Getting Ahead of the Curve:
Strategic Planning for the TMF SM V1 Implementation

Presented by:
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Kathleen Mellet, Associate Consultant, Just in Time GCP

Meet the Speakers

Steph Viscomi

Title: Director, Clinical Documentation and TMF

Organization: Apellis Pharmaceuticals

Steph is a TMF expert who has spent a greater part of her career developing and implementing TMF departments, improving organizational TMF culture, building CRO partnerships and striving for inspection readiness. She has held roles within both the CRO and sponsor settings providing her a broad knowledge base to apply to the evolving TMF industry. She also is a member of the TMF Project Management Committee and Triage Committee. Steph currently leads a TMF team who handles the TMF day-to-day activities across vendors and CRO's at Apellis Pharmaceuticals.

Kathleen Mellet

Title: Associate Consultant

Organization: Just in Time GCP

Contract Project Manager for CDISC TMF – Serving as a member of the v4 Project Management Team, providing coordination across project planning, stakeholder engagement, and delivery activities to ensure alignment with project goals and timelines

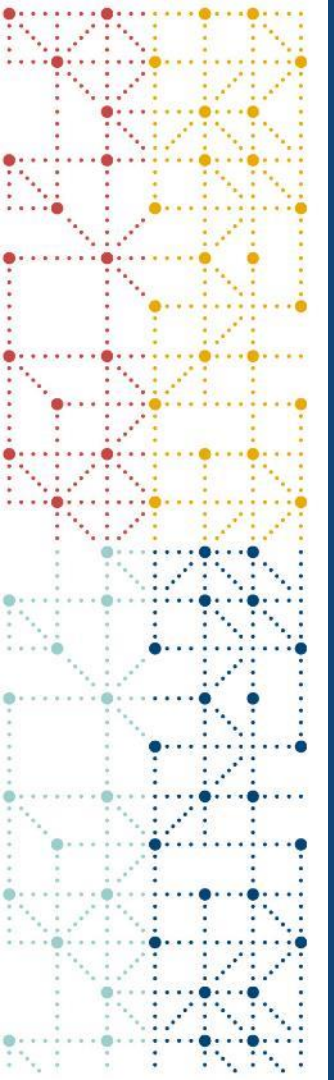
Associate Consultant with JiT, supporting TMF implementation and optimization initiatives for clients across processes, systems, and training.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. Applying the Standard
2. Key Changes in TMF Standard v1
3. Strategic Planning Considerations
4. Q&A



Understanding & Applying the TMF Standard Model

Applying the v1 Standard

The TMF Standard Model v1 is designed to:

