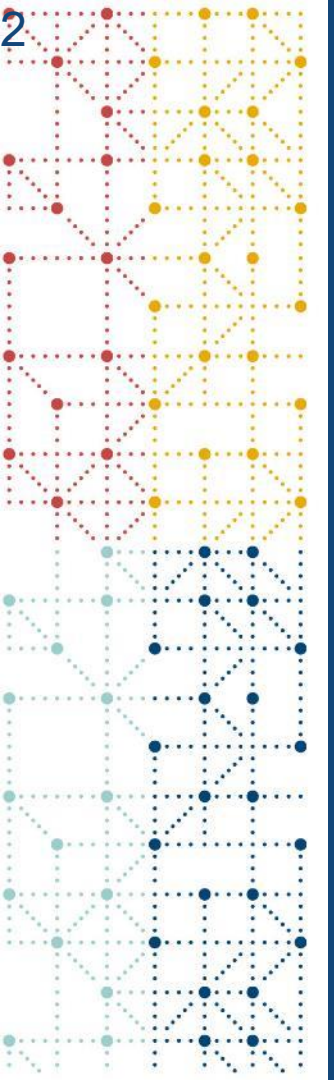
# The TMF Reference Model
# General Meeting December 2025

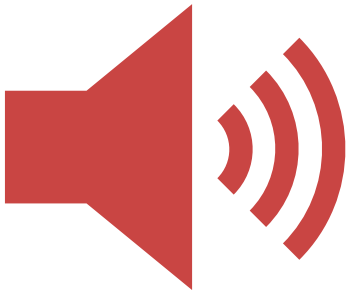
**Presenters:**

- Paul Carter, CEO, Montrium; Chair, TMF Reference Model Steering Committee Chair
- Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOne Medicines; Incoming Chair Elect, TMF Reference Model Steering Committee
- Yuto Kanda, Chugai Pharmaceutical Co., Veeva Vault Clinical Support Manager
- Ayako Koyama, Novartis pharma, CJUG TMF team sub-lead
- Joanne Malia, Sr. Director, Development Records Mgmt, Regeneron, TMF RM SC Member
- Dawn Niccum, EVP, QA, inSeption Group, TMF RM SC Member
- Liz Farrell, Director, Compliance and TMF Oversight (CaTO), Agios Pharmaceuticals, Inc, TMF RM SC Member
- Bryan Souder, GCTO TMF Head, Merck & Co., Inc., TMF RM SC 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 Reference Model Steering Committee Member



# Housekeeping

# Housekeeping

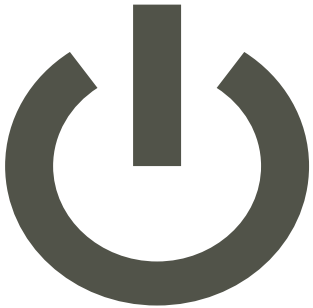


You will remain on **mute**

# Housekeeping

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

# Housekeeping



## Audio Issues?

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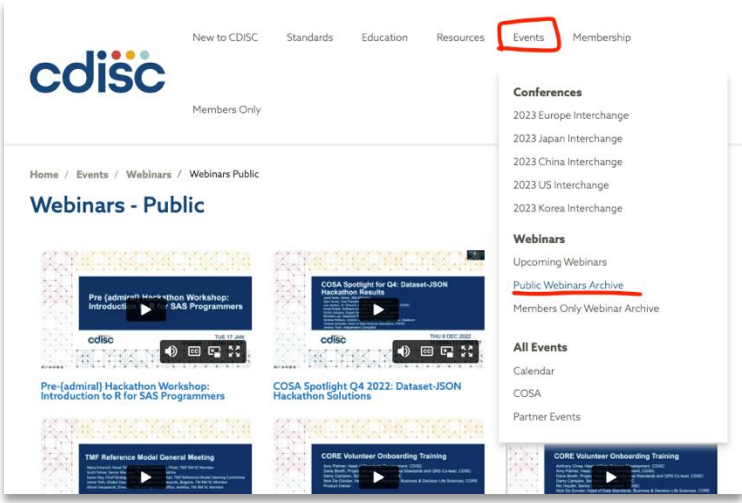
Second, check your local internet connection strength

