# The TMF Reference Model
# General Meeting December 2025

Presenters:

- Paul Carter, CEO, Montrium; Chair, TMF RM Steering Committee
- Karen Roy, Consultant, CDISC; Outgoing Chair, TMF RM Steering Committee
- Joanne Malia, Sr. Director, Development Records Mgmt, Regeneron, TMF RM Steering Committee Member
- Dawn Niccum, EVP, Quality Assurance, inSeption Group, TMF RM Steering Committee Member
- Liz Farrell, Director, Compliance and TMF Oversight (CaTO), Agios Pharmaceuticals, Inc, TMF RM Steering Committee Member
- Bryan Souder, GCTO TMF Head, Merck & Co., Inc., TMF RM Steering Committee Member
- Steph Viscomi, Director, Clinical Documentation and TMF, Apellis Pharmaceuticals, TMF SM v1 PM Team Member
- Kathleen Mellet, Associate Consultant, Just in Time GCP, TMF SM v1 PM Team Member
- Lisa Mulcahy, Mulcahy Consulting LLC, TMF RM Steering Committee Member
- Gillian Gittens, Sr. Director, eClinical Strategy & Solutions, TransPerfect Life Sciences, TMF RM Steering Committee Member

TRIAL MASTER FILE

TMF

powered by
cdisc

REFERENCE MODEL
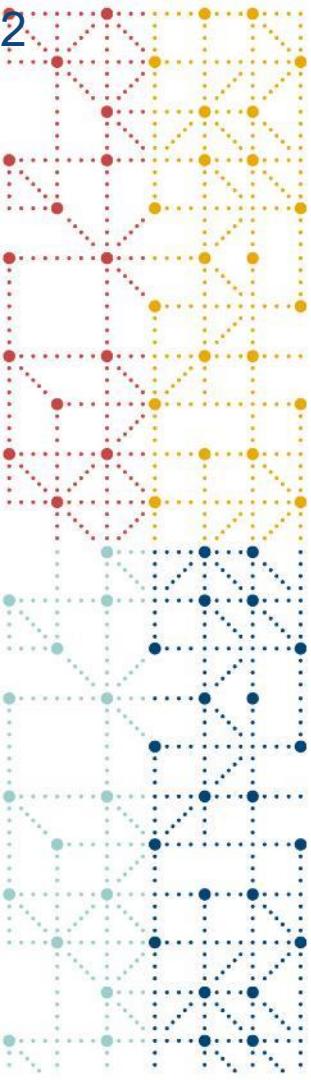
Housekeeping

Housekeeping

You will remain on **mute**

Housekeeping

Submit questions at any time via the Questions tool on your Teams app

# Housekeeping
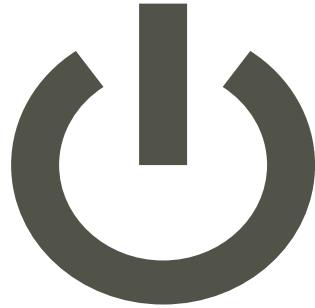
Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength

Housekeeping


Webinar Recording

A recording of this webinar will be available in the Public Webinar Archive on the CDISC website.

Agenda

1. Opening Remarks
2. Events & Interchange
3. Asia Pac Community Update
4. Risk Initiative
5. ISF Initiative
6. Education Committee
7. New TMF Workstreams
8. Work Group Coordination
9. TMF SM V1 Updates
   - TMF SM V1 Implementation Planning
   - TMF SM V1 Q&A Panel
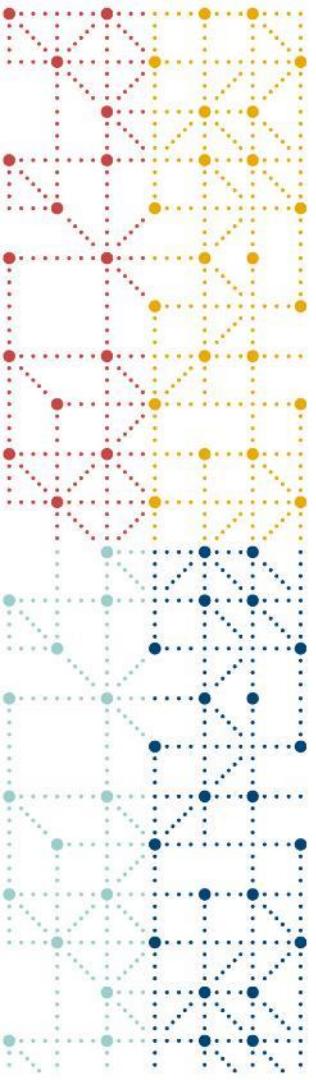
Opening Remarks

2025 – What a Year!

Paul Carter, CEO, Montrium; Chair, TMF RM Steering Committee

Very Active Volunteers!

- 300+ Volunteers on v1
- Several new sub-teams
- Many reviews going on with zone teams and triage committee
- New initiatives starting up in 2026

New Identity

- Move from Reference to Standard
- From V4 to V1
- Digital vision
- Important changes ahead...

ICH E6 R3 Finally Arrived!

- Increased focus on:
    - Risk proportionality and QbD
    - Computerized Systems
    - Essential Records
    - Oversight

Too Much Fun!
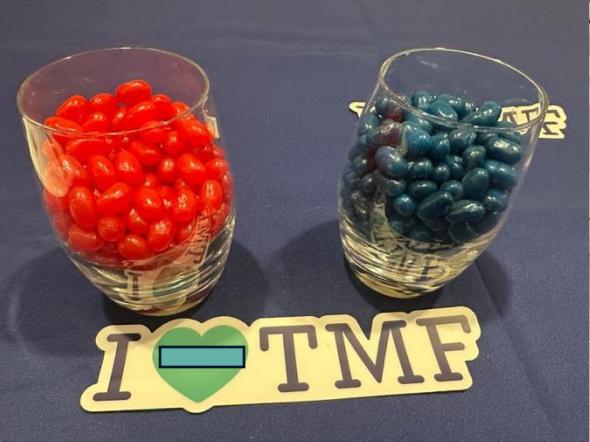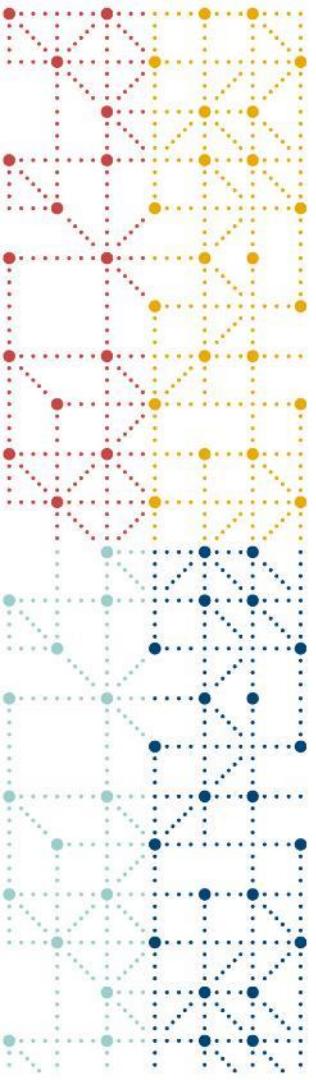
Events & Interchange Update

