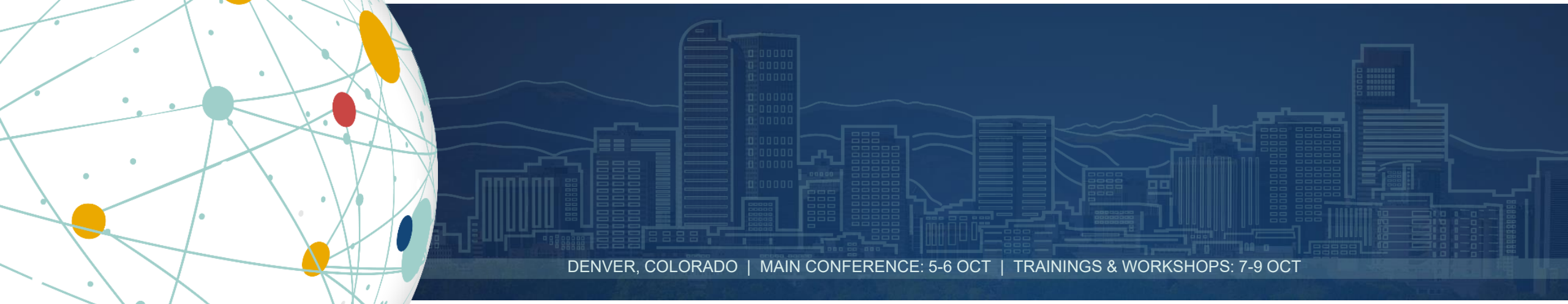


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Leading Change in the Trial Master File

Rhonda Nolan, Senior Manager, TMF, Regeneron Pharmaceuticals, Inc.

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Agenda

1. Defining the Discipline
2. TMF Change Imperative
3. TMF Standard V1
4. Real-World Change Scenarios
5. Change Journey Framework
6. Leadership Behaviors & Outcomes
7. Key Takeaways

Speaker



Rhonda Nolan
Senior Manager, TMF
Regeneron
Pharmaceuticals, Inc.

Rhonda Nolan is Senior Manager, Trial Master File (TMF), within the Research & Development Records Management team at Regeneron Pharmaceuticals in Armonk, New York. She focuses on helping clinical studies maintain a state of continuous inspection readiness and has supported multiple regulatory inspections and audits, including associated follow-up activities. Rhonda also serves as a Change Management Agent at Regeneron, leading Office Hours, CRO Knowledge Sessions, newsletters, and other communications that help make organizational changes clear, compelling, and credible. She brings more than 18 years of experience in the pharmaceutical industry, primarily in TMF management.

Outside of work, Rhonda enjoys hiking, downhill skiing, traveling with her husband, playing Scrabble with her daughters, and spending time with her grandchildren.

