

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

DENVER, COLORADO | MAIN CONFERENCE: 5-6 OCT | TRAININGS & WORKSHOPS: 7-9 OCT

From Reference Model to Standard Model: How We Got Here

Donna Dorozinsky, Founder & CEO Just in Time GCP

Speakers



Donna Dorozinsky
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Donna Dorozinsky is a clinical research and GCP leader with more than 30 years of experience in clinical operations, TMF, inspection readiness, and regulatory compliance. She is the Founder and CEO of Just in Time GCP and has been a long-standing leader in advancing TMF practices across the industry. Donna serves as Program Lead for the CDISC TMF Standard Model V1 and is a long standing member of the TMF RM Steering Committtee, helping lead the evolution of the TMF from a reference model to an industry standard designed for ICH E6(R3) and the digital era. She is also Lead Editor of *Barnett's Good Clinical Practice: A Question & Answer Reference Guide*.

Agenda

Where We Started

The Journey Along the Way

What Lies Ahead

“Sometimes transformation begins not because what we have is wrong, but because what comes next requires us to think differently.”



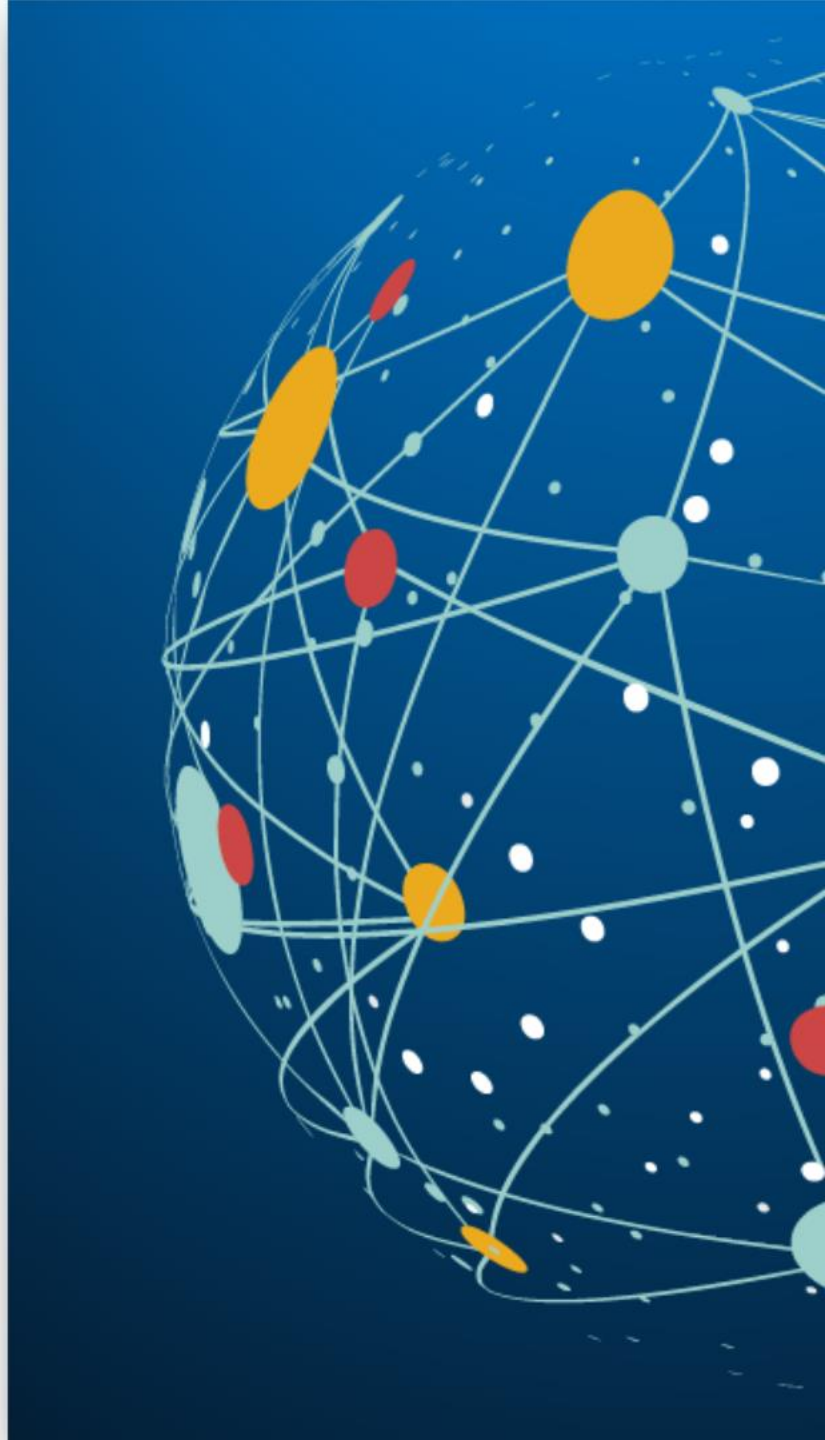
Where We Started

What We Were Seeing

Two years ago, we already knew the environment around the TMF was changing.

- **CLINICAL RESEARCH** — Studies were becoming more complex, distributed, and digitally enabled.
- **REGULATION** — Oversight, risk, data integrity, and essential records were moving to the forefront.
- **TECHNOLOGY** — Evidence was increasingly generated and retained across interconnected clinical systems.
- **THE EVIDENCE ITSELF** — The TMF could no longer be thought of only as a collection of documents.

What we did not yet know was how far that thinking would take us.

