

From Standard to Practice: Bringing TMF SM V1 to Life:
Change Management for TMF SM V1



Meet the Speaker

Steph Viscomi

Title: Sr. Director, Clinical Strategy & Operational Excellence

Organization: Kymera Therapeutics

Steph is a clinical operations and TMF leader with 19+ years of experience across sponsor and CRO environments. Her expertise spans TMF strategy, operational excellence, clinical systems transformation, inspection readiness, and sponsor/CRO partnerships. She currently leads Clinical Operations Excellence and TMF initiatives at Kymera Therapeutics and serves on the TMF Steering Committee, TMF Standard Model V1 Project Management Committee, and Triage Committee, helping shape the future of TMF standards and industry practice.

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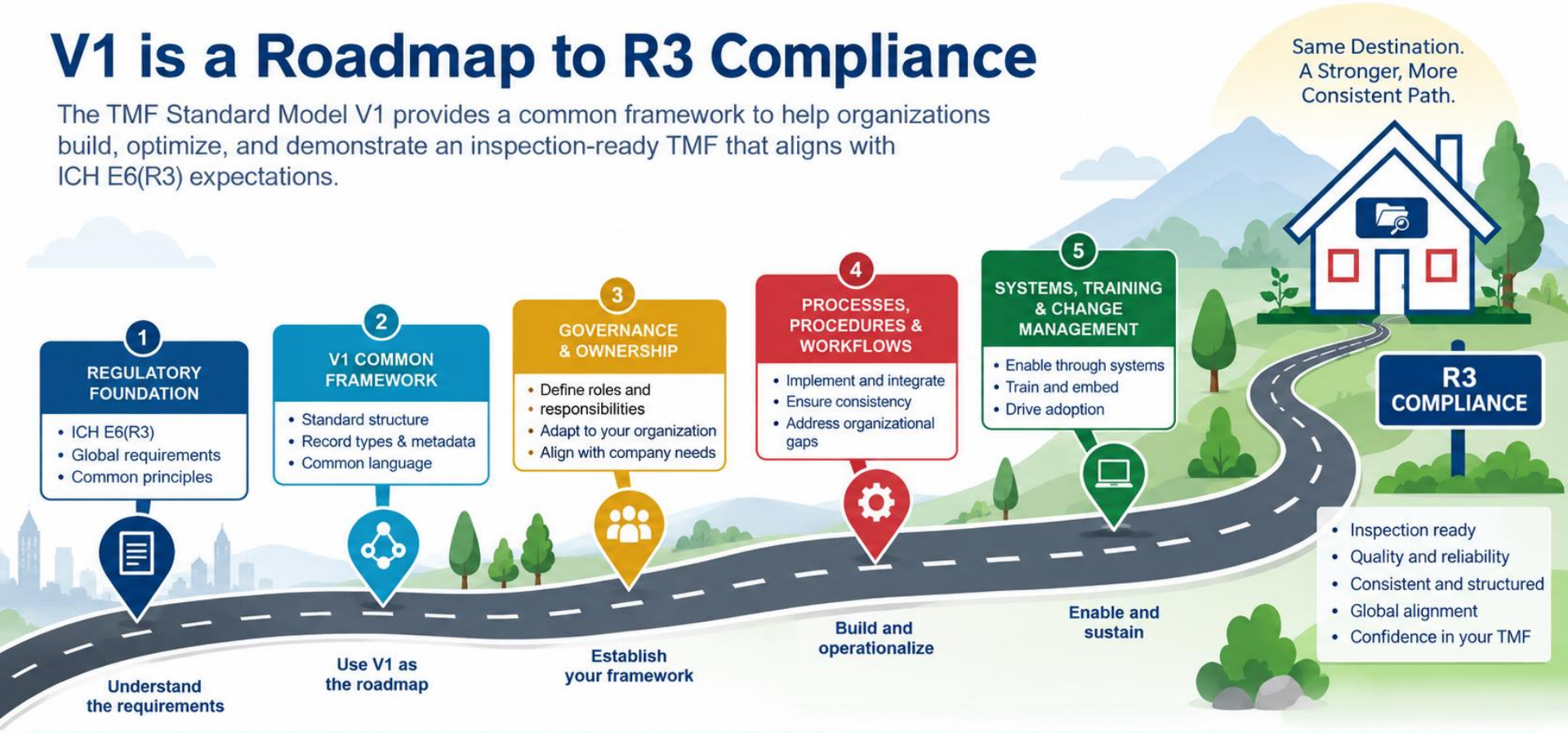
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Agenda

- V1 is a Roadmap to R3 Compliance
- What V1 Changes and Why It Matters
- V1 Implementation Guide
- Change Control Board
- Change Management: From Awareness to Adoption
- Q&A

V1 is a Roadmap to R3 Compliance

The TMF Standard Model V1 provides a common framework to help organizations build, optimize, and demonstrate an inspection-ready TMF that aligns with ICH E6(R3) expectations.



