

WITH STANDARDS – UNLOCK THE POWER OF DATA



2022
US
INTERCHANGE
26-27 OCTOBER | AUSTIN



TMF Implementation Plan



Meet the Speakers



Karen Roy

Title: Chair of the TMF Reference Model Steering Committee

Organization: TMF Reference Model and Phlexglobal



Kathie Clark

Title: TMF Reference Model Steering Committee Member

Organization: TMF Reference Model and Ennov



Paul Fenton

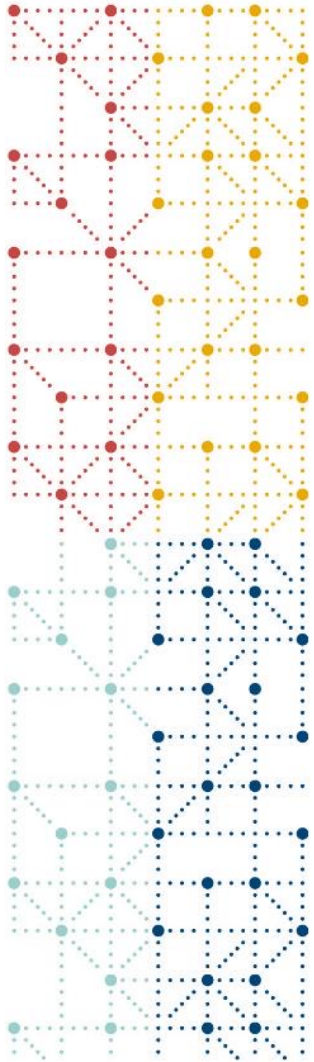
Title: TMF Reference Model Steering Committee Member

Organization: TMF Reference Model and Montrium



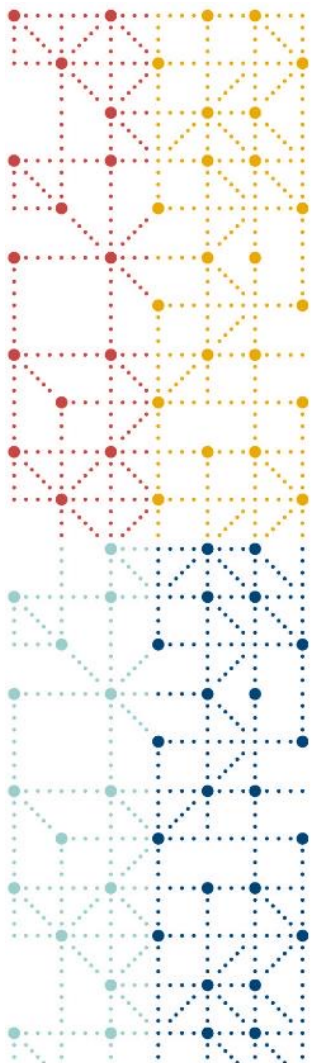
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. History of the TMF Reference Model – Karen Roy
2. Transition to CDISC Progress – Kathie Clark
3. Technology Team – Paul Fenton
4. The Future– Karen Roy



History of the TMF Reference Model

Karen Roy

Co-Founder and Chair of the TMF Reference Model Steering Committee

SVP of Clinical Marketing at Phlexglobal



What *is* the Trial Master File?

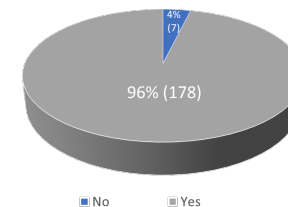
The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated [...]. It shall be readily available, and directly accessible upon request, to the Member States.

[EU Regulation 536/2014]

What *is* the Trial Master File Reference Model?

