

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	3
Contacts.....	3
Database Access	4
Randomisation	4
Logging Onto The Aztec Database	4
Adding A New Participant.....	4
Data Entry	5
Multiple Entry Forms	9
Withdrawal Form	10
Viewing Participants	11
Making Changes To Data.....	11
Audit Log	12
Screening Logs.....	12

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

Sponsor:	Research and Innovation Services Cardiff University Cardiff CF24 0DE Tel: 029 2087 9130 Fax: 029 2087 4189 Email: resgov@cardiff.ac.uk
Sponsor ref:	SPON1595-17
Funder:	NIHR HTA
Funder ref:	16/111/106
REC ref:	18 WA 0199
IRAS number:	108978
EudraCT ref:	2018-001109-99
ISRCTN ref:	ISRCTN11650227
Q-Pulse Document Template Number:	TPL/003/001 v2.0

Contacts

If you have any problems, please get in touch -

Name	Role	Email	Tel No:
Mark Goddard	Data Manager	goddardm@cardiff.ac.uk	029 2251 1592
John Lowe	Trial Manager	LoweJ3@cardiff.ac.uk	029 2251 0484
Generic email	Aztec@cardiff.ac.uk		

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

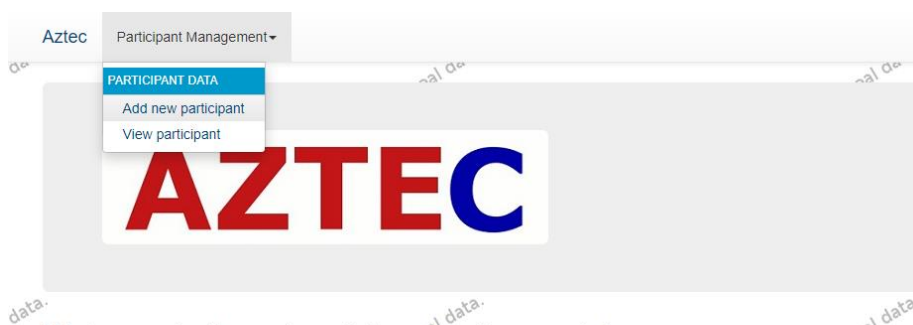
Please note, you must randomise a trial participant into the Sortition randomisation system before they can be entered onto the database, as you will need to enter the 4-digit number generated during the randomisation process.

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 –



Welcome to the aztec data collection portal

To **add a new participant**, please select 'Add New Participant' from the appropriate centre dropdown menu in the tab bar above.

To view a **specific participant's record**, please select 'View participant' from the appropriate centre dropdown menu in the tab bar above.

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.

Data entry system - form selection

Eligibility	Not started
Trial Entry	Not started
Follow up contact	Not started
Week 1 Daily Log	Not started
Week 2 Daily Log	Not started
Week 3 Daily Log	Not started
Baby Outcomes up to 36WK	Not started
Baby outcomes post 36 weeks PMA	Not started

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.

Eligibility (CRF01)

The screenshot shows the 'Eligibility (CRF01)' form. At the top, there is a green header bar with 'CRF01'. Below it, there are two input fields: 'Study ID: 1223' and 'Baby's Date of Birth: 05/2019'. Both fields have a red border, indicating that the data entered is incorrect. Below the input fields, there is a section titled 'Inclusion Criteria' with a green header. The text below reads: 'Please exclude from AZTEC if the answer is 'NO' to any of the following:'. There is a question: 'Was the baby's gestational age at birth ≤29+6d weeks or less? (including infants)' with a radio button selected for 'No'.

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

The screenshot shows the 'Eligibility (CRF01)' form. At the top, there is a navigation bar with 'STUDY ID: 1234' and tabs for 'Data entry forms', 'Transfer', 'Adverse reactions', and 'Withdraw participant'. Below the navigation bar, there is a green header bar with 'CRF01'. Below it, there are two input fields: 'Study ID: 1234' and 'Baby's Date of Birth: 07/2019'. Both fields have a green border, indicating that the data entered is correct. Below the input fields, there is a section titled 'Inclusion Criteria' with a green header.

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.

