DAIDS TMF Index

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DAIDS Regulatory Support Center (RSC)

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No. HHSN272201700014C, entitled NIAID DAIDS Regulatory Support Center (RSC).

Purpose

- **Provide DAIDS Specific TMF Index requirements to Authoritative Sources (AS) and DAIDS Primary Contacts(PC) to facilitate a review of protocol specific TMF Indexes and creation of complete and accurate TMF Indexes.**
- **Identify how to use the Index in correlation with the DAIDS TMF Naming Filing Guide and the Submission Form and how to use these tools to assist with creating accurate and complete submissions within the sponsor TMF.**

Topics

- Index Review
- DAIDS TMF Naming and Filing Guide
- Submission Form
- Creating a Submission
- Resources

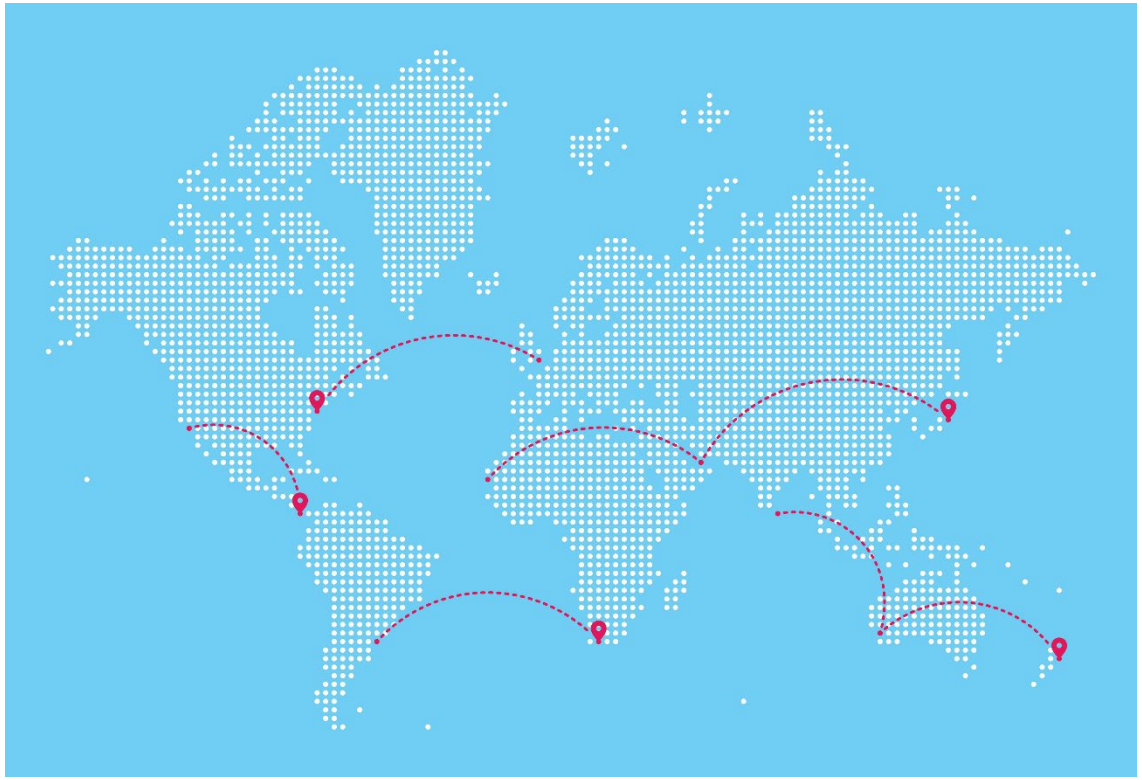
DAIDS TMF Index Review

Index Review – Key points to consider

- **Does the Artifact help to tell the story of a clinical trial?**
  - If no, the document probably does not belong with the TMF.
  - If yes, where does it belong within the classification structure?
- **Any documentation which has been created during the trial and that helps reconstruct and evaluate the trial conduct must be filed in the TMF, irrespective of whether it is explicitly listed in these guidelines**

Index Review – Key points to consider

- **Can the document serve multiple purposes?**
  - If so, it may be that the document would fit in several Artifacts.
- **Are there multiple documents within an artifact type?**
- **Are document types embedded in other document types?**
  - Clear Mapping
    - Identify Sub-Artifacts
    - Referencing Other Artifacts (located elsewhere within the TMF)