A Standardised structure, contents and naming of these Essential documents

2022 Survey:
Organizations using TMF Reference Model



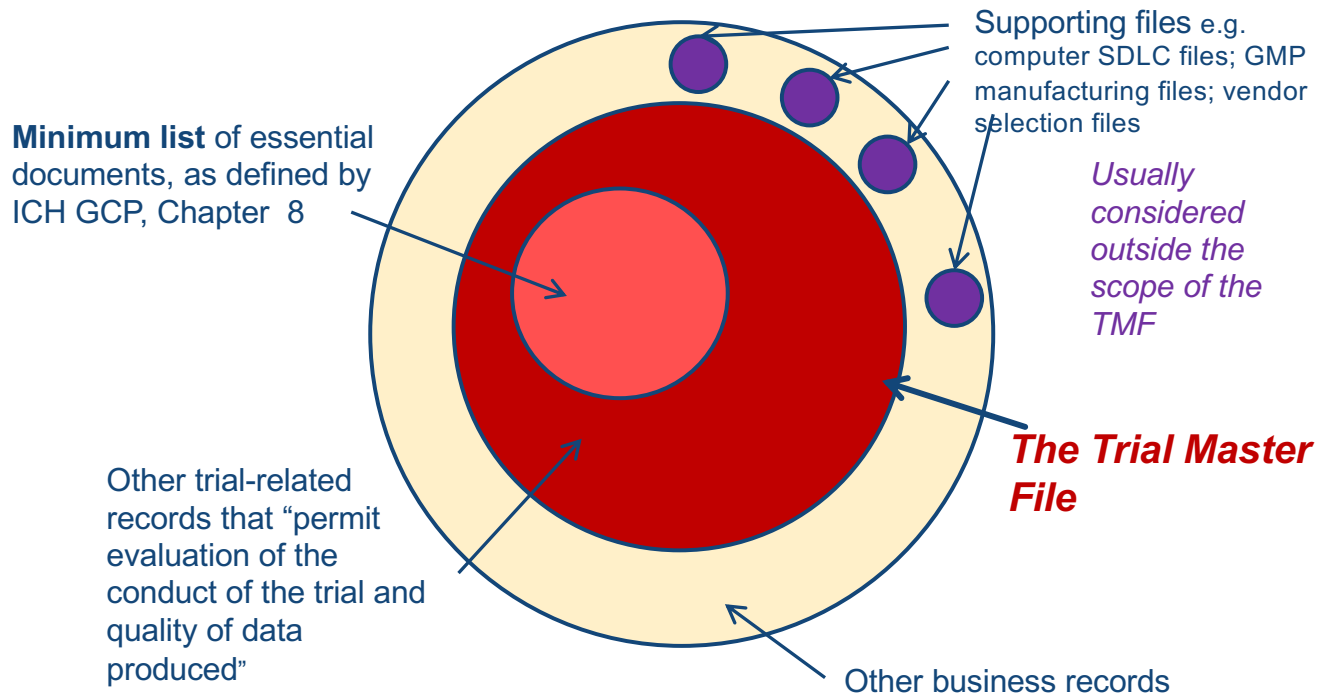


Why a TMF Reference Model?

- ICH GCP Section 8.2 – 8.4
- “The **minimum** list of essential documents that has been developed.....”
- ICH GCP did **NOT** provide a comprehensive contents list for the TMF
 - Examples of missing documentation:
 - Electronic systems
 - Data management and statistical methodology
 - Safety monitoring
- Everyone had their own customised structure – Sponsors, CROs and third parties



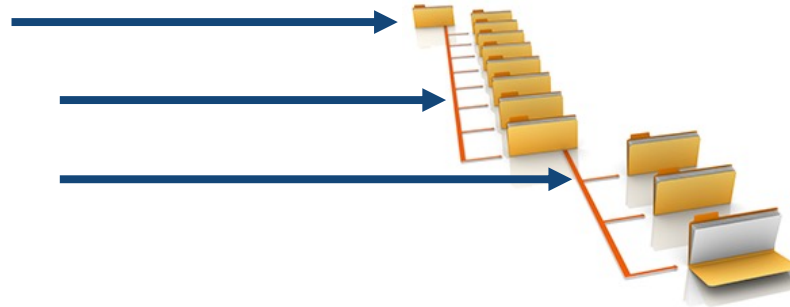
Defining the TMF Reference Model





Structure and Content of the Model

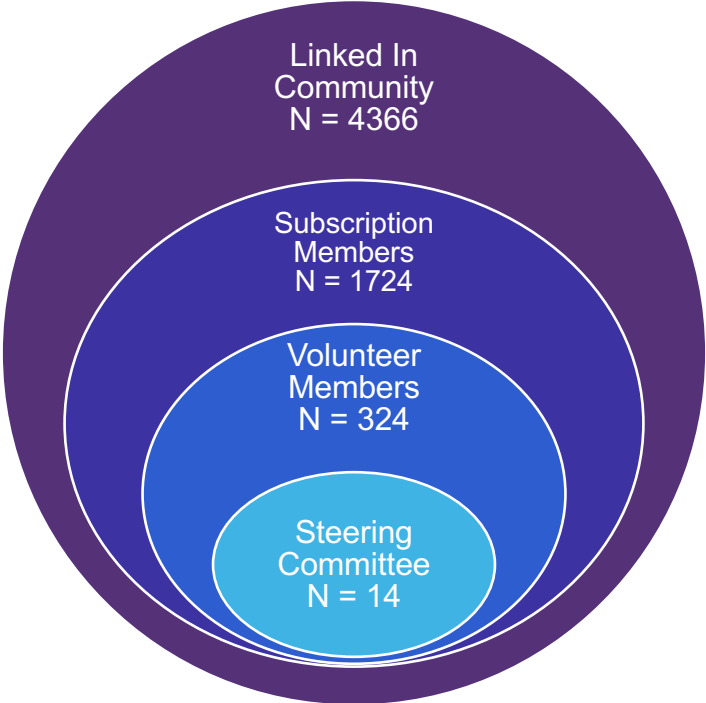
- Data held in a simple Excel spreadsheet
 - Easy for non-technical people to use!
- Hierarchical structure
 - 11 Zones
 - 48 Sections
 - 249 Artifacts



