

ECTU Central Office SOP_DM_07: Data Management Document Version Control and Review

| | |
|-----------------|-------------|
| Version No: | 2.0 |
| Issue Date: | 11 Apr 2024 |
| Effective Date: | 06 May 2024 |

| Authorship and Approval | | | |
|--|--|-------------|---|
| Name and Designation | Author/Reviewer /Approval/ Authorisation | Date | Signature |
| Lynsey Milne Data Manager | Author | 23 Jan 2024 | See retained email approval dated 23 Jan 2024 |
| Ruth Armstrong Assistant Data Manager | Reviewer | 05 Feb 2024 | See retained email approval dated 05 Feb 2024 |
| Tony Wackett, Data Management and Programming Architect | Reviewer | 22 Jan 2024 | See retained email approval dated 22 Jan 2024 |
| Kenton D'Mellow Data Management and Programming Team Lead | Approver | 11 Apr 2024 | See retained email approval dated 11 Apr 2024 |
| Tanya Tharakan QA Manager | QA Authorisation | 22 Jan 2024 | See retained email approval dated 22 Jan 2024 |

| Document Revision History | | |
|---------------------------|----------------|---|
| Version No. | Effective Date | Summary of Revisions |
| 1.0 | 21 Aug 2020 | <ul style="list-style-type: none"> Initial creation |
| 2.0 | 06 May 2024 | <ul style="list-style-type: none"> Updated to new SOP template Wording changes to section 2 Section 3 added Template control instructions for excel templates added throughout and in Appendix 1 Pilot template instructions added to section 4.1 Standard review period added to section 4.3 Wording and numbering changes made throughout document |

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for ensuring all templates and study-specific documents produced by the Data Management team are developed and versioned consistently, and are reviewed on a regular basis to ensure accuracy and efficacy.

2.0 SCOPE

This SOP applies to all members of the ECTU Data Management team where they are responsible for creating and maintaining documents for both template and study-specific purposes.

3.0 RESPONSIBILITIES

Delegation of data management tasks to the ECTU Data Management team will be established at the start of the study as per ECTU Central Office SOP ECTU_SOP_DM_01 Data Management Procedures.

Where a task is delegated to the team, the Data Manager or Assistant Data Manager allocated to that study is responsible for creating all relevant documents.

All members of the ECTU Data Management team are responsible for establishing, reviewing and maintaining document templates.

4.0 PROCEDURE

4.1 Creating a new Data Management Template

4.1.1 Each template developed and implemented by the Data Management team will be assigned a template identifier. The template identifier is unique to each template, starting with DM001. This identifier will remain the same on all versions of the template. Template identifiers are assigned on an ascending basis with each new template developed (e.g., DM001, DM002, DM003).

4.1.2 All templates are subject to version control and will be set at version 1.0 at initial creation. Once set, the version number will remain the same on all draft, pilot and final versions of the template. Version numbers will only change when the template is revised and a new version is created. New version numbers will be set by increasing by one whole number each time (e.g., v1.0, v2.0).

4.1.3 When a new template is created, the following must be included in the header in a word document or in appropriate cells in the first worksheet on excel spreadsheets:

- ECTU Logo
- Study Name/Acronym Field*
- Study Specific Document Name Field*
- Version Number Field*
- Document Version Date Field*

The user of this document is responsible for ensuring it is the current version.

* For completion with study-specific information when the template is adapted for use in a study

4.1.4 In the footer in a word document or in an appropriate locked cell (see Appendix 1) in the first worksheet on excel spreadsheets, the template name should be included in the following naming conventions, depending on the status of the template. These naming conventions should also be used to name the template electronically when saving:

| Template Status | Naming Convention |
|-----------------|---|
| Draft | Identifier and Document Name TEMPLATE_DRAFT_Version Number_Document Date (e.g., DM001 Data Management Plan TEMPLATE_DRAFT_v1.0_1Jan2024 |
| Pilot | Identifier and Document Name TEMPLATE_DRAFT (Pilot)_Version Number_Document Date (e.g., DM001 Data Management Plan TEMPLATE_DRAFT (Pilot)_v1.0_1Jan2024 |
| Final | Identifier and Document Name TEMPLATE_Version Number_EffectiveDate (e.g., DM001 Data Management Plan TEMPLATE_v1.0_1Jan2024 |

4.1.6 If the template is on a word document, page numbers should also be included in the footer in the format Page X of X. For templates in excel spreadsheets, if multiple worksheets are used in the template, these should be clearly labelled to identify them.

4.1.7 All templates must include a Template Revision History section at the end of the word document or in a worksheet at the end in excel spreadsheets. This will be used by the Data Management team to record any reviews and a description of any updates made.

4.1.8 The layout and format of each template should be designed so that it is applicable to various studies and scenarios, however it should be adaptable to suit the needs of an individual study (e.g., sections that are not applicable can be removed and text wording amended as appropriate).

4.1.9 Guidance text can be provided in the template. Any guidance text should be in green italics and identified as being guidance text. This is for instruction on how to complete the applicable section and is to be deleted from the study-specific version before it is finalised.

4.2. Template Status – Draft, Pilot and Final Status

4.2.1. The status of a template must be clear on the document name as specified in section 4.1.4.

4.2.2 A template will be in ‘Draft’ status when a new version is initially created and it is in the process of review or piloting by the Data Management team.

