ECTU Central Office SOP ECTU_DM_01: Data Management Procedures

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<tr>
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<td>Effective Date:</td>
<td>21 Aug 2020</td>
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**Authorship and Approval**

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<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
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**Document Revision History**

<table>
<thead>
<tr>
<th>Version No</th>
<th>Date</th>
<th>Summary of Revisions</th>
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<tbody>
<tr>
<td>1.0</td>
<td>27th March 2018</td>
<td>Initial creation/New Document</td>
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| 2.0        | 21 Aug 2020 | - Updated at scheduled review  
- Document moved to new template  
- Sections added and renumbered throughout  
- Scope simplified to apply to specific teams  
- Responsibilities section added  
- Detail removed from pCRF/eCRF design, DMP, Query and Missing Data Management and Data Quality Control and moved to separate SOP and/or WPD  
- REDCap Development section added |
1. PURPOSE

This Standard Operating Procedure (SOP) describes the responsibilities and procedures of the Data Management team.

This SOP describes ECTU’s process for managing study data to ensure that it is collected, verified and analysed in accordance with the trial protocol and GCP requirements.

2. SCOPE

This SOP applies to all members of the ECTU Data Management Team. Where data management activities are required for a study with an ECTU Trial Manager, this SOP also applies to the ECTU Trial Management team.

3. PROCEDURES

The Data Management and Programming Team Lead, Data Manager, or ECTU Director will determine the procedures and documentation required before any data management activity is completed for the study. This includes a decision regarding the type of data capture system used.

Studies may be provided with the following procedures and documentation by the Data Management Team. This will be assessed and determined on a study-by-study basis, as described above.

- CRF design and specification development
- REDCap project development
- Data Management Plan (DMP) development
- Data and Missing Data Management, including:
  - Data Entry Guidelines (for data entry completed by ECTU)
  - Query and Missing Data Guidelines
- Data Quality, including:
  - Data Quality Control (QC) Checks
  - Data Cleaning

3.1 CRF Design and Specification

3.1.1 The CRF must be developed in accordance with the applicable Sponsor SOPs. The CRF specification must include a definition of all data fields, data queries and validation checks, and other study specific functionality required.

3.1.2 The CRF development, review and amendment process will be detailed in the Data Management Plan (DMP). The DMP must specify where a paper CRF (pCRF) or electronic CRF (eCRF) is used.

3.2 REDCap

3.2.1 The Data Management team will provide development and ongoing maintenance of the REDCap project, where a REDCap system is required.

3.2.2 The procedures used to develop the database are outlined in the ECTU REDCap SOPs (available on the ECTU website).

3.3 Data Management Plan (DMP)
3.3.1 The Data Management Plan sets out the expected data management standards within ECTU against the study specific procedures.

3.3.2 A Data Management Plan must be written by the Data Management team at the start of the study and will be reviewed and maintained regularly throughout. At a minimum, the DMP must be reviewed yearly. The frequency of review may be increased where determined necessary by the Data Manager or designee. The frequency of review will be documented on the DMP.

3.4 Data Entry

3.4.1 Where data is entered from a pCRF on to the study database by the ECTU Data Management team or ECTU Trial Management team, ECTU Data Entry guidelines will be produced and maintained by the Data Management team throughout the study.

3.4.2 The procedure for producing and maintaining the above guidelines is detailed in ECTU Central Office SOP ECTU_DM_04 Data Entry Procedures.

3.5 Data Quality

3.5.1 Data quality is maintained through data query and missing data checks as well as data Quality Control (QC) checks and data cleaning activity.

3.5.2 The Data Management team will assess the study for suitability for data QC checks. This will be documented in the Data Management Plan.

3.5.3 Data cleaning must occur prior to final database lock at the end of the study. The frequency of data cleaning activity can be increased if interim analyses are planned. This will be documented in the Data Management Plan.

3.5.4 The Data Management team will provide a Data Quality Control Check Plan and a Data Cleaning plan where assessed as required.

3.5.5 The procedure for preparing for, completing and documenting Data Quality Checks and Data Cleaning is documented in ECTU Central Office SOP ECTU_DM_05 Data Quality.

3.6 Query and Missing Data Management

3.6.1 The Data Management team advises and assists with the specification of data queries, data query reports and/or missing data reports required on ECTU electronic data capture systems.

3.6.2 The Data Management team will conduct regular query and missing data reviews to a schedule agreed with the Trial Manager. This will include monitoring of queries and responses, query closures and responding to site queries from the reports.

3.6.3 Query and Missing Data Guidelines will be produced and maintained by the Data Management Team throughout the study.

3.6.4 The procedure for producing and maintaining the above guidelines is detailed in ECTU Central Office SOP ECTU_DM_06 Query and Missing Data Management

3.7 Document Version Control and Review
3.7.1 All documents, guidelines and templates produced by the Data Management team will be version controlled and subject to regular review.

3.7.2 This procedure is documented in ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

4. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD

- ECTU REDCap SOPs
- ECTU Central Office SOP ECTU_DM_04 Data Entry Procedures
- ECTU Central Office SOP ECTU_DM_05 Data Quality Control
- ECTU Central Office SOP ECTU_DM_06 Query and Missing Data Management
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

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

Templates

- DM001 Data Management Plan

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