607 Sub-Artifacts



The TMF Reference Model Community



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

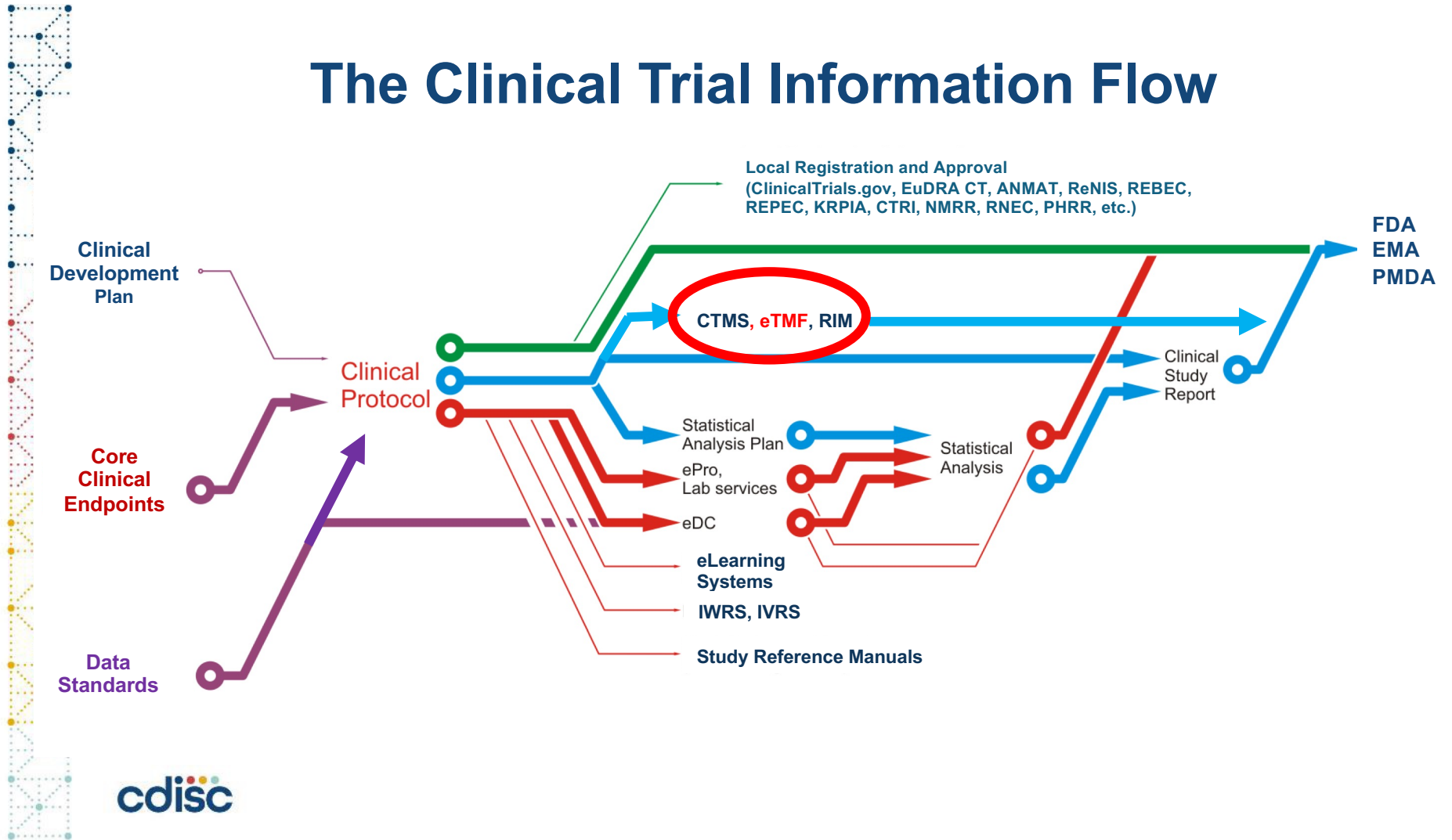


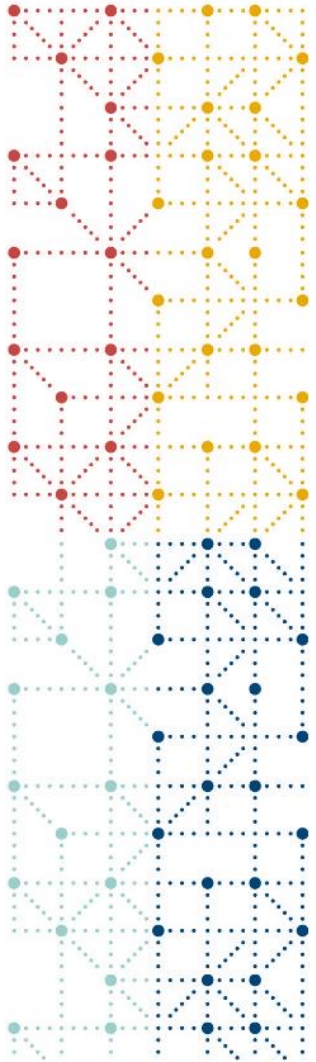
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Forward to Compliance

cdisc

The Clinical Trial Information Flow





Transition to CDISC

Kathie Clark - Product Director, CTMS and eTMF, Ennov; Member, TMF Reference Model Steering Committee



Implementation/Transition Approach

Overview

- Core team defined for transition
 - Members from both CDISC and TMF Reference Model Steering Committee
 - Weekly meetings to define, prioritize and report on activities
- Implementation Plan created
 - Goals & Objectives - Short Term and Long Term
 - Governance
 - TMF Reference Model Maintenance & Rollover
 - Sub-teams
 - Communications