Index Review Core/Recommended

Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)	Zone Name	Section Name	Artifact name
Recommended	Required	DAIDS Quality Officer	DAIDS Quality Officer	Trial Management	Trial Oversight	Quality Plan
Core	Required	Relevant DAIDS Programs & Offices and Vendors	Relevant DAIDS Programs & Offices and Staff	Trial Management	Trial Oversight	List of SOPs Current During Trial

- **Core**
  - If created or collected, the artifact must be in the TMF as dictated by either the ICH Guidelines, regulations, or by consensus of the TMF Reference Model group.
- **Recommended**
  - The artifact does not have to be produced, but if it is created or collected, it is required to be in the TMF.

Index Review – Status

Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)	Zone Name	Section Name	Artifact name
Recommended	Not Generated	RSC	DAIDS RAB SAR	Central Trial Documents	Product and Trial Documentation	Financial Disclosure Summary
Core	Required	CRS	DAIDS PRT	Site Management	Site Set-up	Protocol Signature Page
Core	Not Generated	RSC	DAIDS CTA Team	Site Management	Site Set-up	Clinical Trial Agreement
Recommended	Required	CRPMC	CRPMC COR	IP and Trial Supplies	IP Documentation	IP Supply Plan
Recommended	Not Required	ACTG NCC	DAIDS Network PO	IP and Trial Supplies	Non-IP Documentation	Non-IP Supply Plan
Core	Not Required	DMC	DAIDS Network PO	IP and Trial Supplies	Interactive Response Technology	IRT User Acceptance Testing (UAT) Certification

- **Status**
  - **Required** (Core or Recommend Artifacts): The artifact is/will be generated and collected during the course of a study.
  - **Not Generated** (Core Artifacts Only): The artifact is/will not be generated or collected but may still be required based on applicable regulations. Identifies gaps in the DAIDS processes to be identified and addressed and/or remediated.
  - **Not Required** (Core and Recommended Artifacts): The artifact is not applicable per the protocol.

Index Review – Authoritative Source

Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)
Recommended	Required	RSC	DAIDS TMF Team
Recommended	Required	PPD	DAIDS OCSO MOB

- **The Authoritative Source:**
  - Identifies and uploads documentation for the eTMF, and certifies all documentation, as required per system.
  - Works with the DAIDS PCs and/or Electronic Systems Owners to resolve issues with documentation.

Index Review – DAIDS Primary Contact

Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)
Recommended	Required	RSC	DAIDS TMF Team
Recommended	Required	PPD	DAIDS OCSO MOB

- **DAIDS Primary Contact (DAIDS PC)**
  - A DAIDS employee or group that ensures documents generated during the course of the study have been filed in the Sponsor TMF.
    - Completes document level quality control (QC) of TMF documents per the DAIDS Work Instruction and review requirements outlined in the DAIDS PC Review Checklist.
    - Works with the AS to resolve issues with missing, incomplete or incorrect documentation filed in the TMF.

***May or may not be an Authoritative Source.**

Index Review – Sub-Artifacts

Artifact Name	Sub-Artifact / Examples	Definition / Purpose
Trial Master File Plan	Trial Master File Index, Trial Master File Plan, Electronic Systems Mapping Documents, Trial Master File Guidance, DAIDS TMF Naming Convention and Filing Guide, TMF Index Risk Assessment Tool	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. **Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc**.
Trial Master File Plan	Vendor Specific Trial Master File Plan, NCSM File Review, Project Management Plan, Audit Trail Report (from external system)	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. **Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.**

- **Sub-Artifact**
  - When an artifact name does not explicitly refer to a single kind of record (Trial Management Plan, e.g.), sub-artifacts are intended to provide a means to list all DAIDS specific records that a company would expect to file under a given artifact.

Index Review – Definitions/Purpose

Artifact Name	Sub-Artifact / Examples	Definition / Purpose
Trial Master File Plan	Trial Master File Index, Trial Master File Plan, Electronic Systems Mapping Documents, Trial Master File Guidance, DAIDS TMF Naming Convention and Filing Guide, TMF Index Risk Assessment Tool	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. **Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc**.
Trial Master File Plan	Vendor Specific Trial Master File Plan, NCSM File Review, Project Management Plan, Audit Trail Report (from external system)	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. **Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.**

- **Definition / Purpose**
  - Artifact specific definitions, as per the TMF Reference Model, (along with sub-artifact names) identifying what is specifically included within a given artifact type.

