2025 CDISC + TMF US INTERCHANGE — NASHVILLE

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Blueprint for a Successful TMF Rescue

Presented by Katie Hoover, Founder, Vital GxP Consulting

Meet the Speaker

Katie Hoover

Title: Founder

Organization: Vital GxP Consulting

Katie Hoover, Founder of Vital GxP Consulting, specializes in computerized systems compliance, data integrity, and TMF operations strategy. She enhances existing quality systems through fit-for-purpose digital solutions and streamlined workflows. Katie is known for translating regulatory expectations into practical, actionable frameworks that work in the real world.

Based in Portland, Oregon, Katie partners globally to advance modern, pragmatic quality systems across the biotech landscape. She helps organizations build processes that are scalable, compliant, and ready for inspection.
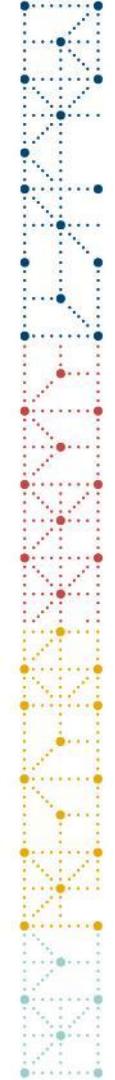
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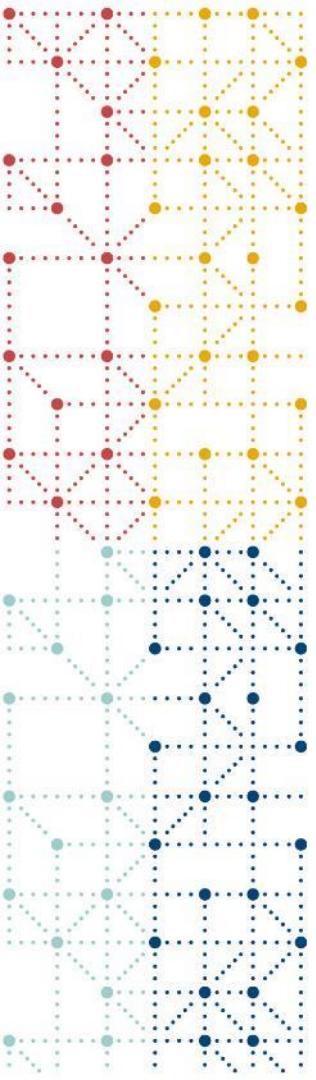
Agenda

1) When You Know, You Know
2) Discover
3) Escalate
4) Gap Analysis & Risk Assessment
5) Stakeholder Agreement
6) Execution and Remediation
7) Governance and Prevention Planning

When You Know, You Know

- It's an unforgettable feeling.
- That sinking feeling the moment you realize your Trial Master File is disorganized, incomplete, or non-compliant and it needs a rescue.
- Don't panic. There's a way forward.

How Did We Get Here?

Misaligned Expectations

Sponsors and CROs don't share the same understanding of TMF requirements or quality standards.

Vendor Underperformance

A vendor fails to deliver on their TMF management responsibilities, often due to a lack of resources or expertise.

Oversight Breakdowns

The sponsor's oversight process is not robust enough to catch issues before they become critical.

The High Stakes of a Failing TMF

COMPLIANCE RISKS

Failed Inspections and regulatory findings

TIMELINE DELAYS

Study milestones are missed, delaying submission

BUDGET OVERRUNS

Unexpected costs from remediation efforts

LOST TRUST

Erosion of confidence between sponsors, CRO, and sites.

TMF Oversight Red Flags

➢ Sponsor doesn't have access to the primary eTMF system

➢ Dashboards and reports always say 99% compliant

➢ No one is talking about the TMF

➢ Records are illegible, duplicate, or missing

➢ No audit trails or no audit trail review

➢ Alternate filing locations are unknown

➢ Study Team functional groups think only ClinOps is responsible for TMF
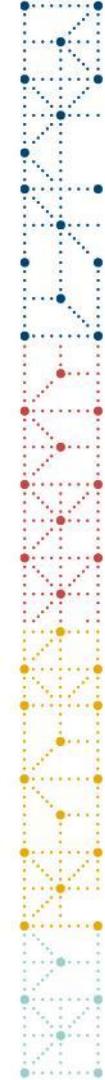
Red Flags & Powerful Remediation Steps

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- Obtain/provide access or escalate, immediately

- Review metrics calculation and cross check with a manual review

- Add meaningful TMF topics to study team meetings, e.g., issues identified in the latest review

- Start reviewing the audit trail - check training, access, deletions, system changes

- Identify & document repositories

- Add responsibility to TMF Index

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A Clear Escalation Pathway

Study Team Leads often know when their TMF is not compliant, they've seen and recognize the red flags…

But hit
a brick wall
when escalating
issues

- Prioritize TMF Oversight, even when resources are lean

- Perform first TMF Periodic or Oversight review 30 days after the first patient is dosed, if not before.

