

## SurfON Collaborators Day 15 June 2022





### Presentation overview

- SurfON origins & launch
- The pandemic
- SurfON status prior to recruitment pause
- Impact of COVID-19
- Activities during recruitment pause
- Recruitment restart plans & the challenge ahead









# SurfON sites opened prior to pause – Feb 2022

#### **Centre Approvals Report**

Showing recruiting centres, grouped by region

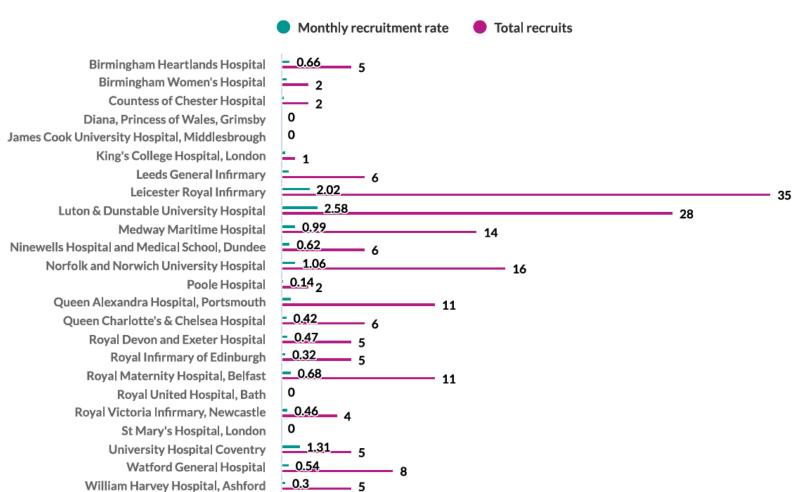
Centre Status	PI	Start date	Centre	Status	PI	Start date
			Birmingham Heartlands Hospital	Recruiting	Dr Harsha Gowda	28/06/21
England			James Cook University Hospital, Middlesbrough	Recruiting	Dr Prashant Mallya	08/09/21
Leicester Royal Infirmary Recruit	ng Prof Elaine M Boyle	07/07/20	Birmingham Women's Hospital	Recruiting	Dr Anju Singh	08/09/21
William Harvey Hospital, Ashford Recruit	ng Dr Kwok Sean Mun	01/10/20	University Hospital Coventry	Recruiting	Dr Kathryn Blake Dr Nitesh Singh	19/10/21
Norfolk and Norwich University Hospital Recruit	ng Prof Paul Clarke	09/11/20				
Queen Alexandra Hospital, Portsmouth Recruiti	ng Dr Tim Scorrer	12/11/20	Diana, Princess of Wales, Grimsby	Recruiting	Dr Ahmed Mohammed	25/10/21
Watford General Hospital Recruit	ng Dr Sankara Narayanan	20/11/20	King's College Hospital, London	Recruiting	Dr Christopher Harris	28/10/21
Poole Hospital Recruit	ng Dr Kiran Khambekar	01/12/20	Scotland			
St Mary's Hospital, London Recruit	ng Dr Ujwal Kariholu	07/12/20	Royal Infirmary of Edinburgh	Recruiting	Professor Ben Stenson	26/10/20
Queen Charlotte's & Chelsea Hospital Recruit	ng Dr Ujwal Kariholu	07/12/20	Ninewells Hospital and Medical School, Dundee	Recruiting	Dr Birgit Wefers	23/04/21
Medway Maritime Hospital Recruit	ng Dr Santosh Pattnayak	10/12/20	Northen Ireland			
Leeds General Infirmary Recruit	ng Dr Kathryn Johnson	05/03/21				
Luton & Dunstable University Hospital Recruiti	ng Dr Doris Iyamabo	19/03/21	Royal Maternity Hospital, Belfast	Recruiting	Dr David Sweet	06/10/20
Royal Devon and Exeter Hospital Recruiti	ng Ms Julia Turner	24/03/21	Totals for Northen Ireland			0
Royal Victoria Infirmary, Newcastle Recruit	ng Dr Stefan Zalewski	26/05/21	-			
Countess of Chester Hospital Recruit	ng Dr Alison Timmis	25/06/21	_			

1<sup>st</sup> participant enrolled – 3<sup>rd</sup> Sep 2020 23 sites, out of which 22 are continuing participation