Index Review – Mapping/Referencing Location*

Artifact #	Artifact Name	Sub-Artifact / Examples	Source Location (System) (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	System Owner (Entity functioning as the Source of the document to review and verify. Adjust as needed.)
06.01.02	IP Instructions for Handling	IP Instructions for Handling, Protocol, MOP, SSP	Transperfect Trial Interactive eTMF **(included in artifact numbers 01.01.05 and 02.01.02)**	FHI 360
06.01.02	IP Instructions for Handling	IP Instructions for Handling, IB/Package Insert	TRI - Veeva Vault **(included in the IB in artifact number 02.01.01)**	TRI

- **Referencing Other Artifacts (located elsewhere within the TMF)**
  - There are instances when a given document (e.g., IP Handling) is found within another related artifact (e.g., Protocol Document) filed elsewhere within the TMF. For these situations, the line item that lists said document (e.g., IP Handling) within the TMF Index will reference the artifact number for the related artifact (e.g., Protocol Document 02.01.01). In addition, the line item will also include the DAIDS AS/PC and Source Location listed for the referenced artifact (e.g., Protocol Document)

*Artifacts that are referenced as being located under another artifact type will only be filed in the referenced location.

Index Review – System Location/Owner

Artifact Name	Source Location (System) (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	System Owner (Entity functioning as the Source of the document to review and verify. Adjust as needed.)
Trial Master File Plan	TRI - Veeva Vault	TRI
Quality Plan	SDMC Veeva Vault	FSTRF

- **System Owner**
  - Vendor responsible for the system utilized to store TMF required documents.
- **Responsibilities**
  - Maintain specific documents outlining TMF related activities within their systems
  - Maintain Validation
  - Provide Inspector Training and Access
  - Ensure availability and/or provision of document specific Audit Trails

Index Review – Milestones

Artifact #	Artifact Name	Start	Conduct	Close
01.01.01	Trial Master File Plan	X	Intentionally left blank	Intentionally left blank
01.01.03	Quality Plan	X	Intentionally left blank	Intentionally left blank

- **Start**
  - Indicator of Artifacts required prior to the start of a trial. Mapped to Open To Enrollment.
- **Conduct**
  - Indicator of Artifacts required during the conduct of a trial. Maps to Close to Accrual
- **Close**
  - Indicator of Artifacts required prior to the completion of a trial. Maps to POS/PAC

Index Review

Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)	Zone Name	Section Name	Artifact Name	Sub-Artifact / Examples	Definition / Purpose	Source Location (System) (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	System Owner (Entity functioning as the Source of the document to review and verify. Adjust as needed.)
Recommended	Required	RSC	DAIDS TMF Team	Trial Management	Trial Oversight	Trial Master File Plan	Trial Master File Index, Trial Master File Plan, Electronic Systems Mapping Documents, Trial Master File Guidance, DAIDS TMF Naming Convention and Filing Guide, TMF Index Risk Assessment Tool	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	TRI - Veeva Vault	TRI
Recommended	Required	PPD	DAIDS OCSO MOB	Trial Management	Trial Oversight	Trial Master File Plan	Vendor Specific Trial Master File Plan, NCSM File Review, Project Management Plan, Audit Trail Report (from external system)	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	PPD - Veeva Vault	PPD
Recommended	Required	ACTG NCC	DAIDS TMF Team	Trial Management	Trial Oversight	Trial Master File Plan	Vendor Specific Systems Plan	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	TRI - Veeva Vault	TRI
Recommended	Required	DMC	DAIDS TMF Team	Trial Management	Trial Oversight	Trial Master File Plan	Vendor Specific Trial Master File Plan, Artifact Comment Log, Confirmation of Expected Documents List Reports Review	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	SDMC - Veeva Vault	FSTRF
Recommended	Required	Westat	DAIDS TMF Team	Trial Management	Trial Oversight	Trial Master File Plan	Vendor Specific Systems Plan, Trial Master File Reports	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	Westat Medidata eTMF	Westat

DAIDS TMF Naming and Filing Guide

DAIDS TMF Naming and Filing Guide*

- General Naming Guideline
- Dating Convention Instructions
- All Zones Tab
- Zones 1-12 Tabs

