AZTEC

Azithromycin Therapy for Chronic Lung Disease

AZTEC: Azithromycin Therapy for Chronic Lung Disease of Prematurity

A randomised, placebo-controlled trial of azithromycin for the prevention of chronic lung disease of prematurity in preterm infants

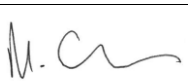
Guidance Sheet 7:

Database Guidance

This document is only to be used by staff trained in the Aztec study. The purpose of this document is to provide guidance for the use of the Aztec database for data entry.

Contents

AZTEC Database Guidance Version Details

Version number	1.0	Effective Date	10.07.2019
Supersedes version:			
Prepared by	Mark Goddard Research Assistant/ Data Manager		08.07.2019
		Signature	Date
Authorised by	John Lowe Research Associate/ Trial Manager		08.07.2019
		Signature	Date

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Database Access

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

http://aztec.sewtudb-test.cf.ac.uk/

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

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

Randomisation

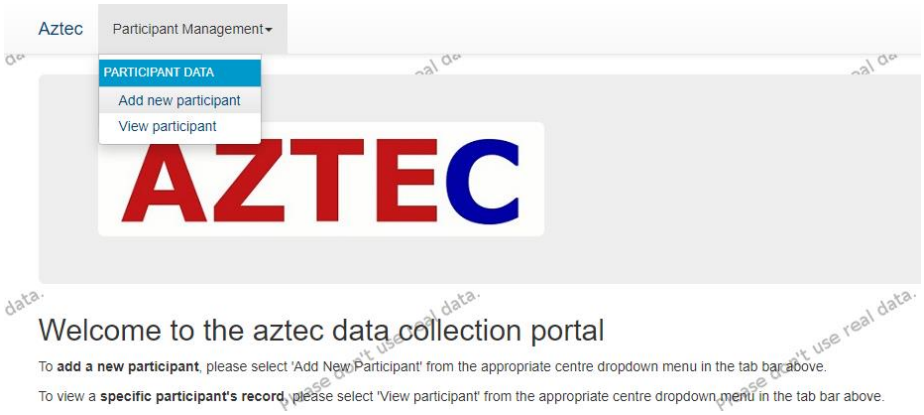
Please note, you must randomise a trial participant into the Sortition randomisation system before they can be entered onto the database, as you will need to enter the 4-digit number generated during the randomisation process.

Logging Onto The Aztec Database

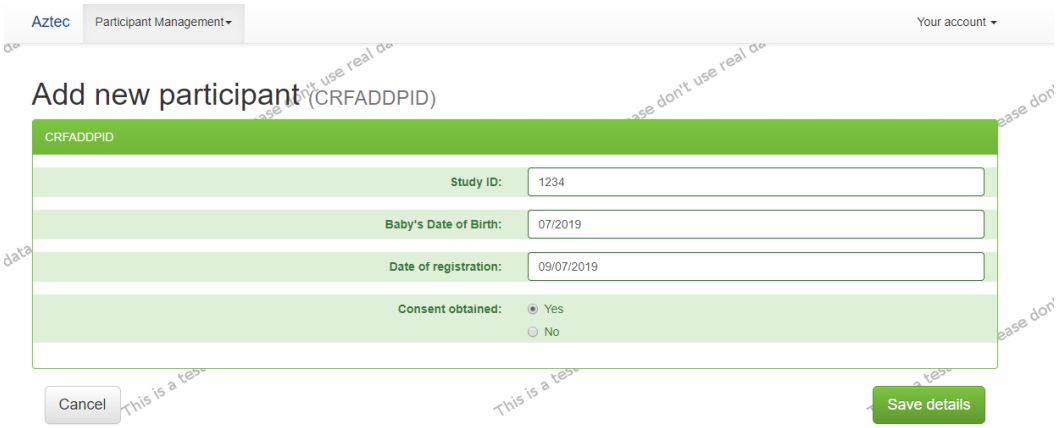
Enter the username and password emailed to you. On first log in you will be given the opportunity to change your password.

