

Guidance Sheet 3:

Randomisation



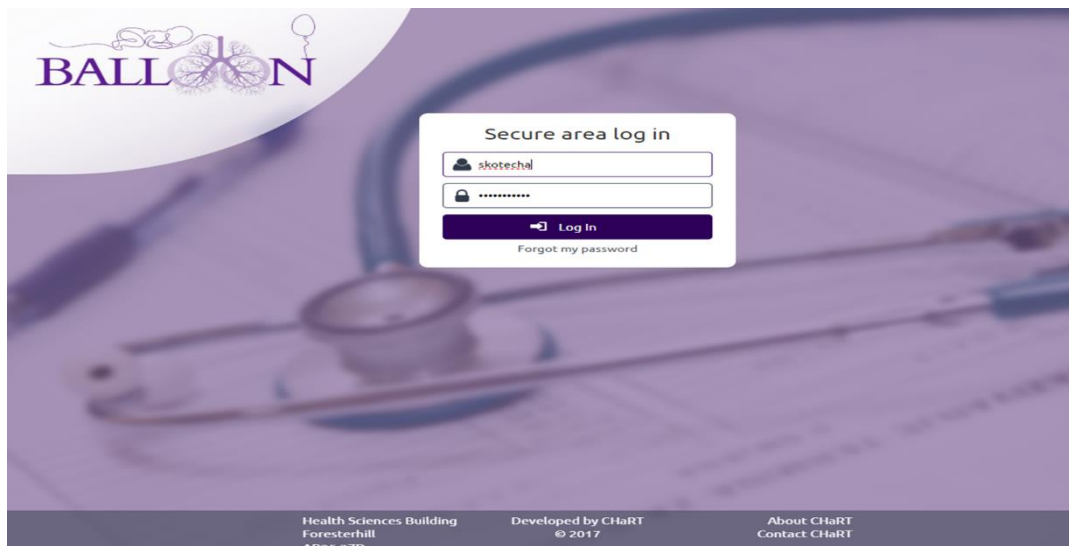
Randomisation

Randomisation must be **carried out** prior to administering or prescribing the IMP

- Confirm that written informed consent from the parents has been taken by someone who has received suitable training and is named on the Delegation Log.
- Confirm the baby still meets all of the eligibility criteria and ensure a medically qualified person (who is delegated this duty on the Delegation Log) has documented clinical assessment of eligibility within the medical notes.

Steps to follow

1. Access the study randomisation program (CHaRT)
<https://w3.abdn.ac.uk/hsru/BALLOON/Login/login.aspx>



2. Login using your individual credentials as assigned by the CTR team

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3. Click on the three lines in the top left corner and then data entry

The screenshot shows the BALLOON web application interface. On the left is a dark purple navigation menu with white icons and text. The menu items are: Dashboard, Office Administration, IMP Management, Audit Log, Data Entry (highlighted with a white arrow), Eligibility, Consent, Randomisation, Unblinding, and Reports. At the top of the menu is a hamburger menu icon. To the right of the menu is the main content area. At the top of this area is a header bar with the BALLOON logo, a search bar labeled 'Select a Study number...', and a 'GO' button. Below the header bar is the 'Eligible Form' section. This section contains two tabs: 'FILTER EXISTING RECORDS' and 'ADD NEW RECORD'. Below the tabs are two dropdown menus: 'Centre : All' and 'Study No : All'. To the right of the 'Study No' dropdown is an 'or' button and a text input field. Below these inputs is a table with a dark purple header row labeled 'Study Number'. The table contains four rows of data, each with a pencil icon in the first column and a study number in the second column: 99001, 99002, 99003, and 99004.

4. Click on eligibility and then add new record
Select your centre and click add new, this will add a new participant and generate a new CHaRT PID when you say OK to proceed.

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Trials Research
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5. The following screen will open, please complete and then save data.

