TMF Standard Model v1 Update

Housekeeping

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


cdisc
TMF
TMF STANDARD
MODEL

Meet the TMF Standard Model Project Team

Paul Carter

Founder & CEO, Montrium

TMF SM V1 Association:
Chair of TMF Steering Committee
V1 Management Committee Member

Donna Dorozinsky

Founder & CEO, Just in Time GCP

TMF SM V1 Association:
Lead for the V1 Project

Gillian Gittens

Senior Director, Life Sciences
TransPerfect

TMF SM V1 Association:
Co-lead of the TMF SM V1 Triage Committee

Lisa Dotterweich Mulcahy

Owner & Principal Consultant, Mulcahy Consulting, LLC

TMF SM V1 Association:
Co-lead of the TMF SM V1 Triage Committee

Steph Viscomi

Director, Clinical Documentation and TMF, Apellis Pharmaceuticals

TMF SM V1 Association:
V1 Project Management Team Member

Kathleen Mellet

Associate Consultant, Just in Time GCP

TMF SM V1 Association:
V1 Project Management Team Member

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. The Evolution
2. What Have We Done So Far
3. What's Next?
4. Q& A - Questions in the Questions Tool

Together

- Evolution
- Unity
- Foundation
- Vision
- Transformation

The Future of TMF: Built Together

The Evolution

- The TMF Reference Model gave us a common taxonomy
- It united an industry – collaboration at global scale
- Now we evolve to a true industry Standard
- Built for interoperability, scalability, and regulatory alignment

Why We Must Evolve

GDPR

ICH

M11, E8 (R1), & E6 **(R3)**

Conducting Clinical Trials With Decentralized Elements

Guidance for Industry, Investigators, and Other Interested Parties

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 March 2023
EMA/INS/GCP/112288/2023
Good Clinical Practice Inspectors Working Group (GCP IWG)

Guideline on computerised systems and electronic data in clinical trials

European Commission

Clinical Trials Regulation EU No 536/2014

Medicines & Healthcare products Regulatory Agency

MHRA

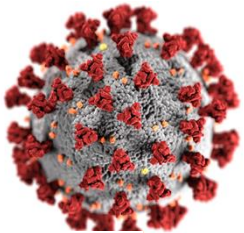
Medicines & Healthcare products Regulatory Agency (MHRA)

'GXP' Data Integrity Guidance and Definitions

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations

Questions and Answers

Guidance for Industry



Guidance

Risk-Adapted Approach to clinical trials and Risk Assessments

Published 28 January 2022

TransCelerate BIOPHARMA INC.

A Risk-Based Approach to Monitoring of Clinical Investigations

Questions and Answers

Guidance for Industry

Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products

Guidance for Industry

Informed Consent

Guidance for IRBs, Clinical Investigators, and Sponsors

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Clinical Policy
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

August 2023

cdisc

#ClearDataClearImpact

The TMF Standard Model V1

- A common foundation for clinical documentation
- Designed to support regulations, not interpret them
- Globally scalable and built for technology enablement
- Future-ready foundation for automation and analytics

Why We Avoid Interpretation

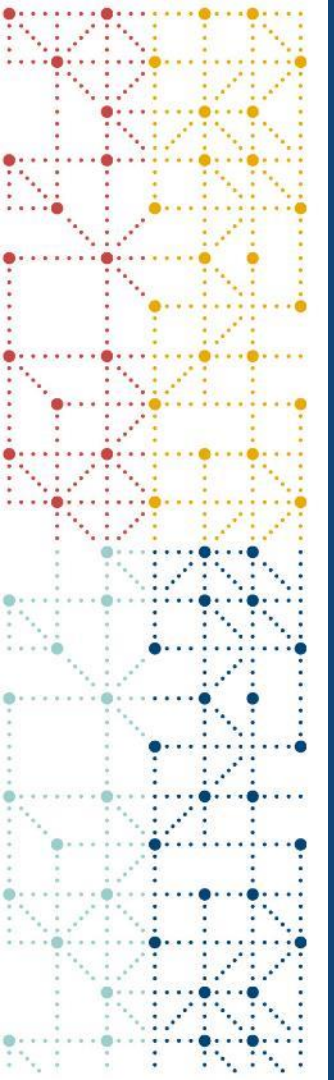
- Regulations differ by region
- If the Standard interprets regulations, it limits adoption
- Our role: provide structure and evidence expectations
- Not: apply policy or define compliance interpretations