Adding A New Participant

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

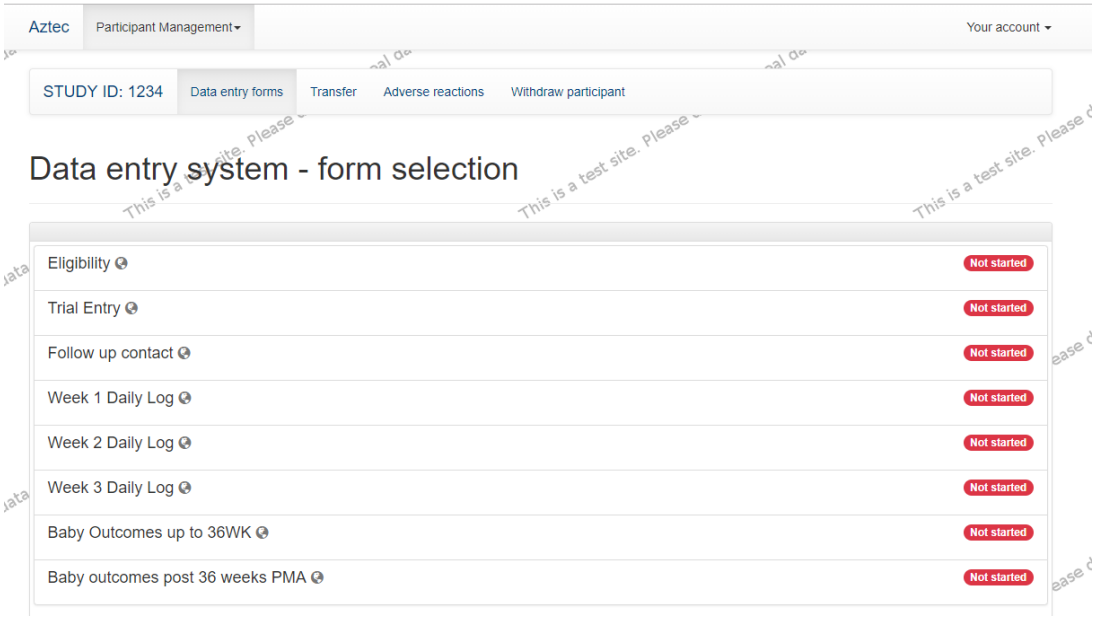


Please enter the 4-digit study ID that was generated from the Sortition randomisation system and complete all other fields. Then press 'Save details'.

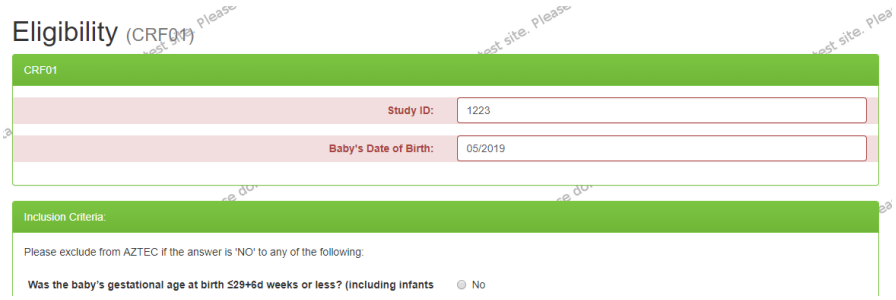


Data Entry

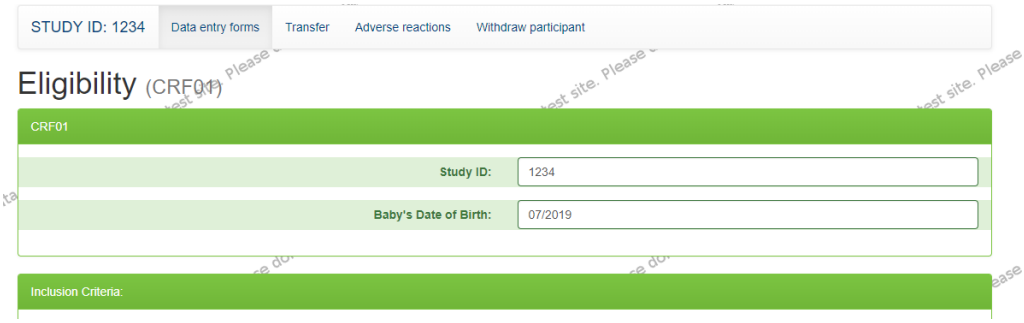
Once the participant has been entered into the system, data entry of the forms can begin by selecting the relevant one from the list below.



At the top of every form you will need to confirm the study ID and baby's date of birth (mm/yyyy). This is to make sure data entered is for the correct baby. If an incorrect study ID or date of birth is entered, they will be highlighted in red.



