

Planet 2 Randomisations:

How Are We Doing?

Here is a table of randomisations carried out since the start of the Planet-2 trial in June 2011. Those units that have been part of the trial since the beginning are at the top of the table, with the newer recruits lower down.

Generally the units that have been participating in the trial for the longest period have the highest number of randomisations, but Portsmouth are doing particularly well, having only joined the trial earlier this year.

By the next issue of the newsletter I hope to be adding a number of new units to the table.

Site	No Randomised
Addenbrooke's, Cambridge	13
St Thomas's, London	15
Norfolk and Norwich University Hospital	10
John Radcliffe, Oxford	8
Imperial (St Mary's and Queen Charlotte & Chelsea)	2
Royal Berkshire Hospital, Reading	0
St Peter's Hospital, Ashford	0
Queen Alexandra Hospital, Portsmouth	3
Luton & Dunstable Hospital	0
North Tees Hospital	1
James Cook, Middlesbrough	0
Royal Bolton Hospital	0
Total	52

Ask Renate



I'm pleased to report that the database is now 'live', and we have started to enter data from the CRFs that have been received. I'd like to get as much of the data entry

completed before the end of the month as possible as I have to provide input for a report to the Independent Data Monitoring Committee (IDMC) so please can you transmit any outstanding forms to me as soon as possible please?

I will also start the process of 'cleaning' the data; part of this will involve sending out queries to the relevant sites by email. The email will contain details of how to deal with the request. I will start looking at SAEs first, and may well request information

regarding event end dates for example. After that I will look at the major bleed forms, and then at the CRFs in general for missing data.

If something looks obviously incorrect when I receive the data, I will change it myself. This is called 'self evident correction'. However, I will need you to check to ensure I have made the correct amendment, so will send out a list for you to review.

Don't forget that you can always contact me if something isn't clear

Helping Each Other

One of the things I learnt from the Study Day was the amount of knowledge and experience many of you have in Clinical Trials. It would be great for the trial, and for each other, if we could support those with less experience or who work alone. I have sent out an email contact list since the Study Day, and investigated the possibility of setting up a forum for discussions on the website. The forum set up would be expensive, so it might be

a better idea initially to send out a distribution list to you all, where queries can be posted up for a response. In the meantime I'll monitor email traffic, and if it appears well used we may be able to more readily justify the expense of a forum based discussion attached to the website.

Helen and Heather gave really interesting and practical ideas for helping the trial to run smoothly on the Study Day, so thanks again to them for their contribution. If any of you have any tips, please do get in touch, either

directly with me through my email address below, or through the distribution list once I have sent it out



Best Wishes, Karen