Redefining TMF Excellence: Embedding Quality by Design Through QMS Integration

Presented by Donatella Ballerini, Head of eTMF Services, Montrium

Meet the Speaker

Donatella Ballerini

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Organization: Montrium

With 17 years of experience in the pharma industry, Donatella Ballerini first gained expertise at Chiesi Farmaceutici in the Global Clinical Development department, focusing on clinical studies in Rare Disease and Neonatology. Later, in Global Rare Disease, Donatella served as a Document and Training Manager, where she developed and implemented documentation management processes, leading the transition from paper to eTMF. In 2020, she became the Head of the GCP Compliance and Clinical Trial Administration Unit at Chiesi, ensuring all clinical operations processes complied with ICH-GCP standards and maintained inspection readiness. In 2021, she joined Montrium as the Head of eTMF Services, where she helps pharmaceutical companies in eTMF implementation and process improvement, and works as an independent GCP consultant. Member of the CDISC TMF RM Education Governance Committee and the CDISC Risk White Paper Initiative.

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What Is Quality?

"Quality is never an accident. It is always the result of high **intention**, sincere **effort**, **intelligent direction**, and skillful **execution**."

William A. Foster

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The Importance of Quality in Clinical Trials

Ensures Patient Safety – Quality management prevents protocol deviations, ensures proper monitoring, and reduces risks, ultimately protecting trial participants from harm.

Maintains Data Integrity – High-quality processes ensure that clinical trial data is accurate, reliable, and reproducible, supporting valid study conclusions and regulatory approvals.

Facilitates Regulatory Compliance – Adhering to quality standards reduces the risk of findings during inspections and ensures the acceptability of trial results.

Enhances Operational Efficiency – A strong quality framework minimizes errors, rework, and delays, enabling smoother trial execution and faster decision-making.

Quality from the Start

Proactive approach

Prevent findings and issues to fix them faster. Analyse data and trends.

Process for detection

Assess processes to minimize errors and future problems, being able to identify gaps for improvement.

Quality to reduce risk

Build quality in and build risk out. Risk can be identified and assessed before escalation.

Reduce effort

Identify critical to quality not to reduce effort, but rather to focus only on what really matters.

Error-proof processes

Error-proof processes. Clinical trials are too complicated and unpredictable to anticipate everything.

Reactive approach

Find and fix issues after the fact with a reactive approach. Waiting for the risk to become a real issue.

Processes (SOPs) for Quality

IMPROVED CONSISTENCY AND QUALITY

Operating procedures ensure tasks are performed the same way every time, leading to consistent product or service quality and **documentation**.

ENHANCED TRAINING AND ONBOARDING

SOPs provide a standardized training tool for new employees, facilitating faster onboarding and reducing training costs. Handovers are quick and well supported.

