

PERCEIVE

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Barts and the London NHS Trust	UK
Bronglais General Hospital	UK
James P. Wilmot Cancer Center	USA
National University Hospital, Singapore	Singapore
Ospedali Riuniti di Bergamo	Italy
University Hospital Messina	Italy

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UK	+ 0 hour (GMT)
USA	- 5 hours (EST)

NEWS SUMMARY

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F-U Time-frame

Date of histological diagnosis: That is the date that the first diagnostic specimen or biopsy was taken as specified on the histology report. Please do not use the date the histology report was approved, as it may be different. It is also day 0 of the study. It is the date used to calculate all F-U periods.

Baseline: Information on previous medical history is collected here. In addition all events occurring in the first 30 days following the date of histological diagnosis: day 0 to 30

Month 6: Collected here events occurring between month 2 and 6 post date of histological diagnosis: date of F-U should at least 5 months after the date of histological diagnosis and no later than 7 months after the date of histological diagnosis.

Month 12: Collected here events occurring between month 7 and 12 post date of histological diagnosis: date of F-U should be at least 12 months after the date of histological diagnosis and no later than 14 months after the date of histological diagnosis.

Yearly F-U: Collected here events occurring in year 2, 3, 4... x post date of histological diagnosis. Date of F-U should at least 24, 36, 48... x12 months after the date of histological diagnosis and no later than 26, 38, 50, ..., x12+2 months after the date of histological diagnosis.

Lost to Follow-up: If a subject is lost to follow-up, please enter the date last seen as the date of follow-up for that follow-up period. That is the date the subject is lost to follow-up and exits the registry and up to which we record their data.

Death: In case of death, please enter the date of death as the date of follow-up for that follow-up period. That is the date the subject is exits the registry and up to which we record their data.

Bloods: one per month: Please note that in order for us to consider the folder complete the following blood data must be entered.

- Baseline compulsory
- Month 6 ideally one per month (=5).
- Month 12 ideally one per month (=6)
- Yearly F-Us ideally one per month (=12)

If only fewer results are available, then please make sure to explain this in a note

Reminders

TNM – Staging: We are very much aware that the TNM classification is somewhat old as when the trial was started this was the most up to date classification. But for the purposes of this registry, please refer to the text in the help-box on-line and the instruction on the investigator's folder for the definitions.

Baseline Surgery Please only record surgery that occurred within the first 30 days after diagnosis. All subsequent surgeries fall in the follow-up periods and should be recorded there.

Date of Follow-up In case of death during a follow-up period, the date of death for that period should be the date of death. That is the date the subject exits the trial and the date up to which we record their data. In case of lost to follow up during a follow-up period, the date of follow up for that period should be the date the patient was last seen. That is the date the subject exits the trial and the date up to which we record their data.

Imaging Only imaging done for suspicion or diagnostic for VTE should be recorded

S Numbers: If by mistake you seem to create an S number then please screen that patient. You would need to click on the eligibility form and go to the inclusion criteria and click on the pencil for New diagnosis and change it to NO which will give you a Z number and the patient is screened.

Radiotherapy Section if patients were given two separate doses but within the same follow-up period then you can add up the GY unit in one sum and add the frequencies in the other sum.

Investigator's Signature: only sign this page when all queries have been resolved

Yearly Follow-up Form: When entering data for year 2 follow-up and above, you need to add a yearly follow up form per year. Please note that in the menu on the left, the folders are allocated a number in the bracket, for example the first folder entered will say (1). That does not relate to the follow-up period and should be ignored. What defines the year of follow-up is the information entered, in the first form within the folder, called "yearly Follow-up". To specify the follow-up period: year 2, 3, etc you need to enter that information in the first form within the folder, called "yearly Follow-up" and choose the relevant year in the "Follow-up Year" Field. Please note that the first available option is two because year one follow-up data is recorded in the month 12 follow-up folder.

Congratulations to:

Singapore

- For the best re-consent rate
- Prompt query resolution.
- For excellent rate of data entry.

Messina

- For the ongoing success in re-consenting subjects
- For all the hard work put into maintaining and completing data entry.

Bronglais

- For re-consent rate per capita
- For maintaining a highly organised database

Barts

- For their continued effort in re-consenting

3 Counties

- For terrific query resolution rate.

Bergamo and JP Wilmott

- Thank you for all your continued effort in devising a strategy for re-consenting.

AKH Vienna

- For a fantastic effort in addressing outstanding queries
- For achieving a considerable data entry and query resolution.

Message to CRAs

From Monitoring Team

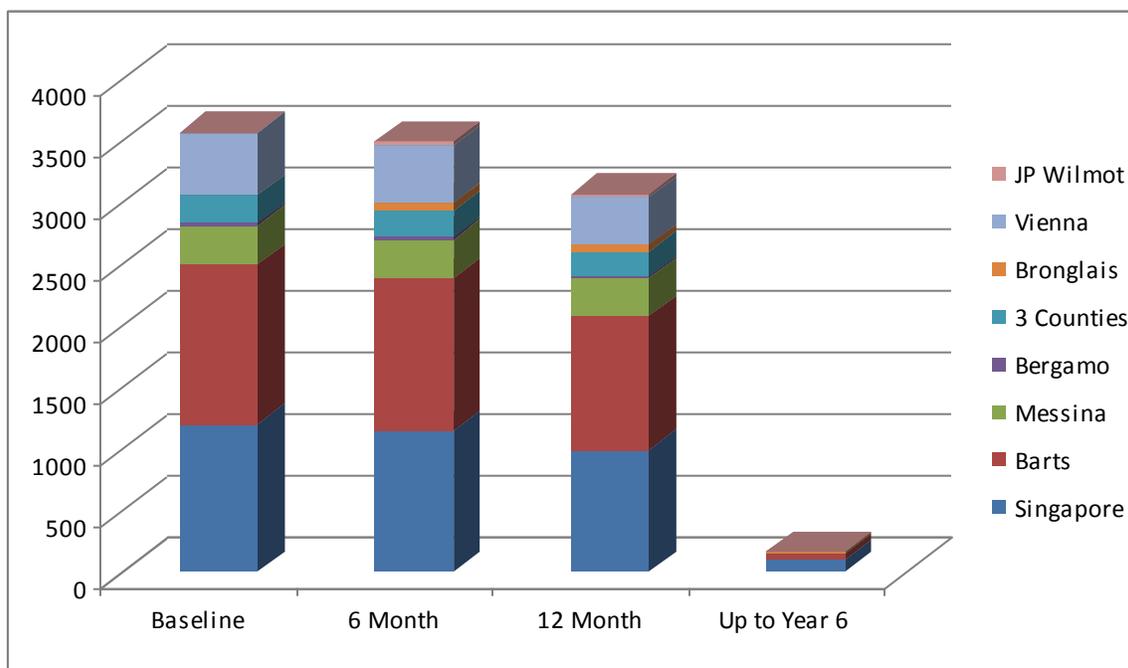
We at the Thrombosis Research Institute would like to formally welcome our new CRAs from University Hospital Messina (Italy) and the National University Hospital (Singapore)

There has been very good progress in collecting long-term data.

Query resolution is also progressing at a good rate.

Can we please encourage you all to continue focusing on re-consenting subjects to achieve a good rate of long-term follow-up data.

Overall Follow-up Data



Data Entry per Site

