



**TRI** Thrombosis  
Research  
Institute



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# Weekly Status Report

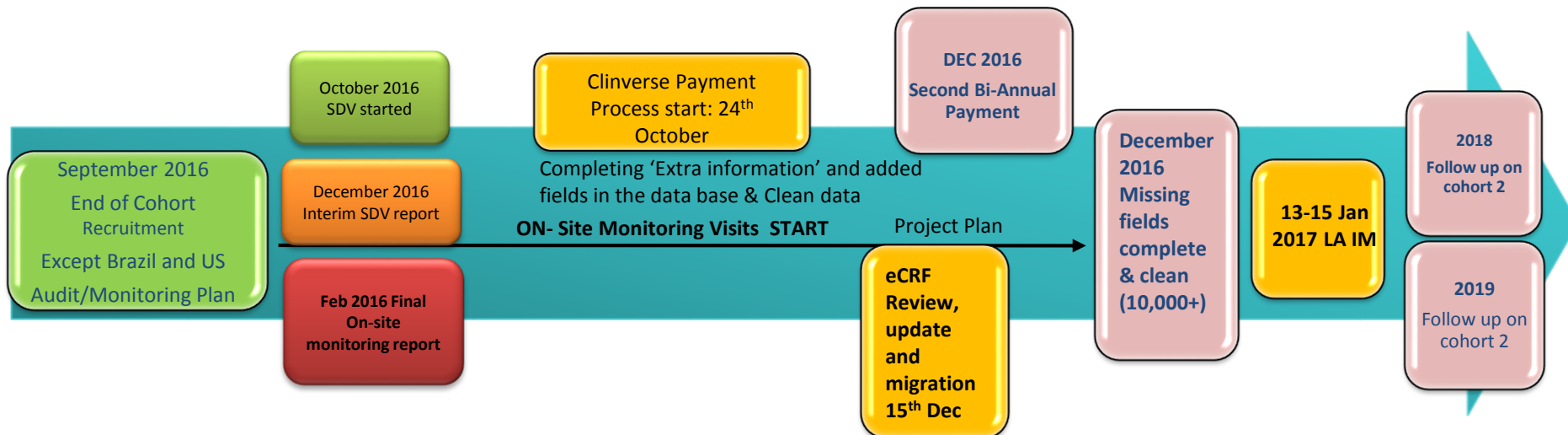
9th December 2016

The GARFIELD Registry is funded by an unrestricted research grant from Bayer Pharma AG

# Project Timeline- Overview

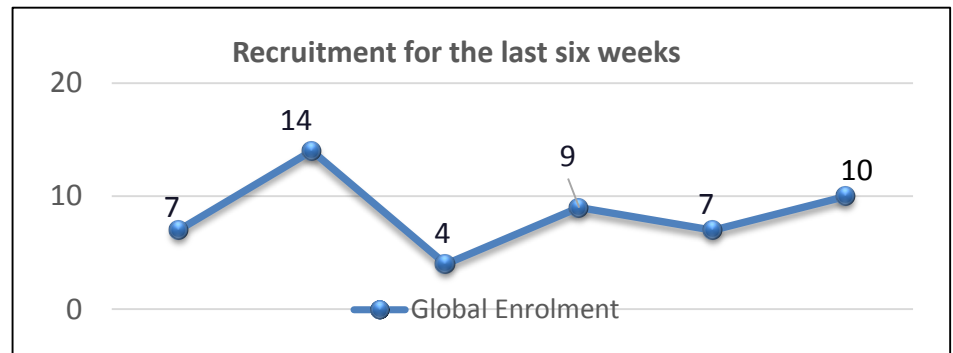
## History

- 01JUL14 – Recruitment Start (FPFV)
- JULY 2014 – CLINVERSE went live and first payment went out to priority sites
- SEPT 2014 – 2<sup>nd</sup> payment went out to the rest of the sites, IM in South Africa
- OCT 2014 – SC & NCI meeting
- DEC 2015 – IM for UAE/Egypt/Turkey
- JAN 2016 – LPFV (COHORT 1), First draft of methods paper
- FEB 2016 - Released additional fields in eCRF, IM for EUROPE, QUINTILES/TRI meeting, Completed data cleaning for existing data, IM for China
- MAR 2016 – IM for ASIAPAC, Submit methods paper, First Draft Base LPFV (Cohort 2)
- JUNE/JULY 2016 – Milestone site payments.
- AUGUST 2016 - As of 12<sup>th</sup> August 2016, we have passed the 10,000 milestone.
- 22 OCT- Ambassador Meeting