- Document the escalation path for issues related to quality, completeness, timeliness, and system enhancements.
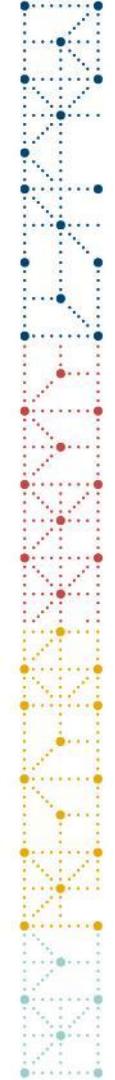
How to Escalate Effectively

1

Be factual,
not emotional

2

Present clear
data on the
initial findings

3

Quantify the
potential risk
to the trial

4

Propose an
effective next
step
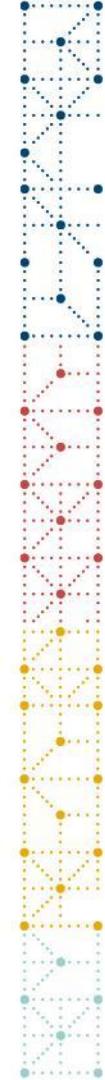
Mid-study Rescue

Mid-study intervention > End-of-study chaos

It's not you. It's both of you!

You *can* take control now—even if you fumbled early

Levels of Rescue

1. Ad-hoc review and remediation for cause

2. Remediation and regular progress meetings

3. Escalation to governance

4. Change in contractual agreements

5. Hiring a different TMF Management Team

6. Moving the TMF out of the current location/system into a compliant system

Stakeholder Agreements

Building the Rescue Team and Defining the Mission

A rescue mission fails without a clear plan that everyone agrees on. This phase is about defining the 'rules of engagement' for the entire remediation project.

The TMF Rescue Charter – Quality Plan

Your project should be formalized in a simple charter that defines:

Scope: What is in-scope vs. out-of-scope for the rescue?

Goals: What specific completeness and quality targets are we aiming for?

Timeline & Milestones: What are the key deadlines for the project?

Resources: Who is on the rescue team and what is the budget?

Quality Criteria: What does 'done' and 'high quality' actually look like?

Communication Plan: How and when we will report progress?
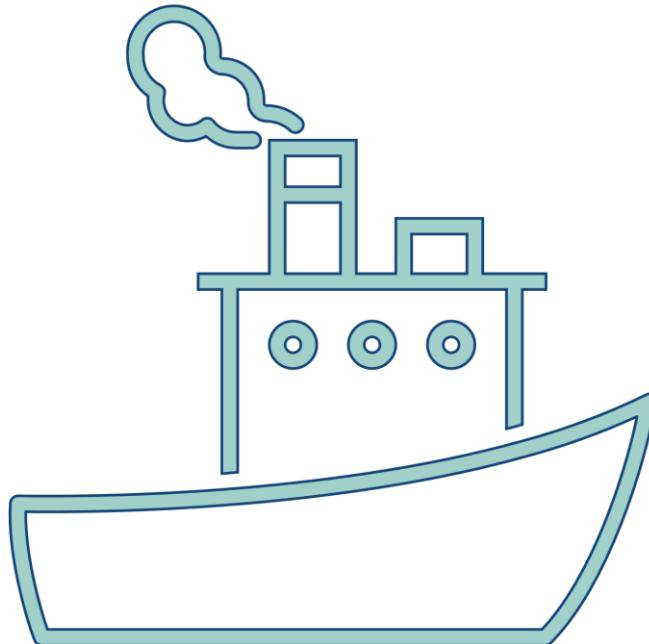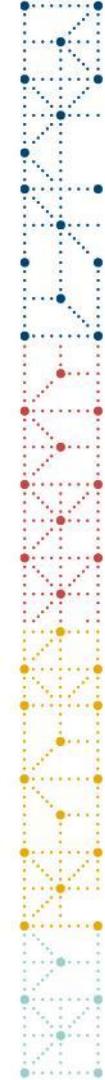
The Human Factor: Rescuing more than TMF

A TMF rescue is a high-stress project. Managing the people is as important as managing the records.

- Common Challenges

  - Team Fatigue & Burnout: Rescues are intense sprints

  - Broken Trust: Sponsors may have lost faith in the CRO.

  - Blame Culture: Teams may point fingers instead of solving problems.

- Critical Solutions

  - Over-Communicate: Provide constant, transparent updates.

  - Celebrate Small Wins: Acknowledge progress to boost morale.

  - Rebuild Trust: Focus on partnership and shared goals

Key Take Aways

Thank You!