V1 does not equal compliance by itself — it gives organizations a structured path to operationalize ICH E6(R3).

Content Refresh

Evolving the content to meet today's needs and tomorrow's opportunities.

What's Changing?

- TMF content is being **reviewed and updated** to align with industry best practices and regulatory expectations.
- Some records will be **reclassified or regrouped** for consistency, **additional records** will be introduced, and **some records will be retired**.

Why is this Changing?

- With the introduction of ICH E6 R3, EU CTR, and other developments, additional record types are required.

Goals

- **Stronger foundation** for indexing, searching, and compliance.
- **Streamlined reviews and inspections** with related records grouped together.
- **Future proof** for industry growth and regulation(s) evolution.

A clearer, more consistent TMF — built for today, ready for tomorrow.



TMF STANDARD MODEL V1

V1 Implementation Guide

Supporting your journey from standard to practice

The TMF SM V1 Implementation Guide provides practical support to help organizations understand and apply the Standard Model in their real-world environment.

Translates the Standard into Practice

Offers guidance, examples, and considerations for real-world implementation.

Supports Multiple Organizational Contexts

Designed to be flexible and applicable across sponsors, CROs, and technology partners.

Enables Consistent Adoption

Helps drive a common understanding and approach to operationalizing the Standard Model.



Implementation Guide: What It Helps Organizations Do

Use the Guide as the bridge between the Standard and local implementation decisions.

The Guide helps answer:

- How do we interpret V1 consistently?
- Where do company-specific decisions begin?
- What changes in systems, SOPs and training are needed?
- How do we stay aligned after release?

Not a replacement for company procedures, a practical companion for adoption.

Interpretation & Use

- Clarifies how Record Groups, Record Types, metadata and model architecture should be understood.
- Provides consistent definitions and intent.
- Supports common understanding across teams and vendors.

Implementation Planning

- Supports impact assessment and gap analysis.
- Informs sequencing and transition decisions.
- Helps define organizational ownership and responsibilities.

Operating Environments

- Recognizes that sponsors, CROs, vendors and hybrid models may apply V1 differently.
- Provides practical guidance for real-world use cases.
- Supports flexibility while maintaining consistency.

Ongoing Maintenance

- Connects implementation to future change control.
- Supports sustainability as the Standard evolves.
- Helps organizations manage updates and maintain alignment over time.



What the V1 Implementation Guide Covers

From foundational concepts to practical adoption

The Guide provides implementation context across the elements organizations and technology providers will need to translate V1 into practice.



Change Control Board (CCB)

Stewarding the evolution of the TMF Standard Model

The Change Control Board (CCB) is a standing body of TMF subject-matter experts responsible for managing and approving changes to the TMF Standard Model.

What it is

A cross-functional group of industry experts who oversee and approve proposed changes to the Standard.

Purpose

To ensure changes are needed, well-defined, and aligned with CDISC governance, principles, and industry needs.

Impact

Helps maintain the integrity, consistency, and real-world applicability of the TMF Standard Model.



Thoughtful change. Stronger standards. Greater impact.

Change Control Board (CCB): Basic Charter Snapshot

A standing body of TMF subject-matter experts responsible for controlled change and maintaining the integrity of the TMF Standard Model.

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MEMBERS

One CCB Lead
Industry SMEs
Cross-functional input

Purpose

Manage and maintain the TMF Standard Model through a controlled, transparent and balanced change process.

