



Database Access

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

<https://redcap.ctr.cardiff.ac.uk/redcap/>

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

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

Logging onto REDCap

Enter the username and password.

A screenshot of a web browser showing the REDCap login page. The browser address bar shows 'https://redcap.ctr.cardiff.ac.uk/redcap/'. The page has the REDCap logo and a 'Log In' heading. Below the heading is a message: 'Please log in with your user name and password. If you are having trouble logging in, please contact CTR.TS.' There are two input fields: 'Username:' with the value 'mcbmp1' and 'Password:' with a masked password '.....'. Below these fields is a 'Log In' button and a link for 'Forgot your password?'. At the bottom, there is a 'Welcome to REDCap!' section with introductory text and a 'REDCap Features' section with three bullet points: 'Build online surveys and databases quickly and securely in your browser', 'Fast and flexible', and 'Advanced instrument design features'.

Testing



You will be given access to the BALLOON database and the BALLOON testing database. Once the testing is done, access will be removed from the testing database to avoid any real data input.

Adding A New Participant

Once logged in, you can then add a new trial participant as follows –

The screenshot shows the REDCap interface for the BALLOON project (PID 324). The left sidebar contains a navigation menu with the following sections:

- Logged in as mcbmp1 | Log out
- My Projects
- REDCap Messenger
- Contact REDCap administrator
- Project Home and Design
 - Project Home
 - Project Setup
 - Designer
 - Dictionary
 - Codebook
 - Project status: Development
- Data Collection
 - Record Status Dashboard
 - Add / Edit Records
- Applications
 - Project Dashboards
 - Alerts & Notifications
 - Multi-Language Management
 - Calendar
 - Data Exports, Reports, and Stats
 - Data Import Tool
 - Data Comparison Tool
 - Logging and Email Logging

The main content area displays project information and three tables:

- Current Users (2)**: A table with columns 'User' and 'Expires'. Two users are listed, both with 'never' in the 'Expires' column.
- Project Statistics**: A table with two rows: 'Records in project' and 'Most recent activity' (15-10-2024 10:27), and 'Space usage for docs' (0.02 MB).
- Upcoming Calendar Events (next 7 days)**: A table with columns 'Time', 'Date', and 'Description'. It shows 'No upcoming events'.

You can check other records or add a new record, click add new record

Guidance Sheet 6c:DATA

ENTRY GUIDANCE REDCAP



Total records: 7

Choose an existing Participant ID	-- select record -- ▾
+ Add new record	

Data Search

Choose a field to search (excludes multiple choice fields)	All fields ▾
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	<input type="text"/>

Data Entry

Once the participant has been entered into the system, data entry of the forms can begin by clicking the coloured button on the relevant one from the list.

The screenshot shows the REDCap interface for a participant. The left sidebar contains navigation options like 'My Projects', 'Project Home and Design', 'Data Collection', and 'Applications'. The main content area is titled 'BALLOON PID 324' and shows a 'Record Home Page' with a table of data collection instruments and their status. A legend explains the status icons: red for Incomplete, yellow for Unverified, green for Complete, and grey for Incomplete (no data saved). A 'Choose action for record' dropdown is visible above the table.

Data Collection Instrument	Status
ADDPID	Incomplete
Trial Pack Allocation	Incomplete
Follow up contact	Incomplete
Trial Entry	Incomplete
Baseline Blood & Lung	Incomplete
Discharge Form	Incomplete
LRTI Verification Form	Incomplete
Withdrawal Form	Incomplete
Adverse event monitoring	Incomplete
Con Meds Form	Incomplete
Month 1	Incomplete



At the top of every form, you will need to confirm the Participant ID for all forms apart from ADDPID which will be displayed automatically.

ADDPID Data Access Group: [No Assignment] ?

Editing existing Participant ID 2.

Participant ID 2

Site ID 4 characters remaining
* must provide value

The database will automatically assign a number ID, please match that number in the Confirm Participant ID box.

Discharge Form Data Access Group: [No Assignment] ?

Editing existing Participant ID 2.

Participant ID 2

Confirm Participant ID 4 characters remaining
* must provide value

Once you input BALLOON ID from the web randomisation on the ADDPID form, it will automatically be completed for the rest of the forms.

