VCU Office of the Vice President for Research and Innovation

Veeva eTMF: Document Collection and Processing Guideline

Contents

1. Purpose

1.1. The purpose of this guideline is to describe the submission, filing, review, and acceptance of documents collected or created for a clinical study.

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
Certified Copy	A copy of an original/source record that has been verified as an exact copy of the original and is intended to permanently replace the original.
Trial Master File (TMF)	The complete set of documents as identified in the TMF Index that individually and collectively permit evaluation of

Term	Definition
	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.
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).
TMF Plan	A document that outlines the processes and responsibilities for TMF activities.
Electronic Documents	Records that are created or received in digital format and are submitted, reviewed, and approved in the eTMF.
Paper Documents	Records that are created or received in physical, hardcopy format and maintained in the TMF in original format due to jurisdictional and/or regulatory requirements.

5. Responsibilities

Role	Responsibilities
Document Owner	Collect or create documentation related to a particular clinical development activity. Perform secondary reviews of paper document content and indexing. Submit valid, non-duplicative, legible, quality documents. Apply accurate and meaningful document information to ensure documents are easily located/discoverable/retrievable in the eTMF. Ensure their documents are filed, reviewed, and approved in a contemporaneous manner. Establish the study's expected documents for their function or department and evaluate the completeness of the TMF for their assigned areas.
VCU OVPRI (OVPRI reserves the right to delegate compliance of this procedure to departments)	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. The TMF must be inspection ready at all times, meaning document filing, quality checks (QC), and approvals will occur as the document or task becomes available.

6.1.2. Whether recorded on paper or electronically, source data should be attributable, legible, contemporaneous, original, accurate, and complete (ALCOA-C). This is verified through both preliminary and secondary QCs.

6.1.3. The collection and processing procedures within this guideline are dependent on whether documents are created within (hereafter electronic documents) or external of (hereafter paper documents) the eTMF.

6.1.4. The Document Owner has the authority to determine the procedures required for their documents, including review, QC, and approval by a verdict or eSignature.

6.1.5. Document workflows and statuses are defined within the eTMF.

6.1.6. Documents will be filed according to the study-specific TMF Index.

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

6.1.6.2. For multi-center studies, important and relevant study- specific documents that are the same for multiple sites can be filed at the study level.

6.1.6.3. Only relevant correspondence is expected in the TMF. See the TMF Index for the business definition and considerations for responsibilities and filing attachments.

6.1.7. A certified copy is required if a document in eTMF will replace a paper, VCU-owned clinical trial record.

6.1.7.1. Certified copies enable VCU to confidently destroy paper documents.

6.1.7.2. Certified copies are not required for the following:

6.1.7.2.1. VCU copies of paper documents from an investigator site because the original remains in the Investigator Site File.

6.1.7.2.2. VCU copies of paper documents from a vendor because the original remains with the vendor.

6.1.7.2.3. Electronic documents.

6.2. Document Collection and Processing

6.2.1. The Document Owner performs a preliminary review of paper documents to ensure document expectations, validity (e.g. not expired), and quality as well as relevance and importance to the trial.

6.2.2. After the preliminary review, the Document Owner files/creates a document in eTMF and applies document information (i.e. metadata) according to the TMF Index as soon as it becomes available and/or is in use on the study.

6.2.3. Filing of documents in alternate locations (i.e. not in eTMF) will be described in the TMF Index.

6.2.4. Documents that are already in use on another study do not need to be uploaded again. All applicable study information will be applied to the document.

6.2.5. The Document Owner certifies the copy immediately after upload, if required.

6.2.5.1. This includes comparing the paper document to the image to confirm it is an exact replicate and addressing any issues (e.g. creating a new scan, collecting a replacement, etc.).

6.2.5.2. After the copy is certified, the paper document is securely destroyed through on-premise equipment and procedures.

6.2.5.3. If an original is received from a site or third-party, it should be returned to the site or third-party.

6.2.6. The Document Owner sends paper documents for QC and resolves any issues noted.

6.2.7. The Document Owner performs secondary QC, including a review of filing accuracy (i.e. indexing), scan quality, pagination, version control, and presence of required signatures.

6.2.7.1. Electronic documents do not require quality control, as this is part of the creation, review, and approval process.

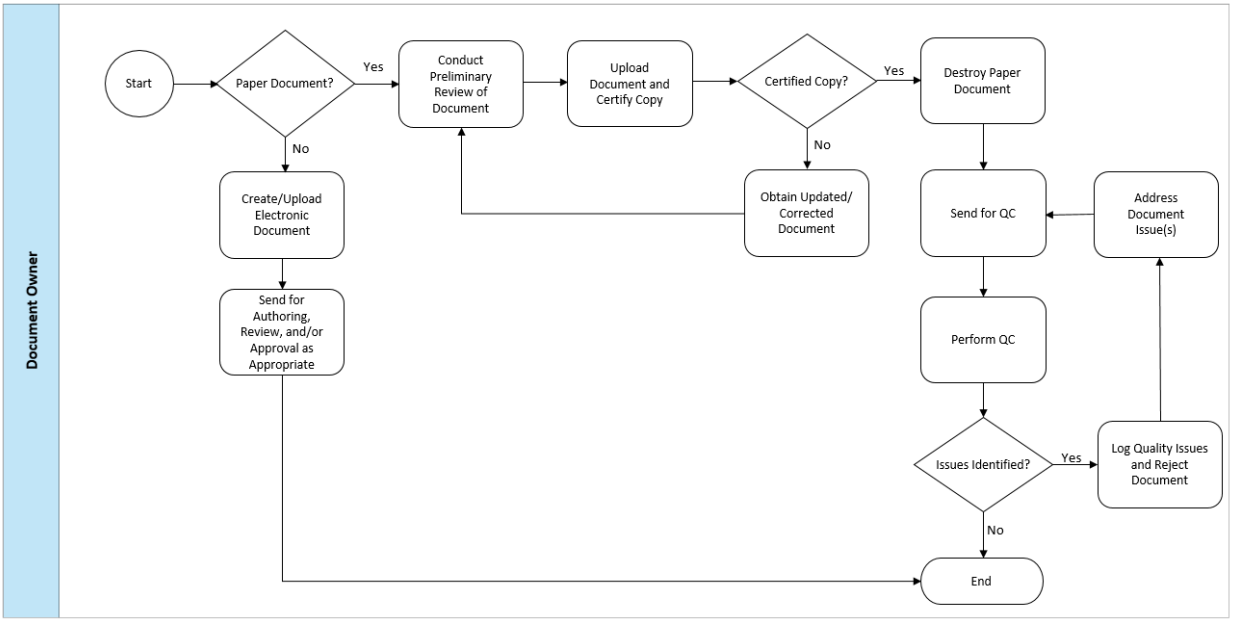
6.2.8. The Document Owner will send electronic documents through creation, review, and approval processes as needed.

6.2.9. The progress of document review, QC, and approval is verified through the process described in Guideline - TMF Oversight and Inspection Readiness.

7. References

- VCU's Template TMF Plan
- VCU's Template TMF Index
- Guideline - TMF Oversight and Inspection Readiness
- Certified Copy Guideline

APPENDIX A - Document Collection and Processing Process Flow Diagram



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Document History

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