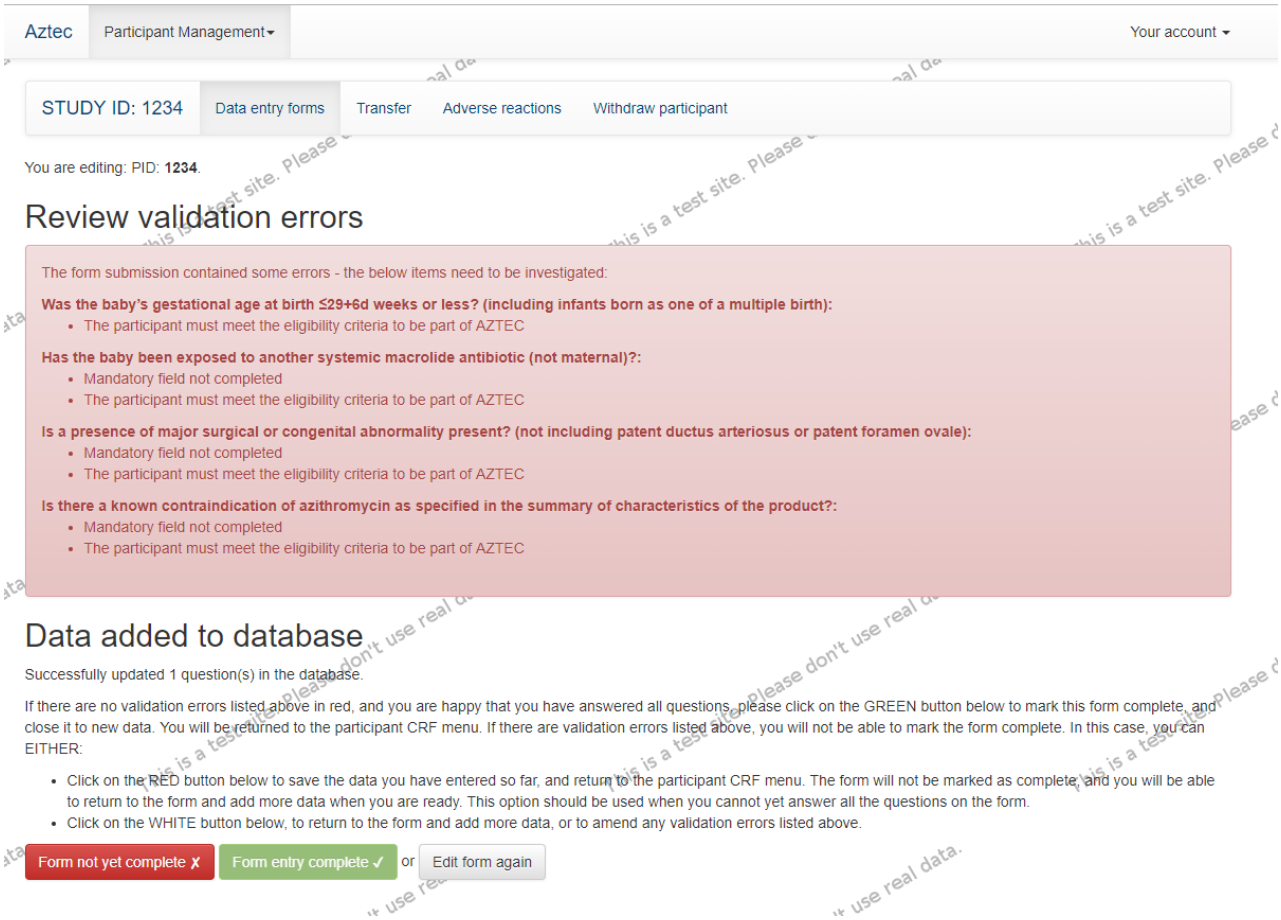
When correct study ID and date of births are entered, they will be highlighted in green.



When completing forms, all questions must be answered. If the database detects anomalies, these will be highlighted in red.

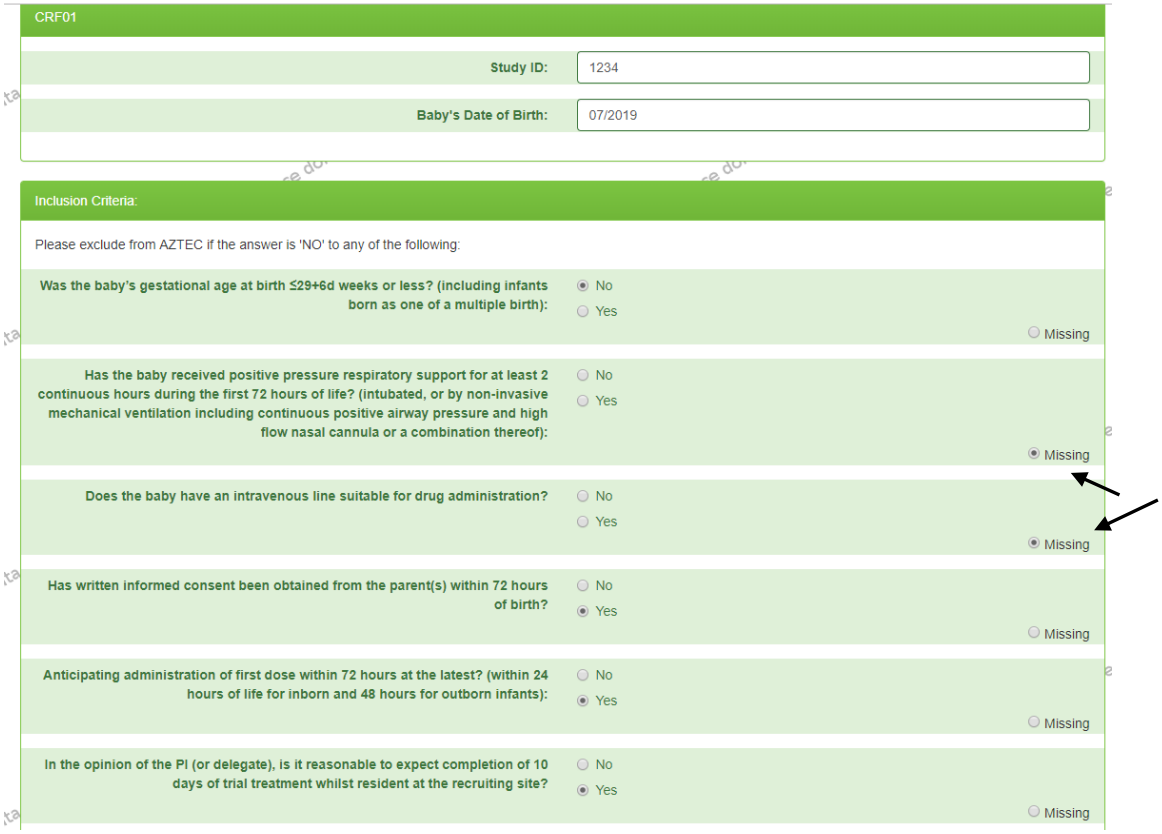
When all questions have been answered, you can save the form by clicking 'Save details' at the bottom of the page.

