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The Newcastle upon Tyne Hospitals NHS Foundation Trust

NPEU Clinical Trials Unit

OXFORD POPULATION HEALTH NPEU

DOLFIN Training Refresher: 2

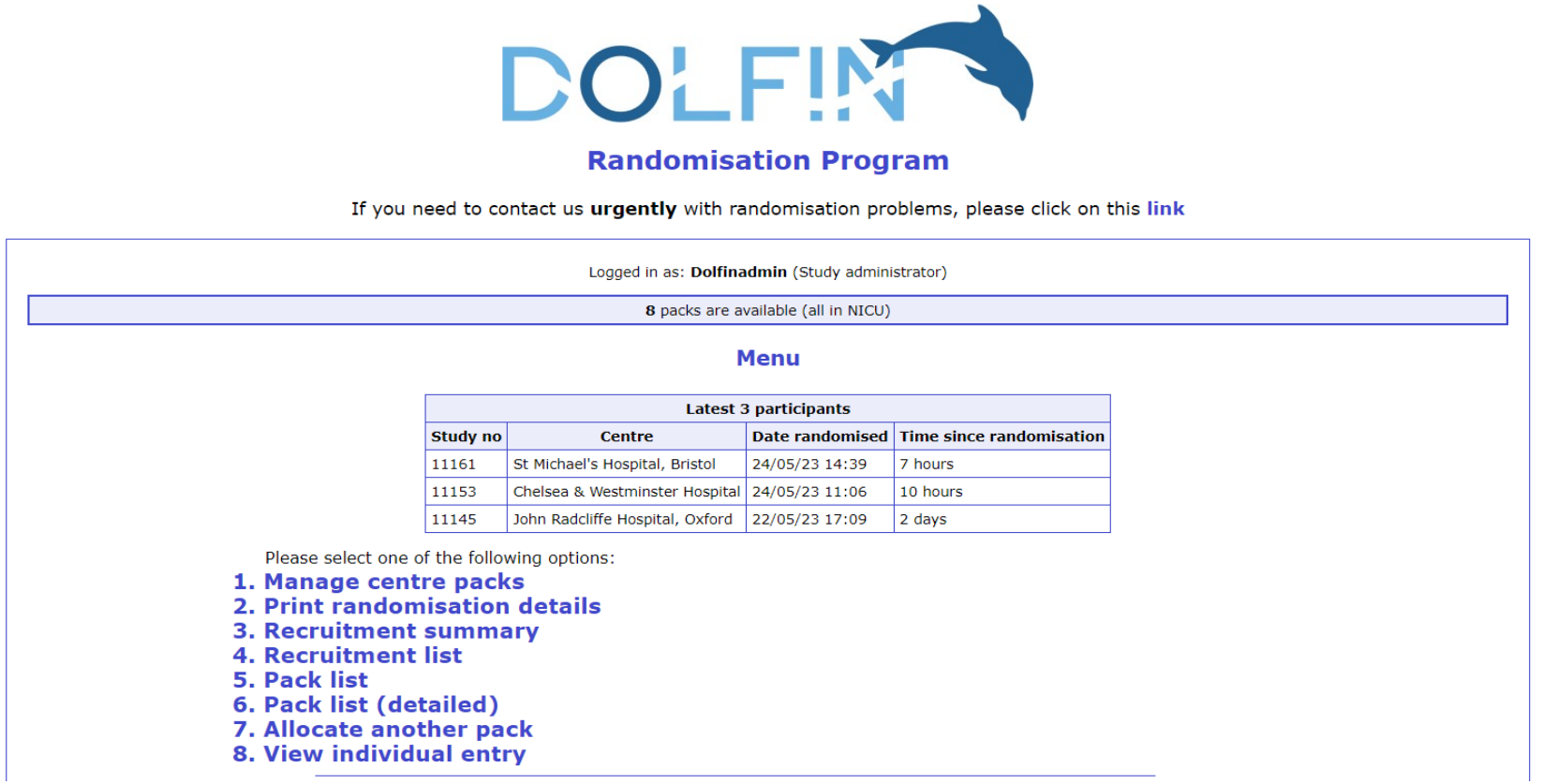
CRF’s and Data Completion

CRF’s and Data Collection

- DOLFIN is an electronic CRF-based trial.
- Sites complete CRFs directly onto OpenClinica
  - SAE Forms, Dosing Logs: paper form option
- Parent questionnaires sent by NPEU via text/email
  – paper form option only if requested by parents.
- Data queries and missing form queries sent monthly.
- Only recruiting sites can complete CRF data entry - NPEU cannot input/edit data

