

Sites Update

15 sites are now open to recruitment—welcome on board Queen’s Hospital, Royal Preston, St Michael’s, Royal Bolton & Leeds General Infirmary!

All sites have now been sent their trial supplies and we are on target to have all 18 sites open to recruitment by the end of January 2016. Thanks to all for your efforts in getting your sites open.

Next sites planned to open:

- Newham University Hospital
- John Radcliffe Hospital
- St Mary’s Hospital

Star Site: Leeds General Infirmary!



Pictured here at their PREVAIL launch are RN Charlotte Reilly and PI Kathryn Johnson with some of the neonatal team.

Leeds recruited their first baby in just over 2 hours from opening to recruitment and have the highest weekly recruitment rate for December so far.

Top Questions

If a baby has a blood culture that falls outside of the 48hrs after line removal but was taken on the date of the baby’s last follow-up day/row on the Daily Follow-up Form, do we record the blood culture?

- No, if the sample was taken outside of the 48hrs after removal you do not need to record it, even if the baby has a row for that day. E.g.: baby reaches 48hrs post removal at 2pm on 01/12/2015 and has a sample taken at 9pm 01/12/2015. This sample would not be recorded despite falling on the same day.

If baby reaches full milk feeds but then becomes unwell and goes back to PN partially or fully before returning to full milk feeds again, which date do we record on Form 3?

- In these cases please use the first date baby reached full feeds, even if they then come off full milk feeds.

Any questions? Feel free to contact us

Christmas Recruitment Drive

Congratulations to Bradford Royal Infirmary who were the top recruiters during the Christmas Recruitment Drive, randomising 5 babies in 2 weeks, and will receive a special Christmas thank you gift!

Congratulations also due to Leeds General & Leicester Royal Infirmary who came joint second and both randomised 4 babies during the drive.

Well done to all!

Recruitment Progress

Site	Opening Date	Recruitment to 14/12/2015	Recruitment rate per week
Bradford Royal Infirmary	10/08/2015	28	1.65
Leicester Royal Infirmary	11/08/2015	26	1.53
The Jessop Wing	01/09/2015	17	1.13
Birmingham Women's Hospital	07/09/2015	17	1.21
Nottingham City Hospital	07/09/2015	9	0.64
Queen's Medical Centre	08/09/2015	12	0.86
The Royal London Hospital	18/09/2015	8	0.67
Royal Oldham Hospital	23/09/2015	11	0.92
Homerton Hospital	02/10/2015	7	0.70
Liverpool Women's Hospital	12/10/2015	7	0.78
Queen's Hospital,	10/11/2015	1	0.20
Royal Preston Hospital	11/11/2015	4	0.80
St Michael's Hospital	01/12/2015	3	1.50
Royal Bolton Hospital	03/12/2015	0	N/A
Leeds General Infirmary	04/12/2015	4	2.00
Totals	Sites: 15	Recruitment: 154	

Recruitment so far has been fantastic– a huge thank you to all. 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.

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PREVAIL is now on Twitter!

The PREVAIL team are now using Twitter to share study updates, site opening news and research site successes. You can follow us at @PrevailTrial or tweet about the study using hashtag #prevailtrial . We hope this will be a good community for you to discuss the study with your colleagues in other centres but please remember that all information shared via the trial twitter account can be viewed by parents of recruited or potential participants. We hope that twitter will be a useful tool in particular while the website is finalised. We anticipate that the website will be live very soon and will let you know when this is the case.

Amendments & Updates

Continuing Care Sites: As per the previous newsletter the majority of CCS are not yet set up. Burnley General and Royal Blackburn have recently gained approvals as their trust were keen to do this outside of the single SSI process. A single SSI form has been drafted for all remaining potential CCS and our lead CRN are working on gaining these approvals. We require a final decision from the CSP unit to allow us to submit this form as they are currently phasing out the option for single SSI forms but remain optimistic that this will be allowed. For the time being please continue to collect follow-up data from the receiving sites where you can. If you need any help liaising with sites when babies are transferred please feel free to let us know.

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.

Amendments: The amendment to the PISC and protocol has been approved by ethics and is now with your trusts for approval. Most trusts have acknowledged these amendments now and all updated paperwork will be circulated this week.

Materials: We have been in touch with all your laboratory contacts regarding some extra materials that we are providing for the storage and transport of Rifampicin resistant isolates.

New Data Manager: I'd like to introduce you all to our new Data Manager, Zoe Craig. Zoe will be working on PREVAIL full time and will become your main point of contact for data queries. Sue will remain as Supervising Data Manager so may still be in touch. You can reach Zoe via zcraig@liverpool.ac.uk or via the usual prevail@liverpool.ac.uk.



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 CTRC, and that we will need a CV and GCP certificate dated within 2 years for the newly delegated team members. Thanks in advance!

CTRC Christmas Closure

The CTRC is closed from 23/12/2015 for the Christmas period and re-opens on 04/01/2016. Over this time the PREVAIL inbox will not be monitored. There will be trial cover by a CTRC colleague called Claire Taylor on 29/12/2015. This cover is provided to meet safety reporting deadlines in the case of any SAEs arising over the closure period. If you have an enquiry requiring a response on 29/12/2015 Claire can be contacted on 0151 282 4726 or ctaylor7@liverpool.ac.uk, but will be prioritising safety matters and urgent queries as there are multiple trials to cover.

I am on annual leave 17/12/2015 to 22/12/2015 but will be back in the office on the 23rd to answer as many emails as possible before the CTRC closure. The PREVAIL inbox will be monitored intermittently during this time but you may not get a response to non-urgent queries. Thank you for letting me know what you need re-supplying before my leave and have a wonderful Christmas if I don't speak to you beforehand!