01 Defining the Discipline

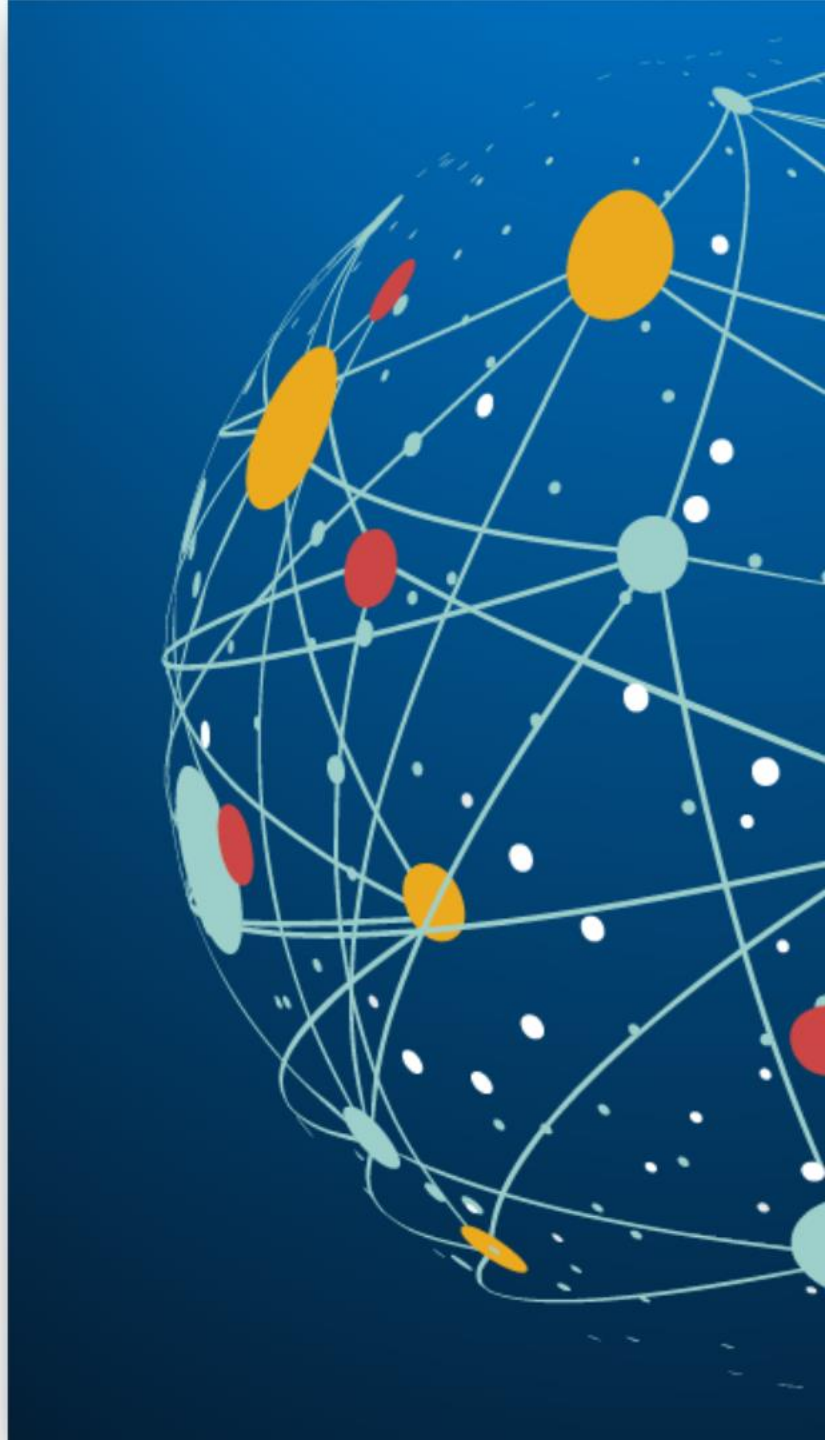
So, What Is Change Management?

What Is Change Management?

The structured approach to preparing, equipping, and supporting people to adopt new ways of working — so the change actually delivers its intended result.