After clicking 'Save details' you might be shown a list of errors that the database has detected. This might include any questions that have not been answered.

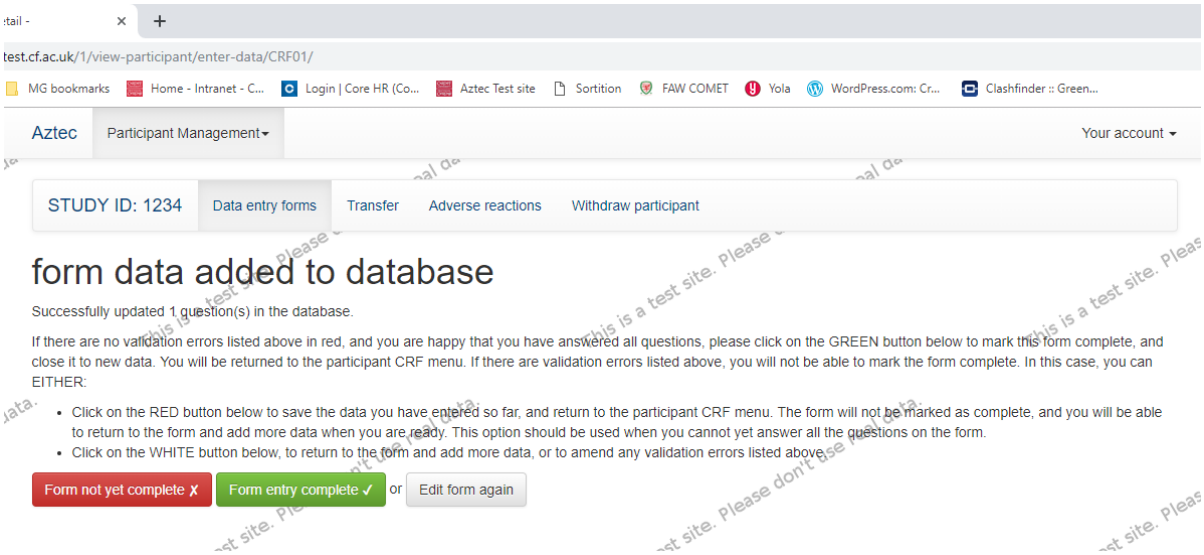


The form will still be saved but you will be unable to mark the form as complete until these errors have been addressed. To save the incomplete form select the red box at the bottom - 'Form not yet complete'.

If you want to address the errors at the present moment, select the grey box 'Edit form again'. If any unanswered questions are not able to be completed, please tick the missing box at the end of the question.