# Housekeeping




## Webinar Recording

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

# Agenda

1. Intro & Announcements
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!

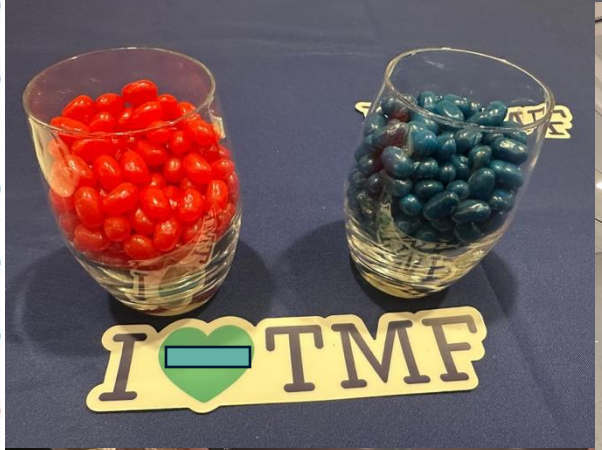
- 300+ Volunteers on v1
- Several new sub-teams
- Many reviews going on with zone teams and triage committee
- New initiatives starting up in 2026

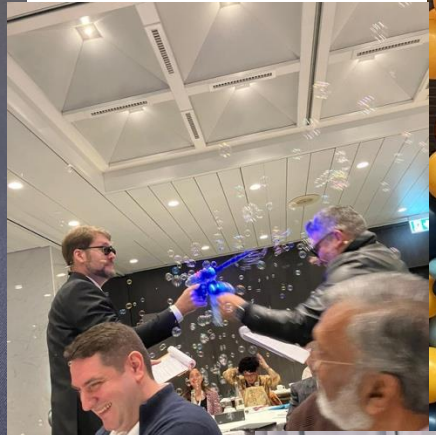
# New Identity

- 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

**Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOne Medicines; Incoming Chair Elect, TMF Reference Model Steering Committee**


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

cdisc

*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

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*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

**Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOne Medicines; Incoming Chair Elect, TMF RM Steering Committee**

**Yuto Kanda, Chugai Pharmaceutical, CJUG TMF team lead**
**Ayako Koyama, Novartis Pharma, CJUG TMF team sub-lead**

# 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 SC Member**

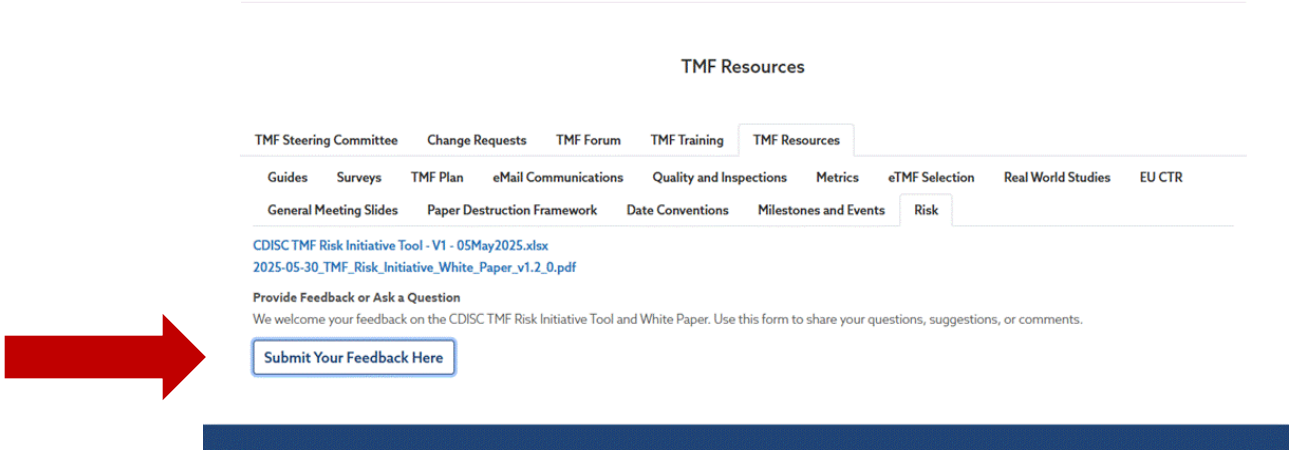
# Availability – CDISC Website

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

**Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOne Medicines; Incoming Chair Elect, TMF RM Steering Committee**

# 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 co-leads Matt Lowery and Aryn Knight!
- 2 years in the making to get us this far!