Karen Roy, Consultant, CDISC; Outgoing Chair, TMF RM Steering Committee

Huge success with over 150 TMF attendees, TMF training on fundamentals, 10 TMF exhibitors and excellent talks

![CDISC 2026 Europe Interchange banner]
The Future is Connected:
Standards and AI Powering Digital Transformation

2026 Europe Interchange

Main Conference: 20-21 May | Trainings & Workshops: 18, 19, & 22 May

MILAN

Call for abstracts closes 9th January 2026

Early bird special ends 20th March 2026

https://www.cdisc.org/events/interchange/2026-cdisc-europe-interchange

The Future is Connected:
Standards and AI Powering Digital Transformation

2026 US Interchange

Main Conference: 5-6 October | Trainings & Workshops: 7-9 October

DENVER

Call for abstracts opens in March

https://www.cdisc.org/events/interchange/2026-cdisc-us-interchange

INDIA CDISC DAY
All the Insights, All the Impact, All in One Day!

Details to follow …. Host applications open

Other Relevant Conferences

- Health Sciences Records & Archives Association (HSRAA) Bi-Annual Conference, Manchester, UK
04-Mar to 06-Mar-2026

- Institute of Clinical Research (ICR) Conference, Birmingham, UK
13-Apr to 14-Apr-2026

CDISC Coordinating Committee (3C)

A CDISC Coordinating Committee (3C) supports CDISC initiatives in a specific region of the world and to provide regional feedback to the central CDISC organization.

Interchange Planning Role

- Sponsor/Exhibitor suggestions and support
- Develop Abstract Topics
- Join Monthly and Bi-weekly Calls
- Lead in Abstract Selection
- Develop Conference Agenda
- Actively Participate at Event Onsite as a Host, Logistics Support, Sponsor & Session Chair

Responsibilities of 3C

- Develop an action plan each year

- Provide support in organizing and promoting CDISC Interchanges and events

- Support scheduling and content of authorized training and other educational seminars

- Support CDISC Education to identify individuals who may wish to be trained to be CDISC authorized instructors.

- Liaise with regulatory authorities, other appropriate institutions and standards developing organizations

- Assist in the creation and coordination of any User Groups in the region

- Report main activities and opportunities in the region to CDISC Leadership Team Liaison

2026-29 Global CDISC Coordinating Committees (3Cs) Call for Nominations

Fill out the form on CDISC.org website   **Nominations Due: Friday, 12 December**

➢ Europe, India, Japan, Korea, and North America.
  - Nominees must be from a CDISC member organization.
  - Members will serve a three-year term from January 2026 - January 2029.

Submit two brief documents for each nominee:
1. Nominee's brief CV
2. Brief letter expressing your involvement/experience with CDISC and your interest in the above position

*Details on the 3C Charter on CDISC website under: Bylaws & Policies | CDISC

If you have questions, please reach out to Karen (kroy@cdisc.org) or Kathleen (kmellet@cdisc.org)
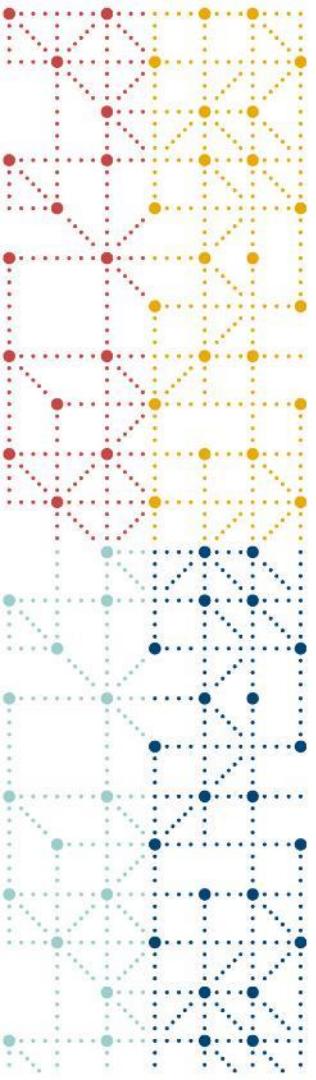
Asia Pac Community Update

Paul Carter, CEO, Montrium; Chair, TMF Steering Committee

APAC Community Update: China

- Huge interest in sharing TMF information with the Community in China!
- CDISC Marketing is engaged to ensure that posts from CDISC will go to the CDSIC User Group reps for posting on WeChat (China's tool for social media posts).
- First TMF WeChat Post went out end of November via promoting the General Meeting.

A presentation on TMF Standard Model V1 was made at the CDISC Shanghai User Group activity on 05-Dec-2025 by Wei Du. No. of attendees: 70 onsite + 140 online TMF session received the most questions! A few outstanding are below:

1. Program level files are not part of Standard, so where to file them?
2. Is there any naming convention recommendations under Standard Model? What's the difference between those under Standard vs Reference Model?
3. How / Through what platform can the community be providing feedback to the draft / in-progress Standard Model?

Update from JP TMFers community

- Miyuki and Yuto attended the US interchange and made a presentation about **the Japanese TMF community** in a session "Culture and Engagement" (Chaired by Steph Viscomi)

- **Topis presented:**
  - History/voices from JP TMFers
  - Current activities
  - Other regional communities(Denmark and Italy)
  - A case study : Safety document management
  - Way to move forward

Thank you @CDISC TMF HQ for the great opportunity!