# Sites recruitment prior to pause – Feb 2022

#### **Total Recruitment 177**

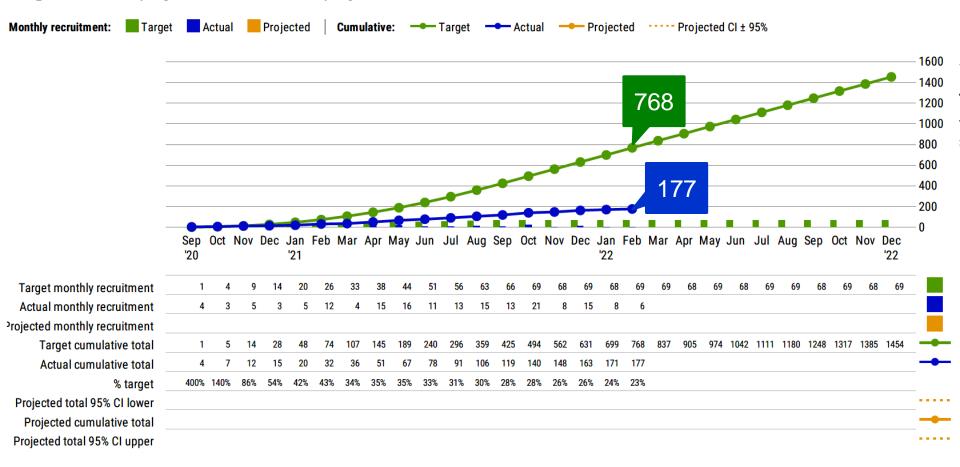






# SurfON prior to recruitment pause – Feb 2022

#### Target, actual & projected recruitment, projected for 6 months





## Adverse effects of COVID-19 on all research

- During the pandemic, the focus was on COVID-19 related studies
- SurfON had a late start and slow set-up
- Fewer sites than anticipated were opened
- Fewer babies were recruited
- Local capacity & capability issues
- Recovery during summer 2021, but then Omicron variant raised further challenges during winter
- NIHR Research Recovery and Reset programme\*
  - some studies will need to close in order to support unprecedented challenges facing the delivery of research, following the COVID-19 pandemic
- SurfON currently under review

<sup>\*</sup>https://www.nihr.ac.uk/researchers/managing-research-recovery.htm



## SurfON recruitment pause – Feb 11 2022

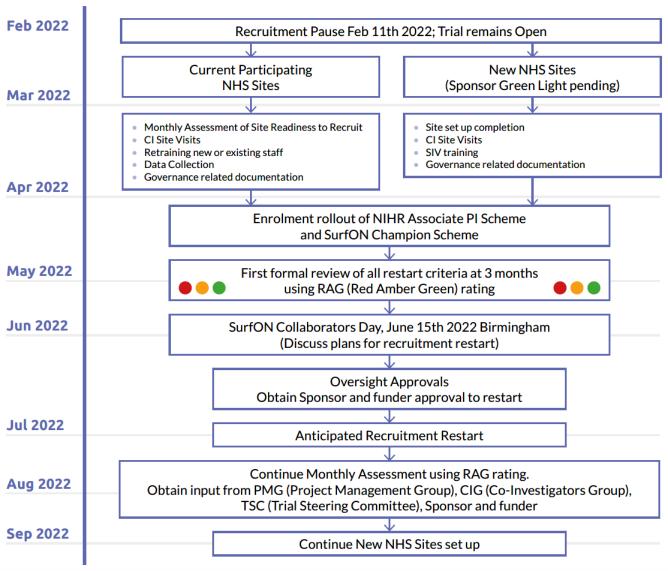






#### **Projected SurfON Recruitment Restart Timeline**

(Pending first formal review in May 2022, updates pertaining to proposed restart will be provided by the SurfON Team)







## What happened during recruitment pause?

- Face to face and online site visits by the SurfON team
- 11 new sites now close to receiving Sponsor Green Light
- Acceptance on the NIHR Associate PI scheme
- Introduction of SurfON Champion scheme
- Regular site communications and updates in newsletters and emails
- Increased engagement via CRN East Midlands
- Raising awareness of SurfON at national and international conferences
- Optimising the management of respiratory distress in late preterm and early term babies - under peer review, Infant journal
- Understanding recruitment challenges, questions around trial equipoise and exchanging tips





