



TMF Standard Model Roadmap

Presented by Paul Carter, CEO, Montrium Inc.

Meet the Speaker

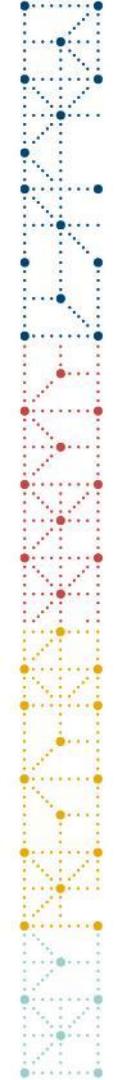


Paul Carter

Title: Founder and Chief Executive Officer

Organization: Montrium

25 year experience in clinical computerized systems. Longstanding Member and Chair of the TMF Reference Model Steering Committee.
<https://www.linkedin.com/in/paul-fenton-360b531/>



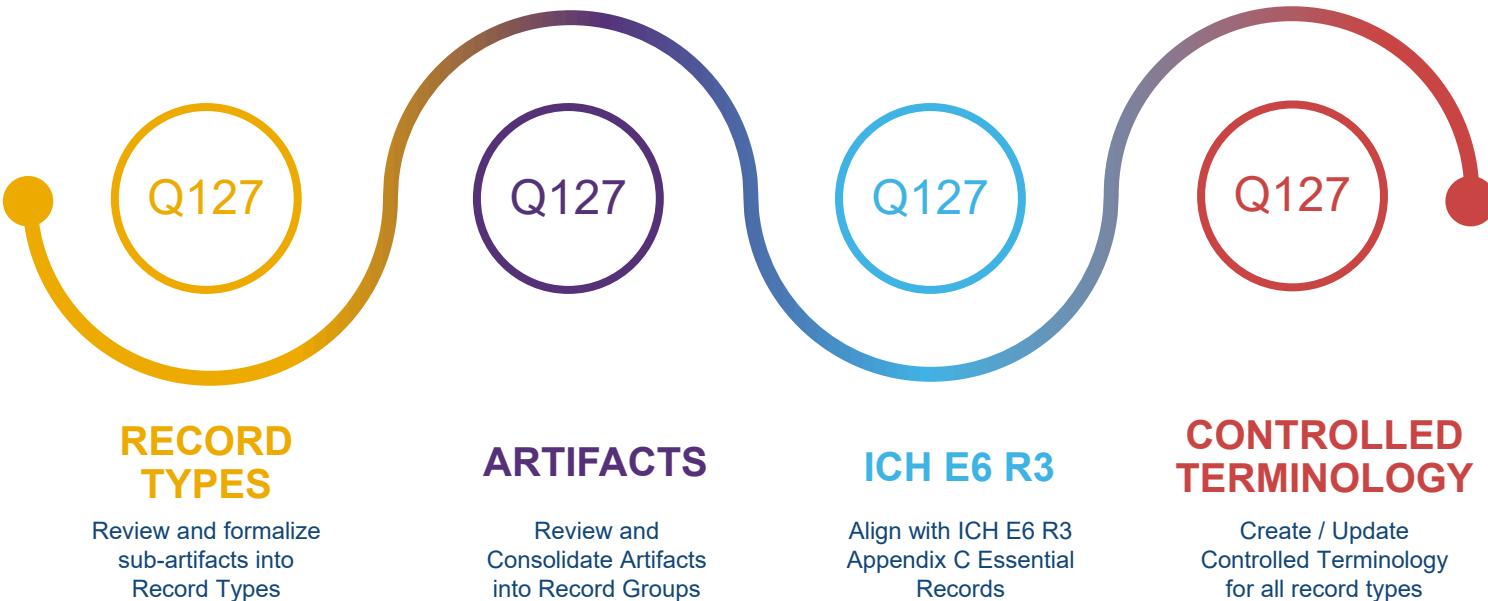
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CDISC TMF RM Roadmap 2025-2028

