



TMF Standard Model Roadmap

Presented by Paul Carter, CEO, Montrium Inc.

Meet the Speaker



Paul Carter

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Organization: Montrium

25 year experience in clinical computerized systems. Longstanding Member and Chair of the TMF Reference Model Steering Committee.
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CDISC TMF RM Roadmap 2025-2028

Planned Versions of CDISC TMF RM Standard

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
- Align metadata standard with USDM
- 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
- Real World Evidence RM
- Medical Device RM
- 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

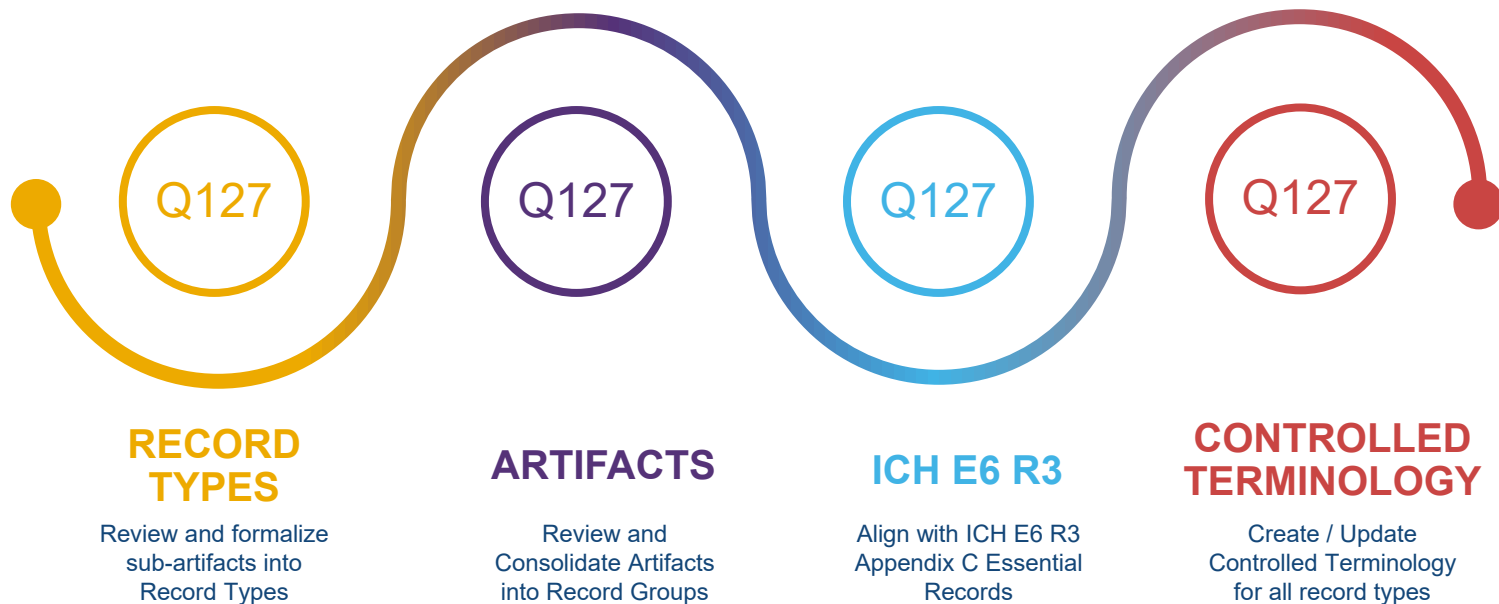
- Maintenance of Risk Based Approach Framework / Tools
- Update and maintenance of standard conventions including date conventions, metrics conventions etc.
- Update TMF Plan Template