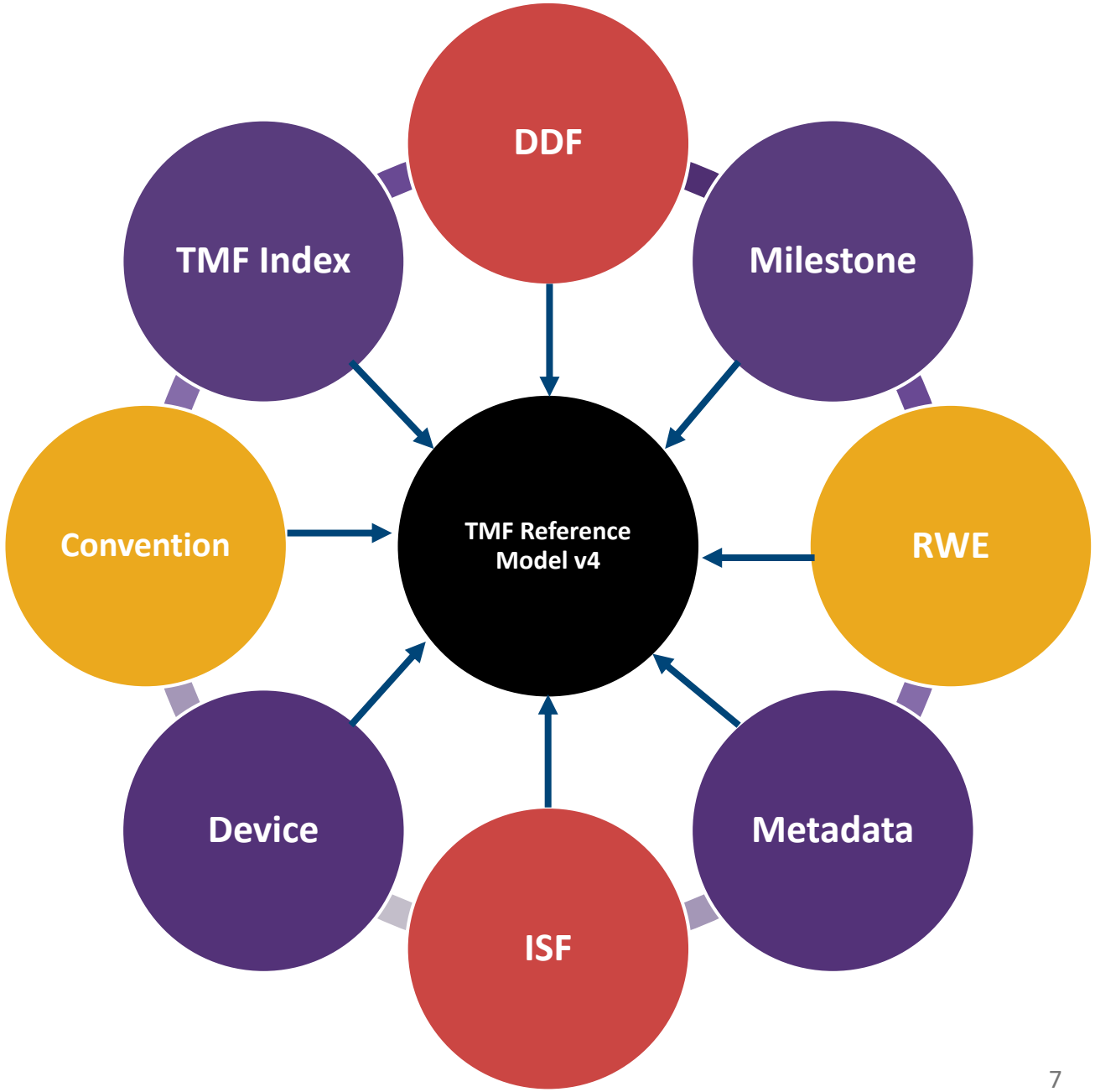


A vision for the Future:

~~TMF Reference Model v4~~

TMF Standard Model V1

Those goals haven't really changed. Our understanding of what it would take to achieve them has.



We Realized We Were Building Something Bigger

This was not about combining sub-artifacts from 3.3.1, RWE, ISF, and Device.

It was about building a Standard aligned to ICH E6(R3), the digital era, and the evidence needed to demonstrate compliance.

In many ways, we were being asked to predict the future — and make it usable.



We were not just reorganizing records.
We were designing the future of evidence.

Digital Change Was Reshaping the Evidence



Connected Trials

More systems
More partners and sites
Evidence across repositories



Evidence Beyond Files

Structured data
Electronic workflows
System-generated records



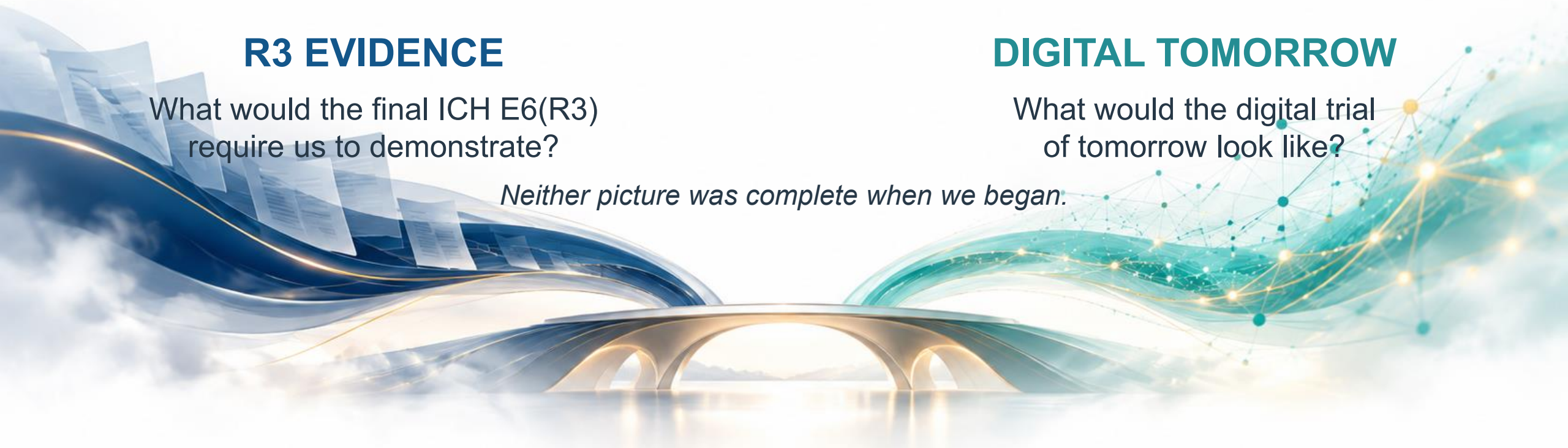
Evolving Capabilities

Interoperability
Automation
Today: AI-enabled eTMFs

The evidence needed a common language,
even as the digital future kept evolving.

