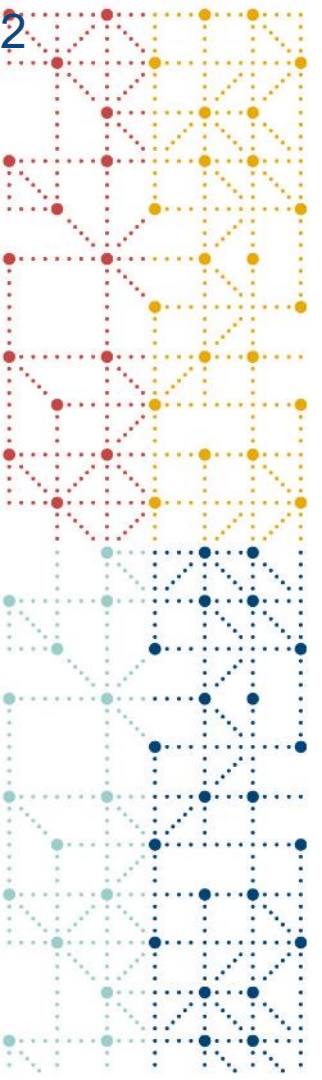


TMF Reference Model General Meeting Q4



TUES 5 DEC
11:00AM – 12:30PM US ET



Housekeeping

Housekeeping



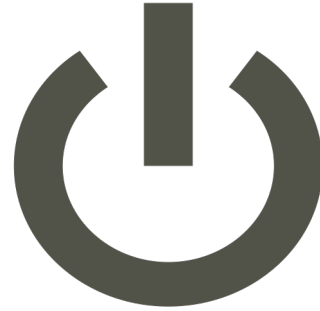
You will remain on **mute**

Housekeeping



Submit questions at any time via the Questions tool on your Zoom app

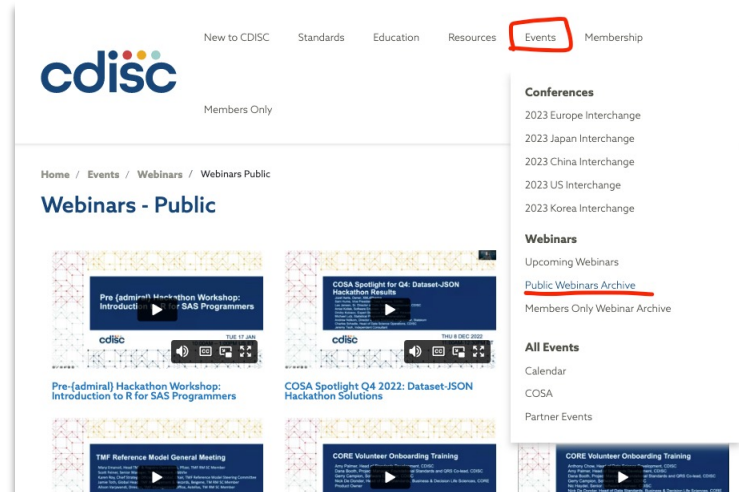
Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping



Webinar Recording

A recording of this webinar will be available in the Public Webinar Archive on the CDISC website.



The TMF Reference Model General Meeting Presenters

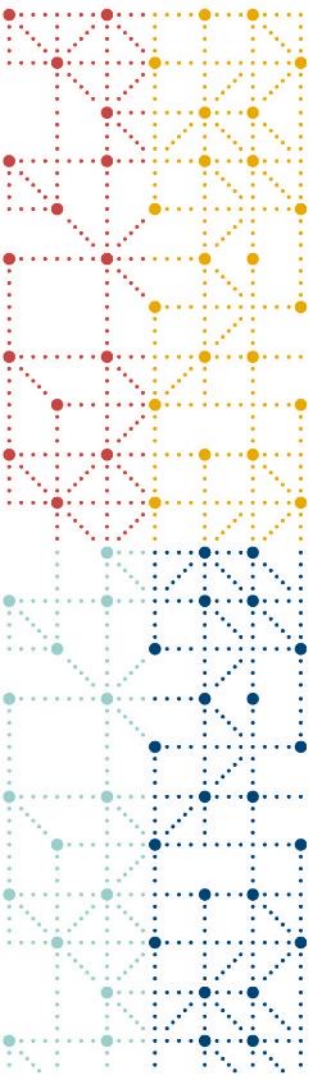


- Karen Roy, Consultant, CDISC; Chair, TMF Reference Model Steering Committee
- Lisa Mulcahy, Mulcahy Consulting; TMF RM SC Member and Co-founder
- Paul Fenton, CEO Montrium, TM RM SC Member
- Jamie Toth, Global Head, Trial Master File Management & Records, BeiGene ; TMF RM SC Member
- Eldin Rammell, Head of Quality Assurance, Phlexglobal; TMF RM SC Member
- Joanne Malia, Director, Clinical Documentation Management, Regeneron; TMF RM SC Member
- Rob DiCiccio, Vice President Portfolio Management, Transcelerate Biopharma Inc.



