

# Relevant Communications & Vendor Management

DAIDS TMF Team

NI/AID



National Institute of  
Allergy and  
Infectious Diseases

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# 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	Section #	Section Name	Artifact #	Artifact name	Sub-Artifact/Examples	Definition / Purpose
09	Third parties	09.01	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.