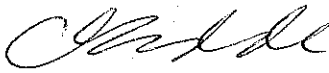




SOP Number 006
SOP Title Trial Master File

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1. PURPOSE

The purpose of this SOP is to describe the standard processes to be followed when preparing and maintaining a Trial Master File (TMF) for clinical research.

2. INTRODUCTION

In Good Clinical Practice (GCP) it states that the essential documents to be filed are 'those documents, which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced'. The filing of trial documents in an orderly manner is necessary for the smooth running of the clinical research and any audits or inspections that may be carried out during or after the conduct of the trial.

3. SCOPE

The scope of this procedure is for all clinical research studies sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit. For University of Oxford sponsored studies, the Clinical Trials and Research Governance Team will hold documentation demonstrating Sponsorship oversight. This documentation is not considered part of the TMF and as such is outside the scope of this SOP.

4. DEFINITIONS

Essential Documents

Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

Trial Master File (TMF)

The Trial Master File consists of essential documents, which enable both the conduct of a clinical trial and the quality of the data to be evaluated. ICH GCP defines that the TMF consists of a Sponsor File and an Investigator Site File.

- **Sponsor File (units may use other terms)**

The Sponsor File consists of essential documents relating to study conduct held by the Sponsor delegate.

- **Investigator Site File (ISF)**

The Investigator Site File consists of essential documents relating to study conduct at a specific site (i.e. location where participant-related trial activities are actually conducted), and which enable both the conduct of a clinical trial and the quality of the data at that site to be evaluated. This may be incorporated into the TMF if the trial consists of one site only.

5. RESPONSIBILITIES

Sponsor

The Sponsor has overall responsibility for the TMF. For OU sponsored studies this responsibility will be delegated to the Chief Investigator and/or the unit.

Chief Investigator (CI)

The Chief Investigator is accountable for ensuring that the TMF is prepared, maintained and is readily available for conduct, monitoring and audit of the trial. In a multi-centre study, maintenance of the ISF may be further delegated, within a written agreement, to the relevant Principal Investigator.

6. SPECIFIC PROCEDURE

6.1 Action Prior to the Start of the Trial

The TMF should be established at the beginning of the trial; organised in a manner to allow efficient maintenance and review of trial-related documentation.

For an example list of documentation required for a TMF see section 8, references. The TMF content may vary depending on the type of trial involved and hence the list must be reviewed on a case-by-case basis.

The TMF may be paper-based or electronic or a hybrid of both as long as this is defined. Documents which are scanned must be quality controlled for accuracy and legibility against the original, and the electronic file should imitate the structure of a similar paper-based file.

The TMF should be labelled with the study title, reference number and trial site identification and should be stored in a secure place. There may be several volumes of a paper-based TMF. There should also be an up to date index.

Only the Chief Investigator or delegate, Sponsor, Monitor, Competent Authority, host organisation, Quality Assurance functions and Named Archivist should have access to the TMF.

Any document stored separately from the TMF, whether physically or electronically, must have a signed and dated file-note within the relevant section, indicating its location.

6.2 TMF Maintenance

All Essential Documents must be maintained in the TMF and updated as appropriate throughout the trial.

Previous versions of the documents must be retained in the TMF, but should be clearly labelled as superseded, and may be relocated in a section for superseded documents.

It is recommended that the file be arranged chronologically with the most recent documents at the front of each relevant section in the case of a paper-based TMF, and ordered by date in the case of an electronic TMF.

6.3 Archiving

See University of Oxford Core SOP 005 - Archiving of the Trial Master File and Essential Documents.

7. RELATED DOCUMENTS

University of Oxford Core SOP 005 – Archiving of the Trial Master File and Essential Documents

University of Oxford Core SOP 013 – Confidentiality and Security of Personal Data

8. REFERENCES

Example list of documents required for a TMF

<https://researchsupport.admin.ox.ac.uk/ctrg/resources>

ICH Harmonised Tripartite Guidelines for Good Clinical Practice (ICH GCP)

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.1	20 Jan 2014	Re-defined TMF as consisting of Sponsor file and ISF. Removed references to ISF throughout document.	1.0
2.0	24 June 2014	SOP text unchanged. Version number updated only.	1.1
3.0	19 June 2017	Redefined definitions and scope to align with other Core SOPs.	2.0
4.0	See page 1	Redefined definitions and scope.	3.0