Agenda

- TMF RM in 2024
- TMF Education Update
- Standards Update
- CDISC TMF Interchanges
- Risk Initiative
- ICH E6 R3 – Health Canada View
- UK Clinical Trials update
- From Documents to Digital - Transcelerate
- Upcoming events and Q&A



TMF RM in 2024

Karen Roy

Strategy Pillars for the Future

Evolution

A new way
to manage
the TMF
RM

Community

Continuity,
good
future
vision and
leadership

Formalization

Align and
engage
with
Regulators

Expansion

Information
and
Expertise
sharing



Expansion

Information and expertise sharing

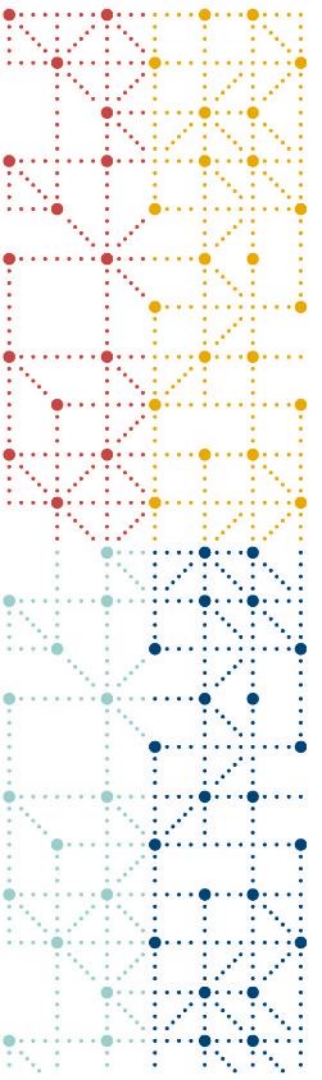
Re-brand to reflect the expanded activity
(aligned to CDISC remit and terminology)

Produce best practices and
documentation

Agree standardized TMF metrics both
internally and externally

Education





TMF Education Update

Lisa Mulcahy

Educational Committee Update

- Members of the Educational Committee Governance Committee
 - Dawn Niccum (Chair), Noreen Bouchard, Jennifer Stamper, Jackie Morrill, and Lisa Mulcahy
 - Outgoing Member: Donatella Ballerini (THANKS SO MUCH!) Incoming Member: Steph Viscomi (WELCOME!)
 - CDISC Education Team
- TMF RM Fundamentals* – Past and upcoming

TMF RM Fundamentals – in person	September 2023 at TMF Interchange	In person - Baltimore, MD
TMF RM Fundamentals – virtual	January 17-19, 2023 – 9A-12N ET	Virtual
TMF RM Fundamentals – in person	April 2024 at TMF Interchange	In person - Berlin, Germany



Educational Committee Update II

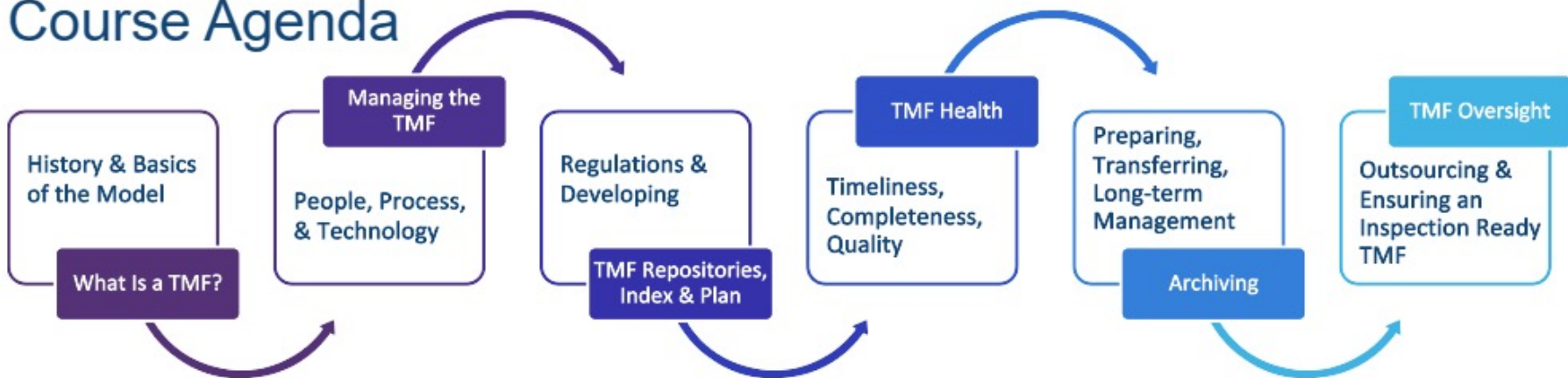
- New courses under development and planned