Engagement with the regulators

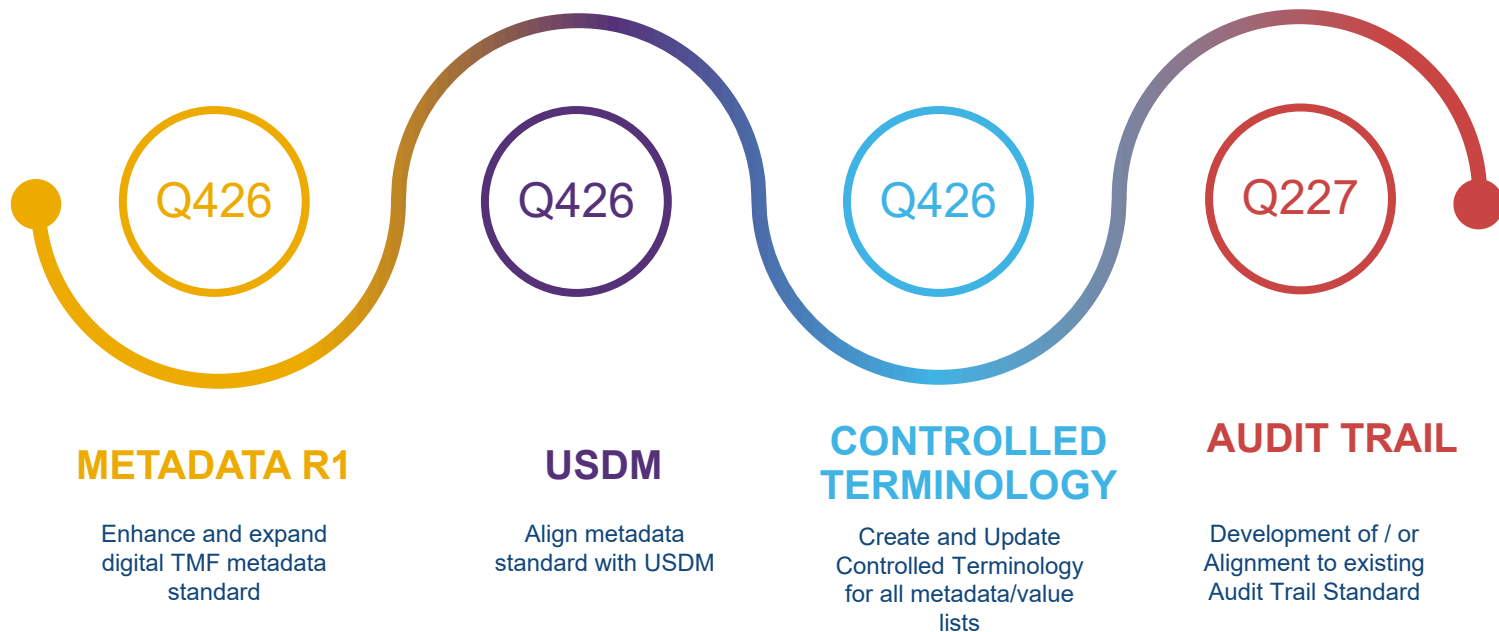
- Regular touchpoint meetings with regulators to inform them of progress and new releases