*** The DAIDS TMF Naming and Filing Guide includes the DAIDS approved Name and Date conventions. If other System Owners have their own established Name and Date conventions, they can be utilized but if not, the DAIDS TMF Naming and Filing Guide should be utilized.**

General Naming Guideline

DAIDS TMF Naming and Filing Guideline **The purpose of this guideline is to identify documents by study, site, person, and signature date, which will allow for easy retrieval from the eTMF during an inspection. This will also allow adequate differentiation between similar documents. Refer to the appropriate zone tabs for more detailed naming conventions.**		**Example**
General Documents	Documents that flow into the eTMF must follow a naming convention so that it may be easily retrieved. Most documents will follow the following format: **<Study#_Name_version#_documentdate YYYY-MM-DD>**	HPTN083_TMFPlanforHPTN083_V2.0_2021-08-27
IRB Approval/ Reg Notifications or Approvals	Documents that are generated by an IRB or regulatory entity. Study#_RegApproval_**Material Type**_<Approvaldate YYYY-MM-DD> *Refer to tabs: Zone 4 for further clarification.	HPTN083_RegApproval_Amendment_2015-01-01
Committee Documents	Documents are generated by a committee such as **SMC** or **DSMB** <Study#_**Entity**_Doc Name_version#_documentdate YYYY-MM-DD>	HPTN083_SMC_TrialMemberList_version2.0_2019-06-07

General Naming Guideline

DAIDS TMF Naming and Filing Guideline		Example
Site Documents	Site documents should have the site number and if listed, the PI last name. <Study#_Site Number__**PI Name**_Doc Name_version#_documentdate YYYY-MM-DD> or <Study#_Site Number__**Doc Name**_version#_documentdate YYYY-MM-DD> *Refer to tabs: Zone 4, Zone 5, & Zone 6 for further clarification.	HPTN083_1234_Smith_IRBAPPROVAL_version4.0_2014-02-7 or HPTN083_1234_IRBAPPROVAL_version4.0_2014-02-7
Documents with Missing Metadata	In the instance, a documents is missing a name, date or version, the guidelines below should be followed: Missing Document Name: **Use document type according to Index** Missing Document Date: Use date **1900- Jan- 01** Missing Version Number: **Leave as blank** Missing Document Name, Date & Version: Use just the document type according to the index and use date 1900-Jan-01	Missing Document Name: HPTN083_TMFPlan_version2.0_2021-08-27 Missing Document Date: HPTN083_TMFPlan_version2.0_1900-1-01 Missing Version Number: HPTN083_TMFPlan_2021-08-27 Missing Document Name, Date & Version: HPTN083_TMFPlan_1900-1-01

General Naming Guideline

DAIDS TMF Naming and Filing Guideline		Example
Documents which pertain to multiple Studies	Utilize **MultiStudies** in place of the study number	MultiStudies_DAIDS_eTMF_Process_Training_Nissao_2021-12-10 (v1.0)
Documents which pertain to multiple sites	Utilize ~~-~~ **MultiSites** in place of the site number	IMPAACT2017_MultiSites_RelCommun_CPQADrugAssay_2021-10-13 (v1.0)
Documents which pertain to multiple lots	Utilize ~~-~~ **MultiLots** in place of the lot number	IMPAACT2017_MultiLots_CPQADrugAssay_2021-10-13 (v1.0)
Name	When a person "Name" is required, use the convention **Last Name + First Initial (e.g., SmithJ).**	IMPAACT2019_5115_OtherFDF_LastF_ViiV_2020-11-02

Dating Convention

DAIDS TMF Naming and Filing Guideline The purpose of this guideline is to identify documents by study, site, person, and signature date, which will allow for easy retrieval from the eTMF during an inspection. This will also allow adequate differentiation between similar documents. Refer to the appropriate zone tabs for more detailed naming conventions.		Example
File Name and Metadata Date Requirements	File name dates and Metadata dates will be selected based on the following algorithm: 1. Utilize the date identified in the column labeled Metadata Dating Convention. 2. If that specific date type is not available, select from the dates available in the following order: • Signature Date (last signature date if multiple) • Effective Date • Approval Date • Version Date • Letter Date • Date on the submission form 3. If a date cannot be determined based on the above criteria, the date of 1900-01-01 is entered. 4. For Metadata dates, enter all as available/applicable for each date field required for a specific document type or the above algorithm as needed.	IMPAACT2017_MultiSites_RelCommun_CPQADrugAssay_1900-01-01 (v1.0)

