

PERCEIVE

Special Edition "Amendment 3 Approved"

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Centres

3 Counties Cancer Research Network	UK
Allgemeines Krankenhaus der Stadt Wien, Vienna	Austria
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
Sir Ganga Ram Hospital	India
University Hospital Messina	Italy

Latest recruitment*

4588 Enrolled

536 Screened

A big thank you to all for your hard work

**(20 July 2010)*

NEWS SUMMARY

- 1** Latest Recruitment
- 2** Indefinite Follow-up Approved
- 2** Message to CRA
- 2** F-U Time-frame

Indefinite Follow-up

Approved!

Amendment 3 ready to be implemented

It is with great pleasure that we can confirm that on the 18th June 2010 we have formally been granted ethical approval for Amendment 3.

In addition to the Baseline, month 6 and month 12 Follow-ups; which will continue as before, a further yearly F-U summarizing major vascular incidents and mortality will be implemented. A guide on the time-frames is in the inserts in this page.

New protocol and approval letter are on their way for you to update your documentation locally. Please ensure that you inform your local authorities of this Amendment and acquire the relevant approval to implement it.

Once you gain approval locally please follow the new protocol and update your patient information sheet and consent forms as appropriate. There are re-consent forms to gain consent for the additional F-U from subjects you have already entered in the database

Contract extensions are on your way and have been updated to reflect the new follow-up schedule.

F-U Time-frame

Death: In case of death occurring in a F-U period, the date of F-U for that period will be the date of death. All events occurring to that date will be collected in the relevant F-U folder and no further data entry will be required. The investigator's signature page will be completed at that stage

Message to CRAs

From Dr. Neelam Saba

Thank you for all the work you have put in to answer the queries. We are working to get the dataset clear.

We would like to formally welcome our new CRAs from Bergamo and 3 Counties for joining the team.

Just a reminder that in the Baseline folder, within the "Risk Factors" Page, in the section on:

PREVIOUS VENOUS THROMBOEMBOLIC EVENTS

Specify number of episodes per type, (0=None, leave blank if unknown)

Please enter 0 to signify that there is no history of

F-U Time-frame

Date of histological diagnosis: this is the date the first histological diagnosis is made. 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 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.