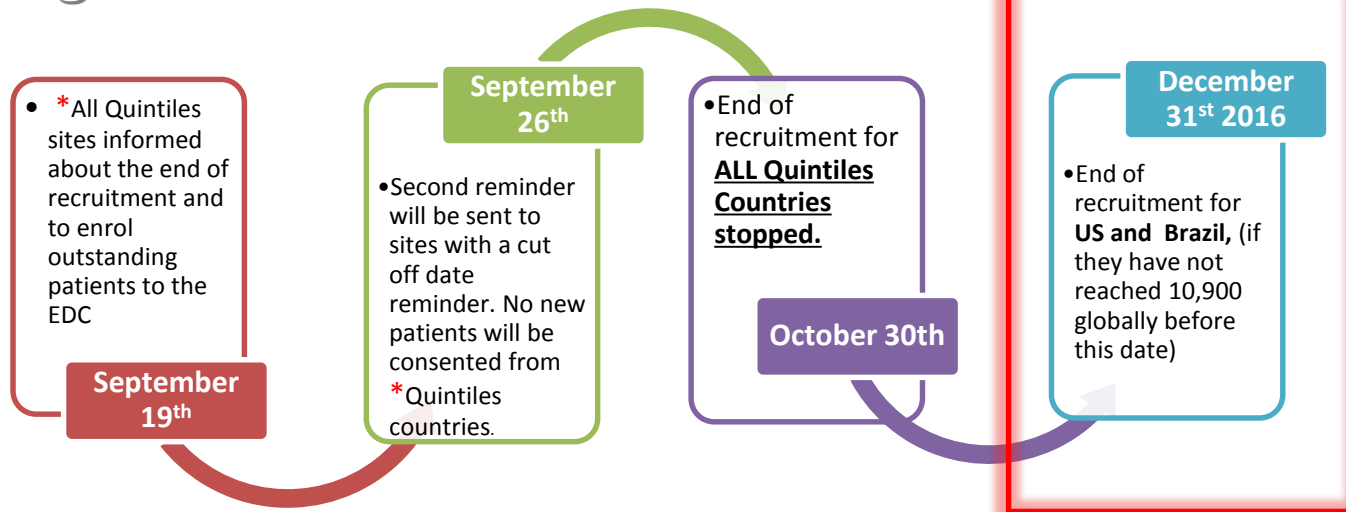


# Recruitment Update

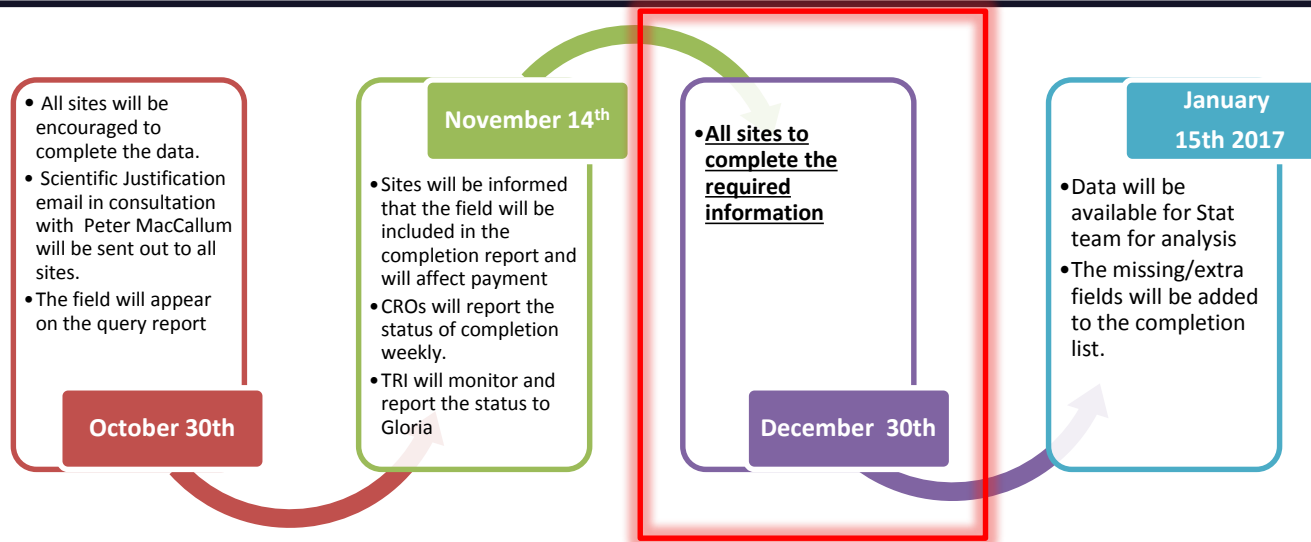
<b>Total Recruitment</b>	<b>10,850 ↑ by 10 from last update</b>
Number of Sites selected	477
Number of sites with EC approval/Regulatory approval	441 same from last update
No of fully executed contracts	442 same from last update
SIVs completed	442 same from last update
This week's recruiting sites total	<b>4 (Brazil and US)</b>