The user of this document is responsible for ensuring it is the current version.

- 4.2.3 There may be several draft versions of a template whilst changes are made to the document, however the version number should not change throughout this process. These versions should be tracked moderating the naming convention (e.g., with a different document date or initials to indicate a reviewer's comments).
- 4.2.4 If a new or updated template is to be introduced it may be appropriate to test the effectiveness of the template as a study-specific document before the template is made live. The template then has 'Pilot' status. This is not a mandatory procedure but may be done on a discretionary basis as appropriate. A template may be piloted by multiple users and/or over various studies as required.
- 4.2.5 A pilot template is regarded as a draft version. Depending of the efficacy of the template, it can be altered during the pilot period before being submitted for finalisation
- 4.2.6 A template will be given final status once it has been reviewed and agreed by the Data Management team. The review may include feedback on the pilot if applicable.
- 4.2.7 Once the template has been finalised and is ready for use, the Data Management Team will ensure the ECTU QA Manager is provided with the finalised copy and been informed of the effective date.

4.3. Template Review

- 4.3.1 Where a template has been specified as part of a Standard Operating Procedure (SOP) and/or Working Practice Document (WPD), it will be included in the review process for that SOP/WPD as specified in ECTU Central Office SOP ECTU_OP_01 Development and Management of Standard Operating Procedures (SOP), Working Practice Documents (WPD) and Policies.
- 4.3.2 If a template requires review outwith the standard SOP review period, the Data Management Team will request a draft version of the document, and ensure the ECTU QA Manager is informed of the new version and the effective date and an electronic copy will be provided for central filing.
- 4.3.3 If after review, a template is found to be no longer required, it can be withdrawn from use. The ECTU QA Manager will be informed of this with the date of withdrawal.
- 4.3.4 When a template is withdrawn, the unique identifier allocated (see section 4.1.1) will also be withdrawn and will not be reused for another template.
- 4.3.5 All reviews will be documented in the Template Review History, including the decision to withdraw.
- 4.3.6 If changes are required to a template after review, this will result in a new version of the template with a new version number allocated for further review and finalisation.
- 4.3.7 If the template does not require any changes after review, the document version number should remain the same but with a new effective date. It should be documented in the Template Review History that no updates were indicated as of the new effective date.

The user of this document is responsible for ensuring it is the current version.

4.4 Creating a study-specific document from a Data Management template

- 4.4.1 Only pilot or final versions of a template should be used to create a study-specific document.
- 4.4.2 In the header or designated cell, the study-specific information as detailed in 4.1.3 should be completed. The study logo may also be added to the header if required.
- 4.4.3 The footer or locked cell containing the template name should not be altered.
- 4.4.4 Complete all necessary information on the template, removing any green guidance text as applicable. The Template Revision History should be removed or hidden (in the case of excel templates) from the study-specific version.
- 4.4.5 Ensure that the document is saved as a study-specific version with a new document name using the following conventions:

| Study-specific Document Status | Naming convention |
|--------------------------------|--|
| Draft | Study Name or Acronym and Document Name_DRAFT_Version No_Document Date (e.g., 123Trial Data Management Plan_DRAFT_v1.0_1Jan2024) |
| Final | Study Name or Acronym and Document Name_Version No_Document Date (e.g., 123Trial Data Management Plan_v1.0_1Jan2024) |

- 4.4.6 Study-specific versions are subject to version control as specified in section 4.1.2 with multiple draft versions tracked as specified in section 4.2.3 whilst in review.
- 4.4.7 Where appropriate, study-specific documentation may require review and approval by other project representatives (e.g., Trial Manager, Trial Statistician). The template or corresponding SOP/WPD will provide further description where formal approval is required.

4.3 Reviewing a study-specific document

- 4.3.1 The Data Management team are responsible for reviewing and updating all study-specific documents they have created from a Data Management template.
- 4.3.2 The standard review period for study-specific documents is yearly from the effective date but this may differ depending on the study requirements.
- 4.3.3 The review period will be specified by the Data Management team when the study-specific version is made effective and will be stated on the document.
- 4.3.4 When reviewing or updating a study-specific document the current final template from the ECTU shared drive should always be used. This may mean moving an existing study-specific document onto a new template.

The user of this document is responsible for ensuring it is the current version.

4.3.5 Reviews to study-specific documents should be documented in the Document Review History sections 4.3.5-4.3.7 for templates.

5.0 RELEVANT DOCUMENTS AND REFERENCES

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

- ECTU_SOP_DM_01 Data Management Procedures
- ECTU_OP_01 Development and Management of SOP and WPD

The user of this document is responsible for ensuring it is the current version.

Appendix 1

Follow these steps to lock specific cells in a worksheet:

1. Select all cells in the sheet (Ctrl + A)
2. Right-click and select 'Format Cells...'
3. Untick the 'Locked' box and click 'OK'
4. Select only the cell/s you want to lock
5. Right-click and select 'Format Cells'
6. Re-select the 'Locked' box for the selected cell/s only then click 'OK'
7. Right-click the sheet name tab at the bottom of the page and select 'Protect sheet...'
8. Set the password as the template ID (e.g. 'DM010'), leaving the checkbox options as the default, and re-enter the password to confirm

The selected cell/s are now protected but the remainder of the sheet may be edited as required.

The user of this document is responsible for ensuring it is the current version.