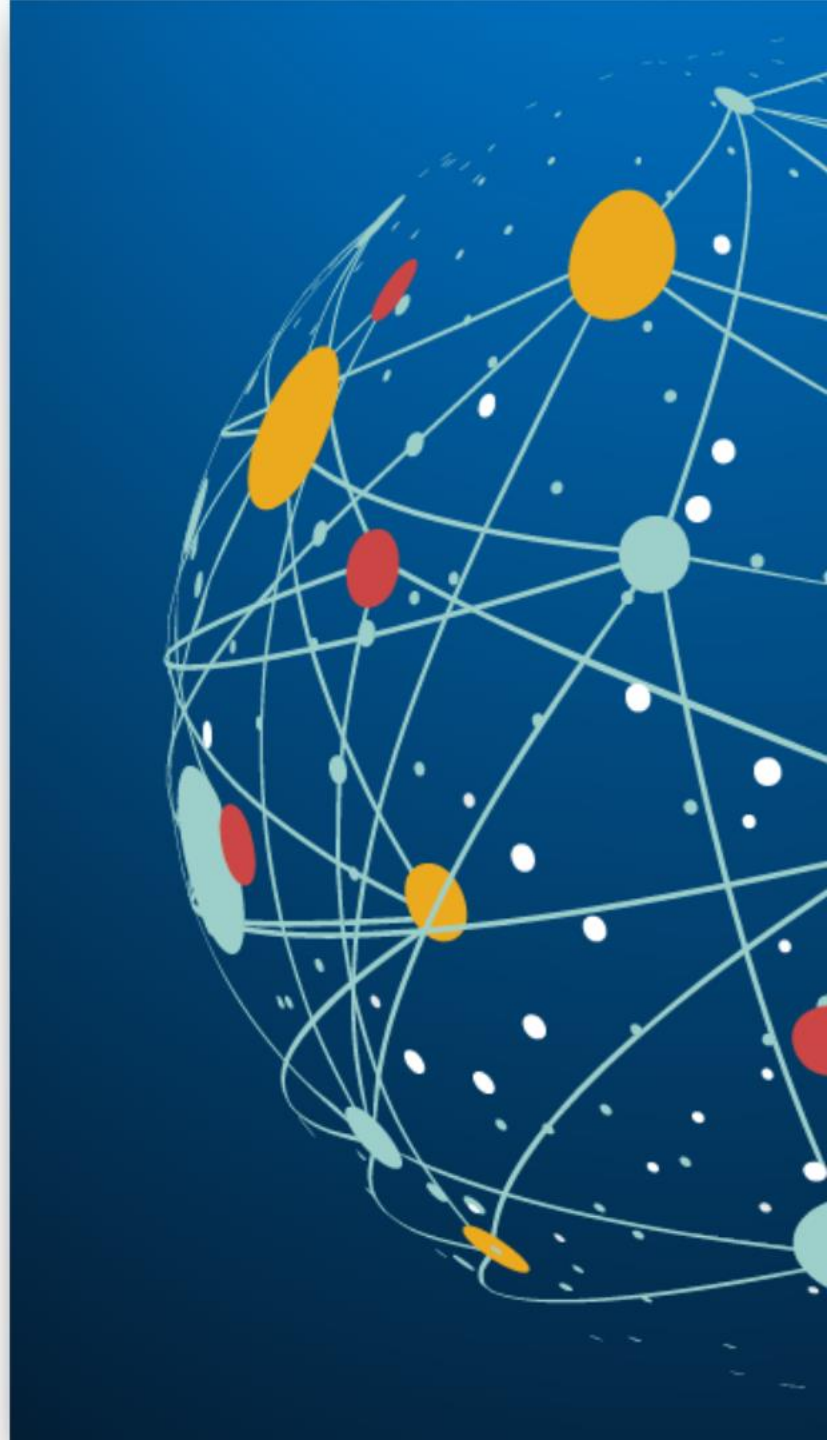
It is the people side of a change: readiness, communication, training, reinforcement.

It isn't a system go-live, a project plan, or a one-time training session.



What Is Change Management?





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02 The TMF Change Imperative

Three Forces Are Converging on the TMF

Rapid Growth

Expanding pipelines, new modalities, and outsourcing partners multiply document volume and TMF complexity.

Evolving Regulations

ICH E6(R3), ICH E8(R1), and the shift to a formal TMF Standard raise the bar for structure and traceability.

Advancing Technology

eTMF platform upgrades and AI-enabled document processing change how teams work day to day.

Each force alone would justify a change program. Together, they make change management a survival skill for TMF.