A Standard for R3 and Digital Tomorrow

This was not about revising TMF RM 3.3.1.



R3 EVIDENCE

What would the final ICH E6(R3) require us to demonstrate?

DIGITAL TOMORROW

What would the digital trial of tomorrow look like?

Neither picture was complete when we began.

ONE STANDARD

A shared language for clinical trial evidence

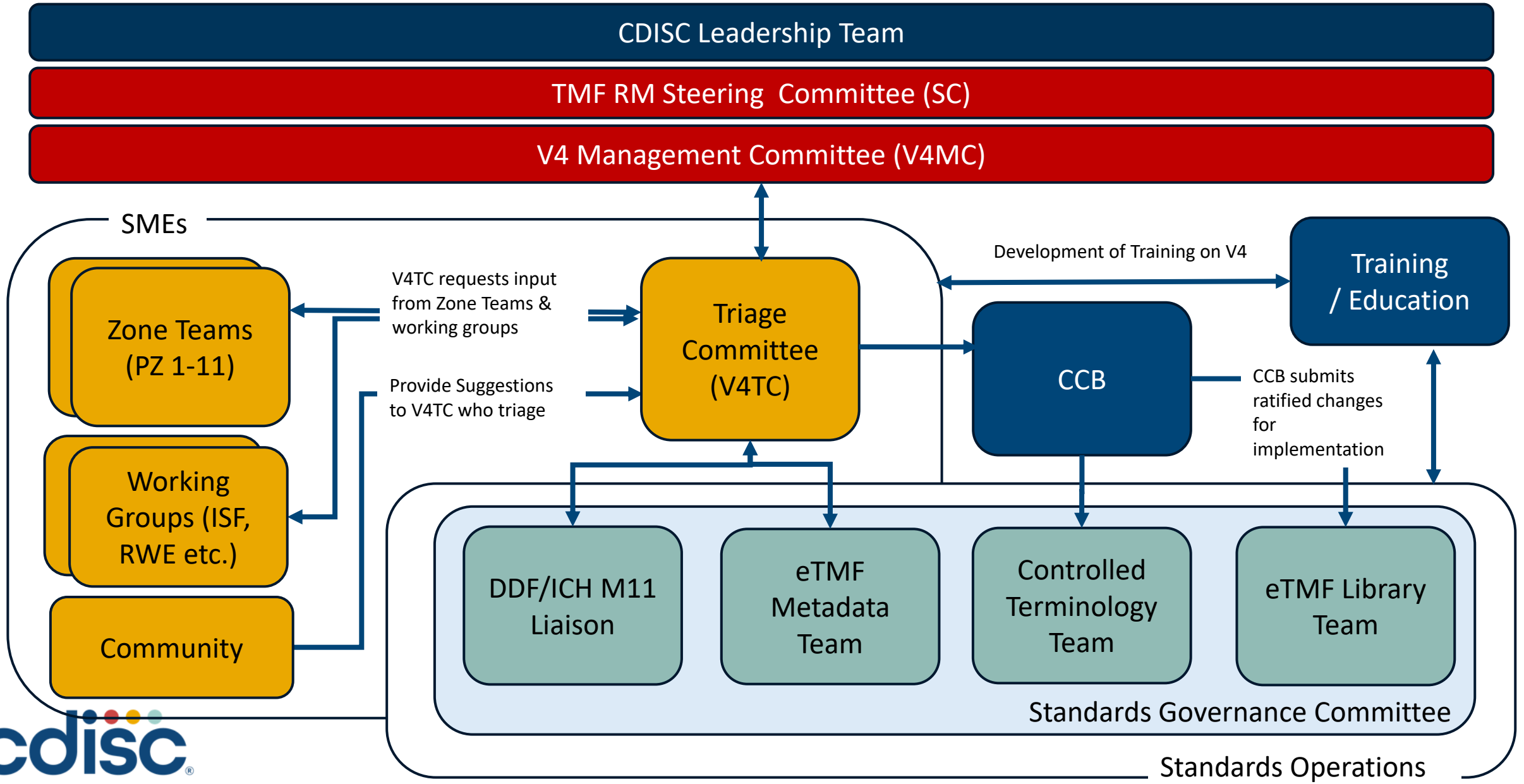
A foundation for R3 and digital tomorrow

Today, that future includes eTMFs that can harness AI.

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The Journey Along the Way

~~V4~~ V1 org chart



From Many Contributions to One Coherent Standard

Our experiences and expertise shaped consistent decisions

INDUSTRY INPUT

Zone teams

Working groups

Subject matter experts

Community review

↔

THE TEAM THAT BROUGHT IT ALL TOGETHER



Paul Fenton
Montrium



Lisa Mulcahy
Mulcahy Consulting



Gillian Gittens
TransPerfect



Steph Viscomi
Kymera Tx



Sydney Stamper
Just in Time GCP



Donna Dorozinsky
Just in Time GCP

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ONE STANDARD

Common definitions

Consistent rules

Shared structure

We brought the diverse inputs together, resolved inconsistencies, and gave the Standard a Shared Picture

Industry supplied the ingredients. Our team brought clarity, consistency, & structure

A Standard Needed a Set of Standards

We could not solve every question independently.