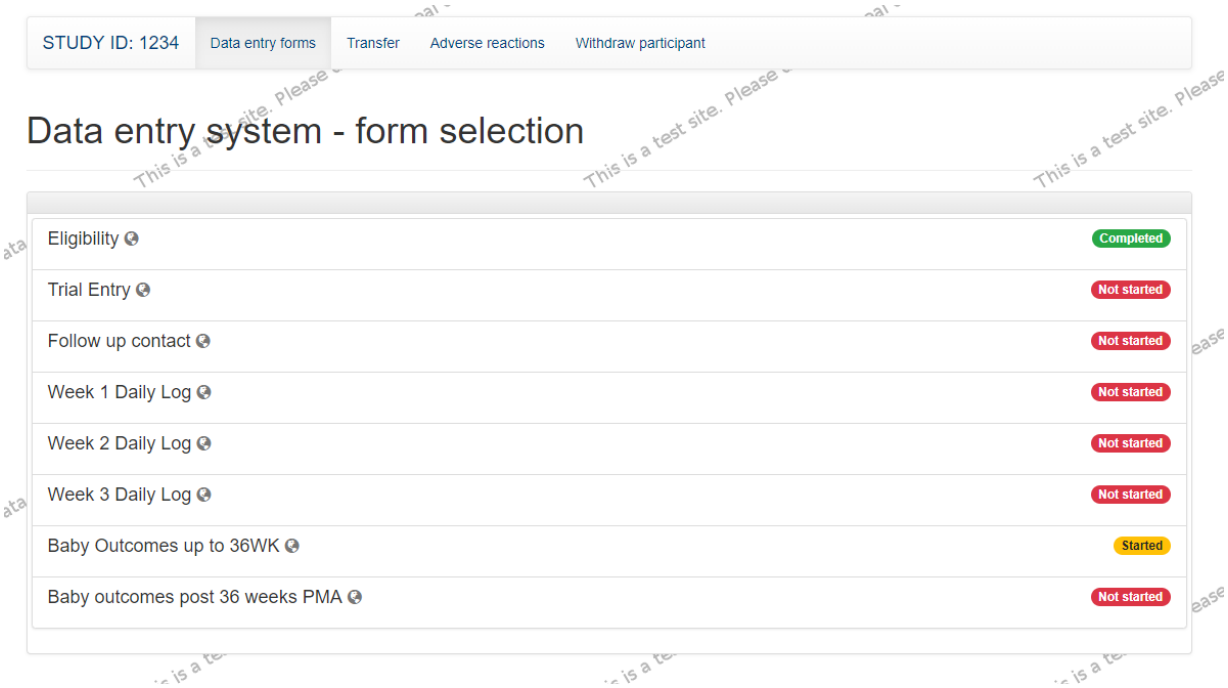


Once the errors have been addresses you will be able to save the form and mark it as complete, (see green button below).



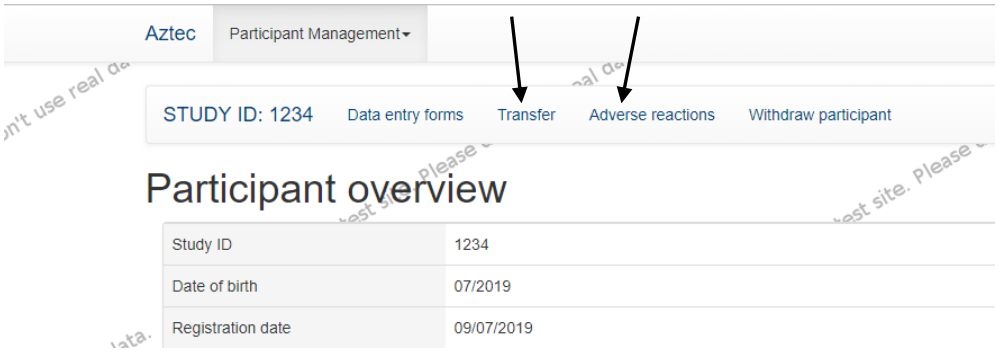
If you are in the middle of data entry and get called away, you can save the form at any point and mark it as not complete.

Forms will be listed as either not started, started or complete as data entry is carried out, see below.