- Align with regulatory requirements and provide a common framework for industry

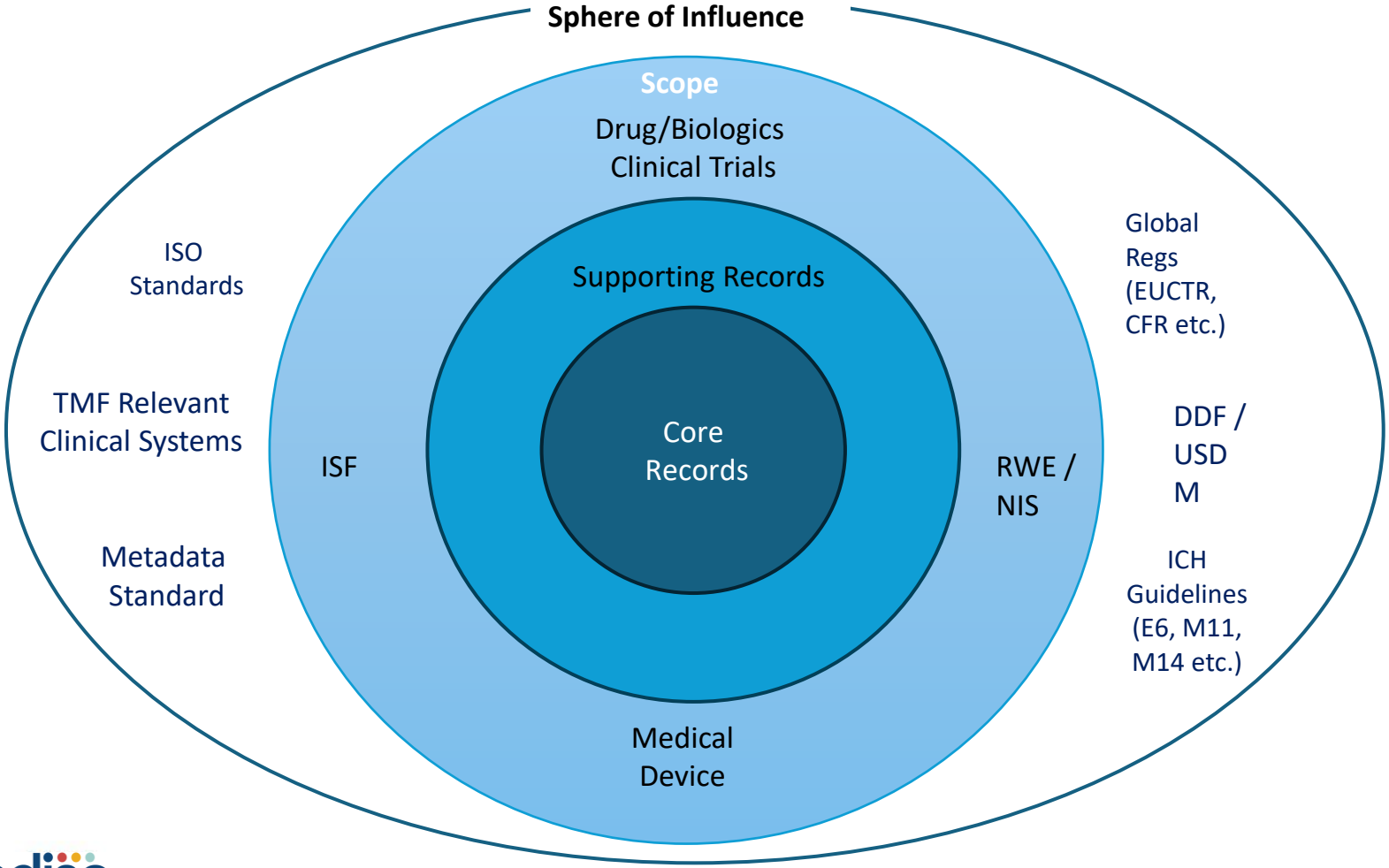
But the Standard is not prescriptive:

- It does not cover every scenario or replace company-specific practices

Each company must still:

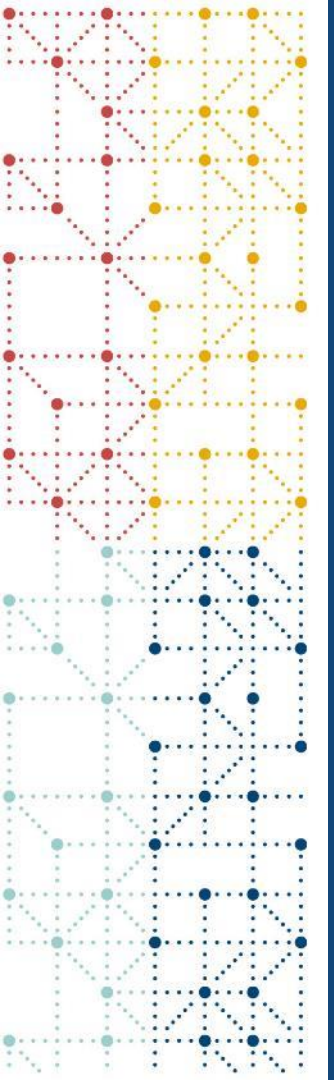
- Define best practices that fit their own processes or organizational gaps not addressed by regulations or v1

Think of the Standard as the foundation, and your company has to build the house


Sphere of Influence
Scope
Drug/Biologics
Clinical Trials
Supporting Records
Core
Records
ISO
Standards
TMF Relevant
Clinical Systems
Metadata
Standard
ISF
RWE /
NIS
Global
Regs
(EUCTR,
CFR etc.)
DDF /
USD
M
ICH
Guidelines
(E6, M11,
M14 etc.)
Medical
Device

