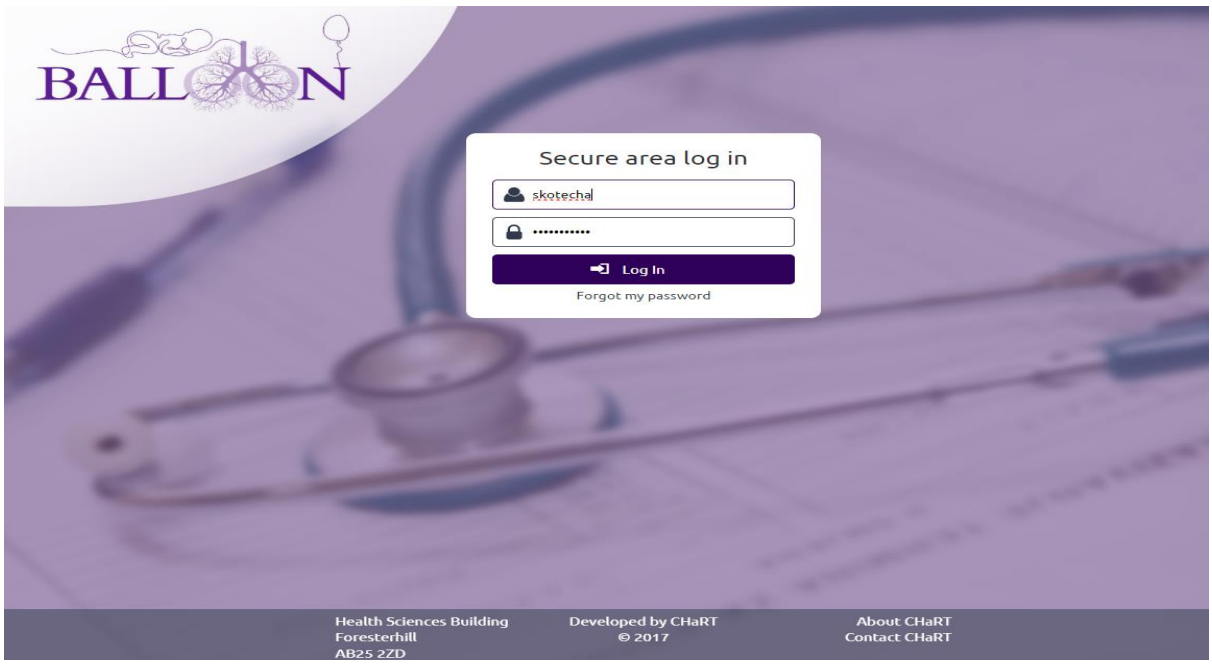
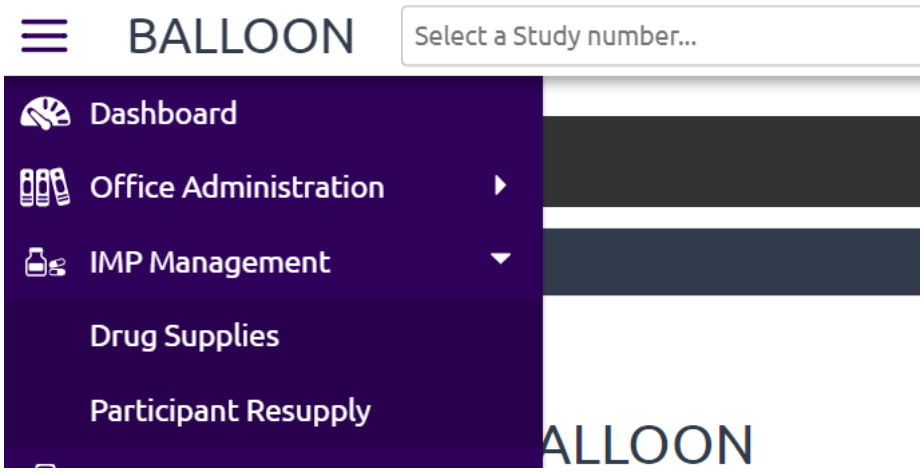
**Guidance Sheet 9:**