	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						R1		
Auxiliary Standards / Mappings								
Map TMF RM Record Types to ICH M11								
Investigator Site File RM	R1				R2			
<i>Real World Evidence RM</i>					R2			
Medical Device RM					R1			
Cross Referencing of CSV Records			R1					
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								

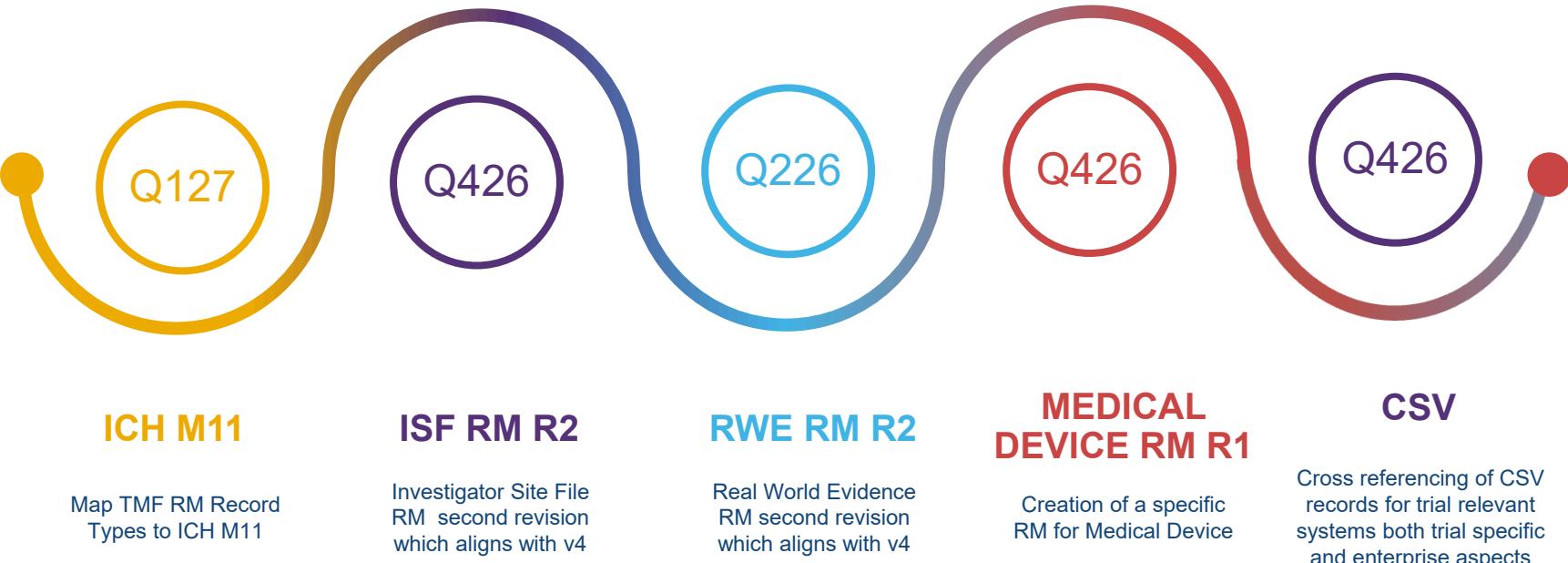
Core Standard Development