02 The TMF Change Imperative

The Stakes of Getting Change Wrong

WHEN CHANGE FAILS

- ✗ Inconsistent filing and metadata gaps
- ✗ Missing or misplaced documents at inspection
- ✗ Workarounds that bypass new systems or process
- ✗ Low adoption, high rework, growing backlog
- ✗ Erosion of trust between sponsor, CRO, and site

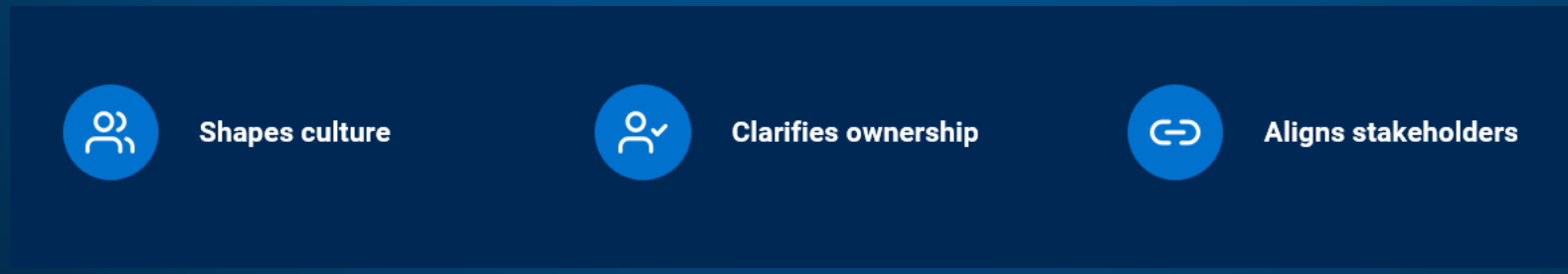
WHEN CHANGE SUCCEEDS

- ✓ Inspection-ready TMF, every trial, every time
- ✓ Faster, cleaner adoption of new tools and process
- ✓ Clear ownership across sponsor, CRO, and vendors
- ✓ Data integrity preserved through every transition
- ✓ A team that trusts leadership through the next change

THE CENTRAL IDEA

Change management isn't a project task.

It's a leadership discipline.



TMF Change Management Leaders turn regulatory pressure and new technology into durable, adopted practice — not just documented procedure.

03 TMF Standard V1

TMF Standard V1 Is Coming — Are We Ready?

A new industry baseline for the TMF, and a change that reaches well beyond the document team.

READINESS AT A GLANCE

The change

TMF Standard V1.0 replaces the Reference Model as the industry baseline.

The gap

Our systems, SOPs, training, and vendor agreements all still speak the old language.

The honest answer

Not yet — readiness is a program we run now, not a switch we flip at go-live.

WHO WILL BE IMPACTED

Study & Site Teams

Day-to-day filing, naming, and metadata change for everyone who touches a document.

TMF & Document Managers

Own the mapping to the new record structure, QC rules, and completeness reporting.

Vendors, CROs & Partners

Transfer agreements, expected document lists, and exchange formats need re-papering.