# Education Committee

Lisa Mulcahy, Mulcahy Consulting LLC, TMF 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 to a full day
  - Content focuses to records created and managed by Biometric Professionals
  - Both for Biometric Professionals and TMF professionals who support those groups

- Investigator Site File Reference Model – Introductory Webinar – Feb 2026
  - Basic course to support the release of the ISF RM

# Training Roadmap

- QC Online Course – Slated for release Q1/2 2026
- Advanced TMF training courses
- Additional focused online courses
- 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

**Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOne Medicines; Incoming Chair Elect, TMF RM Steering Committee**

# 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.

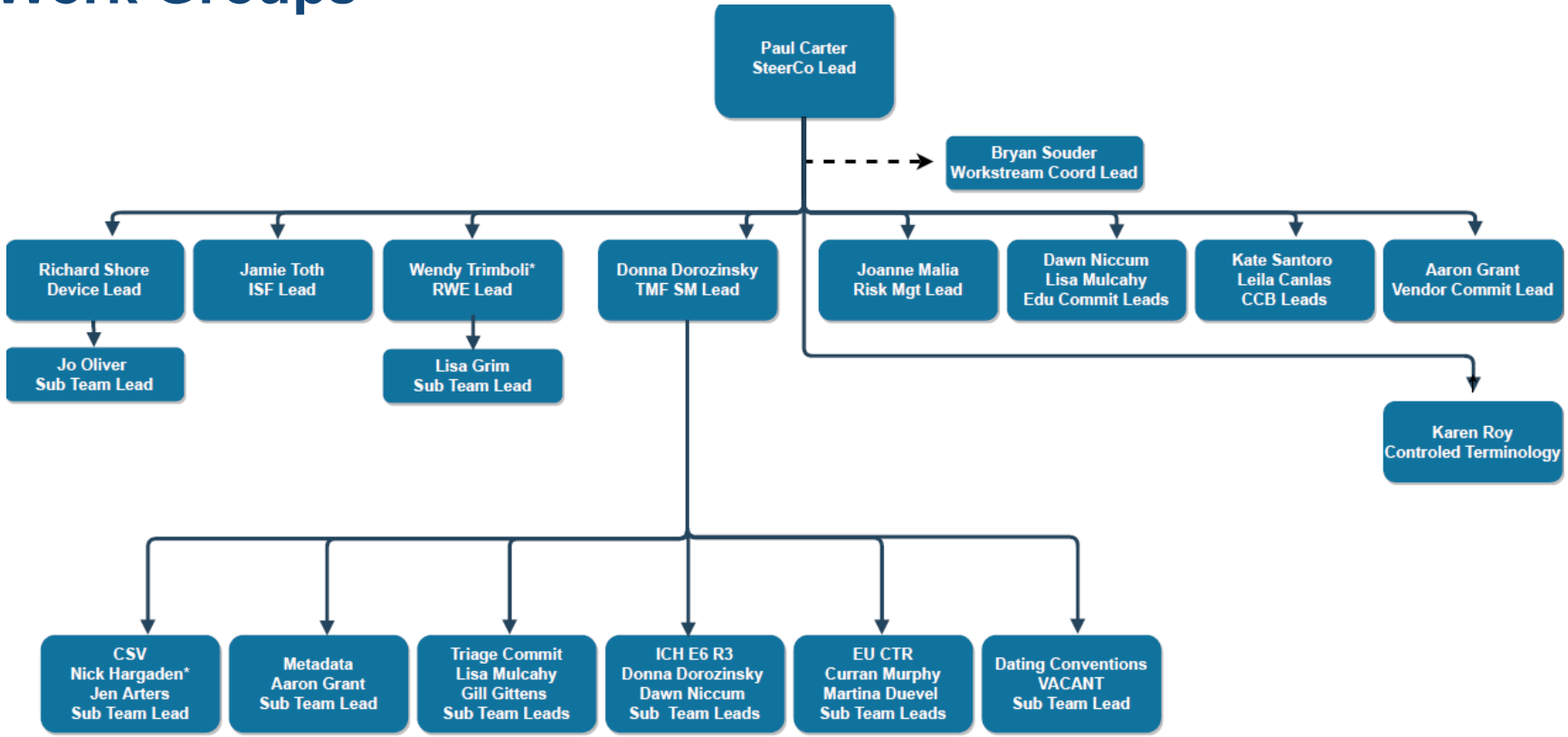
**Next steps:**

- 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.