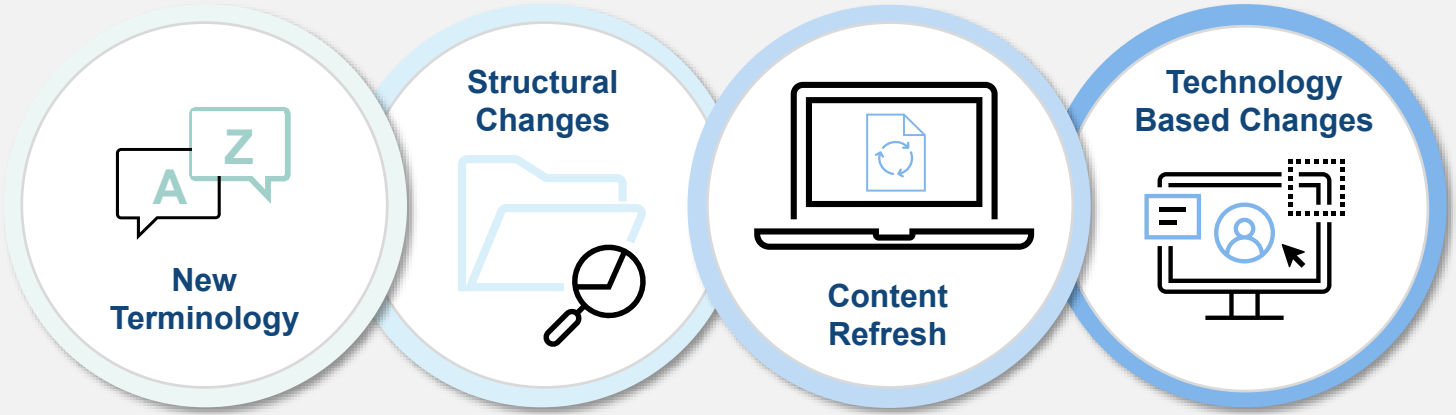
TMF Standard v1 expectations vs Internal Process

	TMF Standard v1 will define:	*Company Specific Process will define:*
Records	✓ Standard list of Record Groups & Types (aligned with regulations)	❑ Custom Record Groups and Record Types ❑ The process for collection, filing, and oversight of records
Filing Hierarchy	✓ Standard filing locations within the TMF Zones & Sections	❑ Define locations for any custom Record within the standard TMF hierarchy ❑ Identify filing repositories for records (e.g., eTMF, RIM, Safety Database)
Metadata	✓ Base metadata required for compliance	❑ Application of metadata and any use of custom metadata
uIDs	✓ Unique 5-digit ID for each standard Record Type (to support interoperability)	❑ uIDs for custom Records ❑ Process for migrating and maintaining systems



Key Changes in TMF Standard Model v1

Overview of Changes



The upcoming changes fall into four main categories, each with a different level of impact on existing TMF structures and processes

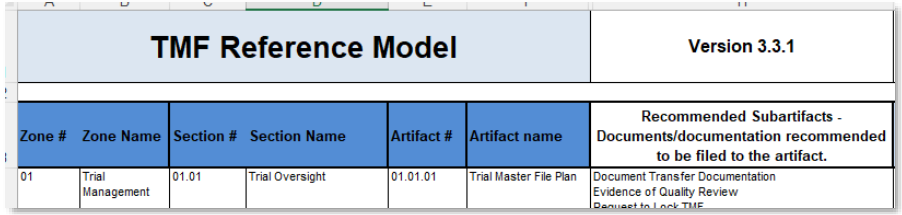
New Terminology

What's Changing?

- The new term *"Record Group"* will replace "Artifact" to highlight collections of related records
- The new term *"Record Type"* will replace *"Subartifact"*

Why is this Changing?

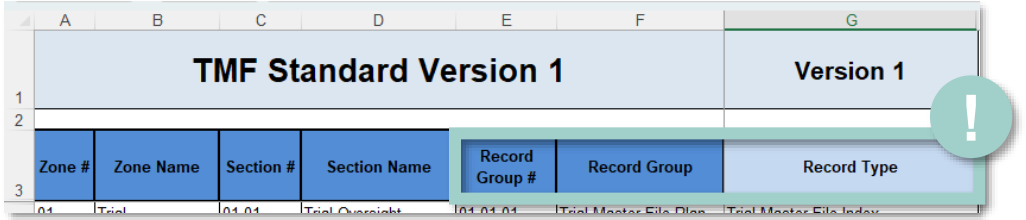
- To better reflect how records are organized and managed across the TMF
- Align with regulatory expectations



TMF Reference Model						Version 3.3.1
Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Recommended Subartifacts - Documents/documentation recommended to be filed to the artifact.
01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	Document Transfer Documentation Evidence of Quality Review Request to Lock TMF

What does this mean for the community?