Update from JP TMFers community

- **We successfully finished our 2nd F2F workshop on 3 Dec 2025**
- **Topics Covered**
  - ✓US interchange feedback by Yuto
  - ✓ISF reference model : **presented by Matt Lowery**
  - ✓Risk based TMF management/Risk Tool : **presented by Sarah Hitching**
  - ✓EDL/TMF completeness management : Group Discussion

- **Next F2F WS will be…10Jun2026 to cerebrate international TMF day? –TBD!**

JP Community X-ray

of total members = 42 from 24 organizations

Type	Organization(A-Z)
Pharma	Asahi Kasei Pharma, Chugai, Merck KGaA, KM Biologics, Novartis, SinoCellTech & Sumitomo Pharma
CRO	A2 Healthcare, CMIC, Linical & PPD-SNBL
Service Provider	Agatha, ClinCloud, CRS cube & Medidata
Academia	Juntendo University, Keio University Hospital, Kobe University Hospital, Nagoya University Hospital and Translational Research Center for Medical Innovation
Consulting	inSeption Group
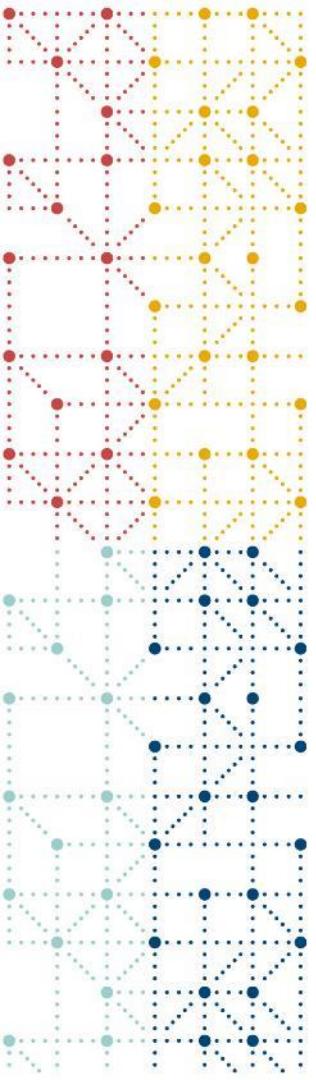
Risk Initiative

Joanne Malia, Sr. Director, Development Records Mgmt, Regeneron, TMF RM Steering Committee Member

Availability – CDISC Website

White Paper

Risk Tool

Status

- Risk Tool v. 1.0 availability ; we want your feedback to improve

- Training Workstream to present at All Hands , early 2026
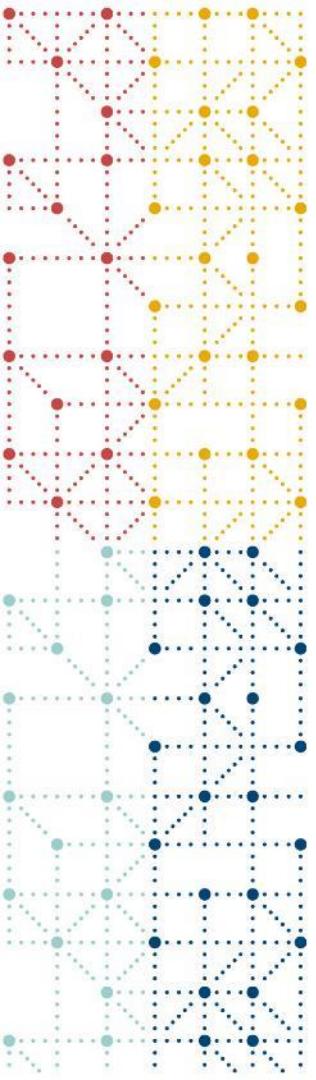
ISF Initiative

Dawn Niccum, EVP, QA, inSeption Group, TMF RM Steering Committee Member

Jamie Toth, Sr. Director, BeOne Medicines, Incoming Chair Elect to TMF RM Steering Committee Member

ISF Reference Model Release 1.0

- The Investigator Site File (ISF) structure standardizes document organization at the site level, improving efficiency, collaboration, and compliance and is aligned to the TMF RM 3.3.1.
- The Investigator Site File (ISF) structure was made available for public review in early July after 1.5 years of effort by the ~50 volunteers!

All public review comments resolved with a disposition; pending finalization/internal review with CDISC week of 09-Dec

Next steps:

- We will be holding training webinars in February – watch for the public launch and webinar communications!

Thank you!

- A **HUGE** thank you and congratulations to all of the members of the ISF Initiative!
- Especially Site co-leads Matt Lowery and Aryn Knight!
- 2 years in the making to get us this far!

ThePhoto by PhotoAuthor is licensed under CCYYSA.
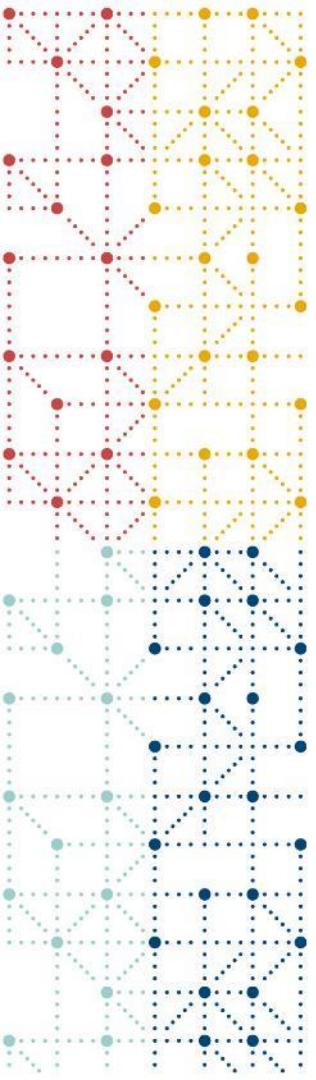
Education Committee

Dawn Niccum, EVP, QA, inSeption Group, TMF RM Steering Committee Member

Upcoming Courses

- Fundamentals of the TMF Reference Model, virtual – Jan 20-22, 2026
  - Not just for those brand new to TMF – offers comprehensive content of the lifecycle of managing TMF
  - Interactive, virtual course

- The Critical Role of Data Managers, Biostatisticians, and Programmers in Achieving TMF Excellence – Feb 3-5, 2026
  - Course has been expanded from 4 to 8 hours
  - Content focuses to records created and managed by Biometric Professionals
  - Both for Biometric Professionals and TMF professionals who support those groups
  - Interactive, virtual course

- Investigator Site File (ISF) Reference Model – Introductory Webinar – Feb 2026
  - Basic course to support the release of the ISF RM
  - Communications to the TMF Community of webinar date will be coming soon.

