PERFORMING TMF QC OVERSIGHT: A Sponsor's Perspective

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MEET THE SPEAKER

Princess Barcelona-Martin

Title: **Senior Clinical Documentation Manager**

Organization: **Beacon Therapeutics**

With nearly 20 years of experience in the clinical research industry, Princess has successfully held various roles in Clinical Operations and TMF Services. Her background includes being a key team member on clinical trials across different phases and multiple therapeutic areas in the US and globally.

She has deep passion for TMF management, including Inspection Readiness, support, and oversight. Known for her strong organizational skills and attention to detail, she excels in leading teams and coordinating cross-functional activities. Currently, managing 3 program of studies within her organization, she leads TMF strategy, drives process improvements, ensures compliance, and supports cross-functional collaboration for successful outcomes.

Disclaimer and Disclosures

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

Agenda

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2. Governance & Roles
3. Vendor Oversight & Training
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5. QC Oversight in Action
6. Metrics & KPIs
7. Communication & Documentation
8. Audit Preparedness & Continuous Improvement
9. Key Takeaways
10. Q&A

Do you perform QC Oversight for your TMF Vendor?
Raise your hand ✋ if your team performs formal QC oversight of your TMF vendor activities.

Why TMF QC Oversight Matters?

From a Sponsor's perspective, Quality Control (QC) oversight of the Trial Master File (TMF) is critical to ensure inspection readiness, regulatory compliance, and alignment with ICH GCP and the TMF Reference Model. Effective TMF QC oversight goes beyond document review, it also ensures that vendors performing QC activities follow a standardized, compliant, and traceable process.

Helpful link:

ICH E6 Good clinical practice - Scientific guideline | European Medicines Agency (EMA)

Governance & Roles

- Effective TMF QC oversight begins with a well-defined governance framework.
- Sponsors must establish SOPs and oversight plans such as the TMF Management SOP and or within the TMF Plan to guide quality control activities.

These documents should outline:

- Vendor monitoring approach; how vendors will be monitored and evaluated.
- Oversight checks frequency; specify how often it will be conducted.
- Key roles and expectations; who is accountable for each aspect of TMF QC.
- Escalation pathways; how issues will be escalated and resolved.
- Define how the Sponsor will assess the quality, timeliness, and completeness of TMF QC activities
- How it applies to activities by both internal teams and external vendors

Vendor Oversight & Training

Scenario Example:

Vendor Qualification:	Onboarding & Training:	QC Tools:
Conduct thorough vendor qualification	Train vendors on Sponsor's SOPs	Checklists
Evaluate expertise in TMF QC and eTMF systems	Communicate filing expectations, SOW, SLAs	Trackers
Assess vendor's regulatory compliance and quality standards	Cover TMF Reference Model mappings	Metadata verification tools

Practical Method for QC Oversight:

1. eTMF System Functionality - QC Review Modules sponsors can utilize, monitor, and record findings
2. TMF Inventory Reports
3. QC Logs & Issues trackers
4. Spot checks & Independent Reviews

Escalation & Pathways

LEVEL 1: Immediate Resolution (Operational Team). TMF Specialist / QC Reviewer addresses minor issues (e.g., missing documents, misfiled artifacts, resolves based on SOPs, checklists, and training. Escalates if issue is systemic, recurring, or unresolved.

LEVEL 2: Functional Oversight (TMF Lead / Manager). Reviews repeated or higher-risk issues. Coordinates with Study Teams, QA, and Vendors. Initiates corrective actions, updates processes or tools. Documents decisions and actions taken.

LEVEL 3: Executive / Quality Oversight Involves QA, Contracts team, or Governance Committees. Triggers Root Cause Analysis (RCA) and CAPAs. Escalates to leadership if impacting inspection readiness or GCP compliance. May lead to SOP revisions or formal vendor reviews.

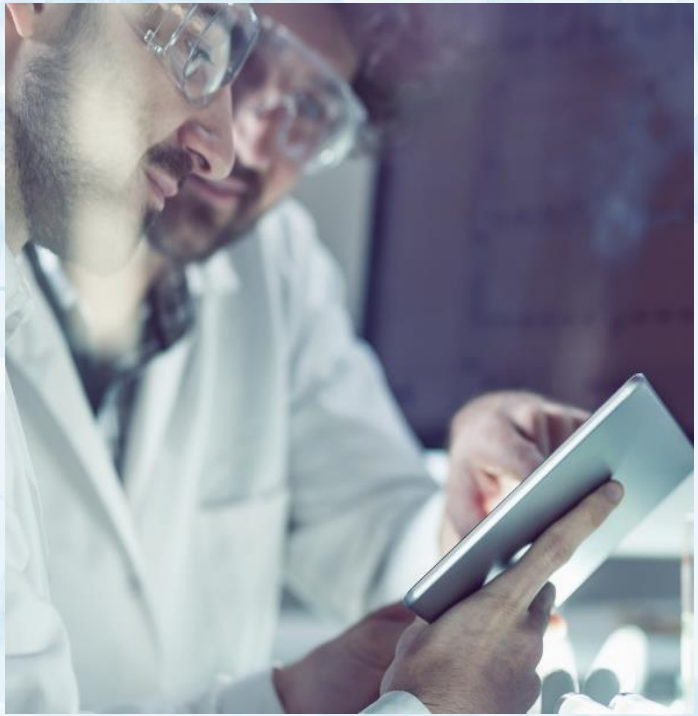
LEVEL 1: IMMEDIATE RESOLUTION **WHO: TMF SPECIALIST / QC REVIEWER**	**LEVEL 2: FUNCTIONAL OVERSIGHT** **WHO: TMF LEAD / MANAGER**	**LEVEL 3: EXECUTIVE / QUALITY OVERSIGHT** **WHO: QA, Contracts Team, GOVERNANCE**
Action: • Handles minor issues • Follows SOPs/checklists • Escalates unresolved/systemic issues	Action: • Investigates recurring/high-risk issues • Coordinates with study team or vendor • Initiates corrective actions / Action Plan	Action: • Conducts Root Cause Analysis • Implements CAPAs • Revises SOPs or triggers vendor audit or change in frequency