Responsibilities

- Review, triage, evaluate and approve proposed changes
- Ensure alignment with CDISC governance, principles and standards
- Maintain the integrity and consistency of the Standard

Outputs

- Documented decisions and rationale
- Updates to the Standard, controlled terminology and related artifacts
- Implementation-ready change packages

CCB Lead

- Serves a 2-year term
- Elected after annual elections
- Provides leadership, coordination and oversight

Community Connection

- Engages Zone Teams and community feedback
- Ensures stakeholder input informs change rationale
- Promotes transparency across the TMF community

Consensus First

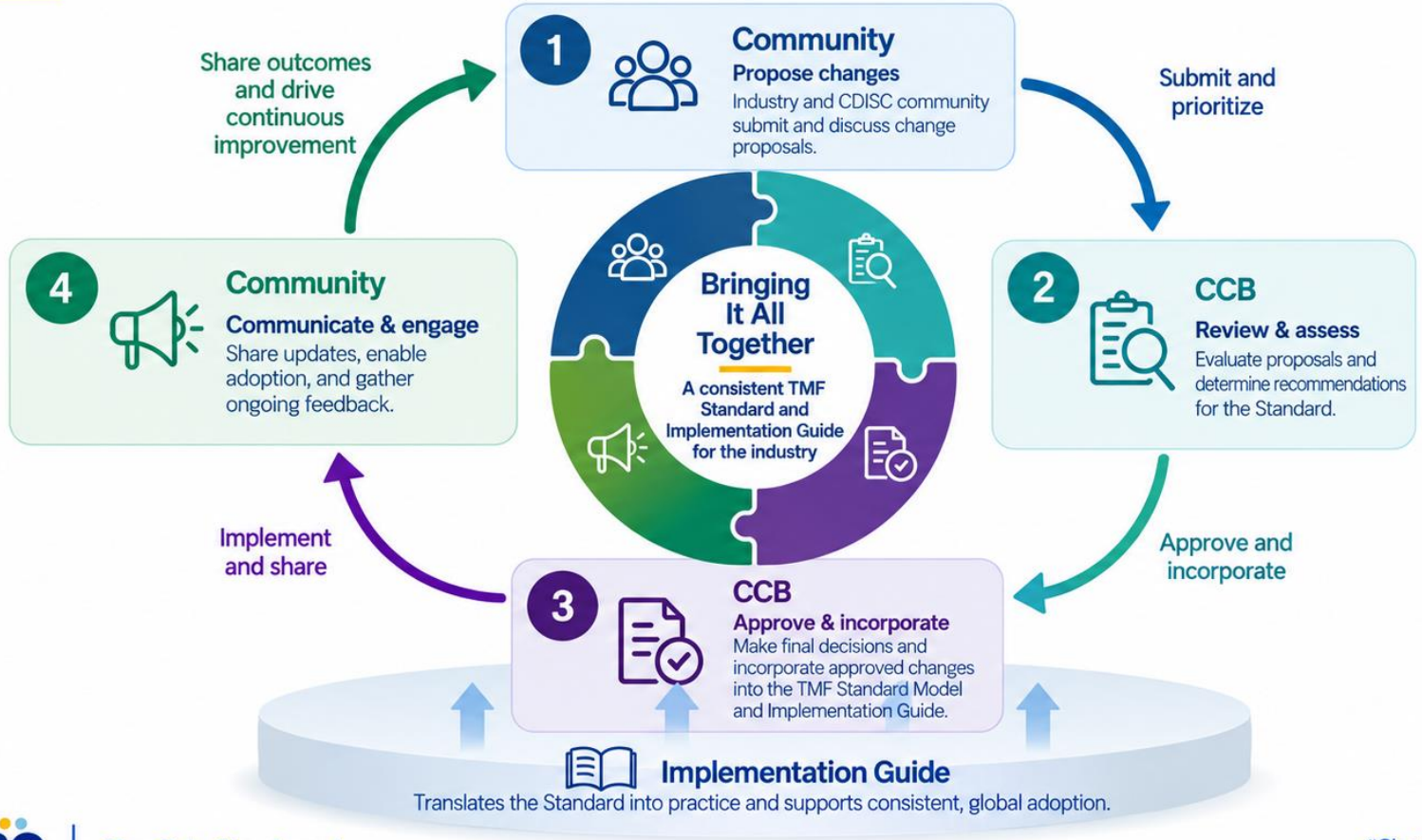
- Resolves decisions through discussion and SME alignment
- Considers broad impact across use cases and operating environments

Escalation Path

- Unresolved items escalate through defined governance
- Maintains alignment with the CDISC TMF Steering Committee

CCB & TMF Community Collaboration

From ideas to impact. Bringing it all together.