Training Roadmap

- Quality Check of TMF Records Online Course – Release planned for Q1/2 2026
- Advanced TMF training courses planned – development starting in 2026
- Additional focused online courses and webinars are being planned
- TMF SM V1 Course(s)
  - Including updates to existing courses
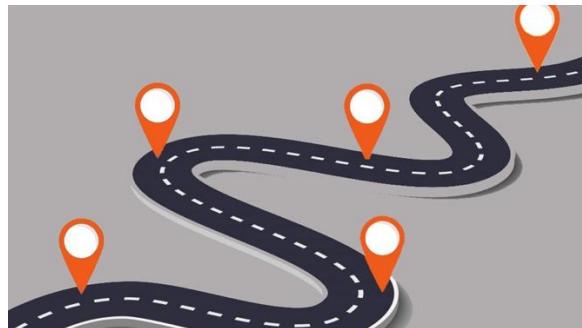
TMF RM Fundamentals Training Instructors
– Call for Trainers in Europe and Japan have been sent to Community

Trainers are to have the following:

- Broad TMF Experience
  - Strong background and involvement with the CDISC TMF RM
  - 5+ years of experience in clinical research at >2 companies, understanding and executing the full TMF lifecycle is a must
  - Involvement with cross-functional teams in their management of their TMF records
  - Risk-based TMF management and support of Health Authority Inspections
  - Technical proficiency with the CDISC TMF RM, TMF processes, TMF repositories/systems, and TMF archiving

- Training Experience
  - Demonstrated formal training on broad TMF management principles
  - Adult Learning principles
  - Needs Assessment of Training attendees
  - Facilitation of course and engagement of all levels of learners
  - Developing and leading practical exercises

Application for Instructions:
https://www.cdisc.org/form/authorized-instructor-application
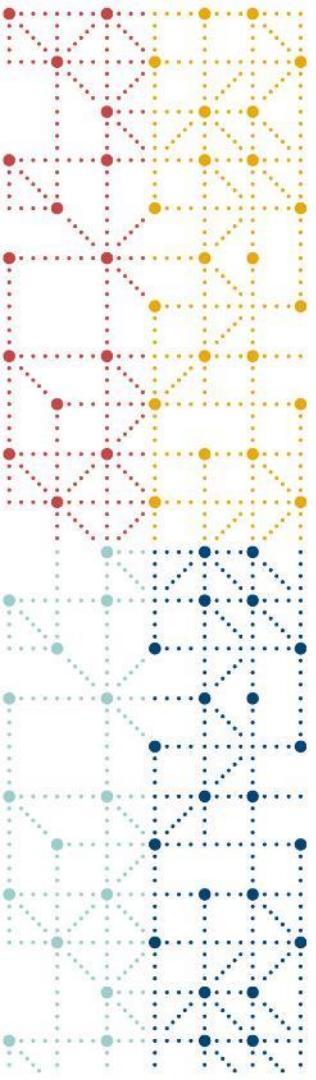
New TMF Workstreams

Liz Farrell, Director, Compliance and TMF Oversight (CaTO), Agios Pharmaceuticals, TMF Steering Committee Member

New Work Streams

In early November, call for Volunteers went out for 2 new work streams; overwhelming response of over 70+ volunteers for each!

TMF Plan Template 3.0
Steering Committee (SC) Liaison: Liz Farrell

This group will review and update the existing TMF Plan template to ensure alignment with regulatory expectations and current industry best practices.

Outreach
Steering Committee (SC) Liaison: Jamie Toth

This group will focus on gathering intel on opportunities for outreach, promoting awareness, understanding, and consistent use of the CDISC TMF Resources and Workstream products.

Next steps:

- Review of volunteers is underway.
- Volunteers will be notified of decisions soon...hopefully before 24-Dec.
- First meeting will be scheduled by end of January by SC Liaison and co-leads will be nominated from the group.
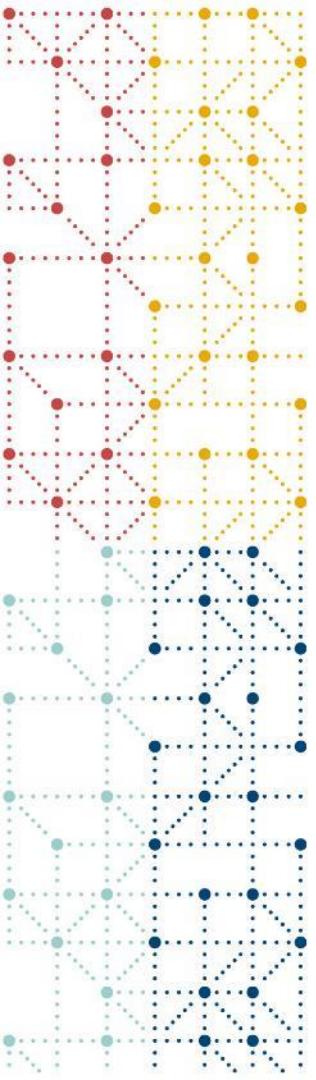
Work group Coordination

