Guidance Sheet 6:
Data Collection Forms

Overview of Data Collection Forms

DCF(s) Completed by site staff Completed by parents	Infant recruit type: Preterm	Infant recruit type: HIE randomised in hospital	Infant recruit type: HIE randomised post-discharge	Where/how completed	When to complete
Consent form	✓	✓	✓	As self-carbonating paper copy (in-person or remote)	As soon as parent decides to take part (having had appropriate time to consider and ask questions) and **before any data is collected**
Randomisation web form	✓	✓	✓	Through DOLFIN randomisation website	As soon as possible after the consent form is completed
Contact details form	✓	✓	✓		
Entry form	✓	✓	✓	Data from randomisation website automatically copied to sections A and B; section C via data entry on OpenClinica	
HIE infants neonatal encephalopathy questionnaire		✓	✓	As data entry on OpenClinica.	
Post-discharge form			✓	As data entry on OpenClinica. Replaces transfer/discharge form when randomised post-discharge.	
Parent baseline questionnaire	✓	✓	✓	Through email/SMS link sent to parent, onto OpenClinica OR if paper copy completed, entered onto OpenClinica at site	
Supplement starter form	✓	✓		As data entry on OpenClinica	As soon as the infant receives first dose of in-hospital supplement, or when they have been discharged home if they never began supplement in hospital

Dosing log	✓	✓		As paper copy which is then entered onto OpenClinica	While infant is in hospital, once supplement has begun
Transfer/Discharge form	✓	✓		As data entry on OpenClinica	Whenever infant is transferred to another hospital, when they are discharged home, or if they die. A new form for each of these events.
Parent discharge questionnaire	✓	✓	✓	Through email/SMS link sent to parent, onto OpenClinica OR if paper copy completed, entered onto OpenClinica at site	Two weeks after infant is discharged from hospital
Parent daily adherence data	✓	✓	✓	Using DOLFIN study app, OR through email/SMS link sent to parent, onto OpenClinica, OR if paper diary completed, entered onto OpenClinica at site	Every day for first 1 month of supplement administration once infant is home
Parent weekly adherence data	✓	✓	✓		Every week for months 2 to 12 of supplement administration once infant is home
Parent 3-month questionnaire	✓	✓	✓	Through email/SMS link sent to parent, onto OpenClinica OR if paper copy completed, entered onto OpenClinica at site	When the infant is 3 months old (post-EDD)
Parent 6-month questionnaire	✓	✓	✓		When the infant is 6 months old (post-EDD)
Parent 12-month questionnaire	✓	✓	✓		When the infant is 12 months old (post-EDD)
Supplement discontinuation form (within the paper dosing log)	*(✓)*	*(✓)*	*(✓)*	*On paper dosing log in the discontinuation form section, entered onto OpenClinica (if discontinuation in hospital); as data entry on OpenClinica (if discontinuation post-discharge)*	***Only** if the infant <u>permanently</u> discontinues the supplement (temporary pauses to be recorded using dosing log). To be completed for all permanent discontinuation of supplement (whether pre- or post-discharge)*

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Serious adverse event (SAE) form	*(✓)*	*(✓)*	*(✓)*	*As data entry on OpenClinica* ***as soon as possible after site becomes aware of event being defined as serious***	***Only*** *if any SAEs occur from when infant starts supplement up until infant is 12 months and 2 weeks old (post-EDD)*
Parent 18-month questionnaire	✓	✓	✓	Through email/SMS link sent to parent, onto OpenClinica OR If paper copy complete, entered onto OpenClinica at site	When the infant is 18 months old (post-EDD)
Parent 24-month questionnaire	✓	✓	✓		When the infant is 24 months old (post-EDD)
2-year outcomes form	✓	✓	✓	As data entry on OpenClinica	When the infant is 24 months old (post-EDD)
Change of consent	*(✓)*	*(✓)*	*(✓)*		***Only*** *if the parent no longer wishes to provide data or otherwise change the consent they originally provided on the DOLFIN consent form.*

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Instructions for Data Collection forms

Consent form

Please see **Guidance Sheet 2 – In Person and Remote Informed Consent** for guidance on completing consent forms.