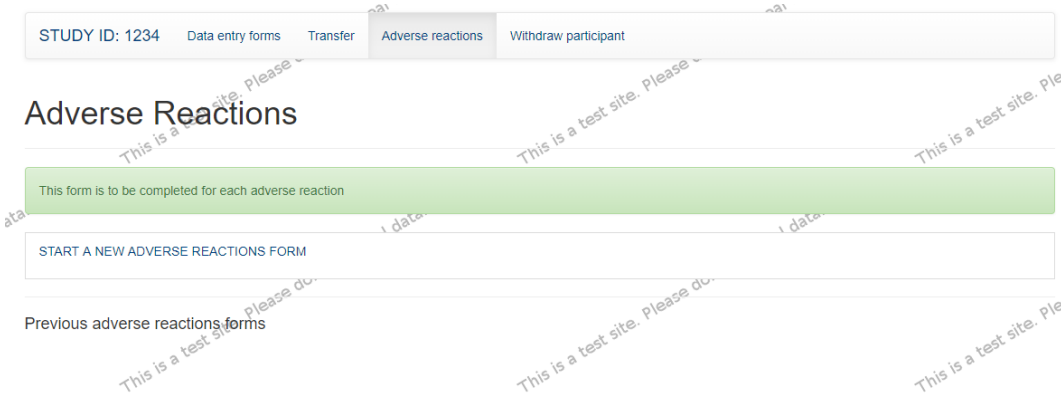


Multiple Entry Forms

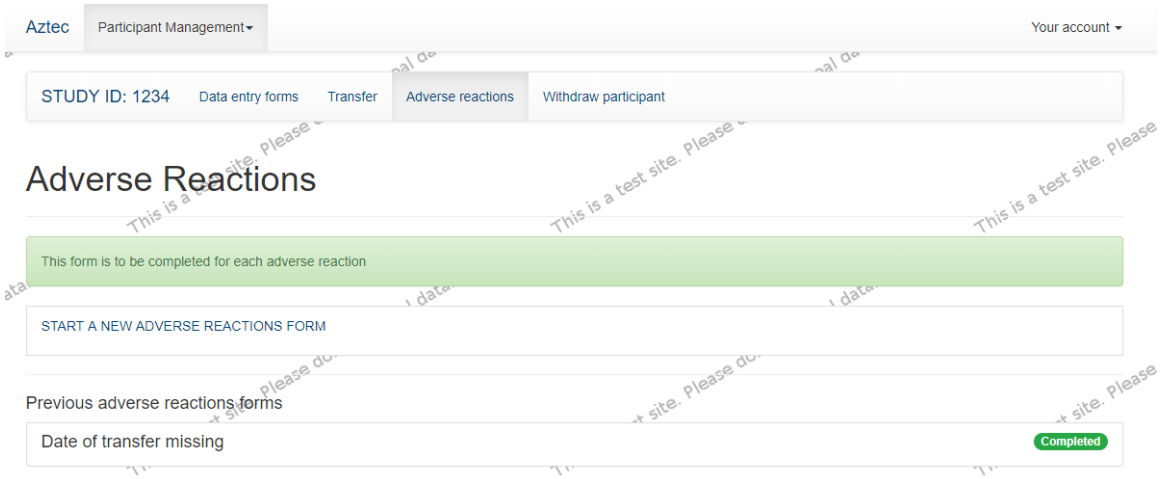
Two forms – Transfer and Adverse Reactions, can be completed multiple times. These are listed, alongside the withdrawal form, at the top of the screen.



To start a form, click on the link as listed above and you should see a screen as below. Click on 'START A NEW …… FORM'



Once that form has been saved, you can then create a new one or open a previously entered one, listed below as 'Completed'.



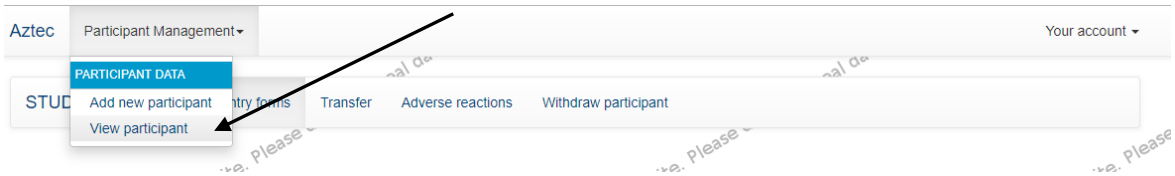
Withdrawal Form

When a withdrawal occurs, depending on the level, other forms will become 'read only'. To summarise –

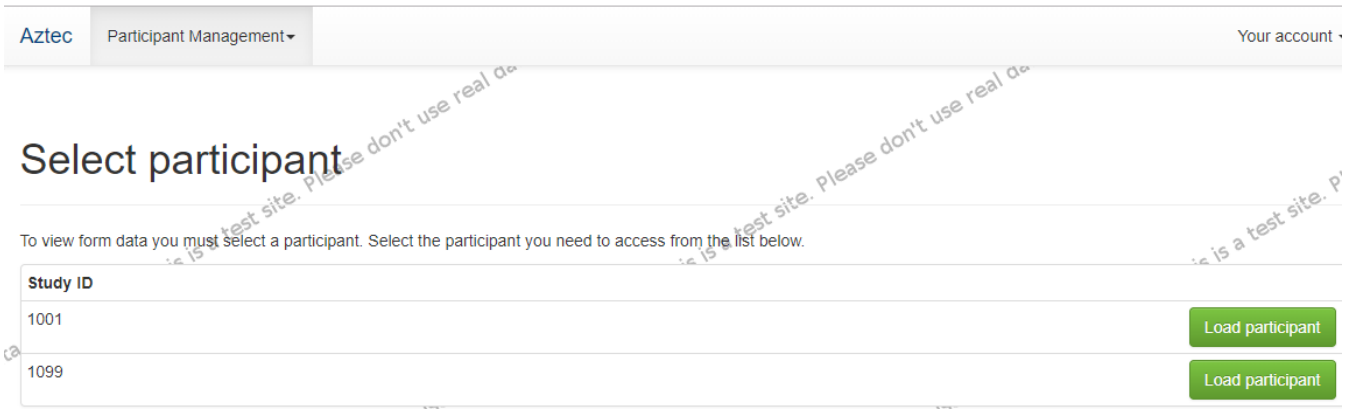
Level	Form that becomes Read Only		
Withdrawal of trial treatment	Week 1 daily log	Week 2 daily log	Week 3 daily log
Withdrawal from samples -	Week 1 daily log	Week 2 daily log	Week 3 daily log
Withdrawal from follow-up assessments	Follow up contact	Baby outcomes 36 weeks	Baby outcomes post 36 weeks
Withdrawal of consent to all of the above	All forms including Adverse reactions, withdrawal and transfer		
Full data withdrawal:	All forms including Adverse reactions, withdrawal and transfer		

Viewing Participants

To view, add or amend data on a previously entered participant, you need to select 'View participant' as follows –