Short Term Goals

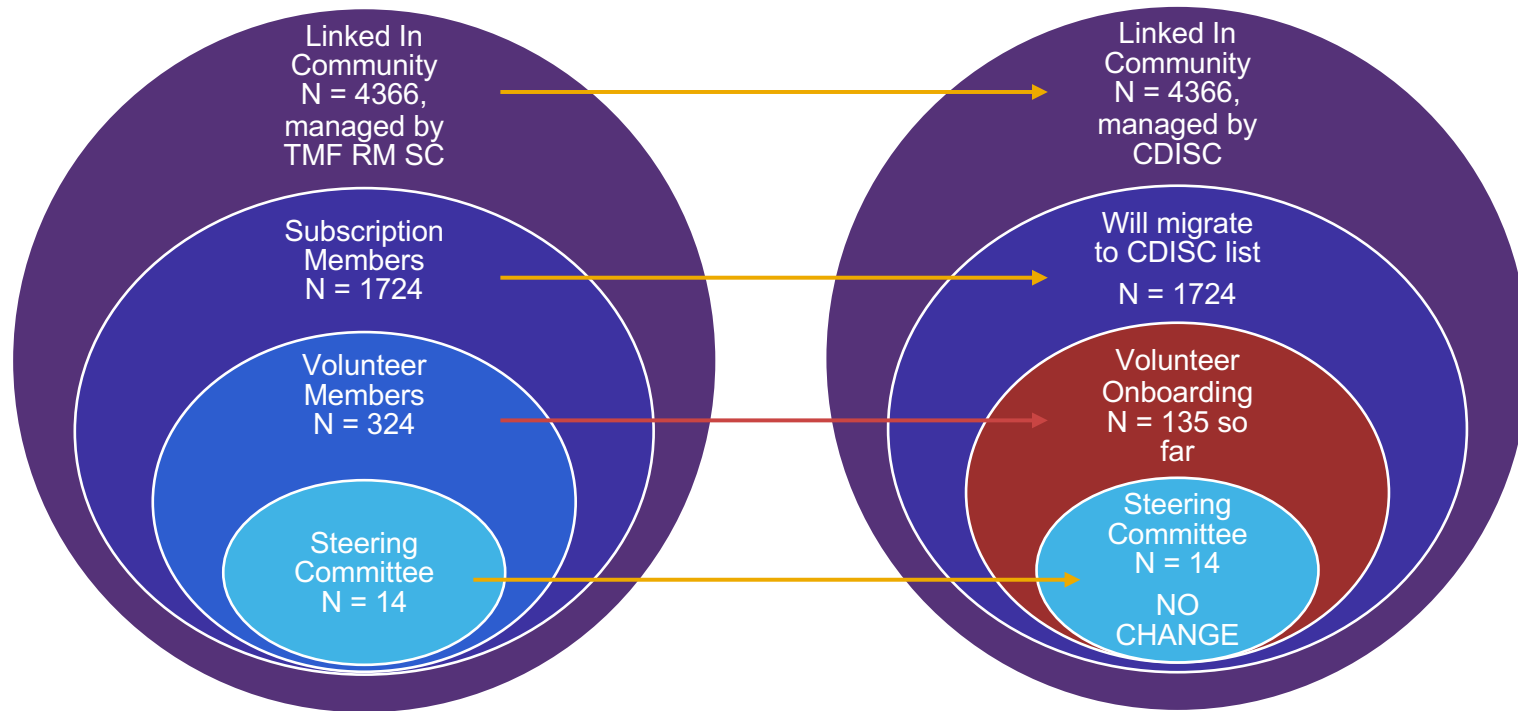
- Maintain forward momentum of TMF activities without disruption
- Develop standards governance and formalization plan for TMF under CDISC
- Develop membership framework for TMF in CDISC
- Load all TMF Models into CDISC Library



CDISC Implementation Areas

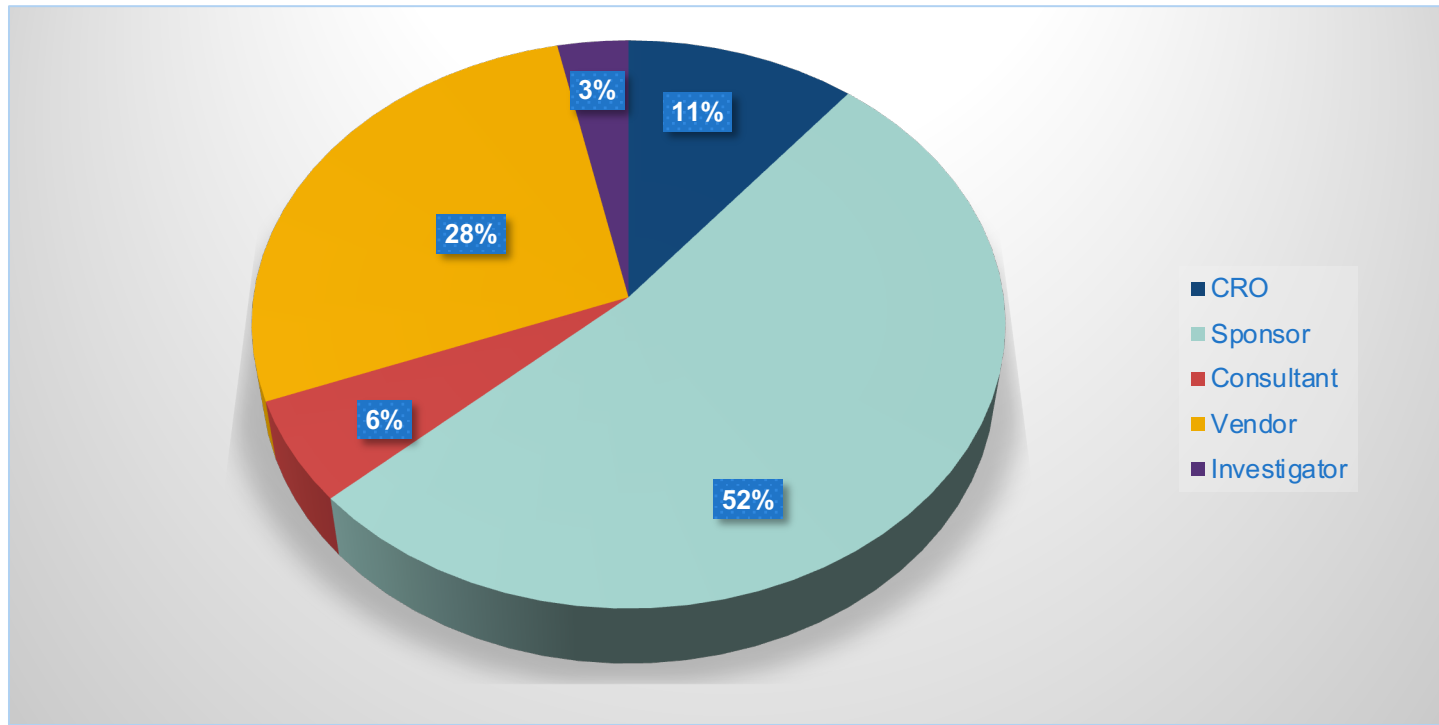
- Membership – Karen Roy, Sheila Leaman, Amy Palmer
- Communications – Kathie Clark, Rhonda Facile
- Events – Mary Emanoil, Sheila Leaman
- Standards – Joanne Malia, Peter Van Reusel, Bess LeRoy
- Technology – Paul Fenton, Sam Hume

