

#### Sites Update

All 18 sites are now open to recruitment! Thank you to all for your patience and commitment to PREVAIL. The sites we've welcomed on board since our last newsletter are:

- Newham University Hospital
- St Mary's Hospital, Manchester
- John Radcliffe Hospital, Oxford

Best of luck to our new centres.

Due to strong recruitment we do not intend to open any new recruiting centres for the time-being and all centres who expressed an interest have been informed of this. We are hoping that most centres who previously expressed an interest in becoming a recruiting centre will choose to join us as CCS instead.

#### Star Site: Homerton University Hospital!



PI Dr Narendra Aladangady (centre) and lead RN Asha Mathew (second from right, front row) picture above with their neonatal colleagues at Homerton University Hospital. The Homerton team have been enthusiastic and committed to PREVAIL since opening and recruited a phenomenal 8 babies in January.

Well done to the Homerton team!

#### Top Questions

How do we answer Q2, Section 4 on CRF 7a "Was the baby transferred for surgery?" if the baby was transferred for surgery but then the surgery did not take place?

- Please answer yes to this question if a baby is transferred for surgery, even if the surgery does not happen.

*Any questions? Feel free to contact us with any concerns!*

#### Website Update

The PREVAIL website is now live!

[www.prevailtrial.org.uk](http://www.prevailtrial.org.uk)

The website contains a copy of the protocol, links to the randomisation system and information about back-up randomisation procedures, a list of current CCS, trial contacts and more.

There is also a parents section containing the PISC and a lay summary of the trial that you can refer parents to.

If you have any suggestions for items to include on the website in future please feel free to let us know.

#### Recruitment Drive

As our Christmas recruitment drive was such a success we will be running another drive in the lead up to Easter.

Every randomisation between 14/03/2016 and 27/03/2016 inclusive will earn one entry into a prize draw– so the more babies you randomise the greater your chance of winning!

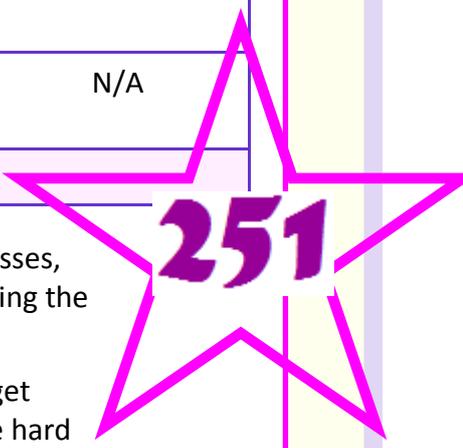
The lucky site will be selected at random after Easter and will receive a special thank you prize. **Good luck to all!**

**Recruitment Progress**

Site	Opening Date	Recruitment to 11/02/2015	Recruitment rate per week
Bradford Royal Infirmary	10/08/2015	38	1.46
Leicester Royal Infirmary	11/08/2015	35	1.35
The Jessop Wing	01/09/2015	21	0.91
Birmingham Women's Hospital	07/09/2015	23	1.05
Nottingham City Hospital	07/09/2015	10	0.45
Queen's Medical Centre	08/09/2015	16	0.73
The Royal London Hospital	18/09/2015	15	0.71
Royal Oldham Hospital	23/09/2015	21	1.05
Homerton Hospital	02/10/2015	19	1.00
Liverpool Women's Hospital	12/10/2015	13	0.76
Queen's Hospital, Romford	10/11/2015	4	0.31
Royal Preston Hospital	11/11/2015	8	0.62
St Michael's Hospital	01/12/2015	7	0.70
Royal Bolton Hospital	03/12/2015	5	0.50
Leeds General Infirmary	04/12/2015	10	1.00
Newham University Hospital	04/01/2016	3	0.50
St Mary's Hospital, Manchester	20/01/2016	3	1.00
John Radcliffe Hospital, Oxford	08/02/2016	0	N/A
<b>Totals</b>	<b>Sites: 18</b>	<b>Recruitment: 251</b>	

The weekly recruitment rates are a good way of viewing your successes, and a rate of 0.6 babies per week would see you comfortably reaching the target of 30 per year.

We are currently recruiting approximately one month ahead of target which is fantastic achievement, so thank you. Please keep up all the hard work and if there is anything affecting your recruitment rate that you would like support with do not hesitate to let us know.



**251**

### Amendments & Updates

**Continuing Care Sites:** We received approval from the UKCRN to use the single SSI approach, which has now helped us to gain R&D approvals for 24 CCS. We're thrilled that so many sites are coming on board in this way and it should help make transfers and data collection easier for staff at recruiting sites, as well as ensuring that babies do not get lost to follow-up.

A list of current CCS approvals is available on the website and will be updated weekly. If you are unsure of whether or not a site has approvals or if you need any help liaising with sites when babies are transferred please feel free to let us know.

Unfortunately some sites have opted not to participate in PREVAIL. Guidance will be issued shortly about the transfer process but if a baby is sent to a centre that has chosen not to become a CCS then we cannot ask them to undertake any data collection. Follow-up in these cases will remain the responsibility of the recruiting centre.

Setting up the CCS is proving to be one of the biggest challenges of the trial so far and your continued patience and support is greatly appreciated.

**Transfer Packs:** The transfer packs that were sent as part of your initial supplies are in need of a reboot! Thanks to everyone who has made suggestions about how we re-work these packs. It's hard to tell what will or won't work in practice until they are actually used so your feedback is really important. A separate guidance document about how to change these packs will be circulated shortly as they contain documents that are now out of date.

**Corrections and Changes:** A polite reminder that all changes to CRFs or Consent Forms should be made in accordance with GCP. Any errors should be scored through (ensuring that the original data remains legible, e.g. ~~striketrough~~ not blacked out), with the change dated and initialled.

**Data Management:** To reduce the number of data queries please double check that all questions on CRFs have been answered, particularly the 'yes or no' questions as these seem to be easily missed. Thank you!

**Consent Forms:** Please try to return consent forms within 7 days of randomisation. Understandably everyone has been busy but in the last few months we have noticed an increase in the number of outstanding consent forms and it would be much appreciated if all teams could return these on time. Don't forget you can return Consent Forms by post (separately from CRFs), by fax and now by email if you have an nhs.net email account. Emails must be from an nhs.net account as they have to be encrypted– if you want further information about returning your Consent Forms via email please feel free to let me know.

**Delegation Logs:** We've noticed that a lot of sites have recently added more staff to their delegation logs– it's great to have more people working on the study. Please remember if you add new members of staff to your logs to send an updated version via fax/email/post to the CTTC, and that we will need a CV and GCP certificate dated within 2 years for the newly delegated team members. Thanks in advance!