Date Convention

Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact Name	Sub-Artifact / Examples	Short Name (additional Short Names to be added as needed based on other potential sub-artifacts/examples)	Dating and Naming Convention (Study, Country and Site name fields based on TMF Level as applicable based on specific artifact received. Name field included as applicable based on specific document)	Metadata Dating Convention (See Dating Convention Instructions)
1	Trial Management	1.01	Trial Oversight	01.01.01	Trial Master File Plan	Trial Master File Index, Trial Master File Plan, Trial Master File Report, Electronic Systems Map, Trial Master File Name File Guide, Guidance for DAIDS eTMFs, Vendor Specific Trial Master File Plan, TMF Index Signature Sheet	TMFIndex, TMFPlan, TMFReport, ElecSysMap, NameFileGuide, eTMFGuidance, <vendor>TMFPlan TMFIndexSigSheet	Study#_<ShortName>_version#_<documentdate YYYY-MM-DD>	Version Date Document Date
1	Trial Management	1.01	Trial Oversight	01.01.03	Quality Plan	Quality Documentation	QualPlan	Study#_<ShortName>_version#_<documentdate YYYY-MM-DD>	Version Date
1	Trial Management	1.01	Trial Oversight	01.01.04	List of SOPs Current During Trial	List of SOPs Current During Trial, SOP Waivers, SOP Deviations	SOPCurrent, SOPWaiver, SOPDev	Study#_SOPCurrent_version#_<documentdate YYYY-MM-DD>, Study#_SOPWaiver_<documentdate YYYY-MM-DD>, Study#_SOPDev_<documentdate YYYY-MM-DD>	Document Date
3	Regulatory	3.01	Trial Approval	03.01.02	Regulatory Approval Notification	Regulatory Approval	RegApproval	Study#_RegApproval_<Regulatory Entity>_<approvaldate YYYY-M_M-DD>	Approval Date
3	Regulatory	3.02	Investigational Medicinal Product	03.02.01	Import or Export License Application	Import/Export License Application	ImpExpLicenseApp	Study#_ImpExpLicenseApp_<Regulatory Entity>_<documentdate YYYY-MM-DD>	Application Date
3	Regulatory	3.04	General	03.04.02	Tracking Information	Tracking Information	TrackInfo	Study#_(Site# if applicable)_TrackInfo_<Material Type>_<documentdate YYYY-MM-DD>	Last Entry Date
4	IRB or IEC and other Approvals	4.01	IRB or IEC Trial Approval	04.01.03	IRB or IEC Composition	IRB/IEC Composition	IRBIECComp	Study#_Site#_IRBIECComp_<IRB Name>_version#_<documentdate YYYY-MM-DD>	Effective Date
6	IP and Trial Supplies	6.06	Interactive Response Technology	06.06.02	IRT Validation Certification	IRT Validation Certification	IRTValidCertif	Study#_IRTValidCertif_version#_<documentdate YYYY-MM-DD>	Certification Date
10	Data Management	10.05	General	10.05.01	Relevant Communications	Relevant Communications	RelCommun	Study#_(Site# if applicable)_RelCommun_Subject_<documentdate YYYY-MM-DD>	Correspondence Date
11	Statistics	11.05	General	11.05.02	Tracking Information	Tracking Information	TrackInfo	Study#_TrackInfo_<Material Type>_<documentdate YYYY-MM-DD>	Last Entry Date

Submission Form

Submission Form

DAIDS RSC eTMF Submission Form								
Authoritative Source Name:	**Person making the submission**							
Authoritative Source Email:	**Person making the submissions email address**							
Submission Date:	**Date entered into VV**							
Protocol #:	**HPTN 084 (Must list protocols independently)**							
DAIDS TMF Index Zone	**Section Name** (You must select Zone first to populate this field)	**Artifact Name** (You must select Section first to populate this field)	**Number of Expected Documents**	**Version**	**Date of Document**	**Site**	**Document Filename**	**Additional Information / Comments**

Submission Form Requirements*

- **Required:**
  - A5300b/Phoenix, A5359
  - IMPAACT 2014, IMPAACT 2017, IMPAACT 2019, IMPAACT 2023, IMPAACT 2032, IMPAACT 2034
  - HPTN 083, HPTN 083-01, HPTN 084, HPTN 084-01
  - MTN-034, MTN-042, MTN-043

- **Not Required**
  - A5418
  - IMPAACT 2036

*Submission forms, when required, are only necessary for submissions to the DAIDS RSC VV.

