Guidance Sheet 9:
IMP Supply and Accountability

AZTEC
Azithromycin Therapy for Chronic Lung Disease

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Centre for Trials Research
Canolfan Ymchwil Treialon

Receipt of trial intervention

- The AZTEC treatment packs are manufactured and supplied by the Saint Mary's Pharmaceutical Unit (SMPU). All deliveries of trial packs will be received by the hospital pharmacy.
- Upon receipt of a delivery, pharmacy should check the delivery for any damage or inconsistencies against the dispatch information enclosed on the **AZTEC drug order form**.
- Section 4 of the drug order form should be completed by pharmacy and returned to the CTR via fax/email and to SMPU. Any issues should be reported to the CTR using the **Drug Quality Form.**
- Each AZTEC IMP treatment pack should be booked in on the **Treatment Pack Accountability Log**.
- Stock levels will be monitored by Sortition, which will instruct the CTR to initiate resupply from SMPU.

Maintaining stock of the trial intervention on the neonatal unit

- To enable prompt randomisation and initiation of trial treatment, a proportion of packs (ideally all) should be transferred from pharmacy for storage on the neonatal unit.
- The **Treatment pack tracking log** will be used to record receipt on the neonatal unit, allocation to baby, return to pharmacy, and transfers to other centres.

Receipt from pharmacy/transfer in			Randomisation			Return to pharmacy		Transfer	
Date received (dd/mm/yy)	Pack ID	Received by (initials)	Date of Pack Allocation (dd/mm/yy)	Patient Study ID number	Recorded by (initials)	Date returned to pharmacy (dd/mm/yy)	Returned by (initials)	Date pack transferred with baby (dd/mm/yy)	Transfer prepared by (initials)
01/07/19	1045	AB	04/07/19	AZ1101	AB	17/07/19	AB		

- When a baby is randomised (see **Guidance Sheet 4: Randomisation)**, the randomisation website will allocate a Study ID and a Pack ID to the baby and populate a Pack Allocation Form. This should be printed out and kept with the baby's notes. Nominated site staff, and the clinical trials pharmacy, will receive an email notification of randomisation. The allocated study ID should be recorded on the **Treatment pack tracking log** next to the appropriate Pack ID

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Missing treatment packs

- In the event an allocated treatment pack cannot be found on the neonatal unit, check with Pharmacy to confirm it has been received. If the allocated treatment pack still cannot be located contact the Trial Manager to report the issue (LoweJ3@Cardiff.ac.uk, 029 2068 7990)

Accountability

- It is essential that the movement and allocation of AZTEC packs are carried out and recorded in an accurate and timely fashion to allow effective control of stock by Sortition.
- **Guidance Sheet 5a: Intervention** has further information for the neonatal study team on how to maintain an accurate accountability record
- Once the intervention is complete, unused vials and the external treatment pack box must be reconciled prior to being disposed. This activity will be performed by the research nurse or pharmacy team (as arranged locally) using the **Treatment Pack Reconciliation Form** (Completing section A). This is then emailed to the CTR team (AZTEC@Cardiff.ac.uk), with the site clinical trials pharmacy copied in.
- The Trial Manager/Data Manager (based at CTR) will review the **Treatment Pack Reconciliation Form**. Where accountability is demonstrated CTR staff will complete section B of the log. The form will be returned to site as authorisation to dispose the outer packaging and any unused vials from the relevant IMP pack.
- Finally, the site will complete and return section C to confirm disposal as per local practice. The fully completed log should then be faxed/emailed to CTR and the original stored in the Investigator Site File/Pharmacy Folder.
- Following expiry of a batch, or at the end of the trial, any **unused** treatment packs stored on the NICU will be returned to pharmacy. Alongside any stock which has not been issued, and on permission with the Trial Manager at the CTR, this stock may be disposed. Disposal will be recorded on the **Treatment pack accountability log**.

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Transfers

- Provision has been made for IMP to be transferred with the baby if they are being moved to an AZTEC recruiting centre, or a site where approvals for continuation of IMP administration are in place. The Trial Manager will notify each recruiting site of arrangements in their local networks during site initiation.
- Pharmacy must be made aware of any transfers that take place during the intervention period.
- If the IMP is being transferred, the treatment pack will be re-sealed using an **IMP Transfer Sticker**, located in the site's document box.

- More detail on transfers is given in **Guidance sheet 12a: Preparing a Transfer.** Final reconciliation of the IMP will then be performed at the receiving site.
- The receiving site will take responsibility for reconciliation and destruction of any packaging and unused IMP.

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