

Job Aid
Document Upload Process – Completion of the Submission Form
Version 1.0
March 27, 2023

Purpose: This Job Aid serves to describes the Document Upload Process of completing a DAIDS TMF Submission form.

The DAIDS TMF Submission Form

The submission form is used to track submission of TMF documents into the DAIDS RSC Veeva Vault eTMF. Before filling out the submission form, Authoritative Sources should review the TMF Naming and Filing Guideline. The purpose of the guideline is to standardize the document names within the system and for easier location.

Location: The latest version of the submission form can be found in the [DAIDS TMF Resources Folder](#).

Filling out the DAIDS TMF Submission Form

Document submitters filling out the submission form are responsible for ensuring all documents that are being uploaded are listed on the form.

1. Filling out the submitter information
 - a. **Authoritative Source's Name:** Enter the name of the person submitting the documents. If the submitter is outside of DAIDS, include organization.
 - b. **Authoritative Source's Email:** Enter the email address of the Authoritative Source.
 - c. **Submission Date:** Enter the date the document is being uploaded to the eTMF.
 - d. **Protocol #:** Enter the protocol number[s] that is/are applicable. Multiple documents can be listed here (See Example 2).

Example 1

A	B	C	D	E	F	G
DAIDS RSC eTMF Submission Form						
Authoritative Source Name:	Mr. Example					
Authoritative Source Email:	Mexample@nih.gov					
Submission Date:	2/19/2023					
Protocol #:	HPTN 084					

Example 2

A	B	C	D	E	F	G
DAIDS RSC eTMF Submission Form						
Authoritative Source Name:	Mr. Example					
Authoritative Source Email:	Mexample@nih.gov					
Submission Date:	2/19/2023					
Protocol #:	HPTN 084, HPTN 084, HPTN 083-01, HPTN 084-01					

2. Filling out the Document Location

*Refer to the DAIDS TMF Index regarding where documents are located (i.e., which DAIDS-approved electronic system they are in). If you are unsure or disagree with a filing location, please contact the DAIDS TMF Team.

- DAIDS TMF Index Zone:** Located in Column A, select the applicable zone from the drop-down list.
- Section Name:** Located in Column B, select the applicable section from the drop-down list.
- Artifact Name:** Located in Column C, select the applicable artifact from the drop-down list.

Example 3

A	B	C
Authoritative Source Name:	Mr. Example	
Authoritative Source Email:	Mr.Example@nih.gov	
Submission Date:	2/19/2023	
Protocol #:	HPTN 083, HPTN 084	
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)
Third_parties	Third_Party_Oversight	Ongoing Third Party Oversight

3. Filling out the Document Information

- Number of Expected Documents:** List the total number of documents that will be uploaded.
- Version:** List the version of the document. If not applicable, list N/A.
- Date of the Document:** Some documents may have more than one date on the document.
 - Follow the Naming & Filing Guideline to determine the algorithm used to find the appropriate date.
- Site:** List the site number(s). If not applicable, list N/A.
- Document File Name:** Follow the Naming & Filing Guideline to determine the file name. Make sure that the name entered here is also entered in the actual document file name.
- Additional Information/Comments:** Enter any additional information or comments that applies to the document(s). This will be read by the processor within the eTMF system. This section also be used indicate if there are supporting documents already submitted that can be linked.

Note: if you have more than one document for a given Zone, Section, and Artifact, Steps C-F will need to be filled out for each document being filed (See example 4)

Example 4

A	B	C	D	E	F	G	H	I
DAIDS RSC eTMF Submission Form								
Authoritative Source Name: Mr. Example								
Authoritative Source Email: example@dmh.gov								
Submission Date: 2/19/2023								
Protocol #: HPTN 084, HPTN 084, HPTN 083-01, HPTN 084-01								
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
Third_parties	Third_Party_Oversight	Ongoing Third Party Oversight	3	3.0	4/23/2022	N/A	HPTN083_OversightChist_RSC_1.0_2022_04_23	
				2.0	2/3/2022	N/A	HPTN083_OversightChist_RSC_1.0_2022_2_3	
				1.0	9/11/2021	N/A	HPTN083_OversightChist_RSC_1.0_2021_09_11	

4. Label the document file to match the file name in accordance with the Naming & Filing Guideline.
5. Label submission form accordingly: Study#_Site#_TrackInfo_<Material Type>_<documentdate YYYY-MM-DD>.
6. Submit submission form and applicable document[s] into the DAIDS RSC eTMF Veeva Vault System.

Appendix: Step by Step Process Flow Chart for Document Submission

Filling out the DAIDS RSC Submission Form A STEP BY STEP PROCESS

STEP 1: Submission Preparation

The DAIDS Submission Form is only utilized for documents that are submitted to the DAIDS RSC eTMF System. As the document submitter, it is your responsibility to identify the documents needed for submission based on the DAIDS TMF Index.

STEP 2: Verify the Document

As the document submitter, you must verify that the document will be submitted to the appropriate Zone, Section, and Artifact within the eTMF structure. The documents being submitted should be TMF ready (ALOCA +). Verify if the document needs to be certified (refer to guidance document for more information)

STEP 3: Planning

Documents that get submitted into the eTMF systems should meet established naming and dating filing guidelines.

STEP 4: Submission Form

Familiarize yourself with the structure of the submission form. Ask questions if you are unsure of how to list the documents via the drop down options.



STEP 8: Submitting into the eTMF

Once your submission form is all ready, log in to the DAIDS RSC Veeva Vault eTMF system. Upload the submission form along with the accompanying documents in a batch.

STEP 7: Filling out the Document Identifiers

1. Enter the number of expected documents.
2. Enter the version of the document. If none, enter N/A
3. Enter the date of the document. Refer to the Naming and Filing Guideline.
4. Enter the site number. If none, enter N/A
5. Enter the Document File Name> Refer to the Naming and Filing Guideline
6. Enter any pertinent information/ comments. This will be read by the RSC TMF Team during processing

STEP 6: Filling out the Document Location

Follow the order below.

1. Column A: Click on the drop down and select the appropriate zone. Section and artifact names will auto populate to the selected zone.
2. Column B: Click on the drop down and select the appropriate Section Name.
3. Column C: Click on the drop down and select the appropriate Artifact

If your document classification is missing please follow-up with the DAIDS TMF Team.

STEP 5: Filling out the submitter information

1. Row 2: Enter the name of the Authoritative Source (submitter)
2. Row 3: Enter the email of the submitter
3. Row 4: Enter the date of submission (should match when the document enters the eTMF system)
4. Row 5: Enter Protocol Number. If more than one protocol applies to the document, separate with a comma.