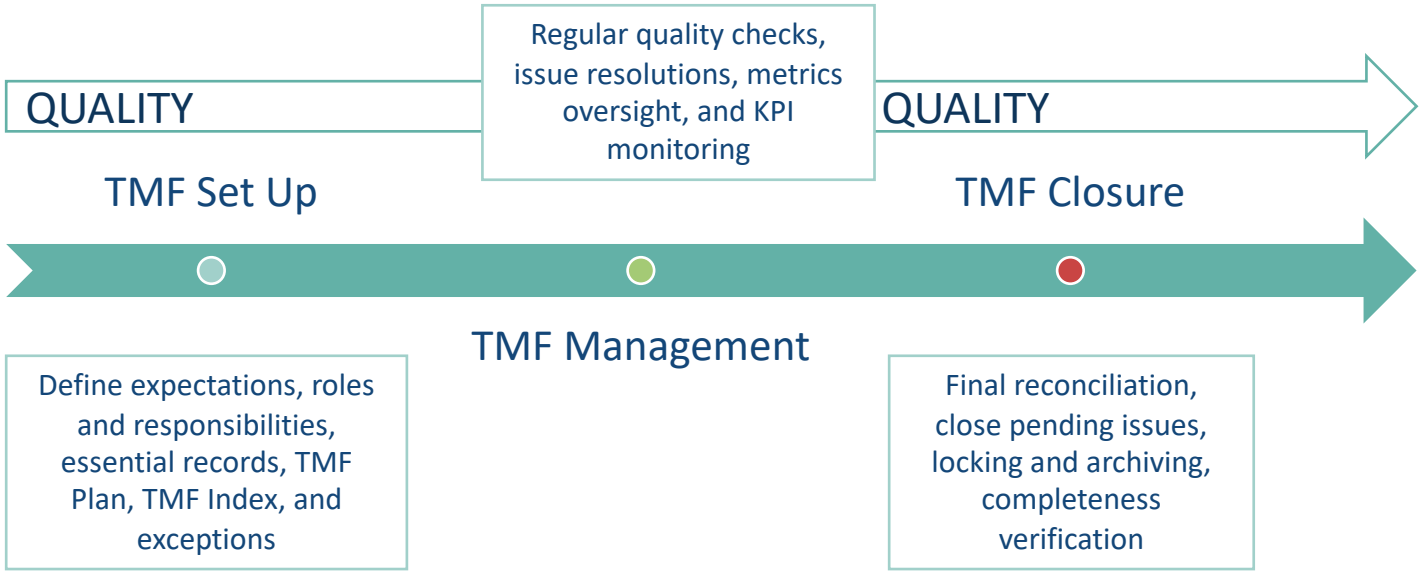
IMPROVED RISK MANAGEMENT

SOPs outline responsibilities and tasks to minimize errors and risks. Risks are assessed from the very beginning and mitigation actions are put in place.

INCREASED EFFICIENCY

Streamlined processes and reduced waste of time and resources contribute to higher overall efficiency.

TMF and Quality: A Lifecycle Approach



Trial Evidence

If QbD principles ensure that every trial process generates high-quality evidence, the TMF should be structured to capture and manage that evidence seamlessly.

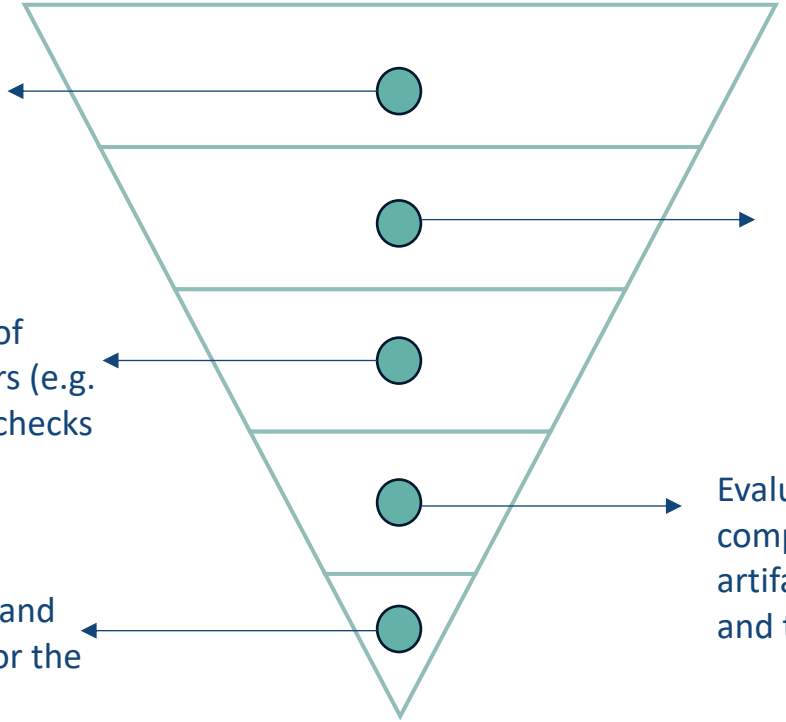
If the TMF documents tell the “story” of a clinical trial, it should also reflect the processes that shape that story.

