

Guidance Sheet 6a:

DATA ENTRY GUIDANCE WEB RANDOMISATION



Database Access

BALLOON will be using an online database for data collection located here

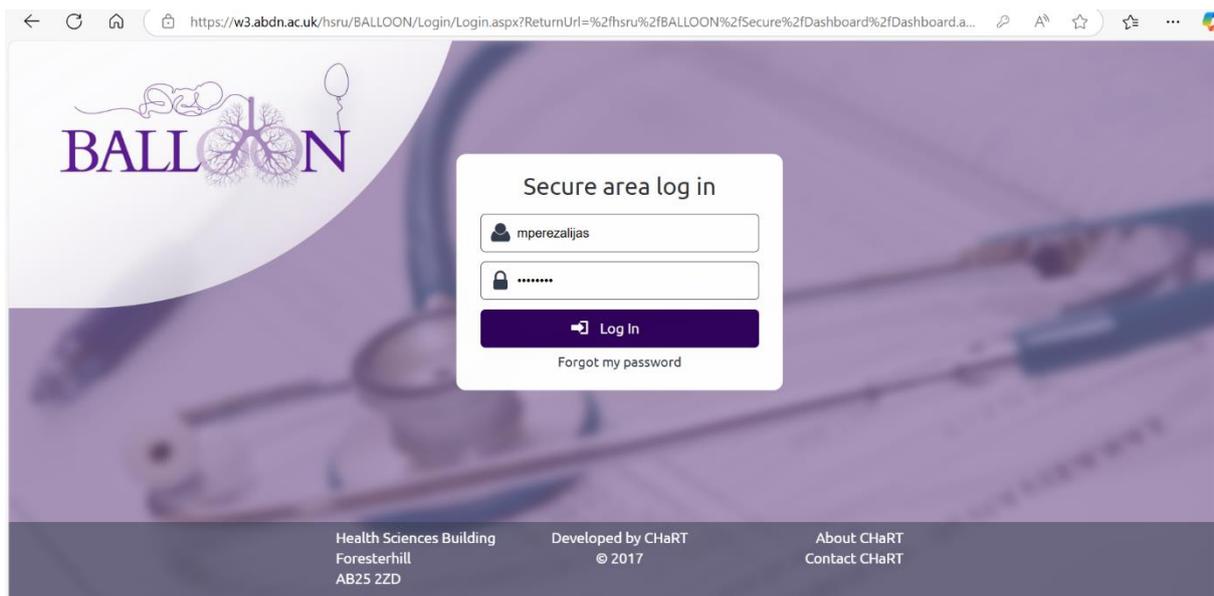
<https://w3.abdn.ac.uk/hsru/BALLOON/Secure/Dashboard/Dashboard.aspx>

Research nurses will be given access to the database on receipt of –

- GCP certificate
- Current CV
- Signed delegation log
- Signed training log

Logging onto the Web Randomisation

Once you have been registered to the web randomisation database, you will receive an email with your username and password. Use your log in username, not your email address.



Adding a new user

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Please contact the CTR team at BALLOON@cardiff.ac.uk to add a user to the database. Please specify the role (pharmacy or research team) as you will be granted different user rights depending on your role.