### What are the restart plans?

## Planned restart date Monday 4<sup>th</sup> July 2022 (~over 2 weeks away) subject to funder approval

- Spread awareness about the trial. Display SurfON banner & poster in clinical areas. Use SurfON posters & stickers
- Ensure all essential staff are signed off by PI correctly on SurfON Delegation log
- Ensure sufficient cover during holiday period & away dates for all key members
- mNCA PPP agreement signature & local C&C confirmation
- Substantial Amendment 07 implementation (1st July 2022)
- Protocol V6.0 31 Mar 2022 (PI Protocol sign off)
- Recruiting sites who have previously received Sponsor Green Light will have to complete Sponsor Pandemic File Note indicating start date at the site (similar to the File Note completed at pause) before recruitment can take place
- New sites will receive Sponsor Green Light before recruitment can take place
- Formal NIHR review at 3 months post restart (predicted 4<sup>th</sup> October 2022)



## What is the minimum recruitment target once we restart?

### 1-2 Babies Per Month Per Site







#### How do we achieve this?



We are looking for SurfON Champions to help us recruit at least

1 Baby Per Month at every site

Could YOU be our local Champion?

















Tweet about your time at SurfON Collaborators Day! Please use #surfontrial @SurfONtrial https://twitter.com/SurfONtrial















Marie Hubbard, UHL, June 15 2022











### Presentation overview

The Leicester Experience

3 Case Studies

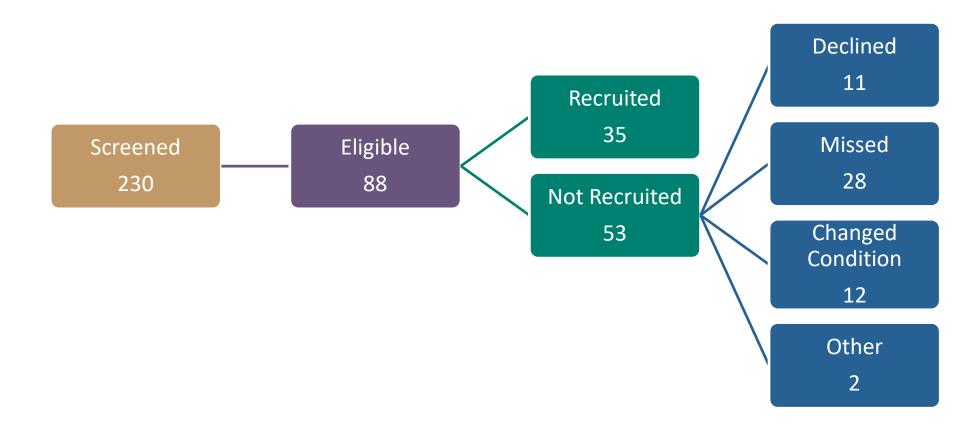
Discussion



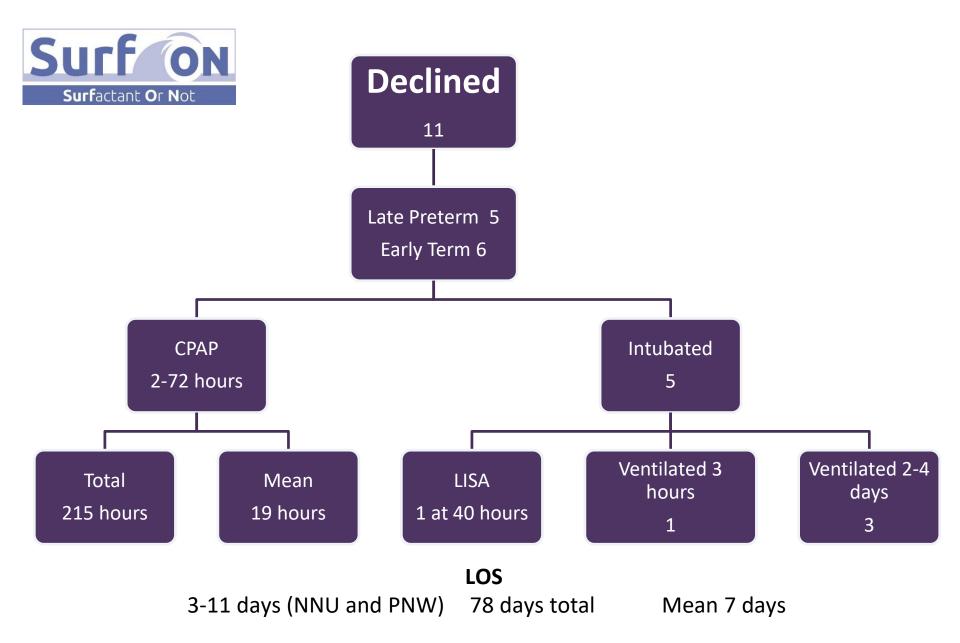


## The Leicester Experience

(data to Jan 2022)