Randomisation website

https://rct.npeu.ox.ac.uk/dolfin



Randomisation website

- Site-wide login for all staff to use
- Training: short video, guidance sheets

Use for:

- Randomising an infant
- Inputting Screening Log data
- Updating participant contact details
- Pack management system – allocating packs

Consent Form Upload

- NPEU secure web-based system for uploading and sending documents containing personal / identifiable data
- Individual account login – will be provided
- Training: 2-page user guide

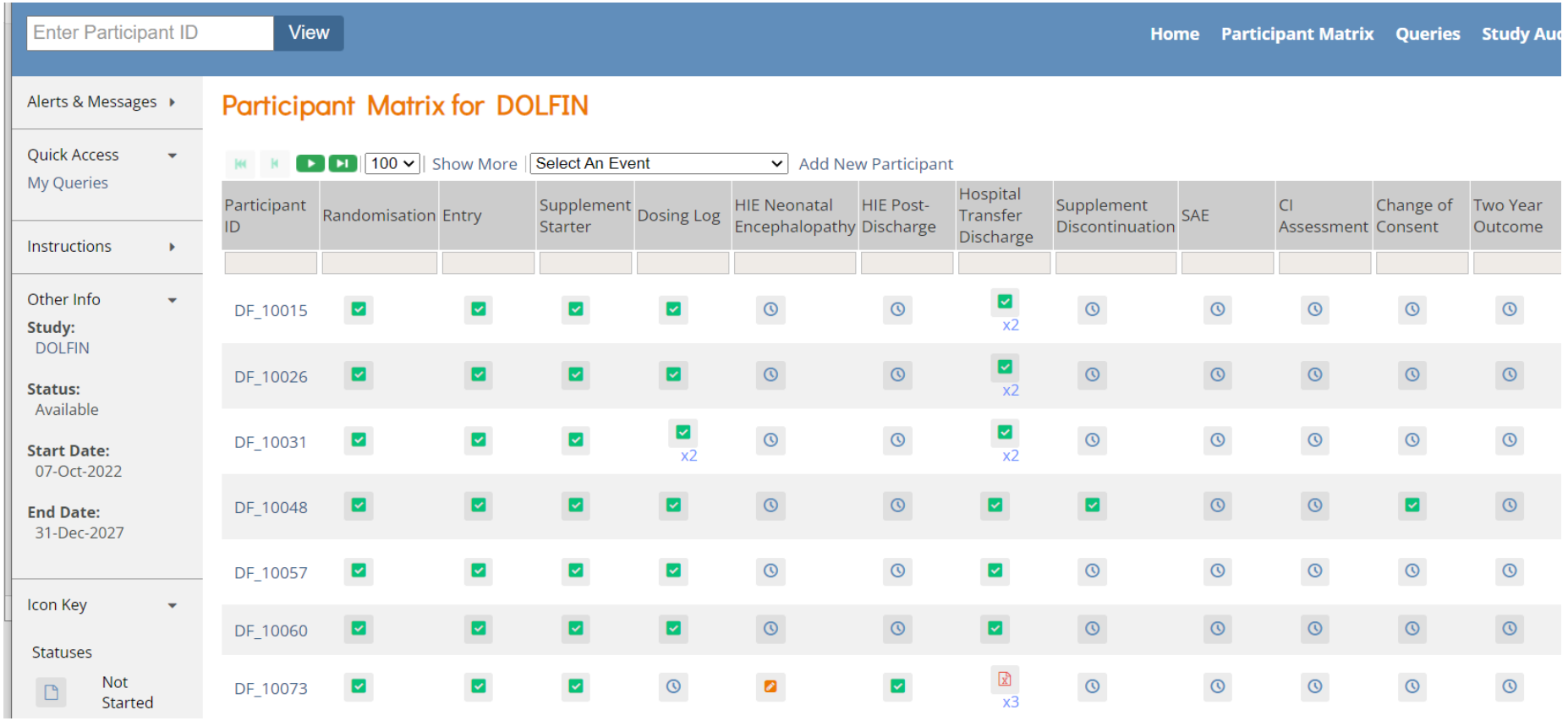
Use for:

- Sending completed consent forms
- Sending completed scanned SAE forms (email to confirm)
- If you ever need to send any other patient data e.g. test results, discharge summaries

Will be rolled out across all NPEU trials – one login for all studies.

