# Guidance Sheet 6: Data Collection

AZTEC Azithromycin Therapy for Chronic Lung Disease

Cardiff University Prifysgol Caerdydd

Centre for Trials Research Canolfan Ymchwil Treialon

## General

- AZTEC data will primarily be captured using an electronic Case Report Form (eCRF)

- There are some circumstances where the initial data collection is made on paper, and requires transcribing to the eCRF. These are outlined in the table below. Paper versions of each CRF form will be available and are kept in the AZTEC document box. If you are running low on stock you can request more by contacting the Trial Administrator at the CTR (AZTEC@Cardiff.ac.uk).

- 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. Consent form must be completed prior to any study procedures being undertaken for all babies in the trial.

- There are 10 case report forms (CRFs) for the study:
    - **Form 1: Eligibility**
    - **Form 2: Trial Entry**
    - **Form 3: Contact details**
    - **Form 4: Daily log**
    - **Form 5: Transfer (< 36 weeks PMA)**
    - **Form 6: Outcomes at 36 weeks PMA (discharge/death if sooner)**
    - **Form 7: Outcomes post 36 weeks PMA**
    - **Form 8: Adverse reactions**

- There are a further 2 CRFs in that may be required for some babies:
    - **Form 9: Baby withdrawal Form**
    - **Form 10: Serious Adverse Event Report Form (SAE)**

- For **all forms** (**Trial Entry** in particular), 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 that can be obtained from the clinical notes

- 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 2: Screening and consent |
| 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 2: Screening and consent |
| Daily log | P+E- paper then transcribed to eCRF | From enrolment until 21 days post start of treatment | Paper version completed at cot-side by qualified health professional. Transcribed to eCRF by delegated individual | Please ensure the daily log is transcribed to eCRF frequently (e.g. every 7 days) | Guidance sheet 7: Data entry |
| Transfer | E- data taken from clinical notes and directly entered onto eCRF<br><br>P (for transfers occurring from continuing care sites only) | At the point of transfer, if this occurs prior to 36 weeks PMA | Entry to eCRF by delegated individual (including paper CRFs returned from continuing care sites) | If completed on paper, transcribe to eCRF asap | Guidance sheet 7: Data entry<br>Guidance sheet 12a: Preparing a transfer |
| Outcomes at 36 weeks PMA | E- data taken from clinical notes and directly entered onto eCRF<br><br>P (if data collected at continuing care sites) | At 36 weeks PMA (± 1 week)- discharge home or death if sooner | Entry to eCRF by delegated individual (including paper CRFs returned from continuing care sites) | If completed on paper, transcribe to eCRF asap | Guidance sheet 7: Data entry<br>Guidance sheet 10: Oxygen reduction test |

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| Form | Electronic (E)/Paper (P) | Completion time | Completed by | Notes | Further information |
|---|---|---|---|---|---|
| Outcomes post 36 weeks PMA | E- data taken from clinical notes and directly entered onto eCRF<br><br>P (if data collected at continuing care sites) | At transfer, discharge home or death, if occurring after 36 weeks PMA | Entry to eCRF by delegated individual (including paper CRFs returned from continuing care sites) | If completed on paper, transcribe to eCRF asap | Guidance sheet 7: Data entry |
| Withdrawal | P+E- paper then transcribed to eCRF<br><br>P (if data collected at continuing care sites) | As soon as withdrawal occurs | Entry to eCRF by delegated individual | Paper copy to go in baby' notes | Guidance sheet 7: Data entry<br>Guidance sheet 11: Withdrawal & Unblinding |
| Adverse reactions | E- Directly entered onto eCRF<br><br>P (if data collected at continuing care sites) | From randomisation, until 36 weeks PMA- discharge home or death if sooner | Entry to eCRF by delegated individual (including paper CRFs returned from continuing care sites) | If completed on paper, transcribe to eCRF asap | Guidance sheet 7: Data entry<br>Guidance sheet: 8 Safety and non-compliance reporting |
| SAE form | P | Within 24 hours of becoming aware of the SAE | Section 1-16: any individual<br>Section 17: medically qualified delegated member of the trial team | Fax/email to the CTR immediately, keep the original in the ISF | Guidance sheet: 8 Safety and non-compliance reporting |
| Screening log | E- directly entered onto the eCRF | At the time of screening | Trial team (after decision on eligibility made) | Please update on a weekly basis | Guidance sheet 2: Screening and consent<br>Guidance sheet 7: Data entry |