- SOPs, training, tools, and systems should adopt **Record Group** and **Record Type** consistently



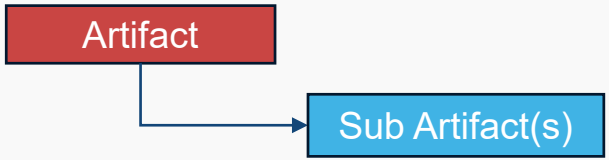
TMF Standard Version 1						Version 1
Zone #	Zone Name	Section #	Section Name	Record Group #	Record Group	Record Type
01	Trial	01.01	Trial Oversight	01.01.01	Trial Master File Plan	Trial Master File Index

Structural Changes

What's Changing?

- ***The TMF structure is evolving.*** Instead of being organized around artifacts, the model will be structured by Record Groups and Record Types, requiring a redesigned framework.

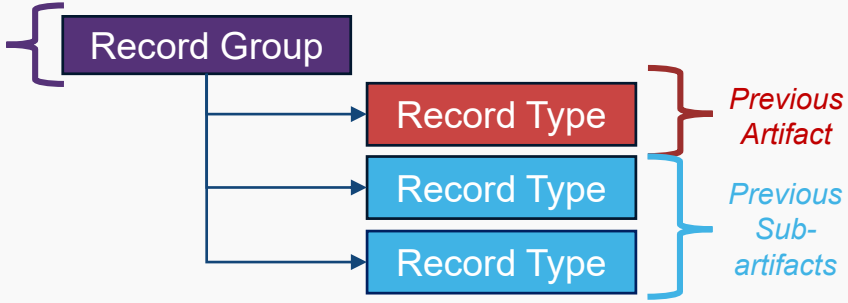
Existing Structure



The existing structure provides only a single layer of organization.

Updated Structure

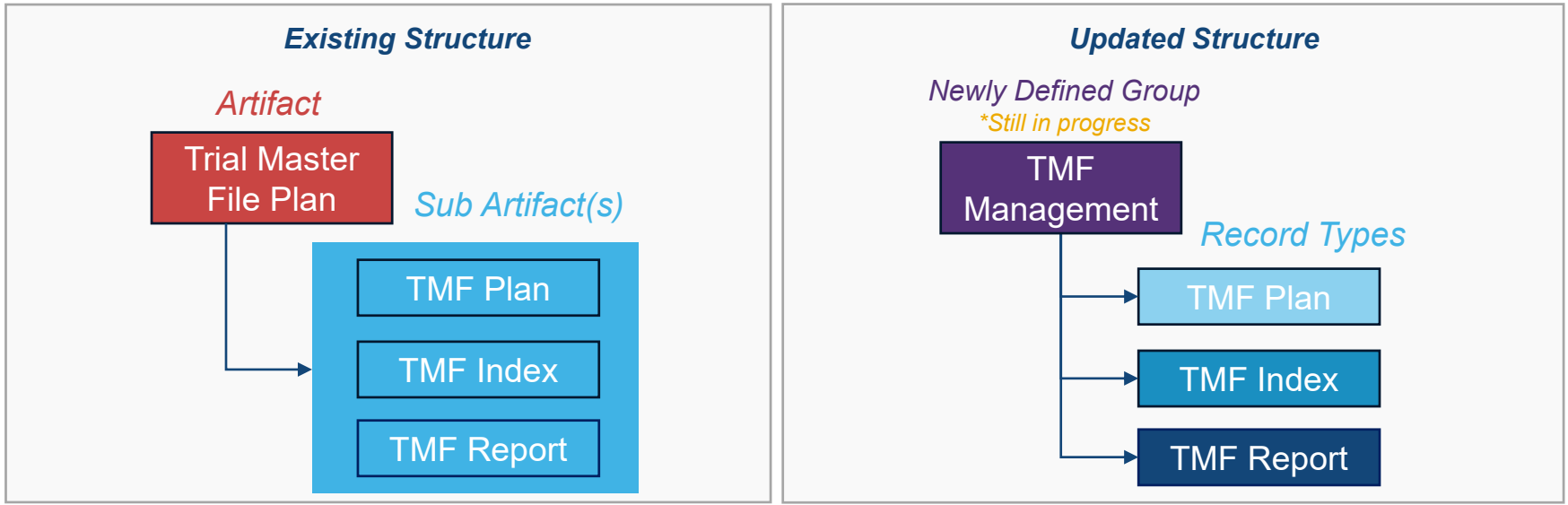
Record Groups provide a layer of organization like Zones/ Sections. Filing happens at the Record Type level, not the Group level.