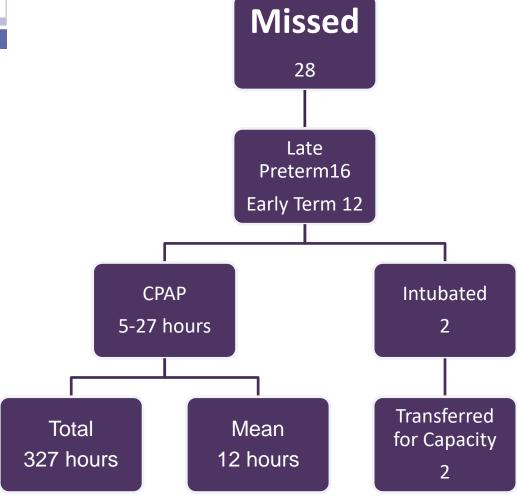










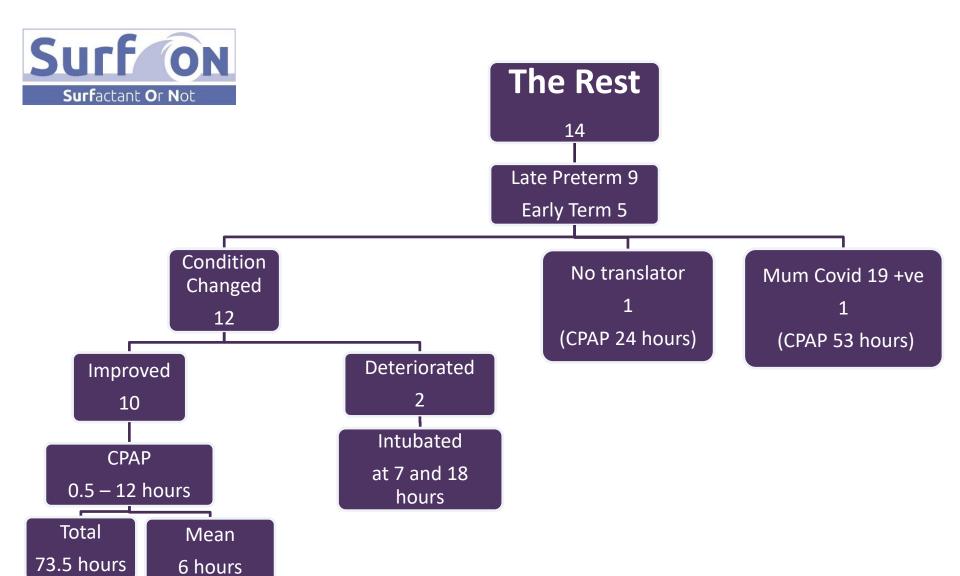


LOS

2-19 days (NNU and PNW)

193 days total Mean 7 days





LOS

3-11 days (NNU and PNW) 83 days total Mean 7 days





## Case Study 1 - Declined

- 35+5 weeks
- 2.6kg
- SROM < 18 hours SVD</li>
- Primip Nil of note medically
- Respiratory distress within 20 mins of age
- Admitted at 45 mins of age ongoing respiratory requirement – to High Dependency



## Case Study 1 – Presentation

- 30-40% Incubator Oxygen
- Sats 85-90%
- Grunting and recessing; tachypneic
- Other observations okay
- Blood gases acceptable
- NBM in view of respiratory status



### Case Study 1 - Outcome

- 7 hours of age
  - in 40% Oxygen
  - X-ray showed RDS
  - Respiratory distress on-going
- Commenced CPAP 6-7cm H2O Oxygen 27-32%
- Surfactant discussed on ward round hold off
- Continued to deteriorate
  - Gases worsening
  - RR 120 a minute



### Case Study 1 – Outcome cont.

- Intubated at 23 hours (too unstable to move to ITU prior to intubation)
- Curosurf Administered at 25 hours of age
- Commenced morphine infusion
- 2<sup>nd</sup> dose of Curosurf at 37 hours of age
- Dopamine and Atracurium also commenced
- Intubated for 2 days; High Flow for 2 days
- LOS 9 days