Where QMS Meets TMF: SOP

Which artifacts are required as **evidence** of quality for a company SOP

Provide **parameters** around required artifacts (evidence of quality) and other parameters (e.g. timeliness) as inputs to edit checks

Manage study-specific SOPs and assign them to **list of SOPs** for the study 01.01.04



Configure clinical **process model** based on artifacts required so that placeholders are generated when a specific process is triggered (quality by design)

Evaluate **compliance** to company processes based on artifacts present and their metadata

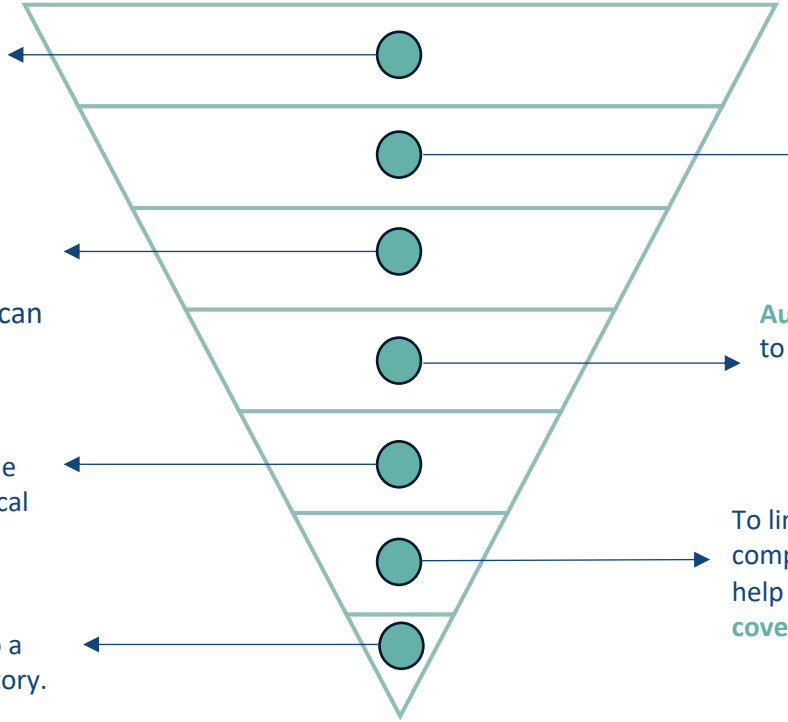
Where QMS Meets TMF

Define **study-specific training matrix** per study team role. Provide access to training records and reports.

Any **SOP deviations or GCP non-compliance** related to the study can be connected to records.

When notified of an **inspection**, the preparation process starts. Historical data, lessons learnt.

Track the **change control** history to a study eTMF to better explain the story.

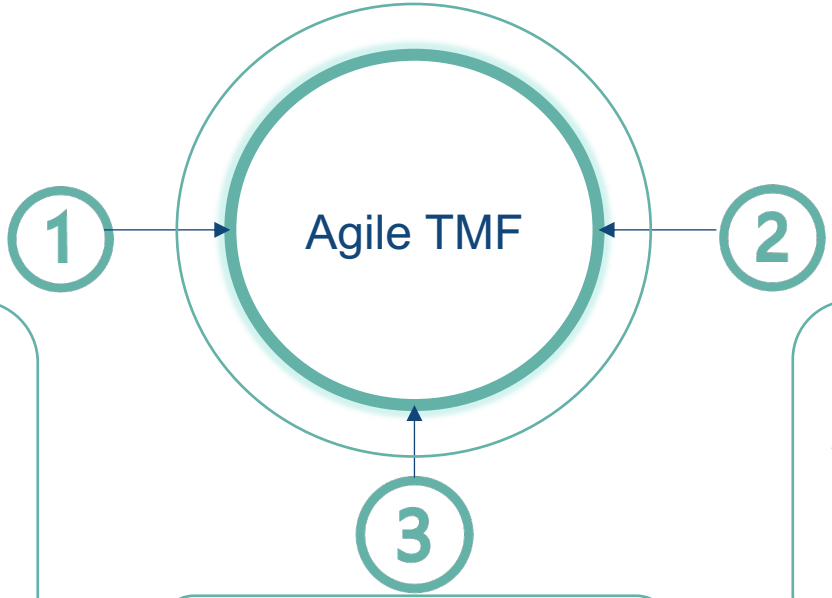


Very often the evidence of a **corrective/preventive action** is linked to a document that has to be filed in the study eTMF as well.

