

QUICK START GUIDE TO ENCEPH-IG

Key Study Documents can be found in your individual Teams Channel or in then Quick Start Channel under files.

****Please confirm you are using the correct version of all documents****

ENROLLING & CONSENTING A PARTICIPANT:

1. Confirm patient is eligible for trial (Protocol Section 8)
 - a. If Possible alert Pharmacy and lab there is a new patient
2. Consent Patient & study Partner (Protocol Section 9.3):

Patient Has Capacity	Patient Does not have Capacity: Friend/Relative available	Patient Does not have Capacity: Friend/Relative not available
Patient Information Sheet	Personal Legal Representative Information Sheet	Professional Legal Representative Information Sheet
Patient Consent Form	Personal Legal Representative Consent	Professional Legal Representative Consent
Study Partner Information Sheet	Study Partner Information Sheet	Study Partner Information Sheet
Study Partner Consent	Study Partner Consent	Study Partner Consent

- a. If patient has consented for screening CSF to be stored for the trial contact lab to secure sample
3. Complete eligibility form online:
 - a. Select Add Participant
 - b. Complete Eligibility Form
 - c. Participant randomised immediately after form is completed and saved
4. Complete prescription (Protocol Section 11.1) & Delivery to Pharmacy
 - a. Work out ideal weight
 - b. Work out *total* dose: ideal weight in kgx2; round down to nearest 10g
 - c. Workout *daily* dose: Total dose/5=daily dose
5. Alert Ward Staff that that the patient has been entered into the Enceph-IG trial.
6. Complete Participant Contact form in the database

BASELINE

1. If patient has consented, collect blood samples (protocol Section 12, Lab Manual)
 - a. EDTA
 - b. SST
 - c. PaxGene
2. Complete baseline GOSE & clinical Assessment either directly onto the database or use paper CRF and then enter information into the database (Protocol Section 13)
3. Start Treatment

2 WEEK FOLLOW UP

1. Complete Capacity Assessment and if participant has regained capacity, provide recovered capacity information sheet and consent form
 RECOVERED CAPACITY INFORMATION SHEET: *Enceph-IG Teams Group>SITE CHANNEL>Files>04.0 Information Sheets & Consent Forms>4.1 Participant Information Sheet*
 RECOVERED CAPACITY CONSENT FORM: *Enceph-IG Teams Group>SITE CHANNEL>Files>04.0 Information Sheets & Consent Forms>4.2 Consent Forms*
2. Complete 2 Week GOSE & clinical Assessment (Protocol Section 13)
3. If patient has consented, collect blood and CSF samples (protocol Section 12, Lab Manual)

- a. EDTA
- b. SST
- c. PaxGene
- d. CSF

DISCHARGE

1. Review follow up windows and if within window complete GOSE (Protocol Section 13)
2. Discuss GOSE Follow up procedure and provide patient with GOSE guidance
3. Complete Discharge/Admission Form online

3 MONTH FOLLOW UP

1. Complete Capacity Assessment and if participant has regained capacity, provide recovered capacity information sheet and consent form:
2. Complete GOSE with patient
3. Complete clinical follow-up: either directly into database or on paper CRF
4. If patient has consented, collect blood samples (Protocol Section 12, Lab Manual)
 - a. EDTA
 - b. SST
 - c. PaxGene
5. Complete EQ5D and EBIQ

12 MONTH FOLLOW UP

1. Complete Capacity Assessment and if participant has regained capacity, provide recovered capacity information sheet and consent form:
2. Complete GOSE with patient
3. Complete clinical assessment

GOSE COMPLETION

1. The GOSE needs to be completed at:
 - a. Baseline
 - b. 2 Week follow up
 - c. Every 2 weeks until the week 10 timepoint
 - d. 3 Month follow up
 - e. Every month until 12 month follow up
 - f. Every 12 months until the 60 month timepoint
2. If the participant is too be discharged whilst in the timeframe for one of the GOSE, please complete the GOSE with the participant before discharging them from the hospital.
3. The rating is the lowest outcome category indicated by the person's responses
4. If the respondent ticks more than one box, it is usually fair to take the lowest category (greatest disability) indicated by the response. However, this pattern of responding suggests that the person does not fully understand the questionnaire.

Other Helpful Tips:

1. Create a ward pack which includes: Ward Nurse Summary, IVIG leaflet, Patient Information, Key study contact details. This can be kept in the patient notes.