[Instructions for use:

* 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 making adjustments to 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 entered with Arial Narrow font.
* Tables have black headings with white font and are designed to split across pages.

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 NAME]***

|  |  |
| --- | --- |
| **Protocol # or Study Identifier:** | ***[ENTER PROTOCOL NUMBER OR STUDY IDENTIFIER]*** |
| **Date:** | ***[ENTER TMF PLAN DATE]*** |
| **Version:** | ***[ENTER VERSION NUMBER OF TMF PLAN, e.g.. 1.0, 2.0]*** |

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# Approvals

[Approval and form of the approval is at the discretion of the sponsor 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.

If electronic signatures or approvals are in place then the below could simply state that.]

|  |  |  |  |
| --- | --- | --- | --- |
| **Sponsor Representative(s)** | | | |
| ***[ENTER NAME HERE]*** | ***[ENTER TITLE]*** | Signature | Date (DD MMM YYYY) |
| [Add more rows as needed.] |  |  |  |
| **CRO/Vendor Representative(s)** | | | |
| ***[ENTER NAME HERE]*** | ***[ENTER TITLE]*** | Signature | Date (DD MMM YYYY) |
| [Add more rows as needed.] |  |  |  |
| **Other Representative(s)** | | | |
| ***[ENTER NAME HERE]*** | ***[ENTER TITLE]*** | Signature | Date (DD MMM YYYY) |
| [Add more rows as needed.] |  |  |  |

# Document Version History

[Enter the version of the TMF Plan that is being changed, and information about the changes.]

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

# Definitions and Abbreviations

[Add other definitions and abbreviations for sponsor specific information.]

|  |  |
| --- | --- |
| **Term/Acronym** | **Definition** |
| CRO | 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 | Shared responsibility with the Owner is passed to the Delegated Owner for a defined period of time. Answerable to the owner. |
| eTMF | Electronic Trial Master File. |
| GCP | Good Clinical Practice. |
| QA | Quality Assurance. |
| RACI | Responsible, Accountable, Consulted, Informed. |
| Record Owner | 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 delegated to another person or another function. |
| Shared Responsibility | The responsibility is shared with others for a defined period of time. Answerable to the Delegated Owner. |
| Sponsor | An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. |
| TMF | 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 Owner | 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]*** |

# Introduction

The purpose of this Trial Master File (TMF) Plan is to outline the process and procedures that [***NAME 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 outlines how records for the trial will be managed and stored during and after the duration of the trial, including study specific processes and documentation for archiving and destruction.

All relevant study team members are expected to understand and adhere to this TMF Plan.

The scope of this TMF Plan covers responsibilities of the sponsor and other parties in ensuring a high quality TMF.

This TMF plan covers: [choose one]

* Sponsor TMF only [reference where investigator TMF is controlled/owned/maintained]
* Sponsor and investigator TMF
* Investigator TMF only [reference where sponsor TMF is controlled/owned/maintained]

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

TMF set-up and maintenance has the following responsible parties as described in the Table below:  
[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** | **Sponsor** | **Type of Ownership** | **Scope of TMF** |
| --- | --- | --- | --- |
| ***e.g. Sponsor*** | ***SPONSOR NAME*** | ***TMF Owner*** | ***Sponsor TMF*** |
| ***e.g. Project Manager*** | ***SPONSOR NAME*** | ***Delegated Owner*** | ***Sponsor TMF*** |
| ***e.g. Project Team Member (e.g., Study Manager, CRA)*** | ***SPONSOR NAME*** | ***Shared Responsibility*** | ***Specific Sections of the Sponsor TMF*** |
| ***e.g. Third Party Provider*** | ***SPONSOR NAME*** | ***Delegated Owner*** | ***Specific Sections of the Sponsor TMF*** |
| ***e.g. Records Manager*** | ***SPONSOR NAME*** | ***Shared Responsibility*** | ***Sponsor TMF*** |
| [Add more rows as needed.] |  |  |  |

[If the TMF is managed by a vendor, add the following text.]

***[ENTER CRO/VENDOR NAME]*** agrees to maintain all TMF records in a confidential 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 ***[ENTER CRO/VENDOR NAME(s) and SPONSOR NAME]*** personnel with access to the TMF are known to ***[ENTER SPONSOR NAME]*** and TMF access is managed according to applicable SOPs.

# TMF Oversight & Access Arrangements

## RACI Matrix

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

The following RACI matrix describes the involvement of all roles in the TMF:   
[Please fill in the boxes to show the task(s) each role is responsible for. Tasks and Roles in **blue** text below are examples only. Optionally, this table could be in a separate document and appended or embedded and/or referenced here.]

