



2023
EUROPE
INTERCHANGE
COPENHAGEN | 26-27 APRIL



TMF Implementation Plan

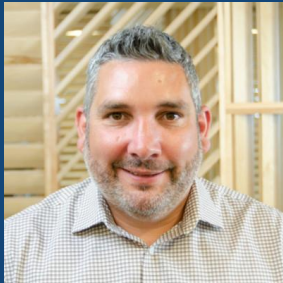
Meet the Speakers



Karen Roy

Title: Chair of the TMF Reference Model Steering Committee

Organization: TMF Reference Model and CDISC



Paul Fenton

Title: TMF Reference Model Steering Committee Member

Organization: TMF Reference Model and Montrium



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.*
- *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 – Karen Roy
3. Standards Team – Paul Fenton
4. The Future–Karen Roy



Trial Master File Reference Model

History of the TMF Reference Model

Karen Roy

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

CDISC Consultant

What *is* the Trial Master File?

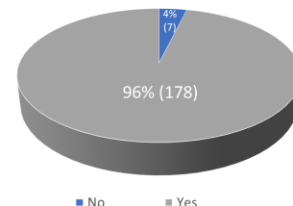
The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated [...]. 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

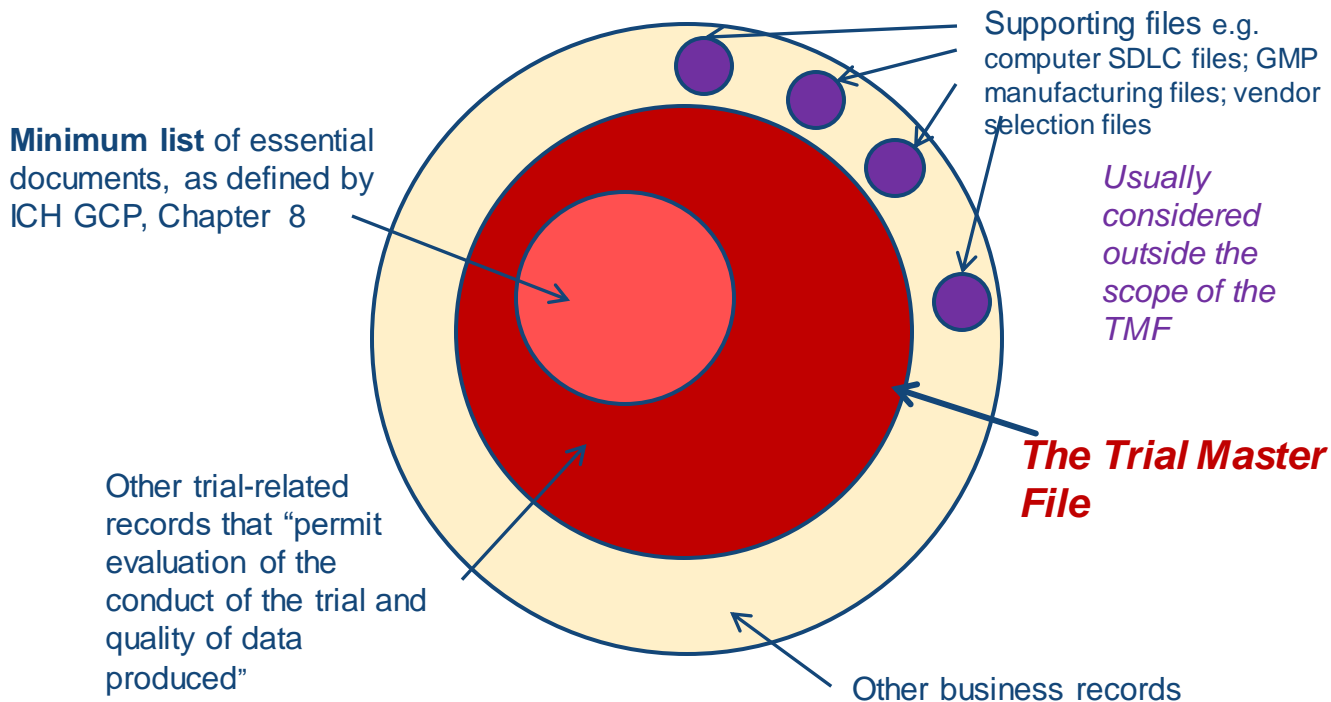




Why a TMF Reference Model?