	2025		2026		2027		2028	
	H1	H2	H1	H2	H1	H2	H1	H2
					v4			v4.1
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								
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								
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								
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 Activities								
Community Engagement Activities								
Maintenance of Risk Based Approach Framework / Tools								
Update and maintenance of standard conventions including date conventions, metrics conventions etc.								
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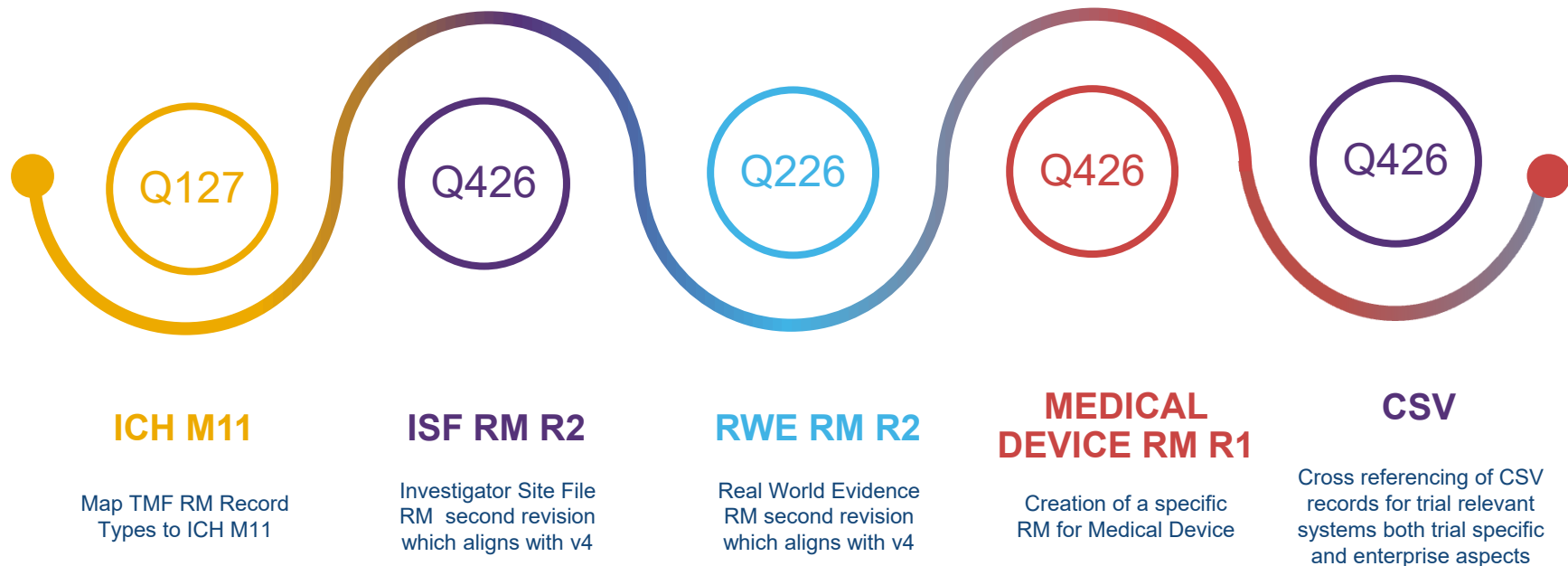
Core Standard Development



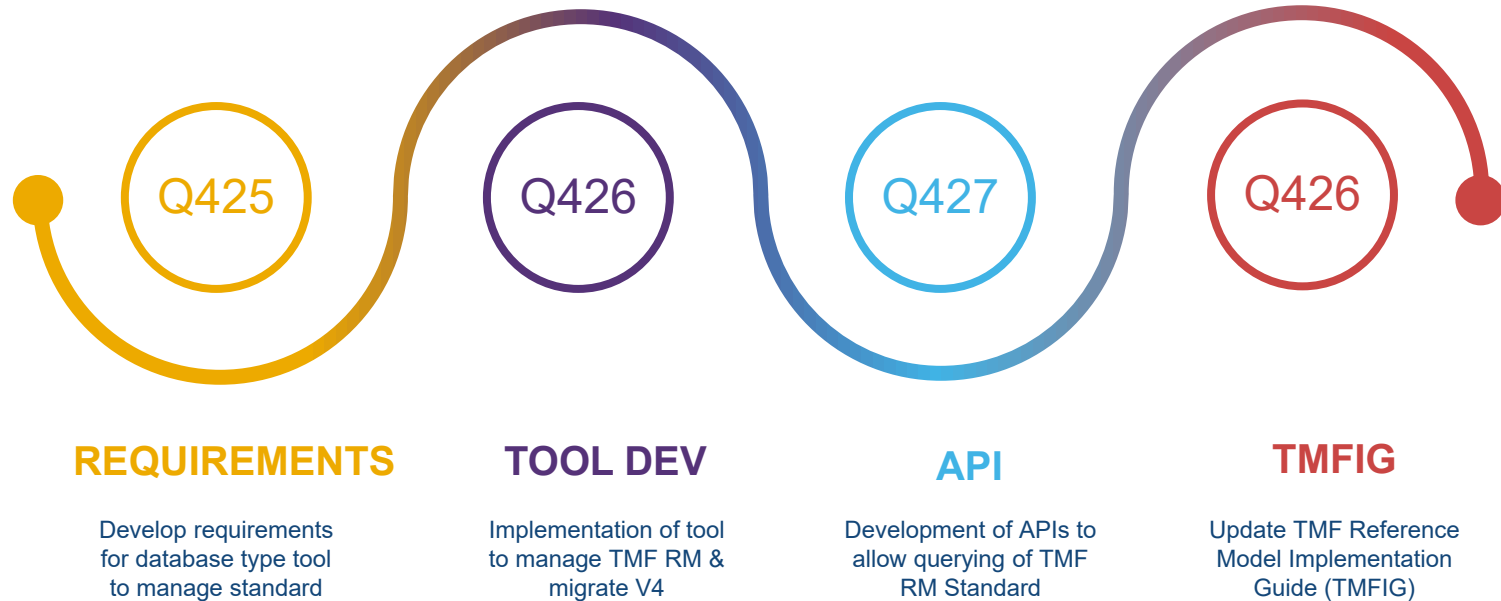
Digital TMF Metadata Standard / Interoperability



