



Veeva eTMF Oversight and Inspection Readiness Guideline

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1. Purpose

- 1.1. The objective of this guideline is to describe the ongoing verification of the quality, completeness, and timeliness of the Trial Master File (TMF).

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.
- 3.2. When document collection and processing will not occur in VCU's eTMF, the TMF Plan will document those procedures and responsibilities and will be used in conjunction with this guideline.

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, TMF is comprised of all such locations.



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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.
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).
Expected Document List	A list of documents that are required or recommended in the TMF (or alternate location) for a specific study, study country, or study site.
TMF Plan	A document that outlines the processes and responsibilities for TMF activities.

5. Roles and Responsibilities

Role	Responsibilities
Project Manager (PM)	<p>Coordinate study and study country level TMF reviews with Document Owners.</p> <p>Identify and escalate aging in-progress documents (i.e., not approved) and overdue inspection readiness milestones to Functional Area Leads as needed.</p>
Clinical Research Associate (CRA)	Ensure completeness of the site level TMF and Investigator Site Files.
VCU OVPRI (OVPRI reserves the right to delegate compliance of this procedure to departments)	<p>Implement and ensure compliance to this procedure.</p> <p>Revise this procedure when required by regulatory requirements or VCU organizational circumstances.</p> <p>Review TMF performance metrics for quality trends and unreasonable process cycle times.</p>
Document Owners	Complete TMF reviews according to schedule.

6. Procedure

6.1. General Principles

6.1.1. Inspection Readiness is a constant state of being. Assurance of this TMF state (i.e., TMF oversight) occurs through both primary and secondary procedures to ensure a TMF meets the following objectives:

6.1.1.1. Quality: documents have been checked for validity, scan quality, and completeness. Document names and information are accurate and meaningful.



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- 6.1.1.1.1. The primary review(s) is described in Guideline - Document Collection and Processing.
- 6.1.1.1.2. The secondary review occurs through monitoring QC issue resolution and the progress of eTMF document statuses.
- 6.1.1.2. Timely: documents are present and final (i.e., approved) in the TMF by the expected milestone(s).
 - 6.1.1.2.1. The primary tasks are described in Guideline - Document Collection and Processing.
 - 6.1.1.2.2. The secondary review occurs through monitoring the progress of eTMF document statuses and completeness of expected documents.
- 6.1.1.3. Complete: all expected documents are in their final approved state and are verified as accurate.
 - 6.1.1.3.1. The primary tasks are described in the Guideline - Trial Master File Setup and Planning.
 - 6.1.1.3.2. CRAs routinely verify the completeness of the site level TMF by reconciling with the Investigator Site File and document this in the visit report.
- 6.1.2. Although TMF activities may be delegated to a vendor, VCU remains accountable for oversight of the TMF and inspection readiness.

6.2. Inspection Readiness Checks

- 6.2.1. The TMF must be inspection ready at all times. Therefore, TMF inspection readiness checks will occur, at least, at each milestone for the study, for each study country, and for all study sites. A review must also be completed after all major study events.
 - 6.2.1.1. These milestones are as follows:
 - 6.2.1.1.1. Study level: first study site initiated, database lock, and study close
 - 6.2.1.1.2. Country level: first country site initiated, country's last subject last visit, and country close
 - 6.2.1.1.3. Site level: site initiated, site's last subject last visit, and site close
 - 6.2.1.2. Major study events include protocol amendments and changes to principal and sub-investigators.



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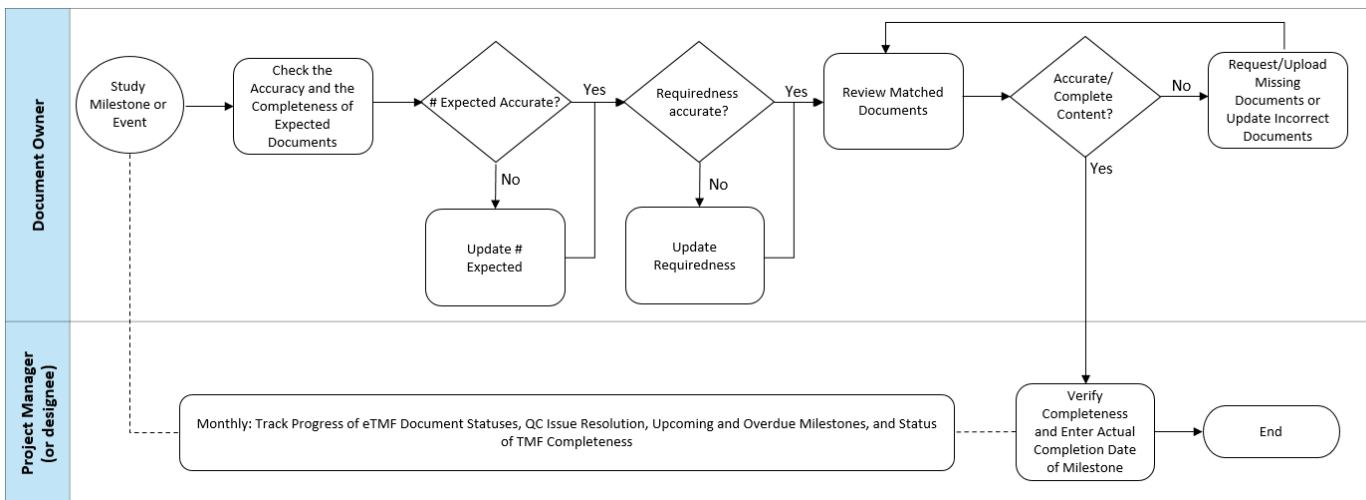
- 6.2.1.3. The actual finish date is calculated by the eTMF, based on actual completion of related milestones and events.
- 6.2.2. The Document Owners check the accuracy and completeness of their expected documents for the milestone or event.
 - 6.2.2.1. Document Owners are identified by the responsible department according to the TMF Index.
 - 6.2.2.2. This check includes:
 - 6.2.2.2.1. Requiredness (i.e., required, not required, pending decision)
 - 6.2.2.2.2. The number (count) of documents required for that document type
 - 6.2.2.3. No expected document may remain as “pending decision”.
- 6.2.3. The Document Owner reviews the matched documents to ensure they are the expected content (e.g., not duplicates or expired).
- 6.2.4. The Document Owner requests and/or uploads missing content and ensures it reaches a final status as described in Guideline - Document Collection and Processing.
- 6.2.5. Once all expected documents for the milestone or event are complete (i.e., the expected document count and approved document count are equal) and verified for accuracy, the milestone is achieved.
 - 6.2.5.1. The PM (or designee) verifies completeness and enters the actual completion date for milestones and events.
- 6.2.6. At a monthly minimum, the PM tracks the progress of eTMF document statuses, QC issue resolution, upcoming and overdue milestones, and status of TMF completeness.

7. References

- VCU's Template TMF Plan
- VCU's Template TMF Index
- Guideline - Trial Master File Setup and Planning
- Guideline - Document Collection and Processing



APPENDIX A - TMF Oversight and Inspection Readiness Process Flow Diagram



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Document History

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