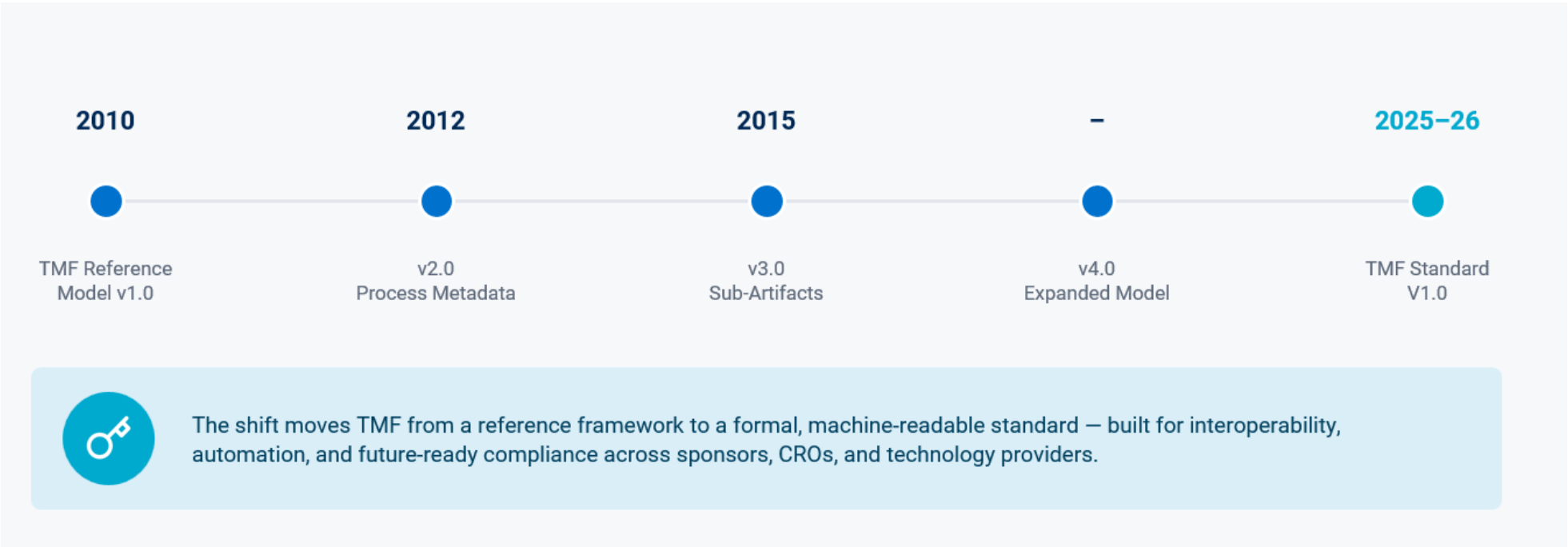
QA, Regulatory & Leadership

Inspection narratives, SOPs, and oversight metrics must reflect the new standard.

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03 TMF Standard V1

The TMF Reference Model has guided the industry since 2010. At the 2025 CDISC US + TMF Interchange, CDISC announced its evolution into Version 1 of the TMF Standard — a digital, machine-readable foundation for TMF interoperability and automation.



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What's Actually Changing?

New Terminology

"Artifact" and "Sub-artifact" become "Record Group" and "Record Type" across the model.

Far More Granularity

The standard expands to many additional record types — a substantial increase over the Reference Model.

Unique IDs & Metadata

Stable unique identifiers and richer metadata fields enable reliable, machine-readable, automated filing.

Regulatory Alignment

Closer alignment with ICH E6(R3) and ICH E8(R1) strengthens inspection readiness by design.

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04 Real-World Change Scenarios

The framework meets reality.

Three real-world scenarios.

- eTMF migration
- System enhancements
- AI-supported QC

For each one, we'll look at the same three things: the challenge on the ground, the leadership response, and the outcome it produced.

Scenario 1: Governance-Led eTMF Migration

Moving from a legacy eTMF to a new platform across active and closed studies, under a fixed regulatory timeline.

THE CHALLENGE

- Legacy filing structures don't map cleanly to the new taxonomy
- Study teams fear losing inspection readiness mid-migration
- Multiple vendors and CROs need a single source of truth

LEADERSHIP RESPONSE

- Set up a governance committee with clear decision rights
- Publish a migration playbook with roles and cutover criteria
- Run parallel validation on a pilot study before full rollout

OUTCOME

- Zero inspection findings tied to the migration
- Reconciled, auditable record counts pre- and post-move
- Reusable governance model for the next platform change

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Scenario 2: System & Functionality Enhancements

Rolling out new eTMF features — automated QC rules, workflow updates, revised metadata fields — to an active user base.

THE CHALLENGE

- Users rely on familiar workarounds that new rules will break
- Enhancements roll out faster than training can keep pace
- Unclear who owns configuration decisions and exceptions

LEADERSHIP RESPONSE

- Name a single functional owner for each enhancement
- Pilot with power users, then cascade role-based training
- Communicate the 'why' before the 'what changes on screen'

OUTCOME

- Adoption within one review cycle, not one quarter
- Fewer help-desk tickets and manual QC overrides
- A trained super-user network for the next release

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Scenario 3: Introducing AI-Supported QC

Deploying AI to support document classification, metadata tagging, and quality checks across the TMF.