Driven by Guiding Principles

- **We don't make change for the sake of making change.** There needs to be strong justification for a change that is driven by these Guiding Principles and that considers digital systems
- Create consistency across TMF Standard to facilitate future migration of content and align with our goal of interoperability
- Where practical, Zone & Section content is organized by the functional area that supports those records.
- Build for the digital future
- Align with industry and regulation
- Construct a Standard that ensures universal industry adoption
- Adapt the RM to a structure that has unique Record Types as core elements

Conventions Driving Structure of TMF Standard Model

- Terminology Standardization for Records and Documentation
  - Where relevant, the term “document” should be replaced with “record”.
  - Keep the term “documentation” when it makes sense.
- Naming Conventions and Acronyms
  - Align Record Group names with ICH E6 R3 terms where possible, and Record Types with industry-standard names including acronyms (i.e., Statistical Analysis plan = SAP)
  - If the Record Type name is repetitive to the Record Group, Zone or Section name, consider removing the repetitive aspect
- Creation of new Record Types
  - When the Record Type content is fundamentally different than any other record type consider creating a new record type



What Have We Done So Far?

We Have….

Agreed program levels are out of scope of the Standard

Committed to standardized terminology

Agreed to a 4-level hierarchy that aligns with a tree view as a an Excel file

Agreed to retain reference numbering for historical artifacts

Committed to enabling compatibility with technology platforms

Big Shift in Scale

Version	Structure	Volume
Current (V3.3.1)	3 levels	250 Artifacts / 515 Sub-artifacts
Standard Model V1	4 levels	**2,000+ Record Types**

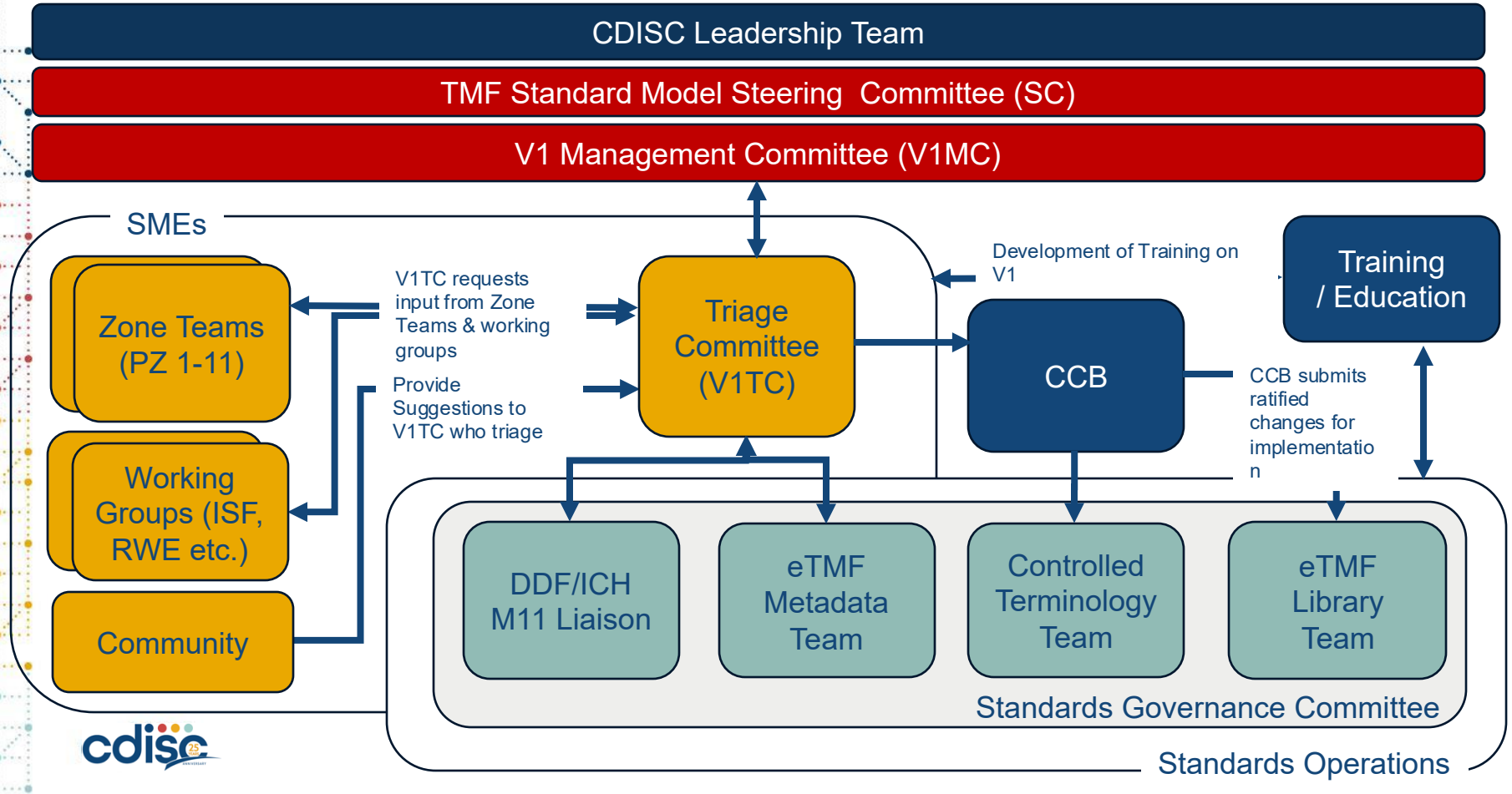
We are shifting from **containers** → to **evidence records**

