

Planet-2 Newsletter



Editorial

Welcome to the first Planet-2 Newsletter. The plan is for a Newsletter to be produced quarterly to provide you with regular updates to the trial. It would also be great to hear from you; you may have examples of practice that could be disseminated throughout the teams,

problems that you have encountered, or general information that could be shared. Contact details can be found at the foot of the page.

For this issue there is an introduction to some of the Planet-2 project team, and on page 2, a general update to progress on the trial.

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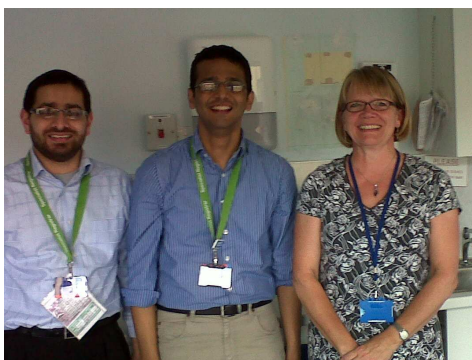
Newsletter Date
October 2011

Meet the Planet-2 Team



This is me, Karen Willoughby; I have probably met most of you by now. I am based in Cambridge and am Trial Manager for Planet 2. I have a clinical background, and have worked in law in the past.

I am here to support you, answer your queries and to ensure we get accurate data for the trial. If you have anything you would like aired in the newsletter, please get in touch.



Rizwan Khan, Vidheya Venkatesh and Alison Deary.

Rizwan and Vidheya are Research Fellows based at Addenbrooke's, and Alison is the Clinical Operations Manager at the NHSBT in Cambridge. You may meet some, or all of them, at the Site Initiation or Monitoring Visits.

News in Brief:

- Planet-2 starts recruiting 13th June 2011
- Addenbrooke's and St Thomas's have a great start
- Welcome to new units joining us.

Inside this issue:

New sites	2
Planet-2 website	2
Practice Point:	2
Forms 1a & 1b / Screening Log	

Trial Progress: New Sites Opening



To date, 5 centres are open and actively recruiting babies to Planet 2.

The first centres involved were Addenbrooke's in Cambridge, St Thomas's in London and Norfolk & Norwich Hospital. More recently the John Radcliffe Hospital in Oxford and Imperial College Healthcare Trust, which includes St Mary's and Queen Charlotte and Chelsea Hospitals have opened to recruitment.

We are also actively looking to bring other new centres on board.

We started recruiting our first babies to the trial in mid June, and have randomised 10 babies so far. With the new centres recently joining us, our recruitment rate should start to increase. The total sample required for the trial is 660, so there is a bit of a way to go!

We are planning to conduct an interim analysis when we reach 100 babies, towards the end of next year. The anticipated number of participants should reach 660 by **Jan 2015**.

Planet-2 Website

A Planet-2 Website is currently under development. We will be loading up to date versions of all the documents, such the protocol, CRF pages and guidance notes, as well as the documents that are specific to each Trust, like the consent forms and Patient Information Leaflets that have Trust Header information.

The intention is also to have a parent / guardian area of the site where they can be directed for information about the trial. A 'lay' summary of Planet-2 will be posted to that area of the site.

In the future we may also post presentations as well.

I'll keep you posted on progress.



Practice Point: Screening Log and Forms 1a & 1b

Discussions with site staff revealed some problems with completion of Forms 1a and 1b for those babies consented and not randomised. This generally occurs because platelets do not drop below $50 \times 10^9/L$. Remembering to complete the forms is an issue; they have to be filled in retrospectively. Getting accurate information can also be problematic as maternal details

are not always available.



We are therefore asking you **not** to complete Forms 1a & 1b for

non-randomised babies (although continue to do so for all randomised babies). However, the Screening Log is to be slightly modified in order to capture information concerning medical diagnosis for potentially eligible babies. The new Screening Log will be emailed out to you, and it will be available on the website eventually.