

Dear all,

Firstly, we would like to thank you all for your efforts over the last several months in providing the finest care for patients during the COVID-19 pandemic. In addition, we would like to thank those who have been able to still obtain follow-up data for STOP-ACEi patients during this difficult time. As we begin to receive correspondence from sites that non-COVID-19 research activity is set to recommence or increase, we wanted to provide some guidance to help restart or get back up to date with research activity for STOP-ACEi. Since the trial did not need to formally pause, an additional R&D review or formal confirmation of capacity will not be necessary. Please continue with follow-up as far as your capacity allows.

1. Patient Follow Up

- As before, please follow national and local policy with respect to infection control. We are continuing to accept follow up visits being completed remotely where it is inappropriate to bring a patient into clinic for an additional research visit.
- We will shortly resume sending out regular email reminders of outstanding and upcoming follow-up visits for STOP-ACEi patients. As it has been some time since the last automated reminders were sent, you may receive a number of these. Please bear with us. If there are any issues, please contact the STOP-ACEi team.
- We will also be resuming more regular correspondence for data cleaning purposes. This includes chasing for responses to outstanding data queries and non-urgent SAE queries that were previously suspended.
- If it is found that any follow up visits have not been completed, we would ask that the follow up CRF is completed using data from the patient's medical record/hospital notes as fully as possible. If no information is available at all, and the visit has been missed altogether, please notify us by e-mail so we can mark the visit as missed on the database. We understand that there may still be a delay with data entry.
- The reason for any missed visits, missing data due to tests not being performed, or data being collected remotely, should be documented in the source records as normal for a protocol deviation.
- There are a number of patients with 36 Month Follow Up visits approaching who may not be willing or able to attend a face-to-face study visit. In order to allow the primary outcome measure (serum creatinine) to be obtained for these patients, we will allow reporting of data taken from after the 36 Month (\pm 6 week) follow up window has passed, either taken from patient medical records (including primary care records, where you have access to these) or from a face-to-face study visit (where permitted by your local Trust policies).

2. SAE Reporting

- In addition to checking through all patients for any missed visits, we recommend that all sites check through all patients still on follow up for unreported SAEs that have occurred over the last few months. SAE reporting guidelines still apply from the time the SAE is known to the Investigator (24 hours for SAEs requiring expedited reporting, 30 days for protocol-defined 'expected' events).
- As access to the BCTU offices, and therefore the fax machines, is still restricted (see below), please **DO NOT FAX** these. All SAEs should continue to be emailed as soon as possible to the trial office mailbox (stopacei@trials.bham.ac.uk), where we will

always confirm receipt of an initial SAE report within 1 working day. As always, please be careful to thoroughly anonymise any clinical reports sent.

3. BCTU and Communication

- Access to the University of Birmingham, including the STOP-ACEi trials office, continues to be restricted, with current plans involving a phased opening of all university buildings over the coming months. As of yet, we do not have a confirmed date for when BCTU staff will be able to return to the office. Please continue to use e-mail as the main means of communications and we can arrange to call you if needed. Always use the trial mailbox rather than e-mailing individual members of staff so we can ensure cover should there be staff absences.

4. Substantial Amendment 13

- For a small number of sites, you will have recently received an e-mail detailing the most recent Substantial Amendment, relating to PI changes and Trust name changes. If there are any issues that may result in SA13 not being reviewed within 35 days, please contact the STOP-ACEi team.

Thank you very much for all of your assistance in this difficult time, with your continued support of the STOP-ACEi trial and your continued care for those in your communities.