[TMF Plan Template Version 2.0 October 2022, authored by the TMF Plan Template Subteam of the CDISC TMF Reference Model. Replace with sponsor header information.]

[Instructions for use:

- The intention of this template is to share the collective experience of the members of the TMF Reference Model Project, a wholly volunteer consortium. The content does not reflect regulatory requirements, rather, shares the real-life knowledge of the consortium and is meant to be adapted to the appropriate scenario.
- This template may be adopted for Sponsor, CRO, or Sponsor/CRO TMF Plan, it may be dependent on study structure, and relationship with CRO. The components of this Plan should be covered no matter if it is the Sponsor, CRO, or combination of both. A Sponsor may be one of the following/t not limited to: a pharma, biotech, or investigator, depending on the type of trial.
- Each company may utilize their own practices; however, if SOPs or Plans are mentioned in the TMF Plan should also be accessible.
- Green text is instructional guidance on how to complete the TMF Plan and must be removed prior to finalization.
- **Blue bold/italicized text** is where expected content should be completed.
- This document has a page break for every section, which you may choose to remove to make the document less pages.
- After adjusting this document, and removing green text, you will need to Update the Table of Contents table on page 2 so that the page numbers are accurate.
- The entire plan is written with Arial Narrow font and majority of text font size is 11 except headings.
- Tables have black headings with white font and are designed to split across pages; font size for the tables is 10.
- The Paragraph Show/Hide is on, so that you can see all the pagination, tables, etc. You should turn this off once you are comfortable with the template.
- Update the header and footer for this page as appropriate for your company.

END Instructional text]

[OVERVIEW PAGE to be completed by initiator of the TMF Plan and fill in as much detail as possible. Change Headers/Footers to match your sponsor information and following your sponsor practices/formats.]

TRIAL MASTER FILE (TMF) PLAN

[ENTER Sponsor/CRO Name]

Protocol # or Study Identifier:	*[ENTER Protocol Number or Study Identifier]*
Date:	*[ENTER TMF Plan Date]*
Version:	*[ENTER Version Number of the TMF Plan, e.g., 1.0, 2.0]*

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Style Definition: Heading 1: Font: (Default) Arial Narrow, Font color: Auto, Outline numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.3", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (No border)

Style Definition: Heading 2: Font: (Default) Arial Narrow, 14 pt, Bold, Italic, Font color: Auto, Left, Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.4", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (No border)

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2 Document Version History 5¶
3 Definitions and Abbreviations 6¶
4 Introduction 7¶
5 TMF Oversight & Access Arrangements 10¶
5.1 RACI Matrix 10¶
5.2 Access arrangements 11¶
5.3 TMF Maintenance delegated to a CRO/Vendor 11¶
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6.2.2 Relevant Correspondence 16¶
6.2.3 Unblinded Records 17¶
6.2.4 Translations 17¶ ... [15]

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1 Approvals

[Approval and form of the approval is at the discretion of the Sponsor/CRO authoring the TMF plan. Consideration should be given as to whom on the project should at a minimum agree to the terms of the TMF Plan.

Example is provided below and can be removed if not needed or replaced by a simple approval statement.

]

Sponsor Representative(s)			
[ENTER Name Here]	*[ENTER Title]*	*[ENTER Approval]*	*[ENTER Date]*
[Add more rows as needed.]			
CRO/Vendor Representative(s)			
[ENTER Name Here]	*[ENTER Title]*	*[ENTER Approval]*	*[ENTER Date]*
[Add more rows as needed.]			
Other Representative(s)			
[ENTER Name Here]	*[ENTER Title]*	*[ENTER Approval]*	*[ENTER Date]*
[Add more rows as needed.]			

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2 Document Version History

[Enter the version of the TMF Plan that is being changed, and information about the changes; if this is the initial version then just state Initial Version in the Summary.]