OpenClinica

https://npeu.openclinica.io/



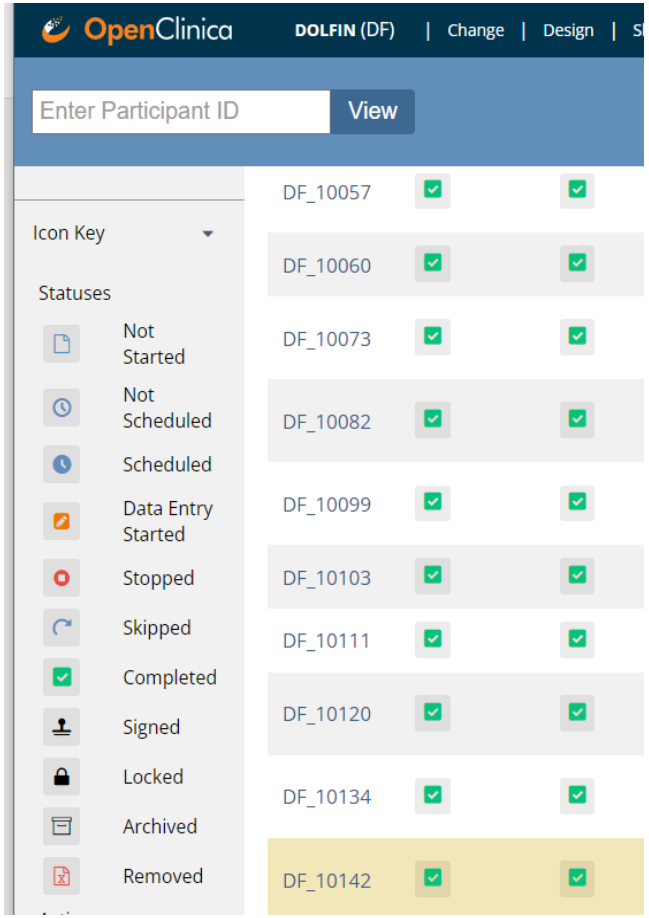
OpenClinica

- Trial database – no personal / identifiable patient data held
- Individual accounts – same login as other NPEU trials
- Training: short video, guidance sheets

Use for:

- Completing clinical CRFs
- Reporting SAEs
- Resolving queries

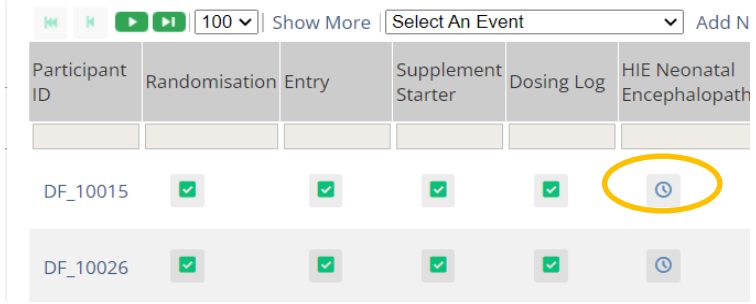
OpenClinica

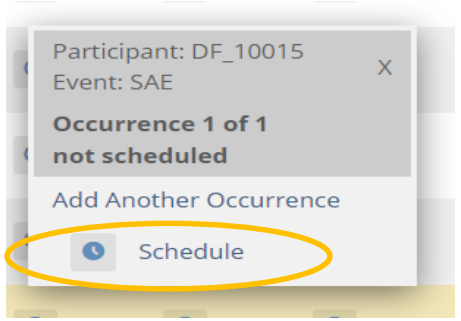


- Scheduled (blue clock icon) – CRFs to be completed for all infants e.g. Trial Entry Form.
- Not Scheduled (white clock icon) – CRFs completed for some infants e.g SAE Form.
- Once ‘Complete’ is pressed on a CRF, any further edits will flag as a change/query.

OpenClinica

- To schedule a form, click white clock icon and choose ‘schedule’
- Forms can be edited up to point of marking as ‘complete’ – then any missing fields will flag as data query and any future edits will flag as a change to form (but can still be made)
- Mark form as ‘complete’ as soon as you are able to, part-completed forms will appear on missing form reports as data entry started.