- ✓ **Improved Filing Accuracy:** Clearer filing locations ensure each record is filed in the correct place, reducing the risk of missing records
- ✓ **Enhanced Searchability:** Users can now search and filter by both Record Group and Record Type, making it easier to quickly locate specific records.

Structural Changes (cont.)

Structure Change Example: 01.01.01



Content Refresh

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** due to lack of use.

Why is this Changing?

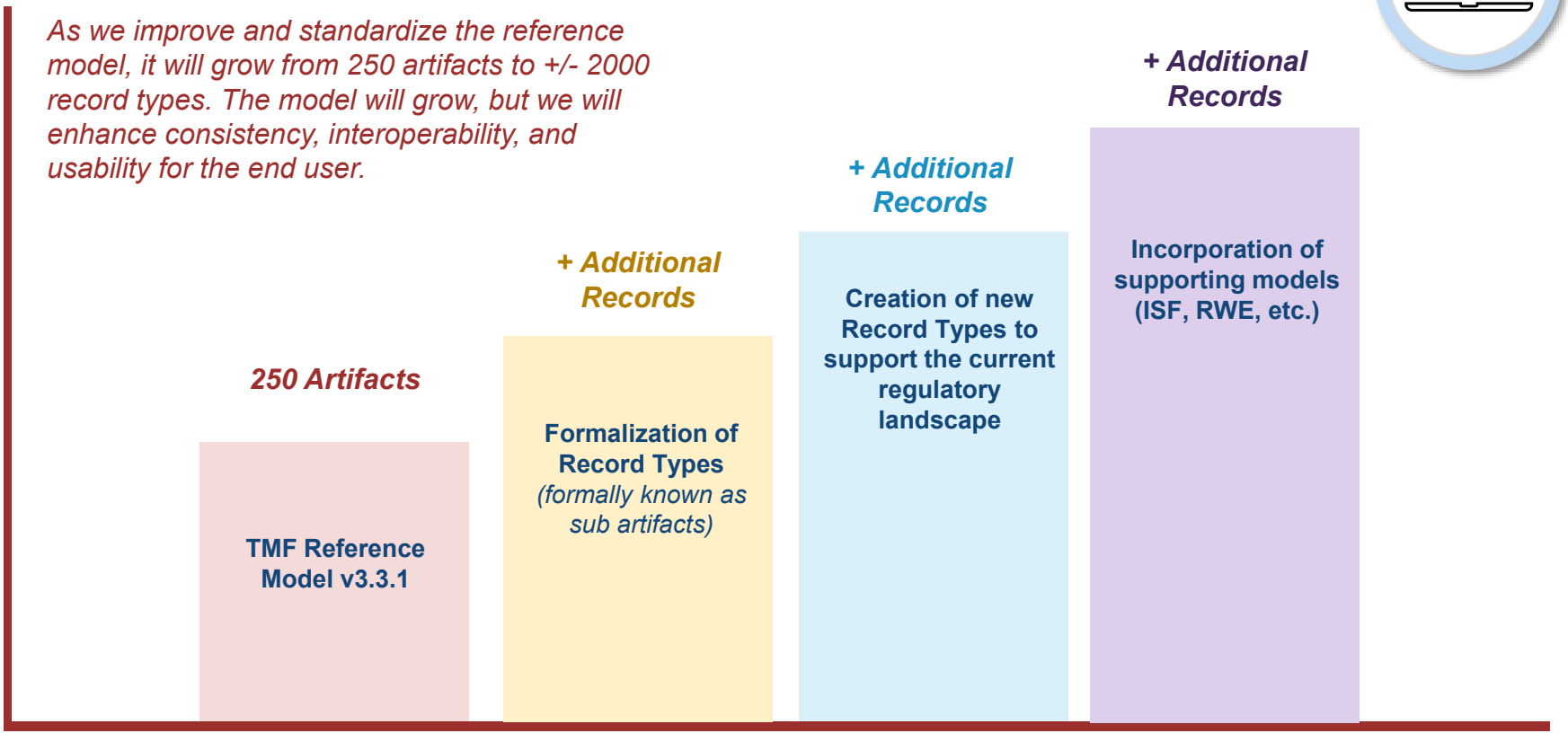
- With the introduction of ICH E6 R3, EU CTR, and other developments, additional record types are required
- Goals:
  - Stronger foundation for indexing, searching, and compliance
  - Streamlined reviews and inspections with related records grouped together