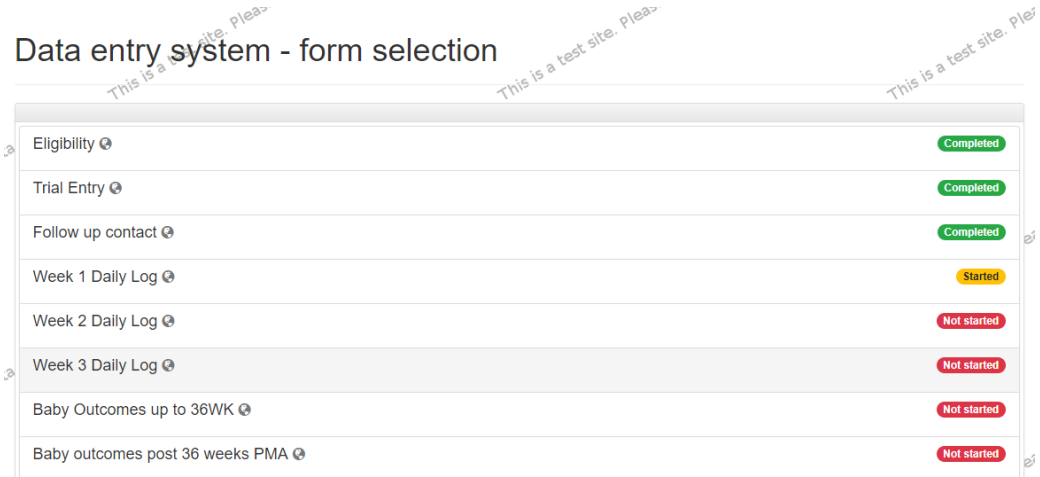


This will then allow you to view all participants entered for your site, as below.



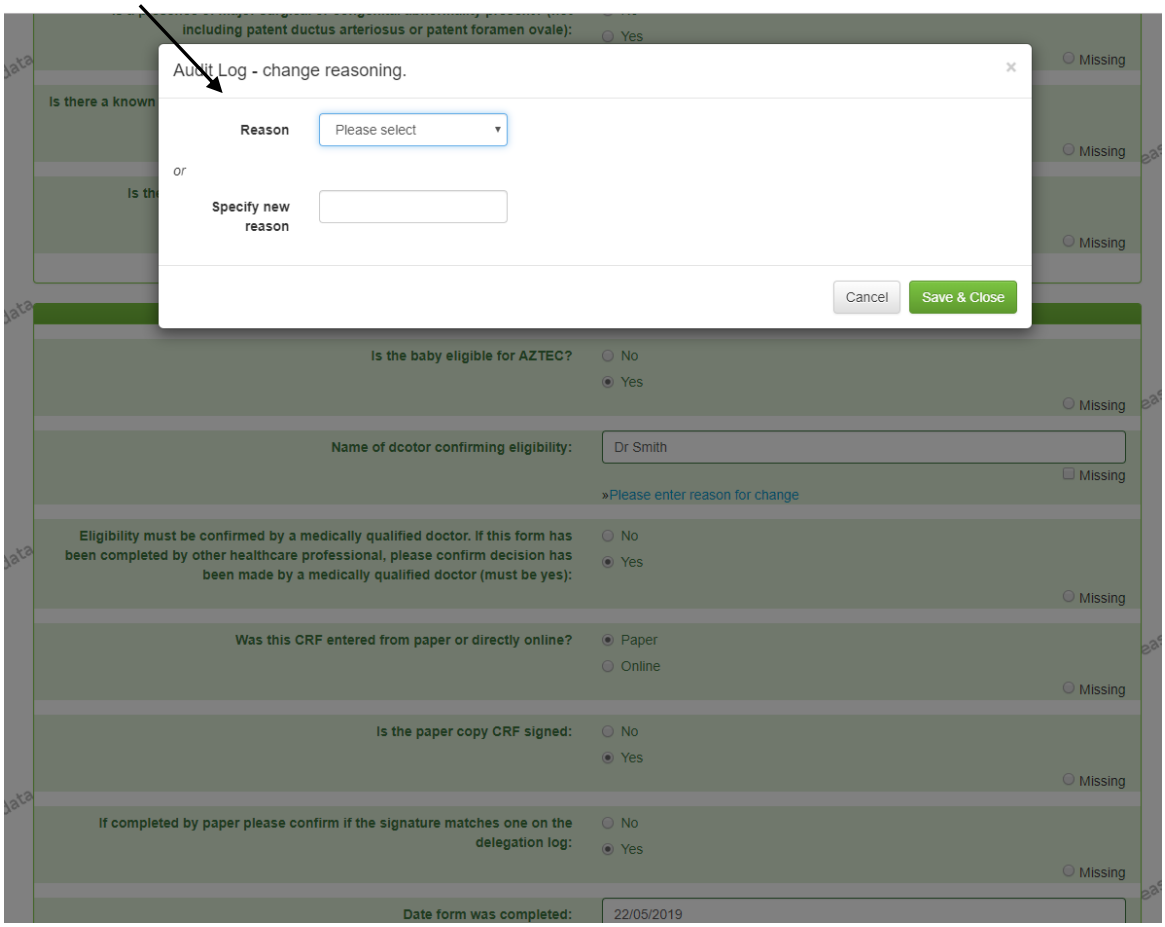
Making Changes To Data

You can add, amend and edit all forms by selecting the form and opening it, carrying out the amendment and saving. However, for forms that have been completed, i.e. appear green as below, if you need to make changes to this form's data, you will see an Audit pop-up box appear.