Audit planning using risk score: Which site to audit? What to audit in the TMF?

To link artifacts within the eTMF with company SOPs kept in the QMS can also help to identify which **processes are not covered** by an SOP.

Transforming TMF into a Dynamic System

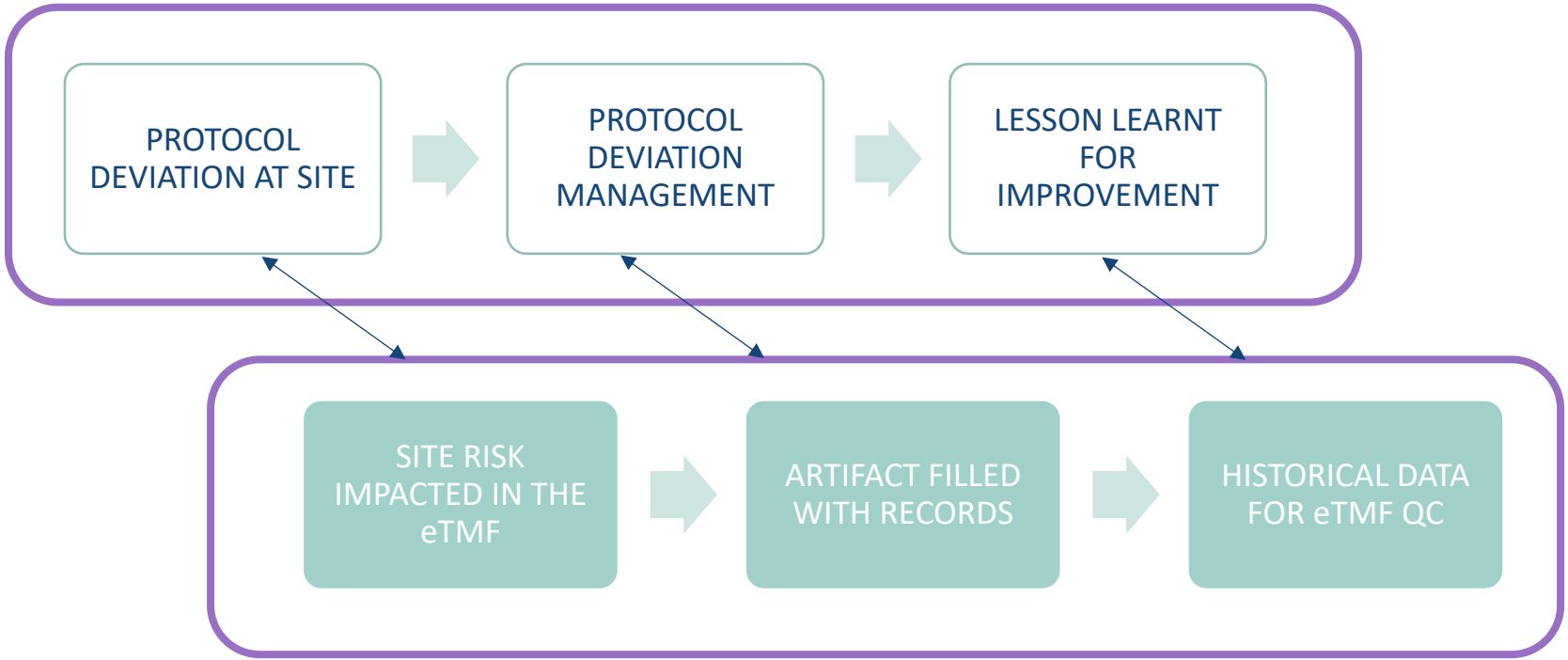


QMS and eTMF
Create seamless data flow between both systems for faster reaction and process improvement. Easier and faster process assessment and compliance verification.

