

TMF Standard Model V1



Wei Du

Life Sciences Director, TransPerfect

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

Regulatory Evolution



Medicines & Healthcare products
Regulatory Agency



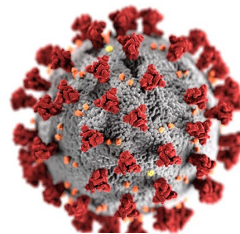
Medicines & Healthcare products
Regulatory Agency (MHRA)

'GXP' Data Integrity Guidance and Definitions



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

Guidance for Industry



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



Clinical Trials Regulation EU No 536/2014



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

Conducting Clinical
Trials With
Decentralized Elements

Guidance for Industry,
Investigators, and Other
Interested Parties



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



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



Gillian Gittens

Senior Director, Life Sciences
TransPerfect

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



Donna Dorozinsky

Founder & CEO, Just in Time GCP

TMF SM V1 Association:

Lead for the V1 Project



**Lisa Dotterweich
Mulcahy**

Owner & Principal Consultant,
Mulcahy Consulting, LLC

TMF SM V1 Association:

Co-lead of the TMF SM V1 Triage
Committee



Kathleen Mellet

Associate Consultant, Just in Time
GCP

TMF SM V1 Association:

V1 Project Management Team
Member

Driven by Guiding Principles

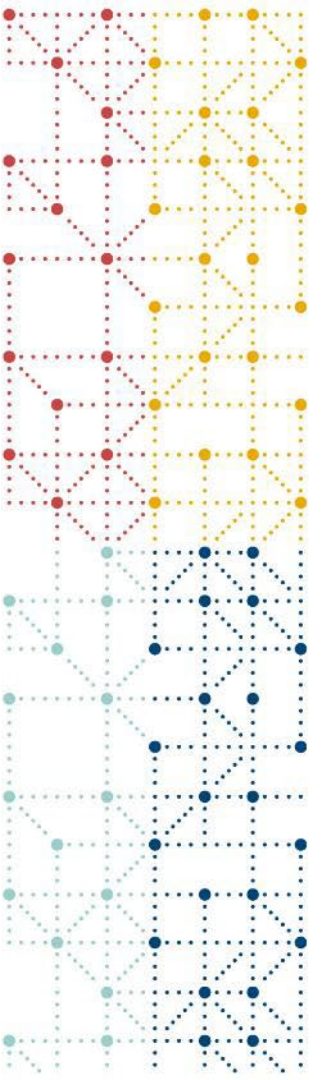
- **We don't make change for the sake of making change.** There needs to be strong justification for a change that is driven by these Guiding Principles and that considers digital systems
- Create consistency across TMF Standard to facilitate future migration of content and align with our goal of interoperability
- 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

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

Artifacts

Sub-artifacts

TMF Structure

New Term

Record Groups

Record Types

TMF Hierarchy

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



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



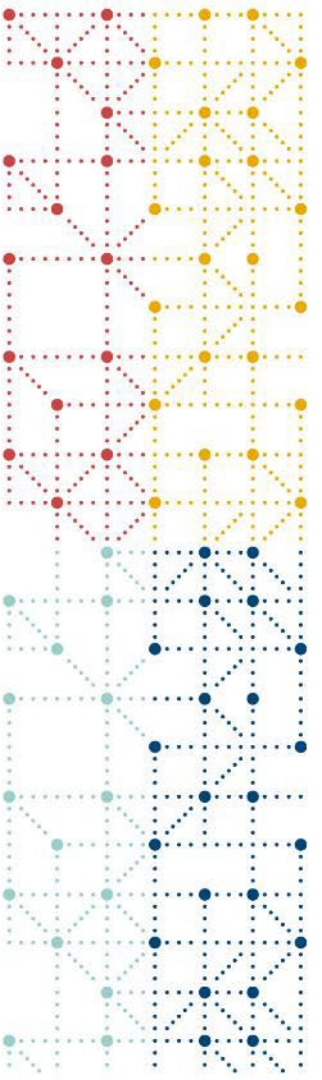
Alignment with architecture & metadata design



Standard will be released to vendors before public launch



Goal: smoother adoption for industry



What's Next?

Next- 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



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!!!