Introduction to the TMF RM	Timelines: March 2024	CDSIC website – Free, On demand
Quality Check of TMF Records	Timelines: Summer 2024?	CDSIC website – Fee \$150, On demand
TMF for Data Managers and Statisticians	Timelines: October 2024	In person - US TMF Interchange
Risk-based Approach for TMF Management – Output of TMF RM Risk Initiative	Timelines: 2025?	TBD



TMF RM Fundamentals

Course Agenda



TMF Fundamentals - Virtual Course

17-19 January 2024 (9A-12N ET)

<https://learnstore.cdsc.org/product?catalog=FundamentalsOfTheTMFReferenceModel>

TMF Fundamentals – In Person Course –

EU TMF Interchange in April 2024

<https://www.cdsc.org/events/interchange/2024-cdsc-tmf-europe-interchange>



TMF RM Fundamentals – Inaugural Course

Student Feedback

- The round tables were useful when working on **open-ending exercises**, potentially very **real examples** with no singular correct answer.
- The **collaborative workshops** and **discussions** allowed for debate about real-life scenarios and solutions.
- The **interactive activities** were a plus, as well as the **instructor's answers** to the questions raised during the presentations.
- I really enjoyed applying what was discussed during the **group exercises**. It was also a **wonderful networking opportunity** and a great start to the conference the following two days.
- The sessions were **interactive** and gave great room for **discussions**.
- As someone with little TMF experience, the training made the **model far less overwhelming and easier to understand** the various pieces.
- The course contained a **wealth of information** including **resources** to the available references regarding TMF management.
- The **instructors spoke from deep knowledge on the subject**, and they gave good answers to all the asked questions.
- As someone relatively new to TMF in an academic setting, the review of the reference model, the regulations around it, and how to manage and implement the model was exactly what I needed. I have so many thoughts and ideas to take back to my team to improve our TMF oversight. **This was an EXCELLENT course that I would encourage anyone involved in TMF to take!!**



Formalization

Align and engage with Regulators

Establish the TMF RM as a formal standard

Secure formal recognition from the regulatory authorities as a standard for managing TMF content

Promote Industry adoption of the Exchange Mechanism Standard



Increased Influence

Health Authorities:

- MHRA
- EMA
- FDA
- Health Canada

• Organizations:

- HSRAA
- ICR / ACRP
- SOCRA / SCRS / AACI
- ARMA
- SQA / RQA / JSQA
- Digital Preservation coalition
- AGxPE
- Pistoia Alliance
- PCMG
- (ISPE)
- ACDM / SCDM
- Magi / AVOCA
- (CRISI)
- EFPIA
- IMI



Community

Continuity, good future vision and leadership

**Strengthen community engagement to
drive evolution**

**Safeguard the continuity of the TMF
RM Leadership**

**Identify and encourage active working
groups to produce deliverables**

Elections for SC (Feb), Volunteers (296)



Why should your Organization become a Member?

- To ensure the CDISC standards remain open and free
- To support CDISC in the development and maintenance of global standards
- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits e.g. discounted conference and training, and training credit.
- To gain visibility in the marketplace
- To increase networking opportunities



Members Only
 Thank you for being a CDISC Member.
 We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.

Industry Job Board <small>Need CDISC expertise?</small> Post your job announcement on our Industry Job Board. Platinum members can post up to 12 job listings annually. Gold members can post up to 6.	Member Online Training Credit Each CDISC member organization receives credit annually based on membership level to apply to our online training.	CDISC Library The authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.
CDISC Library Archives Download CDISC Standards and Controlled Terminology in multiple formats, including Diff files. CDISC LIBRARY ARCHIVES WILL BE RETIRED AT THE END OF 2022.	Webinars Learn from CDISC experts with our Members. Only mini-training sessions and public webinars, archived to access at your convenience.	Interchange Presentations CDISC provides previous presentations from our Interchanges to ensure you have the most useful best practices for implementing CDISC standards as well as hot topics from leading thought leaders and advocates.

