

cdisc

2023

US  
INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER























**Who thought TMF was boring?**

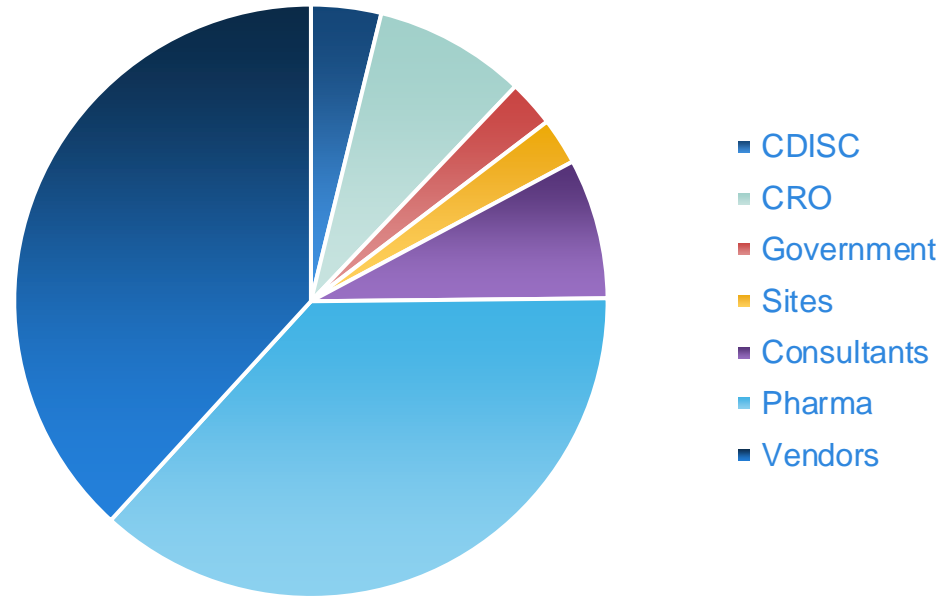


# Inaugural CDISC TMF Interchange in Baltimore

- 156 registered attendees (Target 150)
- 79 companies represented:
  - 35 Pharma
  - 9 CRO
  - 16 Vendors
- 12 exhibitors
- Exceeded target income



## Attendees





# Meet the Speaker

Karen Roy

**Title:** Co-Founder and Chair of the TMF Reference Model  
Steering Committee  
CDISC Consultant

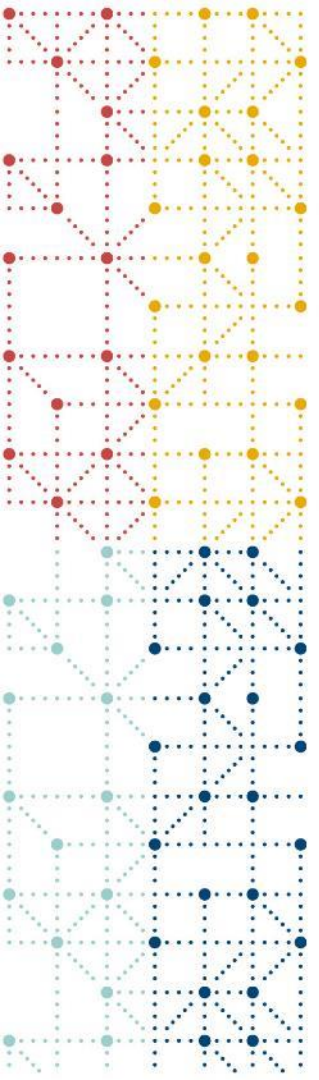
**Organizations:** TMF Reference Model and CDISC





# 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.*
- *I consult for CDISC!*



## **Trial Master File Reference Model**

**Where did the journey start?**





# Development of the TMF Reference Model

**DIA** DEVELOP  
INNOVATE  
ADVANCE



Multiple releases including  
Regulator feedback,  
Investigator Site Files,  
Devices, Process based  
metadata. Workgroups  
established  
Separated from DIA



2009 to 2010

Initial meeting in 2009  
with first version being  
released in 2010



2011 to 2013



2014 to 2021

Formalization with a  
Steering Committee.  
**Release of the  
Exchange Mechanism  
Specification** and  
Version 3



2022 onwards



Forward to Compliance



# The TMF RM is now part of CDISC

*Mission: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*



GLOBAL NON-PROFIT  
CLINICAL RESEARCH  
STANDARDS  
DEVELOPMENT  
ORGANIZATION WITH 40+  
STAFF



RECOGNITION BY  
REGULATORY  
AGENCIES



ABILITY TO EXTEND THE  
TMF METADATA AND  
PROVIDE IN MACHINE  
READABLE FORMAT



FRAMEWORK FOR  
STANDARDS  
DEVELOPMENT  
LIFECYCLE



EDUCATION TEAM  
FOR CERTIFIED  
TRAINING



MARKETING AND EVENTS  
STANDARDS TO REMAIN FREELY  
AVAILABLE



Medicines & Healthcare products  
Regulatory Agency

# ICH E6 (R3) Appendix C

Michelle Gabriel, GCP Inspector  
18 July 2023





# Charting a Course to Standardization: The Future of the TMF Reference Model





# Where is the TMF Reference Model at today?

- The reference model itself is an Excel spreadsheet
- We need to be able to better map the TMF RM to other standard and models
- We need to expand the reference model in terms of metadata
- We have developed an initial standard for eTMF Interchange: the EMS (Exchange Mechanism Standard)
- We are already embarking on our CDISC journey to standardisation!