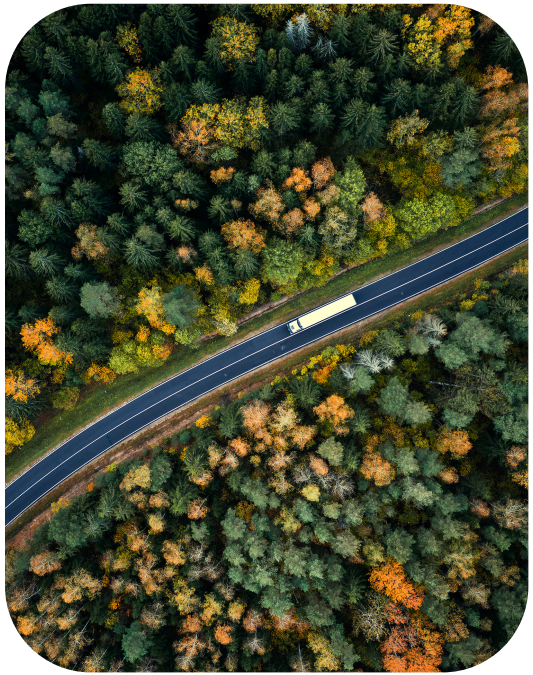
Develop and implement active TMF strategies
Anticipates risks and ensures timely documentation updates. Define more effective TMF QCs based on quality data.

Real-time monitoring
Real-time data and events to perform ongoing oversight and monitoring on compliance, quality, and study KPIs.

Establishing Predictive Quality Systems



The Current Landscape



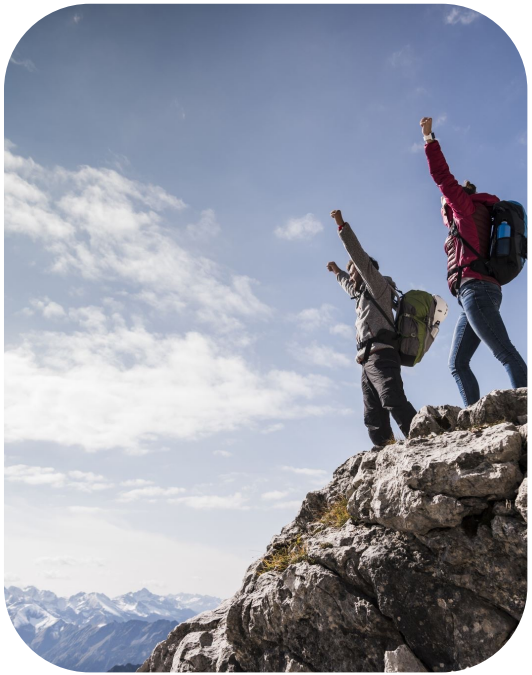
Increased Risks: Deviations, CAPAs, and findings may not be linked to essential trial records in real time, leading to gaps that could impact compliance.

Lack of Real-time Oversight: Stakeholders lack real-time visibility into quality events affecting trial processes and documentation.

Fragmented Risk Management Approach: Without an integrated system to tackle risks as they emerge, organizations struggle to implement proactive strategies.

Inefficient Manual Processes: Clinical teams must manually reconcile documents and track quality-related information across multiple systems.