Randomisation web form and Contact Details form

Please see **Guidance Sheet 3 – Randomisation** for details of how to complete the randomisation and contact details forms.

Please complete the contact details form as soon as possible after randomisation, so that the DOLFIN study team have the email/mobile number to which the link for the parent baseline questionnaire can be sent.

Only the parent(s) who have signed the consent form should have their details inputted onto the contact details form.

Entry form

The data entered for the randomisation web form is copied through to Section A and B of the Entry form on OpenClinica. **Please do not create a participant record manually in OpenClinica. This is done automatically by the system.** When you complete the entry form, check Section A and make sure that all the data is correct. If any data in Section A is incorrect, enter the correct data here. You cannot edit data through the randomisation web form.

Section B can never be edited.

Complete Section C by entering the data. Please see the OpenClinica training video provided via the DOLFIN study team for details of how to perform data entry on OpenClinica.

HIE infants neonatal encephalopathy questionnaire

If the infant recruited is part of the **HIE group**, you must complete this form, which requires data from the neurological assessments performed for the infant on each of their first three days of cooling.

Guidance for performing the neurological assessments can be found at:
https://www.youtube.com/watch?v=sMg3y7L6qSY

If an aEEG was performed for the infant, you will be asked to give the worst aEEG recording at any age during the infant's admission to the recruiting site. Please use the following image for reference (also displayed on the OpenClinica form):

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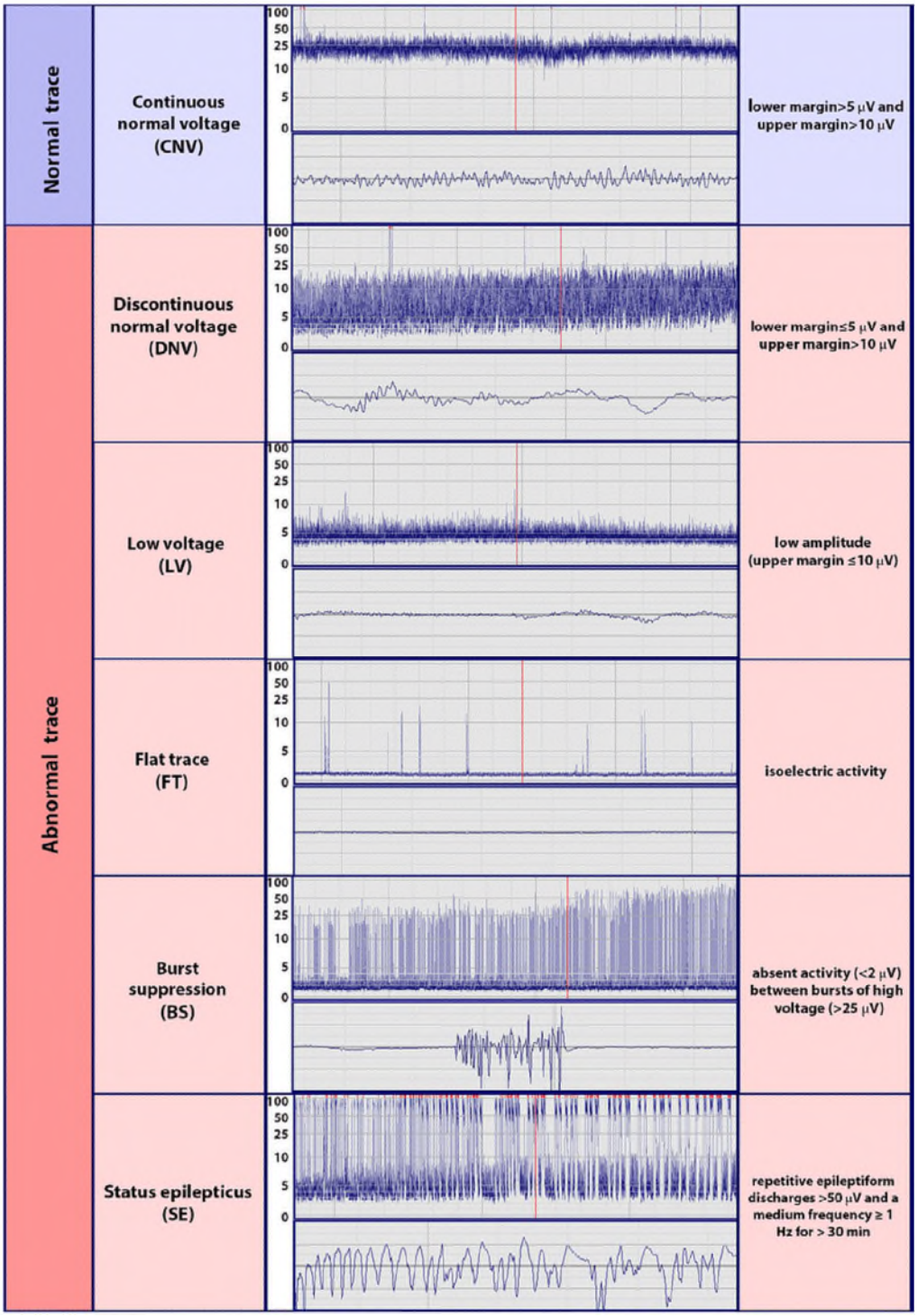