## TMF Standards Sub-Group

- Established in December 2022
- Will oversee the move of the TMF Reference Model from a de-facto standard to a formal standard
- 4 Initiatives:
  - Migration of TMF RM to CDISC Library
  - Evolution of EMS/Interoperability
  - TMF RM Standard Alignment and Management
  - Development of Controlled Terminology and alignment with ICH M11

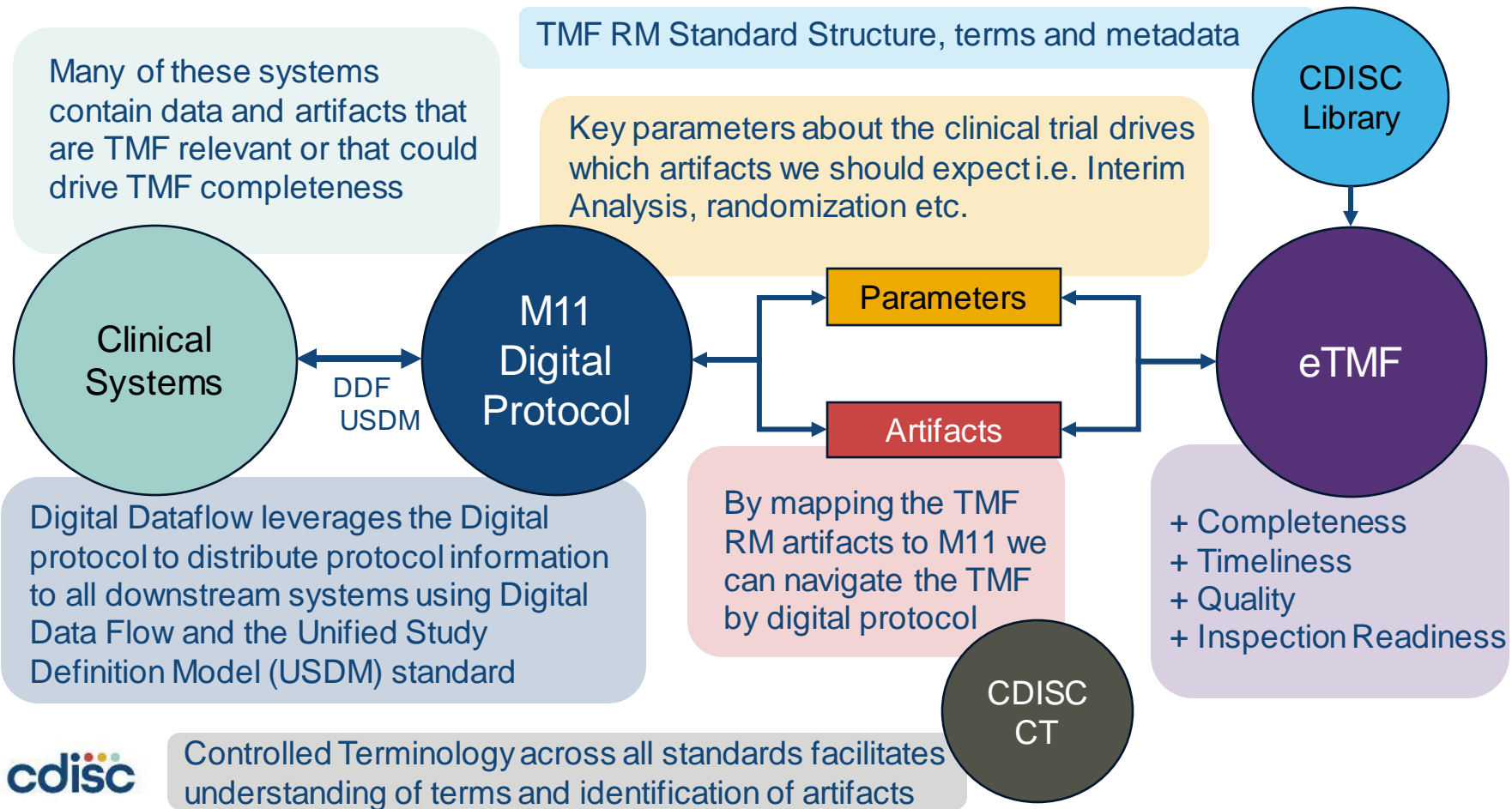


# TMF RM Standard Alignment and Integration

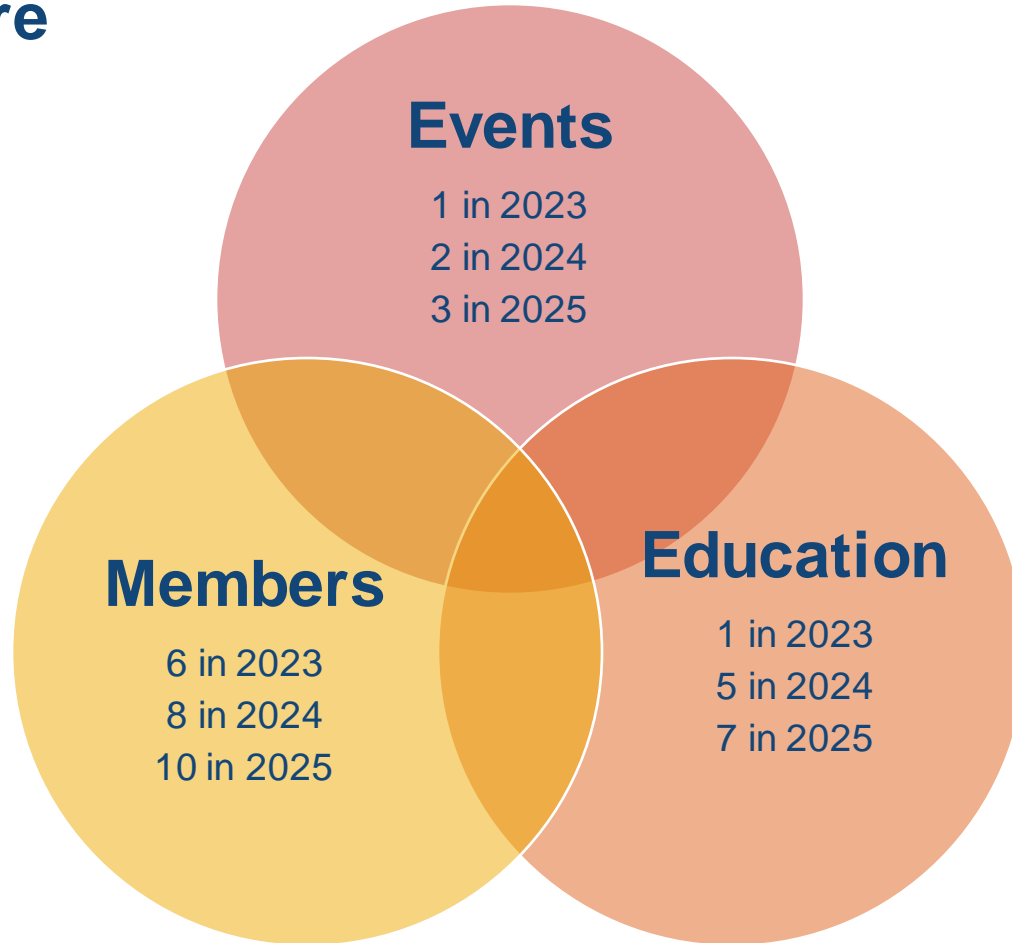