## Stopping Recruitment Plan



# Extra Information Data Field (Distal & Proximal) completion Plan and Status(Global)



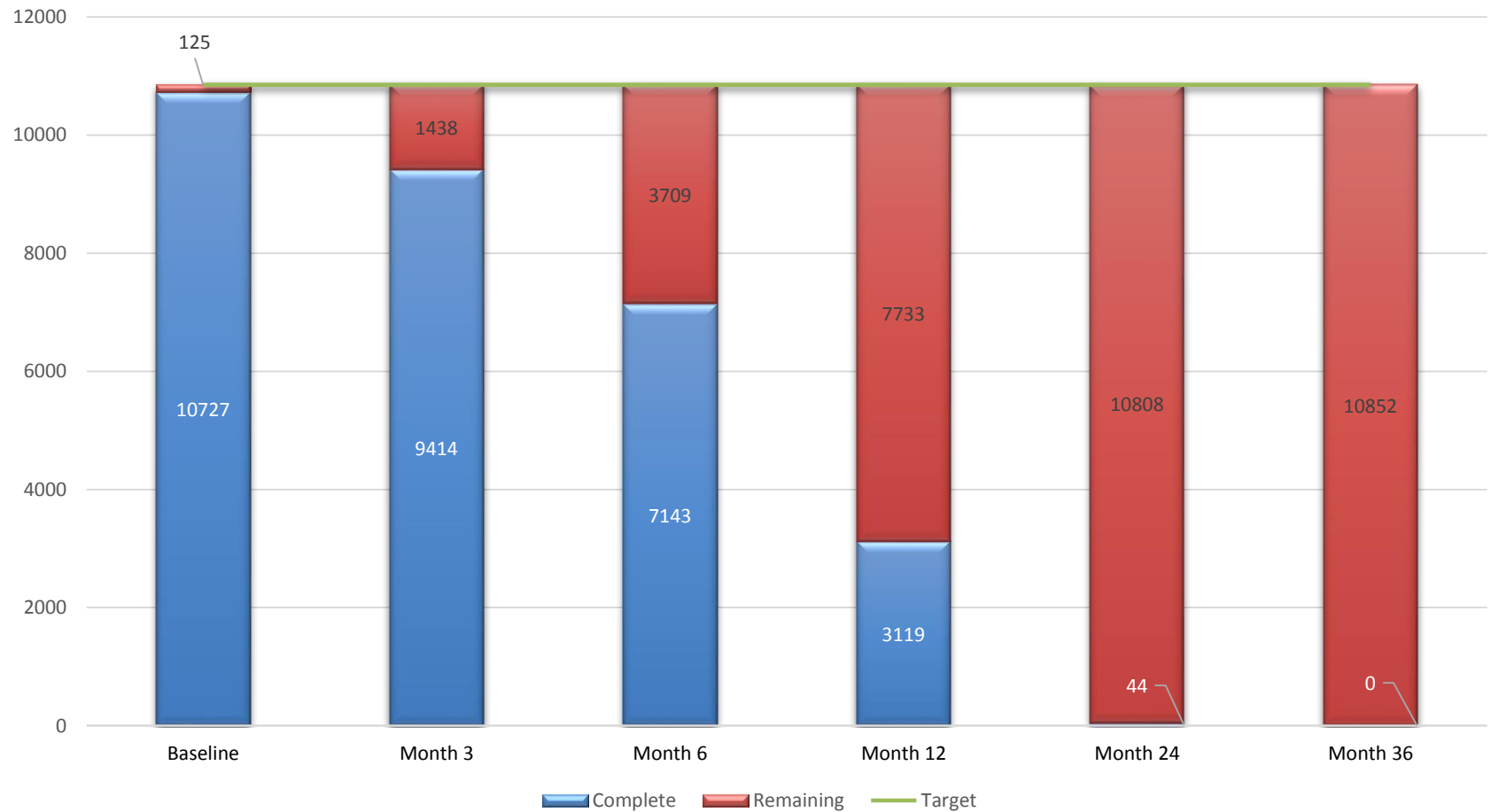
## Issues

- Two sites asked for reimbursement -TRI advised CROs to encourage sites the importance of the information required and a support letter was distributed to sites with the scientific justification of the field required.

