Merry Christmas!

Dear SANAD II collaborators,

I would like to thank you once again for the incredible effort you have made to ensure the success for SANAD II through 2017. Recruitment is over and we are now in follow up mode, so keep up the good work through 2018. We have the exciting prospect of results from Arm B this time next year, which will be vital to inform future practice and guidance given the MHRA and EMA statements on Valproate. In that respect, it is vital that you continue to counsel any women on Valproate and ensure that Valproate is an appropriate treatment choice for them.

Can I also encourage you to give patients the QOL questionnaires whenever you see them as per the article overleaf.

Wishing you a Merry Christmas and Happy 2018.

Tony Marson, SANADII Chief Investigator

IMPORTANT INFORMATION

TRIAL CO-ORDINATING OFFICE AND LABORATORY CHRISTMAS COVER

Trial office arrangements

The trial office is closed from 5pm on Friday 22nd December 2017 and will re-open on Tuesday 2nd January 2018.

Safety Reporting will proceed as usual, however the trial office will not be available for queries.

There will be office cover available on Thursday 28th December 2017 for the management of safety reporting and dealing with other urgent enquiries. If you have an enquiry requiring a response on 28th December please either call 0151 794 9838 or alternatively email helen.eccleson@liverpool.ac.uk.

The Information Systems helpdesk is available on working days throughout the closure period (Mon – Fri excluding bank holidays). The telephone number for this is 0845 68 00 951.

The FAX number for SAR reporting on the 28th December 2017 is 0151 795 8770.

Laboratory arrangements

The final day for posting SANADII samples was Friday 15th December 2017. Please do not post any DNA samples after this date until Tuesday 2nd January 2017. There are no staff members working in the laboratory between these dates to take receipt of samples or process them. Any samples collected during the festive period should be retained locally and refrigerated if possible before posting on 2nd January.

The SANAD-II DNA laboratory sends best wishes to all sites for Christmas and the New Year.
QUALITY OF LIFE QUESTIONNAIRES

Substantial Amendment 16 was approved in November 2017 which now enables research teams to issue Quality of Life questionnaires to patients at site.

Please issue a Qol booklet and SANADII envelope each time you see a patient in clinic. Site teams must complete the randomisation number at the top of the booklet along with the patient initials before issuing the booklet to patients. Electronic copies of questionnaires have been distributed to sites with the amendment approvals. There are four types of questionnaires; they contain different questions based on the age of/relationship to the patient.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Who should this booklet be issued to?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>A patient who is 16+ regardless of the service they belong to</td>
</tr>
<tr>
<td>Parent*</td>
<td>The parent of a child between the ages of 5 and 15</td>
</tr>
<tr>
<td>Children</td>
<td>A patient between the ages of 8 and 11</td>
</tr>
<tr>
<td>Young Person</td>
<td>A patient between the ages of 12 and 15</td>
</tr>
</tbody>
</table>

* A parent questionnaire should always be issued with a young person/children’s questionnaire.

If your site requires any hard copies of questionnaires, please contact the trial office. We are only able to post small amounts of booklets out to sites so every effort should be made to print at site where possible.

DNA SAMPLES

In the New Year we will begin contacting sites again to obtain outstanding DNA samples. SANADII expects to have a DNA sample for ALL patients that have consented to this. It is vital that these samples are collected, so please continue to obtain DNA samples from all consenting patients!

Ensure a DNA sample CRF (Form 8) is returned to the trial office, along with an Ethnicity form (Form 13) which should be completed by the patient. For each DNA sample we hold, we must have an accompanying Ethnicity form.

The trial office are happy to send DNA supplies to sites, so please email the trial office if you require any blood tubes, saliva sample kits or Royal Mail safe boxes.

FIN

From all in the trial office, we wish you a very Merry Christmas and a peaceful New Year!

April—The SANADII trial office welcomed our new Data Manager, Stephanie!

May—Silviya and Nadia attended the Association of British Neurologist’s Annual Meeting in Sunny Liverpool.

June—The final patient was recruited to Arm A by the team at Worthing Hospital on 20th June!

August—The countdown to Arm B closing to follow up begins. One year to go!

October—Silviya and Nadia attended the ILAE in Leeds!