



# T4P All-Site Meeting

09 November 2023

## Summary

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### Non-Substantial Amendment #6

- Received REC approval to open sites in Scotland –
  - Follow-up documents updated and protocol on V3.0 with Scottish specific consent
  - These changes are for Scottish sites and don't need further implementation
  - Implementation date is **12 December**, so please do ask your R&D departments to review

### Sites and Recruitment

- 43 sites open and 221 patients randomised – strong October with 27 patients
- We are currently behind our NIHR targets, but know you are all working hard, and are hoping for increased ICU admissions over winter

### Engagement

- What to do if you are still finding it hard to engage consultants and other clinical staff...
  - Next consent training **Thursday 23 November 14:00-15:00**
  - Next drop-in training session is **Monday 27 November 12:30-13:00**
  - We may do a trial run of a 24/7 helpline to assist with clinical eligibility queries out of hours to help boost recruitment at these times
  - Suggestion that ACCPs are allowed to confirm eligibility as with other trials, this will be taken to our TMG, but it is important to note medical oversight would still be needed

### Common Data Queries

- Please do review the slides on how to respond to DCRs, what to do if data collection stops and how to restart it on MACRO
- There are lots of data collection resources in our Resource Summary [here](#)
- We will be sending round a one-pager on common data queries again so please do circulate amongst staff who use MACRO

### Sealed Envelope Access

- A site suggested receiving a list of staff on the unit with Sealed Envelope access
  - This has now been circulated so please review against your training log and let us know if any access requirements have changed
  - Generic sealed envelope log ins can be created if they are only being used by staff signed off on the training log to randomise
  - Please do ensure you let us know as soon as a staff member has left the role and send us updated delegation logs so sealed envelope/MACRO access can be revoked

**Thank you for your continued hard work on the trial!**