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The Interoperability Advantage: Streamline Your Clinical Trials with TMF Automation

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Jason Methia, VP of Vault Clinical Operations Strategy, Veeva Systems

Meet the Speakers



David Ives

Head, Clinical Document
Management Process

Novartis



Jason Methia

VP, Vault Clinical
Operations Strategy

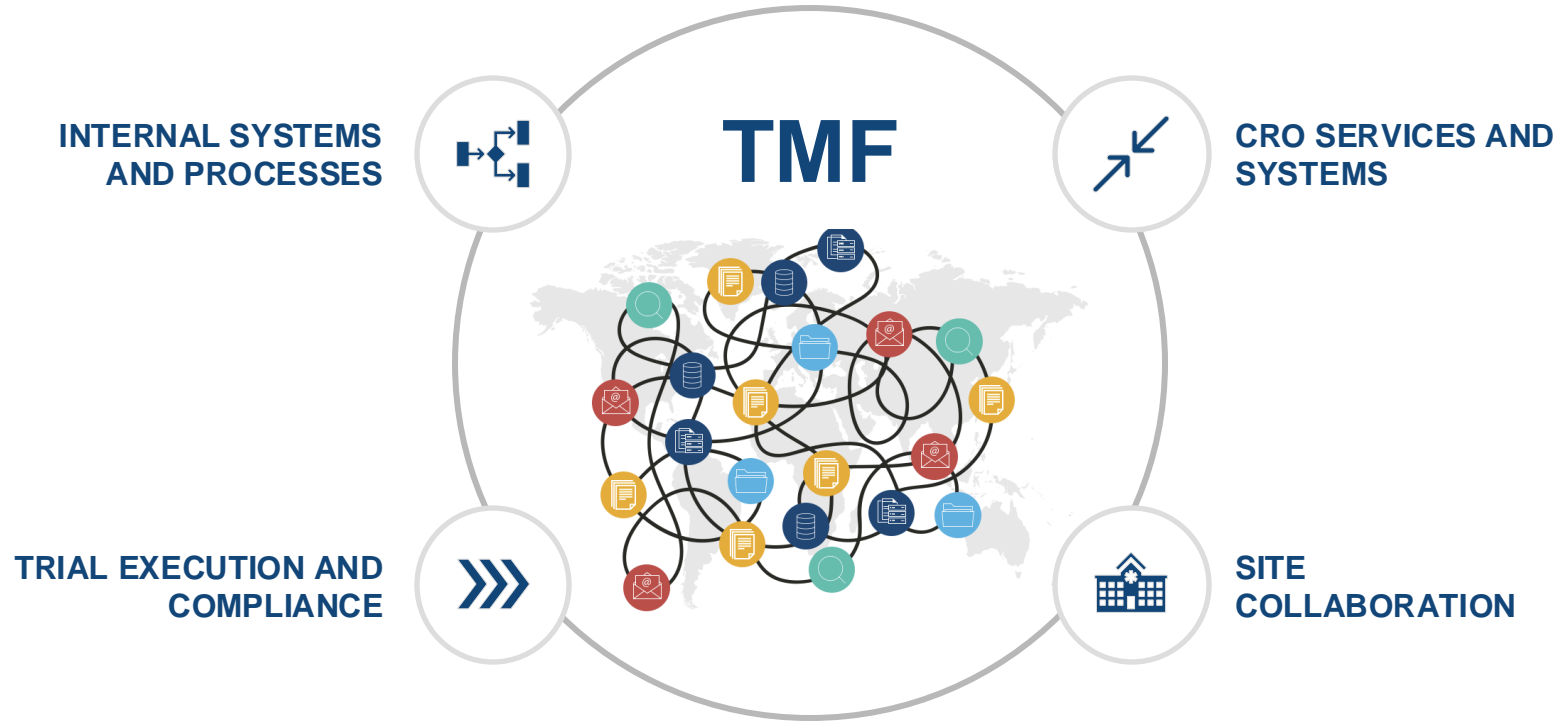
Veeva Systems



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Reduce Friction to Improve Data Access and Automation



Friction in Data and Document Flow



Immense amount of
trapped and untapped
data



People must overcome
friction to unlock data
value

Friction leads to...

