ECTU Central Office SOP_ECTU_DM_09: Data Management Plans (DMP)

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	17 May 2024	• Initial creation/New document
2.0	04 Jun 2025	• Additional text for study-specific DMP and associated DM document review added to section 4.2

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for creating a Data Management Plan (DMP) for a study.

This SOP describes ECTU's process for creating and maintaining a DMP throughout the life-cycle of a study to ensure data is managed and analysed in accordance with the trial protocol and GCP requirements.

2.0 SCOPE

This SOP applies to all studies where data management has been delegated to the ECTU Data Management Team.

3.0 RESPONSIBILITIES

Delegation of this task to the Data Management Team will be established at the start of study as per ECTU Central Office SOP ECTU_DM_01 Data Management Procedures.

Where the Data Management team is delegated this task, the designated Data Manager or Assistant Data Manager will be responsible for implementing and maintaining the Data Management Plan.

4.0 PROCEDURE

4.1 Creating a Data Management Plan (DMP)

4.1.1 Template DM001 Data Management Plan will be used to create the study-specific DMP unless an alternative is required by the study Sponsor.

4.1.2 The DMP includes the following standard categories, which are the minimum required. Additional categories can be added according to the study requirements:

1. **Introduction**
   A brief description of the purpose of the DMP

2. **Study Description**
   A brief description of the study type and proposed outcomes

3. **Personnel and Responsibilities**
   Name, Role and email contact for key study staff and an outline of the delegated responsibilities for the study

4. **CRF and Database Design and Development**
   An outline of the development process and the personnel involved

5. **Randomisation**
   A description of the randomisation system and how this was developed. If no randomisation required, a description of the study mechanism.

6. Data Workflow and Data Entry
A description of what data is collected, how it is collected and who is responsible for entering the data onto the study database.

7. Training and User Access
A description of how initial and ongoing database training is provided and how user access will be requested and granted.

8. Data Quality
A description of Query and Missing Data management, Data Quality Control (QC) Checks, Data Cleaning (including data reconciliation) and Monitoring for the study.

9. Reports
A description of reports included on the study database, the report users and frequency of use

10. Data Transfer
A description of planned transfers of data to or from the study.

11. Coding
A description of any coding (for example, MedDRA coding) requirements for the study.

12. Database Lock and Archiving
A description of when database lock is planned and how this will be completed (including Sponsor involvement). The archiving period and responsibilities are specified.

Appendix A: Abbreviations and Definitions
Appendix B: User Roles
Appendix C: Related Documentation

4.1.3 Standard text has been provided in each of the sections above to assist with completion. This text can be altered to suit the specific needs of the study if required. Additional guidance text has also been provided throughout the template, which should be deleted before finalisation.

4.1.4 For studies sponsored by ACCORD, the DMP will be implemented in accordance with ACCORD Policy POL012 Data Management. The DMP will be approved and made effective as per the requirements of this policy.

4.1.5 For studies that do not fall within the remit of ACCORD Policy POL012 or there is no alternative requirement from another Sponsor, an approved DMP must be in place within three months of the first site opening to recruitment.

4.1.6 The DMP will be approved by the Trial Manager or designee, the Data Manager or Assistant Data Manager and the Trial Statistician or designee. For ACCORD sponsored risk-assessed studies, it will also be approved by the Trial Monitor.

4.2 Reviewing and Maintaining a DMP

4.2.1 All DMP are subject to regular review. The review period will be set by the author of the DMP before approval. Reviews must take place yearly at a minimum although an increased frequency may be appropriate depending on the study requirements. The agreed review period will be stated on the DMP.

4.2.2 Responsibility for reviewing and maintaining a study-specific DMP will lie with the team who authored document, and will be evidenced in the Document History on the first page.

4.2.3 The reviewer should ensure that any updates to other Data Management documents such as Query and Missing Data Guidelines, Data Entry Guidelines, Data Quality Control (QC) Check Plans and Data Cleaning Plans that may impact the DMP are included in the review. If a DMP update impacts any of these documents individually, these can be updated to reflect the changes at the time of their scheduled review.

4.2.4 The Data Management review procedure is documented in ECTU Central Office SOP ECTU_DM_07 Data Management Document Version Control and Review

5.0 RELEVANT DOCUMENTS AND REFERENCES

On ECTU Website

- ECTU Central Office SOP ECTU_DM_01 Data Management Procedures
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Document Version Control and Review

On ACCORD Website

- ACCORD Policy POL012 Data Management Policy

Templates (On ECTU Shared drive)

- DM001_Data Management Plan Template
- DM005_Data Entry Guidelines

ECTU_SOP_DM_09 Data Management Plans (DMP) v2.0 and DM001 v7.0

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