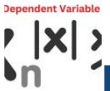
# Workstream Coordination Lead Activities

## 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

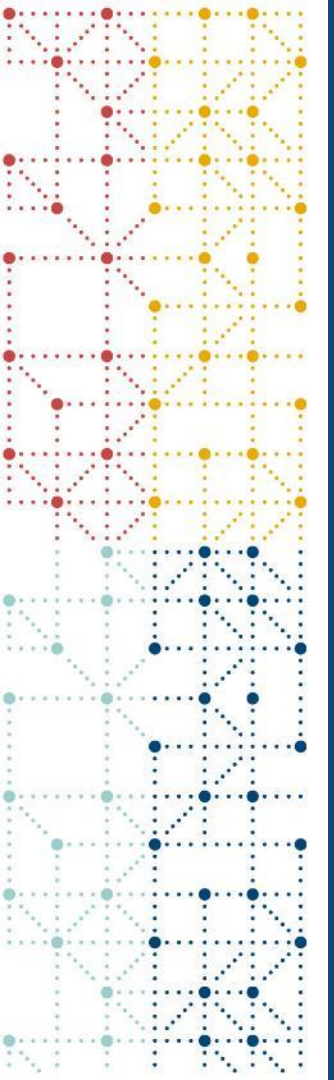
- Identify interdependencies early and track them in a shared plan.
- Proactively resolve conflicts or overlaps between workstreams.


## 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+ record types 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 Stemmler, 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

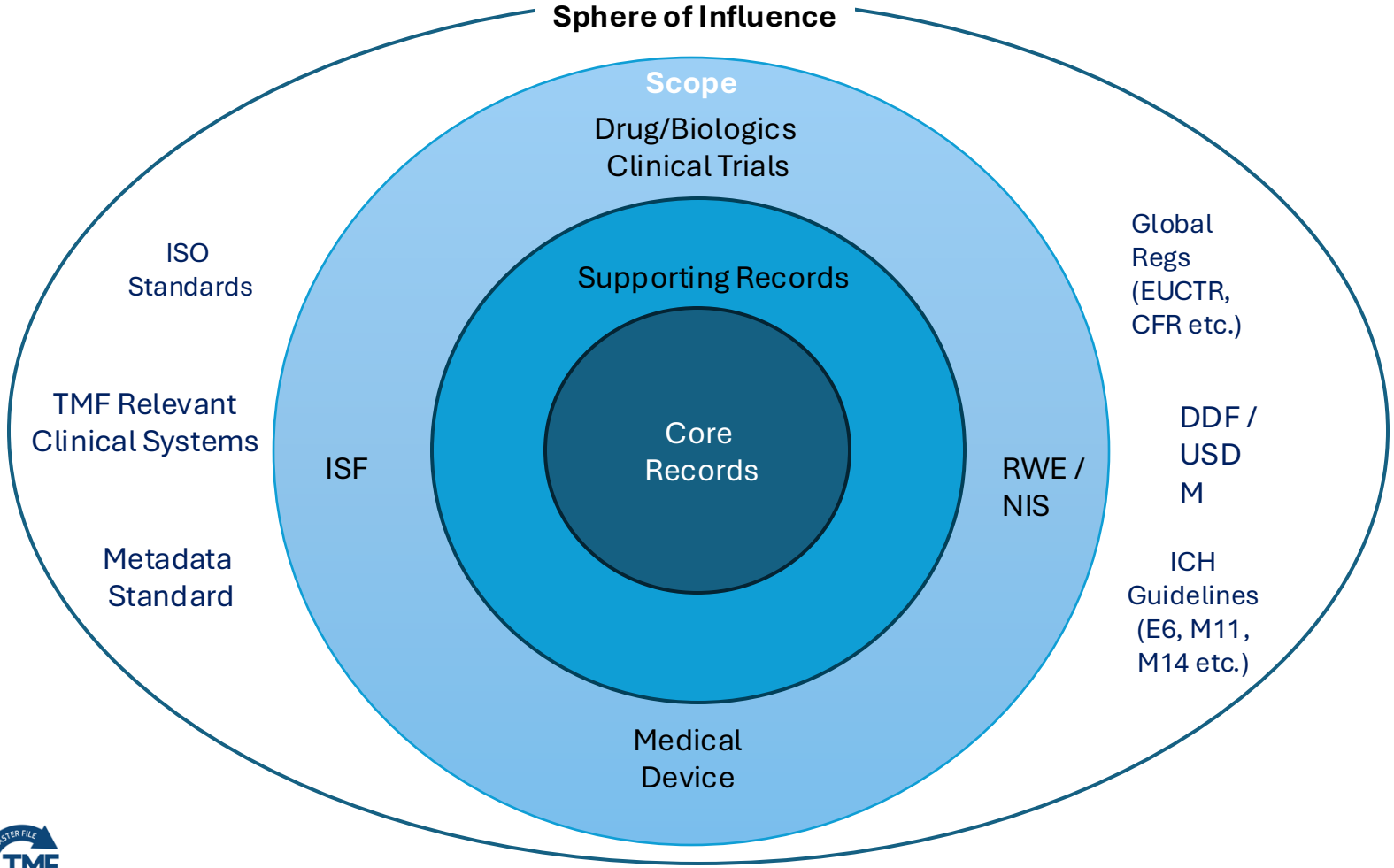
**But the Standard is not prescriptive:**