Digital TMF Metadata Standard / Interoperability



Ancillary Standards and Mappings



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

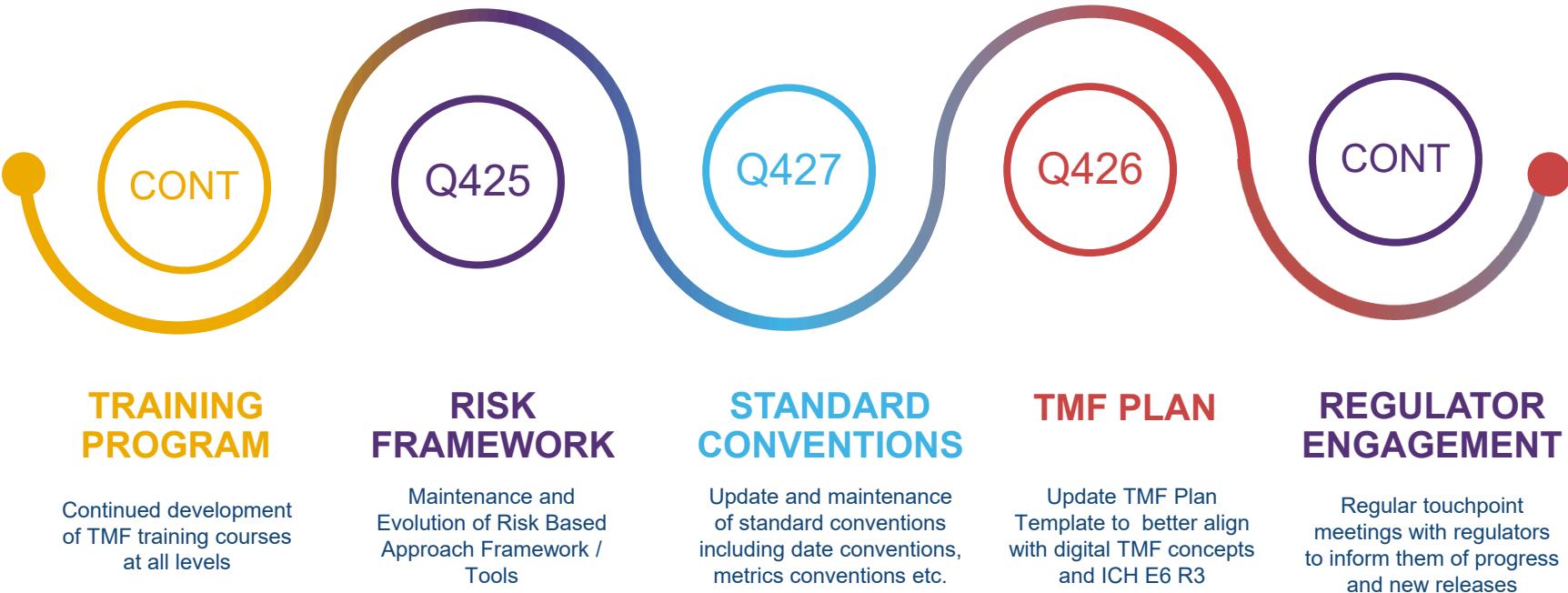
API

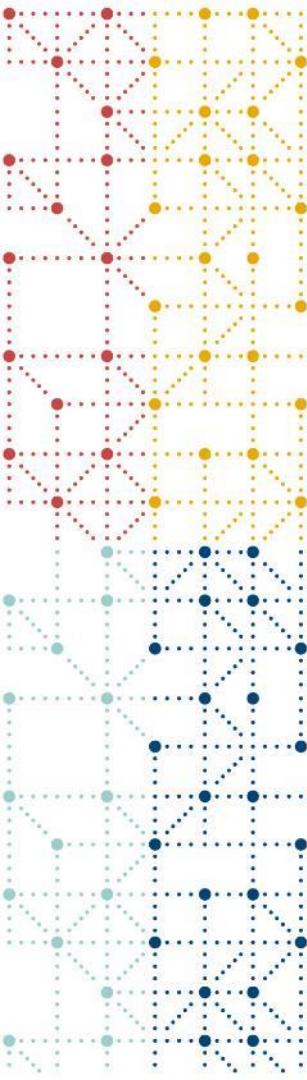
Development of APIs to
allow querying of TMF
RM Standard

TMFIG

Update TMF Reference
Model Implementation
Guide (TMFIG)

Training, guidance and frameworks





Thank You!

