neoGASTRIC

FAQS FOR SITES

SITE SET-UP

1. **Are there any training requirements?**

   Training will be given as part of the Site Initation Visit (SIV), which is done over zoom and takes about 2 hours. In addition relevant site staff who will be assessing eligibility and randomising babies are required to complete Randomisation website training online.

   For those entering data onto the clinical database, they will need to have GCP and OpenClinica (study database) training online,

   For those not able to attend an SIV or who join the group after the SIV, there will be an education package. The education package will be a powerpoint presentation that can be given by site staff already trained and we hope to provide a recording of this too. This will be made available on our website as well.

2. **Who needs to provide a signed CV and GCP training certificate?**

   All those doing data entry, maintaining ISF, or signing off (E-H on delegation log), **we do need to have GCP and CV**. We find that most sites have a smaller number of people doing these tasks and they are often lead nurse and PI plus a couple of others. At minimum we need PI and Lead research nurse documents to start you up, together with anyone for example that is going to be responsible for all the data entry. However, after set-up, we are happy for you to add further details yourselves to the eISF.

   Staff who are only doing screening, eligibility or randomising, do need to be on the delegation log (Items A-C) but **do not need to do GCP or send us their CVs** (if you have a local policy to keep them yourselves in your ISF please do so).

3. **How do the sites obtain Sponsor Green Light to begin recruitment?**

   Once the site set up process is complete, a Sponsor Green Light for neoGASTRIC-related activities at site will be provided.

   This includes:

   - Research & Development confirmation of local C&C
   - mNCA signed
   - All CVs and GCP documentation received for site staff (i.e. PI, lead RN, Associate PI or Co-PI)
   - Delegation log completed
   - SIV attended
   - IT training including the Randomisation website and OpenClinica for key site staff
   - Local PI Protocol sign off

4. **What materials will we receive as a site?**

   All recruiting sites will receive a NeoGASTRIC Site Documents Box containing key trial documentation and guidance sheets. This will be sent to sites around the time of the scheduled SIV. This is provided along with a neoGASTRIC poster and a banner, if the site is able to display this. Sites can ask for any document to be resent to them at any time by getting in touch with the neoGASTRIC study team.

5. **Will a site file be provided? If it's electronic then can we make our own site files?**

   Yes, an electronic site file will be provided to sites after the SIV, then we would ask for you to maintain this and save it securely.

6. **How can I bring awareness of the study in the unit? What tools can I use for this?**

   Please display the neoGASTRIC study posters and banners in visible areas e.g. breastfeeding rooms, parent kitchen/break-out rooms, parental boards and corridors and reception areas. Additionally, you can use promotional and stationery items which could help with raising study awareness, while also acting as visible reminders for screening and recruitment.

7. **When will Site Initiation Visits (SIVs) take place?**

   SIVs will take place throughout the first year of the trial. SIVs will usually take place virtually and all staff involved in the trial at your hospital are encouraged to attend. If you are unable to attend the SIV your site has been invited to, there will be an opportunity to join a subsequent SIV.

   Before recruitment can begin, your key site staff must attend an SIV as part of your required training.

8. **How does the model Non-Commercial Agreement (mNCA contract) get signed off?**

   We request sites to complete payment details on the mNCA and review the document for agreement. Once reviewed, we request sites to confirm direct work email address for the authorised signatory. Please note that we cannot send signature request to generic inboxes in order to comply with audit requirements.

9. **How do the sites get paid for recruitment? Could you clarify details around accrual funding for the site?**

   Under the model Non-Commercial Agreement (mNCA) signed for neoGASTRIC, a recruitment target is set, in addition to payment schedules. Payments will be made to sites every 3 months, as per the number of babies recruited during this time period.

   The trial is adopted onto the NIHR portfolio, so recruits will count as accruals for the portfolio. Every baby randomised will be an accrual and this will be upload monthly by the trial coordinating site NPEU.

10. **Will sites be randomised according to their local standard of care around GRV measurements?**

    No, this is an individually randomised trial where each baby will be randomly allocated to a trial arm (routine measurement of GRV vs no routine measurement of GRV) irrespective of their local practice around GRV measurements.

11. **Our site routinely checks GRV, how can we stop crossover for the babies in the no GRV arm?**

    Sites will be provided with Cot cards and labels to stick on NG tubes to help prevent this from happening. We also have stickers that can be added to patient paper notes where relevant. We are keen to hear any further ideas or suggestions you have to help prevent crossover as well, so please do get in touch if you have any suggestions.