Before we could build the Standard, we had to build the rules for building the Standard.

Define the Evidence

The Rules That Shaped the Standard

One industry Standard, not many organizational models.

Common structure and language, flexible across sponsors, CROs, sites, technologies, and operating models.

Organize around the purpose of the evidence.

Classify by what the record demonstrates, rather than where it has traditionally been filed.

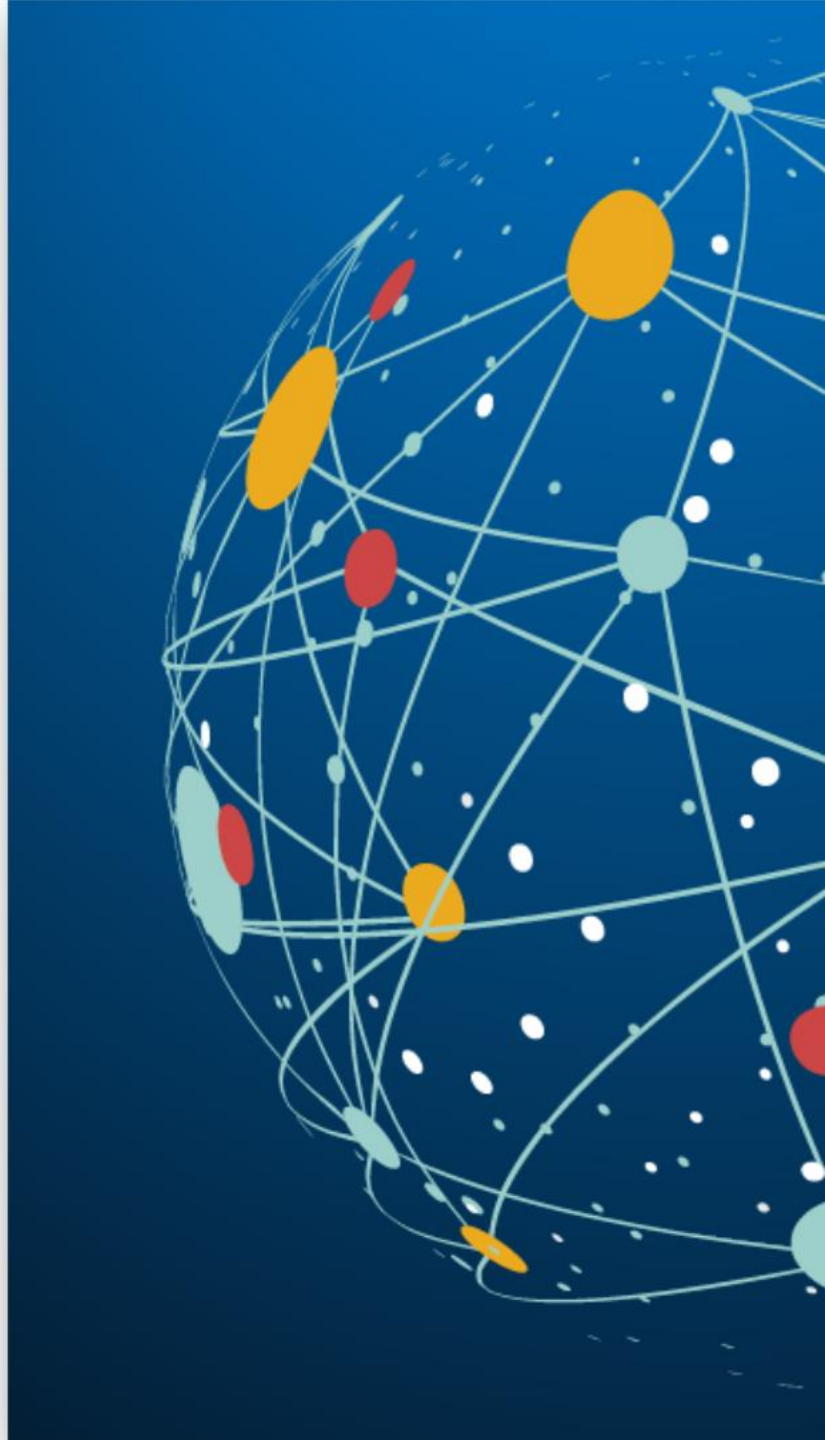
A Record Type represents distinct evidence.

Create a separate Record Type only when the evidence is meaningfully different. *Industry terminology*

Preserve distinctions that change evidentiary meaning.

Consolidate without obscuring meaningful differences in purpose, responsibility, lifecycle, or evidence.

Start with the evidence—not the artifact.



Separate Evidence from Context

The Rules That Shaped the Standard

Same evidence, different context.

Use metadata for differences in trial, country, site, party, role, or other context when the underlying evidence is the same.