Bryan Souder, GCTO TMF Head, Merck & Co., Inc., TMF RM Steering Committee Member

Work Groups

* Steering Committe Liason
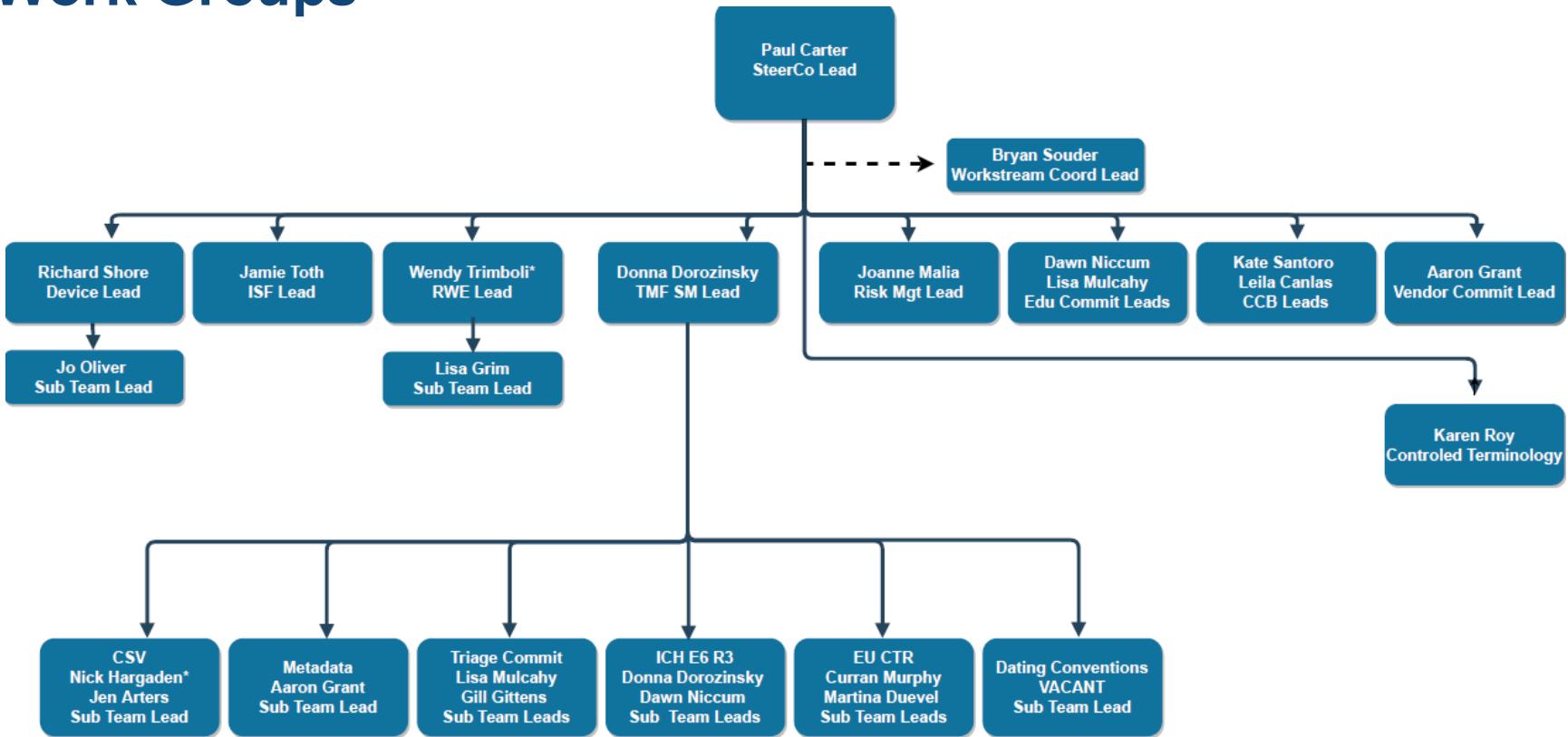
Workstream Coordination Lead:

MISSION STATEMENT

To foster seamless collaboration and alignment across a diverse network of volunteers by providing structured coordination, clear communication, and strategic guidance.

The goal is to empower every contributor, eliminate duplication of effort, and ensure that collective actions drive meaningful impact toward shared organizational objectives.

Workstream Coordination Lead Activities

Centralized Communication
- Utilize a single source of truth (e.g., shared dashboards, collaboration platforms like Teams or SharePoint).
- Schedule regular cross-workstream meetings to share updates and dependencies.

Clear Role & Responsibility Mapping
- Define who owns what and make this visible to all volunteers.
- Use RACI charts or similar frameworks to clarify accountability.

Dependency Management
- Identify interdependencies early and track them in a shared plan.
- Proactively resolve conflicts or overlaps between workstreams.

Transparent Progress Tracking
- Maintain a real-time status dashboard accessible to all stakeholders.
- Highlight risks and blockers openly so teams can collaborate on solutions.

Foster a Collaborative Culture
- Encourage knowledge sharing through forums or working groups.
- Recognize and reward collaborative behavior to reinforce the mindset
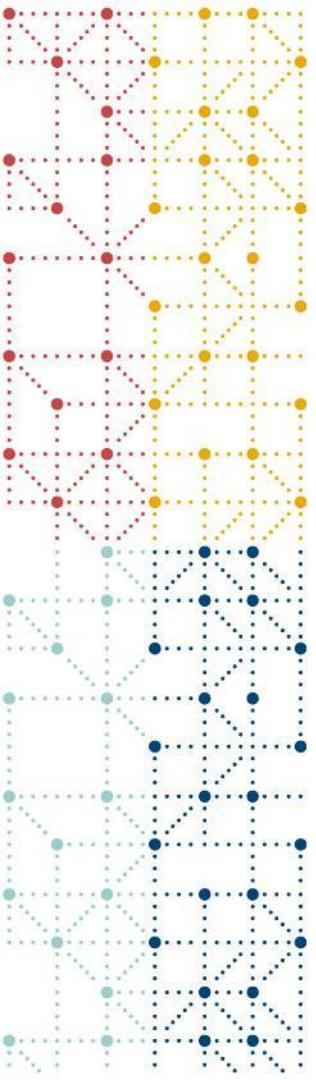
TMF SM v1 Updates

Paul Carter, CEO, Montrium; Chair, TMF RM Steering Committee

V1 is moving along!

- New record types defined by the following sub-teams :
  - ○ ICH E6 R3
  - ○ Computer Systems
  - ○ EU CTR

- Work underway for Medical Device and RWE

- Controlled terminology will start in the new year

- Zone teams currently reviewing initial proposed record types from sub-teams and community feedback

- Consolidated list of record types will be compiled in readiness for the definition of record groups

- Metadata team is getting underway following vendor baseline compilation

EMA GCP IWG Meeting,
EMA Headquarters, Amsterdam Nov 24th 2025

- CDISC TMFSM Presentation well received by the inspectors and guests

- Several questions on the 2000+ artifacts and how they would be used

- Questions on the implication of sites in the new standard

- Presentation by the eClinical Forum group on a framework for essential records required after system decommissioning

- Presentation by Torsten Stemler, Head of the GCP Inspection Unit, BfArM: Focus should be on curation rather than just the collection of essential records

- We aim to present an update next year to the EMA and will be actively pursuing opportunities to engage with MHRA, FDA and PDMA moving forward
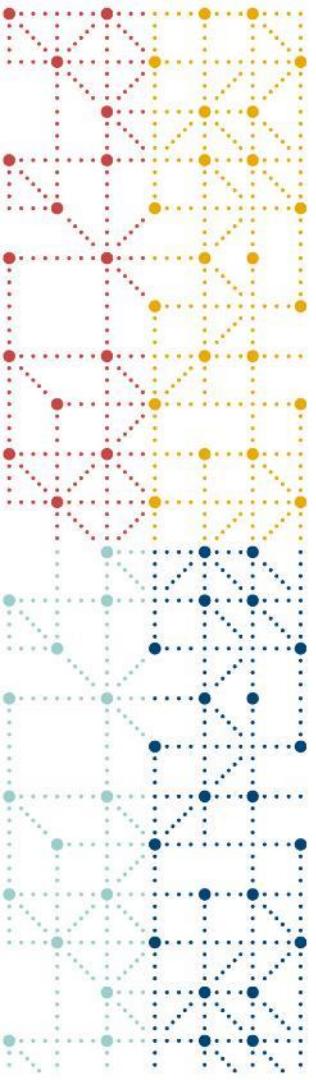
Strategic Planning for the TMF SM V1 Implementation

Steph Viscomi, Director, Clinical Documentation and TMF, Apellis Pharmaceuticals, TMF SM v1 PM Team Member

Kathleen Mellet, Associate Consultant, Just in Time GCP, TMF SM v1 PM Team Member

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

ISO Standards

Global Regs (EUCTR, CFR etc.)