THE CHALLENGE

- Reviewers are wary of trusting AI-flagged quality issues
- Model outputs need human accountability, not blind sign-off
- Change lands on top of an already regulated QC process

LEADERSHIP RESPONSE

- Position AI as an aid to reviewers, not a replacement
- Define human-in-the-loop checkpoints and escalation paths
- Track and share early wins to build confidence in the tool

OUTCOME

- Faster QC cycle times with unchanged human accountability
- Documented rationale for every AI-assisted decision
- A model for evaluating the next AI use case responsibly

05 The Change Journey Framework

Every change is a journey.
Here's how leaders run it.



Purpose first



Risk managed early

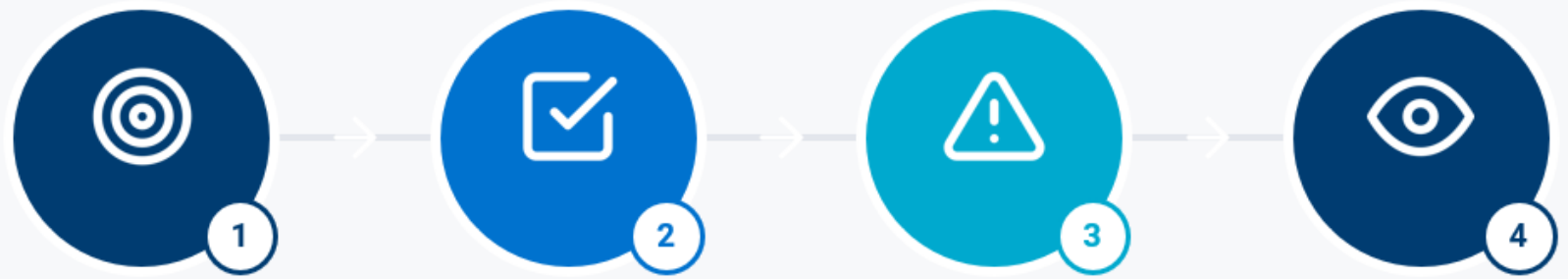


Commitment made visible

Next, we'll walk through A Practical Change Journey for TMF Leaders — four leadership moves you can repeat for every migration, enhancement, or new technology.

A Practical Change Journey for TMF Leaders

Four leadership moves, repeated for every change — migration, enhancement, or new technology.



Articulate Purpose

Set Clear Expectations

Proactively Manage Risk

Demonstrate Visible Commitment

This journey runs continuously — not once per project. Each new TMF change re-enters at step one.

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What Each Step Looks Like in Practice

1. Articulate Purpose

Connect the change to inspection readiness and trial outcomes — not just a system or policy update.

2. Set Clear Expectations

Define what's changing, by when, and what "done well" looks like for every role touched.

3. Proactively Manage Risk

Identify compliance and adoption risks early; build mitigation and rollback plans before go-live.

4. Demonstrate Visible Commitment

Leaders model the new behavior first, remove blockers fast, and follow through publicly.

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Plan It, Teach It, Advertise It

Three practical tools that turn the framework into something teams actually experience — scaled to the size of the change.

Plan Ahead	Build an Engagement Plan before go-live — who is impacted, what they hear, and when. Tools: stakeholder map, RACI, communication calendar, readiness assessment, sponsor talking points.
Train at Office Hours	Hold recurring, open Office Hours so users bring real documents and real questions. Tools: sandbox walkthroughs, role-based job aids, quick-reference cards, recorded demos, super-user network, FAQ log.
Advertise Big Changes	For a major change, run a high-visibility campaign so no one is surprised on day one. Tools: desk drops, posters and floor signage, countdown emails, intranet hub, town halls, leader shout-outs at team meetings.

