



Newsletter

Issue 3
May 2012

Editorial

Since the last edition of the Planet-2 newsletter, **Queen Alexandra Hospital in Portsmouth**, the **Royal Berkshire Hospital in Reading** and the **University Hospital of North Tees** have joined the trial. I would like to welcome all staff at these units who are helping to make Planet-2 a success.

In a previous edition of the newsletter I mentioned that we will be running a Research Nurse Study Day, and as the number of participating units increases the day will also provide an excellent opportunity for those actively involved in the study to meet each other and share experiences of the trial. Details of the Research Study Day can be found at the bottom of the page.

While we will have some presentations on the study day, I hope it will be something we can all actively contribute to.

I think it would be fair to say that one of the main challenges of the trial is to actively recruit babies, so it may be useful to discuss ways we can maximise the numbers of recruits. If you have any useful suggestions, please pass them on to me so that they can be shared, or bring your ideas along to the research day.

The Newsletter also has a new column. 'Ask Renate' will provide readers with a chance to ask those CRF questions they most want answered! In this edition the focus is on Safety Reporting.

Finally, if you have anything you want to see included in the Newsletter, please let me know

Hope to see you at the Study Day!

Best Wishes
Karen



NEWS IN BRIEF

No of recruits to Planet-2 now = 32

Three new sites join the trial

Planet-2 Research Nurse Study Day

3rd July



The venue for our first Planet-2 study day is the Association of Anaesthetists in Portland Place, London, on the 3rd July. We will start with lunch at 1pm, and finish about 5pm. I'll send out invitation emails separately with location maps

The NHSBT can buy your return train tickets to London, but unfortunately we can't reimburse the cost of train tickets if you decide to do it yourself .

If you are able to attend, and would like us to purchase train tickets, can you contact Sue Barton at the NHSBT (susan.barton.nhsbt.nhs.uk), ideally giving a couple of weeks notice. The venue is well placed for Oxford Street and the West End if anyone would like to continue the socialising after the meeting!

Let me know if there is anything you would like included in the programme.

Form A: Pre-randomisation Platelet Transfusion Information

By now you will hopefully have been able to look at the new Form A in the CRF. This is a document that will enable us to collect information on platelet transfusions before randomisation

If a baby has been transferred from another centre, please bear in mind that they may have received transfusions before they reached you. It will also be important to document these transfusions on Form A.

If some details, such as time of transfusion are difficult to track down under these circumstances, just enter NKNK in the time boxes.



You can download the new forms, as well as the Guidance, from the website. As soon as we are able, we will integrate Form A into the CRF, but at the moment it will have to be added as a 'stand alone' document.

If possible please review information on previously randomised babies and enter the data retrospectively. The Form can then be sent to Renate at the NHSBT with the normal transmittal log.

Thanks for all your co-operation with the introduction of this new form

Ask Renate

The column that allows you to ask Renate Hodge, data manager, those questions about CRF completion you've been dying to ask....



I have had a lot of queries about how to complete the SAE forms (14a and 14b); here are some of them:'

Question: When and how should I send follow up information?

Answer: The new form 14a must be used for each follow up report. Just tick the appropriate box to indicate which number follow up the report is, and ensure that the event name and date of onset are consistent with the initial notification, so that we can tie it all up. If the event has resolved by the time you send the follow up information, you can indicate how the event was resolved and complete the date and time of resolution

'Question: When should I complete an SAE (Serious Adverse Event) form?

Answer: Form 14a should be completed and faxed or emailed to the Clinical Studies Unit here at the NHSBT (the CSU) within 24 hours of becoming aware of the event. The minimum amount of information needed is the baby's trial number and initials, the name of the event, the date and time of onset and the reason for seriousness.



Question: When should I use Form 14b?

Answer: Form 14b is for you to write a narrative description of the event, including any treatment given or tests done with their results. The information on this form is used by the Chief Investigator and the Independent Data monitoring Committee to assess the event. It should be completed and sent to the CSU within 5 days of becoming aware of the event

The outcome of the event on the initial notification is likely to be "ongoing" and the date of resolution can be left blank. In the absence of the PI, the person who completes the form should sign it initially. The important thing is that the (CSU) is **notified as soon as possible** and that confirmation of receipt has been acknowledged by the CSU within 2 hours during the standard working day. If you don't get the confirmation, please contact a member of the CSU team.



Question: What should I put in the "event name" field?

Answer: The event name should be a diagnosis. For example, if the baby died following withdrawal of care after they had become very ill with the consequences of NEC, the event name is NEC. We have had a couple of instances where the event name has been noted as "withdrawal of care", but this is not a diagnosis, it is a consequence of the effects of the disease.