Participant ID 1
To rename the record, see the record action drop-down at top of the [Record Home Page](#).

Site ID 4 characters remaining
* must provide value

Participant's Date of birth Today D-M-Y
* must provide value

BALLOON ID (web randomisation) 19003 5 characters remaining
* must provide value

Date of consent Today D-M-Y

Site ID 4 characters remaining
* must provide value

BALLOON ID (web randomisation) 19003

Pack ID allocation 9 characters remaining
* must provide value

Date of randomisation on web randomisation Today D-M-Y
* must provide value



When completing forms, all questions must be answered. If the database detects anomalies, these will be highlighted in red. When all questions have been answered, you will have several options: 'Save and exit form', 'Save and go to the next form' and 'Save and stay'. Please make sure you save your form regularly to not lose any progress. Click 'Complete' at the bottom of the page when asked 'Completed?' and save the form to finish. Please note this will mark the form as completed and any amendments will trigger an audit log. In case you need to make several changes, please make the changes individually then save the form so that a pop-up message appears. All changes need justification so do not make several changes at the same time.

After clicking 'Save and exit' or 'Save and go to the next form' you might be shown a list of errors that the database has detected. This might include any questions that have not been answered.

ADDPID Data Access Group: [No Assignment] ?

Editing existing Participant ID 2.

NOTE: Some fields are required!

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- Site ID
- Vanilla ID

Okay Ignore and leave record Ignore and go to next form

Form Status

Complete? Complete

Save & Exit Form Save & Go To Next Form

- Cancel -

The form will still be saved but you will be unable to mark the form as complete until these errors have been addressed.



If you want to address the errors at the present moment, select ‘Okay’ to remain on the form. If you leave the record, go to Add/Edit records, choose an existing Participant ID and click on the ID number you want to edit.

Forms will be listed as incomplete, unverified or complete as data entry is carried out, see below.

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

[Choose action for record](#)

Legend for status icons:

- Incomplete ● Incomplete (no data saved) ?
- Unverified ● ● ● Many statuses (all same)
- Complete ● Many statuses (mixed)

[Table not displaying.](#)

Participant ID 2

Data Collection Instrument	Status
ADDPID	●
Trial Pack Allocation	●

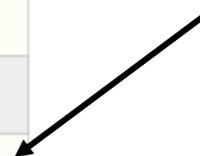
Multiple Entry Forms

Three forms – LRTI Verification form, Con Meds and Adverse Event Monitoring, can be completed multiple times. To complete more than one, click on ‘Add new instance’.



Participant ID 2

Data Collection Instrument	Status
ADDPID	
Trial Pack Allocation	
Follow up contact	
Trial Entry	
Baseline Blood & Lung	
Discharge Form	
LRTI Verification Form	
Withdrawal Form	
Adverse event monitoring	
Con Meds Form	
Month 1	
Month 2	
Month 3 Part 1	



Viewing Participants - Record Status Dashboard

The Record Status Dashboard displays a table listing all existing records/responses and their status for every record. You may click any of the coloured buttons in the table to



open a new tab/window in your browser to view that record. You will only be able to view records that belong to your site.

and if you belong to a Data Access Group, you will only be able to view records that belong to your group

Complete Many statuses (mixed)

Dashboard displayed: [Default dashboard] [Create custom dashboard](#)

Displaying Data Access Group -- ALL --

Displaying record Page 1 of 1: "1" through "7" of 7 records records per page

[+ Add new record](#)

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)
[Table not displaying properly ?](#)

Participant ID	ADDPID	Trial Pack Allocation	Follow up contact	Trial Blood & Lung Entry	Baseline Discharge Form	LRTI Verification Form	Withdrawal Form	Adverse event monitoring	Con Meds Form	Month 1	Month 2	Month 3 Part 1	Month 3 Part 2	Month 4	Month 5	Month 6
1	●	●	●	●	●	○	●	●	●	○	○	○	○	○	○	○
2	●	●	●	●	●	○	●	●	●	○	○	○	○	○	○	○
3	●	●	●	●	●	○	●	●	●	○	○	○	○	○	○	○
4	●	●	●	●	●	○	○	○	○	○	○	○	○	○	○	○
5	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
6	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
7	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

Calendar

Month 1,2,3,4,5,6,7,8,9,10,11 and 12 will be triggered from the date of randomisation and will be scheduled as events.

