CDISC TMF RM Roadmap 2025-2028

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Chair CDISC TMF Reference Model Steering Committee

Meet the Speaker

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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.*

A Vision for the Future

- Digital-First
- Harmonized
- Governed Standard
- Community-Driven
- Interoperable and Integrated
- Data and Process-Driven
- Regulatory Recognition

CDISC TMF RM Roadmap 2025-2028

	2025		2026		2027		2028	
	H1	*H2*	*H1*	*H2*	*H1*	*H2*	*H1*	*H2*
Planned Versions of CDISC TMF RM Standard					*v4*			*v4.1*
Core Standard Development								
Review and formalize Sub-artifacts into Record Types								
Review and consolidate Artifacts into Record Groups								
Align with ICH E6 R3 Appendix C Essential Records								
Create / Update Controlled Terminology for all record types								
Digital TMF Metadata Standard / Interoperability								
Enhance and expand digital TMF metadata standard				R1				R2
Align metadata standard with USDM				R1				
Create and Update Controlled Terminology for all metadata/value lists								
Development of / or Alignment to existing Audit Trail Standard								
Auxiliary Standards / Mappings								
Map TMF RM Record Types to ICH M11								
Investigator Site File RM	R1			R2				
Real World Evidence RM			R2					
Medical Device RM				R1				
Cross Referencing of CSV Records								
TMF RM Standard Management Tools								
Develop requirements for database type tool to manage standard								
Implementation of tool to manage TMF RM & migrate V4								
Development of APIs to allow querying of TMF RM Standard								
Update TMF Reference Model Implementation Guide (TMFIG)								
Training and Community Engagement								
Training Activities								
Community Engagement Activities								
Other tools and frameworks								
Maintenance of Risk Based Approach Framework / Tools								
Update and maintenance of standard conventions including date conventions, metrics conventions etc.								
Update TMF Plan Template								
Engagement with the regulators								
Regular touchpoint meetings with regulators to inform them of progress and new releases								

Core Standard Development

RECORD TYPES

Review and formalize sub-artifacts into Record Types

ARTIFACTS

Review and Consolidate Artifacts into Record Groups

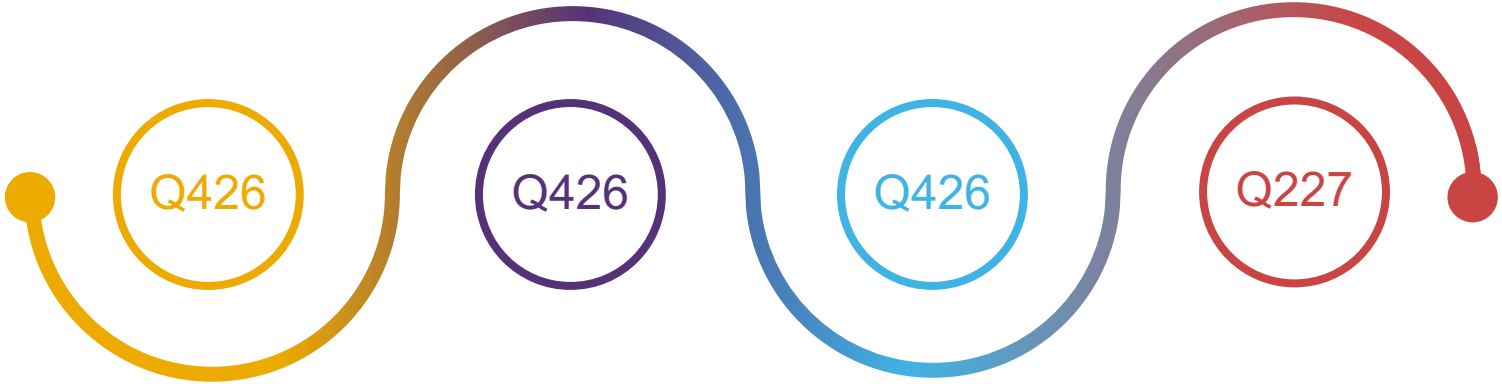
ICH E6 R3

Align with ICH E6 R3 Appendix C Essential Records

CONTROLLED TERMINOLOGY

Create / Update Controlled Terminology for all record types

Digital TMF Metadata Standard / Interoperability



METADATA R1

Enhance and expand digital TMF metadata standard

USDM

Align metadata standard with USDM

CONTROLLED TERMINOLOGY

Create and Update Controlled Terminology for all metadata/value lists

AUDIT TRAIL

Development of / or Alignment to existing Audit Trail Standard

Ancillary Standards and Mappings

ICH M11

Map TMF RM Record Types to ICH M11

ISF RM R2

Investigator Site File RM second revision which aligns with v4

RWE RM R2

Real World Evidence RM second revision which aligns with v4

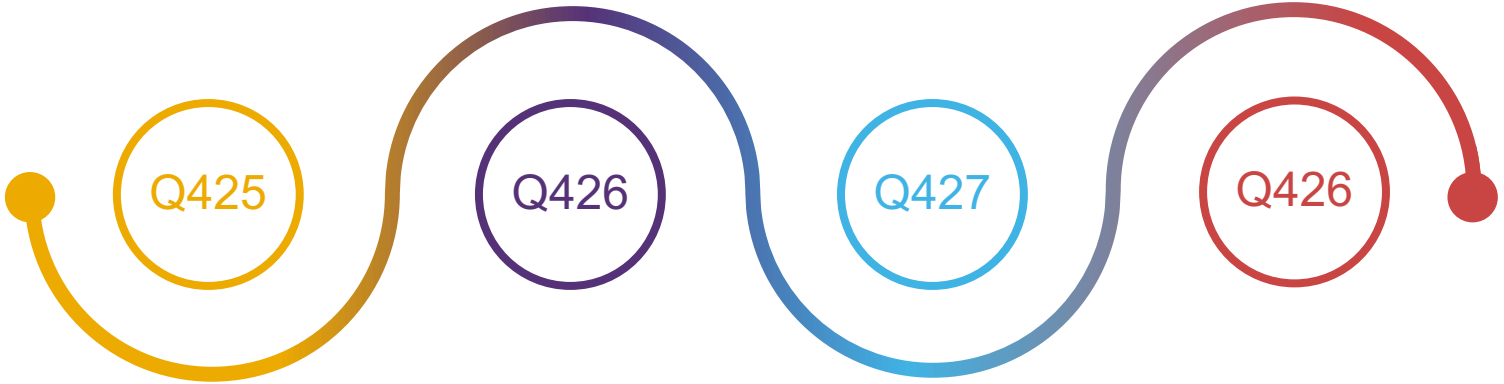
MEDICAL DEVICE RM R1

Creation of a specific RM for Medical Device

CSV

Cross referencing of CSV records for trial relevant systems both trial specific and enterprise aspects

TMF RM Standard Management Tools



REQUIREMENTS

Develop requirements for database type tool to manage standard

TOOL DEV

Implementation of tool to manage TMF RM & migrate V4

API

Development of APIs to allow querying of TMF RM Standard

TMFIG

Update TMF Reference Model Implementation Guide (TMFIG)

Training, guidance and frameworks

TRAINING PROGRAM

Continued development of TMF training courses at all levels

RISK FRAMEWORK

Maintenance and Evolution of Risk Based Approach Framework / Tools

STANDARD CONVENTIONS

Update and maintenance of standard conventions including date conventions, metrics conventions etc.

TMF PLAN

Update TMF Plan Template to better align with digital TMF concepts and ICH E6 R3

REGULATOR ENGAGEMENT

Regular touchpoint meetings with regulators to inform them of progress and new releases

Thank You!