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| Form | Electronic (E)/Paper (P) | Completion time | Completed by | Notes | Further information |
|---|---|---|---|---|---|
| Accountability log | P | At receipt of IMP and on return of any unused 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 |
| IMP reconciliation log | P | At the end of trial treatment for each baby | Research team/pharmacy, then CTR | Once completed, return to the CTR for checking and sign-off prior to disposing of used IMP, 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 event | Trial team | Return to the CTR immediately via fax/email, keep the original in the ISF | Guidance sheet: 8 Safety and non-compliance reporting |
| Non-compliance report | P | Within 24 hours of becoming aware of the event | Trial team | Return to the CTR immediately via fax/email, keep the original in the ISF | Guidance sheet: 8 Safety and non-compliance reporting |

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**Specific points to remember about each data collection form**

**Consent Form**

- This is an NCR (carbon copy) form which comprises of 3 sheets - please ensure that any signatures/initials transfer through to the subsequent duplicate sheets
- ASAP after randomisation directly record the allocated Study ID given by the randomisation program on the consent form alongside the NHS/CHI number of the baby
- The sheets are colour-coded, the top original sheet should scanned/faxed back to the CTR before being placed in the clinical notes. Other copies are to go (i) into the Investigator Site File, (ii) to the parent(s)
- 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. Stickers are provided in the document box to facilitate recording of confirmation of eligibility.
- Please complete the eCRF **within 7 days of birth**

**Trial Entry form**

- Complete the first section of the form prior to randomisation so the required information is at hand to conduct the randomisation
- ASAP after randomisation directly record the allocated Study Number and Pack ID Number given by the randomisation program on the eCRF
- Please complete the whole eCRF **within 7 days of birth**

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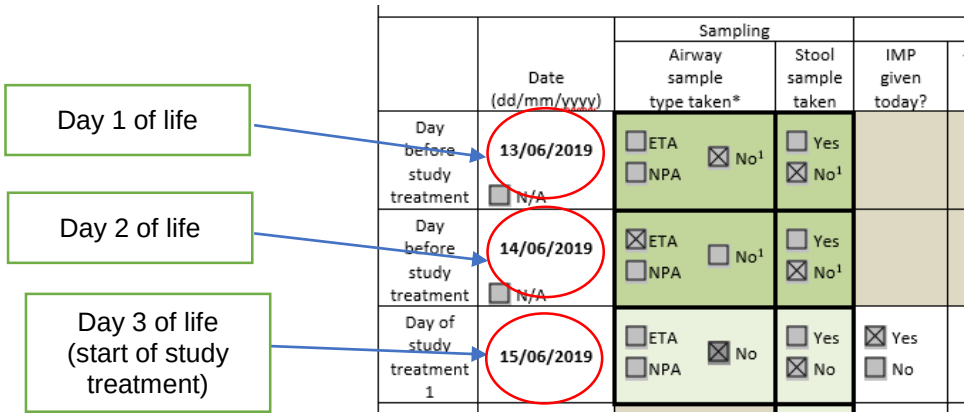
**Daily log CRF**

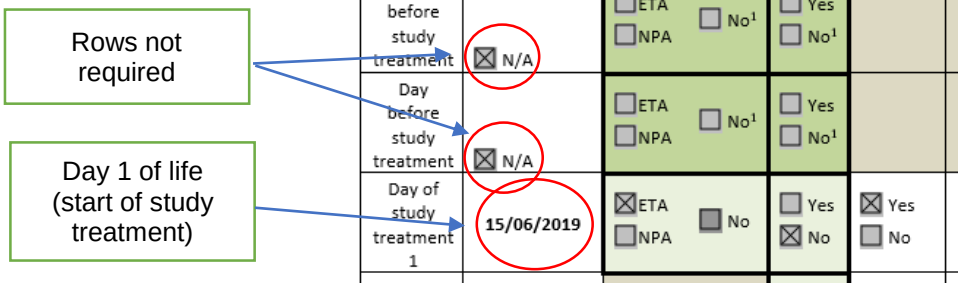
- The daily log is designed to be paper-based and completed at the cot-side
- The first two rows of the daily log capture a limited amount of data on days **prior to commencing the IMP** (as treatment may begin up to 72 hours after birth, at the latest).

Example completion if the baby does not start study treatment until day 3 of life:




| | Date (dd/mm/yyyy) | Sampling: Airway sample type taken* | Sampling: Stool sample taken | IMP given today? |
|---|---|---|---|---|
| Day before study treatment | 13/06/2019 ☐ N/A | ☐ ETA ☐ NPA ☒ No[1] | ☐ Yes ☒ No[1] | |
| Day before study treatment | 14/06/2019 ☐ N/A | ☒ ETA ☐ NPA ☐ No[1] | ☐ Yes ☒ No[1] | |
| Day of study treatment 1 | 15/06/2019 | ☐ ETA ☐ NPA ☒ No | ☐ Yes ☒ No | ☒ Yes ☐ No |