DRAFT subject to change

Zone #	Zone Name	Section #	Section Name	Record Group #	Record Group Name	Record Type
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Document Transfer Documentation
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Evidence of Quality Review
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Request to Lock TMF
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Trial Master File Plan
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Trial Master File Index
01	Trial Management	01.01	Trial Oversight	01.01.01	TMF Management	Trial Master File Report

Content Refresh (cont.)

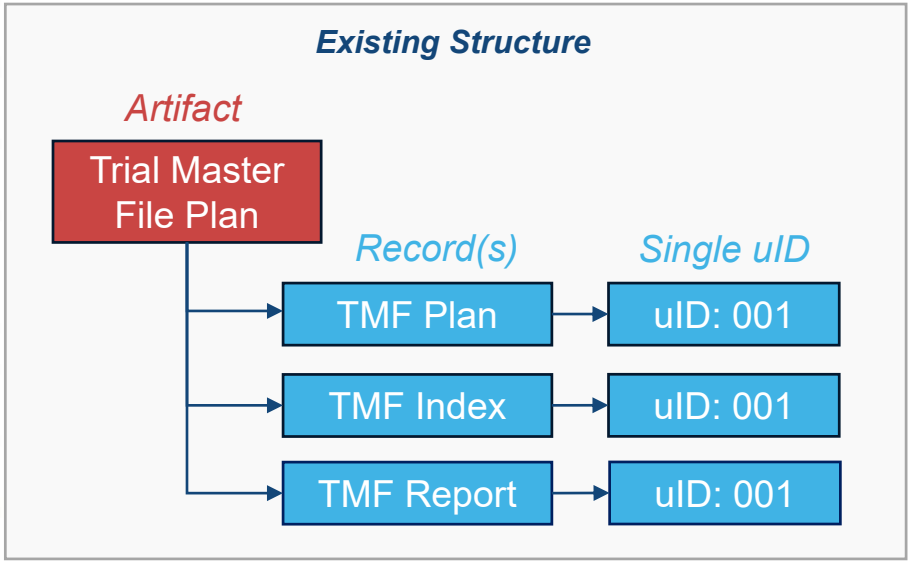
As we improve and standardize the reference model, it will grow from 250 artifacts to +/- 2000 record types. The model will grow, but we will enhance consistency, interoperability, and usability for the end user.

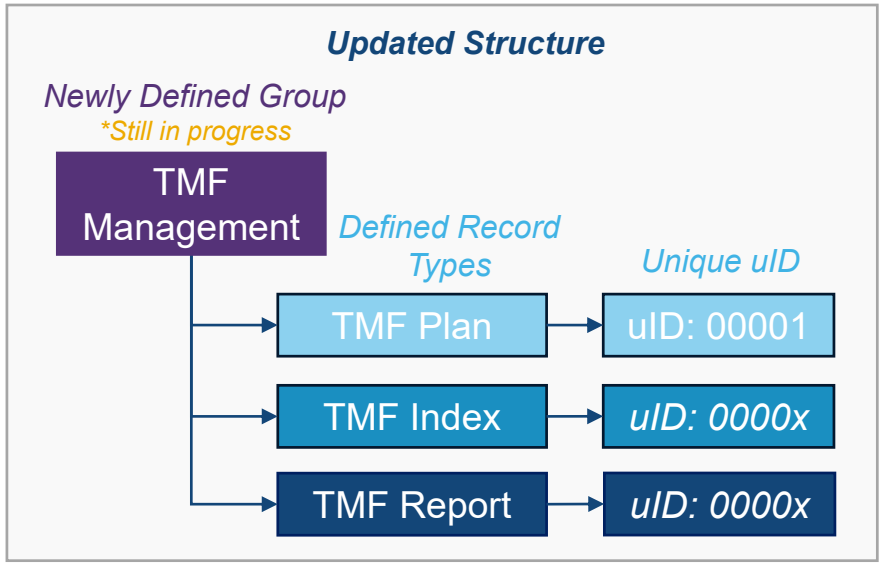


Technology Based Changes

What's Changing?

