

Monthly Newsletter

Issue 4

June 2022

chary Nathan Phillips, with kind permission from his parent

SurfON Recruitment Restarts from 04 July 2022

SurfON is now recruiting after the short pandemic pause. We have 29 NHS sites recruiting and hope to increase this to number to over 45 sites including SCUs alongside NICUs and LNUs. We are now working on SurfON Protocol V6.0 31 March 2022 and an online link to the latest approval Protocol can be found here -

https://www.npeu.ox.ac.uk/surfon/clinicians

We would like to thank our Sponsor, University of Leicester and the Trial Steering Committee and Data Monitoring Committee for their time and support during the pause period and helping us with our restart plans.

SurfON Fastest Recruiter of the Month

Following our restart to recruitment on 04 July 2022 00:00, we had our first baby randomised by an incredible team at the Norfolk and Norwich University Hospitals NHS Foundation Trust at 01:24!



SurfON Collaborators Day, 15th Jun 2022 Birmingham

We would like to congratulate Dr Raducu Clapuci and the team for winning SurfON fastest recruiter of the month award!



Our collaborators day in Birmingham successfully took place and we were thrilled to meet some of the SurfON team in person. Over 100 attendees had enrolled to attend and we also had some new NHS sites participate on the day.

We would like to take this opportunity to thank Dr Doris Iyamabo, Principal Investigator - Luton & Dunstable Hospital, Ms Helen Harizaj - Lead Research Nurse - Medway Maritime Hospital and Dr Vira Ramaswamy, Consultant Neonatologist, Ankura Hospital for Women and Children, Hyderabad, India, Clinical Fellow Neonatology (John Radcliffe Hospital, Oxford University Hospitals, U.K.) for providing great tips and insights for SurfON on the day as our external speakers.



Here are some of the key learning points from the day:

There are wide variations in practice across NNUs in the UK. There
is a clear need for the SurfON trial as practice is not currently
evidence based, reflected by the differing thresholds being used
on when to give surfactant. SurfON will give us the knowledge to
know how to treat this group of babies in the future



- The recruitment target for SurfON is at least **1-2 babies per site per month**. SurfON recruitment will be reviewed by the NIHR in October, so it is key that we meet these targets
- Raise trial awareness and educate team members. Raise awareness of SurfON at internal research meetings
- Approach parents of babies with respiratory distress **as early as possible**, even before they become eligible for SurfON. Any baby is eligible for SurfON if they need non-invasive respiratory support for increased work of breathing, regardless of whether they have an oxygen requirement or not
- Utilise recruitment tools such as SurfON eligibility cards, think posters etc. Certificates for recruiters are also available from the SurfON team
- Boost SurfON engagement through NIHR Associate PI scheme and SurfON Champion scheme
- Encourage junior doctors to be involved in research

Please note that talk slides from the collaborators day is now available online. This is particularly useful if you would like to utilize the case studies for training purposes internally at units:

www.npeu.ox.ac.uk/surfon/clinicians/resources



NIHR Research Recovery & Reset Programme

SurfON is currently under review by the "Research Reset" programme. Now that we have restarted we really need to "hit the ground running" with our recruitment target! This equates to at least 1-2 babies per month per site (more if possible).

We will be reviewed on our restart criteria in October 2022 and we will continue to keep sites informed of all updates.

View SurfON Website & Podcasts

We routinely update our website with news, podcasts and documentation. You can find our latest training materials here - www.npeu.ox.ac.uk/surfon/clinicians/training-materials.

We are also on twitter **@surfontrial** if you would like to tweet about your involvement on SurfON trial. We would love to see your updates and news!

SurfON Delegation Log V4.0 21 June 2022

Following Substantial Amendment 7.0 implementation, <u>we request you to have all the staff signed off by</u> <u>the PI in the latest SurfON Delegation Log V4.0 21 June 2022</u>. The log clearly captures ANNPs being able to confirm final eligibility for babies before randomization, in line with the Protocol and has additional clarification on other responsibility codes. Whilst you are transitioning over, your current log will still be valid and you will still be able to recruit.

Once signed off by the PI, we ask staff members to add an end date to the older version in line with the PI sign off date. For example, if the PI sign off is dated 04 Jul 2022, the end date on the older version would be 03 Jul 2022.

Here are some common errors to look out for:

- PI sign off date is missing but signature is present
- PI sign off date does not align with start date for staff. The start date has to be when they have completed SIV training or when they actually enter themselves on the log
- Start date is missing or confirmation of GCP is missing
- Nurses cannot delegate themselves to responsibility code F (SAE Causality assessment) as this can be completed only by medical doctors. Recommendation to have at least one other medical doctor who can perform F – SAE Causality assessment in order to cover for PI absence/unplanned leave, more than one doctor per site would be even better to cover
- Any corrections that need to be made should be with a single strike through line along with initial and date (GCP compliant)
- Data manager can be delegated to I for management of screening data returns every month online on the Randomisation website
- PI would be delegated using responsibility code H (all the responsibilities on trial) and not just specific responsibility codes as they have overarching responsibility for all activities undertaken on the trial

Please note that ANNPs at site cannot confirm final eligibility unless they have been signed off by Pl on SurfON Site_Delegation Log V4.0_21 Jun 2022.

Thank you for all your hard work and your ongoing support of the SurfON trial.

SurfON Study Team, NPEU Clinical Trials Unit, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF.

℃ 01865 289 437/738 Surfon@npeu.ox.ac.uk Secure Email: ouh-tr.surfon@nhs.net

y @surfontrial @NPEU_CTU ▶ NPEUOxford www.npeu.ox.ac.uk/surfon







This study is funded by the National Institute for Health Research (NIHR) [Health Technology Assessment (HTA) (project reference 17/89/07)]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.