NEW MEMBERSHIP RATES (US\$) - Effective 1 January 2022			
Total Number of Employees in Organization	GOLD Member Annual Fee	PLATINUM Member Annual Fee	First Year PLATINUM Member One-Time Contribution
1-19	\$1,690	\$4,500	Annual fee + \$4,500
20-99	\$4,500	\$7,315	Annual fee + \$7,315
100-999	\$9,570	\$11,820	Annual fee + \$11,820
1,000-9,999	\$24,200	\$27,015	Annual fee + \$27,015
10,000-24,999	\$32,640	\$36,580	Annual fee + \$36,580
25,000-49,999	\$39,395	\$47,270	Annual fee + \$47,270
50,000 +	\$55,445	\$65,280	Annual fee + \$65,280

Evolution

A new way to manage the TMF RM

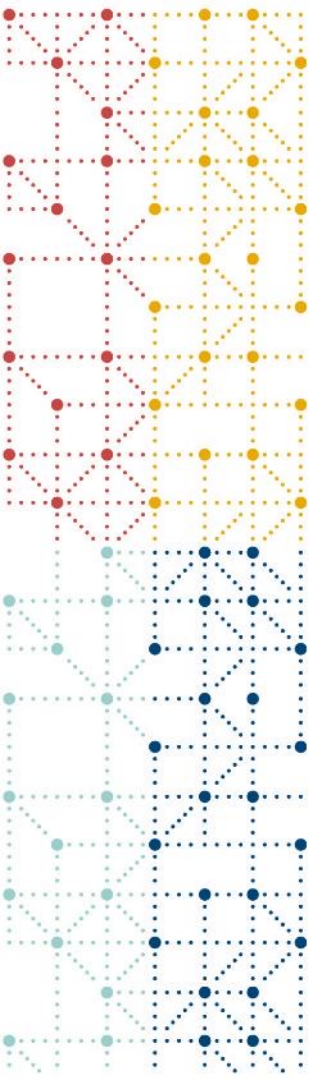
Extend the granularity of the TMF RM

Expand the TMF RM to incorporate different types of studies and data

Implement better tools to manage, map and distribute the TMF RM

Standards Team





Standards Update

Paul Fenton

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



Workstream 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
 - Allow clinical systems (including eTMFs) to query the library through APIs
 - More easily map to other models and standards
 - Define sub-models for different types of trials



CDISC Library TMF Use Cases

- Ability to maintain of all versions of the RM in a controlled state
- Ability to consult the TMF by searching for artifacts or artifact attributes
- Ability to map to other models i.e. RWS, ISF etc.
- Ability to define relationships between artifacts (clustering)
- Ability to expand TMF RM metadata standard (in collaboration with NCI initiative)
- Ability to provide TMF RM structure and metadata programmatically to systems
- Ability to develop study-type TMF structures based on study design parameters
- Ability to develop rules for TMF structure and metadata validation through CORE?
- Others?



Workstream 2 - Evolution of EMS / Interoperability

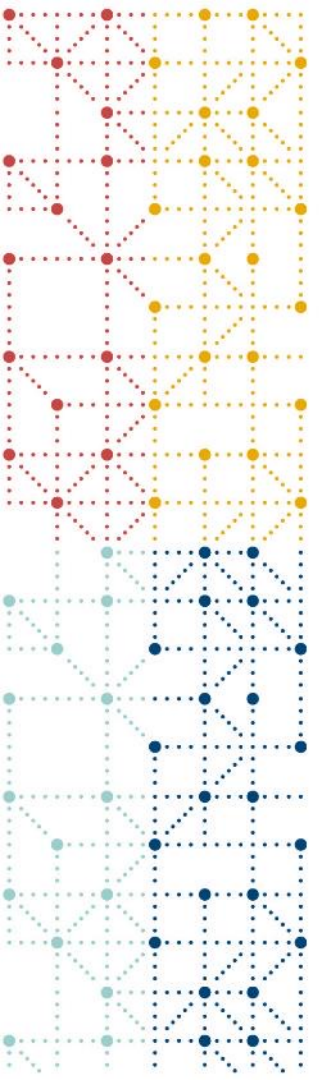
- EMS has been developed, and some vendors are adopting it, but has yet to be reduced to practice in a significant way
- A new workstream has been put together to start to align the EMS to USDM in preparation for integration with DDF
- More modern data formats are also being evaluated to make it easier to integrate into modern computerized systems
- The workstream will also look at aligning/defining terminology with CDISC CT
- Audit trail metadata will also be updated
- The output of the updated standard will be published in the library



Workstream 4 – development of Controlled Terminology / Alignment to ICH M11

- Working with the NCI – EVS to align the TMF RM with CDISC controlled terminology – meeting weekly, on Zone 2!
- Focus is on developing controlled descriptions of each artifact and good progress is being made
- **No artifact names will be updated for the time being**
- Over time aligning to CT will bring more standardization to the TMF RM
- A second project which aims to map the reference model to ICH M11 is also planned
- This will open up new opportunities to navigate the TMF by digital protocol as well as to be able to consume protocol design parameters