- uIDs will now be **5 digits** (previously 3)
- uIDs assigned at the **Record Type** level





*Numbers to be defined

Technology Based Changes (Cont.)

Defining metadata rules for V1

What's changing?

- A core list of metadata will be formally defined to support the new standard and achieve the following goals:
  - Enable consistent usability across records.
  - Improve interoperability between systems.
  - Promote a more standardized, aligned approach

! *eTMF vendors across the industry have provided recommendations to technical changes along with a list of minimum harmonized metadata suggestions*

Strategic Planning Considerations

What do these changes impact?

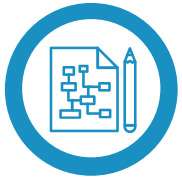
Impact Overview: *The upcoming changes in terminology, structure, content, and technology will require updates to core records and processes.*

Key activities include:

- Aligning procedures with **new terminology** and **workflows**, **re-mapping filing structures**, and **adding or retiring Record Groups/Types** as needed.
- **Development of new procedures** to ensure alignment with the creation and collection of new record types.
- Change management **activities of training, guidance**, and **system updates** will be essential to ensure consistent adoption and ongoing inspection readiness.

TMF SOPs

TMF Index



Forms & Templates

Study Plans, Forms & Templates

Training

External & Supporting Party Documents

Pre v1 Release Checklist

Build Awareness & Foundations *(Q4 2025 – Q1 2026)*

Change Management efforts begins now, by building knowledge and awareness to prepare your teams

- ❑ Educate teams on **why v1 is coming** (organization, compliance, inspection readiness)
- ❑ Share high-level summaries of changes (Record Groups/Types vs. artifacts)

Assess Current State *(Q2 2026 – Q4 2026)*

Review **existing SOPs, Study Plans, Index, Forms, and Templates** for alignment and gaps

- ❑ Identify areas where terminology, filing structure, or workflows will be impacted
- ❑ Document dependencies (e.g., eTMF vendor timelines, training needs)

Plan Ahead *(Q3 2026 – Q4 2026)*

Build a process and timeline for implementation

- ❑ Draft an **internal transition plan**: who owns what updates, key milestones
- ❑ Engage with **eTMF vendors** to understand their roadmap for v1 support

Post v1 Release Checklist

Update Documentation *(Q1 2027 – Q2 2027)*

Engage a cross-functional team to update the documents. Involve all relevant groups to manage risk and ensure adoption of the new processes and documentation.

- ❑ Revise **SOPs** with new terminology, structures, and workflow expectations
- ❑ Update **Study Plans** to reflect filing structure, required artifacts, and roles
- ❑ Refresh **Forms & Templates** (QC checklists, guidance, etc.) with updated terms

Adapt the TMF Index *(Q1 2027 – Q2 2027)*

Update and streamline the TMF structure by reorganizing content and ensuring alignment with v1 standards

- ❑ Re-map zones, sections, and artifacts into Record Groups/Types
- ❑ Add new categories, retire outdated ones, and confirm consistency with v1

Post v1 Release Checklist (continued)

System Readiness *(Q1 2027 – Q2 2027)*

Ensure the eTMF system is configured and validated to support v1 structures and reporting. Your eTMF vendor will have already received a **v1 pre-release** to support configuration updates

