

# Relevant Communications



# 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 only 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 letters.	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 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



# References

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>