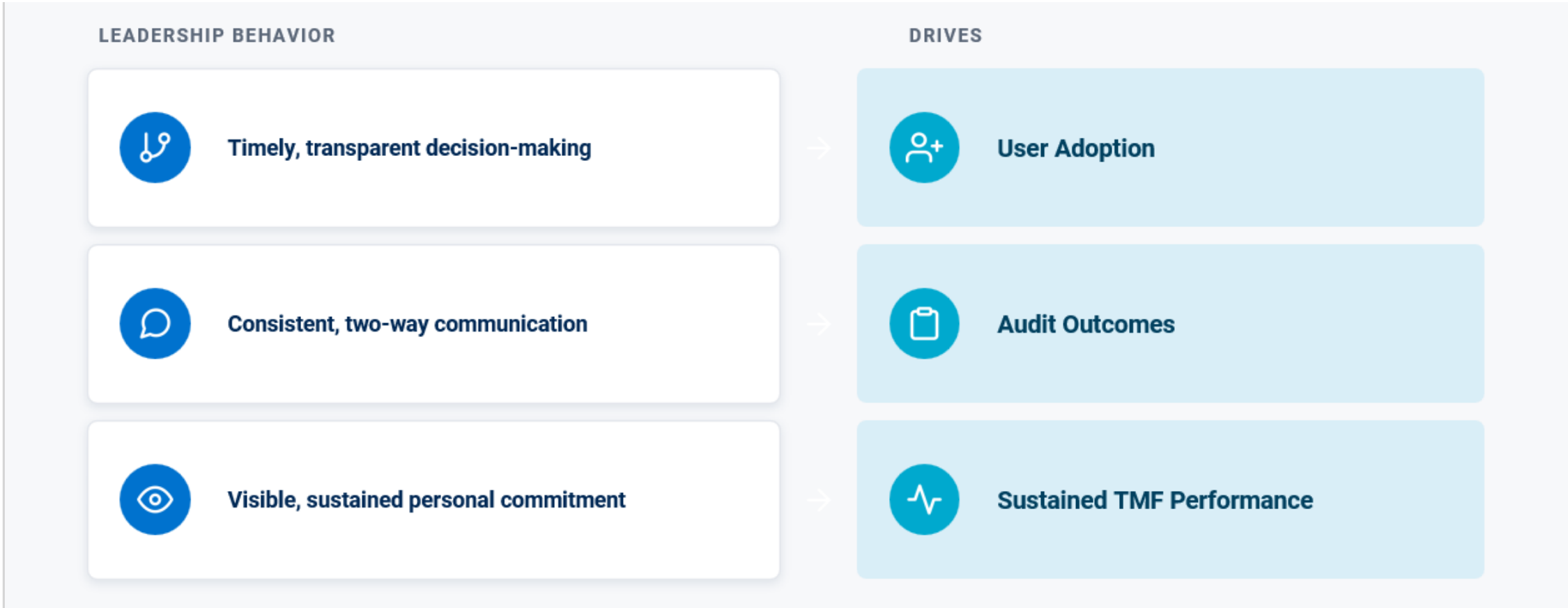
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06 LEADERSHIP BEHAVIORS & OUTCOMES

How Leaders Show Up Determines What Happens Next



06 LEADERSHIP BEHAVIORS & OUTCOMES



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How Leaders Know the Change Took Hold

User Adoption

Active, sustained use of new processes and tools — not a spike that fades after go-live.

Audit Outcomes

Clean inspection results and fewer findings tied to process, filing, or metadata gaps.

Sustained Performance

TMF quality holds steady months later — the true test of durable change.

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What to Carry Back to Your TMF Program

- Treat change management as a leadership discipline, not a project checklist.
- Prepare now for TMF Standard V1 — terminology, metadata, and system impacts.
- Use the four-step journey — purpose, expectations, risk, commitment — for every change.
- Judge success by adoption, audit outcomes, and performance that holds over time.

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Thank You!



Questions?



“The greatest danger in times of turbulence is not the turbulence—it is to act with yesterday’s logic.”

— Peter Drucker