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

**Each company must still:**

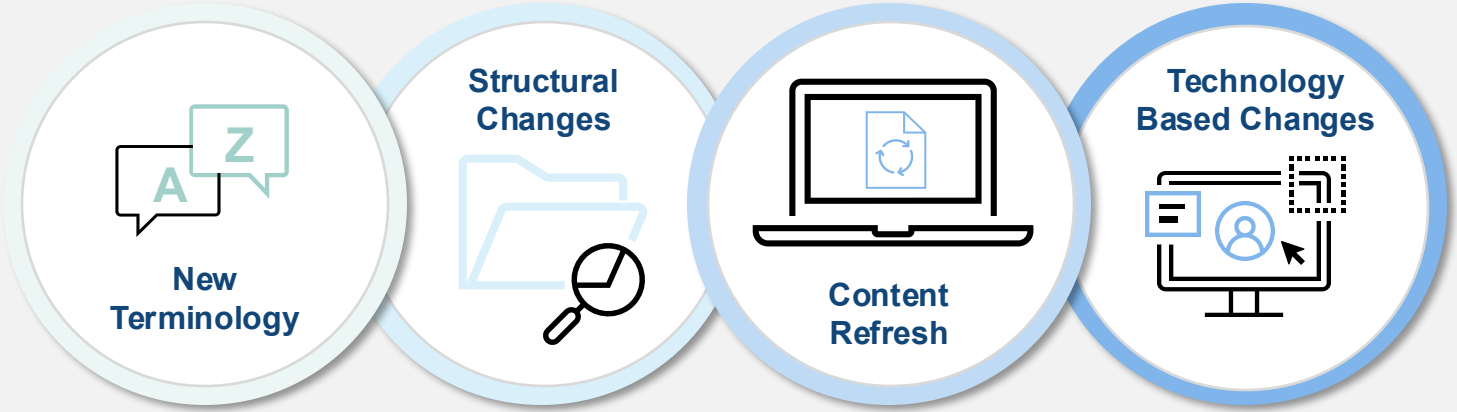
- Define best practices that fit their own processes or organizational gaps not addressed by regulations or v1

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


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

# 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*

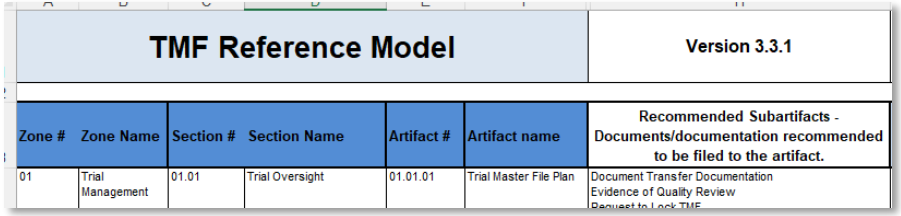
# New Terminology

## 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?

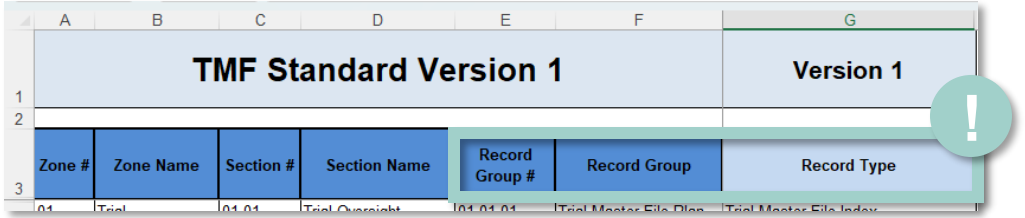
- To better reflect how records are organized and managed across the TMF
- Align with regulatory expectations



| 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<br>Evidence of Quality Review<br>Request to Lock TMF |