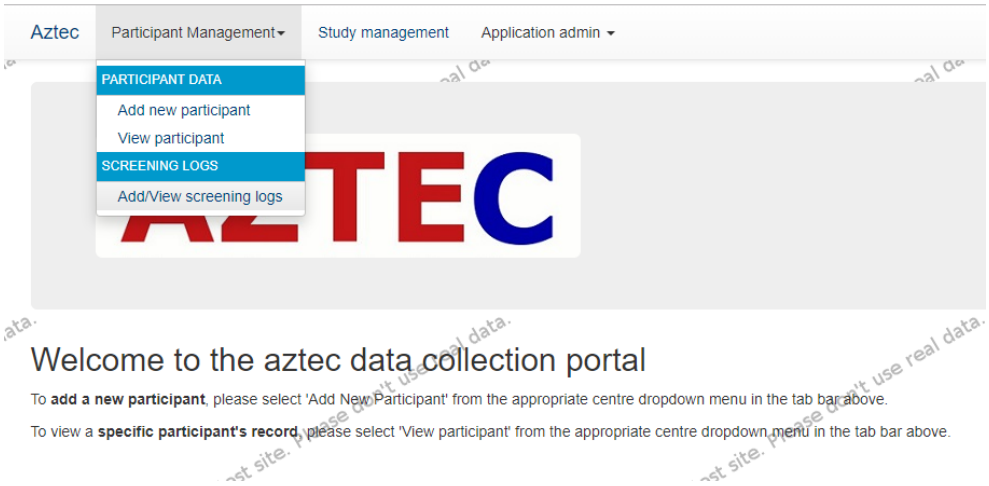
Audit Log

When changes are made to data on forms that have already been saved as complete, the following box will appear. You need to select a reason for the change or specify a new one, save and close.

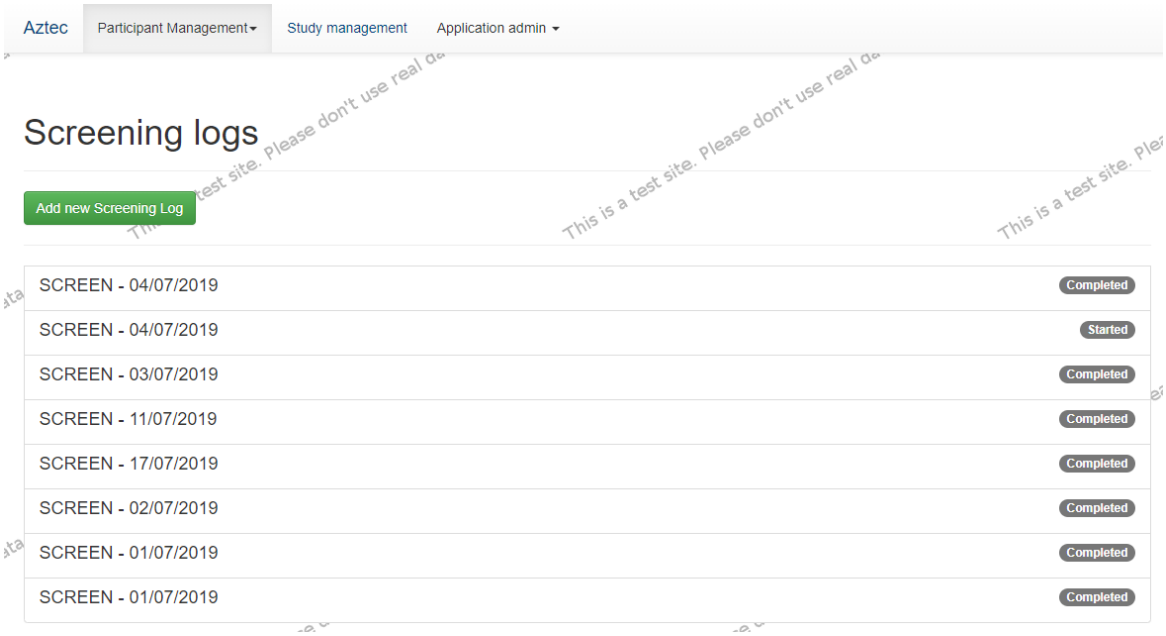


Screening Logs

The screening log form can be accessed under Participant Management.



Clicking on Add/View screening log brings up the following screen –



Click on any previously created screening logs to view their details. Making changes to data already entered on a complete form will follow the same procedures as already discussed above.

To create a new screening log, click on the green button. Entering data onto a new form will also follow the same procedures as discussed previously above.