Document Version Number	Summary of Changes	Author Name	Document Version Date
[ENTER]	*[ENTER]*	*[ENTER]*	*[ENTER]*

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3 Definitions and Abbreviations

[Add other definitions and abbreviations for sponsor specific information. Your company definitions may be different; add those appropriate and update. This section may get removed for implementation of the TMF Plan within your organization; it is dependent on internal organization needs and business process roles which may need to be defined. In lieu of this table, you could spell out the acronym first within the body of the text. Assumption is that organizations are operating with a basic understanding of records management principles and GCP (Good Clinical Practice) compliance.]

Term/Acronym	Definition
[CRO]	[Include your own definition - Contract Research Organization. A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.]
[Delegated Owner]	[Include your own definition - Shared responsibility with the Record Owner is passed to the Delegated Owner for a defined period. Answerable to the Record Owner.]
[Oversight]	[Include your own definition regarding how oversight is conducted; this is definition from MHRA: Oversight is important where the sponsor has delegated functions to other parties, either within the same organisation (for example, to a Chief Investigator within the Trust) or to an external CRO. The sponsor's project management or governance should have sufficient processes in place to verify that the functions are being conducted appropriately. The sponsor should be approving documents and processes implemented to carry out the delegated functions such as (not exhaustive): protocols, case report forms (CRFs), standard operating procedures (SOPs), analysis plans, data management plans.]
[Record Owner]	[Include your own definition - Responsible for the quality and completeness of a specified record prior to it being filed in the TMF. May also be responsible for filing the record in the TMF but filing may be delegated to another person or another function.]
[Shared Responsibility]	[Include your own definition - The responsibility is shared with others for a defined period. Answerable to the Delegated Owner.]
[Sponsor]	[Include your own definition - An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.]
[TMF]	[Include your own definition - Trial Master File for a clinical trial that comprises the sponsor and the investigator files. The TMF contains documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. TMF can be in paper (pTMF) or electronic (eTMF).]
[TMF Archivist]	[Include your own definition - Accountable and has the ultimate authority for the archival of TMF records (pTMF and eTMF). This role has access to both the pTMF and eTMF.]
[TMF Owner]	[Include your own definition - Ultimately responsible for the content and quality of the TMF before the clinical phase of the trial commences, during the clinical conduct of the trial, after completion or termination of the trial and during archiving.]
[ENTER]	*[ENTER]*

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4 Introduction

The purpose of this Trial Master File (TMF) Plan is to outline the process and procedures that ***[ENTER Names of all involved parties -Sponsor (commercial or non-commercial) and other parties such as vendor/CRO]*** will utilize to ensure a high-quality Trial Master File.

This plan describes how an inspection ready TMF that is high quality, complete and real-time ready will be created, maintained, closed, and archived. In addition, this plan describes clear expectations on who is responsible for which action.

All relevant study team members are expected to understand and adhere to this TMF Plan. The TMF Plan is meant to be kept current with the state of the study and revised as required.

The majority of TMF content will reside within ***[ENTER name of system]*** system owned and managed by ***[ENTER whose system it is, e.g., Sponsor or CRO].***

[The plan should not duplicate or repeat information covered in SOPs, standard processes or work instructions maintained elsewhere.]

TMF records will be maintained in a secure manner and in compliance with ICH GCP regulations and local regulatory requirements.

TMF records should be securely managed to ensure that access to the TMF is controlled at all times, and that all persons with access to the TMF are identified and TMF access is managed according to applicable SOPs.

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This TMF plan covers: [choose one]¶

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Investigator TMF only [reference where sponsor TMF is controlled/owned/maintained]¶

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[This could be as simple as submission of appropriate quality documents ranging to overall responsibility or oversight of the entire TMF. Text in **blue** is for examples only. Table should be completed with relevant owners. For definitions, see *Section 3, Definitions and Abbreviations.*]¶
Job Role/Title or Project Function ... [127]

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Deleted: ***[ENTER CRO/VENDOR NAME(s) and SPONSOR NAME]*** personnel…

Deleted: known to ***[ENTER SPONSOR NAME]***

5 Applicable SOPs

In the table below, list the applicable TMF (paper or electronic) SOPs or Policies or Work Instructions/Associated Documents that will be followed, as well as who owns it:

[Examples listed below, enter in your sponsor SOP/Policy names replacing the **blue** text. This table is optional; you can just refer to the List of SOPs and remove this section.]