You can view your upcoming events on the Project Home Page.

REDCap BALLOON PID 324

[Project Home](#) [Project Setup](#) [Other Functionality](#) [Project Revision History](#)

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users (2)	
User	Expires
mcbmp1 (Mahuampi Perez-Al)	never
	never

Project Statistics	
Records in project	7
Most recent activity	23-10-2024 11:27
Space usage for docs	0.00 MB

Upcoming Calendar Events (next 7 days)		
Time	Date	Description
	23-10-2024	2 (Baseline)

Guidance Sheet 6c:DATA

ENTRY GUIDANCE REDCAP



It will display the date, participant ID and timeline (Baseline, Month 1, 2,3,4,5,6,7,8,9,10,11,12 follow up). You can also view it on the calendar under applications.

The screenshot shows the REDCap project dashboard for 'BALLOON' (PID 324). The left sidebar contains navigation options like 'Project Home and Design', 'Data Collection', and 'Applications'. The main area displays project statistics and an 'Upcoming Calendar Events' table.

User	Expires
mcbmp1 (Mahuampi Perez-A)	never
	never

Records in project	7
Most recent activity	23-10-2024 11:27
Space usage for docs	0.06 MB

Time	Date	Description
	23-10-2024	2 (Baseline)

The screenshot shows the REDCap calendar view for November 2024. The calendar grid displays dates from Sunday to Saturday. A red circle highlights the event on Friday, 23rd, which is labeled '+ New 2 (Month 1 follow-up)'. The left sidebar shows the 'Applications' menu with 'Calendar' selected.

Alternatively, you can view a participants' upcoming calendar event for the next 7 days by selection the participant and clicking on the upcoming calendar event.



Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete ● Incomplete (no data saved) ?
- Unverified ● ● ● Many statuses (all same)
- Complete ● Many statuses (mixed)

[Choose action for record](#) ▾

Participant ID 2

1 upcoming calendar event

[Table not displaying properly ?](#)

Data Collection Instrument	Baseline	Month 1 follow-up	Month 2 follow-up	Month 3 follow-up	Month 4 follow-up	Month 5 follow-up	Month 6 follow-up	Month 7 follow-up	Month 8 follow-up	Month 9 follow-up
ADDPID	●									
Trial Pack Allocation	●									
Follow up contact	●									

Data Queries

Data queries will be raised via REDCap by leaving a comment. Only the data manager can open and close queries and verify data. To respond to a query, press on the balloon icon.

Editing existing Participant ID 2.

Participant ID 2

Confirm Participant ID 4 characters remaining

Has the participant consented to the collection of their baby's blood samples being taken? Yes No reset

Has the participant consented for future use of blood samples as per the consent form? Yes No reset

Has the participant agreed for their baby to have their lung function measured during the study? Yes No reset

The data resolution workflow will pop up to leave your comment.



Data Resolution Workflow

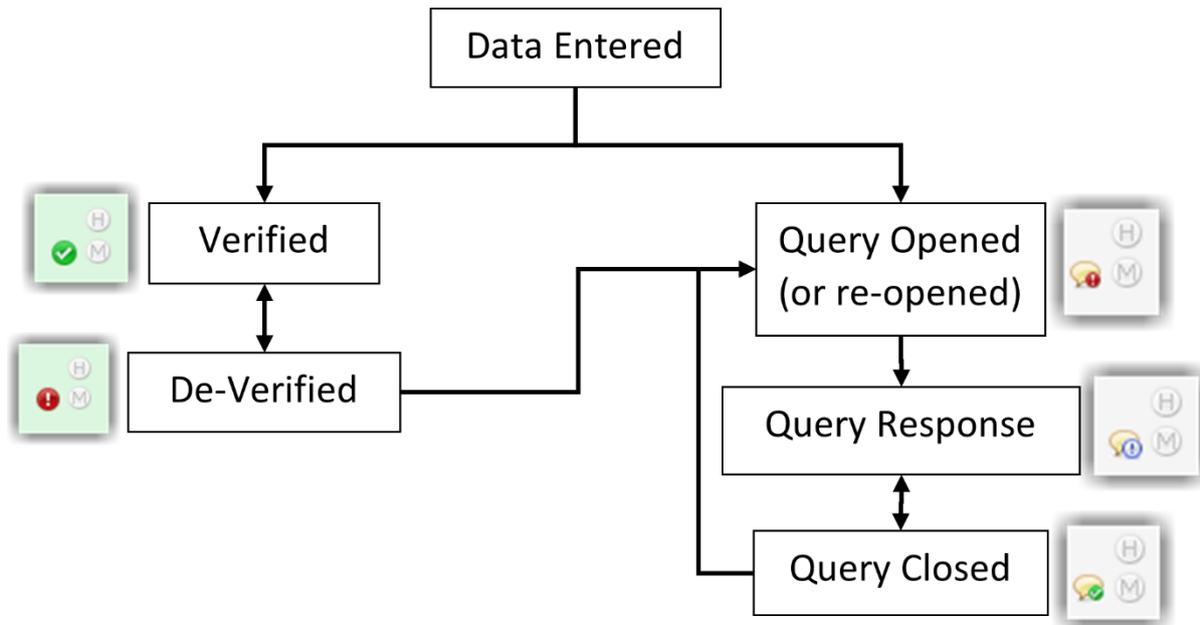
[VIDEO: Data Resolution Workflow](#)

