Pilot Study Completed!

The REST pilot study has now been completed. We have successfully recruited 42 patients to the pilot study and are excited to move forward with the main study. Thank you all very much for your continued hard work!

Welcome to the first edition of the REST Trial Newsletter!

We currently have **23** sites actively screening and we are pleased to say that we have recruited a total of **53** patients to date. Thank you kindly for your ongoing help and support!

Please do not hesitate to contact the CTU if you have any questions regarding the study: rest@nictu.hscni.net

Helpful REST Points!

Adverse Events:

- You must report the SAE within 24 hours of your site becoming aware of the event
- You should only report an SAE to clinicaltrials@nictu.hscni.net
- Please note if the patient is deceased, the event remains ongoing and should be recorded as such on the SAE reporting form
- Please ensure all AEs and SAEs are clearly documented in patient notes
- If the SAE remains ongoing you should follow up to resolution. The SAE follow up form is to be completed and sent to clinicaltrials@nictu.hscni.net stating date of resolution
- For every SAE please ensure you document a corresponding AE in the eCRF

Continuing Consent Reminder:

- If a patient has been discharged prior to you being able to get the consent to continue form signed then you should note this in the "additional comments" section of the eCRF and also in the patient notes

Site Training:

- Please ensure all evidence of onsite device training is filed in the ISF. A copy will be provided by ALung but if not please request from ALung
- Please ensure all training logs for onsite training by ALung are up to date and filed in the ISF

Accountability Process:

- Please ensure you update your accountability log upon receipt/transfer of all ALung consumables
- It is important to keep all documentation in relation to delivery and receipt of consumables in section 17 of the ISF

MACRO:

- **DO NOT** log an SAE on MACRO, this is a paper based reporting document. A template copy has been put in your Trial Manual. Please note that the link to the SAE form on MACRO homepage will be removed and should not be used in the interim
- On the eCRF page titled 'Randomisation' there is a field which asks for the randomisation number. This should be the Patient ID number allocated by the randomisation service and not the randomisation number which refers to the number of patients recruited

FAQ of the month

Q: If a patient is transferred from a different hospital / unit with an endotracheal tube in situ, when do we count the first time of ventilation?

A: If a patient is transferred from another hospital ICU then the time of ventilation is counted from the time the patient was invasively mechanically ventilated in the ICU. For patients that were intubated in ED or operating theatre then ventilated for a short time there and transferred to your ICU, the exact time of intubation may be difficult to determine accurately therefore time of ventilation begins when they enter your ICU.

Prizes from the pilot study!