CDISC TMF Interchanges

Jamie Toth



2023 CDISC TMF Interchange

*Baltimore, Maryland
28-29 September 2023*



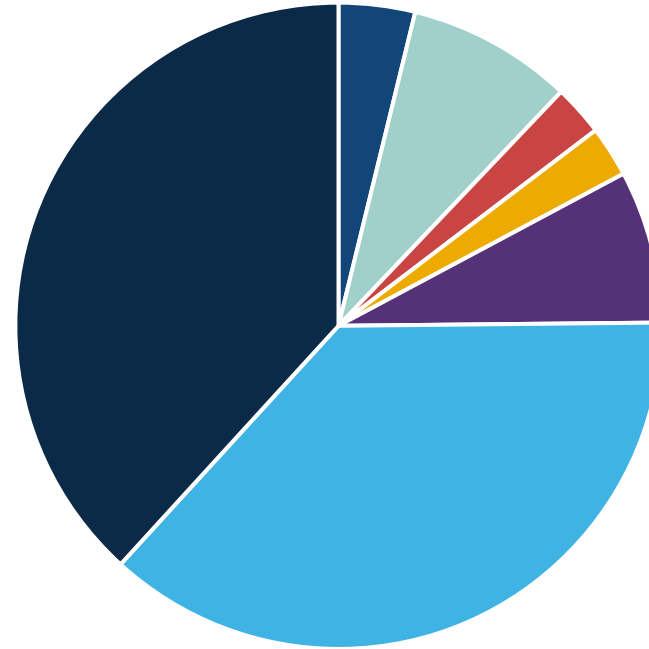


Who thought TMF was boring?

Attendance

- 20 in the Fundamentals of TMF Training
- 156 registered
- 79 Companies:
 - 35 Pharma
 - 9 CRO
 - 16 Vendors

Attendees



■ CDISC ■ CRO ■ Government ■ Sites ■ Consultants ■ Pharma ■ Vendors



Sponsors

Sponsors



Exhibitors

Exhibitors



2023 TMF Interchange Feedback Results

Q: Would you recommend the CDISC TMF Interchange to your contacts?



100% said YES!

Q: Rate your satisfaction with the Interchange sessions and speakers.



~95% reported being satisfied or very satisfied!

2023 TMF Interchange Feedback

Q: Why would you recommend the CDISC TMF Interchange to your contacts?

I would recommend this conference as the speakers provided great discussions and networking opportunities to implement positive change within our respective companies.

This seemed like the most beneficial conference this year for TMF, lessons learned, looking forward, and connecting with other TMF SMEs

Although there were a lot of very experienced people at the conference, there can be much to learn for those just starting out in the TMF world.

The Interchange was not only very informative and educational, but also it was a rare opportunity to meet great industry leaders in person which was a priceless experience. I very much enjoyed and satisfied with the Interchange!

Very useful for TMF newcomers especially!

It was a very fun and informative event, well timed with the changes coming in changing to a standard and R3 coming out



2023 TMF Interchange Feedback

Q: What did you find most valuable about the CDISC TMF Interchange?

As a vendor, interactions with potential clients. Any sessions where people were sharing and discussing problems and challenges.

I learned so much about subjects outside TMF like technology, AI, and DM. It was a very interesting opportunity to meet and network with folks who are TMF adjacent.

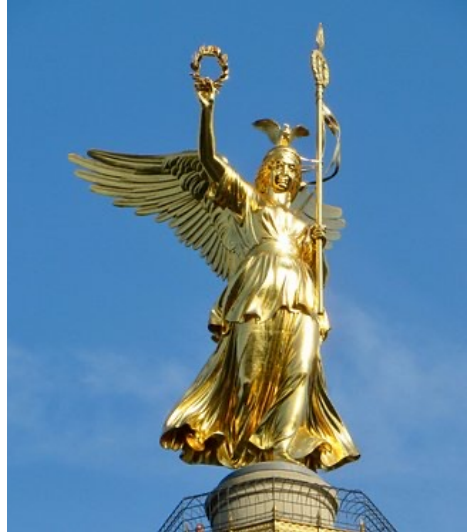
The ghosts.

It was valuable to spend time with other professionals focused on TMF. I am from a small Pharma where and I AM THE TMF department, it was nice to be able to network and hear best practices from like minded professionals.

Connections and interactions with peers. Networking was very easy and enjoyable. The interactive session, and evening event were fun and produced a lot of "offline" discussion about important topics. Additionally, the Vendors did a great job. Liked the pirate theme, and "treasure hunt" to spur discussions with the Vendors. Finally, I found the CDISC members (Karen, Eldin & Paul) to be very engaging. They did a wonderful job presenting and coordinating the event.

