Guidance Sheet 1: Training

AZTEC trial training overview

AZTEC trial training is based on the Site Initiation Visit presentation sessions delivered to sites by the CTR AZTEC team. The PI/research nurse/pharmacy representative should hold a copy of these presentation slides and be able to deliver the presentations to staff, applicable to the roles to be undertaken.

1. Background and Rationale
2. Informed consent and randomisation
3. Prescription and Intervention procedures
4. Data Collection
5. Safety and non-compliance reporting
6. Sampling procedures
7. Pharmacy Procedures

Training for a delegated role is completed when an individual has received the appropriate session(s), has read the mandatory guidance sheets, and has been signed off by the trainer.

Guidance sheets

The following AZTEC guidance sheets for specific aspects of the trial are available in paper format in the Investigator Site File, or electronic versions can be obtained via AZTEC@Cardiff.ac.uk

▪ Guidance sheet 2: Screening and Consent	▪ Guidance sheet 9: IMP supply & accountability
▪ Guidance sheet 3: Notes on informed consent	▪ Guidance sheet 10: Oxygen reduction test
▪ Guidance sheet 4: Randomisation	▪ Guidance sheet 11: Withdrawal & Unblinding
▪ Guidance sheet 5a: Intervention	▪ Guidance sheet 12a: Preparing a transfer
▪ Guidance sheet 5b: IMP administration	▪ Guidance sheet 12b: Receiving a transfer
▪ Guidance sheet 6: Data collection	▪ Guidance sheet 13a: Sampling procedure
▪ Guidance sheet 7: Data entry	▪ Guidance sheet 13b: Sample shipment
▪ Guidance sheet 8: Safety and non-compliance reporting	

For any queries please contact the AZTEC Trial Manager at LoweJ3@Cardiff.ac.uk or 029 2068 7990. Study materials can be requested from the trial administrator, AZTEC@Cardiff.ac.uk.

It is recommended that all staff read:

Guidance sheet 8: Safety and non-compliance reporting
Guidance sheet 11: Withdrawal & unblinding
Guidance sheet 12A: Preparing a transfer

Guidance Sheet 1: Training

Training Requirements: Delegated Duties

All **MANDATORY** training other than GCP training must be recorded on the Training Log in the AZTEC Investigator Site File (or AZTEC Pharmacy Folder for pharmacy staff).

TRAINING DELIVERY

DUTY 1) DELIVER OVERVIEW TRAINING

MANDATORY

- Full GCP (evidenced by a certificate)
- Attend AZTEC site initiation visit/suitable alternative

RECOMMENDED

- All AZTEC guidance sheets

DUTY 2) DELIVER TRAINING ON PREPARATION AND ADMINISTRATION OF IMP

MANDATORY

- Full GCP (evidenced by a certificate)
- AZTEC trial overview- sessions 1, 3 & 4
- Guidance sheet 5a: Intervention
- Guidance sheet 5b: IMP administration

DUTY 3) DELIVER TRAINING ON SAMPLE COLLECTION AND SHIPMENT

MANDATORY

- Full GCP (evidenced by a certificate)
- AZTEC trial overview- sessions 1, 4 & 6
- Guidance sheet 13a: Sampling procedures
- Guidance sheet 13b: Sample shipment

CLINICAL TEAM

DUTY 4) CONFIRMATION OF ELIGIBIITY

Must be medically qualified to undertake this duty

MANDATORY

- AZTEC trial overview- sessions 1 & 2
- Any Trust-specific GCP requirements
- Guidance sheet 2: Screening and consent

RECOMMENDED

- Guidance sheet 4: Randomisation

DUTY 5) OBTAIN INFORMED CONSENT

MANDATORY

- Full GCP (evidenced by a certificate)
- AZTEC trial overview- sessions 1 & 2
- Guidance sheet 2: Screening and consent
- Guidance sheet 3: Notes on informed consent

