



Planet-2 Newsletter

Issue 2
Feb 2012

Editorial

Happy New Year (rather late I know!), and welcome to the second edition of the Planet-2 newsletter. A lot has happened since the last issue; our recruitment numbers have increased, we have new sites on board, and others are in the pipeline.

The website has also gone live and is already proving useful for those wishing to find out more about the trial in the initial stages, or for site staff wanting more detailed information or downloads. There is more information on the website on page 2 of the Newsletter.

We are considering the possibility of having a Research Nurse Study Day later this year. It would be a good time to meet as the number of participating sites is increasing, and new research staff are joining the study. Planning is still in the early stages, but we could cover project updates and try and address queries as well as sharing examples of good practice. If you have any ideas for topics that you would like discussed, please let me know.

Last of all, thank you all for your help over the past few months!

Best Wishes
Karen

News in Brief:

The number of babies randomised to Planet has now reached 18

Welcome to new staff and centres joining the trial

Website goes 'live'.

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Meet the Planet-2 Team



This is Renate Hodge. Renate works at the NHSBT in Cambridge and is the Data Manager for the trial.

When you send in your CRF forms with the transmission logs, Renate will check them and may get back to you if there any queries concerning the data. She has been involved in the process of commissioning the Planet-2 database and it is now being tested.

Safety Reporting



As with all trials, getting the safety reporting procedure correct is essential. Therefore, can I just remind you that major or severe bleeds must be reported on Form 13 (a – c), Serious Adverse Events (SAE) on Forms 14, and any Serious Platelet Transfusion Related Event on Form 15. These must be faxed to the NHSBT Clinical Studies Unit within 24 hours of knowledge of the event.

If the PI is unavailable to sign the form, a delegated member of staff can do this, and the PI should check the form and resend with corrections on their return.

Safety reports should be faxed with the Safety Report Transmission Log; in that way we are quickly aware of the event. If you do not receive an email in response, could I ask you to check with an email or phone call to Renate or Alison that they have received the forms?

Contact Planet-2 Trial Manager: Karen Willoughby. Email: kw369@medschl.cam.ac.uk

Trial Progress:



St Mary's in Portsmouth has now joined the Planet-2 study. We still have to visit for site initiation, but hopefully active recruitment will begin in the next month or so. Two new Research Nurses have also joined the project: Sara Barnett at Imperial (based at St Mary's, Paddington), and Helen Broomfield who is covering maternity leave at St Thomas's, so welcome to the team.

Along with Addenbrookes in Cambridge, the Norfolk and Norwich Hospital and John Radcliffe in Oxford, there are 6 sites now participating in the trial. By the time you receive the next newsletter in a few months time, we hope the numbers will have risen further.

We have now randomised 18 babies to the trial, and we are expecting the rate to increase as more sites come on board.

Planet-2 Website

The website is now 'live' and can be found on www.planet-2.com. On the documents page you will find all the current versions of the trial documentation, including the protocol, CRF and guidance, study logs and transmission forms. Each site also has its own individual folder for localised forms, such as the patient information leaflet, with specific Trust information as the header

There is also a page for Frequently Asked Questions which will provide a quick point of reference. If you can think of any new questions that would be useful to add, let me know and I will add them



The powerpoint presentations for the background to the study and CRF completion are also available to download. Please do direct anyone interested in the study to the website, and if there is any way you think it can be improved, just get in touch.

Practice Points: Screening Logs and Some Good Ideas

Screening Logs have probably changed more than any other document in the trial, and we are currently on version 1.2. The additional information required will provide us with more detail as to why babies are not being consented or randomised if they are eligible. Could you try and ensure you complete the column requesting medical diagnosis? Please fax the forms to me at the end of each month.



Also, don't forget that we have the pre-randomisation stickers and labels to notify other staff members that a baby has been consented to Planet-2.

If you seem to be missing any labels or posters etc, they can be downloaded from the website, or you can contact me for more.

Finally, some sites have found that getting a monthly laboratory report of babies with platelets less than 100 is a good way of checking if any babies have been missed from screening. This just requires someone to contact the laboratory to arrange for the report to be sent.