Guidance Sheet 12b: Receiving a Transfer

AZTEC Azithromycin Therapy for Chronic Lung Disease
Cardiff University Prifysgol Caerdydd
Centre for Trials Research Canolfan Ymchwil Treialon

General considerations

- **Thank you** for support in ensuring that follow up of AZTEC babies is possible
- Please contact the Centre for Trial Research (CTR) (Tel: 029 2068 7990, email: Aztec@Cardiff.ac.uk) to confirm that the baby has been transferred.
- The CTR will confirm who the pre-arranged local PI is and that your site has approval to continue the AZTEC trial. If a local PI has not yet been arranged, the CTR will arrange local permission as soon as possible. Study activities should not be undertaken until permission is in place.
- Please check the Transfer Cover Sheet sent by email from the Recruiting Site to establish the status of the baby in the trial:
    - Whether the IMP should be continued (or is completed)
    - Whether the daily log should be continued (or is completed)
    - When the primary outcome assessment is due (or is completed)
- Guidance documents to support the data collection have been provided electronically to each continuing care site, however these can also be downloaded from the trial website: https://aztec-trial.uk/index.php/information-for-hospitals/, or by contacting the CTR
- Data collection is primarily eCRF-based (aside from the daily log, which is completed on paper and transcribed to the eCRF). Access and training documentation will be provided to each approved AZTEC continuing care sites. If it is preferable to use paper forms, these need to be downloaded and printed from the website, and once completed either faxed, or scanned and emailed to the CTR (Fax: 029 2251 9700, AZTEC@Cardiff.ac.uk).

Receiving a baby who has not finished the AZTEC intervention period (RECRUITING SITES ONLY)

- Please follow the procedures are per **Guidance Sheet 5a: Intervention,** and **sheet 5b: IMP administration**
    - The IMP should be prescribed in the infant's drugs chart by a clinician/ANNP
    - Please continue to complete the Daily Log

End of intervention procedures (RECRUITING SITES ONLY)

- At completion of the intervention (after 10 days), ensure the Daily Log is completed accordingly

- Follow the procedures as outlined in **Guidance sheet 9: IMP supply and accountability** to complete the reconciliation process for the baby's treatment pack. Following permission from the CTR, the pack can be disposed.

Safety reporting (ALL SITES)

- Safety reporting should continue until 36 weeks postmenstrual age
  - Please refer to Guidance Sheet 8: Safety and non-compliances for detailed guidance
  - Please report any events, which in the opinion of the local PI, are associated with azithromycin, using the **Adverse Reactions form**
  - A list of foreseeable SAEs is included in **Guidance sheet 8**- any SAEs that are not included in the list of foreseeable SAEs must be reported to the CTR immediately, but at least within 24 hours of the research site becoming aware of the event
  - A paper SAE Report Form must be completed and faxed/emailed to the CTR Safety team (Fax: 020 3043 2376 Email: CTR-Safety@Cardiff.ac.uk)
  - Please telephone the Safety team (029 2068 7462) to confirm receipt
  - Further information received must be detailed on a new SAE form (contact AZTEC@Cardiff.ac.uk) and faxed/emailed to the CTR Safety team
  - The outcome of events "Resolving" or "Not Resolved" must be followed up until the status of the SAE changes
  - Please retain the **original SAE report form(s)** for your records.

Outcome assessment and data collection up to 36 weeks PMA (or discharge of death if sooner)

- Ensure the remainder of the **Daily Log** has been completed (up to 21 days post-commencement of the intervention)
- At 36 weeks PMA (or discharge home if sooner), the **Outcomes at 36 weeks PMA form** should be completed.

****An oxygen reduction test should also be conducted if required and results recorded on this form****

For more information please refer to **Guidance Sheet 10: Oxygen reduction test**

- Update the **Adverse Reactions form** with any new events (the final time new events are reported).

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- If completing the forms on paper please fax, or scan and email the **Daily Log** (if applicable), **Outcomes at 36 weeks PMA form and Adverse Reactions form** (if applicable) to the CTR, unless you have been instructed otherwise. (Fax: 029 2251 9700, AZTEC@Cardiff.ac.uk)

Data collection after 36 weeks PMA

- When the baby is discharged home (transfers, or dies), please complete the **Outcomes post 36 weeks PMA form**
- Update the **Adverse reactions form** for the final time, reviewing any ongoing events (if persisting- record "ongoing at final follow up")
- If completing the forms on paper please fax, or scan and email the **Outcomes post 36 weeks PMA form and Adverse Reactions form** (if applicable) to the CTR, unless you have been instructed otherwise (Fax: 029 2251 9700, AZTEC@Cardiff.ac.uk).

Withdrawal

- Staff can report withdrawal of a baby at any time if parents wish or if it is deemed necessary for baby's clinical care, by completing the **Withdrawal form**
- The time and date at which the baby was withdrawn should be documented in the baby's medical notes with any other necessary information
- If completing the forms on paper please scan and email the **Outcomes post 36 weeks PMA form and Adverse Reactions form** (if applicable) to the CTR, unless you have been instructed otherwise
- Please fax/email the form to the CTR (Fax: 029 2251 9700, AZTEC@Cardiff.ac.uk)
- Place the original in the baby's medical notes.

Unblinding

- A baby should only be unblinding if it is a genuine emergency AND knowledge of the treatment allocation is necessary to guide the clinical management of the participant. To unblind a baby please contact the recruiting centre, who will unmask the baby and inform you of arm allocation.