TMF Relevant Clinical Systems

Supporting Records

Core Records

ISF

RWE / NIS

DDF / USDM

Metadata Standard

ICH Guidelines (E6, M11, M14 etc.)

Medical Device

TMF
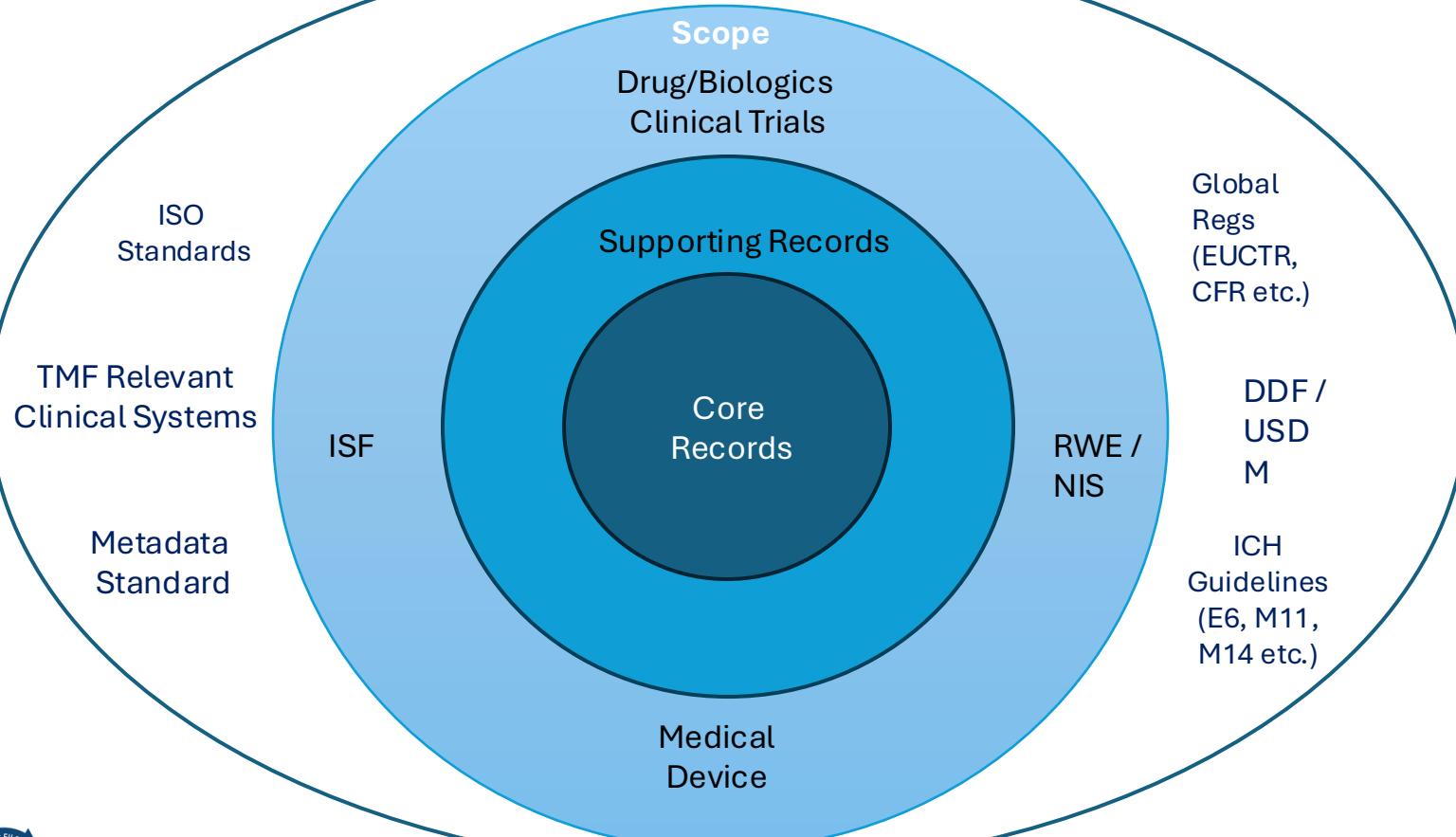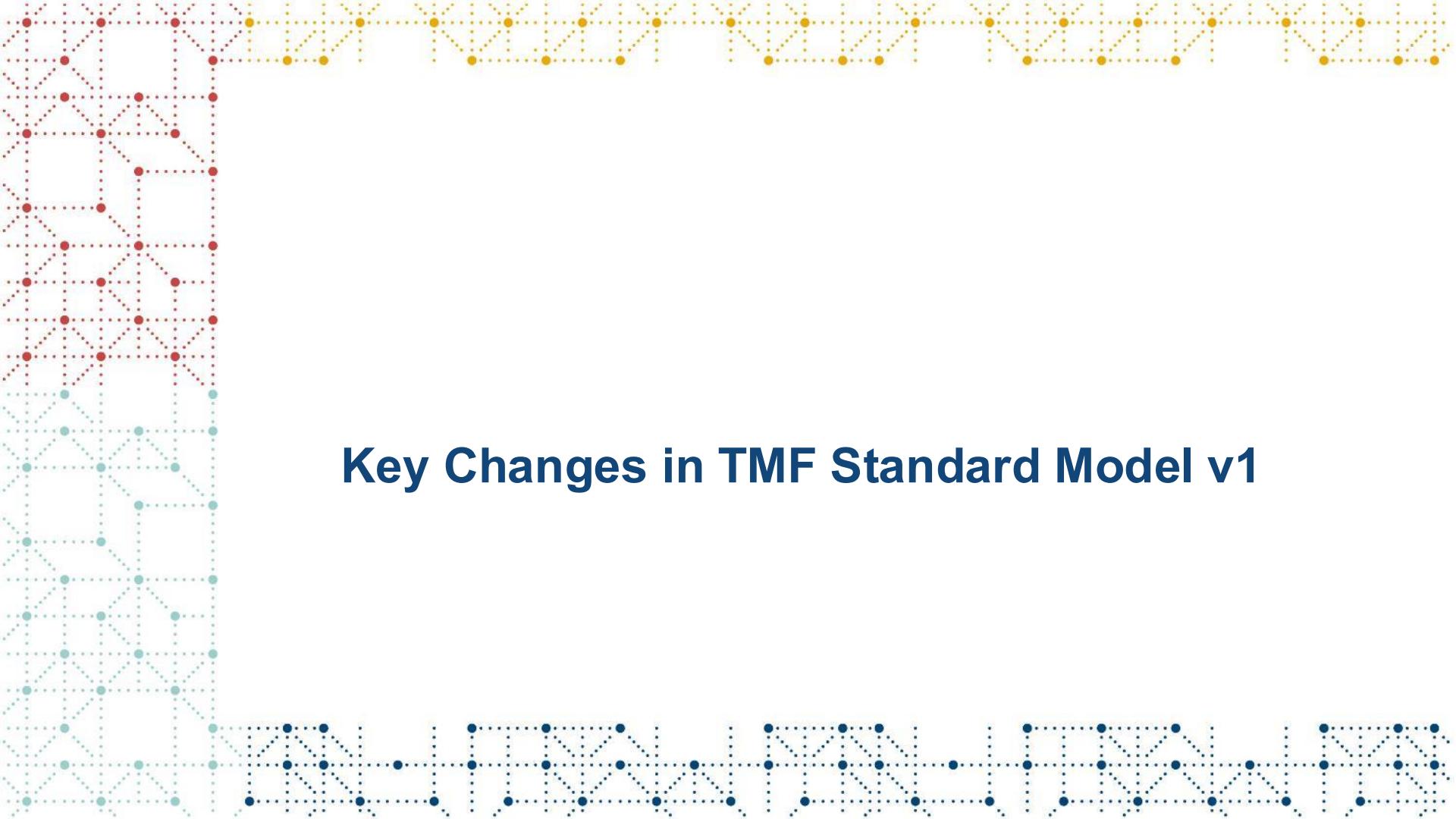
Key Changes in TMF Standard Model v1