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Post-discharge form

If the infant was randomised after discharge home, please complete this form as soon as possible after they have been randomised. This form contains information about their hospital stay. This form should only be completed for infants randomised after discharge home.

Infants randomised after discharge home do not need any forms completed to record any transfers between hospitals, and they do not need the transfer/discharge form completed (the post-discharge form is instead of this).

Parent questionnaires

All parent questionnaires will be sent as a unique link to the parent (wherever possible, the mother) via text message and/or email. (If both mobile number and email address are provided, the recipient will receive both a text message and an email)

Questionnaires should be completed by the mother wherever possible (as they collect information about maternal outcomes). The DOLFIN Study team will manage this process, as well as sending electronic reminders. Site staff may be asked to follow up with parents if questionnaires are not being completed or if the parents' contact details are no longer up to date.

Parents should be encouraged to complete questionnaires electronically wherever possible. The data they enter goes directly onto OpenClinica and does not require entering by the site.

Where no other form of receipt is acceptable to parents, paper copies of questionnaires can also be provided, along with a FREEPOST envelope to return the questionnaire to the DOLFIN study team at NPEU CTU. When received by the DOLFIN study team, data will be entered onto OpenClinica by the DOLFIN study team. If a completed paper questionnaire is returned to a site it should be entered onto OpenClinica at site.

As a last option, a site may offer to complete the questionnaire on behalf of the parent over the phone but the above options should be offered in the first instance. **If you complete a questionnaire with a parent over the phone, please add an annotation on OpenClinica (ideally to the question about who completed the questionnaire) to note that this method was used.**

The template **DOLFIN Contact letter to parents** may be used to contact parents who have not responded to previous communication or are non-contactable via email/phone. If this is required, please contact the DOLFIN study team.

Parent baseline questionnaire

A questionnaire for parents (wherever possible, the mother) to complete as soon as possible after randomisation.

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Parent discharge questionnaire

A questionnaire for parents (wherever possible, the mother) to complete two weeks after discharge.

Parent 3, 6, 12, 18 and 24 month questionnaires

Questionnaires for parents (wherever possible, the mother) to be completed at 3, 6, 12, 18 and 24 months (post EDD).

Supplement starter form

An infant should begin receiving the supplement **as soon as they are eligible to do so** (that is, on full feeds).

For all infants please complete the **DOLFIN Supplement Starter Form** as soon as the infant receives their first dose of supplement, so that the DOLFIN Study Team know that the infant has begun the intervention.

If an infant has been transferred to a Continuing Care Site before starting the supplement, please liaise with this site to confirm when the infant has started the supplement, and ensure that the supplement starter form is completed.

If the infant is discharged home without starting the supplement, please still complete the Supplement Starter Form to record that supplement was not begun in hospital.

Dosing log

Please ensure treatment pack ID is added to the **DOLFIN Daily Dosing Log**. Doses from each new pack should be recorded on separate dosing logs: start a new dosing log when a new pack is begun.

