ECTU Central Office SOP ECTU_DM_05: Data Quality

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Document Revision History		
Version No	Date	Summary of Revisions
1.0	21 Aug 2020	Initial creation/New document

1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures undertaken by the Data Management team to monitor and improve study data quality through data quality checks and data cleaning activity.

2. SCOPE

This SOP applies to all studies where it has been determined that ECTU Data Management will complete data quality checks and data cleaning for a study, as per ECTU SOP DM 01 Data Management Procedures. This SOP is applicable to all members of the team assigned to complete these tasks.

This SOP also applies to ECTU Trial Managers, where trial management activities have been delegated to ECTU.

3. PROCEDURE

3.1   Data Quality is monitored by the Data Management team by the following activity:

- Query and Missing Data Management
- Data Quality Control Checks (QC Checks)
- Data Cleaning

3.2   The procedure for Query and Missing Data Management is described in ECTU Central Office SOP ECTU_DM_06 Query and Missing Data Management.

3.3   Data Quality Checks (QC Checks)

3.3.1   A QC Check consists of a visual check of study data entered onto the database compared to the pCRF or other source document (e.g. lab results report) to ensure accuracy and consistency of data.

3.3.2   Data entered onto the study database from a pCRF by ECTU data management or trial management staff will require regular QC Checks. Where this applies, the Data Management team will assess the arrangements for the study before developing a Data Quality Control (QC) Check Plan.

3.3.3   The Data Management team will provide a Data QC Check Plan specifying the scope, frequency and proposed schedule of the QC Checks for the duration of the study. This will be approved by the Trial Manager and Data Manager/Assistant Data Manager and will be retained in the study-specific data management file.

3.3.4   Data entered onto the study database from a pCRF by site research staff does not require a mandatory QC Check. The Data Management team may advise additional QC checks, if possible. This decision will be documented in the DMP and in a study specific QC Check Plan.

3.3.5   Data entered directly onto an eCRF from source data generally cannot be QC Checked. Methods to ensure the quality of data entered directly on the eCRF must be considered by the Trial Manager during study development. The Data Management team may advise additional QC checks of data entered directly on the eCRF from source documents, where practicable. If appropriate for a study, this decision will be documented in the data management plan (DMP) and in a study specific Data Quality Control (QC) Check Plan.

3.3.6   Guidance on developing a QC Check Plan and preparing for, completing and documenting QC Checks is described in ECTU Central Office WPD ECTU_DM_W1 Data Quality Checks.

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3.4 Data Cleaning

3.4.1   Data Cleaning consists of manual checks to ensure that study data is complete and accurate before any analysis takes place.

3.4.2   Study data will be cleaned before the database is locked for the final analysis.

3.4.3   If any interim analysis is planned, it may be appropriate to clean certain aspects of the study data prior to each interim analysis.

3.4.4   The Data Management team will agree the proposed Data Cleaning periods with the Trial Manager at the start of the study. This will be documented in the DMP.

3.4.5   Study data can be cleaned site-by-site or per CRF as required. This will be discussed and agreed with the Trial Manager in advance. Site close out must not take place until data cleaning is complete.

3.4.6   The Data Management team will provide a Data Cleaning Plan that will specify the data that is to be included in the Data Cleaning and proposed schedule and timeframe. This will be approved by the Trial Manager, Data Manager/Assistant Data Manager and Trial Statistician and will be retained in the study-specific data management file.

3.4.7   Guidance on developing a Data Cleaning Plan and preparing for, documenting and completing the Data Cleaning is provided in ECTU Central Office WPD ECTU_DM_W2 Data Cleaning.

4. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD

- ECTU Central Office SOP ECTU_DM_07 Query and Missing Data Management
- ECTU Central Office WPD ECTU_DM_W1 Data Quality Control (QC) Checks
- ECTU Central Office WPD ECTU_DM_W2 Data Cleaning

Available on the ECTU website - www.ed.ac.uk/usher/edinburgh-clinical-trials/supporting-trials/governance/standard-operating-procedures

Templates

- DM001 Data Management Plan Template
- DM006 Data Quality Control (QC) Check Plan
- DM012 Data Cleaning Plan

Available from the Data Management Team – dm.ectu@ed.ac.uk