Overview of Changes

New Terminology

Structural Changes

Content Refresh

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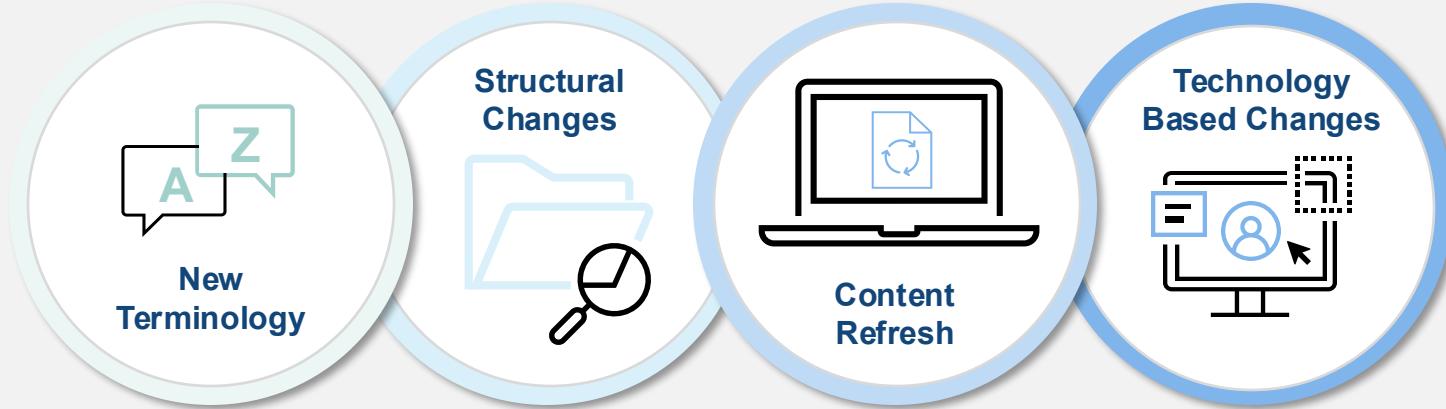
The upcoming changes fall into four main categories, each with a different level of impact on existing TMF structures and processes

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

|						
	A	B	C	D	E	F	G
1		**TMF Standard Version 1**					**Version 1**
2							
3	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

Artifact → Sub Artifact(s)

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.

Record Group → Record Type | *Previous Artifact*

Record Type
Record Type | *Previous Sub-artifacts*

✓ **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


Existing Structure

Artifact

Trial Master File Plan

Sub Artifact(s)