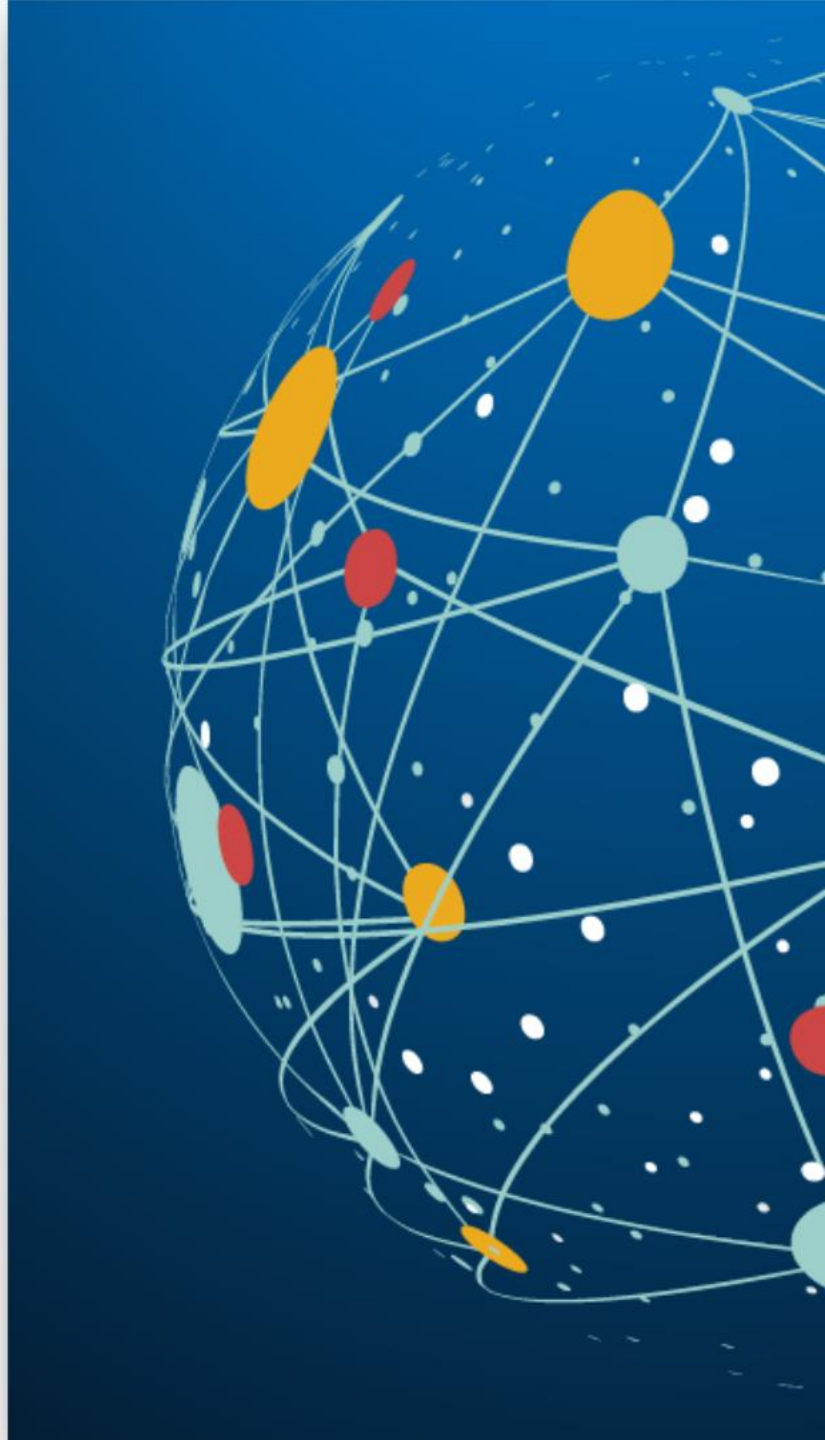
Format does not determine classification.

A log, report, form, listing, system output, or dataset does not automatically require a different Record Type.

Describe what the evidence represents.

Purpose/Descriptions explain why the record exists and what it demonstrates. They are not filing instructions, SOPs, or implementation rules.

Record Type tells us what the evidence is.
Metadata and implementation tell us more about it.



Build a Standard That Can Last

The Rules That Shaped the Standard

Record Groups represent enduring business activities.

They should remain meaningful as technologies, processes, organizations, and record formats change. *ICH E6 R3 terminology*

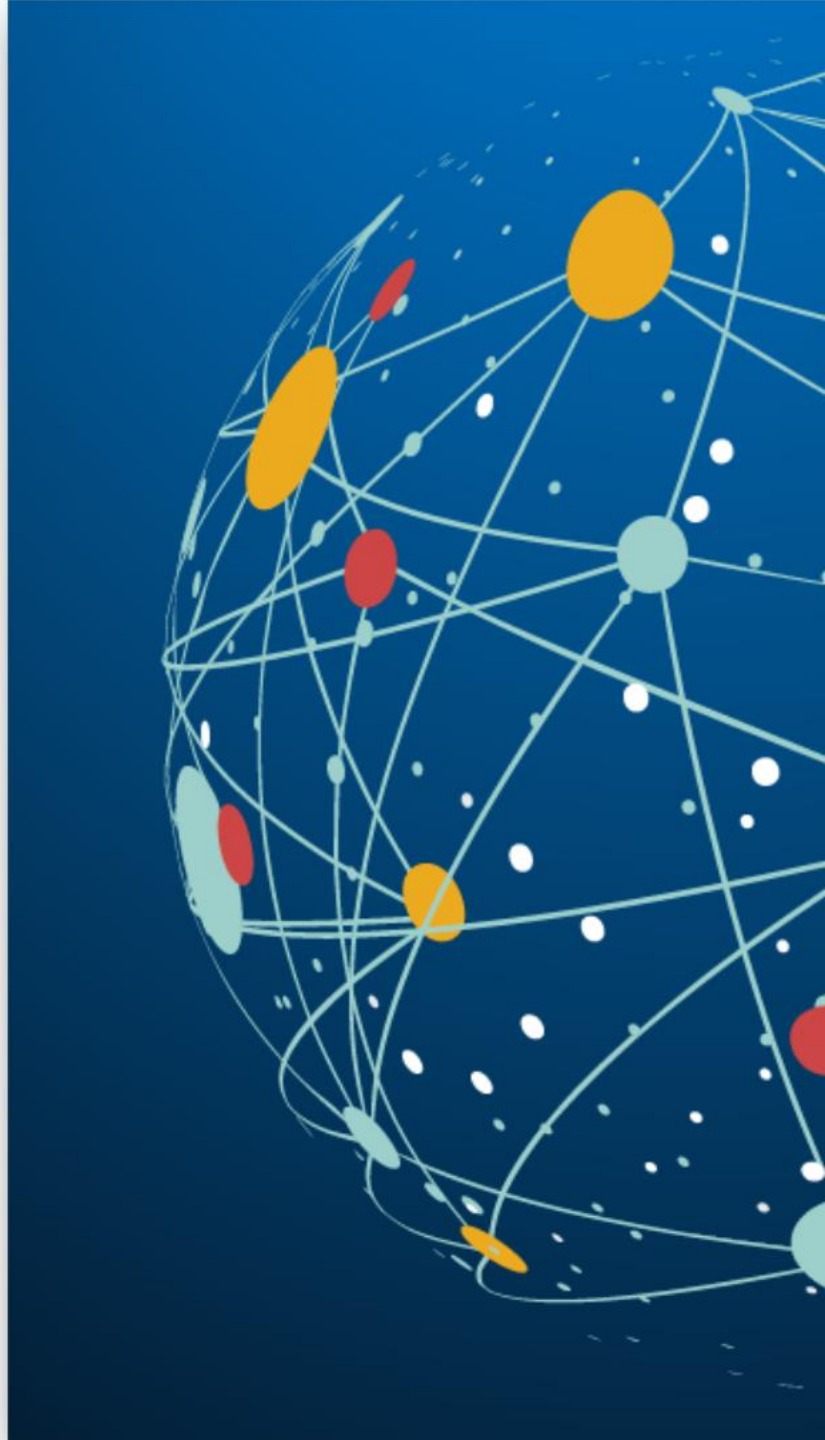
Build for the digital future.

