Staff Newsletter April 2020

Dear All,

Due to the coronavirus pandemic, we find ourselves in an unprecedented situation with most of our staff working on the frontline to help treat those affected. I hope you are well and that so far, you have avoided coughs and fevers. I know this is an uncertain time for everyone and I want to thank you for your hard work, your good wishes and dedication to your projects. I am working full time on the clinical rota, so have limited time, however, will do everything I can to keep the research side of things moving. Please may I ask that you maintain good telephone contact with our Vital BE participants, ensuring delivery of their IMP and by recording all information that you can, particularly the timely reporting of AE's/SAE's and any changes to con meds. Now more than ever we are reminded that research is the only way we can beat nasty diseases. We can do this together!

Very best wishes to all of you,

James

Professor James D Chalmers
Chief Investigator

Changes to patient pathway due to COVID-19

Please see the Supplementary Guidance document sent out from respiratorytrials@dundee.ac.uk team to ensure that you are following instructions for paperwork completion in full at this time. A summary of this guidance is below:

Participant Visits:

- Phone participant on their visit due date.
- Complete CRF, including questionnaires over the phone.
- Ask about AEs, exacerbations and changes to con meds and complete these sections of the CRF for each visit call.

Please remember to phone participants as per the TRUST schedule to ensure patients are starting and stopping their medication every 28 days as per protocol. Good time to remind them to complete their monthly questionnaire too!

Trial Medication:

- All randomised participants are to continue taking IMP.
- Each site must prepare their own WPG/SOP for IMP delivery to participants, to be signed off by the PI and lead Pharmacist. This should then be sent to the TM team at respiratorytrials@dundee.ac.uk
- Advise participants to dispose of used handsets at home.

Safety Reporting:

- If the patient is admitted to hospital, an SAE form needs to be submitted within 24 hours of the staff member becoming aware of the SAE.
- SAE forms need to be downloaded every time an SAE happens from: https://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance
- Use the link provided above to find the latest version of the SAE form to complete. The PI/designated octor must assess for seriousness and causality before sign off and submit directly to pharmacovigilance.tayside@nhs.net
- If the PI is not immediately available to sign the SAE form, the research nurse should submit the SAE form within 24 hours, copying in the PI to the e-mail and asking the PI to confirm to PV that they have reviewed the SAE form and will sign electronically.
- Copy in both James j.chalmers@dundee.ac.uk and RespiratoryTrials@dundee.ac.uk with any SAE submission, to allow us to submit SAE forms to the funder within 15 calendar days.
- The CI/PI will make a clinical judgment as to whether an AE is of sufficient severity to require the participant's discontinuation of treatment as per protocol.

And Finally…..

The most up to date study documents are available on the Vital BE website https://vitalbe.org.uk

The trial management team will continue to keep in touch with you. If you have any queries, please contact Dr Clare Clarke, Trial Manager, at respiratorytrials@dundee.ac.uk