TMF Plan

TMF Index

TMF Report

Updated Structure

Newly Defined Group
Still in progress

TMF Management

Record Types

TMF Plan

TMF Index

TMF Report
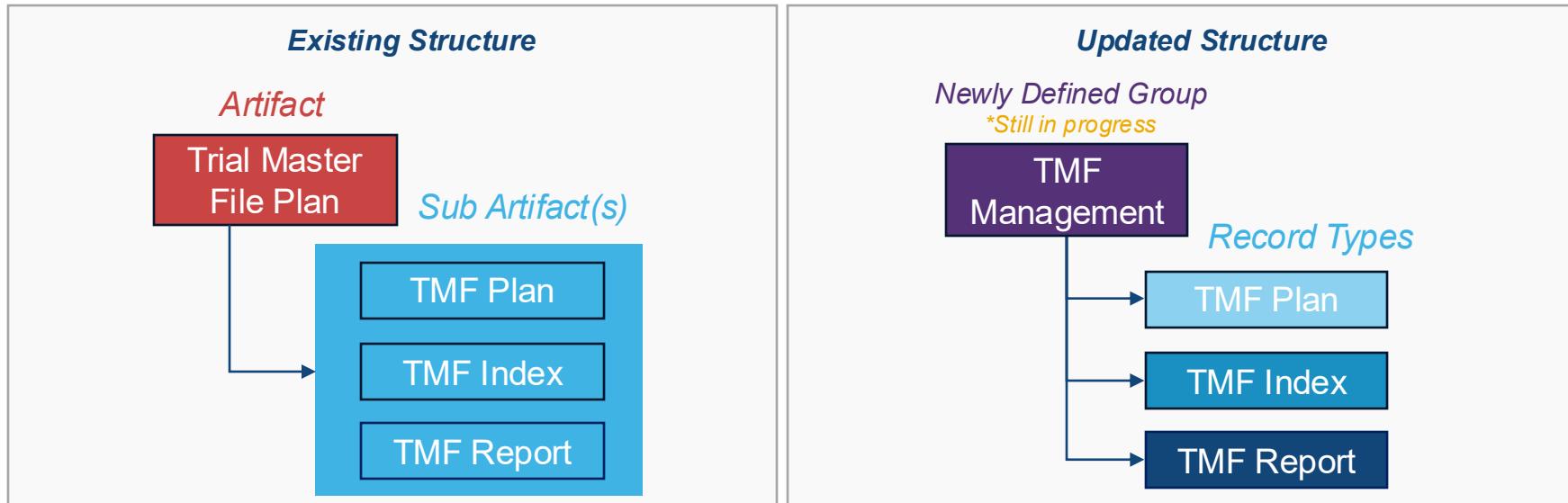
Technology Based Changes

What's Changing?
- uIDs will now be **5 digits** (previously 3)
- uIDs assigned at the **Record Type** level

Existing Structure

Artifact

Trial Master File Plan

Record(s) → *Single uID*

- TMF Plan → uID: 001
- TMF Index → uID: 001
- TMF Report → uID: 001

Updated Structure

Newly Defined Group
Still in progress

TMF Management

Defined Record Types → *Unique uID*

- TMF Plan → uID: 00001
- TMF Index → *uID: 0000x*
- TMF Report → *uID: 0000x*
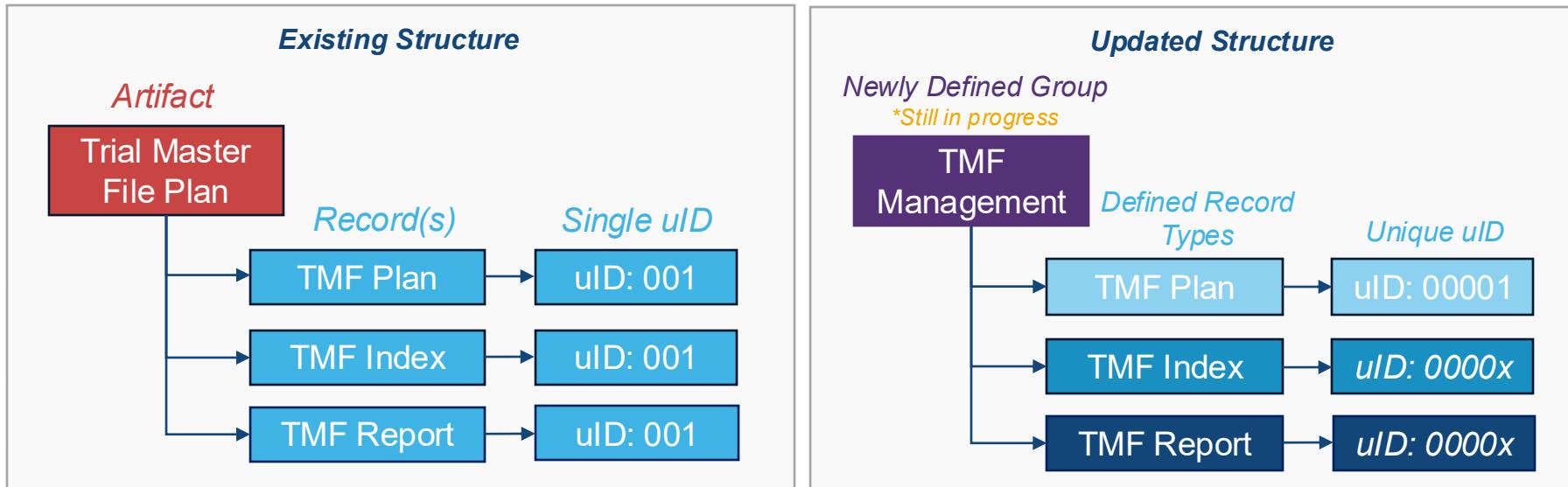
Numbers to be defined

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
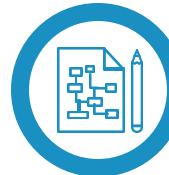
Forms & Templates

Study Plans, Forms & Templates

Training

External & Supporting Party Documents

V1 Implementation Roadmap

2025	2026				2027			
Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

Build Awareness & Foundations

Engage external teams (i.e., CROs, Contractors, Service Providers, etc.)

⭐ *V1 Release*

Assess Current State

Develop process and timeline for v1 pre-release & implementation

⭐ **V1 Pre-release for vendors**

Assess the new standard and update/develop new documents

Develop and Release Training Materials

Change Management →
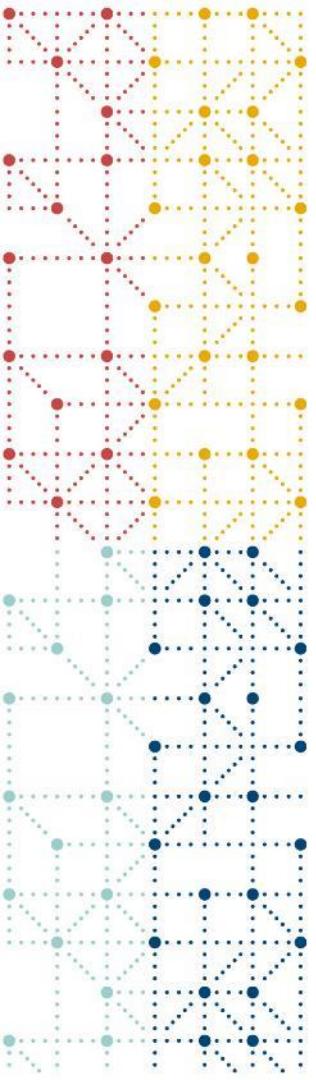
TMF SM v1 Panel Discussion

Paul Carter, CEO, Montrium; Chair, TMF RM Steering Committee

Steph Viscomi, Director, Clinical Documentation and TMF, Apellis Pharmaceuticals, TMF SM v1 PM Team Member

Lisa Mulcahy, Mulcahy Consulting LLC, TMF RM Steering Committee Member

Gillian Gittens, Sr. Director, eClinical Strategy & Solutions, TransPerfect Life Sciences, TMF RM Steering Committee Member