The TMF RM Community move to CDISC



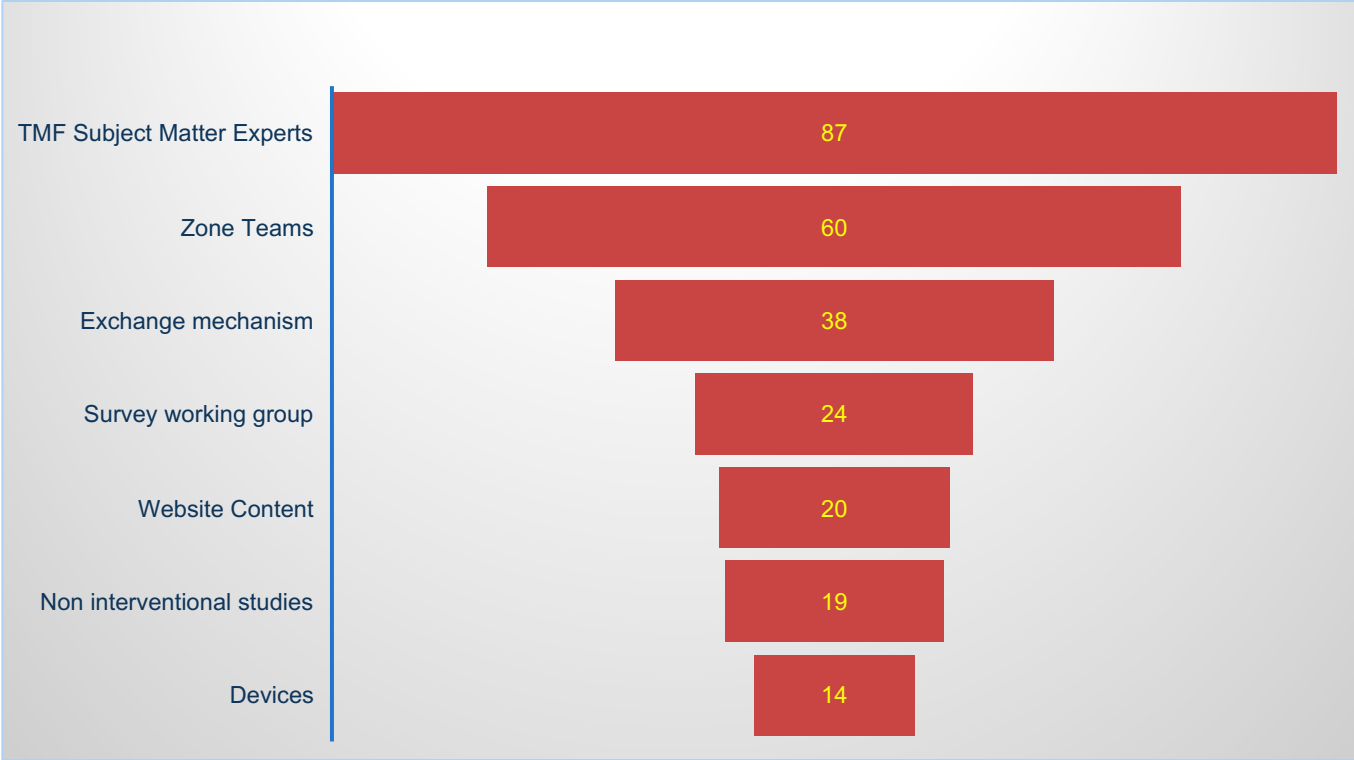


Volunteer Demographics





Special Interests of Volunteers





Registering as a Volunteer



Navigate to <https://www.cdisc.org/volunteer/tmf/form>



Review videos, CDISC policies, procedures, and CDISC and TMF charters



Provide contact information



Choose one or more TMF Volunteer Groups

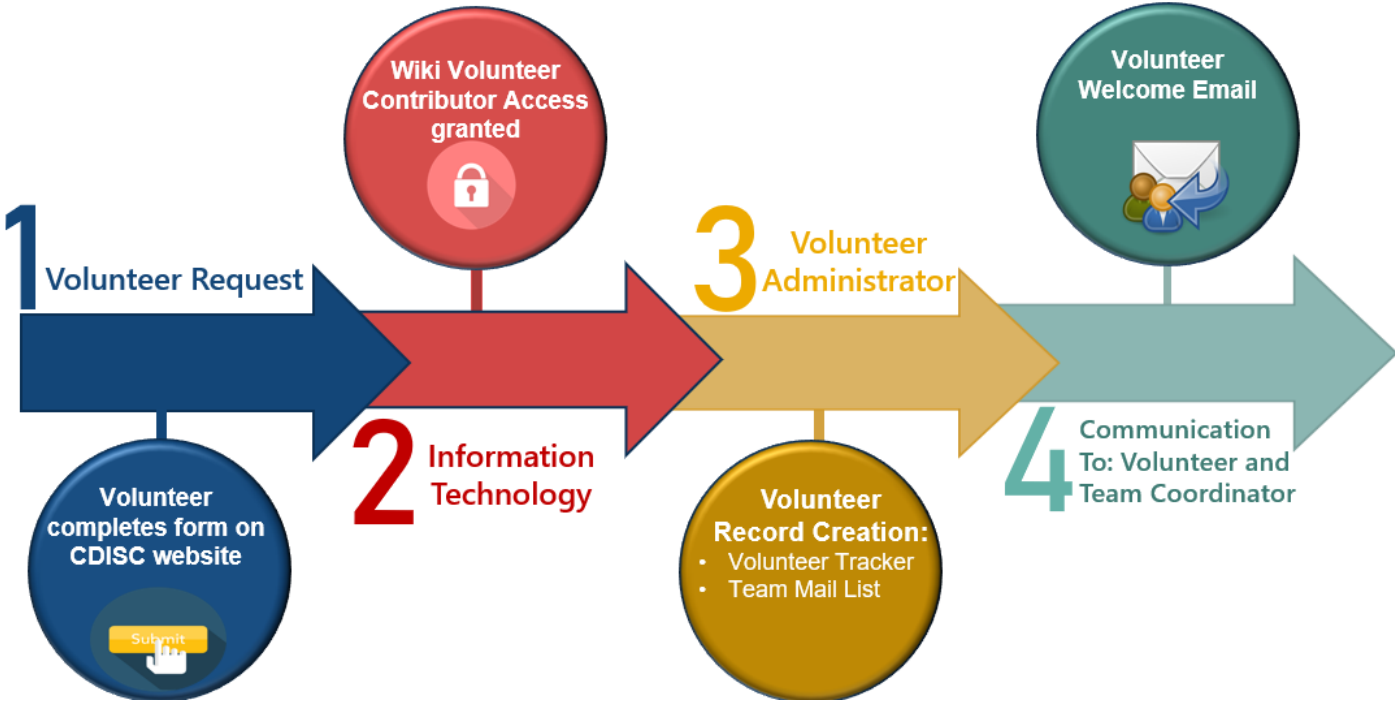


Submit form



CDISC Volunteer Coordinator will begin onboarding process

Volunteer Onboarding



CDISC Implementation Progress

Completed

- Memorandum of Understanding signed on 6-Apr-2022
- Presentation at CDISC Board Meeting on 8-Apr-2022 and 24-Oct-2022
- [CDISC Press Release](#) 27-Apr-2022
- TMF Summit Keynote 03-May-2022
- First General Meeting as part of CDISC 13-Oct-2022

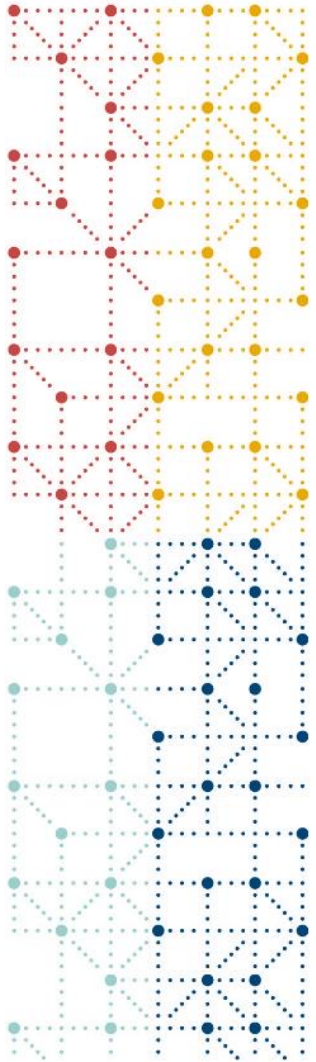
Upcoming and In Process

- TMF Summit London presentation 16-Nov-2022
- Volunteer transition
- Charter updates
- Final implementation plans for
 - Model governance
 - Technology
 - Website content
 - Events



Coming Soon—CDISC Tools for TMF RM

- Wiki
 - Team Collaboration And Development Space (already trialed for Change Control board)
 - Repository Of Draft Standards / Mechanism For Public Review
 - Project Status Updates
- Jira
 - Issue tracking tool
 - Supports comment resolution
 - Integrates with the Wiki
- Knowledge Base and FAQs
 - Curated articles and FAQs
 - Considering development of glossary
 - Considering development of Health Authority guidance page



Technology Team

Paul Fenton – President and CEO, Montrium; Member, TMF Reference Model Steering Committee



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 ready to embark on our CDISC journey to standardization!

