Relevant Communications & Vendor Management

DAIDS TMF Team





What qualifies as relevant communication document

- Highlights key decision-making processes around whether to take action. Provides background discussions of issues and the manner in which they were addressed.
 - Includes: Decisions that impact the study, discussions regarding trial administration and conduct, protocol deviations, & AE Reporting, etc.
 - An e-mail or letter that contains the sole source or evidence of confirmation of an agreement or an approval for processes or for decisions for a particular course of action (e.g. medical advisor approval of subject eligibility) can qualify.

Relevant communication demonstrates Sponsor Oversight and is filed under Relevant Communication [within applicable zone]





Examples of Relevant Communications

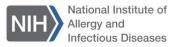
The following are document types that can be considered relevant communications:

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

A document is not relevant if it does not support or contribute to trial decision-making process or clinical study outcomes.

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

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





Vendor Oversight Documentation in the TMF

Documents in Zone 9 of the DIA eTMF Reference Model all relate to:

- The establishment and maintenance of agreements between Sponsors and third parties/vendors used to conduct study-related activities. (e.g., delegation of responsibilities)
- Providing evidence of sponsor oversight of study, as well as any key decisions taken and the supporting rationale. This includes records demonstrating oversight of a specific third party (i.e. contractor, grantee, etc.)

Specific examples: Agendas, presentation materials and other documentation generated during an internal or external zone-related meeting which documents any agreements or significant discussions. Includes meeting minutes or Q&A, attendance sheets and any pre-meeting material.



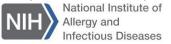
Vendor Oversight Documentation in the TMF

Zone 9 is not intended as the filing location for artifacts that are generated by a third party/vendor.

Relevant communications in this zone may include:

- 1. Documents that contain changes in processes for a vendor/ grantee
- 2. Documents about vendor/ grantee deviations
- 3. Documents from regulatory authorities pertaining to a vendor/ grantee

Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Sub-Artifact/Examples	Definition / Purpose
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.





Ongoing Oversight of Vendors

Vendor management oversight documented through the PC Oversight Memo and Checklist will be filed in Zone 9, "Ongoing Third Party Oversight"

Zone#	Zone Name		ection #	Section Name	Artifact#	Artifact name	Sub-Artifact/Examples	Definition / Purpose
▼	▼		▼.	▼	▼	Ţ	▼	▼
09	Third parties	0	9.01	Third Party Oversight	09.01.03	Ongoing Third Party Oversight	Ongoing Vendor Oversight, Oversight Memo, Oversight Checklist, Oversight Reports	To confirm throughout the duration of a study that a third party continues to meet all relevant criteria to fulfill a contractual obligation.

