How to Manage Study Teams and CROs using TMF Metrics, Action Plans, and Escalations

Jason Weinstein, Head of TMF Operations, Regeneron

Meet the Speaker

Jason Weinstein

Title: Associate Director TMF, Head of TMF Operations

Organization: Regeneron

Jason is the Head of TMF Operations at Regeneron Pharmaceuticals. He has a decade of TMF experience that includes document migrations, regulatory inspections (FDA, PMDA, EMA), vendor oversight, TMF operations management, eTMF system management, and TMF health reporting. In his current role, Jason oversees document governance and processing, study team accountability and support, and the overall health of the TMF portfolio across Regeneron. Jason is also an active member of the CDISC TMF Reference Model.

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- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. TMF Health and Oversight
2. Action Tracking
3. Transparency and Escalations
4. Example Scenarios

TMF Health Metric

Oversight of TMF Health

What are your thresholds? Are they documented in your TMF Plan?

Who is providing monthly updates to the study team?

Who is ensuring non-compliance is corrected? Where are actions documented?

Notification of an issue is only half the battle!

Path to Improvement

- What is the root cause?
  - Ask the “5 why’s”
- Who is responsible to correct it?
  - When is it expected to be resolved. Who will confirm its done?
- What preventative measures can be added
  - Make sure you consider what training/process documents are impacted

- Captures:
  - When was the issue identified?
  - What is the issue?
  - Who is responsible to correct?
  - When is the issue expected to be corrected?

A well-maintained action log can give you insights on **resolution timelines** and **issue trends**

Sample TMF Non-Compliance Escalation Path

- Notify them of TMF issue with proposed CAPA
- Request support to prioritize TMF tasks
- Works with Senior Leadership and Vendor Management

Transparency is Critical!

- You can’t expect accountability if they don’t know what you want
  - The study TMF Plan is a great place to document metric thresholds
  - Details on calculations should also be made available
- Trust is earned. Expect to have your data validated by several of your stakeholders… multiple times
- Action logs need to be available for all stakeholders to view and update
- Action log is a two-way street
  - Actions should be assigned to the Sponsor also

Example Scenarios

What would you do in these situation?

Example Scenario 1

- Data Management quality metrics show a negative trend. They are providing many excel files to the TMF without clearly labeling the study. This is causing queries during QC.

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  - **Root Cause**: Templates missing defined header and training material missing instructions on what information is required for TMF filing.
  - **Corrective Action**: Train Data Management team on why a document header with a title and study info is critical.
  - **Preventative Action**: Update templates and training material to ensure headers are part of the standard process and clearly defined. Work with process and procedure team to ensure study information is part of the template approval process.

Example Scenario 2

- A CRO's upload timeliness shows a negative trend. Notification to Investigators of Safety Information make up over half of their late uploads.

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- **Root Cause**: CRO has a QC process for safety notifications. This process allowed for more time then our TMF upload requirements.
- **Corrective Action**: Perform reconciliation and ensure all recently created IALs are filed.
- **Preventative Action**: CRO process updated to align with TMF Filing expectations. Ask CRO to perform analysis to ensure other late documents are not caused by this same issue.

Example Scenario 3

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  - **Root Cause**: The site startup team was following an old process in which they waited to upload documents until the complete, and fully reviewed, packet was available.
  - **Corrective Action**: Identify the sites currently pending regulatory packet review. Ensure all missing documents are uploaded.
  - **Preventative Action**: Ensure the out-of-date process is retired and the site startup team is re-trained. Work with process and procedure team to refine retirement process.


THANK
YOU!