QC Oversight in Action

The Sponsor is responsible for ensuring that TMF QC activities are conducted in alignment with agreed standards and expectations.

Key responsibilities include:

- Regular Review of QC Trackers and Logs
- Monitoring the types and frequency of QC findings to identify trends and areas for improvement
- Verifying that QC reviews are being performed within agreed timelines
- Ensuring document issues are logged, categorized, and resolved appropriately

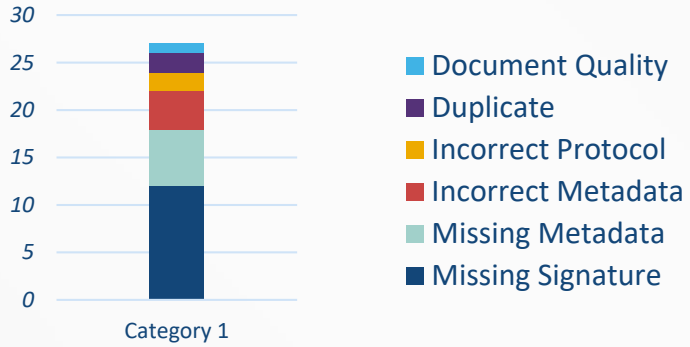


Metrics & KPIs

- Sponsors should be aware of the vendor's acceptable QC rate as defined in their SOP (e.g., 95%).
- In addition, Sponsors should define and routinely monitor TMF QC-specific metrics, including:
  - % of documents passing QC on first review
  - % of documents requiring rework
  - Time from document upload to QC completion
  - Most common QC errors (e.g., incorrect metadata, missing signatures, etc.)
  - Volume of QC'ed documents vs. total TMF content
  - Trends by team or individual reviewer

  These metrics should be reviewed regularly and discussed during TMF team calls and governance meetings. Recurring issues or negative trends should prompt additional QC reviews, preventive actions, or retraining efforts.

BAR CHART EXAMPLE FOR SOME QC FINDINGS:

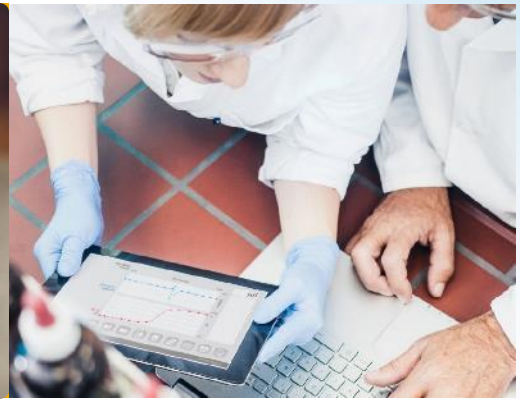


Communication & Documentation

Consistent communication between the Sponsor and the vendor is essential for effective oversight.

Sponsors should:

- Hold routine touchpoints (weekly or bi-weekly) to discuss QC progress, address questions, system issues, resolution status, and escalate concerns
- Ensure QC issues are tracked to closure, documented in CAPA logs when needed, and followed up to prevent recurrence
- Maintain proper records of decisions and training activities to support traceability and compliance



Audit Preparedness & Continuous Improvement

Sponsors must maintain a documented trail of all TMF QC oversight activities, including review logs, QC trackers and reports, and meeting minutes. This documentation supports both regulatory inspections and internal audits. When gaps or inefficiencies are identified, Sponsors should conduct root cause analyses and implement corrective actions to strengthen the QC process, with vendor support if needed.

Additionally, Sponsors are expected to perform vendor audits and adjust audit frequency based on performance and risk.

Key Takeaways

- TMF QC oversight is a core Sponsor responsibility that ensures the quality and compliance of clinical trial documentation. Structured oversight, meaningful metrics, and strong vendor collaboration drive TMF quality and support successful audits and inspections.
- QC oversight approach must be structured, proactive, data-driven, and reactive to have a balanced and robust QC oversight.
- Governance, training, metrics, and communication are foundational to effective TMF QC oversight.
- Inspection readiness is a continuous improvement process, not a one-time activity.
- Sponsors are ultimately accountable for the quality, timeliness and completeness of the Trial Master File.

Thank You!