RECOMMENDED

Guidance sheet 4: Randomisation

DUTY 6) RANDOMISATION

MANDATORY

- AZTEC trial overview- sessions 1 & 2
- Any Trust-specific GCP requirements
- Guidance sheet 4: Randomisation

RECOMMENDED

- Sortition randomisation user guide
- Guidance sheet 2: Screening and consent

DUTY 7) PRESCRIPTION OF IMP

Must be medically qualified or an Advanced Nurse Practitioner (ANP) with suitable qualification

MANDATORY

- AZTEC trial overview- sessions 1, 2 & 4
- Any Trust-specific GCP requirements
- Guidance sheet 5a: Intervention

RECOMMENDED

- Guidance sheet 5b: IMP administration

DUTY 8) OXYGEN REDUCTION TEST

MANDATORY

- AZTEC trial overview- sessions 1 & 4
- Any Trust-specific GCP requirements
- Guidance sheet 10: Oxygen reduction test

RECOMMENDED

- Guidance sheet 6: Data collection

DUTY 9) SAE CLINICAL REVIEW AND SIGN OFF

Must be medically qualified to undertake this duty

MANDATORY

- Full GCP (evidenced by a certificate)
- AZTEC trial overview- sessions 1 & 5
- Guidance sheet 8: Safety and non-compliance reporting
- Guidance sheet 11: Withdrawal & Unblinding

RECOMMENDED

- Sortition site unblinding user guide

RESEARCH TEAM

DUTY 10) COMPLETION OF eCRF AND RESOLUTION OF DATA QUERIES

MANDATORY

- AZTEC trial overview- session 1 & 4
- Any Trust-specific GCP requirements
- Guidance sheet 6: Data collection
- Guidance sheet 7: Data entry

RECOMMENDED

- Guidance sheet 9: IMP supply control and accountability

DUTY 11) INVESTIGATOR SITE FILE MAINTANCE

MANDATORY

- Any Trust-specific GCP requirements

DUTY 12) MANAGEMENT OF IMP ACCOUNTABILITY ON NEONATAL UNIT

MANDATORY

- AZTEC trial overview- session 1, 3 & 4
- Any Trust-specific GCP requirements
- Guidance sheet 4: Randomisation
- Guidance sheet 5a: Intervention
- Guidance sheet 9: IMP supply control and accountability

RECOMMENDED

- Sortition Randomisation user guide
- Guidance sheet 11: Withdrawal & Unblinding

DUTY 13) UNBLINDING

Must be medically qualified to undertake this duty

MANDATORY

- Any Trust-specific GCP requirements
- AZTEC trial overview- sessions 1 & 5
- Guidance sheet 8: Safety and non-compliance reporting
- Guidance sheet 11: Withdrawal & Unblinding

RECOMMENDED

- Sortition site unblinding user guide

PHARMACY

DUTY 14) IMP ISSUE AND ACCOUNTABILITY

MANDATORY

- AZTEC trial overview- session 1 & 7
- Any Trust-specific GCP requirements
- Guidance sheet 5a: Intervention
- Guidance sheet 5b: IMP administration
- Guidance sheet 9: IMP supply control and accountability

RECOMMENDED

- Guidance sheet 11: Withdrawal & Unblinding

DUTY 15: PHARMACY SITE FILE MAINTANANCE

MANDATORY

- AZTEC trial overview- session 1 & 7
- Any Trust-specific GCP requirements
- Guidance sheet 9: IMP supply control and accountability

RECOMMENDED

- Guidance sheet 11: Withdrawal & Unblinding

Training Requirements: Study-specific tasks

All **MANDATORY** training other than GCP training must be recorded on the Training Log: Study-specific tasks in the AZTEC Investigator Site File

PREPARATION AND ADMINISRATION OF IMP

This duty does NOT need to be recorded on the delegation log.