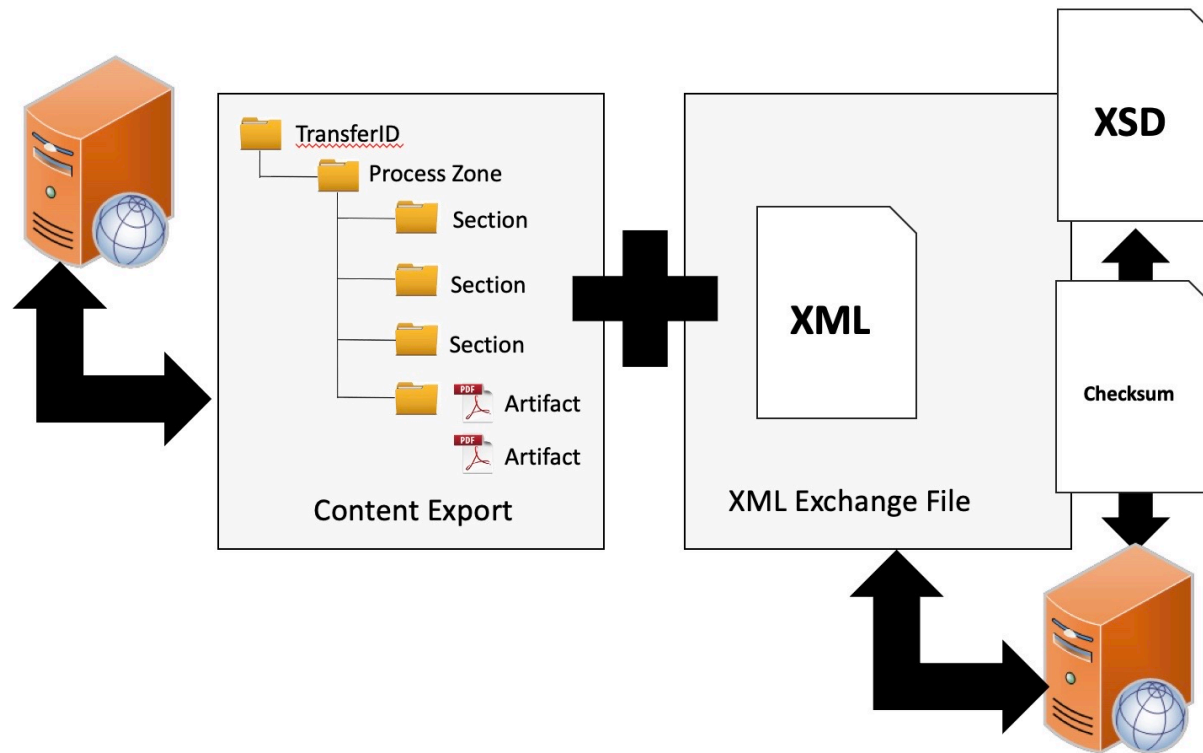


What is the EMS?

Electronic Trial Master File – Exchange Mechanism Standard

- An extension of the TMF RM which focuses on the transfer of content, metadata, audit trail and eSig information
- A TMF metadata standard
- A mechanism for exchanging TMF content between systems
- A method for describing TMF artifacts which is comprehensible by both humans and machines

EMS – How it works





How can the EMS be used?

- **Final eTMF transfer** to sponsor from CRO for archiving
- **Interim transfer of eTMF content** to central eTMF or other trial management system
- **Migration of eTMF content** following **merger and acquisition**
- **Migration of eTMF content** following **upgrade** or change of eTMF system
- **Long term archiving** of eTMF content and associated metadata



Where are we at today?

- Version 1 of the specification and schema was launched
- Some vendors have started to implement
- Uptake has not been as strong as we had hoped
- We need to re-engage with the sponsor, CRO and vendor community to drive adoption
- We need guidance on how to evolve the EMS moving forward - this is where CDISC can help!

