

Data Collection & Data Entry

Castor eCRF

- Data entry is performed in the electronic case report form (eCRF) using the Castor
- This can be accessed here: <https://uk.castoredc.com/>
- It is a secure, hosted system that is GCP-compliant

Castor training

- Inform the Data Manager which site team members need access to Castor
- Access to a test site will be provided
- Castor training will be provided by the Data Management Team
- Castor training consists of:
 - Brief data training sheet to enter test data & become familiar with Castor
 - Supported by a data entry guideline document
 - PI data verification guidelines
 - Additional one-to-one training if required
- Access to the live system will be given when training is completed and the person is delegated this task on the Delegation Log
- The Data Management Team can be contacted on: Great-2-DM@dundee.ac.uk

Paper worksheets

- Sites will be provided with a paper worksheet for all visits.
- Concomitant Medication Log & AE Log are separate worksheets. These should be reviewed at each visit.
- The use of worksheets is optional. Worksheets will not be monitored and should not be archived at the end of the trial. 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.