The full list of SOPs/Policies/Work Instructions is to be filed in the TMF? ☐ Yes ☐ No

If ***Yes***, in which location in the TMF is the SOP list filed: ***[ENTER location]***

5.1 Sponsor Specific

Policy, SOP, Work Instruction Title	Version	Effective Date
[TMF Management Setup, Maintenance, Close Out, Archival SOP]		
[Redaction SOP or Policy]		
[Good Documentation Practices (GDP)]		
[Scanning and Destruction SOPs or Work Instructions]		
[System Access and Removal SOP/Work Instruction]		
[Sponsor Oversight SOP]		
[Translation SOP]		
[ENTER others as appropriate]		

5.2 Vendor/CRO Specific

Policy, SOP, Work Instruction Title		Version	Effective Date
[CRO]	*[Document Quality Checking (QC) Work Instructions]*		
	[Periodic Review or Functional QC Work Instructions]		
	[Business Technology Administration SOPs]		
[Processing Vendor]	*[Other Manuals, Work Instructions, etc. pertinent to TMF]*		
	[Translation SOP]		
[ENTER others as appropriate]	*[ENTER others as appropriate]*		

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6 TMF Training

[Describe how training will be handled both for internal and external users as appropriate. If necessary, append or embed training plans or other documents in this section or simply state the location of those documents.

In the table below enter the following:

- Provider: Sponsor or Vendor, depending on who maintains the TMF (paper or electronic) and is responsible for training the end users.]
- How training is conducted, i.e., Instructor-led; electronic learning module; training materials.]
  Description of how filed and where, as a training report may be filed to the TMF, if an eLearning system is the authoritative source for the certificates.]

Upon successful completion of TMF Training, new users will be provided with the appropriate access to the TMF: [Below are **examples** only]

TMF Role	Training Content	Provider	Method	Certificates Filing Location
[CRA]	*[Full Training]*	*[TMF Vendor]*	*[Enter Method]*	*[Study TMF]*
[Inspector]	*[Brief Overview]*	*[Sponsor Host]*	*[Enter Method]*	*[Study TMF]*
[ENTER others as appropriate]				

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7 TMF Oversight & Access Arrangements

7.1 Responsibilities

There are different roles involved in a TMF setup and maintenance and all are responsible for always ensuring inspection readiness of the TMF during the conduct of the study. Therefore, records must be submitted on an ongoing basis.

The following matrix describes the high-level activities of the TMF:

[Please fill in the as appropriate for your organization. Optionally, this table could be in a separate document and appended or embedded and/or referenced here.]

Activity	[Sponsor]	[CRO or other Vendors; add as many as needed]				
eTMF Systems Training						
eTMF Access Management						
Write and maintain the TMF Plan and TMF Map/Index - The TMF Plan should include all activities and responsibilities of the TMF. If a CRO is authoring the TMF Plan, then it should include sponsor activities or a second TMF Plan should be written to address gaps in CRO Plan.						
Document collection, review and finalization for documents associated with contracted services.						
Management of paper records See *section 8.3, e-signatures, originals, wet inks, and raised seals*						

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[TMF Plan Template Version 2.0 October 2022, authored by the TMF Plan Template Subteam of the CDISC TMF Reference Model. Replace with sponsor header information.]