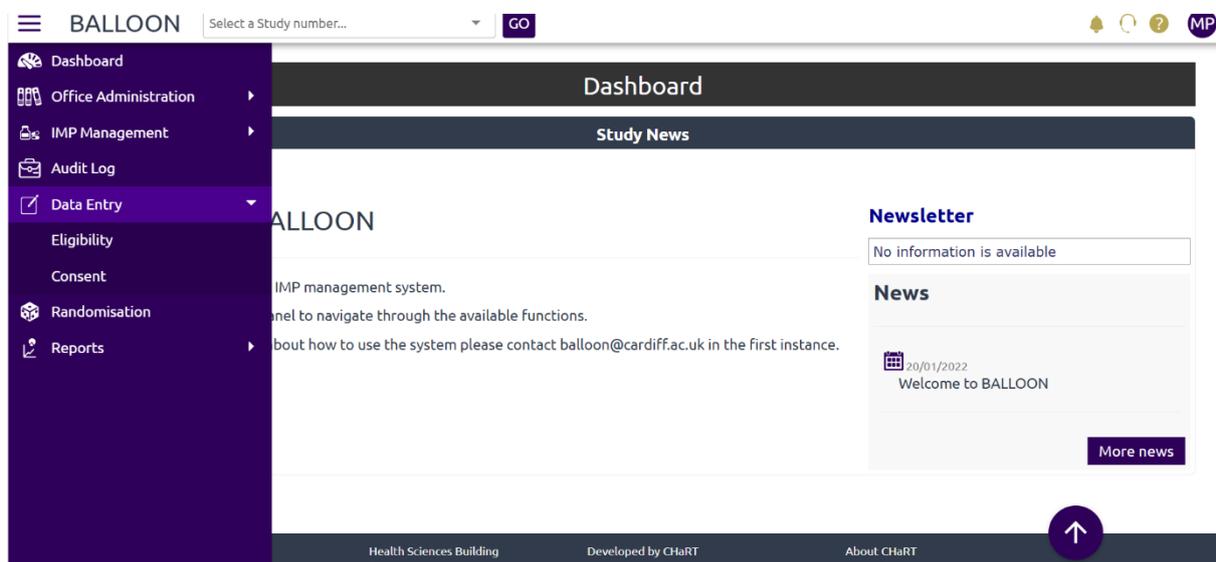
Testing

You will be given access to the test centre. Use the test centre as your site to randomise and receipt the IMP. Once the testing is done, access will be removed from the test centre to avoid any real data input and access will be given to your centre.

Randomising a Participant

Before you can randomise a participant, please complete the consent and eligibility forms. You won't be able to randomise a participant without completing those forms.

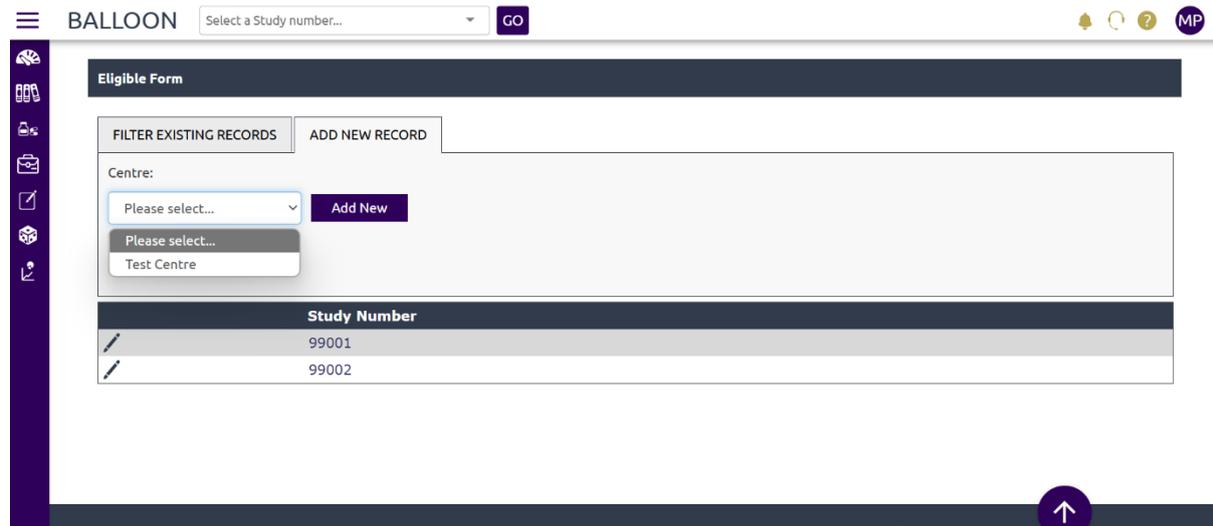
To begin, go onto the left side menu, select data entry then select eligibility.



Here you can filter existing records or add new record. Select ADD NEW RECORD and choose your centre from the dropdown list. Then click add new. A pop up message will appear asking if you wish to proceed creating a new record, select OK.

