

ECTU Central Office SOP_ECTU_DM_01: Data Management Procedures

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| Authorship and Approval | | | |
|--|--|-------------|---|
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| Tanya Tharakan QA Manager | QA Authorisation | 27 Feb 2024 | See retained approval email dated 27 Feb 2024 |

| Document Revision History | | |
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| Version No. | Effective Date | Summary of Revisions |
| 1.0 | 27-Mar-2018 | Initial creation |
| 2.0 | 21-Aug-2020 | <ul style="list-style-type: none"> • 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 |
| 3.0 | 15 Mar 2024 | <ul style="list-style-type: none"> • Updated to new SOP template • Extensive changes throughout document to include implementation of ACCORD Policy POL012 and to reflect the delegation of DM procedures to the TM team. • Sections simplified and renumbered throughout |

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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes ECTU's procedures for managing study data to ensure that it is collected, verified and analysed in accordance with the trial protocol and GCP requirements.

2.0 SCOPE

This SOP applies to all members of the ECTU Data Management team where any of these tasks have been delegated to the team to complete.

If the ECTU Trial Management Team is delegated any of the Data Management tasks covered by this document then this SOP and any corresponding SOP and Working Process Document (WPD) should be adopted for the delegated task.

3.0 RESPONSIBILITIES

The Data Management and Programming Team Lead and/or Data Management and Programming Architect are responsible for determining the level of data management support that will be allocated to each study based on the funding available and the study requirements. This includes the type of data capture system (either a bespoke system or a REDCap system) that will be used and which tasks will be delegated to the ECTU Data Management Team throughout the study.

Once the level of Data Management support has been established, the designated Data Manager or Assistant Data Manager is responsible for implementing the procedures and documentation required before any data management activity is completed for the study.

4.0 PROCEDURE

Once the level of support has been established as above, studies may be provided with any or all the following procedures and documentation as applicable:

- eCRF specification development
- REDCap/ Bespoke Database Development
- REDCap/ Bespoke User Access Administration and Review
- Data Management Plan (DMP) development and review
- Query and Missing Data Management, including Query and Missing Data Guideline development and review
- Data Entry, including Data Entry Guideline development and review (only applicable where data entry is completed by ECTU)
- Data Quality Control (QC) Checks including Data Quality Control (QC) Check plan development and review

Data Cleaning including Data Cleaning Plan development and review (once study reaches data cleaning stage)

4.1 eCRF Specification Development

- 4.1.1 The eCRF must be developed in accordance with the applicable Sponsor SOPs. The eCRF specification must include a definition of the required data fields,

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automated data queries and validation checks, and other study specific functionality required.

- 4.1.2 The eCRF development, review and amendment process will be detailed in the Data Management Plan (DMP). Where a paper version is required, the Trial Manager or designee will design Data Collection Sheets.

4.2 REDCap Database Development

- 4.2.1 Where the study will require a REDCap database, this will be developed and maintained by the ECTU Data Management Team in accordance with Sponsor SOPs and the study protocol.
- 4.2.2 At a minimum the ECTU Data Management Team will be provided with a document or set of documents specifying the required content of the database by the Trial Manager, Chief Investigator, or designee.
- 4.2.3 The procedures used to develop the database are outlined in the ECTU REDCap SOPs and WPDs.

4.3 Bespoke Database Development

- 4.3.1 Where the study will require a bespoke database, this will be developed and maintained by the ECTU IT/ Programming Team in accordance with Sponsor SOPs and the study protocol.
- 4.3.2 At a minimum the ECTU IT/ Programming Team will be provided with a document or set of documents specifying the required content of the database by the Trial Manager, Chief Investigator, or designee
- 4.3.3 The procedures used to develop the database are outlined in the ECTU IT SOPs and WPDs.

4.4 Data Management Plan (DMP)

- 4.4.1 The Data Management Plan (DMP) sets out the expected data management standards within ECTU against the study specific procedures.
- 4.4.2 The procedure for producing and maintaining a DMP is specified in ECTU Central Office SOP ECTU_DM_09 Data Management Plans.

4.5 Data Entry

- 4.5.1 Data entry methods and responsibilities will be specified in the DMP.
- 4.5.2 Where data is entered from a paper source on to the study database by the ECTU Data Management team, Data Entry Guidelines will be implemented and maintained throughout the study.
- 4.5.3 The procedure for producing and maintaining the above guidelines is detailed in ECTU Central Office SOP ECTU_DM_04 Data Entry Procedures.

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4.6 Query and Missing Data Management

- 4.6.1 A method for identifying and addressing data discrepancies, non-conformant data and missing data will be established when using either a bespoke or REDCap database. This will most commonly include queries, data quality rules and reports that are included in the database specification to facilitate this.
- 4.6.2 The Query and Missing Data Management procedure is detailed in ECTU Central Office SOP ECTU_DM_06 Query and Missing Data Management

4.7 Data Quality Control (QC) Checks

- 4.7.1 Data quality can be monitored through data Quality Control (QC) Checks in addition to data queries.
- 4.7.2 Data Quality Control (QC) Checks completed by the ECTU Data Management Team are distinct from any checks that are completed by the study Monitor. The criteria for Data Quality Control (QC) Checks within ECTU is specified in ECTU Central Office SOP ECTU_DM_10 Data Quality Control Checks. These criteria will be used to assess whether Data Quality Control (QC) Checks by ECTU are required for the study.

4.8 Data Cleaning

- 4.8.1 Data Cleaning consists of a number of checks and reviews to ensure the data is complete and correct prior to final analysis. Data Cleaning must occur prior to final database lock at the end of study.
- 4.8.2 The procedure for preparing for, completing and documenting Data Cleaning is detailed in ECTU Central Office SOP ECTU_DM_11 Data Cleaning.

5.0 Study Document Version Control and Review

- 5.1 All documents, guidelines and templates (unless stated otherwise) produced by the Data Management team will be version controlled and subject to regular review.
- 5.2 This procedure is detailed in ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Document Version Control and Review.

5.0 RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD ([On ECTU Website](#))

- ECTU REDCap SOPs
- ECTU Central Office SOP ECTU_SOP_DM_04 Data Entry Procedures
- ECTU Central Office SOP ECTU_SOP_DM_06 Query and Missing Data Management
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Document Version Control and Review

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- ECTU Central Office SOP ECTU_SOP_DM_10 Data Quality Control (QC) Checks
- ECTU Central Office SOP ECTU_SOP_DM_09 Data Management Plans
- ECTU Central Office SOP ECTU_SOP_DM_11 Data Cleaning
- ECTU Central Office WPD ECTU_WPD_DM_W1 Preparing for and Completing Data Quality (QC) Checks
- ECTU Central Office WPD ECTU_WPD_DM_W2 Data Cleaning Procedures
- Accord Policy POL012: [Policies | Accord](#)
- Accord SOP [CR013 CRF Design and Implementation v5.0](#)

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