

PERCEIVE

September 2010



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Austria	+ 1 hour (ECT)
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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*

4,609 Enrolled

538 Screened

A big thank you to all for your hard work

**(13 Sep 2010)*

NEWS SUMMARY

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News

From Core Team

Thank you all for working very hard throughout the summer period in supporting the study and working towards the implementation of Amendment 3.

Version 2.0 of the Investigator's file should be with you all. Please make sure you upgrade your study files as appropriate.

All administrative paperwork should have reached you by now. Please check that they meet your requirements and return them at your earliest opportunity

Address Book

Thank to all of you who have confirmed your preferred contact details.

If you have not done so yet, or if you would like to inform us of any changes, please sent a brief e-mail to the study address:

perceive@tri-london.ac.uk

Message to CRAs

From Dr. Neelam Saba

I hope you found the training for the new eCRF version 304 useful. The eCRF is now live, please resume data entry. As you know it implements indefinite follow-up in line with Amendment 3 framework.

Full instructions are available within the new version of the Investigator's file, but please do not hesitate to contact us should you require any further information.

Please note there have been some minor changes in the main body of the eCRF as well; please see insert in this page.

Otherwise the main change is the addition of two new forms available from the drop down menu: "Add event" in the subject's main page:

- the yearly follow-up folder
- the re-consent form

If you have any queries in regards to their use, please do not hesitate to contact us.

Thank you for all the hard work in addressing the monitoring queries.

eCRF Changes

Help-text for Ovarian Staging:

FIGO stage

IA → T_{1a} N₀ M₀
 IB → T_{1b} N₀ M₀
 IC → T_{1c} N₀ M₀
 IIA → T_{2a} N₀ M₀
 IIB → T_{2b} N₀ M₀
 IIC → T_{2c} N₀ M₀
 IIIA → T_{3a} N₀ M₀
 IIIB → T_{3b} N₀ M₀
 IIIC → T_{3c} N₀ M₀
 N₁ M₀
 IV → M₁

Help-text for Lung Staging:

Lung stage

Occult → T_x N₀ M₀
 0 → T_{is} N₀ M₀
 IA → T₁ N₀ M₀
 IB → T₂ N₀ M₀
 IIA → T₁ N₁ M₀
 IIB → T₂ N₁ M₀
 T₃ N₀ M₀
 IIIA → T₁₋₂ N₂ M₀
 T₃ N₁₋₂ M₀
 T₃ N₂ M₀
 IIIB → N₃ M₀
 T₄
 IV → M₁

eCRF Changes

Page renamed; all cancer types:

Old name: **Staging**

New name: **Diagnosis**

Page renamed; all cancer types:

Old name: **Investigator's Signature**

New name: **Data Entry Completed for this subject**

Surgery field changed for breast:

Old name: **Segmental Mastectomy**

New name: **Segmental Resection**

Surgery Axillary dissection field type changed for breast:

Old field type: **Tick Box**

New field type: **drop-down menu**