## Case Study 2 - Missed

- 37+0 weeks
- 3.7 kg
- EMCS for maternal reasons
- 1 dose Dexamethasone prior to delivery
- Pethidine, Dihydrocodeine, Oromorph and Buscopan prior to delivery for pain management
- Well at birth then apnoeic at 5 mins of age
- Admitted at 20 mins of age on CPAP and with respiratory distress – Intensive Care



## Case Study 2 - Presentation

- CPAP from delivery suite
- 40% Oxygen weaned to 24% on admission
- Sats High 90's%
- Grunting; Increased work of breathing
- Other observations okay
- Gases not improving (OA pH 7.12; CO2 10.2
- NBM as no colostrum available



## Case Study 2 - Outcome

- X-ray done at 2 hours showed TTN
- Parents not approached as baby would be transferred out if remained on CPAP
- Intubated around 9 hours of age for transfer
- Surfactant not given
- Intubated for 1 day and High Flow for 1 day
- LOS 4 days



## Case Study 3 – Not Eligible?

- 37+3 weeks
- 3.2kg
- Induced LGA; Vaginal delivery
- T2DM
- · Well at birth
- Admitted at 3 hours of age failed oximetery on PNW to Special Care



## Case Study 3 - Presentation

- 26-32% Incubator Oxygen
- Sats Low 90's
- Tachycardic; Tachypneic
- Pyrexial 38.2°C (Environmental?)
- 2 hourly blood gases then 6 hourly
- 3 hourly bottle feeds changed to NGT in view of low sats (NBM by shift change)



## Case Study 3 - Outcome

- 18 hours of age
  - In 50% incubator oxygen
  - Increased work of breathing
- Transferred to ITU
  - Intubated and given surfactant
- Extubated to air after 12 hours, but then onto CPAP (as not coping) for 36 hours
- LOS 6 days





















## SURFON TRIAL; Success and Challenges. Experience of a single recruiting site.

Doris Iyamabo

Principal Investigator

Luton and Dunstable Hospital



### **Site Information**

SIV:14th January 2021

Site given the green light 19<sup>th</sup> March 2021

Number of participants recruited before recruitment pause: 28





### **Site Success**

- Delegate team; strong delegate team with lots of enthusiastic trainees
- Certificate and gift for the highest recruiter every month
- Awareness raised at departmental monthly research meetings; opportunity for the PI to provide education, answer questions and encourage more participation





- Research nurse and PI attend daily handovers and safety briefings to hear about potential participants so we approach as soon as possible.
- Delegates and the neonatal team encouraged to approach early as soon as an eligible participant is admitted to offer the patient information leaflet and a delegate will return to have a chat and obtain informed consent.
- PI always available on the phone to answer delegate questions and confirm eligibility of potential participants.



# Challenges



- Attending Clinician interpretation on eligibility criteria
  - The PI and delegate use opportunities when there may be queries to discuss with the attending clinician and team.
- Missed opportunities to recruit if no delegate available.





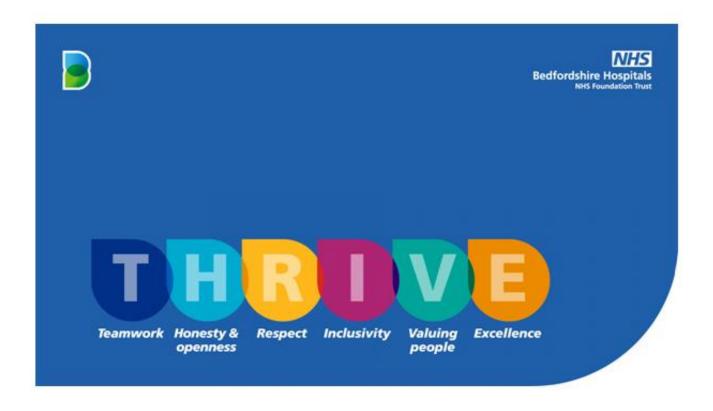
# On site reopening....

- Signed up to the Associate PI Scheme
  - Associate PI Samantha Sadoo Neonatal Trainee
- SURFON Champion
  - Julie Bermejo NICU ANNP
  - More champions encouraged.



