

We ask sites to approach all eligible infants even if the infant is likely to be, or has been, transferred to a Continuing Care Site (CCS). Remote consent can take place for eligible infants and if an infant is transferred to a CCS without approvals supplement can be paused and restarted as soon as possible (either when infant is transferred to a recruiting site or a CCS with approvals, or when discharged home). This process is outlined in the PIL and should be discussed with parents as part of consent

Study procedures e.g. administration of the supplement can only be carried out at sites that have the necessary local approvals i.e. site R&D approval. **It is therefore important that sites notify the DOLFIN study team of any transfer as soon as the site are aware that an infant may be transferred, or has been transferred** using the contact details below (during normal working hours (between the hours of 9am – 5pm Monday to Friday):

Tel. No.: 01865 617919 / 01865 617924

Email: dolphin@npeu.ox.ac.uk

Sites can check whether a hospital is a participating site in the DOLFIN study by going to the DOLFIN study website (<http://www.npeu.ox.ac.uk/dolphin/>) and selecting the 'Sites' link.

If the infant is being transferred to a hospital that is not listed, approvals may be in progress or it may be possible to obtain approvals, so sites should contact the DOLFIN study team immediately.

As soon as the transfer of an infant to a different hospital has occurred, please complete the **DOLFIN Transfer/Discharge Form** in OpenClinica. A Transfer/Discharge form is not required for transfers within the same hospital e.g. between wards or units. Discharge date is discharge home, a transfer to another hospital is not a discharge. A new DOLFIN Transfer/Discharge Form is required for each transfer.

Transfer to an approved site

If the infant is being transferred to another DOLFIN study-approved site (recruiting/continuing care), supplementation can commence or continue whilst the infant is at that hospital. Supplement can be given by the clinical team at the CCS or by parents (according to local policy and parent preference).

At transfer, recruiting sites should ensure the following:

- ✓ Contact the DOLFIN study team to inform them of the transfer. Sites should also, where possible, contact the receiving site and inform them that the infant is in the DOLFIN study.
- ✓ Any relevant personal identifiable or medical information should be shared directly between local clinical teams at the recruiting site and CCS, it should not be included in any emails to the DOLFIN study email address.
- ✓ The **DOLFIN Transfer Pack** should be sent with the infant, including a copy of the signed Consent Form and **DOLFIN NNU Daily Dosing Log** (please photocopy prior to sending). If the Transfer Pack is not sent, please send it to the CCS as soon as possible or contact DOLFIN study team.

- ✓ Supplement is sent with the infant. Please allocate another box from the randomisation system if required (to ensure at least 8 weeks supply). If supplement is not sent at time of transfer, please allocate another box to be sent to the parent's home for them to take in to the CCS. See **Guidance Sheet 11 – Supplement Management and Control**).
- ✓ The cot card can be placed with the infant to identify infant as a DOLFIN infant.
- ✓ Send the **DOLFIN Transfer Pack**, with the infant to the receiving unit.

The **DOLFIN Transfer Pack** should include:

- DOLFIN NNU Daily Dosing Log
- DOLFIN Parent Information Leaflet (Preterm or HIE)
- DOLFIN Serious Adverse Event (SAE) Report Form
- DOLFIN Incident and Deviation Form
- DOLFIN Cot Card
- DOLFIN Guidance Sheet 8 for Continuing Care Sites (CCSs)
- DOLFIN Guidance Sheets 4a, 4b, 5, 7, 9 and 10
- FREEPOST Envelope (for returning Daily Dosing Log)
- DOLFIN Discharge Pack (for parents at discharge)

Key points to remember:

- **DOLFIN Transfer Pack** and supplement should be sent when an infant transfers, whether the Continuing Care Site is approved or not so that it is available if/when approvals are in place.
- It is important to note that although a **DOLFIN Transfer Pack** is provided when the infant is transferred, **the recruiting site is responsible for collecting all data related to the participant** and entering it on OpenClinica.
- The Continuing Care Site are asked to notify the recruiting site or DOLFIN study team as soon as an infant has been discharged, transferred, or died. Recruiting sites should check central NHS hospital records where possible and the DOLFIN study team may contact recruiting sites to check if there are any updates.
- In the event of twins or higher-order multiples, a separate **DOLFIN Transfer Pack** should be sent for each individual infant.
- Continuing Care Sites must continue to report safety events (e.g. SAEs) until discharge home.
- If required, incidents must be reported by continuing care sites according to **Guidance Sheet 9 – Safety & Incident Reporting** provided
- Ensure the **DOLFIN Cot Card** is with the infant at transfer

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Transfer to an unapproved site

If a transfer is planned to a **hospital that does not have local approvals** to act as a continuing care site or recruiting site for the DOLFIN study, please contact the DOLFIN study team immediately who will try to gain these urgently.

The DOLFIN Transfer Pack and supplement should still be sent with the infant so that they are available for if/when approvals are obtained.

If local approvals are not possible, parents should be advised that supplement will be paused during their stay at the CCS and should be commenced or recommenced as soon as possible, either when transferred to a recruiting site or approved CCS or after discharge home. Recruiting sites should maintain contact with the parents to ensure supplement is restarted as soon as possible and that parents are suitably trained in supplementation.

Please note: participation in the DOLFIN study must not interfere with the planned timing of the infant's transfer. Infants should be transferred according to usual local processes regardless of their involvement in the DOLFIN study.

Any information received from the receiving hospital, recruiting site, parents, or DOLFIN study team should be shared with relevant parties. Recruiting sites should check central NHS hospital records where possible to check if the infant has been transferred, discharged or died.

The DOLFIN study team will liaise with the recruiting site and the receiving hospital.

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