You are editing: PID: 1234.

Review validation errors

The form submission contained some errors - the below items need to be investigated:

- Was the baby's gestational age at birth $\leq 29+6$ weeks or less? (including infants born as one of a multiple birth):**
 - The participant must meet the eligibility criteria to be part of AZTEC
- Has the baby been exposed to another systemic macrolide antibiotic (not maternal)?:**
 - Mandatory field not completed
 - The participant must meet the eligibility criteria to be part of AZTEC
- Is a presence of major surgical or congenital abnormality present? (not including patent ductus arteriosus or patent foramen ovale):**
 - Mandatory field not completed
 - The participant must meet the eligibility criteria to be part of AZTEC
- Is there a known contraindication of azithromycin as specified in the summary of characteristics of the product?:**
 - Mandatory field not completed
 - The participant must meet the eligibility criteria to be part of AZTEC

Data added to database

Successfully updated 1 question(s) in the database.

If there are no validation errors listed above in red, and you are happy that you have answered all questions, please click on the GREEN button below to mark this form complete, and close it to new data. You will be returned to the participant CRF menu. If there are validation errors listed above, you will not be able to mark the form complete. In this case, you can EITHER:

- Click on the RED button below to save the data you have entered so far, and return to the participant CRF menu. The form will not be marked as complete, and you will be able to return to the form and add more data when you are ready. This option should be used when you cannot yet answer all the questions on the form.
- Click on the WHITE button below, to return to the form and add more data, or to amend any validation errors listed above.

Form not yet complete ✘ Form entry complete ✔ or Edit form again

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.

CRF01

Study ID: 1234

Baby's Date of Birth: 07/2019

Inclusion Criteria:

Please exclude from AZTEC 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): No Yes Missing

Has the baby received positive pressure respiratory support for at least 2 continuous hours during the first 72 hours of life? (intubated, or by non-invasive mechanical ventilation including continuous positive airway pressure and high flow nasal cannula or a combination thereof): No Yes Missing

Does the baby have an intravenous line suitable for drug administration? No Yes Missing

Has written informed consent been obtained from the parent(s) within 72 hours of birth? No Yes Missing

Anticipating administration of first dose within 72 hours at the latest? (within 24 hours of life for inborn and 48 hours for outborn infants): No Yes Missing

In the opinion of the PI (or delegate), is it reasonable to expect completion of 10 days of trial treatment whilst resident at the recruiting site? No Yes Missing

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

test.cf.ac.uk/1/view-participant/enter-data/CRF01/

Aztec Participant Management Your account

STUDY ID: 1234 Data entry forms Transfer Adverse reactions Withdraw participant

form data added to database

Successfully updated 1 question(s) in the database.

If there are no validation errors listed above in red, and you are happy that you have answered all questions, please click on the GREEN button below to mark this form complete, and close it to new data. You will be returned to the participant CRF menu. If there are validation errors listed above, you will not be able to mark the form complete. In this case, you can EITHER:

- Click on the RED button below to save the data you have entered so far, and return to the participant CRF menu. The form will not be marked as complete, and you will be able to return to the form and add more data when you are ready. This option should be used when you cannot yet answer all the questions on the form.
- Click on the WHITE button below, to return to the form and add more data, or to amend any validation errors listed above.

Form not yet complete X Form entry complete ✓ or Edit form again

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.

STUDY ID: 1234 Data entry forms Transfer Adverse reactions Withdraw participant

Data entry system - form selection

Eligibility	Completed
Trial Entry	Not started
Follow up contact	Not started
Week 1 Daily Log	Not started
Week 2 Daily Log	Not started
Week 3 Daily Log	Not started
Baby Outcomes up to 36WK	Started
Baby outcomes post 36 weeks PMA	Not started

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.

