Guidance Sheet 5:

Data Collection

Centre for Trials Research
Canolfan Ymchwil Treialon

General

BALLOON data will primarily be captured using an electronic Case Report Form (eCRF) and the parent App.

There are some circumstances where the initial data collection may be made on paper and requires transcribing to the eCRF. These are outlined in the table below.

If you make a mistake when completing a paper form, strike through once and initial and date the correction; please do not use Tipp-ex or scribble out the mistake.

A screening log should be completed for each baby less than 30 weeks' gestation considered for entry to the trial. A consent form must be completed prior to any study procedures being undertaken for all babies in the trial.

There are 9 case report forms (CRFs) for the study:

- Form 1: Eligibility
- Form 2: Trial Entry
- Form 3: Follow up contact
- Form 4: Discharge Form
- Form 5: Month 1,2,4,5,7,8,10 &11
- Form 6: Con Meds Form
- Form 7: Month 3,6,9 &12
- Form 8: LRTI Verification Form
- Form 9: Adverse event monitoring

There are a further 2 CRFs in that may be required for some babies:

- Form 10: Baby withdrawal Form
- Form 11: Serious Adverse Event Report Form SAE

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For all forms please add as much information about the baby as possible. This is particularly important if the baby has no first name yet, or it is a multiple birth e.g. Female or Male, Twin 1, Triplet 2 etc.

All the data requested in the forms are routine clinical items or family information that can be obtained from the clinical notes or the parents/guardians.

Please answer all questions, explain missing data, avoid ambiguous answers.

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Form	Electronic (E)/Paper (P)	Completion time	Completed by	Notes	Further information
Eligibility	E- directly to eCRF	At time of enrolment	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 1: Screening and Eligibility
Trial entry	E- directly to eCRF	At time of enrolment (after eligibility confirmed by clinician)	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry
Discharge Form	E- data taken from clinical notes and directly entered onto eCRF	After the baby is discharged from the neonatal unit	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry
Month 1,2,4,5,7,8,10 &11	E- directly to eCRF	At 1,2,4,5,7,8,10 &11 months corrected age	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry
Con Meds	E- directly to eCRF	1 month corrected age and then update	Entry to eCRF by delegated individual OR	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry

		at 2,3,4,5,6,7,8,9, 10,11&12 months corrected age	Self reported by the parents and entered directly to eCRF OR Prescribed in hospital		
Month 3,6,9 &12	E- directly to eCRF	At 3,6,9&12 months corrected age	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry
LRTI Verification Form	E- directly to eCRF	When the parents/guardians have reported a LRTI	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry
Withdrawal	P+E- paper then transcribed to eCRF	As soon as withdrawal occurs	Entry to eCRF by delegated individual	Paper copy to go in baby' notes	Guidance sheet 6: Data entry Guidance sheet 8: Withdrawal & Unblinding
Adverse events monitoring	E- Directly entered onto eCRF	From randomisation until 13 months corrected age.	Entry to eCRF by delegated individual	If completed on paper, transcribe to eCRF asap	Guidance sheet 6: Data entry Guidance sheet 7: Safety and non-compliance reporting

SAE form	P	Within 24 hours of becoming aware of the SAE	Page 1-2 any individual Page 3: medically qualified delegated member of the trial team	Email to the CTR immediately, keep the original in the ISF	Guidance sheet: 7 Safety and non-compliance reporting
Screening log	P	At the time of screening	Trial team (after decision on eligibility made)	Please update on a weekly basis	Guidance sheet 1: Screening and eligibility Guidance sheet 6: Data entry
BALLOON IMP receipt form	E- directly to eCRF	At receipt of IMP	Pharmacy team		Guidance sheet 9: IMP supply and accountability
Drug quality form	P	On receipt of IMP shipment	Pharmacy team	Only if quality issues are noted	Guidance sheet 9: IMP supply and accountability
BALLOON Participant Level Accountability Log	P	Initial dispensing of IMP, subsequent dispensing. At the end of trial treatment for each baby. On return of any unused IMP.	Pharmacy team	Once completed, return to the CTR for checking and sign-off prior to disposing of unused IMP and the outer packaging, keep the original in the ISF	Guidance sheet 9: IMP supply and accountability
Dosing error report	P	Within 24 hours of becoming aware of the overdosing event	Trial team	Return to the CTR immediately via	Guidance sheet: 7 Safety and non-compliance reporting

				fax/email, keep the original in the ISF	
Non-compliance report	P	Within 24 hours of becoming aware of the event	Trial team	Return to the CTR immediately via secure email, keep the original in the ISF	Guidance sheet: 7 Safety and non-compliance reporting

