VitalBE

Value of inhaled treatment with aztreonam lysine in bronchiectasis

Data Collection and Data Entry

Data Management System

- Castor Electronic Data Capture System – electronic Case Report Form (eCRF)
- This can be access by clicking https://castoredc.com/
- It is a secure, hosted system that is GCP compliant
- Training will be provided by TCTU Data Management Team

VitalBE
Value of inhaled treatment with aztreonam lysine in bronchiectasis

Castor Training

- Email the trial Data Management Team to request training vitalbe-dm@dundee.ac.uk
- Data Management team will email a login for the test system
- On successful completion of the training package data entry staff will be provided access to the live site
- At least one team member must have completed the training and have access to Castor prior to site being open to recruitment

Data Recording

- Sites will be provided with a paper worksheets for all visits.
- Concomitant Medication Log & AE Log are separate worksheets. These should be reviewed at each visit.
- The use of the worksheets is optional. If used to record source data they must be filed in the medical notes.
- Sites will also be provided with a continuation sheet, to record source data for each visit. Use of this is optional but if not used the information must be documented in the medical records.
- Questionnaires – ensure the correct questionnaires are completed at each visit.

Data Entry

- Should be completed within 2 weeks of a participant visit.
- Data queries – The DM team will carry out regular query and batch validation checks, and raise queries on Castor
- Visual verification should be carried out according to Data Management Plan
- Source data should be recorded/filed in participant's medical notes and be available for monitoring purposes
- PI is responsible for verifying eligibility, sign off any AEs and Completion of Trial/Early Withdrawal form

Value of inhaled treatment with aztreonam lysine in bronchiectasis

Data Management Team – vitalbe-dm@dundee.ac.uk

Trial Management Team - respiratorytrials@dundee.ac.uk