## Action

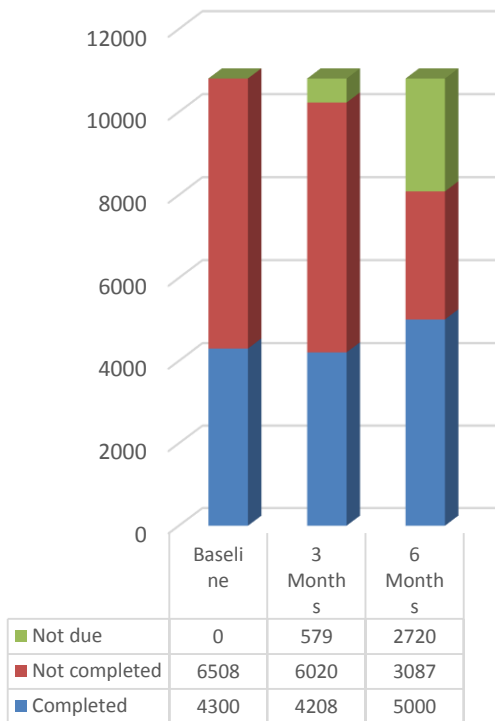
- TRI will closely monitor the adherence of sites on the completion of the fields.
- The additional fields will be part of the query report and flagged on the system.
- Motivational letter from TRI will be sent to Investigators following eCRF changes

# Global Data – Patients Milestone Update



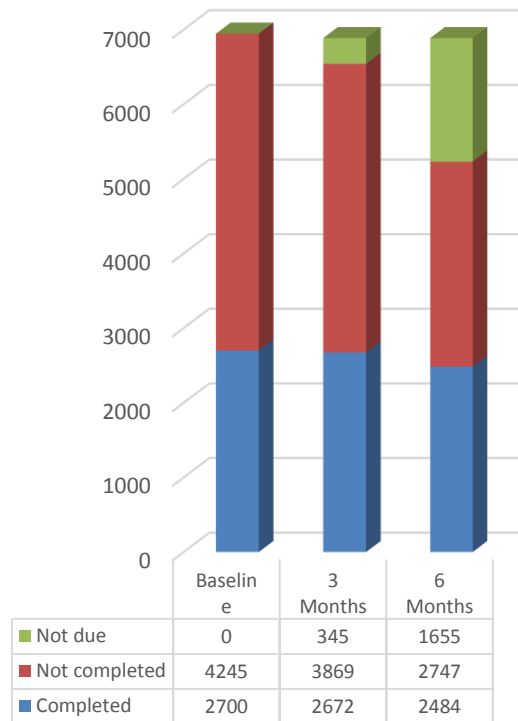
# Questionnaire Completion Report (November)