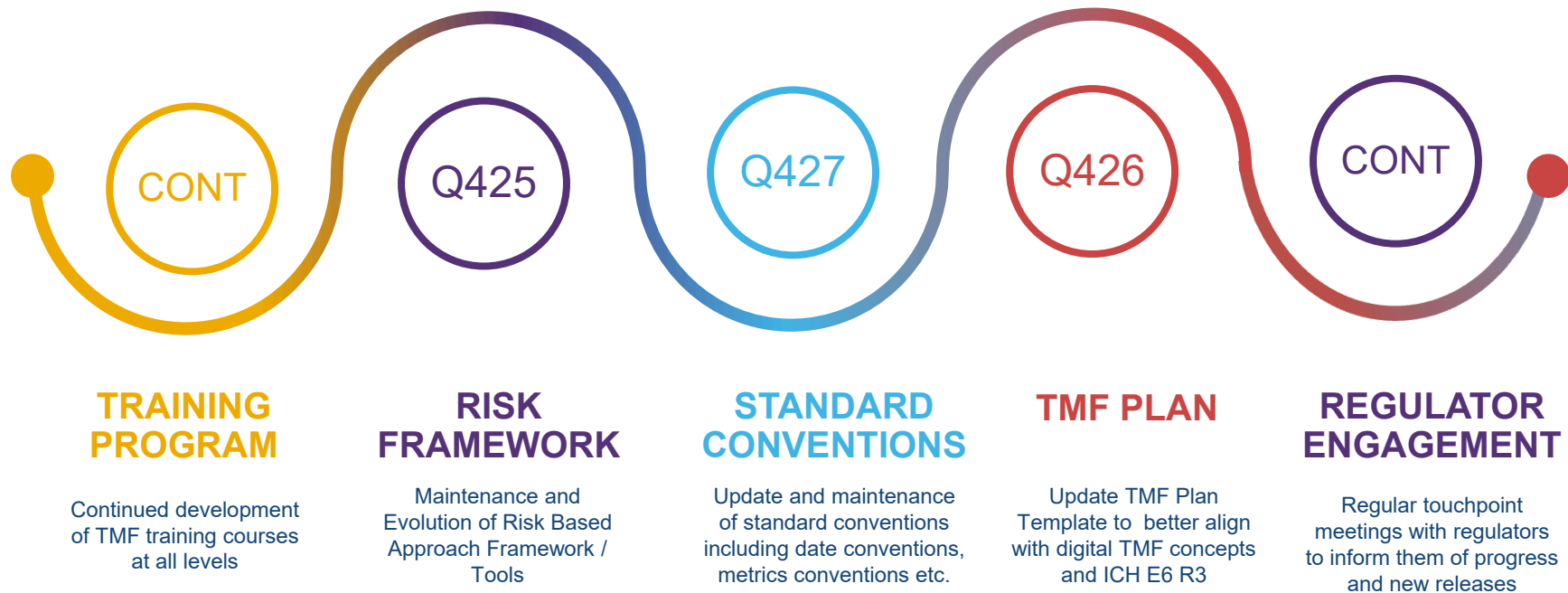
Ancillary Standards and Mappings



TMF RM Standard Management Tools



Training, guidance and frameworks





Thank You!

