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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

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Human + AI: Driving TMF Excellence Through Culture, Collaboration, and Connected Systems

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SPEAKER

Harinarayan Gopichandran

Sr. Director, Product Services | Sycamore Informatics

Harinarayan Gopichandran is an executive with 23+ years of progressive leadership at the intersection of Biostatistics, Statistical Programming, and Clinical AI spanning pharmaceutical giants (Novartis, Allergan, AstraZeneca, BMS) and cutting-edge life sciences technology firms (Sycamore Informatics, Saama, Cognizant).

His career has been defined by one core mission: accelerating drug development through smarter, technology-driven clinical data solutions from hands-on statistical programming to architecting enterprise-grade AI frameworks.

Currently, as Sr. Director, Product Services at Sycamore Informatics, he leads deployment of the Clinical Agentic Framework™ a next-generation AI platform transforming how pharmaceutical companies execute clinical data operations.

He believes the future of drug development belongs to those who can bridge deep domain expertise with emerging AI and he is actively building that future.

IMPORTANT

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 Sycamore Informatics and/or CDISC.

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

SESSION ROADMAP

What We'll Cover

25-minute session • CDISC 2026 US Interchange • Denver, CO

01	**Why This Matters Now**	Five forces putting Human + AI at the center of TMF strategy
02	**Where Manual TMF Processes Fall Short**	The gaps that put inspection readiness at risk
03	**The Connected TMF Model**	Systems, standards, and shared visibility across sponsors, CROs & sites
04	**AI's Role and Its Limits**	Where automation helps, and where people still decide
05	**Building Trust: Culture & Collaboration**	Turning transparency into quality and readiness

SECTION 01

Why This Matters Now

Five Reasons Human + AI Should Be Top of Mind for TMF

Why This Matters Now

> *Trial Master Files sit at the intersection of regulatory scrutiny, distributed teams, and growing document volume. AI can automate the busywork of TMF management, but it is the people; sponsors, CROs, and sites working from a shared, trusted system who ultimately determine whether a study stays inspection-ready.*
>
> *The TMF Mandate*



Regulatory Scrutiny Is Rising



Trials Are More Complex & Distributed



Manual TMF Work Doesn't Scale



Trust in AI Must Be Earned



People Remain the Differentiator

SECTION 02

The TMF Landscape Today

Where Manual Processes Fall Short

Where Manual TMF Processes Fall Short

Four recurring gaps that put inspection readiness at risk



Fragmented Systems

Documents live across email, shared drives, and multiple eTMF instances with no single source of truth.



Delayed Visibility

Completeness status is discovered at monthly reviews, not in real time.



Manual Reconciliation

Sponsors, CROs, and sites re-key or re-upload the same artifacts more than once.



Inspection-Day Scramble

Gaps surface only when a regulator asks for a document that isn't there.

Why Connected Systems Matter for the TMF

What's Slowing Teams Down and Where the Industry Is Headed

CHALLENGES IN TMF OPERATIONS

41.6% cite an incomplete TMF as their biggest obstacle to inspection readiness

33.7% cite documents not being filed on time

45.9% point to unmotivated contributors as the root cause of late filing

WHAT CONNECTED TMF ENABLES

Inspection Readiness Becomes Inspection Steadiness

Continuous audit-trail discipline replaces pre-inspection scrambles

Site Collaboration Closes the Biggest Gap

Sites generate 75%+ of TMF document volume —connected workflows target it directly

Shared Standards Enable Interoperability

TMF Reference Model V4 (targeted 2027) focuses on data flow and harmonization across systems

Sources: Montrium, The State of TMF Industry Report 2023 (245 TMF professionals, Oct 2023); Veeva Systems, 6 Trends Driving TMF Strategy / TMF Trend Report 2025