## SF 12



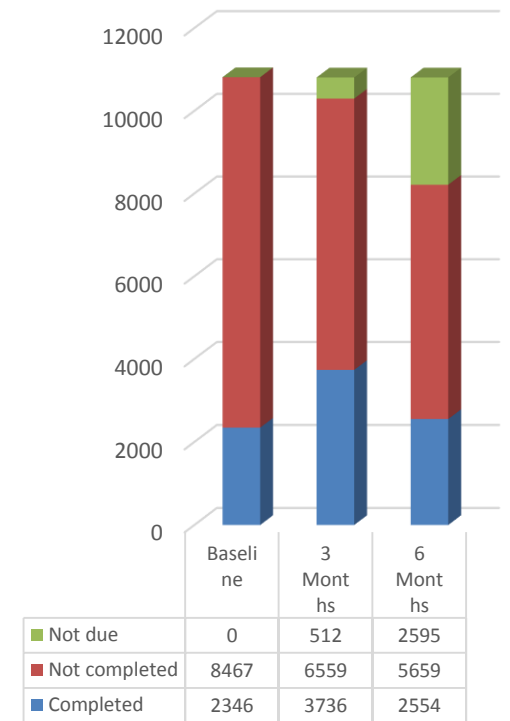
Completed Not completed Not due

## ACTS



Completed Not completed Not due

## Villalta



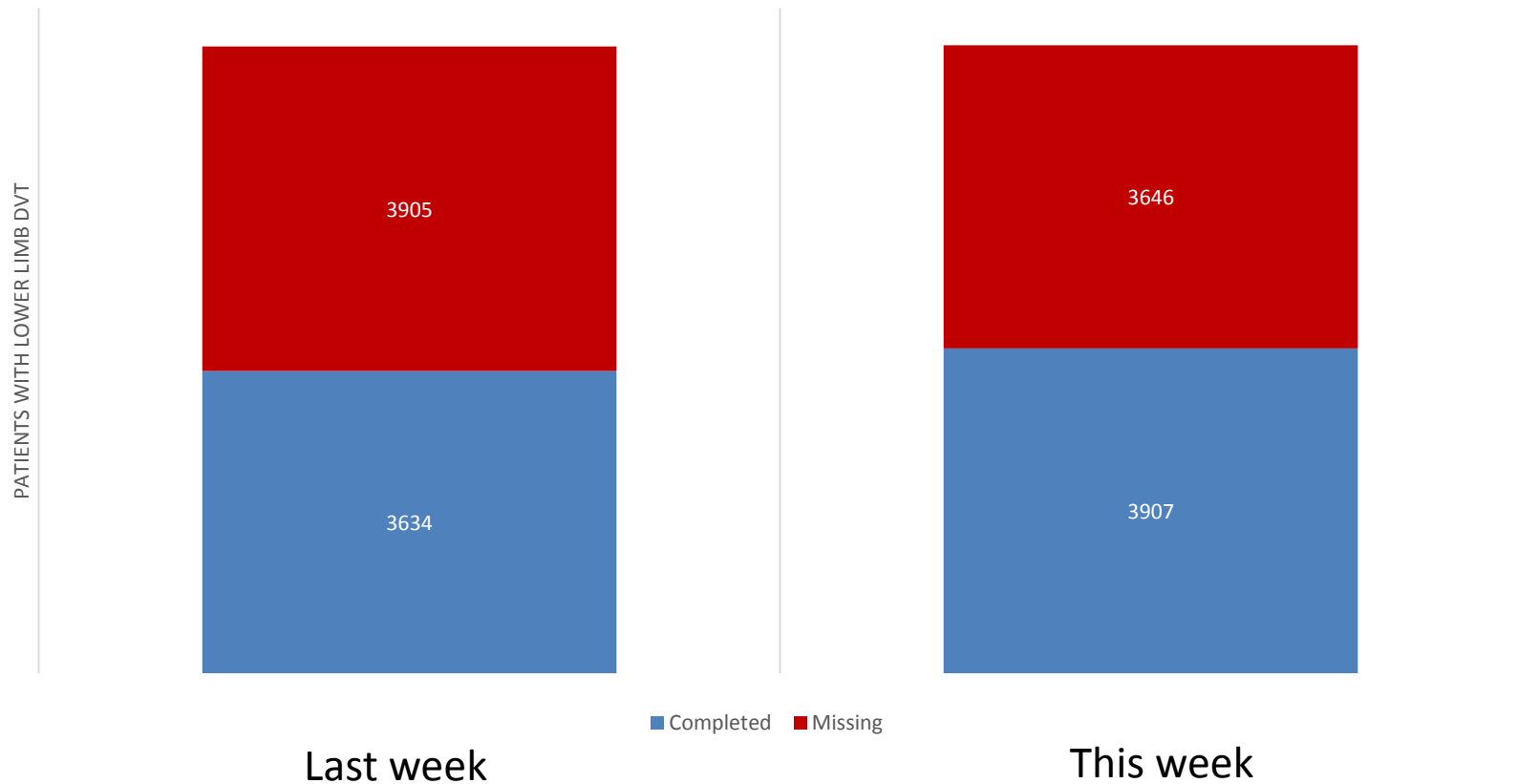
Completed Not completed Not due

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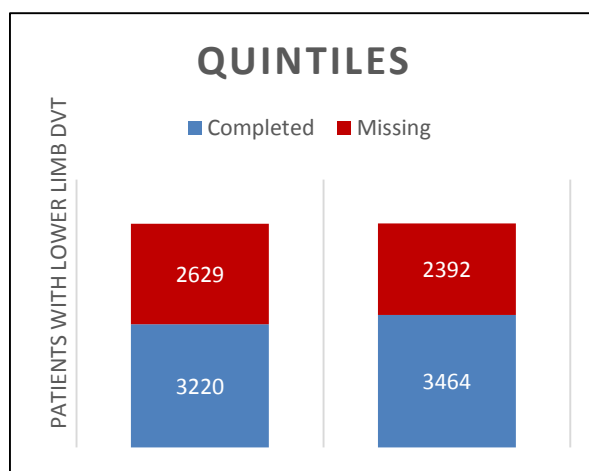
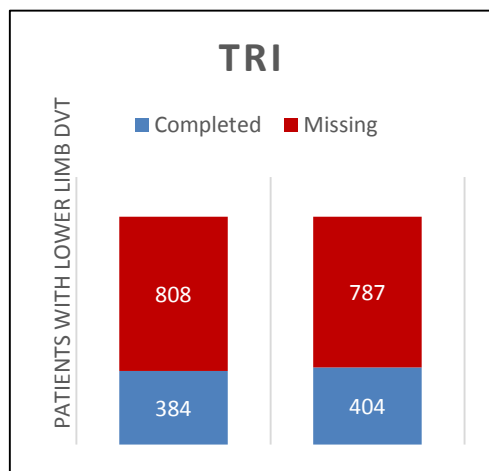