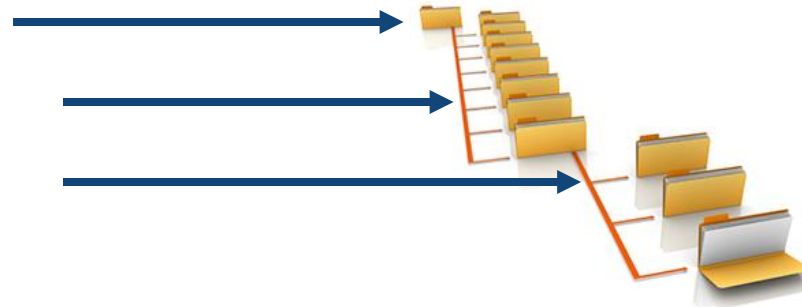
- ICH GCP Section 8.2 – 8.4
- “The **minimum** list of essential documents that has been developed.....”
- ICH GCP did **NOT** provide a comprehensive contents list for the TMF
 - Examples of missing documentation:
 - Electronic systems
 - Data management and statistical methodology
 - Safety monitoring
- 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

Development of the TMF Reference Model

DIA DEVELOP
INNOVATE
ADVANCE



Document & Records Management
Community



2009 to 2010

Initial meeting in 2009
with first version being
released in 2010

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



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 Move to **cdisc**



H1 2022

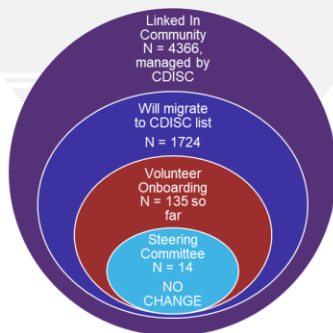
- Volunteer onboarding process established (230 to date)
- Management of LinkedIn migrated
- General meetings moved to quarterly, CDISC managed
- Presentations at EU TMF Summit
- SC Chair attendance at CDISC Board
- CDISC Interchange presence (US)
- Update Charters
- Set-up Wiki and JIRA workflows
- Decommission Groups.io

H1 2023

- *TMF RM to CDISC Library (database)*
- *Develop Education Offerings for TMF RM training accreditation*
- *Develop Accreditation for TMF RM Implementation*
- *Focus on Regulatory acceptance*

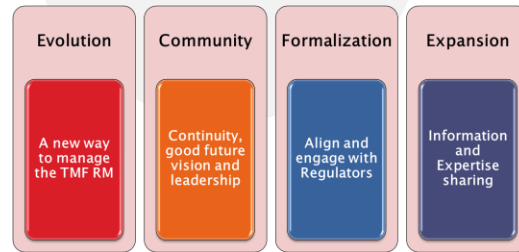
- Final decision made with community input
- Memorandum of Understanding signed
- Implementation team created and plan produced
- SC attended CDISC Board meeting
- New Logo
- Press Release
- Presentations at US TMF Summit

H2 2022



- *Develop TMF RM Roadmap*
- *Standards governance and formalization plan*
- *Marketing plan and materials*
- *TMF Events*
- *TMF RM website in CDISC, incorporating forums*
- *TMF RM deliverables to Knowledge Base*
- *TMF RM spreadsheet to Wiki*
- *CDISC Interchange presence (EU)*

H2 2023



The NEW Initiatives

- The Education Team
- The CDISC TMF Interchange!
- The Standards Team





Education Team

- Purpose

- Oversee the development of training courses through CDISC to increase and support the knowledge of the TMF RM.

- Trainings

- Format: in-person, webinars, and eLearning
- CEUs will be available
- Supported by CDISC's education team

- First Deliverable:

- In-Person Workshop at the CDISC TMF Interchange – 27 Sep

NEW ANNUAL CONFERENCE

2023
CDISC TMF
INTERCHANGE

28-29 SEPTEMBER
BALTIMORE



The CDISC TMF Interchange

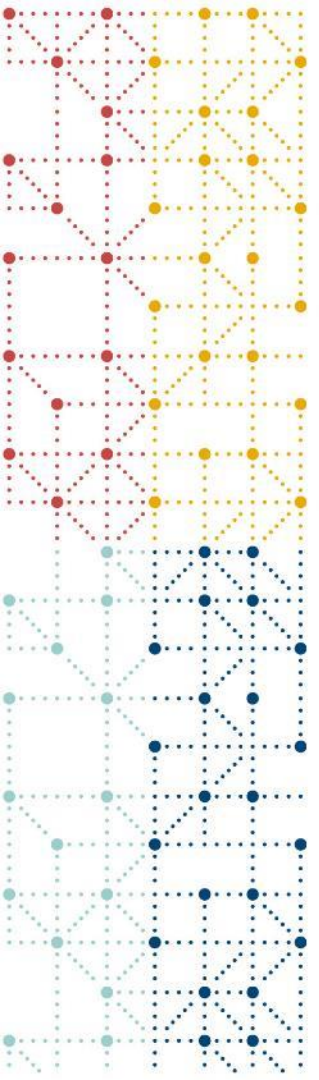
Program Development

- Program committee
- Call for abstracts
- 60-day window
- Submission review based on merit

Abstract Acceptance Criteria

- Potential to educate audience
- Anticipated audience interest
- Timeliness of topic
- Uniqueness of the topic and approach
- Vendor neutrality





Standards 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!

K

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
- 3 Initiatives:
 - Migration of TMF RM to CDISC Library
 - Evolution of EMS/Interoperability
 - TMF RM Standard Alignment and Management



Initiative 1 – Migration of TMF RM to CDISC Library

- We want to move away from a Spreadsheet to a more dynamic format
- The CDISC library is a database where all CDISC standards are mapped and managed
- We will be able to search the library to find information on specific artifacts
- We should also be able to extract the model in Excel format
- Advantages to moving to the library include:
 - Ability to expand the RM (metadata)
 - Better control changes and version history
 - More easily map to other models and standards
 - Define sub-models for different types of trials

Team Leads: Kelley Robinson, Sam Hume



Objective 2 – Evolution of EMS / Interoperability

- EMS has been developed but has yet to be reduced to practice in a significant way
- Some vendors are adopting it, however, we need to re-engage with the vendor and business communities
- There are multiple use cases which we need to account for in future versions
- We need input from CDISC on how to better structure the initiative and promote its use
- The EMS should also be integrated into the CDISC library as part of the overall TMF RM standard
- We also need to ensure that we are aligned with the DDF initiative which has similar objectives

Team Leads: Jamie Toth, Aaron Grant



Objective 3 – TMF RM Standard Alignment and Management

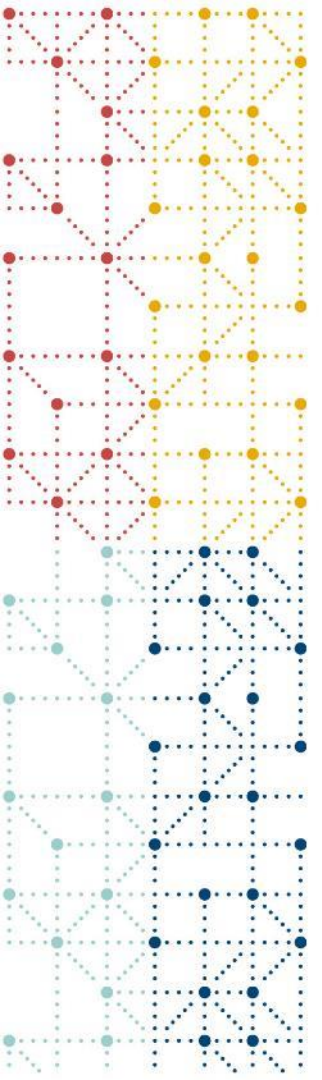
Part 1 – Process implementation

- We will adapt and apply formal CDISC standards management processes to properly manage the CDISC TMF RM as a standard

Part 2 – Standards Alignment and Integration

- The CDISC vision is for TMF to be full integrated into the standards landscape
- As DDF and digital protocol standards evolve, we should align and integrate the CDISC TMF RM Standard
- We also need to ensure alignment with CDISC controlled terminology and taxonomy