- Regulatory Alignment
- Industry Collaboration
- Global Consistency
- Real-World Impact

Standard + Guide + CCB: The Sustainment Model

The Standard defines the model, the Guide supports implementation, and the CCB governs controlled evolution over time.

TMF Standard Model V1

Common industry framework for the **"what."**

- Record Groups & Record Types
- Controlled terminology
- Metadata and unique identifiers

+

Implementation Guide

Practical guidance for the "how."

- Interpretation and application
- Implementation considerations
- Supports adoption and maintenance

+

Change Control Board (CCB)

Governance for the "what's next."

- Review, approve and prioritize changes
- Ensure alignment with CDISC principles
- Maintain the integrity and ongoing evolution of the model

What organizations need to operationalize



Assess
What is changing and who is impacted?

Decide
What will we adopt, adapt or defer?

Implement
What SOPs, systems, training or partner processes change?

Sustain
How will we monitor future changes and adoption?

Together, the Standard, Implementation Guide and CCB provide the foundation. Organizations turn that foundation into sustained adoption.

Change Management: Setting the Journey in Motion

People. Alignment. Adoption. Impact.

V1 introduces a new common framework for the TMF. Realizing its value requires more than document updates — it requires people, process and system changes across the organization.

Change management ensures we are ready, aligned and enabled to successfully adopt V1.

People

Build awareness, understanding and confidence across all stakeholders.

Process

Align and update SOPs, workflows and ways of working to reflect V1.

Technology

Prepare systems, tools and data to support new standards and metadata.

Impact

Enable consistent implementation, greater efficiency and stronger compliance.

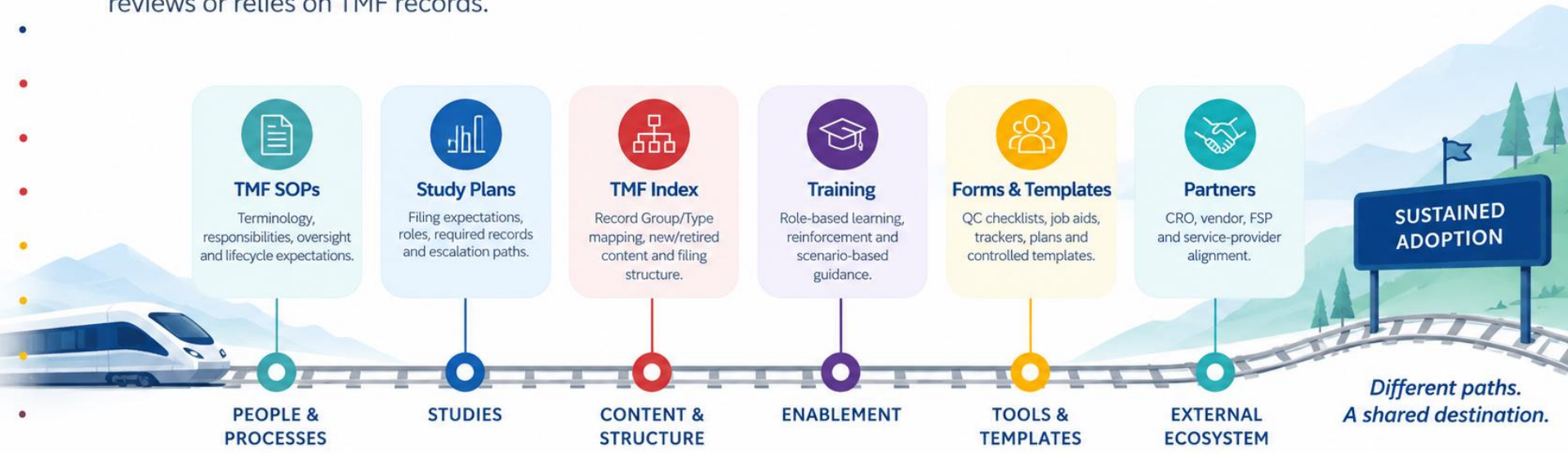


Change management is the bridge between the standard and real-world impact.

Together, we can turn V1 into lasting value.

The Change Footprint: V1 Touches More Than the TMF Index

Organizations should assess the full operating model and every stakeholder who creates, manages, exchanges, reviews or relies on TMF records.