Document uploads to eTMF - Documents are uploaded to **[ENTER]** within **[ENTER # of days]** days of finalization or collection. [Even if identified in sponsor SOPs, this should be specified in the TMF plan so all parties are informed]						
Document Quality and Metadata QC following upload to the eTMF						
TMF Completeness Reviews See *section 9, Conducting TMF Reviews*						
eTMF query resolution						
Metrics reporting [Briefly describe how metrics will be reported and circulated for review.]						
Archiving and Study Document Retrieval See *section 10, Record and TMF Disposition*						
[ENTER other activities as needed]						

7.2 Access arrangements

[Describe how access to the TMF (paper or electronic) is granted and removed when no longer required. Reference system applicable SOPs as required below.]]

TMF access will be handled by: ***[ENTER Sponsor or CRO, depending on who maintains the pTMF or the eTMF system].***

Access is handled ***[ENTER how handled]***, including a periodic review of user access: ***[ENTER]***

For Training information, see *Section 6, TMF Training*.

7.3 CRO/Vendor

Whereas a contracted CRO/Vendor is responsible for the TMF maintenance and overall quality, the sponsor retains the ultimate responsibility for the trial and integrity of trial data including the TMF.

[In the table below, enter the level of access provided and what is provided and how frequently, example how long access is granted for, to what, what kinds of reports and if other types of trackers/listings are provided. Add text related to transfer of records as needed and refer to *Section 11, Transfer and Archival* of the plan for details.]

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Sponsor oversight between ***[ENTER Sponsor Name]*** and ***[ENTER CRO/Vendor Name(s)]*** will be executed as marked below:

☐ TMF access ***[ENTER]***	☐ Routine inspection and audit reports
☐ TMF Metrics reports ***[ENTER]***	☐ Other (specify): ***[ENTER or put NA if Not Applicable]***

How access to the CRO/Vendor system will be handled is covered in *Section 7.2, Access Arrangements*, and how Training will be handled is covered in *Section 6, TMF Training*.

7.4 For Inspections

[The below text should be modified to be in line with SOPs, procedures. You may also just reference a company specific SOP or WI. . [Direct access to the TMF should be planned as it may be required. For eTMF, this includes providing the inspectors with suitable equipment and brief training, as required.]

In the event of a regulatory inspection, ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** will notify ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** as soon as the inspection has been announced. All parties involved in managing the TMF will work together to determine a strategy for planning for and managing the inspection. This includes the updating of the TMF Map/Index with the intent to provide to the inspection.

The ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** to be inspected will inform the relevant ***[ENTER Key TMF Contact]*** of the inspection purpose, scope, date, and time. The ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** Quality Assurance (QA) representative will inform the inspector of the location of the study specific TMF.

The ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** QA representative will coordinate the logistics of the inspection with the ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** The inspection will be conducted as per the respective ***[ENTER CRO/Vendor Name(s) and Sponsor Name]*** procedures, as applicable.

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Deleted: regulatory audit/inspection, ***[ENTER CRO/VENDOR NAME(s) and SPONSOR NAME]*** will notify ***[ENTER CRO/VENDOR NAME(s) and SPONSOR NAME]*** as soon as the inspection has been announced. ¶ The sponsor to be inspected will inform the relevant ***[ENTER Key TMF Contact]*** of the audit/inspection purpose, scope, date, and time. The sponsor Quality Assurance (QA) representative will inform the auditor/inspector of the location of the study-
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Deleted: CRO(s). If there is an audit/inspection post-transfer of the final TMF from the CRO/Vendor, the auditable TMF is located at the Sponsor.¶ The sponsor QA representative will coordinate the logistics of the audit with the CRO(s). The audit/inspection will be conducted as per the respective Sponsor and/or CRO(s) procedures, as applicable.
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8 TMF Content

8.1 TMF Format, Structure/Content Map/Specifications

[Select the appropriate checkbox to confirm which format the TMF is in.]

☐ Paper	☐ Electronic	☐ Hybrid (a blend of paper and electronic)

[State the index you are using, e.g., TMF Reference Model and version number or sponsor own and version number. Note: this should be completed as a study specific index with documentation on where records are not expected for the trial; this would avoid the need for an expected document list.