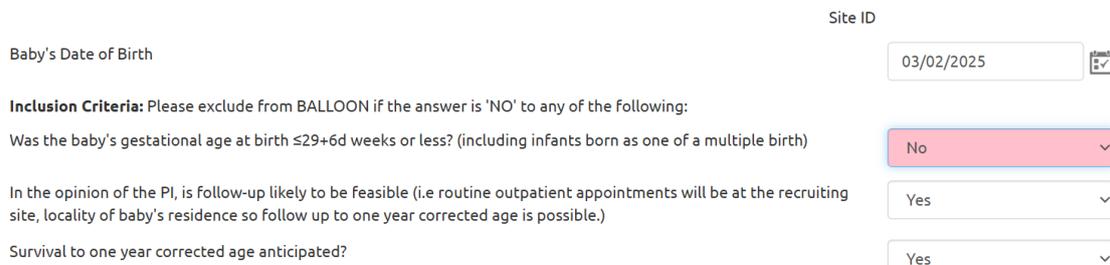
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The screenshot shows the BALLOON web application interface. At the top, there is a navigation bar with the BALLOON logo, a search bar for study numbers, and a GO button. Below the navigation bar is a sidebar with various icons. The main content area is titled 'Eligible Form' and contains a 'FILTER EXISTING RECORDS' and 'ADD NEW RECORD' section. The 'ADD NEW RECORD' section has a 'Centre:' dropdown menu with 'Please select...' and 'Test Centre' options, and an 'Add New' button. Below this is a table with two columns: 'Study Number' and '99001', '99002'.

Complete the eligibility form. If the participant does not meet the inclusion/exclusion criteria, the database will warn you, and the field will appear red.



The screenshot shows the eligibility form fields. The 'Site ID' field is set to '03/02/2025'. The 'Baby's Date of Birth' field is set to '03/02/2025'. The 'Inclusion Criteria' section includes the following questions and answers:

- Was the baby's gestational age at birth $\leq 29+6d$ weeks or less? (including infants born as one of a multiple birth) **No**
- 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.) **Yes**
- Survival to one year corrected age anticipated? **Yes**

Once you have completed the eligibility form, click save data at the bottom of the page. You will remain on the page and a notification will appear at the top to notify you the data has been submitted successfully.

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BALLOON 

Eligibility StudyNo : 99003

✓ The data has been submitted successfully.

Baby's Date of Birth

Site ID

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)

Next, go onto the left menu again and select data entry then consent.

BALLOON 

Consent StudyNo : 99003

Has the parent(s) consented to all mandatory aspects of the trial?

Date of consent given

Name of the person collecting consent



Health Sciences Building
Foresterhill
AB25 2ZD

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Complete the consent form and save data. Again, a notification will pop up at the top of the page to let you know you have saved the data successfully and you will remain on the page.

Next, go to the left menu and select Randomisation.

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Complete the randomisation form then select review data. The data review page will open, check all the data is correct then select Randomise.

Field	Value
StudyNo	99003
Baby's date of birth	03/02/2025
Gestational Age at Birth	<28 weeks
Is the baby on or are there plans for the baby to receive anti-RSV prophylaxis medication?	Yes
Is the baby a singleton or multiple?	Multiple
If multiple, mother's date of birth	27/08/1990
If multiple, is this the first infant enrolled?	Yes
Please list the BALLOON Study ID of the first randomised infant	Not Applicable
Has the participant been confirmed as eligible?	True
Has informed consent been obtained?	True

< Back to data Randomise

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Once you have randomised a participant you will receive the BALLOON ID (StudyNo) from the web randomisation and the Pack ID.

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The screenshot shows the BALLOON web application interface. At the top, there is a navigation bar with the BALLOON logo, a search bar containing 'Select a Study number...', and a 'GO' button. On the right side of the navigation bar, there are icons for a bell, a speech bubble, a question mark, and a user profile labeled 'MP'. Below the navigation bar is a table titled 'Randomisation Results'. The table has two columns: 'StudyNo' and 'Pack'. The first row shows 'StudyNo' as 99003 and 'Pack' as 10004. At the bottom of the page, there is a footer with contact information for the Health Sciences Building, Foresterhil, AB25 2ZD, and a note that it was developed by CHaRT in 2017. There is also a 'Back to top' button on the right side of the footer.

Randomisation Results	
StudyNo	99003
Pack	10004

You will need both numbers to complete the ADDPID/Trial Pack Allocation form on REDCap.

Please note you won't be able to randomise a participant if there are insufficient packs at site.

Randomising a Baby from a Multiple Birth

To randomise a baby from a multiple birth, start by randomising the first baby. Repeat the process shown above by completing the eligibility and consent form. On the randomisation form, to the *question 'is the baby singleton or multiple?'* Select multiple and add the mother's date of birth. To the question *'If multiple, is this the first infant enrolled?'* select yes. Then continue with the randomisation.