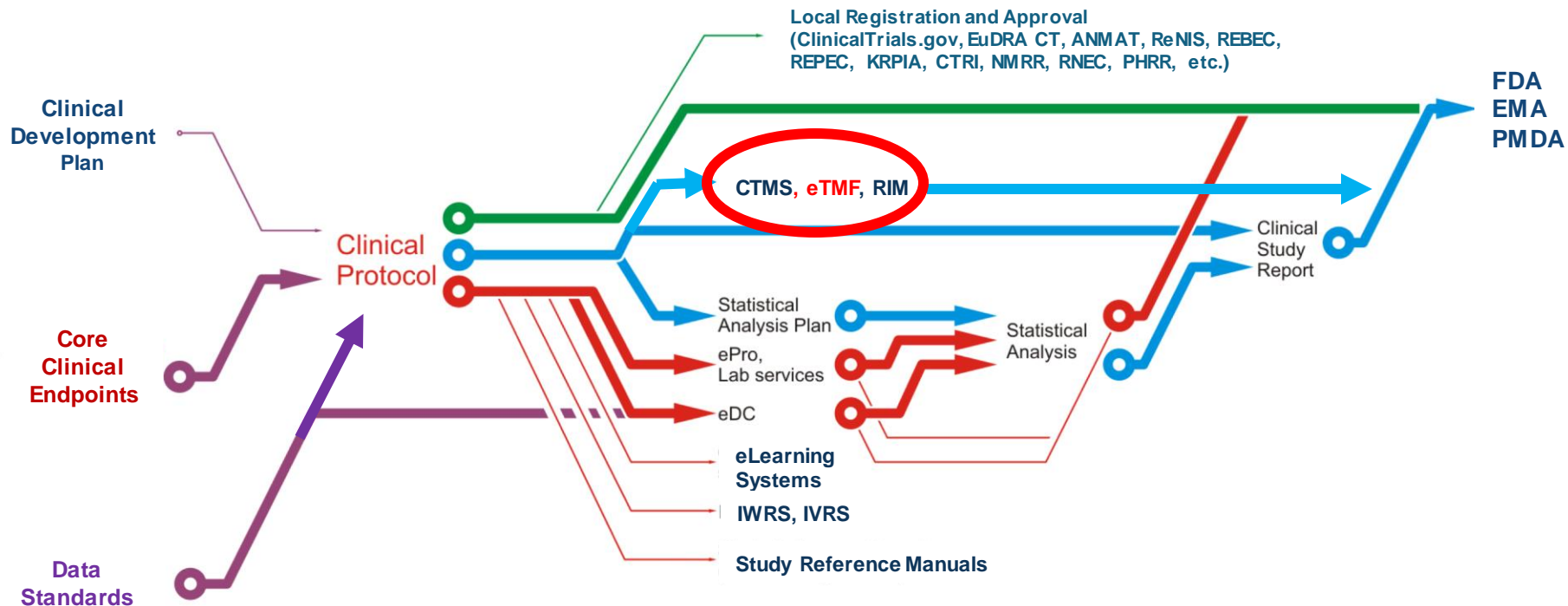
Team Leads: Bess LeRoy, Paul Fenton



The Future

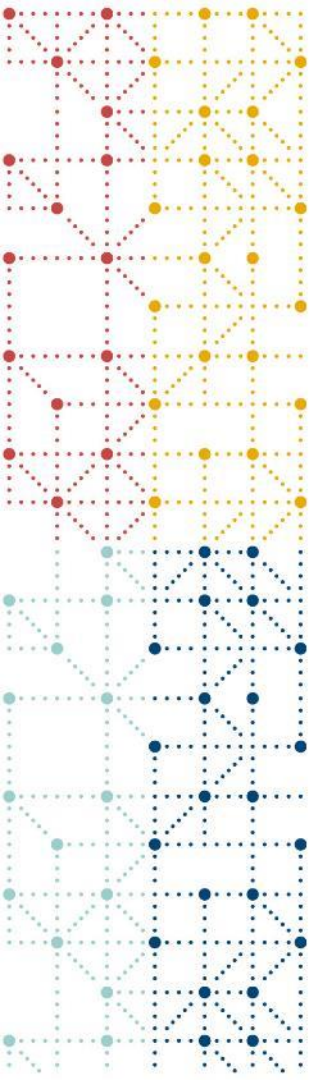
Karen Roy

The Clinical Trial Information Flow



Strategy Pillars for the Future





Thank You!

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