# Extra information field: Proximal / Distal Global

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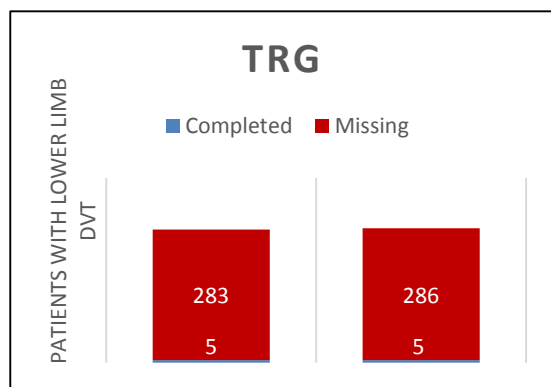
## EXTRA INFORMATION ENTRY PROGRESS



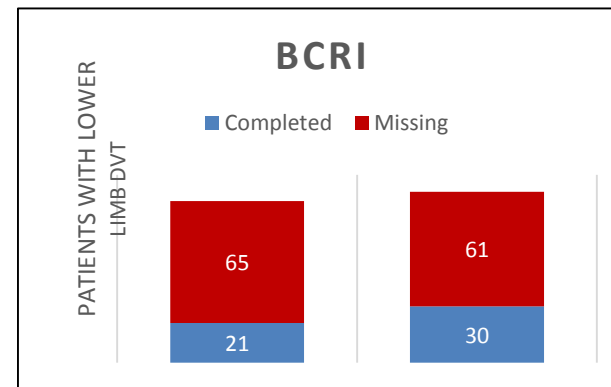
# Extra information field: Proximal / Distal per CRO (Last week and this week)



\* Still recruiting



\* Still recruiting





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

**Total Enrolled = 10,850**

↑ Countries still recruiting

