

# Guidance Sheet 14: Post-discharge follow-up



## Procedures for Post-discharge Follow-up

This guidance sheet outlines the procedures for post-discharge follow-up. It provides information on the steps to be taken, the timeframe for follow-up, and the process to be followed.

The post-discharge follow-up window will be from the time the patient is discharged from the hospital up to 24 months post-EDD.

### 1. First 6-months Post-Discharge:

1.1 Send the electronic/paper versions of the GP letter and Health Visitor letter provided as part of electronic Investigator site file/paper Investigator site file.. Please update the letters with the participant's details and send to the GP and Health Visitor of each participant..



1.2 Conduct monthly calls during the first 6 months post-EDD

#### What to cover in monthly check-ins:

- Conduct monthly calls during the first 6 months post-EDD to check-in with the parents and to confirm the correct dosage based on the infant's weight.
- If parents have issues accessing regular weight checks at their GP, suggest alternatives like a health visitor, local clinic, or community health centre. If needed, they can weigh their babies at home if that is possible for them.
- Identify parents who may need additional support to administer the supplement. If there is continued difficulty with supplementation, identify the barriers to supplementation, and offer appropriate support to address these with assistance from site clinical trial team as needed and reach out to DOLFIN trial team if required.
- Encourage parents to complete the form on the app that describe supplement given. For additional guidance on using the app, direct parents to the DOLFIN website [www.npeu.ox.ac.uk/DOLFIN](http://www.npeu.ox.ac.uk/DOLFIN). For those who prefer not to use the app, email or text can be used. Where digital options are not possible, a paper dosing log can be used. Please remind parents to return the paper log to us using the prepaid envelope included in the DOLFIN transfer pack.
- Encourage parents to inform the site research team of any pause of supplement or discontinuation of the supplement.

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- Track completion of post-discharge questionnaires, including the discharge form and the 3-month questionnaires via OpenClinica. Missing questionnaires will also be detailed in the monthly missing form reports.
- Ensure parents are aware to report any unplanned hospital admissions via the app or by contacting their local NHS clinical team. Follow up with parents and any local hospitals for any unplanned hospital admissions and report to NPEU CTU if it is a reportable SAE.

### 2. Ongoing Follow-Up (6-12 months post-EDD)

#### 2.1 Instructions for Completion of the Supplementation period (12 months post-EDD):

at 12 months post EDD, the NPEU CTU will send an email to parents letting them know that they have reached the end of the supplementation period and giving them additional instructions.

#### 2.2 Points to remember after 12 months EDD:

- Supplement will not be provided beyond this period, and supplement allocation online will be stopped.
- Any expired or unused supplement can be disposed of by placing it in a domestic bin
- Encourage parents to complete the 18 and 24-month questionnaires. Notifications with links to complete the questionnaires will be sent via email, WhatsApp, or text message.
- Remind parents to inform the research team if they change their contact details such as phone number or home address, so that their information can be updated.

### 3. Ongoing Follow-Up (after 12 months post-EDD):

- NPEU may request site assistance to contact non-responding parents to complete the 24-month questionnaire – this is the questionnaire that includes the primary outcome measure, and is crucial for the study.