**R-Responsible, A-Accountable, C-Consulted, I-Informed**

| **Task** | **Functional Line Representatives** | **Project Manager** | **Monitor** | **TMF Owner** | **Other1** | **Other2** |
| --- | --- | --- | --- | --- | --- | --- |
| ***Oversight of TMF*** |  |  |  |  |  |  |
| ***Write & maintain TMF plan*** |  |  |  |  |  |  |
| ***File TMF plan*** |  |  |  |  |  |  |
| ***User access management*** |  |  |  |  |  |  |
| ***Creation of binders*** |  |  |  |  |  |  |
| ***Shipping of originals*** |  |  |  |  |  |  |
| ***Destruction paper copies*** |  |  |  |  |  |  |
| ***Filing in TMF*** |  |  |  |  |  |  |
| ***Paper reconciliation*** |  |  |  |  |  |  |
| ***Ongoing checks - CRO*** |  |  |  |  |  |  |
| ***Ongoing checks - Sponsor*** |  |  |  |  |  |  |
| ***Readiness review*** |  |  |  |  |  |  |
| ***Issue resolution*** |  |  |  |  |  |  |
| ***Progress reports*** |  |  |  |  |  |  |
| ***Archiving*** |  |  |  |  |  |  |
| ***Trend analysis and action plan*** |  |  |  |  |  |  |
| ***TMF transfer*** |  |  |  |  |  |  |

## Access arrangements

[Describe how access to the TMF (paper or electronic) is granted and removed when no longer required.]

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

Access is handled in this manner: ***[ENTER]***

For Training information, see *Section 9, TMF Training*.

## TMF Maintenance delegated to a 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. Therefore, ***[ENTER SPONSOR NAME]*** is required to have continual access to the TMF in order to perform oversight responsibilities.

[Add text related to transfer of records as needed and refer to *Section 11, TMF Transfer*s of the plan for details.] ***[ENTER]***

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

|  |  |
| --- | --- |
| ☐ Full TMF access ***[ENTER]*** | ☐ Custom TMF access ***[ENTER*]** |
| ☐ TMF Metrics reports ***[ENTER]*** | ☐ TMF trackers and QC checklists/reports |
| ☐ Routine inspection and audit reports | ☐ Other (specify): ***[ENTER or put NA if Not Applicable]*** |

How access to the CRO/Vendor system will be handled is in *Section 5.2, Access Arrangements*, and how Training will be handled is in *Section 9, TMF Training*.

## For Inspections/Audits

[The below text should be modified to be in line with sponsor SOPs, procedures.]

In the event of a 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-specific TMF, i.e., Sponsor and/or 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. 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.

# TMF Content

## 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 so as 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.]

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

## Authoritative Sources

[In this section, the Authoritative Sources where TMF Content is stored during the study are expected to be listed. Authoritative sources are physical locations of records. Note: This section comes from MHRA GCP Guide section 10.2.3, page 331-332.]

Is a CRO/Vendor(s) responsible for the creation, collection, and/or management of TMF content for the study?

☐ Yes, complete below

☐ 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.]

|  |  |
| --- | --- |
| ☐ 1. Trial Management: ***[ENTER]*** | ☐ 2. Central Trial Documents: ***[ENTER]*** |
| ☐ 3. Regulatory: ***[ENTER]*** | ☐ 4. IRB or IEC and other Approvals: ***[ENTER]*** |
| ☐ 5. Site Management: ***[ENTER]*** | ☐ 6. IP and Trial Supplies: ***[ENTER]*** |
| ☐ 7. Safety Reporting: ***[ENTER]*** | ☐ 8. Central and Local Testing: ***[ENTER]*** |
| ☐ 9. Third Parties: ***[ENTER]*** | ☐ 10. Data Management: ***[ENTER]*** |
| ☐ 11. Statistics: ***[ENTER]*** | ☐ ***[OTHER]: [ENTER]*** |

### Originals, Wet Inks, and Raised Seals

[Originals may be in the form of paper, electronically created records or both of these. 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).

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

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

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

If applicable, describe how wet inks/raised seal documents will be handled: ***[ENTER, IF NOT APPLICABLE, ENTER NOT APPLICABLE]***

### 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.

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, .pdf, etc.) you will accept.]

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

### 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.

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.]

Describe how relevant records for the study will be handled, if not applicable, enter not applicable: ***[ENTER]***

### Translations

[Consider translations – has a plan been created for the study? Where is that plan stored? etc. This section is optional, if not needed, remove.]

