Don’t Fear the Audit Trail: It’s Your TMF’s Insightful BFF

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Meet the Speaker

Lori Braun

Title: TMF Consultant

Organization: working with Mulcahy Consulting

Lori Braun is a TMF Specialist with over six years of experience supporting the biopharmaceutical industry. She specializes in optimizing Trial Master File (TMF) processes and implementing eTMF systems including Trial Interactive, PhlexTMF, and Veeva Vault. Her work bridges project management, quality oversight, and system administration, with a focus on compliance, operational efficiency, and inspection readiness.

Disclaimer and Disclosures

- *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.*

- *The author has no real or apparent conflicts of interest to report.*

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3. How can an Audit Trail be your BFF
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Introduction

Audit trails in the electronic Trial Master File (eTMF) are often regarded as a compliance necessity—a way to demonstrate that documents followed the proper workflow. In practice, they offer far more: visibility into how the system is used, insight into team behaviors, and opportunities to strengthen processes.

Why Audit Trails Matter

- Demonstrate compliance and workflow integrity
- Provide real-time visibility into system use
- Highlight process inefficiencies and risks
- Support proactive inspection readiness

How can an Audit Trail be your BFF (Best Friend Forever)

It Always Has Your Back

Just like a best friend, your audit trail **defends you when it counts most**.
During inspections or audits, it's your strongest ally — proving who did what, when, and why.
It never forgets, it never lies, and it's always there to back up your story.

It Keeps You Honest

A BFF keeps you grounded — and so does your audit trail.
It reminds you to follow **ALCOA++ principles** and good documentation practices.
No shortcuts, no mystery edits — just transparency and accountability.

It Helps You See the Bigger Picture

Reveals process trends and workflow bottlenecks.
Tells the story behind every document action.
Helps identify opportunities for improvement.
When you read between the timestamps, it tells the story of your TMF.

It's Loyal, Even When You're Not Perfect

Records both successes and missteps.
Demonstrates accountability and CAPA follow-through.
Shows regulators that transparency > perfection.
Your audit trail proves you learn and adapt — not hide and deny.

It Helps You Shine During Inspections

Provides fast, defensible answers to auditor questions.
Builds trust through evidence-based responses.
Turns inspection panic into calm confidence.
"Yes, we can show you that — here's the audit trail."

Content of this slide developed with assistance from ChatGPT (OpenAI, 2025).

Regulatory Context: EMA 2023 Guidance

- Secure, time-stamped audit logs are required
- Regular review of access and activity records encouraged
- Focus is on reliability of data and the correct use of systems
- Emphasis on proactive issue detection, not just retrospective review

The Two Key Types of Audit Trails

AD-HOC

IN-STREAM

Ad-hoc Audit Trails (Proactive)

- Pulled manually to address specific questions or anomalies
- Best for targeted quality checks and investigations

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Ad-hoc Audit Trails in Practice

- **Investigate anomalies (e.g., delayed approvals)**
- **Validate specific workflows**
- **Support targeted training and corrective action**

In-stream Audit Trails (Retrospective – Compliance)

- Captured automatically during user activity
- Provide ongoing, background insights into workflows and user behavior

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In-stream Audit Trails in Practice

- **Reveal usage patterns and workflow bottlenecks**
- **Track recurring errors or rework trends**
- **Enable continuous monitoring without extra effort**

Compliance Based Review (Common Practice)

- Periodic User Audit Trail Review
- Periodic Document Audit Trail Review

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User Audit Trail Review

- Reviewed against the user access management log
- Check user log in activity

Document Audit Trail Review

- Identifies who, what, and when regarding the record
- Security of record – data integrity

Moving Beyond Compliance

- Audit trails should answer not only what happened but also how and why
- They can be used as operational tools to improve system use
- Early detection and resolution prevent issues from escalating
- Foster stronger team engagement with the eTMF
- Ensure record security and user access

Example – Clinical Monitoring Plan

Early detection and resolution prevent issues from escalating
Foster stronger team engagement with the eTMF

- **Why? If CRAs are not collecting and uploading the correct documents.**
  - *Ad-hoc Audit Trail – export the Audit Trail for the most current version of the Clinical Monitoring Plan*

What to look for

- **Who accessed the record?**
- **How did they access the record? View only or export?**

How does this help?