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

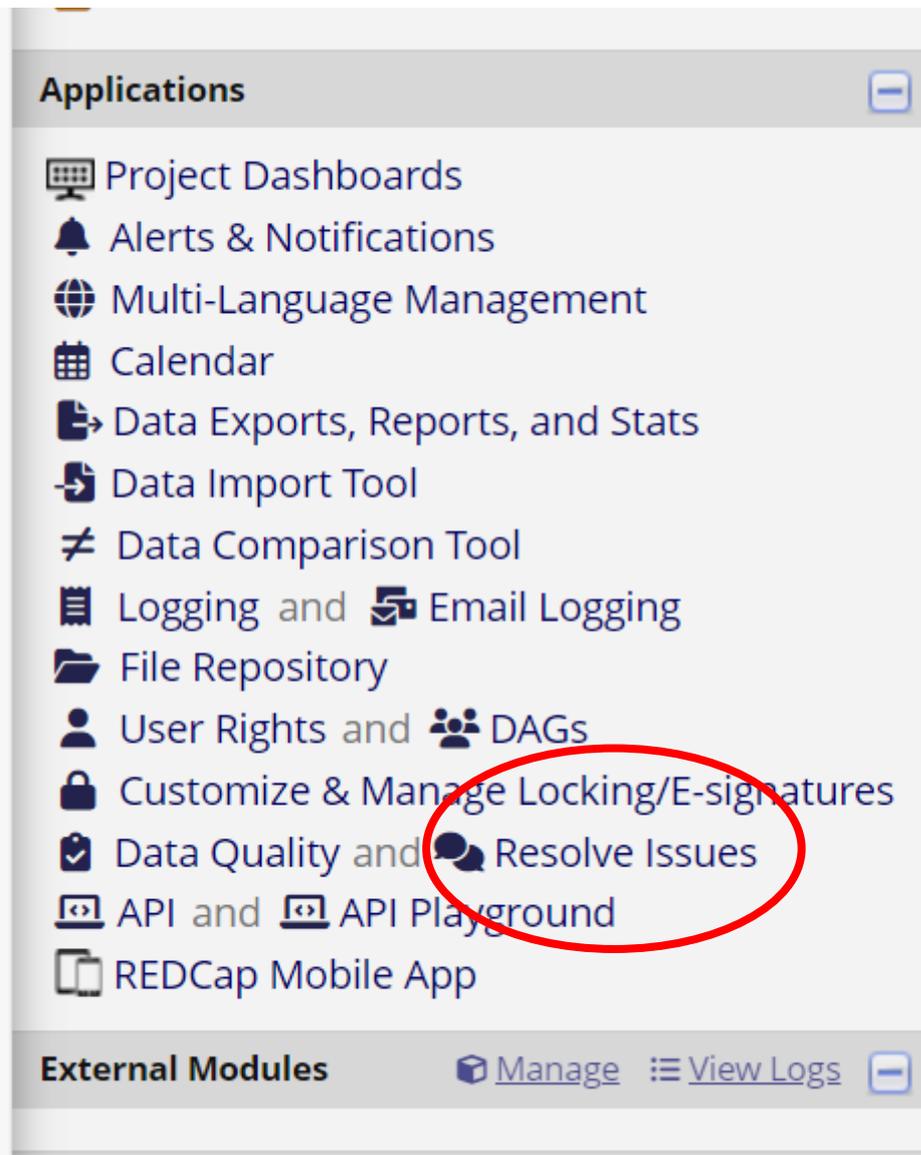
Participant ID: [2](#)
 Event: **Baseline**
 Field: **ppid** ("Confirm Participant ID")
 Status: **Not Opened**