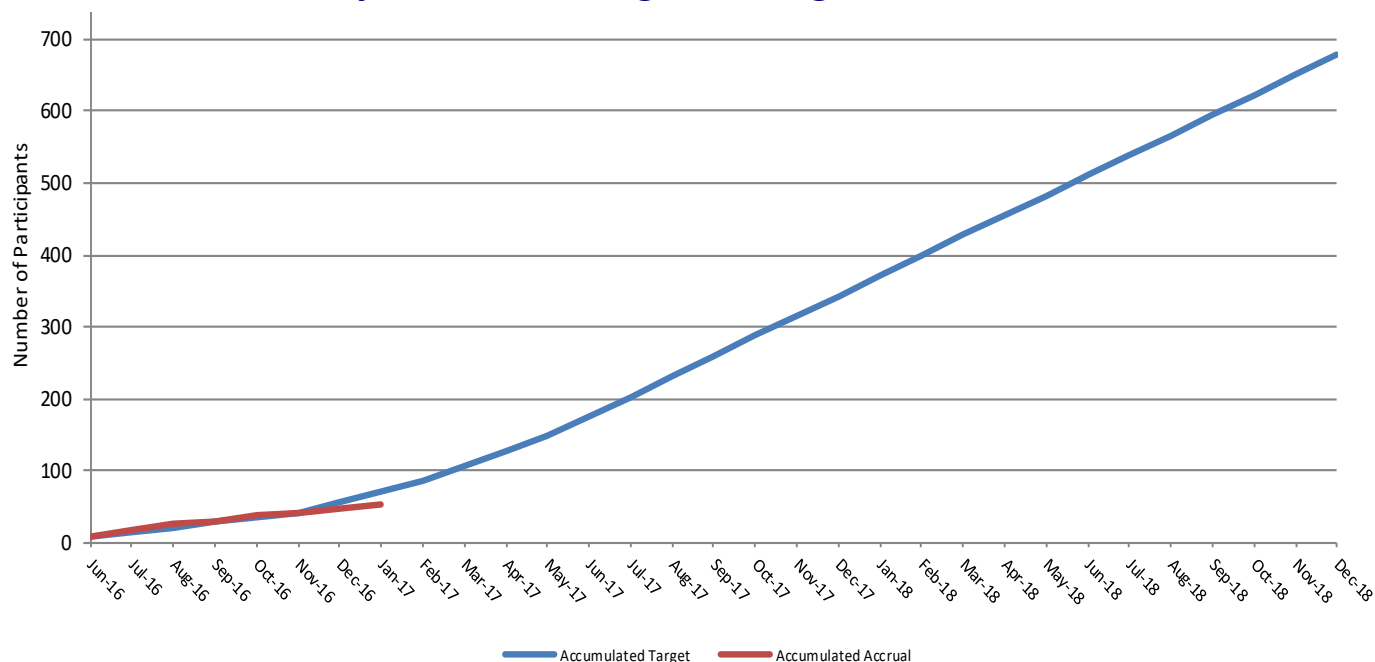**Top Screening Site:** Royal Liverpool

Last patient recruited : Queen Elizabeth Birmingham

Research Nurse: Gillian Andrew

A BOTTLE OF CHAMPAGNE IS ON ITS WAY TO YOU!

Have any staff named on your Delegation log <u>not</u> been approved to work on the REST study?
If so, please forward all required paperwork to the CTU to allow you to get your full team up and running!

REST Monthly Recruitment against Target Recruitment (Jan 2017)

Accumulated Target — Accumulated Accrual
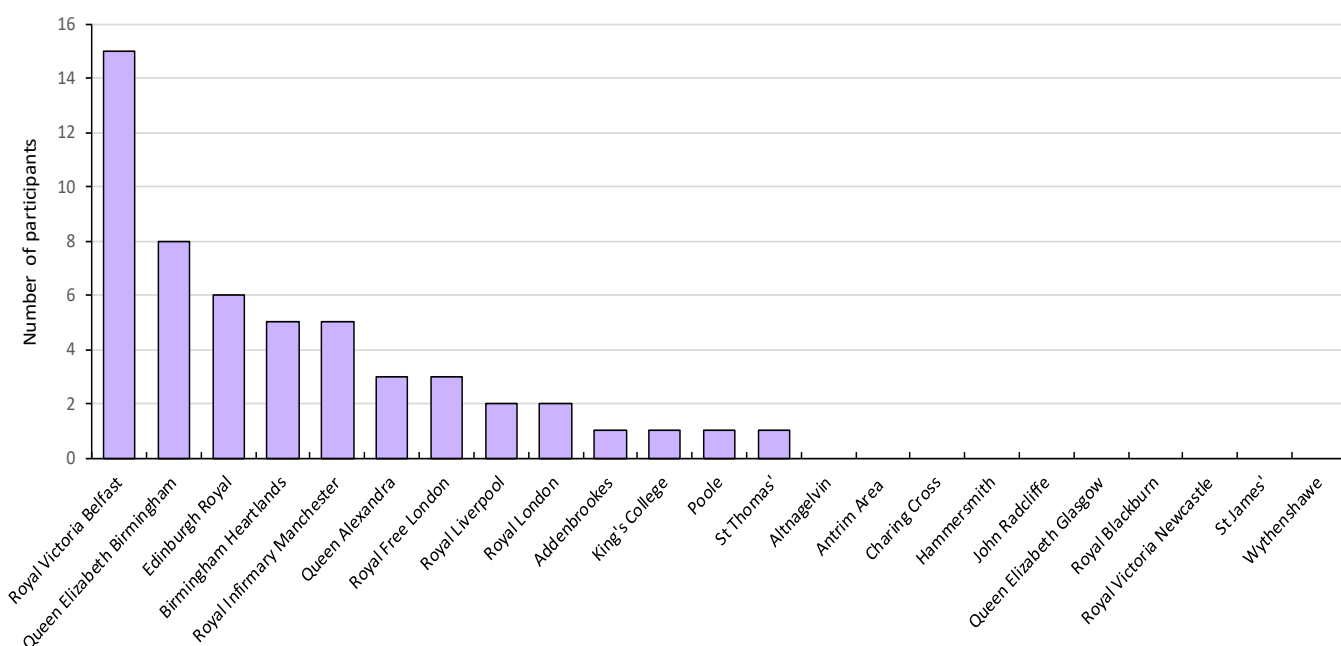
TOP RECRUITING SITES: ⭐1 Royal Victoria, Belfast ⭐2 Queen Elizabeth, Birmingham ⭐3 Edinburgh Royal

Randomisations per Site

PI teleconference dates for your diary

1st February @ 1pm	*4th May @ 4pm*	*2nd August @ 1pm*	*2nd November @ 4pm*
2nd March @ 4pm	*7th June @ 1pm*	*7th September @ 4pm*	*6th December @ 1pm*
5th April @ 1pm	*6th July @ 4pm*	*4th October @ 1pm*	

Dial in details : UK: 0844 846 4000 USA: 712 432 2977
Pin Number: 4151760

Remember...

PI Teleconferences are the best time to raise any issues, for example patient eligibility and recruitment, as attendees may be able to offer advice on the problem using their experience