



Presented by

Janine Penman
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Bringing TMF Management In-House

The Year of the Sponsor eTMF

The logo for Montrium, featuring the word 'montrium' in a lowercase, teal-colored, sans-serif font.

Housekeeping

- This session will be recorded and made available to all registrants
- All recordings will be available on demand via a link sent following each event
- The Certificate of Attendance will be provided at the conclusion of the eTMF Bootcamp series
- Registrants must attend at least 1 eTMF Bootcamp session to receive the certificate

Other Bootcamp Sessions



eTMF
BOOTCAMP
FROM TMF NOVICE TO EXPERT

Session 6

Stephanie Viscomi,
Associate Director,
TMF Operations, Alexion

Paul Fenton,
President & CEO,
Montrium

**How to Manage a
Multi-Vendor
eTMF Ecosystem
Effectively.**

March 4th @ 10am EST
(7am PST / 4pm CET)



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TMMF

WEEK

JUNE 14TH - 18TH

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Your speakers today



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Agenda

- Current issues with outsourcing TMF management
- Common Myths about Outsourcing TMF Management
- Solutions for TMF Harmonization in Outsourcing

Polling Question

What comprises the TMF in your organization?

- a. Single electronic TMF system
- b. Multiple systems that feed into a TMF system
- c. File cabinets (we still use paper - no judgement)
- d. Multiple sources: electronic system(s) + other sources of information
- e. Unsure - The CRO handles it

Section 1

Issues with Outsourcing TMF Management

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The Known Issues with Sponsor/CRO Shared eTMF

1. Lack of Sponsor Oversight
2. Remediation Over Readiness
3. Redundant Maintenance

Polling Question

What has stopped your organization from implementing an eTMF in-house?

1. Not enough time to implement processes & systems
2. No inhouse personnel with TMF management knowledge
3. Not enough budget to fund system & change
4. Our CRO takes care of everything

What has stopped us from bringing TMF Management in-house?

1. So Much to Do... So Little Time
 - Not enough time to implement appropriate process and systems
2. Lack of TMF Resources
 - No inhouse personnel with TMF management knowledge
3. Expensive!
 - Building a TMF community of practice takes resources and funds
4. Not my problem....
 - Sponsors traditionally push the responsibility to CROs

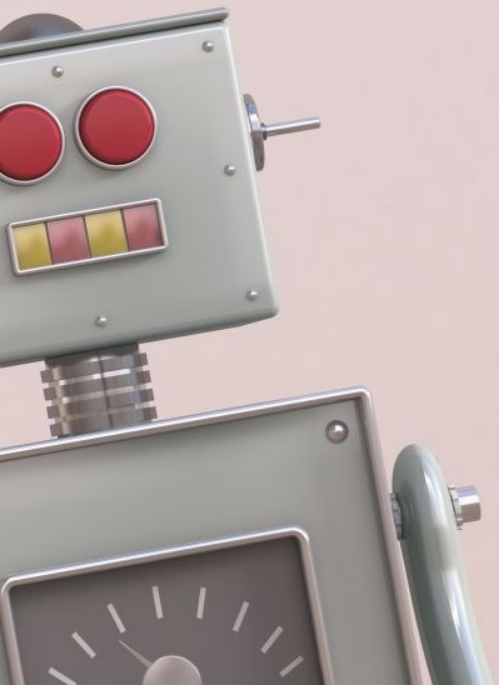
Ease the Burden - Put it on Autopilot

MYTH: Brining the TMF inhouse will burden us with additional work that my team can't handle

- More Responsibility = More Work = More Burden

FACT: Brining your TMF inhouse can decrease your resource allocation if implemented correctly

- A properly designed TMF system will largely manage itself through the right pairing of technology and process



Top 5 Reasons you *should* bring TMF Management inhouse

5. Reduction of the dreaded end-of-study cleaning process
4. Enable oversight ... and clearly demonstrate oversight
3. More control over ensuring continuous quality
2. Data readily available to enable better program decisions

And the Number One Reason to bring your TMF inhouse....

1. TMF is a Sponsor Responsibility

Section 2

TMF: A Sponsor Responsibility

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The TMF is a Sponsor Responsibility

- TMF: NOT just a juggernaut of documents
- TMF: Primary source of information for an inspector
- TMF: Your Responsibility
 - Although it may be shared with the CRO, the TMF is ultimately the Sponsors responsibility

Sponsor Responsibility: TMF Quality Risk Management

What does TMF have to do with Quality Risk Management?

- TMF demonstrates the history of decision making = shows the level of vigilance applied to the study to support ICH and GCP
- TMF is the repository for essential documents that demonstrate regulatory compliance

R(3) Put the “P” in Perpetual Inspection Readiness

- Updated process will be necessary for most organizations to comply with R(3)

The TMF that is PIR is QRM-ready

- In other words → De-risked
- Quality risk is continuously managed and documented

Existing in a state of PIR requires **Sponsors** to maintain consistent and adequate oversight of the TMF

Polling Question

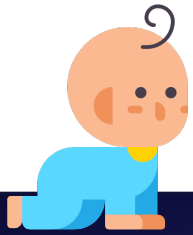
Who is assigned to manage the TMF in your organization?

- Dedicated clinical operations resource(s)
- Dedicated business operations or non-clinical resource(s)
- Anyone with a free hand
- No one
- CRO's problem

The Solution

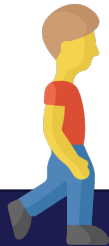
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Stages of Sponsor eTMF Maturity – Crawl, Walk, Run...SPRINT



Archive

“I’m implementing a system to store completed TMFs at the end of the study”



Shadow

“I’m using an eTMF to develop sponsor documentation, but my CRO still manages their own TMF”



Centralized

“My TMF is centralized in one eTMF at the sponsor and my CRO works in that system”



Integrated

“My eTMF is integrated with my stakeholders system to fully integrate process and users”

eTMF
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 FROM TMF NOVICE TO EXPERT

Polling Question

What stage of TMF maturity do you think your organization is in?

- Archive
- Shadow
- Centralized
- Integrated

Let your system work for you

- A well-designed System + Agile Process = Decreased Workload Burden
- But what is a well-designed system? And what are agile processes?

What impacts do Sponsor TMFs have on CROs?

- A better educated sponsor team, is good for the partnership
- Shares the burden of TMF management across stakeholders
- Better alignment and involvement by the sponsor
- Clear guidelines for TMF throughout the study

Summary

- There are known issues in TMF management, but they aren't impossible to overcome
- There are some common misconceptions that easily combatted
- TMF is ultimately a sponsor responsibility, so putting steps in place to get started now
- TMF is a major component of quality risk management
- Walk before you run!



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Get in touch

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