Example completion if the baby starts study treatment on day 1 of life:




| | Date (dd/mm/yyyy) | Sampling: Airway sample type taken* | Sampling: Stool sample taken | IMP given today? |
|---|---|---|---|---|
| Day before study treatment | ☒ N/A | ☐ ETA ☐ NPA ☐ No[1] | ☐ Yes ☐ No[1] | |
| Day before study treatment | ☒ N/A | ☐ ETA ☐ NPA ☐ No[1] | ☐ Yes ☐ No[1] | |
| Day of study treatment 1 | 15/06/2019 | ☒ ETA ☐ NPA ☐ No | ☐ Yes ☒ No | ☒ Yes ☐ No |

- If IV antibiotics have been given, use the coded list on page two to record which were given

| I.V. Antibiotics given today? | If yes, which anti-biotics? ** | Positive blood or CSF culture today? | If positive, which sample? | If positive, date sample taken (dd/mm/yyyy) | If positive, which organism(s) |
|---|---|---|---|---|---|
| ☒ Yes ☐ No | 1 2 | ☒ Yes ☐ No | ☒ Blood ☐ CSF | 29/08/2019 | 1. *Streptococcus* 2. _____ 3. _____ |

| **Antibiotic code list | |
|---|---|
| 1. Benzylpenicillin | 8. Meropenem |
| 2. Gentamycin | 9. Teicoplanin |
| 3. Amoxicillin | 10. Piperacillin/tazobactam |
| 4. Flucloxacillin | 11. Cefotaxime |
| 5. Ceftazidime | 12. Ampicillin |
| 6. Metronidazole | 13. Clindamycin |
| 7. Vancomycin | 14. Ceftriaxone |

- Complete the form up to 21 days post start of treatment (the last sampling timepoint).

- Please transcribe data from the paper daily log to the eCRF regularly **and at least every week**
- If the baby is **transferred**, please contact the CTR. See **Guidance sheet 12a** for more details regarding preparation of a transfer.

**Transfer CRF (prior to 36 weeks PMA)**

Information to be recorded on the Transfer form should only be for the **time they spent in your unit**.

- To be completed when the baby leaves your hospital to be transferred to another hospital, prior to reaching 36 weeks PMA
- If a baby is transferred for less than 24 hours, e.g. for surgery and returned to you, there is no need to complete a separate Transfer CRF for this brief stay, instead incorporate the associated data on the one form; You will need to inform the surgical centre of the transfer so that you can collect any relevant data easily.
- When reporting cerebral ultrasounds, if there are multiple scans, enter the data for the scan closest to date of transfer with the worst abnormality
- In addition, ensure that you have confirmed the 'abnormality' or responded 'none, and ticked at least one box in both 'left' and 'right' columns.

**Outcomes at 36 Weeks PMA CRF**

To be completed at 36 weeks of PMA or at discharge if discharged home earlier, or dies. Information to be recorded on the form should only be for the **time they spent in your unit**.

- Only perform the oxygen reduction test if baby has received oxygen, and/or respiratory support for ≥ 28 days and the following:
    - the baby is not receiving mechanical ventilation (invasive and non-invasive), CPAP, or high flow oxygen therapy
    - FiO2 < 0.3, or low flow oxygen < 1.1 L/min to maintain saturations of ≥ 91%
    - In previous 24 hours, baby has not required respiratory support.
- When reporting cerebral ultrasounds, if there are multiple scans, enter the data for the scan closest to 36 weeks of postmenstrual age with the worst abnormality

- In addition, ensure that you have confirmed the 'abnormality' or responded 'none', and ticked at least one box in both 'left' and 'right' columns.
- In the event of death please send a copy of the discharge summary and, if and when available, a copy of the post-mortem examination report. This should be redacted of personal identifiers and labelled with the baby's Study ID.

**Outcomes post 36 weeks PMA CRF**

To be completed at transfer to another hospital, discharge home or if the baby dies post-36 weeks PMA. The information to be recorded on the form should only be for the **time they spent in your unit** post 36 weeks PMA.

**Adverse Reactions CRF**

- The safety reporting period will be defined as beginning at the point of randomisation, and will continue until 36 weeks' postmenstrual age, or discharge home from hospital (whichever is soonest).
- Use this form to record
    - Events which a study physician considers to be attributable to azithromycin (causality assessment: probably, definitely, almost certainly). **This is regardless of whether they meet the criteria for being 'serious'.**
- Any **unforeseen** serious adverse events, or serious adverse reactions must be recorded on **a Serious Adverse Events form**
- Please see **Guidance Sheet 8: Safety and non-compliance** for more details

**Baby withdrawal CRF**

- 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 to retention and use of the data already collected, for

data collection to continue to completion and for the oxygen reduction test to be conducted (if applicable)

- 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.

**Serious Adverse Event Report Form (SAE) CRF**

- The safety reporting period will be defined as beginning at the point of randomisation, and will continue until 36 weeks' postmenstrual age, or discharge home from hospital (whichever is soonest).
- 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 8: Safety and compliance**