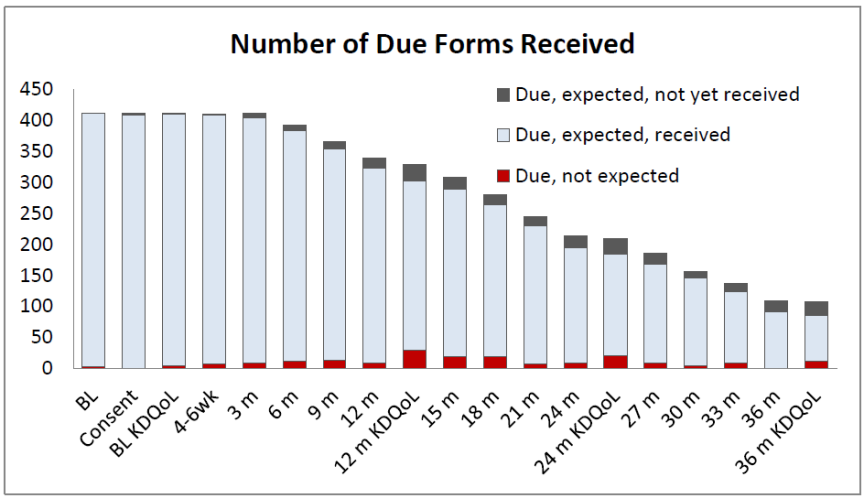
STOP-ACEi Newsletter

Issue 16, October 2018

STOP-ACEi Data Return Update

With recruitment completed, the amount of data collected is growing every day. All patients recruited into the trial have now passed the month 3 time point and over 100 STOP-ACEi patients have actually finished 36 months follow up. Looking at the below graph, return rates do drop off the further along patients progress in the trial. It is important that we collect as much data as possible. I'd like to remind you all about the advice that was published in last months newsletter on what to do about missed visits and collecting routine clinical monitoring data.



4,500 follow-up forms have been received

All Baseline forms have been received

Remember to click 'Submit' after you have finished entering data into an eCRF

The current return rate for follow-up data is an excellent 95%

A big thank you to everyone for completing follow-up visits

Message from the Chief Investigator

Having reached the required recruitment target in June, we are now fully into the follow-up period of the study. The focus now shifts from recruitment numbers to maximising data returns and maintaining the quality of data collection.

As a special plea, I would ask all investigators to try and ensure as many of the patients complete the quality of life questionnaires (KDQOL-SF™).

As the table below shows, the questionnaires are the one thing where the return rate from sites is a little disappointing, with a number of questionnaires not expected to be returned.

It is really important to capture what impact the study is having on patients. I am sure you agree this is critical to improving the care for our patients. These patients have committed a huge amount of time to the study and I am keen to ensure we provide as much data to them as possible.

Finally I would personally like to thank each and every one of you (research nurses, PIs, data managers and others) who have contributed to the ongoing success of this study.

Best Wishes,

Prof Sunil Bhandari

	Total Number of Forms Due	Total Number of Forms Not Expected	% Not Expected
ALL Forms	5431	190	3.5
KDQOL-SF Month 12	329	29	8.8
KDQOL-SF Month 24	210	21	10.0
KDQOL-SF Month 36	108	11	10.2

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STOP-ACEi is sponsored by Hull & East Yorkshire Hospitals NHS Trust

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Guidelines for Completion of SAE Reports

Following the STOP-ACEi SAE masterclass we held earlier in the year, we have now produced a 'Guidelines for Completion of SAE Reports' document.

This guide not only covers how and when to submit an SAE report but also goes into detail on how to complete an SAE report and minimise follow up queries.

Also included are details on the revised SAE query process. As part of a general move to using Data Clarification Forms (DCFs) to log and resolve queries, SAE queries will now be sent on DCFs. These will require sign off by PIs to confirm any new information has been reviewed and assessed for causality.

The email templates we use to confirm receipt and query SAE reports have also been updated.

If you have any questions on the SAE process or the new query process and DCFs then please do not hesitate to contact us.

A Few Reminders About Trial Samples

Remember to collect the extra trial samples at:

- 12 month visit
- 24 month visit
- 36 month visit

The following samples should be taken at every annual sampling visit:

- 2 x aliquots of serum
- 2 x aliquots of EDTA plasma
- 3 x aliquots of serum for biomarkers*
- 3 x aliquots of urine for biomarkers*
- Total = 10 tubes

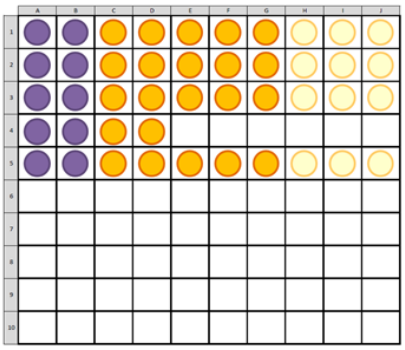
*The biomarker samples are optional, depending on participant consent.

Make a note of any problems with sample collection on the eCRF for that visit.

Packing samples for collection:

- Always use the provided labels, tubes and sample storage boxes
- Use the correct colour-coded caps for the type of sample
- Yellow = serum
- Purple = EDTA plasma
- Clear = urine
- Put samples for one visit along 1 row in the sample storage box
- Update your freezer log electronically whenever you add new samples to the freezer

This is what your sample box should look like for 5 sample visits, with 1 patient not giving consent for the additional biomarker samples:



For further information, please check the 'Guidelines for Trial Sample Preparation'.

In Other News

- A research nurse teleconference will be held on Wednesday 12th December at 2pm. More details will be sent via email closer to the time. Research nurse teleconference dates for 2019 will be included in the next newsletter.
- @STOPACEi_trial now has over 300 followers on Twitter. Recent Tweets suggest the renal community is very keen to see the results.
- And last but not least, huge congratulations to Marie on recently getting married.

Study Contact details

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Next Newsletter due December 2018