Consider including version 1 (current version) of the structure/content map/specifications here, but subsequent versions will not be to avoid updating the plan - check SOP compliance.

You may append or embed the index into the plan as an object or have as an appendix or reference it here; however, avoid hyperlinks which may break, also consider ultimate size of the file. Or simply state the location of the file.

Data integrity/confidentiality should be considered and ensured that TMF records comply according to applicable regulations and sponsor standards.]

Timeliness or expectations to file documents are dependent on your internal processes/expectations and could be called out in this section.

The TMF Index should list the authoritative sources of where TMF content is stored during the trial. Authoritative sources are physical or cloud-based locations of records. It is advisable that the authoritative sources are access controlled, secure, validated, and maintain records throughout the retention period. Note: This section comes from MHRA GCP Guide section 10.2.3.]

Enter details of the TMF Index/structure/content map/specifications here: ***[ENTER]***

Content generated by vendors beyond ***[ENTER CRO Name/Vendor Name(s)]*** for the active phase of the study and disposition at the end of study is described in the following table:

[All vendors generating TMF content should be listed here]

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☐ No [Remove sections below.]¶
¶
Indicate name of CRO/Vendor(s) and corresponding location(s) - city, state, country - where TMF content resides, if not contained in the TMF:
[Note: These sections come from the TMF Reference Model version 3.0 zones but should be aligned with your organization's structure/content map/specifications.]¶

Vendor Type	Vendor Name	Vendor Managed by:	Content Management
CMO (Contract Manufacturing Organization)	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]
EDC	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]
IXRS	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]
Central Laboratory	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]
Specialty Laboratory [Define]	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]
Pharmacovigilance	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study].** [If content remains at the vendor at the end of the study, then update this section accordingly.]

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Vendor Type	Vendor Name	Vendor Managed by:	Content Management
IP Depot	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study]**. [If content remains at the vendor at the end of the study, then update this section accordingly.]
Other	*[Name of Vendor]*	*[Sponsor/CRO]*	Content will be submitted to **[TMF location]** by **[Vendor/Sponsor/CRO]** at this timing **[through-out the life of the study/at the conclusion of the study]**. [If content remains at the vendor at the end of the study, then update this section accordingly.]

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8.2 E-Signatures, Originals, Wet Inks, and Raised Seals

[Define if your organization or CRO/Vendors are using e-signatures that are compliant with FDA CFR Part 11/Annex 11 in the TMF process and how those e-signed documents are handled. If a company SOP or WI exists, just list that. Originals may be in the form of paper, electronically created records or both. This section should:

- state how originals will be handled
- consider how originals are generated
- how they are stored, for example investigator source records are kept at site and a copy is collected or an electronic version is provided
- Consider certified copies (if certified by wet ink signature or raised seal).

Reference EMA Guidance 06 December 2018, EMA/INS/GCP/856758/2018, Good Clinical Practice Inspectors Working Group (GCP IWG) Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) and the Framework for the destruction of Paper Version v2.0 18 January 2019 and make determination for your company.

As per ICH GCP E6 R2, consideration should be given as to which original signatures need to form part of the TMF:

- Protocol and any amendments
- Contracts
- Informed consent (investigator TMF only)
- CRF
- Signature sheet/delegation of duties]

Describe if e-signatures are used within your process [Include the Platform version and what all other parties are using including Sites that they are]: ***[ENTER]***

Describe how originals will be handled: ***[ENTER]***

If applicable, describe how wet inks/raised seal documents will be handled: ***[ENTER]***

8.3 Relevant Correspondence

[This section should define what your organization considers relevant correspondence to be unless this is defined elsewhere in other SOPs. If in SOPs, refer to SOP stating how relevant correspondence is handled and who is responsible, e.g., sponsor vs. CRO/Vendor to avoid duplication. Relevant Correspondence guidance can be found on the TMF Reference Model website, under Community Exchange, Resources.]

