

# STOP-ACEi Newsletter

Issue 22, December 2020



## Message from the Chief Investigator

2020 has been a challenging year that I'm sure we are looking forward to put behind us and look towards a brighter 2021. This has been an unprecedented year for many of us and, to echo my sentiments at the start of this pandemic, the entire nation is incredibly proud of the efforts that all of you have made over this year.

Despite this pandemic, we find ourselves in a strong position as we draw closer to the end of the study, with fewer than 40 patients left to complete follow-up. We would not be in this position without the work of you all to adapt to the constantly-evolving situation and your tireless commitment to research in order to minimise the impact of COVID-19 on the study despite redeployments, staff absences and illness. We also ask that, as we approach the end of the study, that all investigators consider whether treatment compliance can be re-established for any patients where this has changed, but only where clinically appropriate, and the investigator has discretion on this.

The conversation surrounding the STOP-ACEi study has not waned this year, with clinicians all over the world waiting eagerly for the final results and the study being continuously cited throughout the year. We expect the coming year to bring us results that many have been waiting for and I hope may provide valuable information to maximising care for our patients.

I wish you all a happy Christmas and New Year, and hope that you all manage to find some time to relax and safely spend time with your loved ones, COVID free and perhaps vaccinated.

Best Wishes,

Prof Sunil Bhandari



## BCTU Christmas closure and SAE reporting

Birmingham Clinical Trials Unit, including the *telephone* randomisation service will be closed from:

17:00, Friday 18th December 2020 until

09:00, Monday 4th January 2021

The *online* randomisation and data entry systems will still be available over the Easter period.

### SAE reporting continues over Christmas.

Please e-mail any new SAE reports directly to the Chief Investigator and CC in the trial mailbox:

Sunil.Bhandari@nhs.net

stopacei@trials.bham.ac.uk

These will be monitored over the Christmas break.

## Retrospective Coding of SAEs by Principal Investigators

The initial response to the recent request for retrospective coding of all SAEs has been positive, with nearly 40% of all SAEs already accounted for. While we understand that many of you will be unable to complete this owing to redeployment of research staff or PIs, we would ask that this be completed, preferably by the end of the year. If this is not possible, please let the STOP-ACEi team know. The majority of sites have fewer than 10 SAEs, so we anticipate the workload for most of you to be relatively low.

If you have any further questions regarding this task, or require further guidance, then please contact the STOP-ACEi mailbox.

The visit window is now  $\pm 6$  weeks to help with pragmatic follow-up.

Nearly 7000 forms have now been received for STOP-ACEi

Remember the extra research assessments at the annual visits:

- KDQoLSF™
- 6-minute walk test
- ECG
- Trial samples
- Weight

Remember to document any missed visits or missing data as a protocol deviation, in addition to documenting this on the eCRF

Remember to click 'Save' and then 'Submit' after you finish entering data into an eCRF

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STOP-ACEi is sponsored by Hull University Teaching Hospitals NHS Trust.

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## Data Return, Follow-Up and KDQoL forms

Data completeness and quality has been a priority throughout the trial, and the CRF return rate sits at nearly 94%, with 23 sites having a return rate of over 95%, which is an incredible statistic.

Throughout the trial, form returns are lower for later time-points and for KDQoL forms.

Please remember to complete the data and submit your forms as the patient progresses through the trial, and please let us know about any missed visits or quality of life forms, especially during the ever-developing COVID-19 situation.

We have also noticed a number of missed KDQoL forms that do not have a sufficient reason for them not being completed. We ask sites to please complete the KDQoL forms either by posting them to patients or by completing them remotely with patients before marking the forms as not complete. Please remember that any missed visits or forms are still required to be documented as a protocol deviation.

## BCTU Staff update

Marie Chadburn, former STOP-ACEi Trial Manager and current Deputy Team Leader at BCTU, has gone on maternity leave as of Friday 11th December 2020, so we hope you'll join us in wishing her a well earned-break and best of luck. Her position will be covered by Bill McKinnon, an experienced Team Leader here at BCTU, for the remainder of the trial.

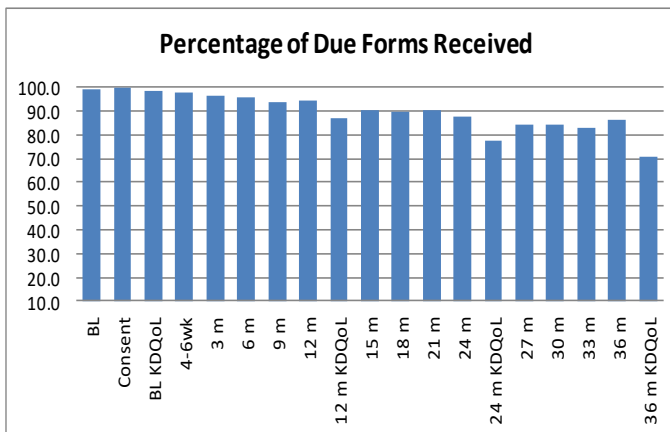
## Research Nurse

### Teleconferences 2021

Please add the date for this year's Research Nurse teleconference to your calendar:

- Tuesday 09 March 2021, 2pm

Another Research Nurse teleconference may be scheduled near the end of the study.



## SAE Form v2.0 Implementation

While we understand that a number of sites will not have been able to implement v2.0 of the SAE form, we are asking sites to ensure that, going forward, they are using the new version of the form, as found on the STOP-ACEi website. We are also asking for sites to:

- Remove all blank copies of the SAE form v1.0 or The Guidelines for Completion of SAE Reports v1.0 from circulation, e.g. research offices and clinics
- File 1 blank copy of the SAE form v.1.0 in ISF section 3.9 and mark it 'superseded' with initial and date. Discard any other blank copies of the SAE form v1.0 from the ISF
- File blank copies of SAE form v2.0 in section 6.1.
- Mark The Guidelines for Completion of SAE Reports v1.0 as 'superseded' with initial and date, and retain in section 8.6.
- File a copy of The Guidelines for Completion of SAE Reports v2.0 in section 8.6



## BCTU Operations

BCTU offices have now reopened, but the majority of BCTU staff are engaged in a combination of office-based and remote working. This means that STOP-ACEi staff now have regained access to:

- Physical versions of the TMF and patient files
- Sample supplies for shipment to sites

While this does signify a gradual return to 'normal' working, we do still ask that email via the STOP-ACEi mailbox is used as the preferred means of communication, as we cannot guarantee that a member of the STOP-ACEi team will be in the office on a given day, and this ensures the query will be picked up in the event of illness or annual leave. We also still ask that any SAEs continue to be sent via email, as opposed to via fax.



### Study Contact details

#### Chief Investigator

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#### STOP-ACEi Trial Staff

##### at BCTU

Marie Chadburn  
(Deputy Team Leader)  
Bill McKinnon  
(Team Leader—Mat. Leave  
Cover)  
Alastair Maund  
(Trial Manager)  
Aisha Khan  
(Data Manager)

#### Website

[www.birmingham.ac.uk/stopacei](http://www.birmingham.ac.uk/stopacei)

#### Email

[STOPACEi@trials.bham.ac.uk](mailto:STOPACEi@trials.bham.ac.uk)

#### Twitter

@STOPACEi\_trial

#### POSTAL ADDRESS

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