## What does this mean for the community?

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



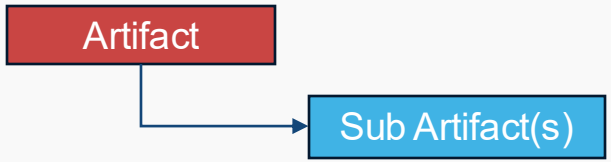
| TMF Standard Version 1 | | | | | | Version 1 |
|---|---|---|---|---|---|---|
| Zone # | Zone Name | Section # | Section Name | Record Group # | Record Group | Record Type |
| 01 | Trial | 01.01 | Trial Oversight | 01.01.01 | Trial Master File Plan | Trial Master File Index |

# 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.

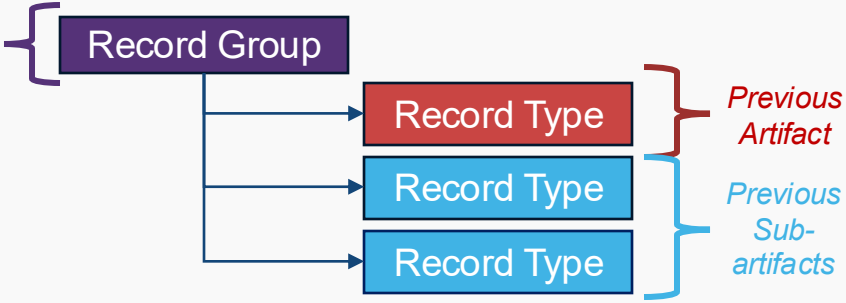
### *Existing Structure*




The existing structure provides only a single layer of organization.

### *Updated Structure*

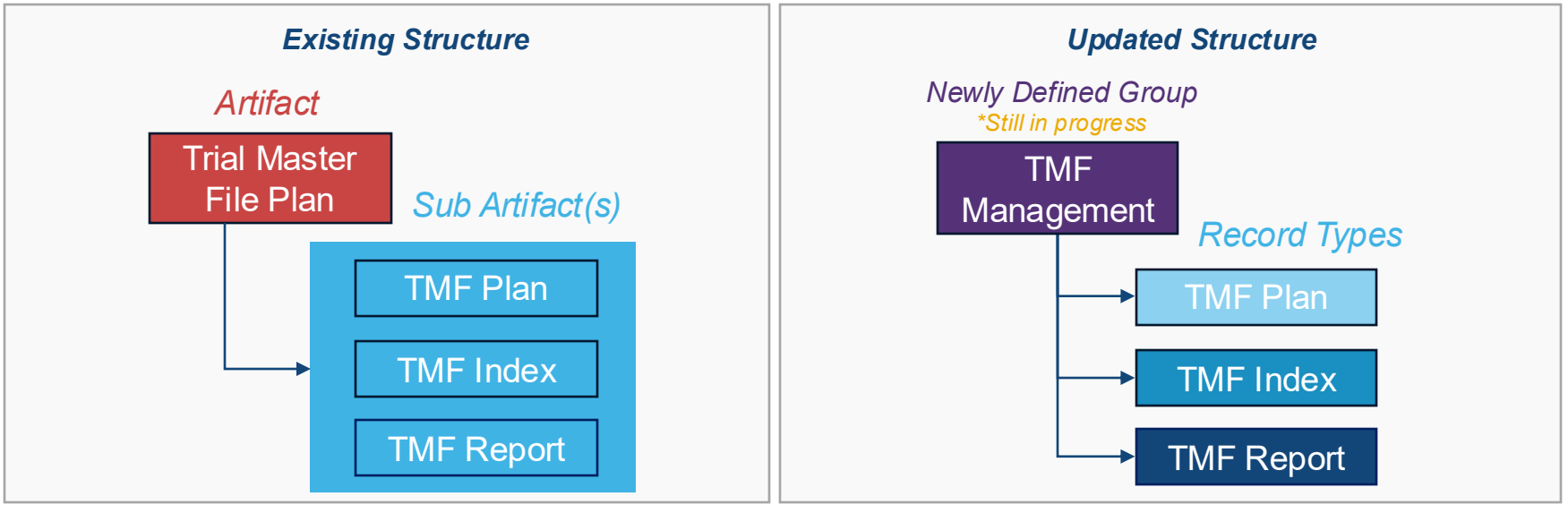
*Record Groups provide a layer of organization like Zones/ Sections. Filing happens at the Record Type level, not the Group level.*




- ✓ **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.)