You may also wish to include how such relevant correspondence should be filed, e.g., batched by month, by trial/country/site, and in what format (.msg, .eml, .pdf, etc.) you will accept.]

Describe how relevant correspondence for the study will be handled: ***[ENTER]***

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8.4 Unblinded Records

[NOTE: Different companies refer to either blinded or unblinded records for the same purpose. Refer to company SOPs for consistency. Update the 6.2.3 title to reflect either blinded or unblinded. Ensure your CRO is aligned with your organizational standards.)

Provide the following information:

- location where records that contain unblinding information are maintained until formal unblinding
- when documentation is filed in the TMF and by whom
- ensure security within the system is appropriate to maintain the blind

[ENTER]

8.5 Translations

[If an SOP covers translations summarize the requirements here beyond the sponsor activities so that other parties supporting the trial have access to the requirements. Has a plan been created for the study? Reference the plan here and indicated where it is stored. If no Plan, then at minimum list the documents that will need to be translated for the study and include how the original plus translated document plus certificate will be filed. This section is optional, if not needed, remove.]

Translations are managed by ***[ENTER].***

List Translation SOP, if applicable: ***[ENTER]***

Is there a Translation Plan been created for this study? ☐ Yes ☐ No

[If **Yes**, either append or embed the Translation Plan to the TMF Plan in *section 12, Appendix*, or state the location of where the Translation Plan resides. If **No**, list the records that require translation in this section]

Translated documents filed: ***[ENTER how filed].***

8.6 Living/Fluid Documents

[Describe how living/fluid documents such as Delegation of Authority (DOA), Visit, training logs, etc. are managed and when uploaded to the TMF.]

Living/fluid documents are managed by ***[ENTER].***

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9 Conducting TMF Reviews

[General Considerations:
Comprehensive reviews of the TMF content should be performed based on the study design, the status of the study, decisions that have been made, events that have occurred, and SOPs and standards that apply. Describe a risk-based approach in the review of the TMF to ensure overall quality.

Some questions to ask when completing a TMF content review:

- Are the TMF specifications up to date to provide visibility on expected records? If not, what is missing?
- Are all versions of expected records available?
- Are all correspondence/emails relevant to the study present?
- Are there any duplicate records that can be removed?
- Are all records complete, legible and, where appropriate, signed?

Ensure to reference any list of process standards/SOPs and/or work instructions and guidance documents to be followed for the TMF content review in *Section 5, Applicable SOPs*.

If no references are available, the Trial Master File Quality Control Toolkit can be used. This document was approved on 12-Oct-2016 and is available on the TMF Reference Model website https://tmfrefmodel.com/ under Community Exchange, then Resources.]

Describe the plans for the TMF Reviews: ***[ENTER]***

9.1 TMF Review Plan

[General Considerations:
The following may be managed in a separate SOP or can be appended as an appendix to this document.

- The study team documents when TMF reviews are performed based on the study duration, phase, and/or business criticality. Study TMF reviews are recommended (i.e., timing of the reviews is at the discretion of the study team) at study milestones and/or at time of major events (e.g., protocol amendment).
- For long duration studies it is recommended to define frequency of review (e.g., quarterly, every 6 months). It is best practice to conduct periodic reviews on at least a quarterly basis.
- Completeness checks and cross checks among related records are expected during TMF content review. Enter in the table below, all reviews that are planned to be performed and any additional review that may be performed by the sponsor to validate review performed by a CRO/Vendor(s).
- Consider including the table below as a separate document appended or embedded as version 1 (current version), but state where subsequent versions will be located to avoid constant updating to the plan.]
- Recommend including completeness, quality, and timeliness as TMF KPIs, and how they are measured.
- Describe quality expectations for the different types of reviews: primary vs. secondary QC, periodic QC, etc.
- Evidence of TMF Health should be filed in the TMF along with evidence of the reviews.