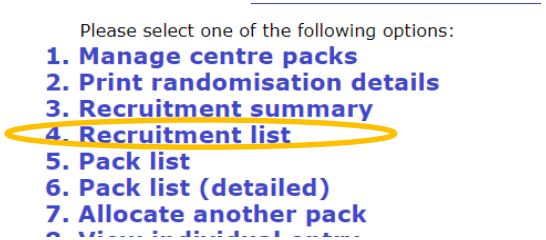




Randomisation and Trial Entry

Contact Details Form

- On randomisation website
- After an infant has been randomised, click ‘Enter contact details’ button (on screen where study ID is provided)
- To add or update contact details at a later date, login to randomisation website, click ‘Recruitment List’ > Edit.



Randomisation and Trial Entry

Contact Details Form

- Add contact details as soon as possible – triggers Parent Baseline Questionnaire
- Mobile number and/or email address
- Address to send resupply of supplement to parent home
- Confirm periodically that contact details are up to date
- See Guidance Sheet 3 – Randomisation after Informed Consent

Randomisation and Trial Entry

Entry Form

- Data from randomisation website automatically copied to sections A and B; section C completed via data entry on OpenClinica.
- Complete as soon as possible after the consent form is completed

Post-discharge Form

- For infants randomised after discharge home recruited post-discharge using remote consent process
- Contains information about their hospital stay
- Completed on OpenClinica
- Complete as soon as possible after randomisation

HIE Questionniare

- Neonatal encephalopathy questionnaire - for HIE infants
- Requires data from neurological assessments performed for infant on each of their first three days of cooling
- Completed on OpenClinica
- Completed as soon as possible after randomisation
- Must be signed off by PI – see Guidance Sheet 13

Supplement Starter Form

- For all infants randomised before discharge home who started supplement in hospital (recruiting or transfer site)
- Completed on OpenClinica
- Complete as soon as infant starts supplement
- Infants randomised after discharge do not need this form completed
- Infants randomised in hospital but only started supplement at home do not need this form completed

Daily Dosing Log

- For recording daily supplement dosing – adherence monitoring and for clinical monitoring
- Doses from each pack should be recorded on separate dosing logs: start a new dosing log when a new pack is begun
- Enter paper logs onto OpenClinica at least monthly where capacity allows
- Transfers - dosing logs to be sent to recruiting sites for data entry
- File paper dosing logs in site folder

Transfer/Discharge Form

- To be completed for each transfer to another hospital **and** when an infant is discharged home, or if the infant dies prior to discharge home
- For all infants randomised before hospital discharge
- Complete a new form for each transfer and discharge
- Complete as soon as possible after transfer/discharge

  - Transfer details are needed to follow up with transfer hospital
  - Discharge date triggers Parent Discharge Questionnaire (discharge date can be provided to trial team via email/phone if necessary)

- Follow up transfers to discharge – request discharge date and clinical information from transfer hospital or use NHS records

2-year Outcomes Form

- Site to complete as close as possible to 24 months post-EDD
- Primary outcome data – really important it is completed

Parent Questionnaires

- Sent to parents via email/SMS link
  - if both email and SMS provided, parents will receive both
- Mother to complete where possible as includes maternal data
- Data pulled into OpenClinica
- Reminder sent after 2 weeks
- If parents have not responded to link sent by NPEU, please contact parent to complete over phone or in clinic
- Paper copy/pre-paid envelope available at site/parent request

Parent Questionnaires

Baseline

- To complete as soon as possible after randomisation
- For multiples, only 1 baseline questionnaire required as collects maternal data (complete for 1st infant randomised)

Discharge

- To complete as soon as possible after infant discharged home. For multiples, 1 completed for each infant.

3, 6, 12, 18 and 24 months post EDD

SAE Form

- Serious Adverse Events (SAEs) - reported directly onto OpenClinica or via paper form
- Paper forms need to be entered onto OpenClinica by site
- Causality assessment to be completed and signed by medically trained professional – can be completed by directly on OpenClinica (PI/safety delegate would require OpenClinica account access to sign).
- New form for follow-up information – ignore queries for missing fields if data already provided.

Discontinuation of supplement form

- Complete if infant permanently discontinues supplement
- Complete on OpenClinica
- Temporary pauses are recorded on dosing log – discontinuation form not needed
- If at parent request, ask parent if they want to change consent for trial participation – data collection

  - Complete Change of Consent Form to record any change in consent …

Change of Consent Form

- Complete on OpenClinica if parent changes consent for participation in trial:
- Parent questionnaires
- Infant's clinical data from hospital records
- Study updates
- Complete as soon as possible so parent messages can be stopped if required.
- Does not need to be completed if parent only wants to discontinue supplement
- See Guidance Sheet 12 – Change of Consent