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The screenshot shows the BALLOON web application interface. At the top, there is a navigation bar with the BALLOON logo, a search bar containing '99003', and a 'GO' button. On the right side of the navigation bar, there are icons for notifications, help, and a user profile labeled 'MP'. Below the navigation bar is a sidebar menu with various icons. The main content area is titled 'New Randomisation' and contains a form with the following fields:

StudyNo	99003
Baby's date of birth	03/02/2025
Gestational Age at Birth	<28 weeks
Is the baby on or are there plans for the baby to receive anti-RSV prophylaxis medication?	Yes
Is the baby a singleton or multiple?	Multiple
If multiple, mother's date of birth	27/08/1990
If multiple, is this the first infant enrolled?	Yes
Please list the BALLOON Study ID of the first randomised infant	Not Applicable
Has the participant been confirmed as eligible?	<input checked="" type="checkbox"/>
Has informed consent been obtained?	<input checked="" type="checkbox"/>

At the bottom right of the form, there is a 'Review Data>' button.

Once you are at the randomisation results, remember to save the BALLOON ID (StudyNo) and Pack ID. You will need the ID to link the rest of the babies to the first one randomised.

Next, add a new participant and complete the eligibility and consent forms. On the randomisation form, again, answer multiple, enter the mother's date of birth but this time, when asked '*if multiple, is this the first infant enrolled?*' select no. Then select the participant ID from the previously randomised infant from the list. If the mother's date of birth does not match the first randomised baby, then an error will occur, and you won't be able to randomise.

You can repeat the process to add more babies but always use the first randomised baby's ID.

IMP Management

Sites will receipt the IMP by going onto the left menu and selecting IMP management then drug supplies.

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On the drug admin page, select Packs then go onto assigned to centre and select your centre from the list.

<input type="checkbox"/>	Pack No.	Centre	Batch No.	Date Requested	Date Dispatched	Dispatch No.	Date Received	Expiry Date	Destroyed Date	Study No.	Date assigned	Status
<input type="checkbox"/>	10001	Test Centre (99)	1	30/01/2025				01/04/2026				Ordered by CTU

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You can check the status of the pack on the right-side column. Select a pack marked as 'Dispatched to Site'. Please note, you can only receipt pack that have been marked as dispatched.

Study number	Centre	Batch No	Date Requested	Date Dispatched	Date Received	Expiry Date	Status	Action
10006	Centre (99)	2	30/01/2025	30/01/2025	30/01/2025	01/04/2026	Received by Site	
10007	Centre (99)	2	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	
10008	Centre (99)	2	30/01/2025	30/01/2025	30/01/2025	01/04/2026	Received by Site	
10009	Centre (99)	3	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	
10010	Centre (99)	3	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	
10011	Centre (99)	3	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	
10012	Centre (99)	3	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	
10013	Centre (99)	3	30/01/2025	30/01/2025		01/04/2026	Dispatched to Site	

To select a pack, click on the pencil icon, the edit drug pack page will open. Enter the date received then select save. You will remain on the page and a notification will appear at the top of the page with the message 'Update was successful'.

Edit Drug Pack: 10020

Batch No : 3 Status : Dispatched to Site

StudyNo: Not assigned Participant Id: Date pack assigned:

Date Requested : 30/01/2025 Date dispatched : 30/01/2025

Dispatch No : 3 Date Received :

Expiry Date : 01/04/2026

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Alternatively, if you want to receipt a block of packs, click on the squares on the left-side column and go to the bottom of the page and select *'Mark as received'*. Please note only a CTR member can action a pack as expired, destroyed, quarantined or lost.

<input type="checkbox"/>	10018	Test Centre (99)	3	30/01/2025	30/01/2025	3	01/04/2026	Dispatched to Site	
<input type="checkbox"/>	10019	Test Centre (99)	3	30/01/2025	30/01/2025	3	01/04/2026	Dispatched to Site	
<input type="checkbox"/>	10020	Test Centre (99)	3	30/01/2025	30/01/2025	3	01/04/2026	Dispatched to Site	

1 | 2

Mark as Dispatched **Mark as Received** Mark as Damaged Update Expiry Date Mark as Destroyed Mark as Quarantined Mark as Lost

You will be directed to the mark as received page. Check the pack ID are correct and enter the date then select proceed.