Keep the Standard technology-, system-, product-, and format-neutral so it can represent records, structured data, and evidence in clinical systems.

The study determines applicability.

The Standard defines the evidence universe. Inclusion in V1 does not mean a Record Type is required for every study.

The Standard must remain stable even as the way we create and manage evidence changes.



Standardizing Purpose/Description

A shared definition of evidence each Record Type represents

Begin with why the record exists.

State the activity, responsibility, or outcome the record demonstrates.

Use a consistent writing structure.

“To describe…” “To provide evidence…” “To provide a record…”

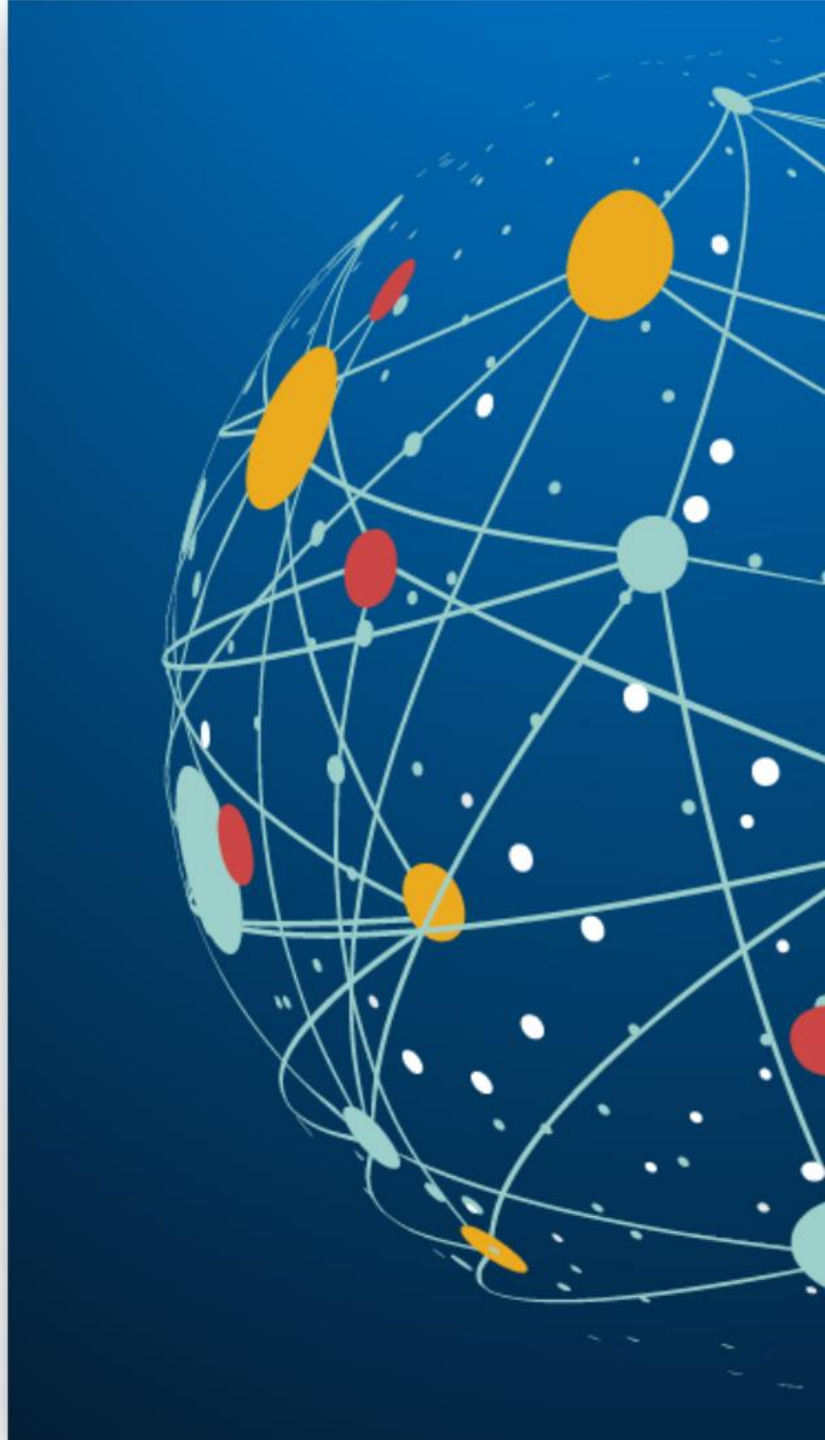
Define the evidentiary boundaries.