The best value came from my vendor(sponsor) interactions.

Great presentations, sessions. Well-thought through agenda. Loved it!!



2024 CDISC + TMF Europe Interchange

Berlin, Germany
24 – 25 April 2024

<https://www.cdisc.org/events/interchange/2024-cdisc-tmf-europe-interchange>



Call for Abstracts Open
Registration Open
Sponsors / Exhibitors Open

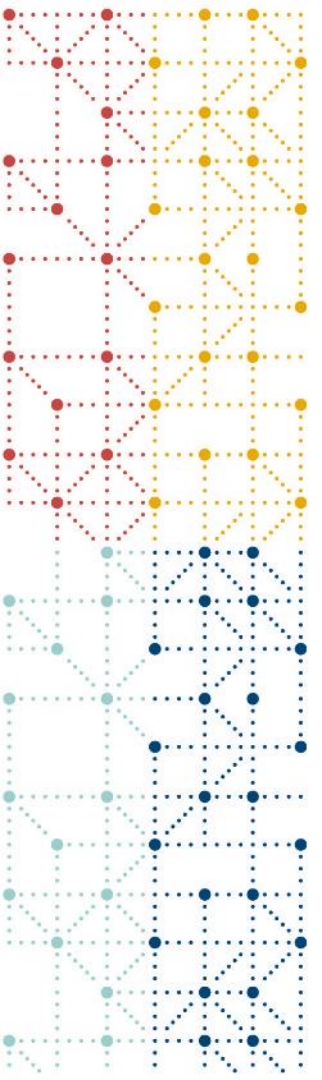




2024 CDISC + TMF US Interchange

*Scottsdale, Arizona
23 - 24 October 2024*

<https://www.cdisc.org/events/interchange/2024-cdisc-us-tmf-interchange>



Risk Initiative Update

Joanne Malia and Eldin Rammell

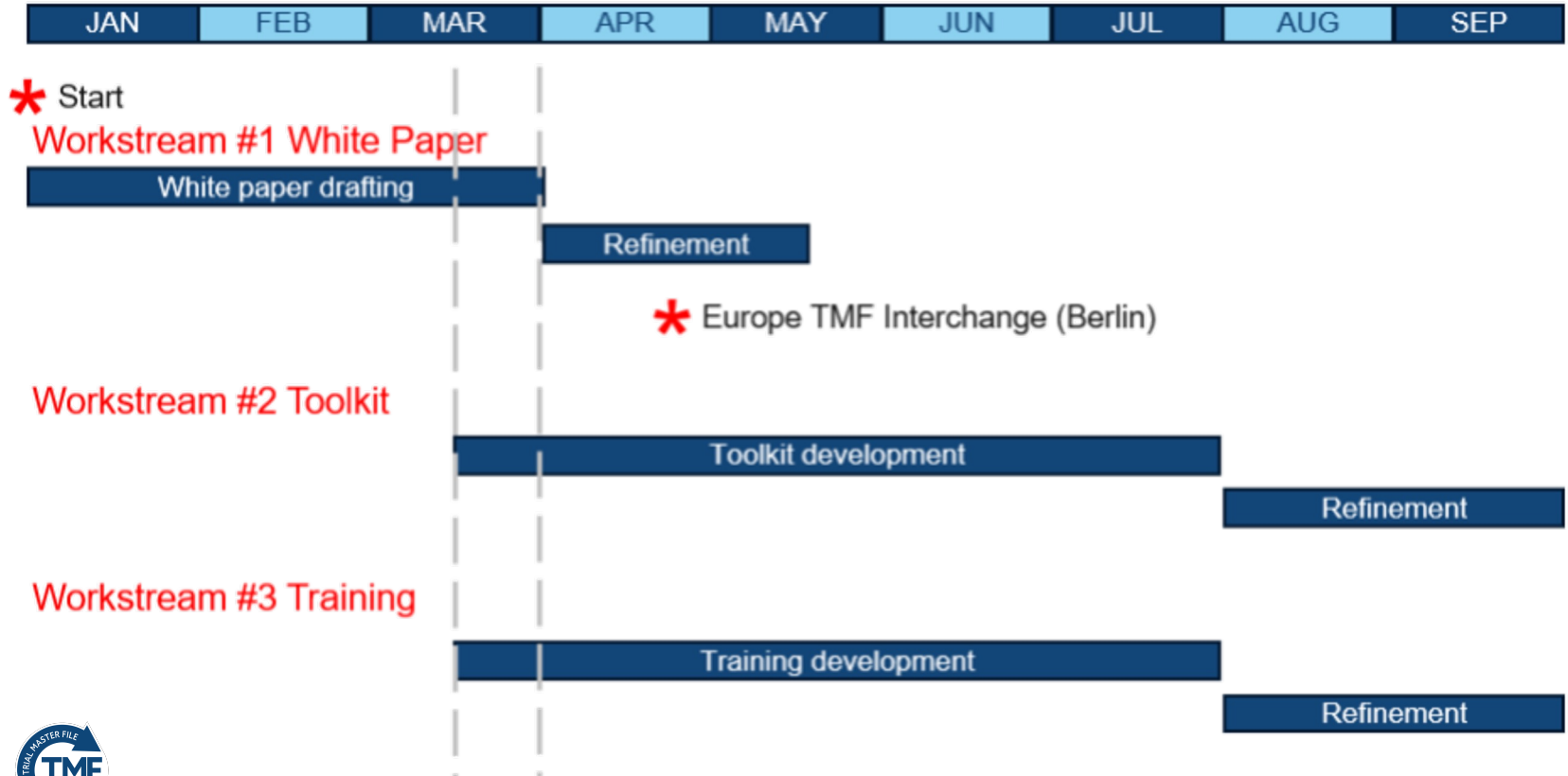
Risk Management Initiative

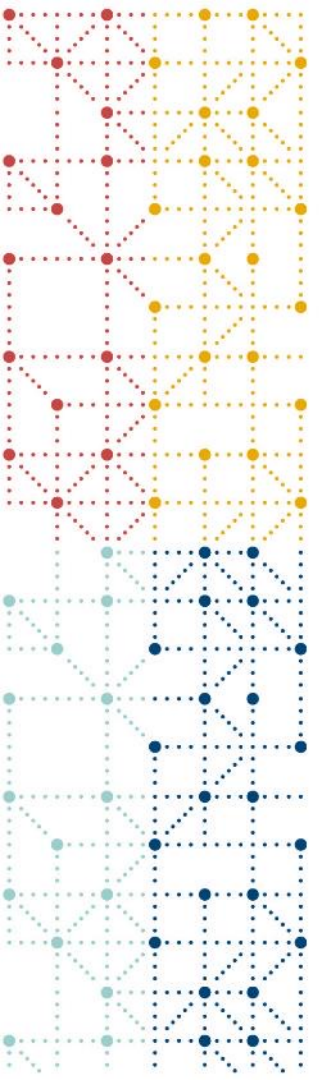
- Excellent response to “call to action” – 48 volunteers
 - Volunteer request will close early!
 - North America 28; Europe 15; Asia 4; South America 1
 - Pharma 24; Consultant 9; CRO 7; Vendor 6; Site 1; NGO 1
- Kick-off meeting: Thursday Dec 14 8am [ET], 1pm [UK], 6.30pm [IST]
 - Recording will be shared with team members not available for kick-off
- Three workstreams:
 - White Paper [10]: Principles, Approaches, Recommendations
 - Toolkit [25]: Practical tools to implement risk management strategies
 - Training [22]: Content to provide to Education Team

[number of volunteers]



Initial Draft Timeline





ICH E6 R3 – Health Canada View

Joanne Malia

E6 R3 Update – Society of Clinical Research Associates (SoCRA) Annual Meeting (September 29 - October 1, 2023)

Presentation by Kathy Soltys, Health Canada:

- E6 Revision will build on principles outlined in E8: General considerations for clinical studies

E8 clinical trial design principles ↔ E6 GCP clinical trial conduct principles