- **Shows if retraining of the CMP is needed to ensure the correct records are collected and uploaded**
- **It will show that the team the importance of using the eTMF**

Example – Protocol

Audit trails should answer not only what happened but also how and why
They can be used as operational tools to improve system use
Foster stronger team engagement with the eTMF

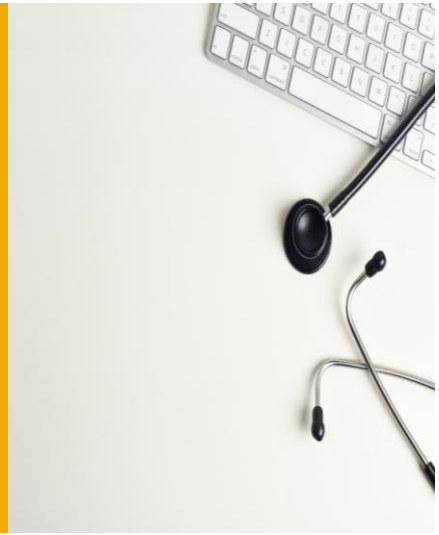
- **Why? Check to see if eTMF is Authoritative Source**
- *Ad-hoc Audit Trail – export the Audit Trail for the word version of the Protocol*

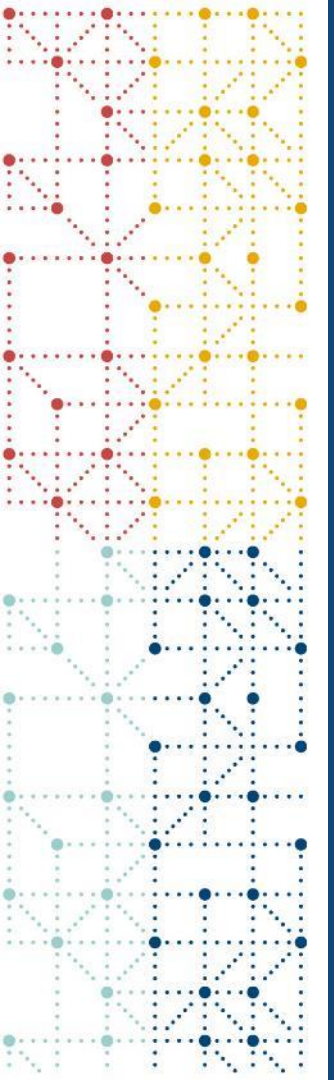
What to look for

- **Who accessed the record?**
- **How did they access the record? View only or export?**

How does this help?

- **During revision of a Protocol, it shows if the protocol is being stored elsewhere or if the eTMF is the Authoritative source**
- **It will show that the team the importance of using the eTMF**





Practical Strategies

- Regular trend analysis of in-stream data
- Targeted use of ad-hoc reviews for training needs
- Integrate audit insights into continuous improvement cycles

Benefits of a Proactive Approach

It Helps You Shine During Inspections

Provides fast, defensible answers to auditor questions.
Builds trust through evidence-based responses.
Turns inspection panic into calm confidence.
“Yes, we can show you that — here’s the audit trail.”

- Early issue detection
- Improved documentation quality
- Stronger inspection readiness
- More confident, empowered teams
- Alignment with regulatory expectations

Key Takeaway

Audit trails are more than compliance trails; they are your insightful **bff**.

- **They drive visibility**
- **Enable continuous improvement**
- **Help you understand and optimize how your eTMF is used**

Your Audit Trail – The Ultimate Best Friend in Findings

- **Protects you**
- **Reminds you**
- **Teaches you**
- **Defends you**
- **It's not just metadata – it's your TMF's memory and your compliance safety net**

Thank You! Any questions?