Date/Time	User	Comments and Details
22-11-2024 10:23	mcbmp1	<input checked="" type="radio"/> Verified data value — OR — <input type="radio"/> Open query Assign query to a user (optional): <input type="text" value="-- select user --"/> Notify this user of their assignment using: <input type="checkbox"/> Email <input type="checkbox"/> REDCap Messenger Comment (optional): <input type="text"/> <input type="button" value="Verified data value"/> <input type="button" value="Cancel"/>

Users with access to data entry forms may respond to one or more comments on any field on a data collection instrument, after which the balloon icon will change as shown below.



All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Resolved issues](#) page in this project, under the applications section.



The data resolution dashboard will display the record ID, field queried, days open, first update and last update. It will also display the user who responded to the query. You can filter the queries by selection the filters for open/unresolved issues, open unresponded or open responded.



Data Resolution Dashboard		Filters: Open / unresolved issues (2)				
<input type="button" value="Export"/>		All fields and rules All events All data access groups User assigned (all users) or not assigned				
Click button to view data query	Record (Sorted by DAG)	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
2 comments	781-1 Baseline (University Hospital of Wales)	Field: add_dob (Participant's Date of birth)	-	0	mcbmp1 (22-11-2024 10:25): "testing"	mcbmp1 (22-11-2024 10:26): "testing"
2 comments	781-1 Baseline (University Hospital of Wales)	Field: add_van (Vanilla ID)	-	0.8	mcbmp1 (21-11-2024 14:07): "testing"	mtedh (21-11-2024 14:08): "testing testing 123"

Trial Allocation Pack

There are 3 important variable labels in this form, the BALLOON ID, the Pack ID allocated and the date of randomisation on web randomisation. The BALLOON ID and Pack ID allocated are the only identifiers connecting the participant in the web randomisation to REDCap as those systems are not linked. The date of randomisation on the web randomisation will be used to determine the treatment duration.



Editing existing Participant ID 1.

Event: **Baseline**

Participant ID 1

Confirm Participant ID
* must provide value
7 characters remaining

Site ID
* must provide value
4 characters remaining

BALLOON ID (web randomisation) _____

Pack ID allocation
* must provide value
9 characters remaining

Date of randomisation on web randomisation Today D-M-Y
* must provide value

Weight of the spray A at dispensing? In grams
* must provide value

Weight of the spray B at dispensing? In grams
* must provide value

Form Status

Complete?

Spray A and Spray B need to be weighted at first dispensing.

Follow-up Month 3,6,9,12

These forms correspond to the home/clinic visit and are divided into Part 1 and Part 2; you will need to complete both. They are long forms and frequent saving is advised. Allow plenty of time for their completion.

Month 6 and month 12 also have an extra section to collect weight, length and head circumference as well as blood samples and lung function for selected sites only.

When completing Part 1 of these forms, you will need to collect the weight of the old sprays along with the new sprays. You will also need to collect the number of doses missed. The information about the doses missed can be found on the app.



Additional Properties

Baby Birth date: 2024-06-11

Expected Due Date: 2024-07-31

Used sprays: 21

Missed or Expired sprays: 0

There's a possibility parents have only return 1 of the 2 sprays for disposing. In this case, for the question '*Did the parents return the spray?*' answer yes. This will prompt the question '*If yes, were the returned sprays disposed?*', answering yes will follow up with '*if yes, number of sprays disposed by the research team*', then you will have the option of selecting 1 spray or 2 sprays.

LRTI Verification form

If the parents have reported their child has breathing symptoms via the app, please complete the LRTI form on REDCap.