- The intent of the revised guideline is to **facilitate innovations** in clinical trial design and conduct, while at the same time provide guidance to help ensure **participant safety** and that the clinical trial produces **reliable results**. Will provide flexibility whenever appropriate to facilitate the use of **technological innovations**.
- Health Canada website public consultation **21 June – 20 Oct 2023**



E6 R3 Objectives

- New Structure to provide clarity and better readability
 - **Principles to remain relevant as technology, methods, and trial design evolve**
 - Annexes and appendices (strategy intended to enable easier and faster updates in the future)
- Provide additional clarity of scope
 - Investigator – clarifies training requirements for trial staff; requirements for supervision
 - Sponsor – clarifies expectations for monitoring; safety assessment and reporting; responsibilities around transfer of activities; **expectations for processes for data handling**
- Language to facilitate innovations in clinical trial design, technology and operational approaches
 - Facilitate **innovative clinical trial designs**, for example, clinical trials utilizing Decentralised Clinical Trial (DCT) elements and pragmatic elements, reflecting trials that closely resemble routine clinical practice
 - Facilitate the use of **Digital Health Technologies (DHTs)**, **healthcare infrastructure**, and other tools to facilitate enrollment and retention, capture data, monitor, and to analyse results
- Set a foundation for **practical/feasible expectations** around the responsibilities of sponsor and investigator in a digital ecosystem

