

Understanding the CDISC Reference Model Revision and Roadmap

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Agenda



A Vision for the Future



TMF Reference Model V4 Update



Upcoming Initiatives



Q&A

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A Vision for the Future

A Vision for the Future



Digital-First

Harmonized

Governed Standard

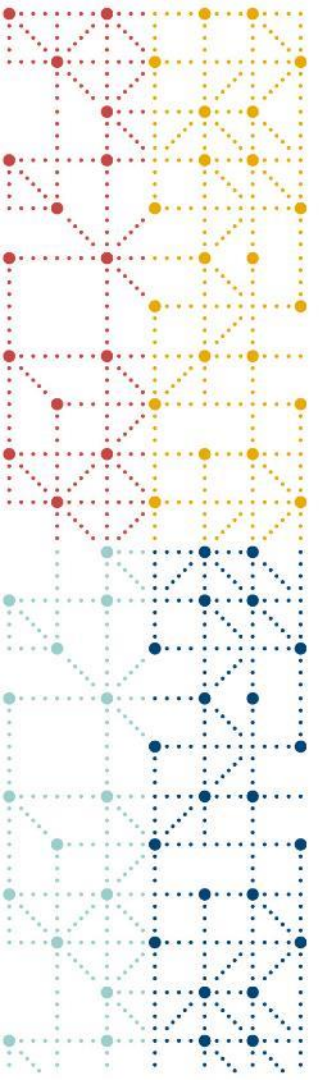
Community-Driven

Interoperable and Integrated

Data and Process-Driven

Regulatory Recognition

TMF Reference Model V4 Update



TMF RM V4 Organization: Large Community Effort

CDISC Leadership Team

TMF RM Steering Committee

V4 Management Committee

SMEs

Triage Committee

Zone Teams

Working Groups

Community

Standards Operations

DDF/ICH M11 Liaison

eTMF Metadata

Controlled Terminology

eTMF Library

Change Control Board

Training / Education

V4 Progress

Completed:

- Rename artifacts and sub-artifacts to record group and record type

In progress:

- Combine feedback from different groups and individuals
- Triage Committee to review and submit changes to Zone Teams
- Prepare for anticipated release in **early 2027**



**Creating alignment
and coordination
through workshops
and meetings with
industry SMEs and
vendors**

Key Areas of Focus for V4

1

Numbering
of Record
Types

2

Revision of
Record
Groups

3

Metadata
Standard
Scope

4

Repeating
Records

5

Interoperability

6

Mapping /
Migration

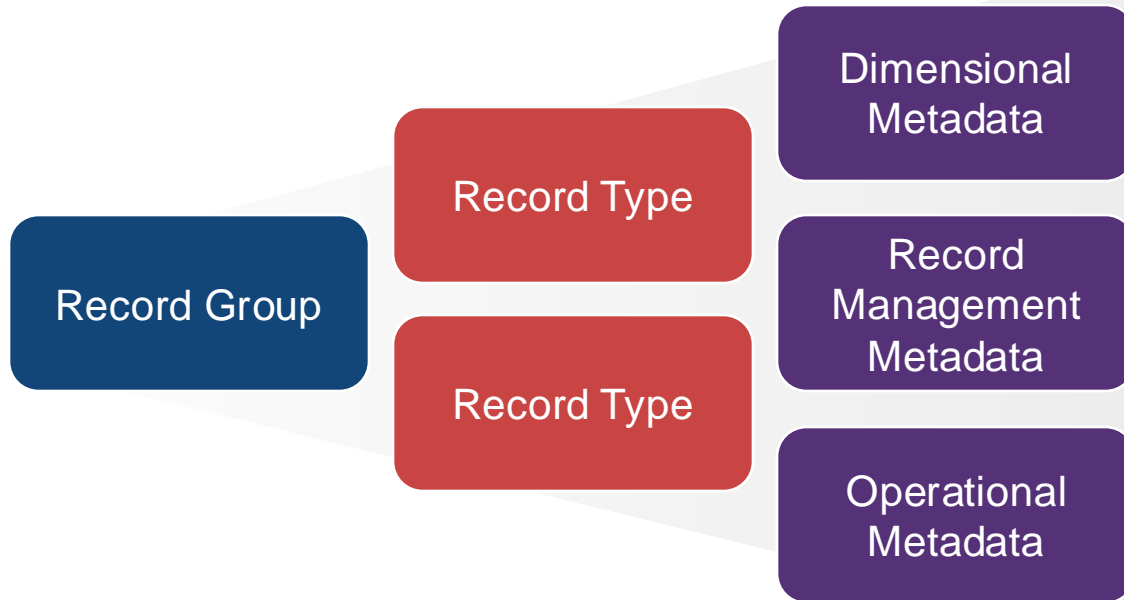
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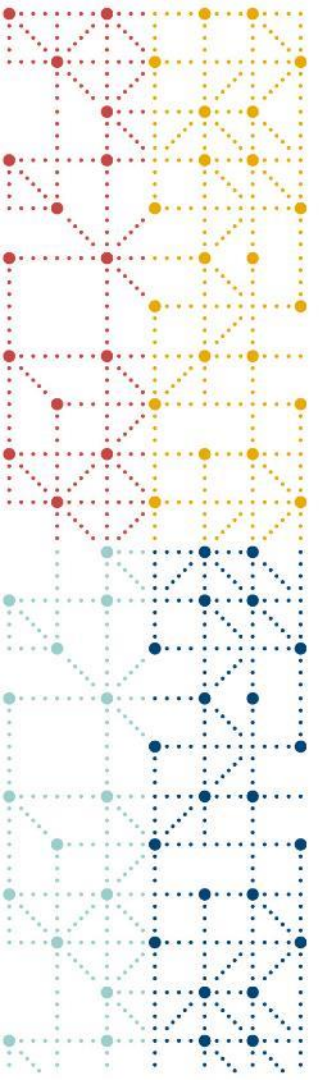
ICH E6(R3)
Requirements
/ Alignment

8

CSV
Records

Core Concept: Record Group and Record Type





Upcoming Initiatives

Upcoming Initiatives: ISF, Risk-Based TMF, and More

- ✓ Develop **ISF reference model** to standardize ISF structure, naming conventions, and essential records for sites (*releasing to the public soon*)
- ✓ Apply **risk-based approaches** across the TMF lifecycle, from planning to long-term archival (*releasing to the public soon*)
- ✓ Real-world evidence
- ✓ Devices

The *Only* TMF Conference in Europe in 2025



CDISC+TMF Europe Interchange
-GENEVA

Conference: 14-15 May | Trainings: 12, 13, 16 May

The agenda is live, and registration is open:



Upcoming Events in 2025



***The call for abstracts (deadline April 25)
and registration are open:***



How to Get Involved



Visit the CDISC TMF Reference Model website, [*cdisc.org/tmf*](https://cdisc.org/tmf)



Sign up to be a volunteer

Questions?



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Thank you!