

Trial Master File Plan

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| **Protocol Number** |  |
| **Date** |  |
| **Version** |  |

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# TMF Plan Approval

*<When using electronic signatures, indicate so in the signature block>*

|  |
| --- |
| **Sponsor Representative(s)** |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |
| **Vendor Representative(s)**, if applicable |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |
| **Other Representative(s)**, if applicable |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |
| *<Name>* | *<Title>* | Signature | Date (DD MMM YYYY) |

# Document Version History

|  |  |  |
| --- | --- | --- |
|  **Version Number** | **Summary of Changes** |  **Version Date** |
| 1.0 | Original Final Version | Date (DD MMM YYYY) |

# Definitions and Abbreviations

|  |  |
| --- | --- |
| **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. |
| Document 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 be delegated to another person or another function. |
| eTMF | Electronic Trial Master File. |
| Oversight | Oversight is important where the sponsor has delegated functions to other parties, either within the same organization (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. |
| VCU OVPRI  | VCU Office of the Vice President of Research and Innovation. |
| 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 (TMF) and/or electronic (eTMF). |
| TMF Archivist (Project Manager) | Accountable and has the ultimate authority for the archival of TMF records (TMF and eTMF). This role has access to both the TMF and eTMF. |

# Introduction

The purpose of this Trial Master File (TMF) Plan is to outline the processes and procedures that all VCU responsible parties will follow 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 archival.

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.

# TMF Oversight

1.
2.

## Responsibilities

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

*Add and/or delete rows as applicable*

| **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 Index |   |   |
| Document collection, review, and finalization for documents associated with contracted services |  |  |
| Management of paper records |   |   |
| Document uploads to eTMF - Documents are uploaded to **[ENTER]** within **[ENTER # of days]** days of finalization or collection.  |  |  |
| Document Quality and Metadata QC following upload to the eTMF |   |   |
| TMF Completeness Reviews |   |   |
| eTMF Query Resolution |  |  |
| Metrics Reporting |   |   |
| Archiving and Study Document Retrieval |  |  |
| ***[ENTER other activities as needed]*** |  |  |

## Inspections/Audits

In the event of a regulatory audit/inspection, the Project Manager will ensure all impacted study team members are informed as soon as the inspection has been announced.

The *<ENTER Key TMF Contact>* will be informed 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. 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 and Disposition Plan

|  |  |
| --- | --- |
| **TMF Format** | [ ]  Electronic[ ]  Hybrid (electronic and wet ink originals) |
| **Primary TMF** | [ ]  Veeva Vault eTMF[ ]  Shared Drive or Sharepoint[ ]  Both used per study specific eTMF Index attached |
| **Disposition of Originals /****Wet-Inks** | [ ]  Destroyed per certified copy process[ ]  Archived through study close out at: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Management of Unblinded Records** | [ ]  Uploaded by unblinded study team members with restricted access[ ]  N/A - Open label trial or natural history trial |
| **Translations** | [ ]  Managed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Is there a Translation Plan created for this study? |
| **Was there a TMF Migration** | [ ]  Yes, Sharepoint to Vault Transfer[ ]  No, historical documents maintained in \_\_\_\_\_\_\_. Document filing to Vault TMF effective as of \_\_\_\_*date*\_\_\_\_\_.[ ]  Not Applicable |
| **Archival** | [ ]  Sponsor will archive at the following location per local regulations:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

## Document Alternate Locations

Those documents which are required but will not be filed in the TMF will be identified, and have their alternate location described in the study-specific TMF Index.

## Vendor Management

| **Vendor Type** | **Vendor Name** | **Vendor Managed by:** | **Content Management** |
| --- | --- | --- | --- |
| 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].**  |
| 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].**  |
| 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].**  |
| 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].**  |
| 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].**  |
| 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].**  |
| 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].**  |

# Applicable SOPs

The applicable TMF SOPs that will be followed are listed in the table below.

|  |
| --- |
| **SOP Name** |
| Trial Master File Setup and Planning |
| Trial Master File Document Collection and Processing  |
| Trial Master File Oversight and Inspection Readiness |
| Trial Master File Closeout and Archival  |

# TMF Reviews

Inspection Readiness checks will occur per the TMF Oversight and Inspection Readiness SOP. These reviews will occur, at least, at each milestone for the study, each country, and all sites. *<Any study specific variance should be listed here.>*

#  Appendix

## Study Specific TMF Index