MANDATORY

- AZTEC IMP preparation training video
- Any Trust-specific GCP requirements
- Guidance sheet 5a: Intervention
- Guidance sheet 5b: IMP administration

RECOMMENDED

- AZTEC trial overview- session 1
- AZTEC trial overview- session 3
- "Fundamentals of Clinical Research Delivery for Administering IMPs" document

COLLECTING RESPIRATORY AND STOOL SAMPLES

This duty does NOT need to be recorded on the delegation log.

MANDATORY

- AZTEC trial overview- session 6
- Any Trust-specific GCP requirements
- Guidance sheet 13a: Sampling procedures

RECOMMENDED

- AZTEC trial overview- session 1
- Guidance sheet 13b: Sample shipment

Guidance Sheet 1: Training

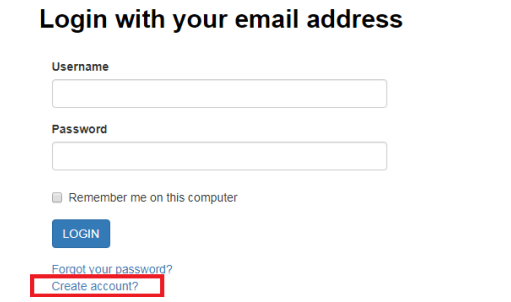
AZTEC Azithromycin Therapy for Chronic Lung Disease

Cardiff University Prifysgol Caerdydd — Centre for Trials Research / Canolfan Ymchwil Treialon

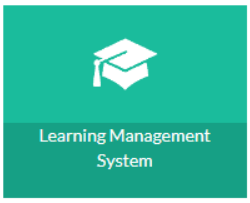
Access to NIHR online GCP training

- Any member of staff involved in an NIHR portfolio study can access online training in GCP (introduction and refresher training) and informed consent.

- To access the training, you first need to create an account on NIHR learning portal: https://learn.nihr.ac.uk



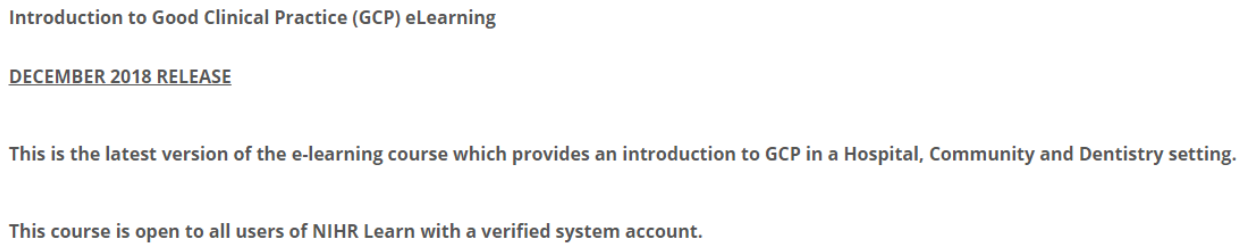
- Once an account is created, you can access the learning management system



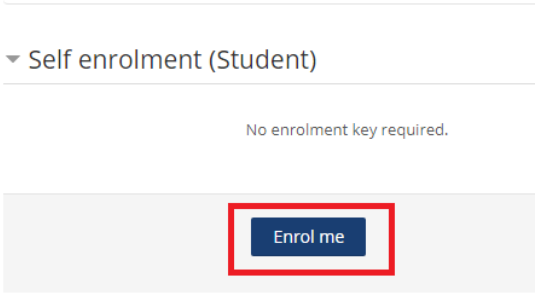
- The link to GCP training is in the bar at the top of the page

- A number of different courses are available. Refresher training is suitable for individuals who have previously completed the introductory course. Training on informed consent is also available here

- Clicking on the appropriate course brings you to the start page



- You can then enrol on a course by clicking the link at the bottom of the page



- All modules have to be completed before a certificate can be issued. Please save the certificate and keep this in a safe place