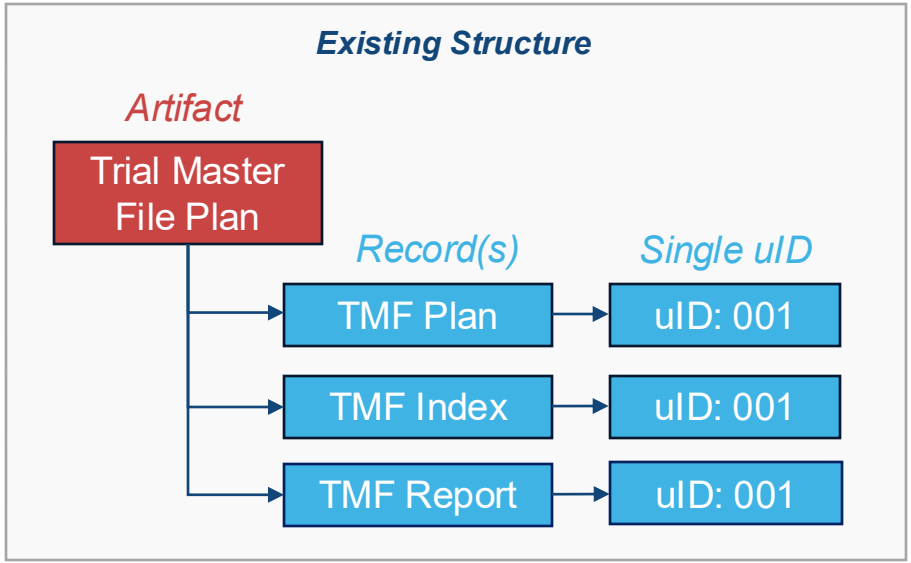
## Structure Change Example: 01.01.01

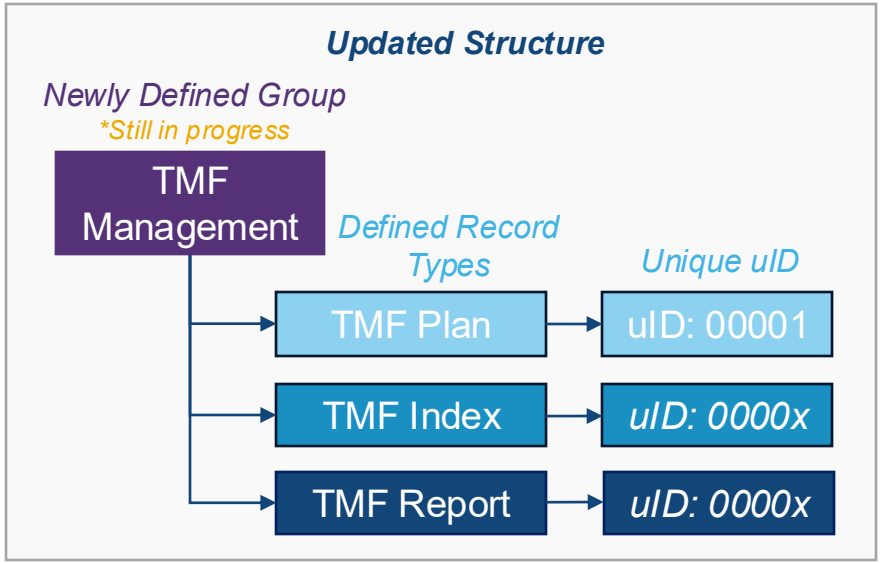


# Technology Based Changes

**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?

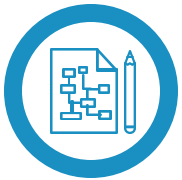
***Impact Overview:*** *The upcoming changes in terminology, structure, content, and technology will require updates to core records and processes.*

