



A pragmatic randomised controlled trial comparing the effectiveness and cost-effectiveness of Levetiracetam and Zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II)

## ARM B CLOSURE

It has been almost two years since the final patient was recruited into Arm B of the study. Time really does fly!

As you will be aware following recent email communication from the trial Data Manager, Stephanie Roberts, there is a process in place to ensure all follow up information is collected efficiently prior to the closure of the Arm. The process is outlined below. Please note this applies to **ARM B PATIENTS ONLY**. Arm A follow up continues.

- Check the date of each patient's last hospital visit or telephone consultation and ensure a Follow –up CRF (Form 5) has been returned to the trial office for this appointment.
- When all Follow-up CRFs have been returned to the trial office, please forward the wet ink copy of the patient's Adverse Reaction CRF (Form 10) to the trial office. No further follow-up CRFs are required following the receipt of this.
- A CRF reconciliation document will be distributed to sites. Please complete and return this document to the trial office, alerting the trial team to any discrepancies.
- Complete and return any data queries **as soon as possible**. Our trial statisticians will begin checking the data in the coming months and this will generate a number of queries which will require expedited responses.
- Once all data queries have been closed satisfactorily, a PI data query sign off will be distributed to all sites. This should be completed and returned to the CTCR. **Only the PI at site may complete this document.**

This will be a busy phase within the trial and so the trial office will work to site teams to ensure the process runs as smoothly as possible.

## QUALITY OF LIFE QUESTIONNAIRES

Please continue to 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. There are four types of questionnaires; they contain different questions based on the age of/relationship to the patient.

Questionnaire	Who should this booklet be issued to?
Adult	A patient who is 16+ regardless of the service they belong to
Parent	The parent of a child between ages between 5 and 15
Children	A patient between the ages of 8 and 11
Young Person	A patient between the ages of 12 and 15

## Sodium Valproate

Following the MHRA statement released earlier in the year about Sodium Valproate, it is vital that you continue to counsel any women taking this medication. For women staying on Sodium Valproate the demand is that a pregnancy prevention plan is initiated.

## CONTACTS

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