Clarify what belongs within the Record Type. Keep filing instructions, SOPs, and metadata rules separate.

Apply a shared language.

Use “trial” and “record” consistently, with concise, globally applicable, technology-neutral wording.

We standardized what the record means, not just what it is called.



Communications, Notes to File, and Meetings

Classification follows the evidence

Communications have no single filing place.

File each communication under the Record Type for the evidence of the activity, decision, or oversight it represents.

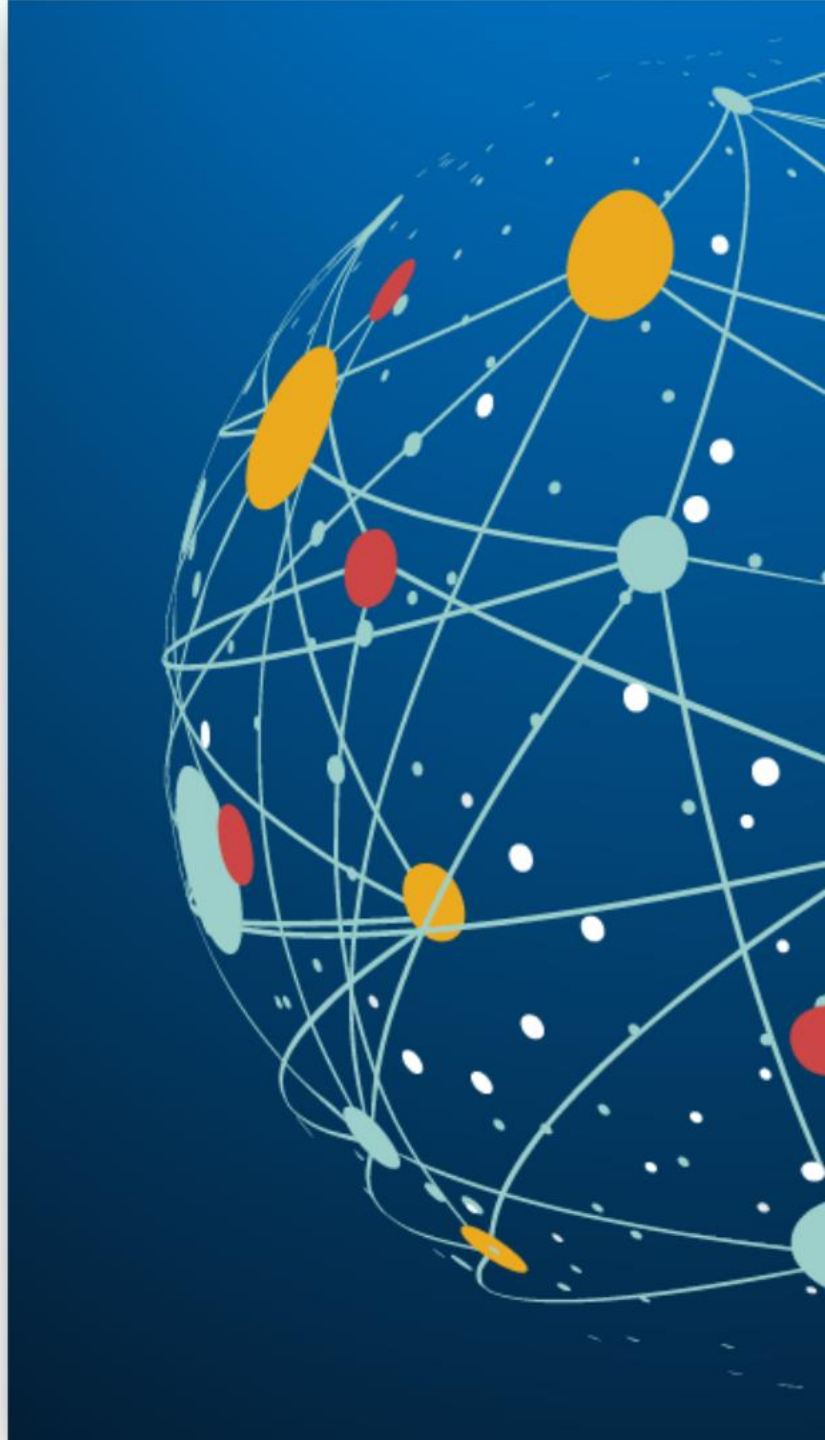
Notes to File follow the same principle.

Classify by what the note demonstrates, rather than simply the event or occurrence it describes.

Meetings are critical evidence.

With the Industry Advisory Group, we identified potential meetings and created specific Record Types to represent their evidence.

Classify each record by the evidence it represents.



Provisional Metadata - DRAFT

For information only, not finalized required fields

ICF

ICF distinctions add context to the evidence without requiring a separate Record Type for every variation.

