





## ECTU Central Office SOP ECTU\_ST\_06: Establishing and Maintaining a Statistics Master File (SMF)

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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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Tanya Tharakan QA Manager	QA Authorisation	20-Aug-2024	 <a href="#">Tanya Tharakan (Aug 20, 2024 13:06 GMT+1)</a>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	22 <sup>nd</sup> Nov 2017	Initial creation
2.0	6 <sup>th</sup> Nov 2018	Document moved to new template. Alterations to section 1 – now moved to section 3.1 (subsections 3.1.1 and 3.1.2). 3.1 renumbered due to additional subsections. Statistical Review Checklist added to section 3.2. ECTU_WPD_TM_W2 added to section 4
3.0	04 Mar 2021	Alterations to section 3.2 regarding file notes and location of the Trial Master File. Additional responsibility of maintenance of SMF has been added to subsection 3.3.1. Addition of 'File note template' added to section 4.
4.0	04 Sep 2024	Moved to new template (v3.0). Definition to paper-based and electronic backup for SMF. DMC folder removed

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		from SMF but instruction of recording the locations of DMC reports in form ST006A kept. 'File notes' under 4.2 updated to incorporate new templates. Other minor wording and formatting changes throughout.
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## 1.0 PURPOSE

This Standard Operating Procedure (SOP) provides instruction on establishing and maintaining a Statistics Master File (SMF).

## 2.0 SCOPE

This SOP applies to all studies with statistical support provided through the Edinburgh Clinical Trials Unit (ECTU).

## 3.0 RESPONSIBILITIES

The Trial Statistician (or designee) is responsible for the implementation of this SOP.

## 4.0 PROCEDURE

### 4.1 Establishing a Statistics Master File (SMF)

- 4.1.1 A paper-based Statistics Master File (SMF) will be established for each Clinical Trial of Investigational Medicinal Products (CTIMP) or regulated device study that requires ECTU statistical team input. The necessity for a paper-based SMF for other types of study should be considered by the Trial Statistician at the start of study.
- 4.1.2 All studies should have an electronic backup of the SMF; however, when a paper-based SMF exists (e.g., for a CTIMP), it is considered the main one.
- 4.1.3 The paper-based SMF will be held in a secure location within ECTU with restricted access. The electronic backup of the SMF is located on the ECTU shared drive.
- 4.1.4 The paper based SMF will contain nine sections as detailed in the 'Statistics Master File Essential Document Checklist (ST006A)'. The corresponding folder structured for the electronic backup of the SMF can be obtained from ECT Unit\DRIVE RESTRUCTURE.
- 4.1.5 The paper-based SMF will be held in clearly labelled ring binders, using 'SMF Divider Label Template (ST006B)' and 'SMF Spine Label Template (ST006C)' for identification.
- 4.1.6 The Trial Statistician (or designee) will populate the 'SMF Essential Document Checklist (ST006A)' with the appropriate document and location information. This will be maintained throughout the study.
- 4.1.7 All relevant documents will be filed in the SMF in accordance with the 'Statistics Master File Essential Document Checklist (ST006A)'. Documents will be filed in descending chronological order (current document first).
- 4.1.8 When a document has multiple dates (e.g. date document was finalised; reviewers sign off dates), the 'date finalised' in the document should be recorded in the 'SMF Essential Document Checklist (ST006A)', even if the document has been signed off at a later date.

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## 4.2 Section Headings and Contents

The 'Statistics Master File Essential Document Checklist (ST006A)' will be used as the index for the SMF. This will be the first page of the folder. A contents description for each of the nine sections of the SMF is as follows:

### 0. SMF Essential Document Checklist

#### 1. Statistical Review Checklist (ST007)

#### 2. Sample Size Calculation

- Signed and validated Sample Size Estimate form
- Any other documentation relating to the sample size calculations – this should only be included in the SMF if the documentation relates to a sample size that is included in the study protocol

#### 3. Randomisation

- Current Randomisation System Description Document
- Previous Randomisation System Description Documents

#### 4. Statistical Analysis Plan (SAP)

- Current version SAP (signed)
- Previous version(s) SAP (signed)

#### 5. Analysis Population Agreement

- Analysis Population Agreement form (signed)

#### 6. Final Report Authorisation

- Signed Final Report Authorisation form
- Final Report – to be held electronically with location stated on the Essential Document Checklist

#### 7. File Notes

- All statistics-related file notes throughout the study, should be file in this section. with a short description of the file note subject and the date of the file note.
- For partial service studies:
  - A 'File Note - Partial Service - Location of TMF (AD-T005a)' should be created and filed in this section to state the location and contact details of the non-ECTU Trial Master File (TMF), and
  - A 'TMF Place Holder - TMF Section X.X Statistical Documentation (AD-T005d)' should be created and send to the external trial manager for filing.

#### 8. Other Relevant Documents

- This section may be used to hold any other documents that may be relevant. This can be populated at the discretion of the Trial Statistician (or designee) but care should be taken not to duplicate the contents of the TMF. A short description of the document type, version and date should be included in the 'Statistics Master File Essential Document Checklist (ST006A)'.

**Notes on Data Monitoring Committee Reports:** DMC Reports should not be filed in the SMF but should be held electronically. Their location should be indicated on the 'Statistics Master File Essential Document Checklist (ST006A)'.

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### 4.3 File Maintenance and Review

- 4.3.1 The Trial Statistician (or the designee) will be responsible for the ongoing maintenance of the SMF throughout the study. All filing and updates should be completed in a timely manner.
- 4.3.2 The SMF will be formally reviewed and finalised by the Trial Statistician (or designee) prior to archiving to ensure that all documentation is complete and signed off in the 'SMF Essential Document Checklist (ST006A)'.
- 4.3.3 This must be completed before the file can be sent for archiving as per ECTU Central Office WPD\_TM\_W2: Archiving of Essential Study Documentation.

## 5.0 RELEVANT DOCUMENTS AND REFERENCES

### On ECTU Shared Drive

- Statistics Master File Essential Document Checklist Template - ST006A
- Statistical Review Checklist Template - ST007
- SMF Divider Label Template - ST006B
- SMF Spine Label Template - ST006C

### AD Templates

- File Note - Partial Service - Location of TMF Template - AD-T005a
- TMF Place Holder - TMF Section X.X Statistical Documentation Template - AD-T005d

**On ECTU Drive Restructure** (ECT Unit\DRIVE RESTRUCTURE\ latest folder structure for the electronic backup of the SMF

### On ECTU Website

- ECTU Central Office WPD ECTU\_TM\_W2 Archiving of Essential Study Documentation

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