Examples listed below in **blue** text, each company will need to define their QC types.]

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TMF Review Scope	Responsible Party	Location /Format of Review	Frequency	Documentation of Review
[QC1]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*
[QC2]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*
[Sponsor Oversight Review]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*
[Completeness Checks]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*
[Audit Trail Reviews - Understand what will be reviewed and how e.g., following a document through a process]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*
[Other reviews of specific sections or documents e.g., relevant communications, file naming conventions]	*[ENTER]*	*[ENTER]*	*[ENTER]*	*[ENTER]*

9.2 TMF Review Documentation

[Describe the records expected to be generated, maintained and where filed to support the TMF review performed during the study. Plans for resolution should be included. If information exists in procedural documentation, refer to *Section 5, Applicable SOPs]* .

[ENTER]

10 Record and TMF Disposition

[This section is to provide information regarding destruction, retention, archiving, and legal hold.
Guidance: the below is addressing agreements that should be covered between a Sponsor and their TMF Vendor or CRO. If the sponsor does not have a Records Management Program with a retention schedule, they may consider leveraging this section to include additional text or sections to cover both situations.]

10.1 Archiving

[This section assumes the sponsor has a TMF management process that includes archiving. If not, then provide a short paragraph about the Archiving and retention process.] ***[ENTER]***

10.1.1 Sponsor TMF at CRO/Vendor

1. Please refer to ***[ENTER Sponsor Name] [ENTER SOP that discusses Archiving]*** for full archiving requirements.

2. Contact for GCP Archivist or Records Management Contact: ***[ENTER]***

3. Will ***[ENTER Sponsor Name]*** fully archive the TMF within their own processes/electronic system(s)?
   ☐ **Yes**, Electronic system(s) name and version: [Note: This may be the same as the eTMF system or could be a separate Archiving system.] ***[ENTER]***
   ☐ **No** [If no system is involved, i.e., paper, then remove system language.]

4. Paper/Wet Inks [this may also include Paper with Raised Seals.]
   Location of archive: ***[ENTER complete name of archive vendor and address]***

5. Will any TMF content remain at ***[ENTER CRO/Vendor Name(s)]*** as the official archival copy for long-term retention?
   ☐ **Yes**, see details below: [Complete table as appropriate.] ☐ **No**

a)	CRO/VENDOR(s) Name: ***[ENTER, including all CRO/Vendor(s)]***
b)	Content archived: ***[ENTER]***
c)	Archive address: ***[ENTER]***
d)	Applicable archive-related SOPs: ***[ENTER]***
e)	Retention period agreed with ***[ENTER CRO/Vendor Name(s)]***: ***[ENTER]***
f)	Describe process agreed for retrieval and review of archived records in the event of a regulatory inspection or for other purposes: ***[ENTER]***
g)	Comments: ***[ENTER]***

10.1.2 Investigator Site File

[NOTE: The intent is not to list ALL locations, but to list where the archiving information is stored. For some sponsors, this may be in the Investigator Site Contract.]

Investigator records must be archived by the investigator. Details are available: ***[ENTER References.]***

10.2 Retention by CRO or Vendor

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Destruction¶
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Retention¶

[TMF Plan Template Version 2.0 October 2022, authored by the TMF Plan Template Subteam of the CDISC TMF Reference Model. Replace with sponsor header information.]

[Record retention timeframe should adhere to regulations and local laws. Retention timeframe should be defined at the sponsor level and investigator TMF retention documented in the contracting agreement, ensuring that legal, regulatory, and business requirements are met, and that the documentation is protected and maintained as required.]

Describe what the retention for the sponsor TMF (paper and electronic) records and for the Investigator TMF records, if applicable for this plan, are and how retention will be handled for each of the TMF components: ***[ENTER]***

10.3 Legal Hold

[This section is to capture information about the Preservation Notice or Legal Hold process that is followed by the sponsor. We recommend that a sponsor's Legal counsel agree with this section before it is implemented. This section may be deleted if not applicable or covered by other SOPs/documents.]

