

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

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Authorship and Approval			
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Document Revision History		
Version No	Date	Summary of Revisions
1.0	22 <sup>nd</sup> November 2017	Initial creation
2.0	6 <sup>th</sup> November 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 March 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.

## 1. PURPOSE

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

## 2. SCOPE

This SOP applies to all studies where an ECTU Statistician is responsible for, or has oversight of the statistical analysis.

## 3. PROCEDURE

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

- 3.1.1 The Trial Statistician or designee will be responsible for establishing the SMF for the study.
- 3.1.2 A Statistics Master File (SMF) will be established for each CTIMP or regulated device study.
- 3.1.3 The necessity for an SMF for other types of study should be considered by the Trial Statistician at the start of study.
- 3.1.4 The SMF will be held in clearly labelled ring binders.
- 3.1.5 The SMF will contain nine sections as detailed in the ECTU Statistics Master File Essential Document Checklist.
- 3.1.6 The Trial Statistician or designee will populate the Essential Document Checklist with the appropriate document and location information. This will be maintained throughout the study.
- 3.1.7 All relevant documents will be filed in the SMF in accordance with the Essential Document Checklist. Documents will be filed in descending chronological order (current document first).

### 3.2 Section Headings and Contents

The Essential Document checklist 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:

1. **Statistical Review Checklist**
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. **DMC Reports**
  - DMC Reports should not be filed in the SMF but should be held electronically. This should be indicated on the Essential Document Checklist and the location stated
6. **Analysis Population Agreement**
  - Analysis Population Agreement form (signed)
7. **Final Report Authorisation**
  - Signed Final Report Authorisation form
  - Final Report – to be held electronically with location stated on the Essential Document Checklist



## 8. File Notes

- Signed stats-related file notes throughout the study. A short description of the file note subject and the date of the file note should be included on the Essential Document Checklist.
- A file note stating the location of the formal Trial Master File (TMF) shall be created and filed in this section of the SMF. The location of the TMF shall be confirmed by the Trial Manager (or equivalent). The level of detail required will vary depending on whether the TMF is located on or off site.

## 9. 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 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 Essential Document Checklist.

## 3.3 File Maintenance and Review

- 3.3.1** The Trial Statistician (with support from the designee) will be responsible for the ongoing maintenance of the SMF and the Essential Document Checklist throughout the study. All filing and updates should be completed in a timely manner.
- 3.3.2** The SMF will be formally reviewed by the Trial Statistician prior to archiving to ensure that all documentation is complete and correct.
- 3.3.3** Once the review has been completed, the Trial Statistician will complete the File Review section of the Essential Document Checklist. This must be completed before the file can be sent for archiving.

## 3.4 Storage

The SMF will be held in a secure location with restricted access.

## 4. RELEVANT DOCUMENTS AND REFERENCES

### **ECTU Statistics Master File (SMF) Essential Document Checklist ST006A v3.0**

ECT Unit/SOPs/Finalised SOP and WPD/ST/Supporting Documents and Templates/Current

### **SMF Divider Label Template ST006B v2.0**

ECT Unit/SOPs/Finalised SOP and WPD/ST/Supporting Documents and Templates/Current

### **SMF Spine Label Template ST006C v1.0**

ECT Unit/SOPs/Finalised SOP and WPD/ST/Supporting Documents and Templates/Current

### **ECTU Central Office WPD ECTU\_TM\_W2 Archiving of Essential Study Documentation v1.0**

ECT Unit/SOPs/Finalised SOP and WPD/TM/WPD/PDF Versions/Current

### **File Note Template**

ECT Unit/SOPs/Finalised SOP and WPD/ST/Supporting Document and Templates/Current