

2026 Europe Interchange

Session 7: TMF Plenary - Supporting V1 Implementation – Formula V1: Un Granpremio Tutto da Vedere

Chair

Jamie Toth, BeOne Medicines USA, E3C

Data Standardization as the Foundation for an Autonomous TMF

Jason Methia, Veeva Systems and Vittoria Sparacio, Novartis

Panel Discussion: Practical Strategies and Change Management Recommendations for Adopting the Standard Model

Katie Hoover, Vital GXP Consulting

Panel Discussion: Vendor Implementation of Standard V1

Aaron Grant, Just in Time GCP

Moving to a Standard: TMF SM V1 and Beyond

Paul Carter, Montrium, CDISC Board of Directors, E3C

Next

Session 8: Closing Plenary - Regulatory Panel Discussion

Program:





2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Data Standardization as the Foundation for an Autonomous TMF

Jason Methia, VP, TMF Strategy, Veeva

Vittoria Sparacio, VP & Global Head, Clinical Document Governance & Mgmt, Novartis

Speakers



Jason Methia

VP, TMF Strategy
Veeva Systems



Vittoria Sparacio

VP & Global Head, Clinical Document Governance & Management
Novartis Pharma AG



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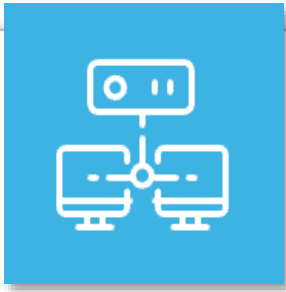


Agenda

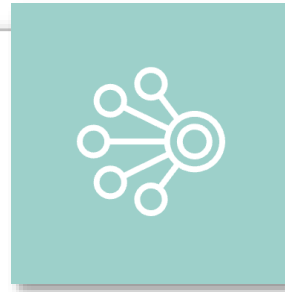
- Vision of autonomous TMF
- Paving the way to autonomous TMF
- Importance of clear standards and clean data
- Making the shift to AI
- Q&A

Autonomous TMF

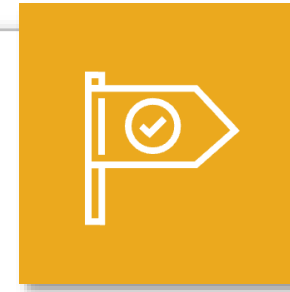
Human Oversight, AI Execution



Integrated
intelligent ecosystem



Standard & Connected
software, data, and AI



Improved
insights and oversight

Autonomous TMF Evolution

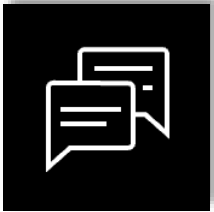
Today
Manual TMF Execution



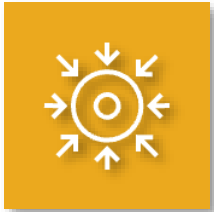
Tomorrow
Autonomous TMF Request



A Major Concept Shift



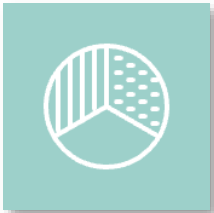
Transition humans from “processors” to “process architects”