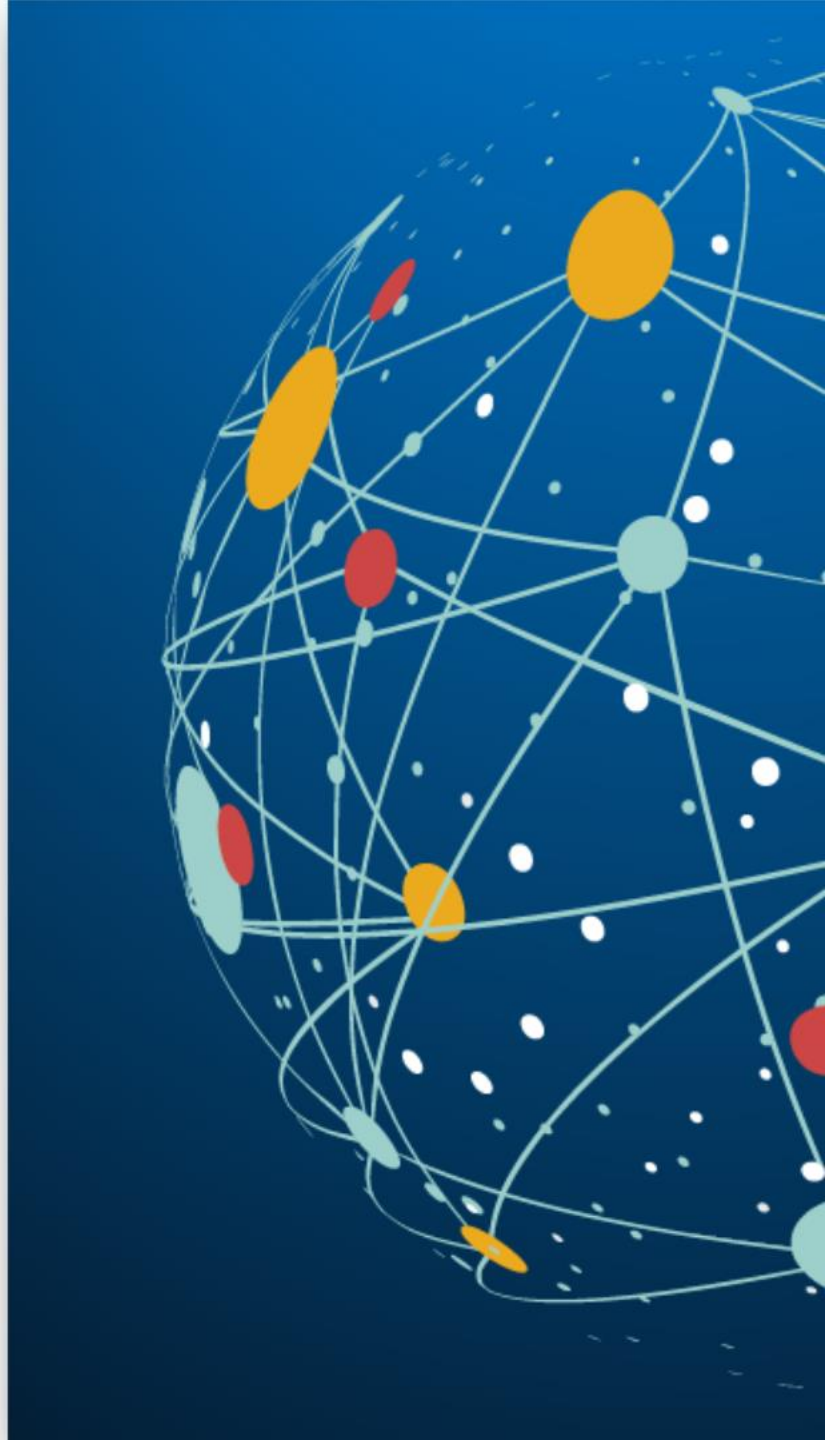
Committees

Committee type adds context. Shared evidence can use the same Record Type across different committees.

Pharmacologic / Medical Device / IVDR

Trial or product context helps distinguish applicability while preserving shared Record Types for the same evidence.

Record Type identifies the evidence.
Provisional metadata explains the distinctions.



Right Turn / Left Turn

Different choices can still lead to the same objective.



Progress Since July

TMF Standard Model V1

JULY

Structure shared with vendors

Zones
Record Groups
Record Types

SINCE JULY

Purpose/Descriptions
Integrated and standardized

Specialized content
Integrated ISF, RWE, Medical Device, and IVDR

Dating Conventions
Developed and standardized

R3 evidence mapping
Mapped every Record Type to R3

THIS PAST WEEK

Steering Committee review

Submitted this past week



The structure now carries standardized content and links to R3 evidence.

What Lies Ahead

Community Release for Review

TMF Standard Model V1

RELEASE DATE

OCTOBER

19

Community review

Included in the release

Zones, Record Groups, Record Types

Purpose/Descriptions

Dating Convention

RWE, ISF, IVDR, Medical Device

ICH E6(R3) mapping



Provisional metadata is not final

Sample Prompt to Compare TMF Reference Model 3.1.1 to TMF Standard Model V1

I have attached the CDISC TMF Standard Model V1 and my company's current TMF index. Please compare the two and show me how my index differs from V1.

1. Crosswalk every artifact in my index to a V1 Record Type. Label each mapping as Direct (one-to-one), Split (one artifact becomes several V1 types), Consolidated (several artifacts become one V1 type, with differences captured as metadata), Partial (V1 covers only part of the artifact), or Gap (no V1 home). Before labeling anything Partial or Gap, read the V1 Purpose/Description and apply V1's format-neutral principle, since many items that look missing fit a broader Record Type.

2. List the V1 Record Types with no match in my index. Separate genuinely new evidence from finer-grained versions of records I already have.

3. Summarize the key structural differences: zone or group moves, artifacts that split or consolidate, places where V1 uses metadata instead of separate types, and new areas such as eClinical systems.

4. Keep in mind that V1 intentionally has no catch-all correspondence or note-to-file type, and that a Record Type being listed does not mean it is required for every study.

5. Summarize what adopting V1 would change for my company, including filing rules, eTMF configuration, system integrations, completeness tracking, and training.

Please deliver an Excel workbook with the crosswalk, the unmatched V1 types, and the impact summary, plus a short plain-language summary of the most significant differences. Ask me any clarifying questions before you start.

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Finalizing the Standard

TMF Standard Model V1

FINAL PHASE

Finalize metadata

Incorporate CDISC definitions from NIH

Integrate community feedback

→

Q1 2027

Final public review

→

APRIL 2027

Planned release



Community feedback will inform the final Standard

This Is a Transformation

The Standard changes how we define and manage clinical trial evidence.

Transformation is hard.

Start planning now.

Make transformation a leadership priority.



Thank You!



Questions?

