VCU Office of the Vice President for Research and Innovation

Veeva eTMF: Trial Master File Setup and Planning Guideline

Contents

1. Purpose

1.1 The purpose of this guideline is to define the process for creating the Trial Master File (TMF), planning TMF milestones and the associated expected documents, and establishing how the structure and indexing of the files are documented.

2. Audience

2.1 This guideline applies to all VCU staff and External Service Providers (ESPs) involved in the management of a VCU-sponsored clinical study and responsible for the collection and retention of clinical study documents in the VCU TMF.

3. Scope

3.1 This guideline applies to all clinical studies where documents generated or collected are maintained in an eTMF. It does not apply to studies maintained as paper TMFs.

4. Definitions

Term	Definition
Trial Master File (TMF)	The complete set of documents as identified in the TMF Index that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. If documents are filed in more than one location, the TMF is comprised of all such locations.
TMF Index	List of possible document types collected or created for a study by all participating parties, if and when they are required, filing level, structure, responsible department, and any filing conventions or rules (e.g., document date).

Term	Definition
TMF Plan	A document that outlines the processes and responsibilities for TMF activities.
Expected Document List (EDL)	A list of documents that are required or recommended in the TMF (or alternate location) for a specific study, study country, or study site.
Electronic TMF (eTMF)	A content management system that facilitates a TMF in electronic format, providing a formalized means of organizing and storing documents, images, and other digital content for clinical trials.

5. Roles and Responsibilities

Role	Responsibilities
Document Owner	Collect or create documentation related to a particular clinical development activity. Establish the study's expected documents for their function or department and evaluate the completeness of the TMF for their assigned areas.
Project Manager (PM)	Ensure the TMF and expected document lists are set up according to study, country, and site-specific requirements. Provide support for clinical development activities in assurance of a timely, quality, and complete TMF. Work with the Document Owners (e.g., PM, Lead Statistician, Monitor, etc.) to adapt and maintain the expected document lists.
VCU OVPRI (OVPRI reserves the right to delegate compliance of this procedure to departments)	Create user accounts that permit the role-specific activities in this and other TMF processes. Implement and ensure compliance to this procedure. Revise this procedure when required by regulatory requirements or VCU organizational circumstances.

6. Procedure

6.1 General Principles

6.1.1. This process is not a point-in-time activity, but repeated with each new site, each study, country, or site status change or event, and when there are updates to planned study milestones, procedures, and involved parties.

6.1.2. The eTMF is the central repository of clinical development documentation for clinical and/or GCP audits and inspections.

6.1.3. A TMF will be maintained for each clinical study in the designated eTMF, per the study-specific TMF Plan.

6.1.4. Documents that are expected or recommended for the TMF, but not filed in the eTMF, will have their alternate location described in the study-specific TMF Index. These documents will also be accessible in the event of an audit or inspection.

6.1.5. Documents will be structured and indexed according to the study-specific TMF Index.

6.1.5.1. The Template TMF Index is not a study-specific document but should be updated on an ongoing basis to provide a central resource for all Document Owners to ensure consistent filing across all TMFs.

6.1.5.2. Edits to a study's document expectedness will be made within the eTMF using Expected Document Lists (EDLs).

6.1.5.3. Documents that are not anticipated for a study are recorded with a new expectedness value (e.g., not required or pending decision).

6.2 TMF Setup

6.2.1. The PM (or designee) creates the study, study country, and study sites in the eTMF and enters the baseline dates for associated milestones.

6.2.1.1. The baseline finish dates are entered at the start of site selection activities.

6.2.1.2. The PM works with Document Owners to update the expected documents per study specifics.

6.2.2. Before the first study site is initiated, the PM (or designee) will create and finalize a TMF Plan.

6.2.2.1. Although TMF activities may be delegated to a third-party, the PM is accountable for oversight of the TMF Plan.

6.2.2.2. When the TMF setup and planning will not occur in VCU's eTMF, the TMF Plan will document if and how the internal application will be used for tracking and oversight of activities.

6.2.3. The PM (or designee) updates the study, study country, and study site statuses and initiates events (e.g., protocol amendment) when applicable.

6.2.3.1. The PM informs Document Owners of the status change or event.

6.2.3.2. With each status change or event, the PM works with Document Owners to amend the new expected documents to study, country, and site specifics.

6.2.3.3. When a study is cancelled, or study country or study site is withdrawn or not selected, the expected documents are reviewed to determine what is still required to document that evaluation or decision.

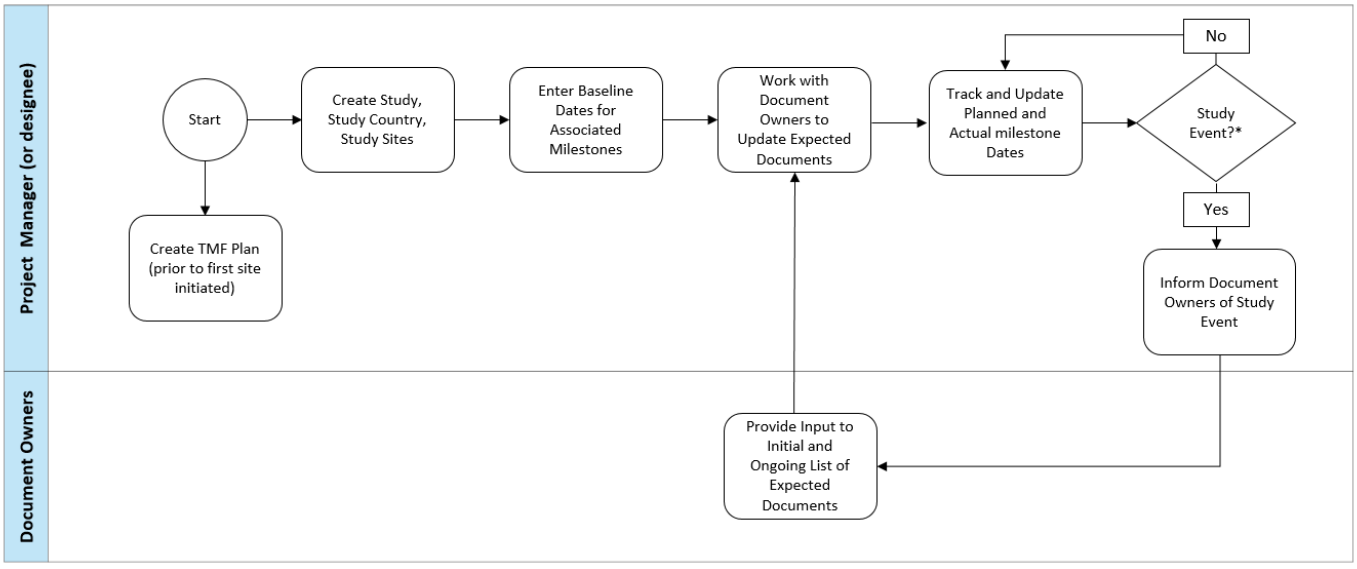
6.2.4. The PM (or designee) tracks and updates the planned and actual milestone dates.

6.2.5. The accuracy of the expected document lists is verified through the process described in Guideline - TMF Oversight and Inspection Readiness.

7. References

- VCU - Template TMF Plan
- VCU - Template TMF Index
- Guideline - TMF Oversight and Inspection Readiness

APPENDIX A - TMF Setup and Planning Process Flow Diagram



*Study Events may include, Protocol Amendment, Change in Site Staff, or cancellation of Study, Study Country, or Study Site.

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Document History

Version	Effective Date	Brief Description of Change
1.0	**01/05/2023**	Initial