Implement AI as the “executor”, handles the routine work



Understand TMF logic for optimal AI performance



Prioritize strategic direction over manual interaction

Path to Autonomous TMF

80% Automation: AI orchestration

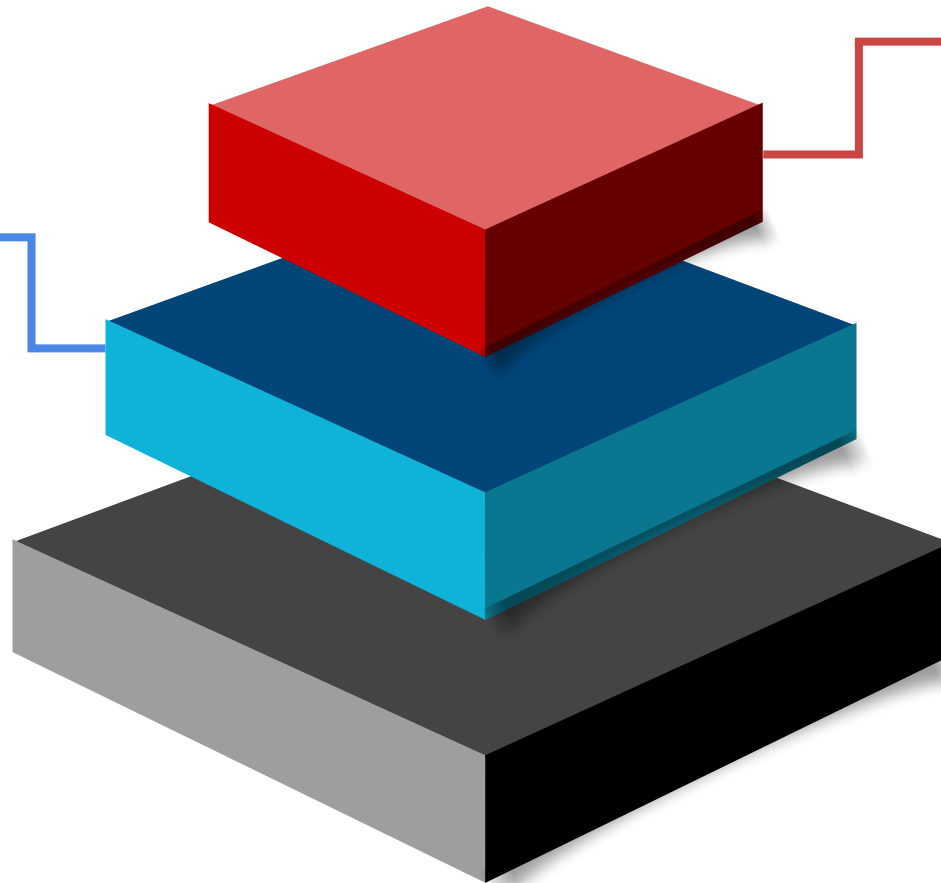
Users dictate "what" the outcome is, not "how" to find it

95% Automation: Automated prompting

Humans become "process architects" focused on strategic oversight and approvals

60% Automation: Initial AI agents

Users experience fewer manual steps as AI takes on standard execution



Role of Data



- **Dynamic Context Engineering**
- **TMF as the “Master Consumer”**
- **Interactive Risk Storyboards**

Role of Standards



- **Deterministic Gap Analysis**
- **Cross-System Interoperability**
- **Regulatory Explainability**

Role of **Clean** Data

**Trusted Source
Powered by AI**



- **Less AI hallucinations & bias; more confidence**
- **Full story, right context, the way you need it**
- **Interactive prompts aiding study management**

Role of **Clear** Standards

Trusted Source
Powered by AI



- **Universal language**
- **Robust master data management**
- **Consistency**



From Backseat to Fast Forward

- What has changed that makes this achievable **now**?
- Why is **now** the best time?
- What may **now** hold us back?

(Did I say ***now***...)





We Are at the Edge of a Revolutionary Road

- It's Human + AI, not Human vs AI
- Humans ask the critical questions, interpret outcomes in context, and ensure innovation serves patients rather than efficiency alone
- AI's real value depends on how responsibly it is built, governed and applied

AI may be the most critical revolution humanity has unleashed, and the real challenge is not only to use it powerfully, but to use it wisely.

To Develop Human-propelling AI, Develop AI-propelling Humans



Focus on people,
not technology



Teach judgment
intentionally



Make AI literacy a
core capability



Build a culture of
curiosity &
accountability

Prepare for a Marathon Not a Sprint

Human + AI, Responsibly

Campaign

Create buzz through bite-sized agentic AI tools that augment human abilities

Culture

Foster a culture of curiosity, adaptability, critical and system thinking, and integrity

Change

Offer diverse learning opportunities, support, and recruiting strategy to strengthen in-house expertise

Perfect Storm for TMF

- Teams delegate transactional prep, admin follow-ups, data analysis to AI so they focus on outputs review, and signal and pattern detection
- Entry-level TMF roles interrogate AI through query prompts
- Data and records together in a cohesive narrative
- Events predicted and managed, risks mitigated, and issues prevented





Questions?





Thank You!

