National Institute of Allergy and Infectious Diseases

# **Relevant Communications**





National Institute of Allergy and Infectious Diseases March 2024

#### **Best Practices for Filing Relevant Communications**

- All relevant communications should be assessed for relevance on a case-by-case basis and those determined to be relevant should be filed in the TMF.
- It is ultimately the responsibility of the Authoritative Source (AS) to determine if documentation should be filed in the TMF as relevant communications.
- If an e-mail is the sole source of evidence or confirmation of; 1) agreement; 2) an approval; 3) a decision; 4) instruction/guidance; then the e-mail should be filed as a relevant communication in the TMF.
  - **NOTE** If it has been determined by the Authoritative Source (AS) that an e-mail is relevant communication and it contains an attachment, the e-mail and the attachment should be filed in the TMF.



#### What Qualifies as Relevant Communication Document?

- Anything that highlights key decision-making processes and/or provides background information regarding discussions of issues and their resolutions.
- A document is not relevant if it does not support or contribute to trial decision making process or clinical study outcomes.
- Includes but is not limited to: Decisions that impact the study, discussions regarding trial administration and conduct, protocol deviations, AE Reporting, etc.
- May be e-mail(s), letter(s), memo(s), etc., that are the sole source documentation or provide evidence of sponsor decisions for a particular course of action or are an approval/agreement given to the study team, clinical research sites, contractors, grantees, collaborators, etc.



#### **Examples of Relevant Communications**

The following **are** document types that can be considered relevant communications:

- Protocol instructions, clarifications, and violations/deviation resolution
- Documents that show safety information and reporting
- Documents that demonstrate awareness and resolution of issues arising during the study, especially exceptional or critical circumstances.
- Documents that show processes or decisions made where there is no SOP or policy to support that process or decision.

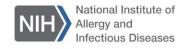
The following **do not** qualify as relevant communications and should not be filed in the TMF:

- Invitations to meetings
- Cover transmittals (e.g., 'Please find enclosed...')
- Information for logs or reminding sites to upload information
- Duplicate (or extracted) information already held elsewhere in the TMF



### When to File Relevant Communications

- It is the responsibility of the Authoritative Source (AS) to ensure that a relevant communication is filed in the appropriate location of a TMF in a contemporaneous manner (e.g., within 10 business days of the date the guidance/advice/direction was sent in writing).
- It is recommended to adopt a "file-as-you-go" strategy to ensure that the TMF is always contemporaneous and is inspection ready.
- The timeline for submitting documentation is 10 business days from the date when a relevant communication is deemed completed from an Authoritative Source's point of view.



# When to File Relevant Communications

- If guidance goes to another group and the Authoritative Source (AS) no longer has visibility to the discussions/guidance provided by others, then the AS is **NOT** required to file any communications/guidance on behalf of another group.
- It is recommended that an AS <u>only</u> take responsibility for filing guidance under their purview in the TMF when it is determined to be a relevant communication.

#### **SCENARIO:**

- ProPEP provides guidance on a specific issue that they deem to be relevant communications. (ProPEP would file their guidance within 10 days)
- Program staff receives ProPEP's guidance and discusses further. Program makes a decision and communicates to the LOC and study team. (*Program would file their* decision within 10 days from the date they informed the LOC and study team).



# Where to file Relevant Communications

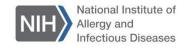
 Each zone of a TMF has a section and specific artifact identified in the Index where relevant communications should be filed (see example in table below).

Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Sub-Artifact/Examples	Definition / Purpose	Source Location (System)	System Owner
01	Trial Management	01.05	General	01.05.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but are not limited to letters, memo, electronic communications and faxes. Correspondence referring to general topics and/or topics across multiple zones may be filed with this zone	TRI - Veeva Vault, Transperfect Trial Interactive eTMF, SDMC - Veeva Vault, Westat Medidata eTMF	TRI, FHI 360, FSTRF, Westat
02	Central Trial Documents	02.04	General	02.04.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	TRI - Veeva Vault, Transperfect Trial Interactive eTMF, SDMC - Veeva Vault, NIAID - EDRMS	TRI, FHI 360, FSTRF, DAIDS
03	Regulatory	03.04	General	03.04.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	TRI - Veeva Vault	TRI
04	IRB or IEC and other Approvals	04.04	General	04.04.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	NCRMS - DPRS	DAIDS
05	Site Management	05.05	General	05.05.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes. Should not include monitoring visit follow-up letter.	TRI - Veeva Vault, Transperfect Trial Interactive eTMF, SDMC - Veeva Vault, Westat Medidata eTMF	TRI, FHI 360, FSTRF, Westat
06	IP and Trial Supplies	06.07	General	06.07.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	CRPMC - Veeva Vault, TRI - Veeva Vault	PPD, TRI
07	Safety Reporting	07.03	General	07.03.01	Relevant Communications	Relevant communications	Zone-specific, thial specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes. (Does not include program level communications.) Email communications related to EAEs are in DAERS.	TRI - Veeva Vault, NCRMS- DAERS, SDMC - Veeva Vault	TRI, DAIDS, FSTRF
08	Central and Local Testing	08.03	General	08.03.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	TRI - Veeva Vault, Westat Medidata eTMF, SDMC - Veeva Vault	TRI, Westat, FSTRF
09	Third parties	09.03	General	09.03.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	TRI - Veeva Vault, SDMC - Veeva Vault, Westat Medidata eTMF, CRPMC - Veeva Vault, PPD - Veeva Vault	TRI, FSTRF, Westat, PPD
10	Data Management	10.05	General	10.05.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	SDMC - Veeva Vault	FSTRF
11	Statistics	11.05	General	11.05.01	Relevant Communications	Relevant Communications	Zone-specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.	SDMC - Veeva Vault	FSTRF



# Where to file Relevant Communications

- After an AS determines something is a relevant communication, the AS should refer to the protocol specific TMF Index to determine the exact zone and artifact # where a relevant communication should be filed.
- The AS should file the relevant communication in the appropriate electronic system.
  For example:
  - DAIDS staff will file relevant communications in the RSC Veeva Vault or the NIAID eTMF (when available)
  - FSTRF staff will file relevant communication in the FSTRF Veeva Vault





Guidance for the Management of e-Mail Communications in Clinical Studies, Version Date: 31-Jul-2020

https://tmfrefmodel.com/wp-content/uploads/TMF-RM-Deliverable-eMail-Communications-Guidance-v1-2020-07-31.pdf