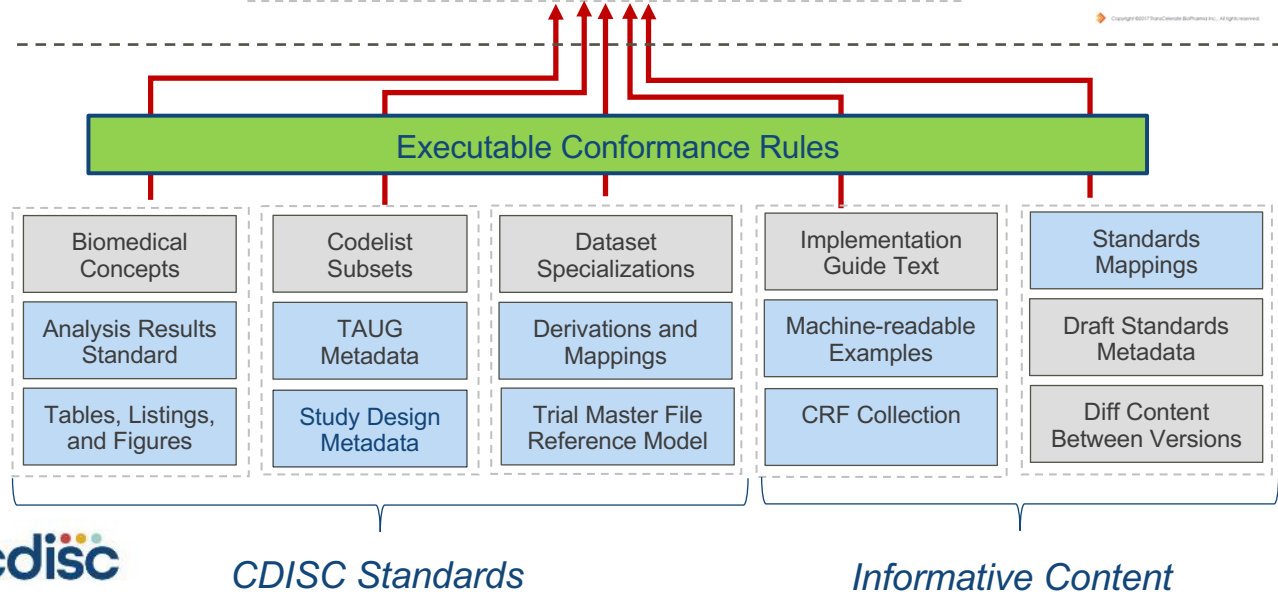
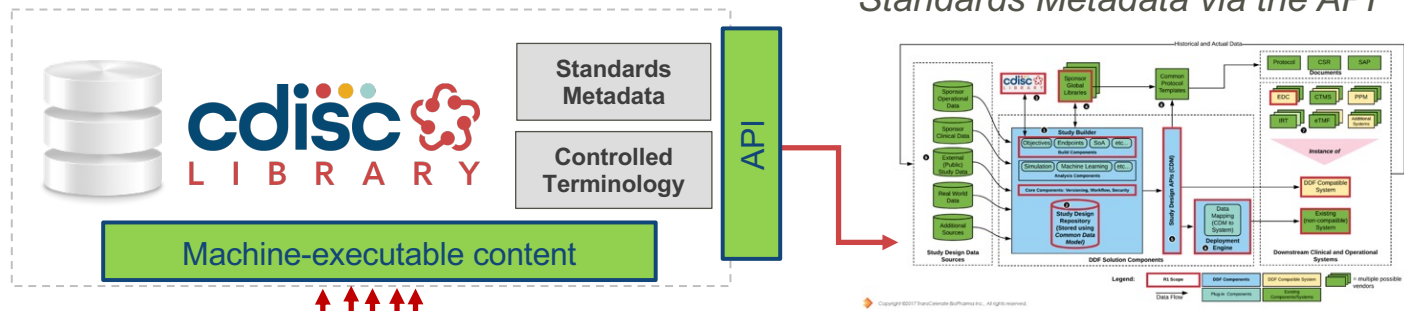


New Tech Sub-team

- Migration of the Reference Model from the current spreadsheet format to the CDISC Library database
- Integration of future evolutions such as an expanded metadata model, controlled taxonomy, artifact relationships and mapping to other standards into the CDISC Library
- Integration and alignment with other CDISC and Industry standards from a technical standpoint
- Continued evolution of the Exchange Mechanism Standard and alignment with other technical initiatives

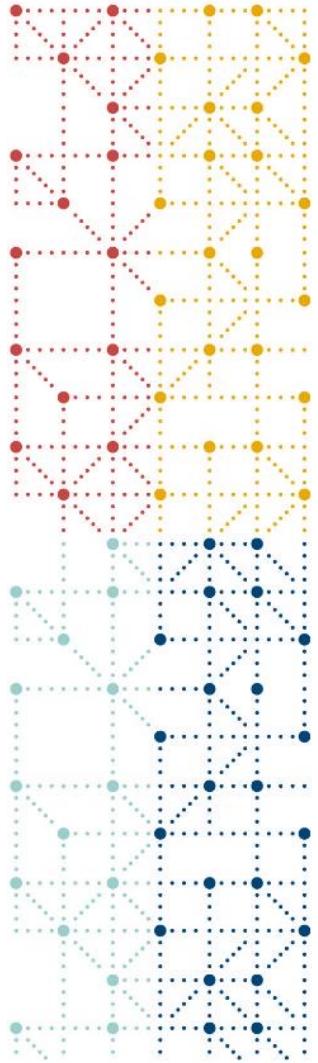
CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



CDISC Standards

Informative Content



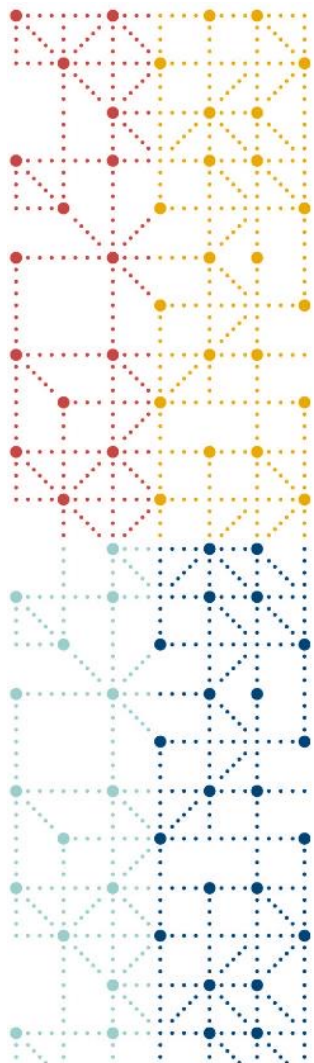
The Future

Karen Roy



Strategy Pillars for the Future





Thank You!

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