We are Moving to a Modern Language

Old Term	New Term
Artifacts	Record Groups
Sub-artifacts	Record Types
TMF Structure	TMF Hierarchy

- ✓ **Retaining** the tree view
- ✓ UI Numbers **carried over for mapping**
- ✓ Historical traceability preserved

V1 (TMF Standard) org chart



Working Group Activities

ICH E6(R3) Working Group – Record Types aligned with focus on oversight & risk management

CSV Working Group – vision on clearly defining a means of managing CSV content within a study

EU CTR Working Group – regional alignment

Vendor Collaboration

- Vendors engaged early for technology readiness
- Alignment with architecture & metadata design
- Standard will be released to vendors before public launch
- Goal: smoother adoption for industry

Zone Teams are Active

BEGIN REVIEW OF COMMUNITY INPUT

BEGIN REVIEW OF V1 MANAGEMENT TEAM INPUT

R3, CSV, & EU CTR IS NEXT

What’s Next?

Getting Started……

- Definitions for the new Record Types and update to definitions for existing Record Types
- Metadata Working Group
- Device Working Group
- Dating Convention Working Group
- Controlled Terminology input

Organizational Impact

New Record Types will expose new process gaps

Gaps require SOP updates

Evidence model shifts expectations under E6(R3)

TMF becomes proactive quality driver, not passive storage

Regulatory Engagement

EMA presentation in November

Intend a dialogue with US and UK regulators

Goal: **global recognition as an industry standard**

We Are Building This Together

- ✓ Community-led
- ✓ Regulator-engaged
- ✓ Technology-enabled
- ✓ Built by all of us
- ✓ Free to all

This is the Future of TMF

It's bold!

It's transformational!

It will outlast all of us!

It Takes a Village!

Q4 TMF General Meeting

Want to learn more about CDISC TMF? Scan the QR Codes below to register for the quarterly TMF General Meeting

Session 1: Tuesday December 9th
11 am to 12:30 pm ET

Session 2: Tuesday December 9th
7 pm to 8:30 pm ET

Thank You!!!