Specific points to remember about each data collection form

Consent Form

- ASAP after randomisation directly record the allocated Study ID given by the REDCap on the consent form alongside the NHS/CHI number of the baby, please ensure it is the baby's not the mother's NHS/CHI number.
- Please make two copies of the consent form after adding the REDCap Study ID and NHS/CHI number:

  a. Email a copy to BALLOON@Cardiff.ac.uk. Please use an encrypted message as provided by your NHS organisation. Then, place a copy in the baby's clinical notes together with a copy of the Parent Information Leaflet.

  b. a copy to the Investigator Site File

  c. a copy to a parent

- If the father consents for the baby to participate into the trial, **ensure** the mother countersigns in the space provided. We need her consent for some of the maternal data collected at trial entry/randomisation.

Eligibility Form

- The decision for eligibility and trial enrolment must be made by a medically qualified doctor and there should be clear documentation of this in the baby's notes.

Trial Entry Form

- Please complete the form ASAP at time of enrolment (after eligibility confirmed by clinician) . Some of the information may need to be obtained from the parents/guardians.

Discharge Form

- Please complete the form ASAP after the baby is discharged from hospital.

Month 1,2,4,5,7,8,10 &11 Form

- To be completed during the telephone call with the parents/guardians at 1,2,4,5,7,8,10 and 11 months corrected age.

Con Meds Form

- To be competed at the monthly face-to-face/telephone encounters with the parents/guardians at 1 month corrected age and then updated at 2,3,4,5,6,7,8,9, 10,11&12 months corrected age. Please enter start and stop dates for the medications. Please exclude vitamins and minerals, calcium, phosphate, iron or milk or reflex medication.

Month 3,6,9 &12 Form

- To be completed at the face-to-face encounter with the parents/guardians at 3,6,9 and 12 months corrected age.

LRTI Verification Form

- To be completed when the parents/guardians have reported a LRTI on the App. Please complete as soon as possible after the parents/guardians have reported a LRTI.

Withdrawal Form

- To be completed and signed by the Principal Investigator or delegated deputy for any baby who is totally withdrawn from the trial, or whose parents request to stop their baby's ongoing participation in the trial

- It is important that you clarify with the parent(s) and record on the form whether, despite stopping the medication, they would agree for data collection and for sample collection to continue and for sub study participation to continue if eligible.
- Depending on the wishes of the parent(s) further data collection and form completion may be required
- Remember to place a copy of the completed Form in the baby's clinical notes.

Adverse Events Monitoring Form

- The safety reporting period will be defined as beginning at the point of randomisation, and will continue until 13 months corrected age.
- Use this form to record
    - Events which a study physician considers to be attributable to the IMP (causality assessment: probably, definitely, almost certainly). **This is regardless of whether they meet the criteria for being 'serious'.**
- Any **unforeseen** serious adverse event, or serious adverse reactions must be recorded on **a Serious Adverse Events form**
- Please see **Guidance Sheet 7: Safety and non-compliance** for more details

SAE Form

- The safety reporting period will be defined as beginning at the point of randomisation, and will continue until 13 months corrected age.
- Unforeseeable Serious Adverse Events will be reported to the CTR within 24 hours of staff at the site becoming aware of the event using this form
- A study physician (Investigator) is responsible for reviewing the SAE and considering whether the event was related to the study drug.

- If a study physician is not available to make the causality assessment send in the SAE Reporting Form without this information and re-send the form as soon as this assessment has been made.
- A Physician who is not a member of the study team may offer an opinion as to whether the event was related to the study drug(s) and this opinion should be documented in the participant's medical records.

- For further information, please see **Guidance Sheet 7: Safety and compliance**