Aztec Participant Management

STUDY ID: 1234 Data entry forms Transfer Adverse reactions Withdraw participant

Participant overview

Study ID	1234
Date of birth	07/2019
Registration date	09/07/2019

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'

STUDY ID: 1234 Data entry forms Transfer Adverse reactions Withdraw participant

Adverse Reactions

This form is to be completed for each adverse reaction

START A NEW ADVERSE REACTIONS FORM

Previous adverse reactions forms

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

Aztec Participant Management Your account

STUDY ID: 1234 Data entry forms Transfer Adverse reactions Withdraw participant

Adverse Reactions

This form is to be completed for each adverse reaction

START A NEW ADVERSE REACTIONS FORM

Previous adverse reactions forms

Date of transfer missing Completed

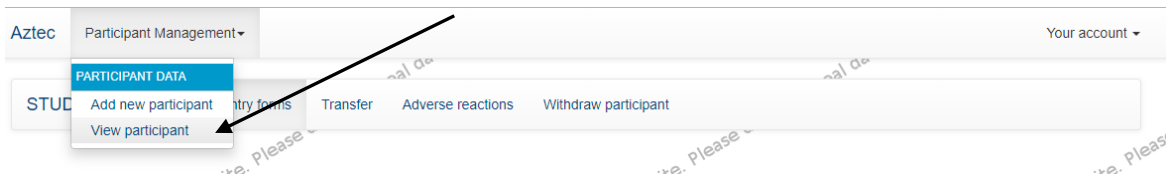
Withdrawal Form

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

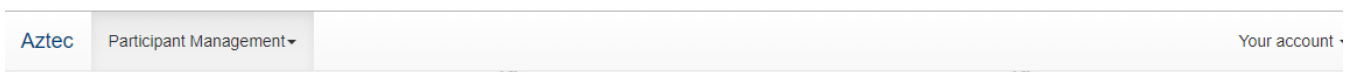
Level	Form that becomes Read Only		
Withdrawal of trial treatment	Week 1 daily log	Week 2 daily log	Week 3 daily log
Withdrawal from samples -	Week 1 daily log	Week 2 daily log	Week 3 daily log
Withdrawal from follow-up assessments	Follow up contact	Baby outcomes 36 weeks	Baby outcomes post 36 weeks
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.



Select participant

To view form data you must select a participant. Select the participant you need to access from the list below.

Study ID	
1001	Load participant
1099	Load participant

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.

Data entry system - form selection

Eligibility	Completed
Trial Entry	Completed
Follow up contact	Completed
Week 1 Daily Log	Started
Week 2 Daily Log	Not started
Week 3 Daily Log	Not started
Baby Outcomes up to 36WK	Not started
Baby outcomes post 36 weeks PMA	Not started

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.

The screenshot shows a modal dialog box titled "Audit Log - change reasoning." overlaid on a form. The dialog has a "Reason" dropdown menu with "Please select" as the selected option. Below the dropdown is a text input field labeled "Specify new reason". At the bottom right of the dialog are "Cancel" and "Save & Close" buttons. The background form contains several questions with radio button options, such as "Is there a known...", "Is the baby eligible for AZTEC?", "Name of doctor confirming eligibility:", "Eligibility must be confirmed by a medically qualified doctor...", "Was this CRF entered from paper or directly online?", "Is the paper copy CRF signed:", and "If completed by paper please confirm if the signature matches one on the delegation log:". The date "22/05/2019" is visible at the bottom of the form.

Screening Logs

The screening log form can be accessed under Participant Management.

The screenshot shows the navigation menu of the AZTEC web application. The "Participant Management" dropdown menu is open, displaying the following options: "PARTICIPANT DATA" (Add new participant, View participant) and "SCREENING LOGS" (Add/View screening logs). The "AZTEC" logo is visible in the background.

Welcome to the aztec data collection portal

To add a new participant, please select 'Add New Participant' from the appropriate centre dropdown menu in the tab bar above.

To view a specific participant's record, please select 'View participant' from the appropriate centre dropdown menu in the tab bar above.

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

Aztec Participant Management Study management Application admin

Screening logs

Add new Screening Log

SCREEN - 04/07/2019	Completed
SCREEN - 04/07/2019	Started
SCREEN - 03/07/2019	Completed
SCREEN - 11/07/2019	Completed
SCREEN - 17/07/2019	Completed
SCREEN - 02/07/2019	Completed
SCREEN - 01/07/2019	Completed
SCREEN - 01/07/2019	Completed

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.