If an infant is mistakenly given a dose from another infant's pack, this should be reported as an incident (see **Guidance Sheet 9 – Safety and Incident Reporting**).

Once you use up a pack or run out of space on a paper dosing log, the log should be entered onto OpenClinica. Data can be entered onto OpenClinica more regularly, please click 'Save' each time the log is updated and click 'Complete' when you have finished that pack or the infant has been discharged home. If you click 'Complete' before the pack is finished, schedule a new Dosing Log form on OpenClinica and continue entering data for that treatment pack.

Paper dosing logs should be stored at site in the site folder. These do not need to be sent to the DOLFIN study team. When an infant is transferred to another hospital a photocopy of the current **DOLFIN Daily Dosing Log** should be sent with the infant in the Transfer Pack. **Please retain a copy of the completed Daily Dosing Log** (scanned or photocopied) before sending.

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Transfer/discharge form

All infants randomised before hospital discharge need the transfer/discharge form completed when they are transferred to another hospital or discharged home, or if they die while in hospital. **Please complete a new form for each new transfer or discharge.**

Note: Transfer/Discharge form is not required for transfers within the same hospital e.g. between wards or units, and only transfers after randomisation need to be recorded. Discharge date is discharge home, a transfer to another hospital is not a discharge.

When an infant is transferred to a Continuing Care Site (CCS) (whether an approved CCS or not) recruiting sites should follow up the infant until they are transferred out to another hospital or discharged home, or they die at the continuing care site. This may be via contacting the Continuing Care Site or using central hospital records. Approved CCSs are asked to notify the recruiting site or DOLFIN study team when an infant is transferred again, discharged home or dies at the CCS. The DOLFIN study team will forward any relevant information received. Recruiting sites should complete the **DOLFIN Transfer/Discharge form** on behalf of continuing care sites (i.e. when an infant is discharged home from or transfers out of a continuing care site, or dies at a continuing care site).

It is especially important that the DOLFIN Study team are made aware of an infant's discharge home or death as soon as possible (even if you do not have time to complete the whole transfer/discharge form at that time). Notification of death of infant is needed to ensure parents are not sent trial communications. Date of discharge home is needed to ensure that links for parent questionnaires are sent out promptly. Date of transfer or discharge, or notification of death, can be provided to the DOLFIN Study team via email and added into the system at NPEU if necessary.

If an infant is being discharged to somewhere other than the parental home, please ensure that the DOLFIN Study team has the correct address for supplement deliveries by updating the infant's contact details via the randomisation website (see **Guidance Sheet 3 – Randomisation**).

Parent daily and weekly adherence data

See **Guidance Sheet 5 – Parent Training** for information on parent supplement adherence and weight reporting.

2-year outcomes form

Please complete this form as close as possible to when the infant is 24 months old (post-EDD) by entering the data on OpenClinica.

Discontinuation of supplement form

If the infant permanently discontinues supplement **in hospital**, there is a section to record this on the paper **Dosing Log**. Please then enter this section onto the **Discontinuation of Supplement form** on OpenClinica.

GUIDANCE SHEET 6

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If the infant has discontinued supplement **at home**, please complete the Discontinuation of Supplement form directly onto OpenClinica. A discontinuation of supplement form is not required if an infant dies.

If, in addition to discontinuation of supplement, a parent wishes to change consent for their infant's involvement in the trial (for instance, they no longer want to complete follow-up questionnaires, or they no longer want DOLFIN to collect clinical data on their infant) the **Change of Consent form** should also be completed (see below).

Serious adverse event form

Please see **Guidance Sheet 9 – Safety & Incident Reporting** for information on when to report adverse events.

If you have a serious adverse event to report, report to the DOLFIN study team **as soon as possible** (even if you do not yet have all the information). This would ideally be directly onto OpenClinica as the DOLFIN team will receive an alert as soon as data entry on an SAE form is begun.

Change of consent form

Please see **Guidance Sheet 12 – Change of Consent** for information on when to complete the change of consent form. This form does not need to be completed if an infant is discontinuing supplement but otherwise their involvement in the trial remains unchanged.

The DOLFIN study team will receive an alert as soon as data entry on a change of consent form is begun.

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