- The CDISC vision is for TMF to be full integrated into the standards landscape
- As DDF and ICH M11 standards evolve, we will align and integrate the CDISC TMF RM Standard
- We have initiated a project with the NCI-EVS team to develop and align controlled terminology for TMF

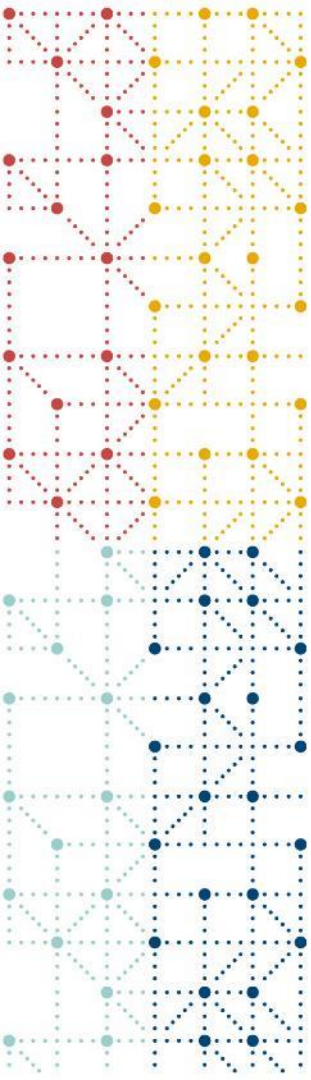


# Using M11 and DDF to drive the eTMF



# The Future





**Thank you!**

[kroy@cdisc.org](mailto:kroy@cdisc.org)

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