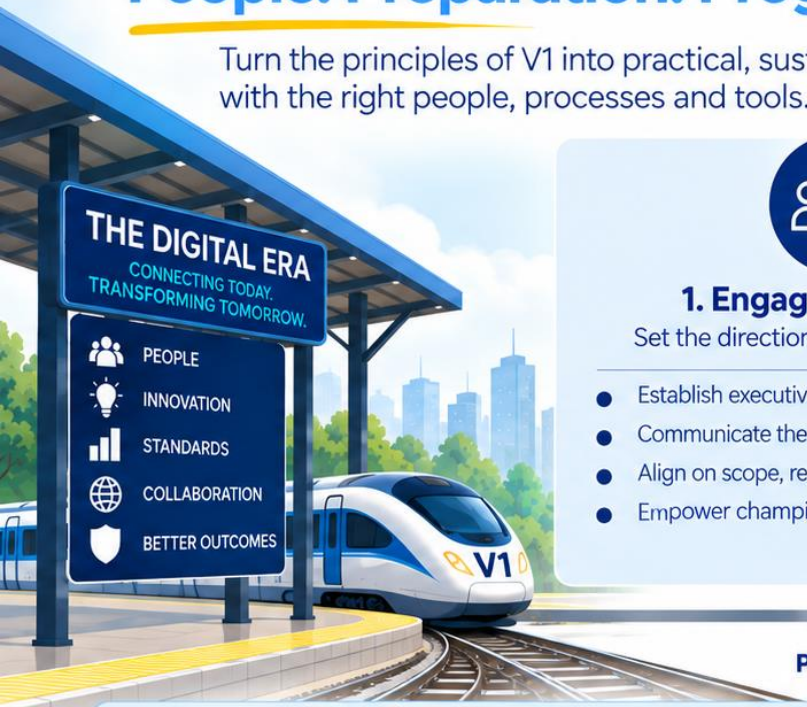
Key message: Implementation is an operating-model change — not a document-relabeling exercise.

Change Management Before V1 Rolls Out

People. Preparation. Progress.

Same Standard. Many Possibilities.

Turn the principles of V1 into practical, sustainable change across your organization — with the right people, processes and tools.



1. Engage Leadership

Set the direction and build momentum.

- Establish executive sponsorship
- Communicate the why and expected benefits
- Align on scope, resourcing and success measures
- Empower champions across the organization

2. Prepare & Align

Assess current state and plan for change.

- Review and update SOPs, study plans and templates
- Identify impacts across functions and systems
- Define roles, responsibilities and training needs
- Create a shared vocabulary and timeline
- Communicate early and often

PEOPLE → **PREPARATION**

Leadership Support Across All Stages

Visible sponsorship | Clear communication | Resource alignment | Accountability | Celebrate progress

Mobilize for Adoption

Enablement. Adoption. Lasting Impact.

Same Standard. Many Possibilities.

Equip your organization with the tools and knowledge to succeed — and drive adoption for sustained impact.



3. Enable & Equip

Provide the tools and knowledge to succeed.

- Update forms, templates and guidance
- Deliver training and job aids
- Engage vendors and partners
- Ensure systems and processes are ready
- Address gaps and build confidence

4. Drive Adoption

Measure progress and sustain success.

- Validate readiness across teams
- Conduct change impact reviews
- Reinforce through ongoing communication
- Monitor progress, address risks and open items
- Capture feedback and continuous improvement
- Confirm go-live support model

ENABLEMENT → **ADOPTION**



Start now, so your organization arrives ready.

Change management is not a phase — it's the foundation for lasting adoption.

V1 Train Schedule

Key Stops on the Road to Adoption

Community input today. A stronger standard tomorrow.

**Same Destination.
Greater Impact.
Together.**



DESTINATION / MILESTONE	DATE	STATUS
V1 SM Community Review All aboard for feedback	October 2026	On Track
2nd V1 SM Community Review Refine and strengthen	March 2027	Next Stop
V1 SM Official Release Ready for implementation	April 2027	Coming Soon

Different Trains. A Shared Destination.

Standards, Innovation and Regulation Moving TMF Forward.

E6(R3), AI in TMF, the V1 Standard Model and other key considerations are each advancing us toward a more efficient, consistent, and inspection-ready future.



Different tracks. A stronger tomorrow.

Document Management to Evidence Control

Same Foundation. A More Impactful Journey.



From **Documents** → To **Information** → To **Evidence** → To **Better Outcomes**

Thank You

For your time, insights and continued support.

Same Standard. Many Possibilities.