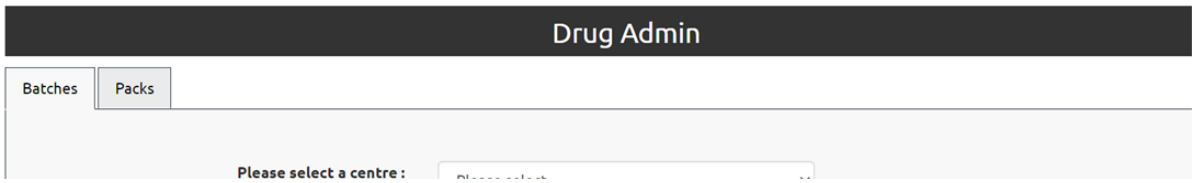
**IMP Supply & Accountability**

## Receipt of trial intervention

- The BALLOON treatment packs are supplied by the Saint Mary's Pharmaceutical Unit (SMPU). All deliveries of trial packs will be received by the hospital pharmacy.
- Each treatment pack contains 5 boxes each containing a pair of sprays (10 sprays total), sufficient for the treatment period, plus a "back up" pair.
- BALLOON IMP requires storage in a refrigerator (2-8°C). Short temperature deviations e.g. during transport are acceptable.
- Pharmacies will be provided with access to the BALLOON IMP management system as part of the site activation process:
  https://w3.abdn.ac.uk/hsru/BALLOON/Login/Login.aspx
- Upon receipt of a delivery, the **online BALLOON IMP receipt form** should be completed by pharmacy noting any issues with individual packs . Any issues should be further reported to the CTR using the **Drug Quality Form** (located in the pharmacy site file).
- Log into CHaRT
- 

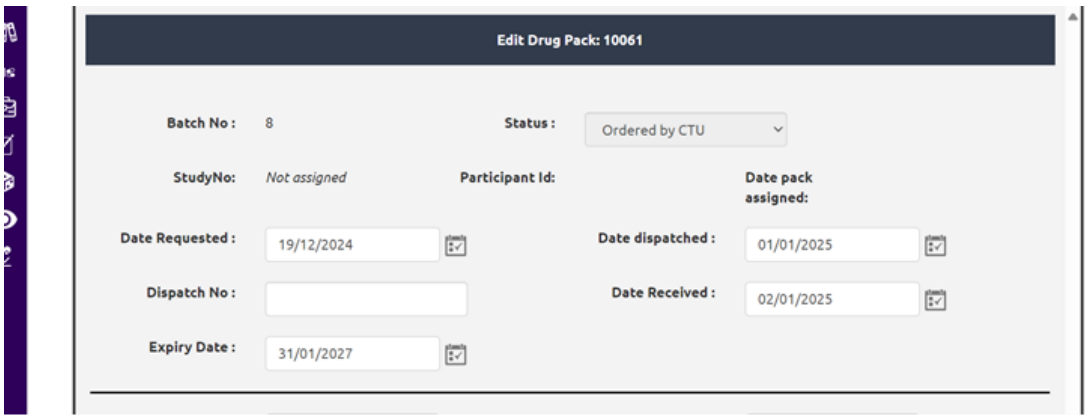
- Click on the 3 lines and then IMP management and then drug supplies

