Guidance Sheet 6b:

DATA ENTRY GUIDANCE APP



Centre for Trials Research Canolfan Ymchwil Treialon



Database Access

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

Your Research

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

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

Logging onto Your Research

Enter the username and password.

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You will receive a text or an email with a login verification code. The code will only be valid for 5 minutes.





Once you enter the code you will be directed to the participant's page.

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Adding A New Participant

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

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Complete the general information, notification preference and additional information. The baby BALLOON ID will be generated automatically.

General information



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Next

Notification preferences



And additional information



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General	Additional configuration	^
Preferences	Baby name *	
Additional	Baby birth date *	۵
	Expected due date *	۵
		Add

Note the name displayed on the participant dashboard is the parents' name and surname, not the baby.

Participant Dashboard

There are 4 icons next to the participant.

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The status, the inbox, the participant record and the participant edit.

Viewing Participant Records and Compliance

On the participant record dashboard, you can view the activity. You can check if a form is open, closed or expired. If a form is closed it means the participant has completed it, if open, the form hasn't been completed but they have time to complete it (forms expired after 3 days) and finally expired means the form was not completed within the time stipulated and is now expired, meaning they cannot complete it anymore.



On the right side you can view the events and tasks. You can check if the participant hasn't completed the weekly journal, the participant has respiratory symptoms or has been hospitalised.

Study Forms

- Daily Diary: Triggers every day.
- Respiratory symptoms: Triggers if parents answer 'yes' to respiratory symptoms on a daily journal.
- Weekly Journal: Triggers on a weekend.
- Weekly Journal Episode: Triggers if parents have completed the weekly journal but their child has new symptoms.

All forms expire after 3 days and can be reopened by the research team once expired. If the parents have completed the daily diary but their child has new symptoms, they can press the 'respiratory symptoms' bottom on their app dashboard, this will trigger a new daily diary.



Amending Forms

If parents have made a mistake while completing the form, you can amend the mistake. To do this, go to the participant record dashboard, look at activity view and click on the form (Note this will only work if the form has been completed).



It will open the inbox, click on the form and click on the eye icon to view, it will open the edit task.



BALLOON Guidance Sheet 6b DATA ENTRY GUIDANCE APP V1.0 dated 13/02/2025

Page 8 of 13



Click edit and make the changes. Once you save the changes it will ask you for a reason for the changes. Write the reason then save.

Reopening a Form

To reopen a form, go onto the participant record dashboard, activity view and click on the form you want to reopen (the form needs to be expired). It will open the inbox. Click on reopen.

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Ē	Open task - BALLOON study	10/25/2024 08:01
	Diary - Friday Participant	10/25/2024 01:00
		Expired
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It will open a new window to confirm you want to reopen the form and a text box. Write the reason for reopening the form and save.

Scheduling a Form

To schedule a form, go to the participant inbox and click on the icon add task.



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Select the date, time and the forms you want to schedule.

Participant Notifications

Participants can receive alerts via email, text or push notifications. You can select the notifications participants will receive when you add them, however, you can change them on the participant edit by changing the preferences.

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Checking Completeness and Participant Status

To check if a participant has missed any forms, medications, has respiratory symptoms or has been hospitalised, go to the participant inbox and click the flag icon to go to events.





If a participant has respiratory symptoms, please contact the participant and complete the LRTI verification form on REDCap.

Month 3,6,9,12 Follow-up - Checking Compliance with treatment

To check the amount of sprays a participant has missed, go to the participant dashboard, check under additional properties.

Page 12 of 13

Guidance Sheet 6b:

DATA ENTRY GUIDANCE APP



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Additional Properties

Baby Birth date: 2024-06-11

Expected Due Date: 2024-07-31

Used sprays: 21

Missed or Expired sprays: 0