

# STOP-ACEi Newsletter

Issue 21, April 2020



## Message from the Chief Investigator

While we all came into 2020 hoping to continue the momentum from previous years, we unfortunately all find ourselves in the midst of the COVID-19 pandemic. I wanted to take a moment to thank you all for your efforts, not only on the STOP-ACEi trial but in all efforts to ensure patients are receiving the best treatment possible in these trying times for our healthcare service. The entire nation is appreciative of all that you are doing to ensure that their loved ones are cared for.

We thankfully find ourselves in a strong place with the STOP-ACEi trial, with over 250 patients who have completed follow-up. With patient safety and infection control being paramount, we understand that there will inevitably be missing data. However, we hope that through a combination of the flexibility of follow-up visits and your hard work, that this will be minimised.

I am also encouraged by the continued interest in the STOP-ACEi trial as it approaches completion. Observational studies continue to be published on the effects of ACEi/ARBs on patients with CKD, with the most recent being a publication in JAMA last month. We hope that, with your continued efforts, we will be able to answer this question.

We would like to wish you all the best of luck in the coming months during this outbreak, and hope that you still manage to spend some quality time with family and friends over the Easter period.

Best Wishes,

Prof Sunil Bhandari

## BCTU Easter closure and SAE reporting

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

17:00, Thursday 9th April 2020 until

09:00, Monday 20th April 2020

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

### SAE reporting continues over Easter.

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

Sunil.Bhandari@hey.nhs.uk

stopacei@trials.bham.ac.uk

These will be monitored over the Easter break.

## MHRA Guidance regarding ACEi/ARBs and COVID-19

On 27th March 2020, MHRA released a statement regarding ACEi/ARBs and potential effects with COVID-19:

*“While some media reports and publications have suggested that treatment with ACE-I or ARBs might worsen COVID-19 infection, there is no evidence from clinical or epidemiological studies to support this [...] It is vital that anyone currently taking these medicines to treat their medical condition, continues to do so.”*

The full statement may be found here:

<https://www.gov.uk/government/news/coronavirus-covid-19-and-high-blood-pressure-medication>

As more information pertaining to COVID-19 and any possible relation to the conduct of the trial is released, we will endeavour to inform sites as soon as possible.

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

Over 6000 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 click 'Save' and then 'Submit' after you finish entering data into an eCRF

STOP-ACEi is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR Partnership.

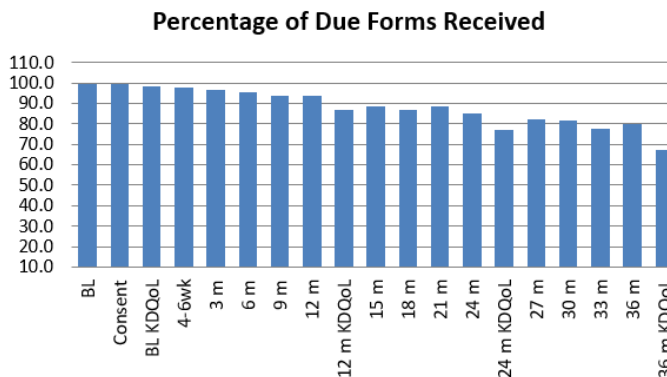
STOP-ACEi is sponsored by Hull University Teaching Hospitals NHS Trust.

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# Data Return and Follow-Up Completion during COVID-19

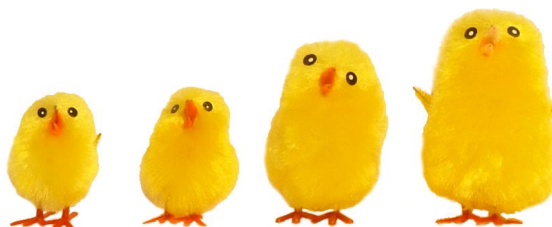
We expect a significant decrease in the amount of Follow-Up data uploaded during the COVID-19 pandemic, owing to suspensions in research activity at a large number of sites. We thankfully find ourselves in a very strong position, with the total CRF return rate currently over 92% thanks to your ongoing hard work, with 20 sites having a return rate of over 95%.

Due to the restricted research activity at a number of large number of sites, we will cease chasing outstanding CRFs for the foreseeable, but still encourage sites to complete them if they still have the capacity. The majority of follow-up data can be taken via telephone follow-up or scraping from medical records. The only data that would not be able to be obtained this way would be exploratory tests e.g. the 6-minute walk test, which we would not be expecting sites to complete in the current circumstances. Any follow-up data taken from outside of the protocol-defined follow-up periods will still be required to be documented as a protocol deviation, however we understand that sites may not be able to document this until normal working practice resumes.



## Trial Manager update

Following Marie Chadburn's promotion to Deputy Team Leader at BCTU, Alastair Maund has been hired to the role of Trial Manager for STOP-ACEi and is quickly settling into the role. Marie will still be involved in the trial in an oversight capacity, with Alastair taking over the Trial Management work. Make sure you send any emails to the STOP-ACEi mailbox so these can be picked up promptly.



## Research Nurse Teleconferences 2020



Please add the dates for this year's Research Nurse teleconferences to your calendar:

- Tuesday 23 June 2020, 2 pm
- Monday 14 September 2020, 10 am
- Wednesday 09 December 2020, 2 pm

## BCTU Operations during COVID-19

From 18th March, all BCTU staff are now working remotely, with restricted access to the BCTU offices. While most operations will continue as normal, the restricted building access means that BCTU staff will not have access to:

- Faxes, meaning all SAEs should be sent to the STOP-ACEi trial mailbox
- Physical versions of the TMF and patient files
- Sample supplies, so any sites requesting additional supplies may face a significant delay in receiving these

Email is the preferred means of communication, but if a call is preferred then this can also be arranged. To ensure cover in case of any staff absences, please use the trial mailbox as opposed to individual staff members' email addresses.



### Study Contact details

#### Chief Investigator

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#### STOP-ACEi Trial Staff at BCTU

Marie Chadburn  
(Deputy Team Leader)  
Alastair Maund  
(Trial Manager)  
Aisha Khan  
(Data Manager)

#### Website

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

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