- 

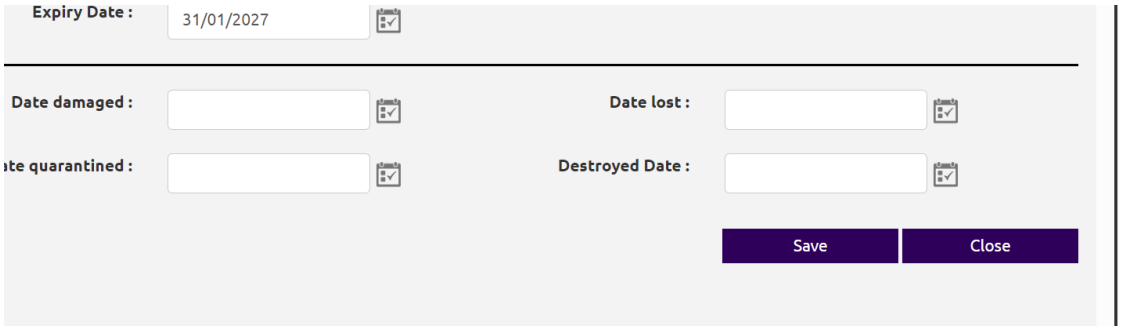
- Click on packs
- 

- Click on the pen at the end of the line of the pack number you want to receipt.
- 

| Pack No. | Centre | Batch No | Date Requested | Date Dispatched | Dispatch No | Date Received | Expiry Date | Destroyed Date | Study No | Date assigned | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 10061 | CTR DM testing (16) | 8 | 19/12/2024 | | | | 31/01/2027 | | | | Ordered by CTU |

- Enter the date received
- 

- Click save




- Once receipted online, the packs will automatically be made available for use in randomisation.
- Stock levels will be monitored by the IMP management system, which will instruct the CTR to initiate resupply from SMPU.
- When a baby is randomised (see **Guidance Sheet 3: Randomisation)**, the randomisation website will allocate a CHaRT Study ID and a Pack ID to the baby. The research nurse or PI will complete a prescription for the baby, including the pack ID. Please note the baby will also be given a PID by REDCap which will be used rather than the CHaRT PID.
- As part of the initial dispensing process, a **BALLOON Participant level accountability log** will be started so that individual dispensing against the allocated pack can be recorded. Please note, it is anticipated that IMP will require dispensing on 4 occasions, every 3 months approximately.
- An example of a completed **Participant level accountability log** is provided with additional instructions**.**

## Missing treatment packs

- In the event an allocated treatment pack cannot be found, check to confirm it has been received. If the allocated treatment pack still cannot be located contact the Trial Manager to report the issue (kotechasj@cardiff.ac.uk)

## Accountability

- It is essential that accountability of BALLOON packs is carried out and recorded in an accurate and timely fashion to allow effective control of stock by the IMP management system.
- Following each 3 monthly dispensing it is not anticipated that used IMP will be returned to pharmacy. The research nurses will collect the returned sprays from the parents/guardians approximately every 3 months and weigh them to obtain data on adherence. Rather, the research nurses will record on the study database that the sprays have been returned or the reason for the sprays not being returned. They will also record the disposal of the sprays on the study database.
- Once the intervention is complete for each individual participant, the treatment pack must undergo a final reconciliation.
- Please note, the same process is followed in the event the site team informs CTR of a participant withdrawal from IMP.
- The completed **Participant level accountability log** for the baby should be emailed to the CTR team (BALLOON@cardiff.ac.uk) once the baby has completed the full course of treatment at 1 year corrected age (please note this is not a year after the baby's date of birth).
- The Trial Manager/Data Manager (based at CTR) will review the **Participant level accountability log** for the baby and the database entries. Where accountability is demonstrated CTR staff will authorise pharmacy to dispose of any undispensed sprays and the outer packaging.
- Finally, the disposal of any unused sprays and the outer packaging will be recorded on the **Participant level accountability log** for the baby and the form will be signed by the **IMP consignee** (person responsible for overall BALLOON IMP management within the site pharmacy). The fully completed log should then be emailed to CTR (BALLOON@cardiff.ac.uk) and the original stored in the Investigator Site File/Pharmacy Folder.

- Following expiry of a batch, or at the end of the trial, any stock which has not been allocated, and on permission with the Trial Manager at the CTR, may be disposed. Disposal of entire packs will be recorded on a **Site Participant level accountability log**. Please see the example log provided on how this should be documented.