Benefits of the integration



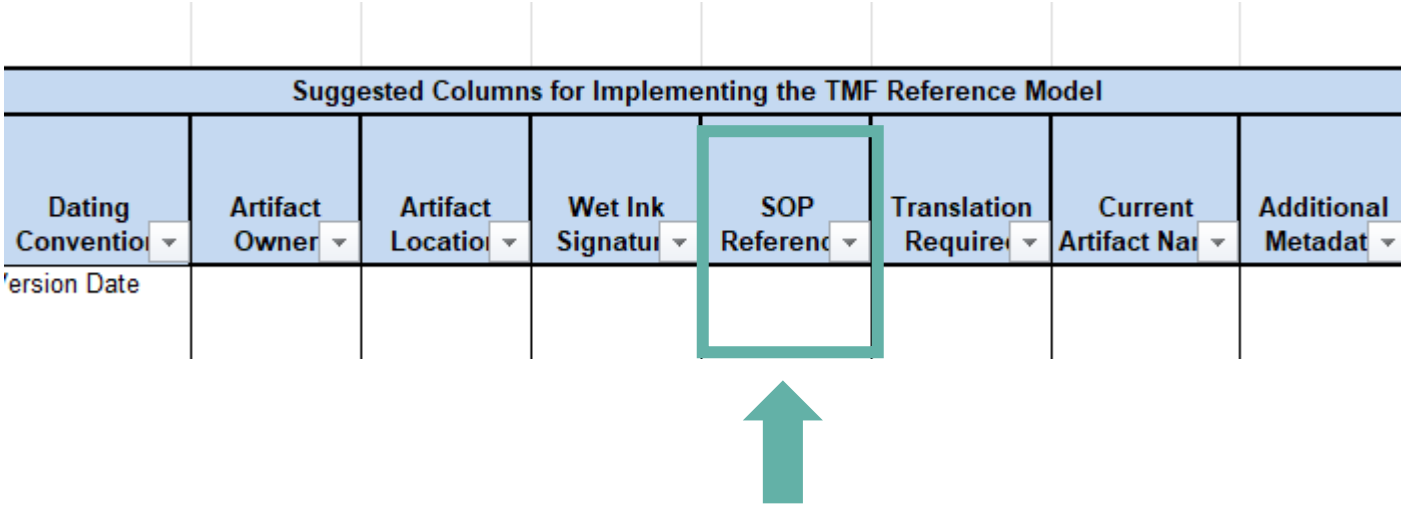
Inspection Readiness: The TMF evolves into a living system, always complete, accurate, and ready for regulatory scrutiny.

Operational Efficiency: Integration eliminates redundancies and reduces manual oversight, enabling study teams to focus on critical activities.

Proactive Compliance: By addressing risks early, organizations foster a culture of continuous improvement, minimizing audit findings and non-compliance.

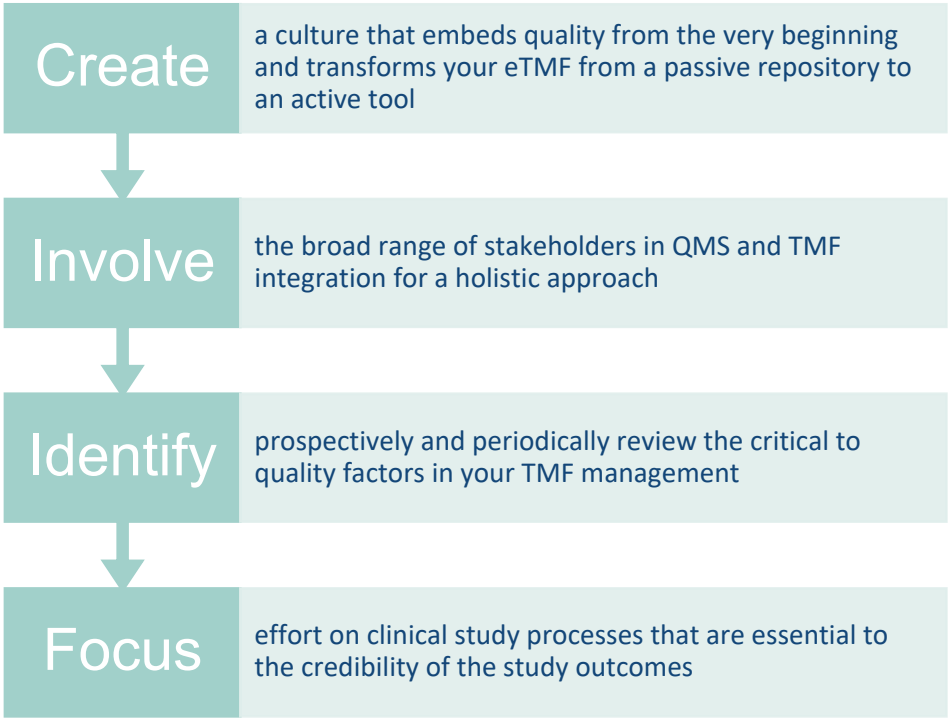
Manual Integration

- Processes are described in an SOP
- SOPs are managed through QMS
- Adaptation column in the TMF RM for SOP Reference



The Future of Integration

QbD Isn’t Just a Methodology—It’s a Mindset



Thank You!

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