Eligibility		StudyNo : 99036
Baby's Date of Birth	<input type="text"/>	
Inclusion Criteria: Please exclude from BALLOON if the answer is 'NO' to any of the following:		
Was the baby's gestational age at birth $\leq 29+6$ weeks or less? (including infants born as one of a multiple birth)	<input type="text" value="Please select..."/>	
In the opinion of the PI, is follow-up likely to be feasible (i.e routine outpatient appointments will be at the recruiting site, locality of baby's residence so follow up to one year corrected age is possible.)	<input type="text" value="Please select..."/>	
Survival to one year corrected age anticipated?	<input type="text" value="Please select..."/>	
Exclusion Criteria: Please exclude from BALLOON if the answer is 'YES' to any of the following:		
Is there a presence of major surgical or congenital abnormality? (not including patent ductus arteriosus or patent foramen ovale)	<input type="text" value="Please select..."/>	
Is there a known contraindication of BACTEK as specified in the summary of characteristics of the product?	<input type="text" value="Please select..."/>	
Is the baby participating in another interventional trial that precludes participation in BALLOON?	<input type="text" value="Please select..."/>	
Does the baby have any primary immune deficiencies?	<input type="text" value="Please select..."/>	
Is the baby eligible for BALLOON?	<input type="text" value="Please select..."/>	
Name of doctor confirming eligibility	<input type="text"/>	
Eligibility must be confirmed by a medically qualified doctor. If this form has been completed by other healthcare professional, please confirm decision has been made by a medically qualified doctor (must be yes)	<input type="text" value="Please select..."/>	
Back to list	Save data	

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- Click on the three lines in the top left corner and then consent, please complete the form and then save data.

The screenshot shows the BALLOON web application interface. At the top, there is a navigation bar with the BALLOON logo, a dropdown menu showing '99036', and a 'GO' button. On the left, a sidebar menu lists various options: Dashboard, Office Administration, IMP Management, Audit Log, Data Entry, Eligibility, Consent, and Randomisation. The main content area is titled 'Consent' and displays 'StudyNo : 99036'. It contains three form fields: 'Has the parent(s) consented to all mandatory aspects of the trial?' with a dropdown menu, 'Date of consent given' with a date picker, and 'Name of the person collecting consent' with a text input field. A 'Save data' button is located at the bottom right of the form.

- Click on the three lines in the top left corner and then randomisation, please complete the form. The Date of birth and eligibility and consent answers will be populated from the previous forms. Click review data, please check it carefully and then click randomise

The screenshot shows the BALLOON web application interface for the 'New Randomisation' form. The top navigation bar and sidebar menu are identical to the previous screenshot. The main content area is titled 'New Randomisation' and displays 'StudyNo : 99036'. It contains several form fields: 'Baby's date of birth' with a date picker, 'Gestational Age at Birth' with a dropdown menu, 'Has the baby received anti-RSV prophylaxis medication?' with a dropdown menu, 'Is the baby a singleton or multiple?' with a dropdown menu, 'If multiple, is this the first infant enrolled?' with a dropdown menu, 'Please list the BALLOON Study ID of the first randomised infant' with a text input field, 'Has the participant been confirmed as eligible?' with a dropdown menu, and 'Has informed consent been obtained?' with a dropdown menu. A 'Review Data>' button is located at the bottom right of the form.

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8. You will see the results and will also get an email with the randomisation results. Please print the email for the baby's notes

Randomisation Results	
StudyNo	99036
Pack	10006

9. If you are randomising a baby from a multiple birth you will need to enter the mother's date of birth.

If you are randomising a baby from a multiple birth and it is the second or third baby to be randomised you will need the CHaRT ID number of the first baby to be randomised

10. If the correct Pack ID cannot be located, or the package is open, please report this to the trial manager, kotechasj@cardiff.ac.uk

11. Finally, please ensure the following:

- CHaRT ID will need to be recorded in the REDCap database. Please put the PID generated by REDCap on the consent form
- Screening log updated with the PID generated by REDCap

12. If CHaRT cannot be accessed please email BALLOON@cardiff.ac.uk