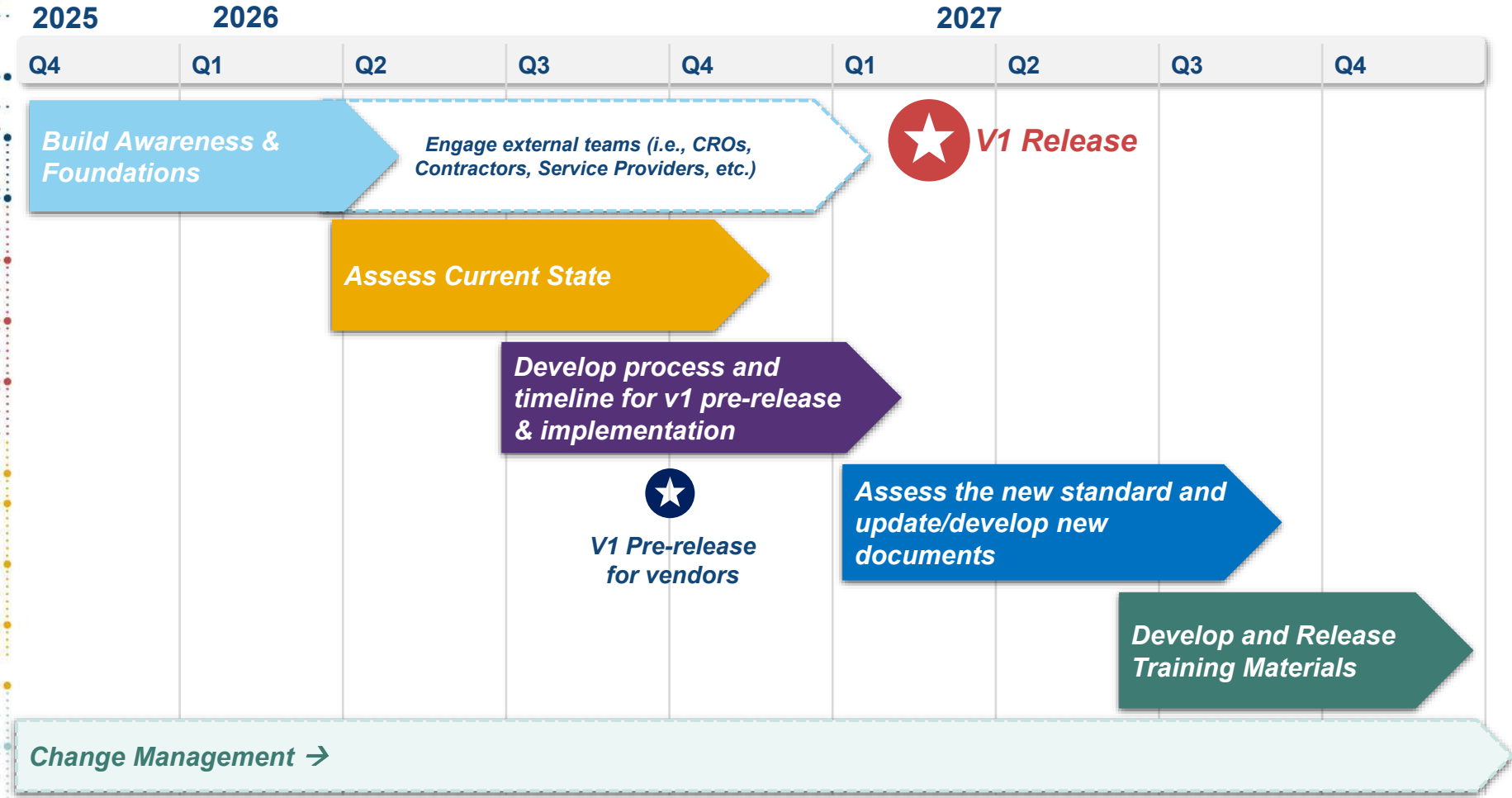
- ❑ Work with eTMF system providers to implement v1-compliant structures
- ❑ Validate **system configurations, metadata fields, and reports**

Training and Roll out *(Q3 2027– Q4 2027)*

Roll out **targeted training** on the updated TMF structure and processes, providing role-specific guidance and **gathering feedback to refine adoption**.

- ❑ Deliver updated training on new terminology, structure, and filing expectations
- ❑ Provide role-specific guidance (e.g., filing staff, QC reviewers, study managers)
- ❑ Monitor early use and capture feedback for refinement

V1 Implementation Roadmap



Thank You!

Don’t forget to meet us tomorrow morning in the **Ocean Room at 8 am** for breakfast

Fuel up and dive into all things v1!