



Veeva eTMF Closeout and Archival Guideline

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1. Purpose

1.1. The objective of this guideline is to describe the process for verifying completeness of and archiving the Trial Master File.

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 may be used in conjunction with or in lieu of 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.



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. Responsibilities

Role	Responsibilities
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>Create user accounts that both permit and limit access as stated in this guideline.</p>
Project Manager (PM)	<p>Verify the TMF is ready for archival.</p> <p>Assume the role of Archivist:</p> <ul style="list-style-type: none"> ● Initiate and oversee the archival process ● Preserve the documents, information, and audit trails from unauthorized changes.

6. Procedure

6.1. General Principles

6.1.1. A TMF will be maintained for each clinical study in the designated eTMF and archiving occurs solely in that application, therefore:

6.1.1.1. Paper/electronic copies or shadow files (i.e. a set of files intended to replicate the source TMF) are not permitted.

6.1.2. This process occurs once for each TMF.

6.1.3. Documents, information, and audit trails for completed studies must be restricted from unauthorized changes and remain retrievable for audit or inspection.

6.1.3.1. These items are left in a read-only state for VCU operations and document re-use.

6.1.3.2. View access is entirely removed from participating third parties.

6.1.3.3. Only the archivist can authorize changes.



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6.2. TMF Closeout and Archival

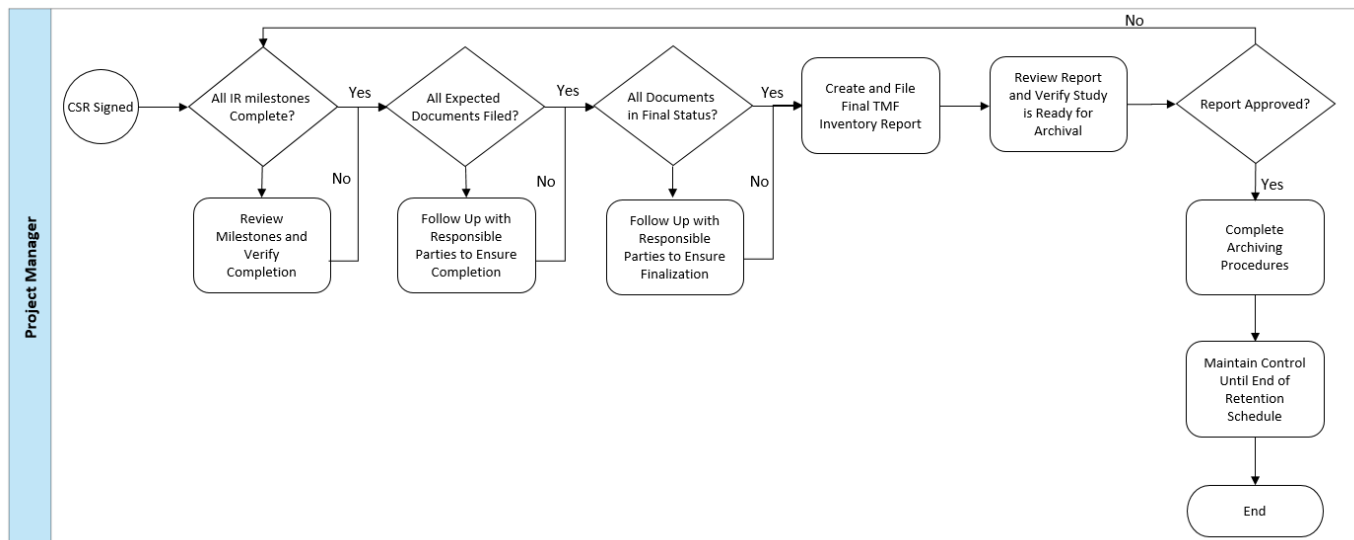
- 6.2.1. As study closure nears, the PM will continue to monitoring the eTMF document statuses, resolution of QC issues, and tracking TMF completeness as described in Guideline - TMF Oversight and Inspection Readiness.
- 6.2.2. The PM confirms all Investigator Site Files (ISF) have been reconciled with the TMF and sites reminded of their archive responsibilities, as described in the applicable department-specific Monitoring Guideline/SOP.
- 6.2.3. Once the following criteria have been met, the PM will create and upload the final TMF report (i.e. inventory):
 - 6.2.3.1. The clinical study report (CSR) is signed
 - 6.2.3.2. All inspection readiness milestones are complete
 - 6.2.3.3. All expected document lists are complete
 - 6.2.3.4. All documents are at a final status
 - 6.2.3.4.1. In the event that all other completeness requirements have been met, but the CSR is not complete, the study may be temporarily archived until the final signed CSR is available.
 - 6.2.3.4.2. In the event that a study is cancelled or otherwise not completed, the PM (or designee) reviews expected documents to determine what is still required. Archiving may proceed without a CSR in this instance.
- 6.2.4. The PM approves the TMF report, confirming the above criteria have been met and that the study is ready to archive.
- 6.2.5. The PM completes the archiving procedures as stated in the *eTMF Training Material*.
- 6.2.6. The PM maintains control until the end of the Document Control Retention Schedule as defined in the Records Retention Policy.
 - 6.2.6.1. If documents are received after archival, the PM reviews the document and TMF to determine if changes need to be coordinated.

7. References

- Guideline - TMF Oversight and Inspection Readiness
- VCU's Template TMF Plan
- Department-Specific Monitoring Guideline/SOP
- Records Retention Policy
- eTMF Training Material



APPENDIX A - TMF Closeout and Archival Process Flow Diagram



Contact

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Document History

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