### **Questions?**











# "MY EXPERIENCE AS A RESEARCH NURSE"

Helen Harizaj
Medway NHS Foundation Trust
15<sup>th</sup> June 2022





### Biography



#### Work Life

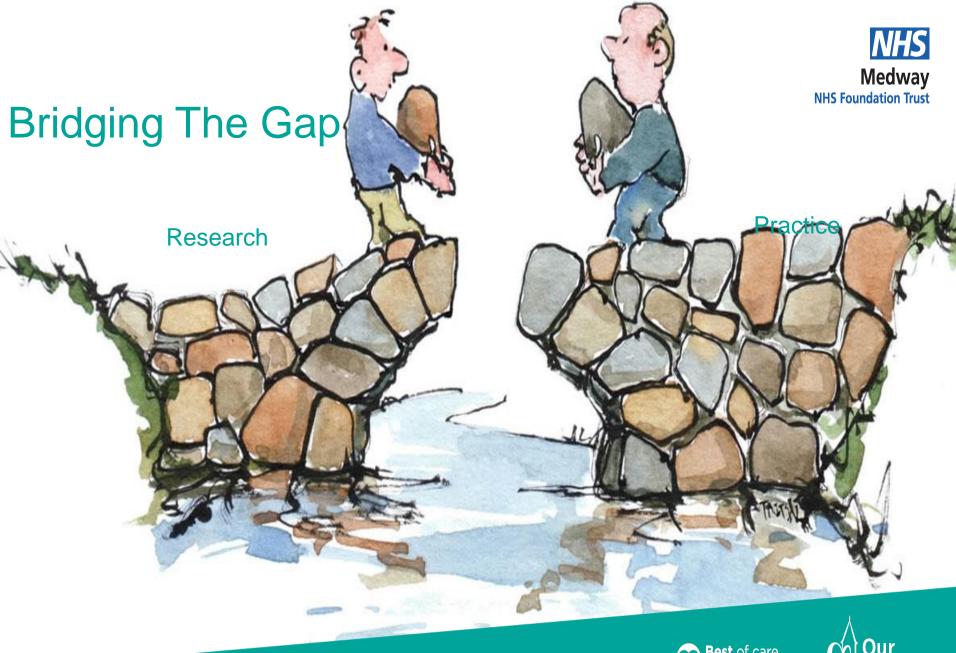
- Qualified as a paediatric nurse in 2003 Canterbury Christ Church University College
- 2003-2007 Neurology and Metabolic Ward, plus General Medicine at The Evelina Children's Hospital
- 2007 Neonates Medway NHS Foundation Trust
- 2008 Qualified in Speciality in Neonatal ITU
- 2014 Present Neonatal Research Nurse at Medway NHS Foundation Trust

#### Personal Life

- Avid Runner, currently training for the London Marathon in October 2022
- Cooking
- Retail Therapy
- Sunshine











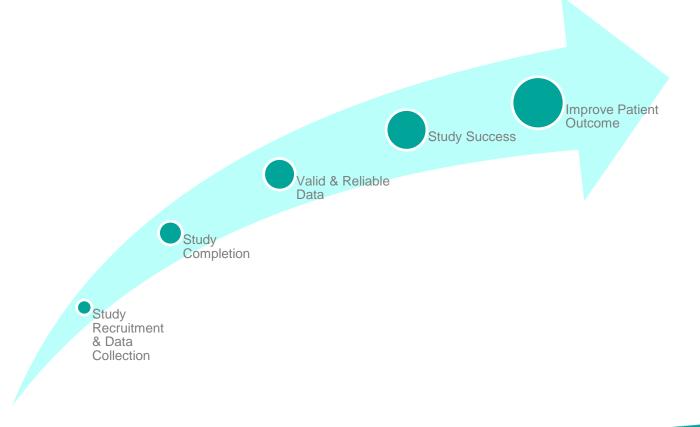








### **Ultimate Goal**







# Key to Study Success



- 1. Collaboration with all parties
- 2. Engagement of Staff





- 3. Manage expectations
- 4. Study specific training/GCP











### Top Tips



- Research on your doctors induction programme
- Bimonthly research meetings
- Research on agenda at weekly grand rounds
- Research on agenda at unit governance meetings
- Ways to engage staff
  - Top recruiter for the week chocolates
  - Top recruiter for the month bottle of wine
- Research What's App Group for NICU team
- Individual Recruitment Packs





### Still Learning



- We continue to learn and face new challenges
- At Medway we have recently moved over to Badger EPR
- More patients eligible than approached for SurfON
- Next Steps for SurfON @ Medway...





## Key Message



- If admitting a patient for RDS or signs of RDS between 34+0-38+6 wks
- Consider SurfON