***Key activities include:***

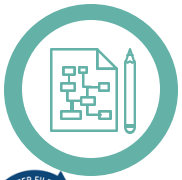
- Aligning procedures with **new terminology** and **workflows**, **re-mapping filing structures**, and **adding or retiring Record Groups/Types** as needed.
- **Development of new procedures** to ensure alignment with the creation and collection of new record types.
- Change management **activities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

TMF SOPs

TMF Index



Forms & Templates

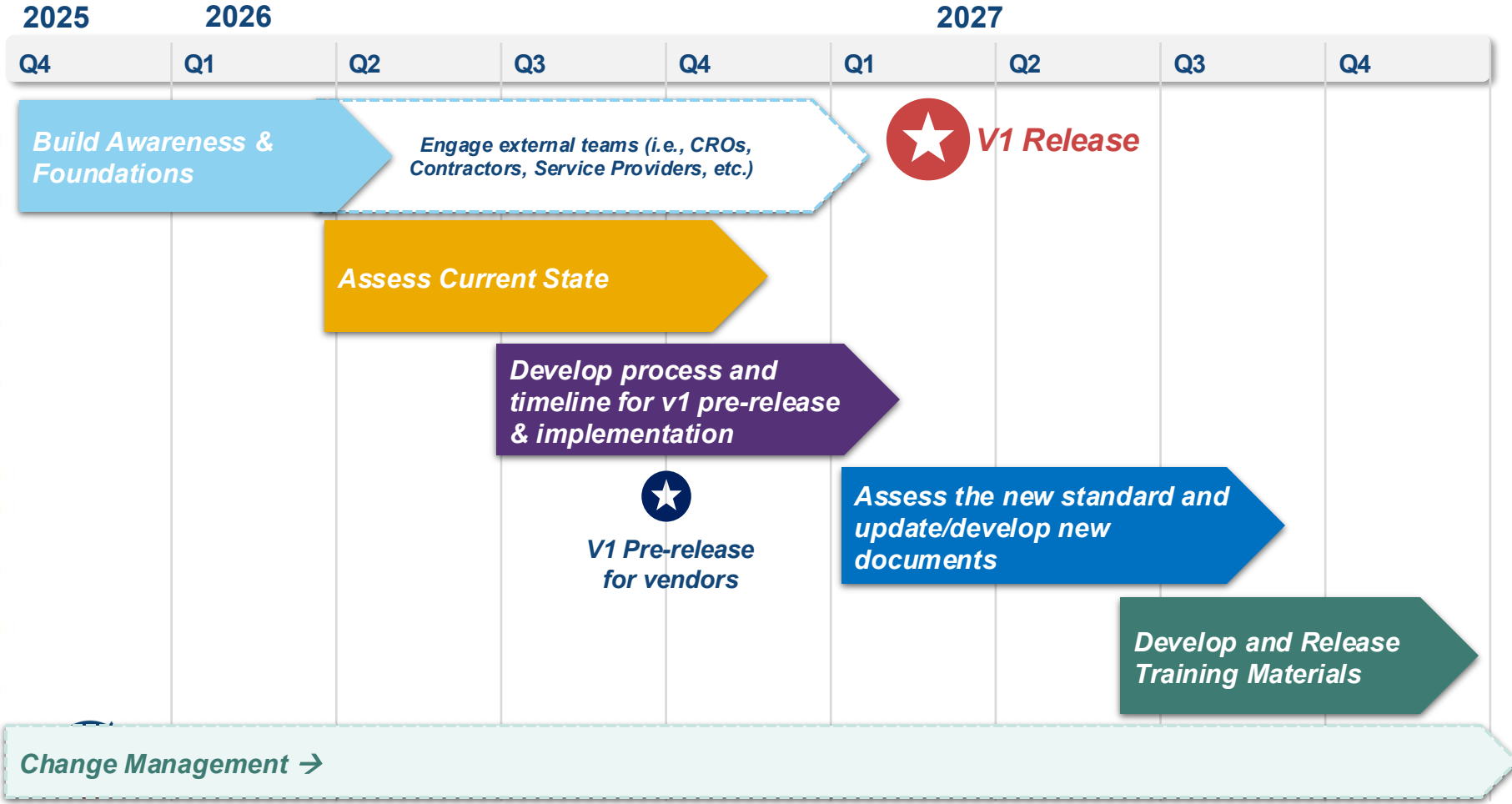


Study Plans, Forms & Templates

Training

External & Supporting Party Documents

# V1 Implementation Roadmap



# TMF SM v1 Panel Discussion

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

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

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