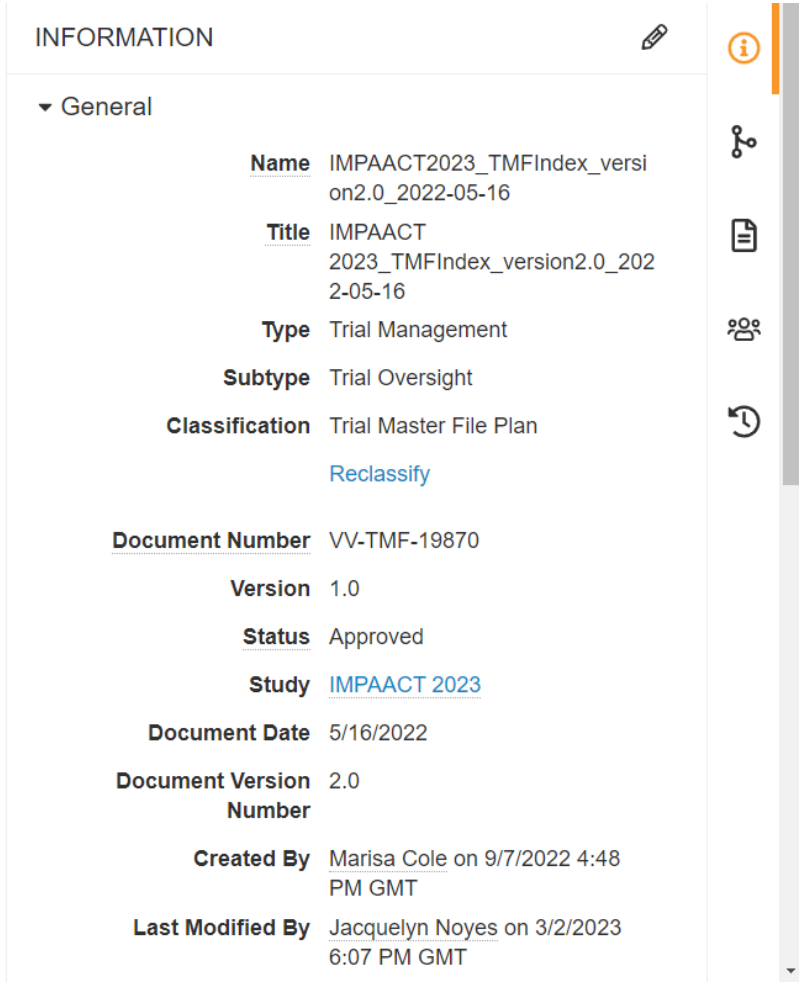
Creating a Submission

Creating a Submission

- **Step 1: Open the Protocol Specific Index, DAIDS TMF Naming and Filing Guide (NFG), Submission Form and the RSC Veeva Vault TMF.**
- **Step 2: Review sub-artifacts in Protocol Specific Index and DAIDS TMF Naming and Filing Guide**
- **Step 3: Populate the submission form**
  - If sub-artifact is not available in the Index and or the NFG, identify in the comments. The DAIDS RSC TMF will work with DAIDS to make applicable updates.

Creating a Submission

- **Step 4: Submit the document using the file name and entering metadata dates as defined in the DAIDS TMF Naming and Filing Guide as well as other applicable metadata when uploading documents.**
  - Any discrepancies will be adjusted during review



Resources

Resources

- **Clinical Data Interchange Standards Consortium** (CDISC)
  - **TMF Reference Model** (https://tmfrefmodel.com/)
- **DAIDS RSC Website** (DAIDS electronic Trial Master File (eTMF) Resources | DAIDS Regulatory Support Center (RSC) (nih.gov)
  - **TMF Page** (Trial Master File (TMF) | DAIDS Regulatory Support Center (RSC) (nih.gov))
  - **DAIDS TMF Guiding Principles** (DAIDS TMF Index Guiding Principles (nih.gov))
  - **DAIDS RSC eTMF Submission Form** (DAIDS eTMF Submission Form_V3.1_1.xlsx)
- **DAIDS TMF Team Email** (niaiddaidstmf@mail.nih.gov)
- **DAIDS RSC TMF Team** (daids_tmf@tech-res.com)

Questions