SECTION 03

The Connected TMF Model

Systems, Standards & Shared Visibility

What a Connected TMF Model Looks Like

Systems, Standards & Shared Visibility: From manual to connected

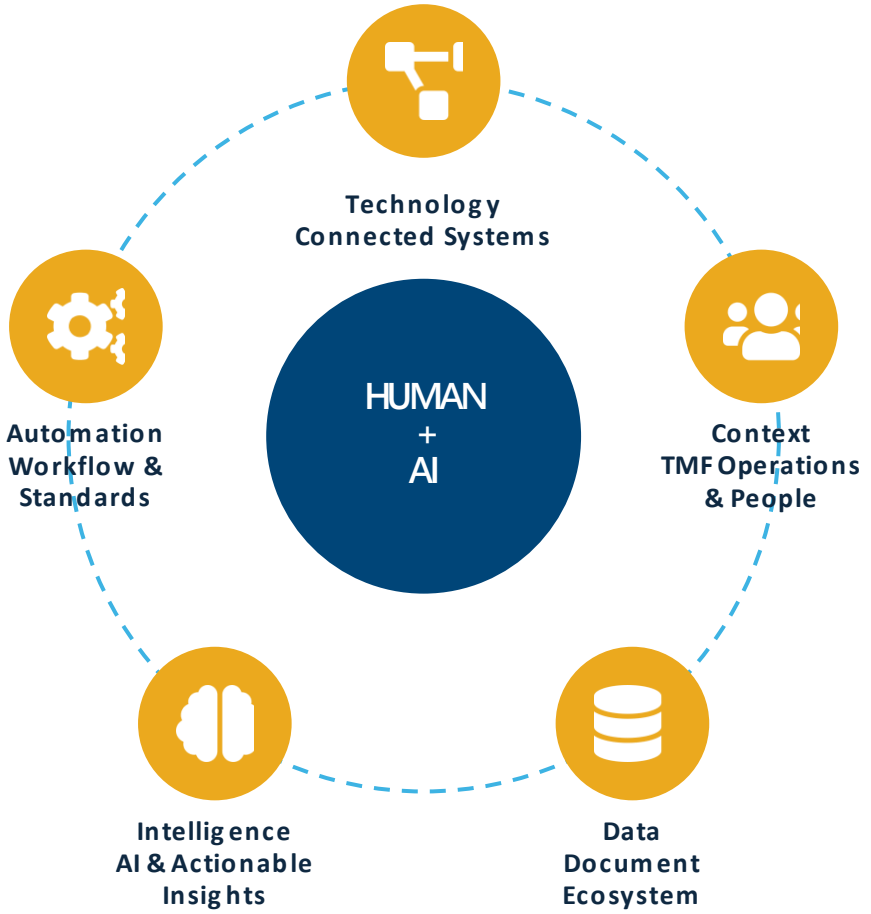
MANUAL TMF	CONNECTED TMF
Static folder structure	**TMF Reference Model-aligned, standardized taxonomy**
Periodic manual uploads	**Real-time, direct-from-source upload**
Siloed sponsor / CRO / site systems	**Shared visibility across all parties**
Reactive quality checks	**Active, always-on completeness & quality metrics**

AI Is Only Part of the Puzzle

Technology, data, and intelligence only work through people and process.

Where AI Excels

- Pattern recognition at scale, across thousands of documents
- Flagging anomalies and likely duplicates instantly
- Classifying documents against TMF Reference Model types



Where People Still Decide

- Judgment calls on ambiguous or novel context
- Accountability for what gets confirmed and approved
- Relationships across sponsors, CROs, and sites

A Connected TMF in Action

From practice — a composite, illustrative example



SECTION 05

Building Trust, Together

People remain the differentiator

Practices That Build Trust

People remain the differentiator — concrete practices, not slogans

Transparent Metrics	Shared dashboards, not siloed reports ; every party sees the same completeness picture.
Clear Escalation Paths	Defined owners for every artifact type and every exception.
Human-in-the-Loop AI	AI flags and suggests; people confirm and decide.
Change Management as a Workstream	Training and onboarding built into the rollout, not bolted on afterward.

Bringing It Together…

Culture

- Shared Ownership of TMF Quality
- Less Friction in Cross-Functional Handoffs
- Faster Trust in AI-Assisted Insights
- Change Management Built Into the Rollout

Collaboration

- Connected Sponsor, CRO & Site Workflows
- Shared Visibility Into TMF Completeness
- Standardized Review & Escalation Paths
- AI-Assisted Document Triage
- Self-Service Dashboards & Alerts

Connected Systems

- Real-Time Inspection Readiness
- Higher TMF Completeness Rates
- Fewer Manual Handoffs Across the Document Lifecycle
- Scalability — Standardized Processes That Scale Across Studies

Key Takeaways

- Connected systems create transparency — culture and collaboration turn it into quality.
- AI removes busywork, not accountability. People still own trust.
- Shared standards, like the TMF Reference Model, are what let "connected" actually mean connected across sponsors, CROs, and sites.
- Inspection readiness is the by-product of daily discipline, not a pre-inspection sprint.

Thank You!

The most successful TMF programs won't be the ones with the most automation; they'll be the ones where AI and people trust each other enough to work as one team. Connected systems create the transparency; culture and collaboration turn that transparency into quality, inspection readiness, and better trials.

Thank you for joining this conversation — let's keep building that future together.

Harinarayan Gopichandran

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