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

* If **Yes**, either append or embed the Translation Plan to the TMF Plan, or state the location of where the Translation Plan resides: ***[ENTER]***
* If **No**, list the records that require translation in this section or if not applicable, enter ‘Not Applicable’ ***[ENTER]***

# Record and TMF Disposition

This section is to provide information regarding destruction, retention, archving, and legal hold.

## Destruction

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***

## Retention

[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 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]***

## Archiving

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

### Sponsor TMF

1. Please refer to ***[ENTER SPONSOR NAME]*** TMF Management SOP for full archiving requirements.
2. Name of GCP Archivist: ***[ENTER]***
3. Will ***[ENTER SPONSOR NAME]*** fully archive the TMF within their own processes/electronic system(s)?   
   ☐ **Yes**, complete A below ☐ **No** [If no system is involved, i.e. paper, then remove system language.]
   1. Electronic system(s) name and version: [Note: This may be the same as the eTMF system or could be a separate Archiving system.] ***[ENTER]***
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**, complete A-G below ☐ **No**
   1. CRO/VENDOR(s) Name: ***[ENTER, including all CRO/Vendor(s)]***
   2. Content archived: ***[ENTER]***
   3. Archive address: ***[ENTER]***
   4. Applicable archive-related SOPs: ***[ENTER]***
   5. Retention period agreed with ***[ENTER CRO/VENDOR NAME(s)]***: ***[ENTER]***
   6. Describe process agreed for retrieval and review of archived records in the event of a regulatory inspection or for other purposes: ***[ENTER]***
   7. Comments: ***[ENTER]***

### Investigator TMF

[This section can be removed if not applicable for this plan. [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.]***

## 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.]

1. Is there a Preservation Notice or Legal Hold in place?

☐ **Yes**, complete A-B and 2 below ☐ **No**, see C below

1. If **Yes**, then no destruction of paper should be conducted.
2. If **Yes**, are CROs/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.

1. If **No**, then records can be destroyed as per *Section 7.1, Destruction.*
2. Reference to Preservation Notice or Legal Hold in place: [This is optional to enter, but recommended.] ***[ENTER]***

# 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.]

| **Policy, SOP, Work Instructions Name** | **Version** | **Date** | **Sponsor/CRO/Other Third Party** |
| --- | --- | --- | --- |
| ***TMF Management Setup, Maintenance, Close Out, Archival SOP*** |  |  |  |
| ***Redaction SOP or Policy*** |  |  |  |
| ***Good Documentation Practices (GDP) Policy or SOP*** |  |  |  |
| ***Scanning and Destruction SOPs or Work Instructions*** |  |  |  |
| ***Document Quality Checking (QC) Work Instructions*** |  |  |  |
| ***Periodic Review or Functional QC Work Instructions*** |  |  |  |
| ***Business Technology Administration SOPs*** |  |  |  |
| ***Other Manuals, Work Instructions, etc. pertinent to TMF*** |  |  |  |
| [Add more rows as needed.] |  |  |  |

The full list of SOPs/Policies/Work Instructions is filed into the TMF?

☐ Yes ☐ No

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

# 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.]

TMF training to be handled by: ***[ENTER Sponsor or CRO, depending on who maintains the TMF (paper or electronic) and is responsible for training the end users.]***

TMF training will be provided to all new users via ***[ENTER how training is conducted, i.e. Instructor-led; electronic learning module; training materials.]***

TMF training completion certificates will be filed ***[ENTER 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.

# Conducting TMF Reviews

[General Considerations:

Comprehensive reviews of the TMF content should be performed based on the study design, the current status of the study, decisions that have been made, events that have occurred, and SOPs and standards that apply.

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 8, 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 Resources.]

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

## 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).
* 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 also 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 so as to avoid constant updating to the plan.]

| **Review to be performed (Indicate type and scope)** | **Review Coordinator (Role accountable to facilitate/lead)** | **Review Due By (Milestone/Event/Date)** |
| --- | --- | --- |
| ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** |
| [Add more rows as needed.] |  |  |

## TMF Review Documentation

Describe the records expected to be generated, maintained and filed to support the TMF review performed during the study. If information exists in procedural documentation, refer to *Section 8, Applicable SOPs*: ***[ENTER]***

# Transfers 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.).]

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)** | **TMF format (paper, electronic)** | **From (indicate the organization/sponsor name) via TMF Media** | **To (indicate the organization/ sponsor name)** | **Frequency of Transfer (Milestone/Event/Date)** |
| ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** |
| ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** | ***[ENTER]*** |
| [Add more rows as needed.] |  |  |  |  |

# Appendix

[List or append or embed or state the location of any other documents that would be beneficial to include in the TMF Plan.]