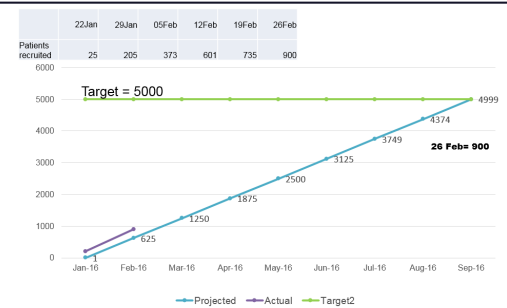
Updates to Clinpal. Several changes have been made to the EDC system in order to enhance the experience of site users. These include the following:

- 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

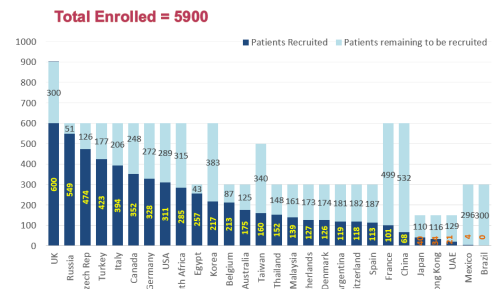
Investigators Meetings : An investigator meeting was held in London on 20 February for the European sites and another one was held in China for the sites in China on 27 February. Two additional meetings will be held in the coming month, one in Japan (17 March) and another in Hong Kong (19 March) for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



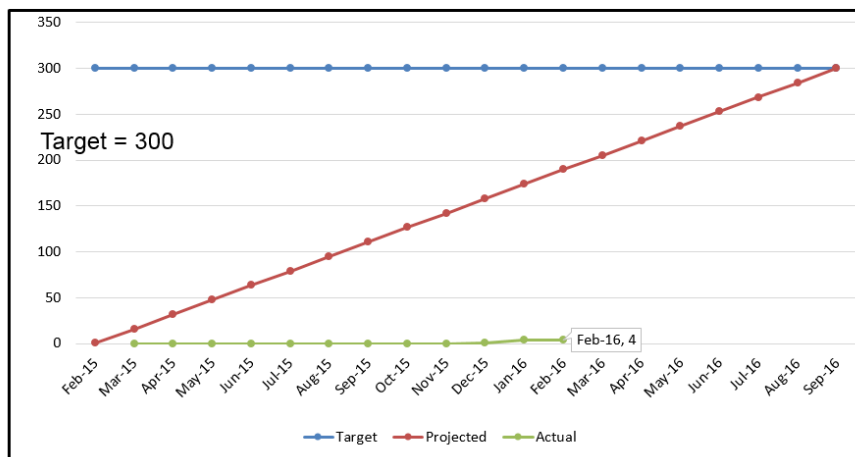
Global Enrolment : By Country (Target vs Actual Recruitment Cohort 1 and 2)



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 Mexico



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Country Highlights

Sites selected	
EC submissions completed	15
EC/Regulatory approvals in place	15
Clinical Trial Agreements fully executed	7
Site Initiation Visits completed	6
Patients enrolled	4
Patients expected to date	190



Site Regulatory Start-up

PI Name	Country	Site #	SIV	Projection during IMVs	Expected Enrolment to date	Actual Enrolment per EDC
Flota Cervera, Luis	Mexico	MEX0332	4-Nov-15	10	4	1
Alcocer Gamba, Marco	Mexico	MEX0388	08-Oct-15	18	7	0
de los Rios Ibarra, Manuel	Mexico	MEX0389	01-Dec-15	6	2	0
Llamas Esperón, Guillermo	Mexico	MEX0392	03-Dec-15	7	2	2
Nandayapa Flores, Oscar	Mexico	MEX0393	19-Nov-15	11	4	1
Tristan Galvan, Javier	Mexico	MEX0396	28-Oct-15	20	7	0