**Time-consuming
processes**

**Uncertainty in
data integrity**

Delays

Optimizing for Connectivity





Novartis Case Study

How Novartis Approaches
Interoperability

Operating Environment: By the Numbers

3

eTMF systems:
Centralizing on one

2

Primary CROs

900

Active studies

7,000

Initiated sites

Outsource: Early research

Insource: Late-phase studies

Why We're Focused on Interoperability



Establish TMF
as the central hub



Demonstrate value with
stakeholders and partners
via interoperability

Novartis' Interoperability Methodology



Fully Understanding the Ecosystem Is Key



Start internally across functions

Understanding your core operating model allows the foundation to build upon



Expand to areas of exception

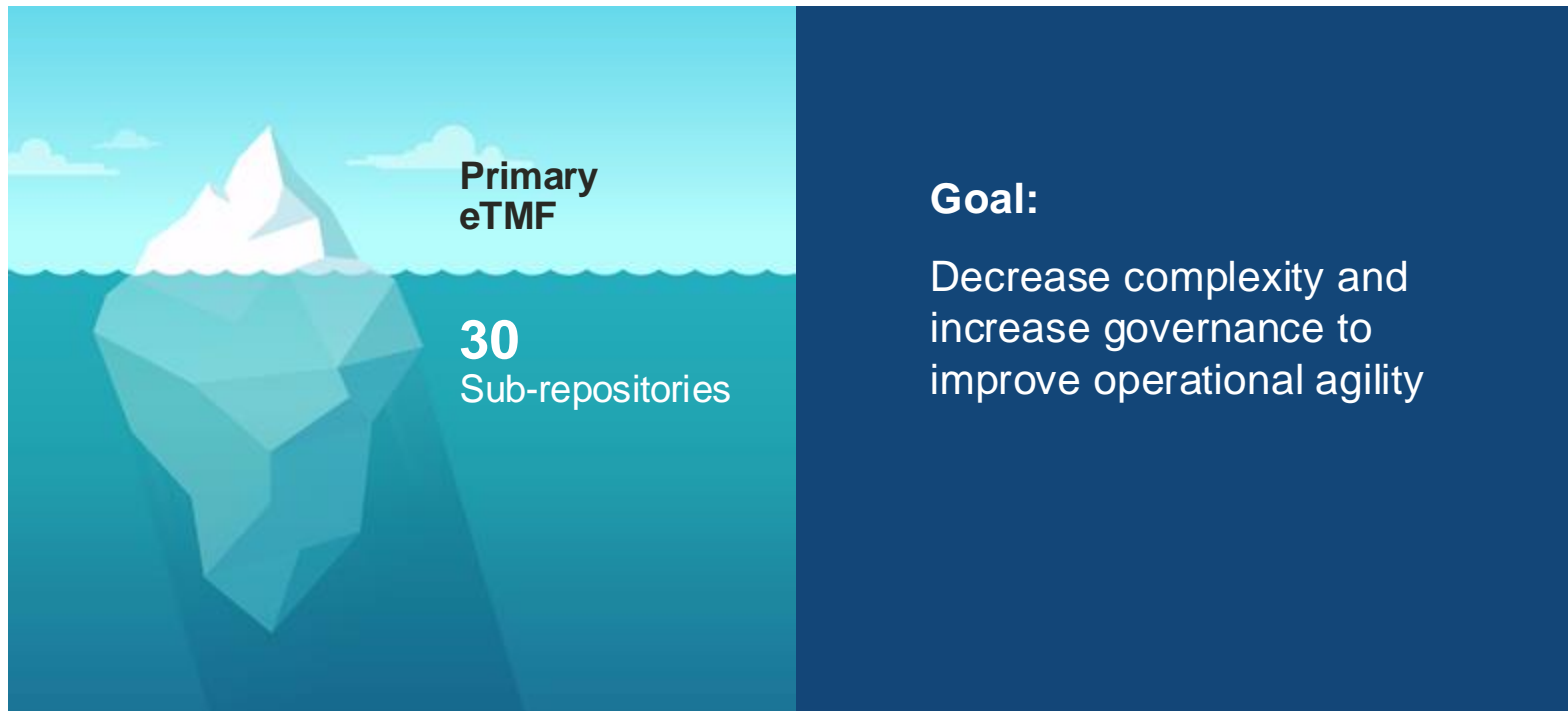
Business units, therapeutic areas, etc. where the operating model fluctuates from the norm



Establish the basis to approach interoperability

With outside partners and organizations, including sites, in a more standardized manner

Novartis Assessment Identified 30+ Sub-Repositories



Next Steps to Simplify Internal Ecosystem



Identify where eTMF functionality supports tasks

- Managing study-related tasks
- Authoring key plans and managing their lifecycle
- Automating reminders about planned tasks and upcoming events
- Managing living documents (e.g., action-decision-issue logs)



Support a mindset shift for eTMF as source of truth

- e.g., training people to send a link to a document rather than emailing a file



Consider automations and integrations in parallel based on volume and risk

Next Steps to Simplify External Ecosystem



Site Collaboration

- Simplifying how we provide and collect documents, data, and information
- Standardizing our content generation reuse approach *and* changing how we interact with site technology





Partner Collaboration

- Moving beyond complex migrations and integrations with partners, including CROs

Benefits and Anticipated Benefits

Benefits Now

-  **Increased understanding** of systems, processes, and quality control of content
-  **Increased awareness** of functional involvement in TMF

Anticipated Benefits

-  **Reduced sub-repositories**
-  **Proactive governance** of the ecosystem
-  **Increased influence** on future technology decisions

Tips To Increase TMF Influence at Your Organization

1

Embrace Technology

Simply implementing eTMF is not enough

2

Standardize

Create clear processes, use templates, and limit exceptions

3

Collaborate

Enhance the functional area experience

4

Focus on quality

Establish modular risk-based approaches, such as escalating or de-escalating QC

5

Master the regulations

Most people do not understand them — we need to

6

Measure and improve

Continuous improvement is a mindset that requires true measures of the impact of your efforts



Questions?