Preservation Notice or Legal Hold in Place?	What to do?
Yes	**No destruction of paper should be conducted.** Are CRO(s)/Vendor(s) aware about the Preservation Notice or Legal Hold that is in place? ☐ Yes ☐ No, If **No**, communications to the CRO/Vendor(s) has to be completed. Reference to Preservation Notice or Legal Hold in place: [This is optional to enter but recommended.] ***[ENTER]***
No	Records can be destroyed as per *Section 10.4, Destruction by CRO or Vendor.*

10.4 Destruction by CRO or Vendor

Within ***[ENTER timeframe***] following expiration of the required retention period, arrange for confidential destruction of paper and/or electronic records as per relevant SOPs/procedures.

Reference to specific process, procedural forms, destruction certificate, etc.: ***[ENTER]***

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11 Transfer and Archival of TMF

[In this section, describe how the data are to be transferred, e.g., via TMF media (sFTP, USB, CD/DVD, hard drive, hard copy etc.). Follow any company specific SOPs, Wis for data transfers or migrations.

Transfers of TMFs should be documented in a TMF transfer agreement. This agreement should document:

- What is being transferred?
- When the transfers will occur?
- Which organizations are the issuers and beneficiaries of the transfer?
- What format and method will be used to transfer?
- Which method will be used to verify the transfer?
- Clear statements as to whether the transfer is of certified copies or authoritative source.

If using the eTMF Exchange Mechanism Standard (EMS), it is also possible to draw up an exchange agreement as specified in the EMS specifications.

A copy of the agreement(s) should be approved and retained as an annex to the TMF plan. If multiple transfers are expected, then multiple agreements can be drawn up.

This section should include details of the final TMF transfer/archival. Include details of where the TMF will be stored for the duration of the retention period. Discuss how the integrity of the artifacts, metadata, and audit trail will be maintained.]

The table below is intended to record planned transfers (movements, migration) of TMF records for the study.

TMF Scope (e.g., country and site levels records)	Type of Documentation (e.g., DM or Safety)	TMF format (paper, electronic)	From (indicate the organization/sponsor name) via TMF Media	To (indicate the organization/ sponsor name)	Frequency Transfer (Milestone/ ate)
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12 Appendix

[List or append or embed or state the location of any other documents that would be beneficial to include in the TMF Plan; this may include and not limited to a processing plan/workflow and other key documents that may contain elements of this template and are separate documents. Any embedded files should be retrievable/accessible when the plan is final].

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Page 1: [6] Style Definition **Jamie Toth** **10/21/2022 2:25:00 PM**

Heading 6: Font color: Auto, Outline numbered + Level: 6 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.8", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (N

Page 1: [7] Style Definition **Jamie Toth** **10/21/2022 2:25:00 PM**

Heading 5: Font color: Auto, Outline numbered + Level: 5 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.7", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (N

Page 1: [8] Style Definition **Jamie Toth** **10/21/2022 2:25:00 PM**

Heading 4: Font color: Auto, Outline numbered + Level: 4 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.6", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (N

Page 1: [9] Style Definition **Jamie Toth** **10/21/2022 2:25:00 PM**

Heading 3: Font: Italic, Font color: Auto, Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.5", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border)

Page 1: [10] Formatted **Jamie Toth** **10/21/2022 2:25:00 PM**

Left, Space After: 0 pt, Bulleted + Level: 1 + Aligned at: 0" + Indent at: 0.25", Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border), Between : (No border)

Page 1: [11] Formatted **Jamie Toth** **10/21/2022 2:25:00 PM**

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Page 1: [12] Formatted **Jamie Toth** **10/21/2022 2:25:00 PM**

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Page 1: [13] Formatted **Jamie Toth** **10/21/2022 2:25:00 PM**