☰ BALLOON Select a Study number... GO

Mark as Received

You have selected following packs:
10025,10026,10027

Received Date :

Proceed Close

A notification will appear at the top of the page with a message *'Packs have had their Received Date updated successfully'* and you will remain on the page.



Pack Management

If you are running out of stock or a pack is lost, quarantined, damaged, expired or destroyed, please contact the CTR team at BALLOON@cardiff.ac.uk or the CTR DM at perez-alijasm@cardiff.ac.uk. You can check the pack status on the drug admin page.

☰ BALLOON

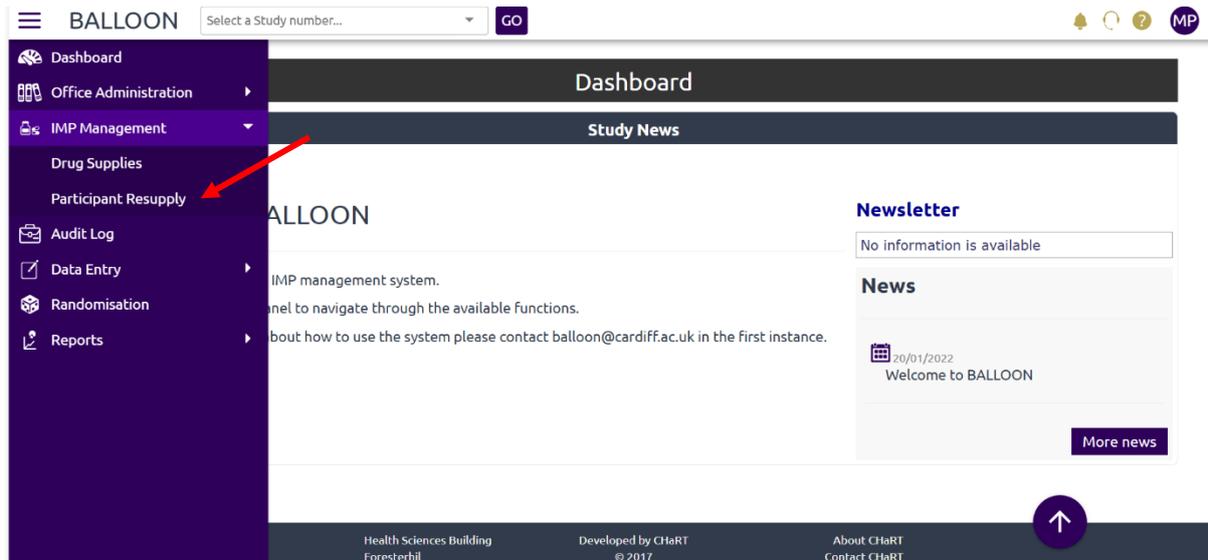
Pack No.	Centre	Batch No	Date Requested	Date Dispatched	Dispatch No	Date Received	Expiry Date	Destroyed Date	Study No	Date assigned	Status
<input type="checkbox"/>	Test Centre (99)	1	30/01/2025				01/04/2026				Ordered by CTU
<input type="checkbox"/>	Test Centre (99)	1	30/01/2025				01/04/2026				Ordered by CTU
<input type="checkbox"/>	Test Centre (99)	1	30/01/2025				01/04/2026				Ordered by CTU
<input checked="" type="checkbox"/>	Test Centre (99)	2	30/01/2025	30/01/2025		30/01/2025	01/04/2026		99003	03/02/2025	Allocated
<input checked="" type="checkbox"/>	Test Centre (99)	1	30/01/2025	30/01/2025		30/01/2025	01/04/2026		99002	30/01/2025	Allocated
<input type="checkbox"/>	Test Centre (99)	2	30/01/2025	30/01/2025		30/01/2025	01/04/2026				Received by Site
<input type="checkbox"/>	Test Centre (99)	2	30/01/2025	30/01/2025			01/04/2026				Dispatched to Site

Resupply Pack

All boxes have 2 spare sprays (the equivalent of one treatment for 3 months). If the sprays are damaged or lost by sites or the participant after a pack has been allocated, you can allocate a new pack. To resupply a pack, go to the left menu, select IMP Management then select Participant Resupply.

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You will be directed to the participant resupply. Select the participant from the list, the existing pack ID will be filled automatically. Check you are resupplying the correct participant. Then, select a reason for resupplying.