E6 R3 Objectives

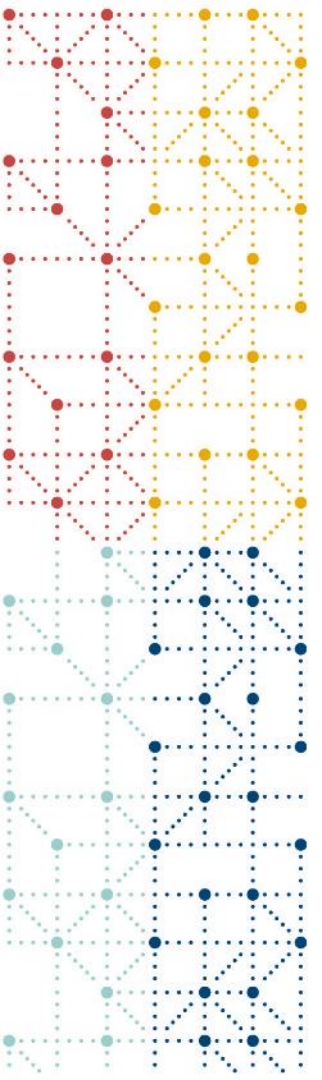
- Encourage **fit-for-purpose** approaches
 - Proportionality and risk-based approaches with a focus on the clinical trial's critical-to-quality factors whose integrity is fundamental to safety of participants and the reliability of trial results;
 - Thoughtfulness in the design and conduct
- Incorporate learning from innovative clinical trial designs and lessons from public health emergencies/pandemics
- Encourage transparency by clinical trial registration and result reporting
- Provide additional language to enhance the informed consent process



Expectations

- Anticipating finalisation as a Step 4 document to be implemented in the local regulatory system:
Fall 2024
- Also includes:
 - Annex 1: Interventional clinical trials
 - Annex 2: Additional considerations for non-traditional interventional clinical trials
- Will include designs such as pragmatic clinical trials and decentralized clinical trials, as well as those trials that incorporate real world data sources
- **Extensive training materials** are planned to be developed (with use-cases) that clarify or provide supplementary explanation to the application of GCP guidelines





UK Clinical Trials Update

Karen Roy

UK Clinical Trials Yesterday

- Clinical trial numbers in UK have decreased over time
- Regulatory application approval timelines increased dramatically during 2023
- Contracting timelines increased
- Lord James O'Shaughnessy commissioned to write a report on the state of Clinical Research in the UK in Feb 23, final report May 23, Government response Nov 23
 - 27 recommendations including clinical trial acceleration networks, clinical trial data transparency, reduced regulatory approval timelines



UK Clinical Trials Today

- MHRA backlog cleared in August and September
- Notification scheme for Phase 4 and low risk Phase 3 studies: 14 day timeline (October 23)
- Centralized commercial template agreement for clinical trials (updated October 2023)
- ABPI survey – Equality, diversity and Inclusion in clinical trials is the key public concern



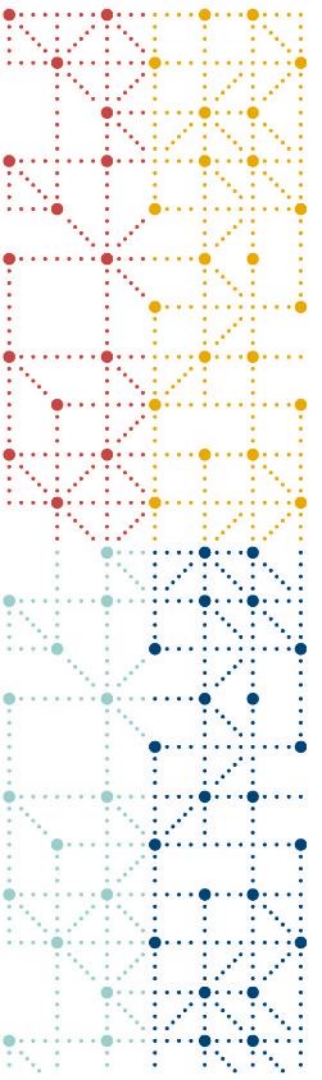
The Institute of Clinical Research



- Started as ACRPI – the Association of Clinical Research for the Pharmaceutical Industry
- Incorporated as a Company on 29th February 2000
- Became Institute of Clinical Research on 13th June 2000

Developing Professionals
Sharing Knowledge
Raising Standards

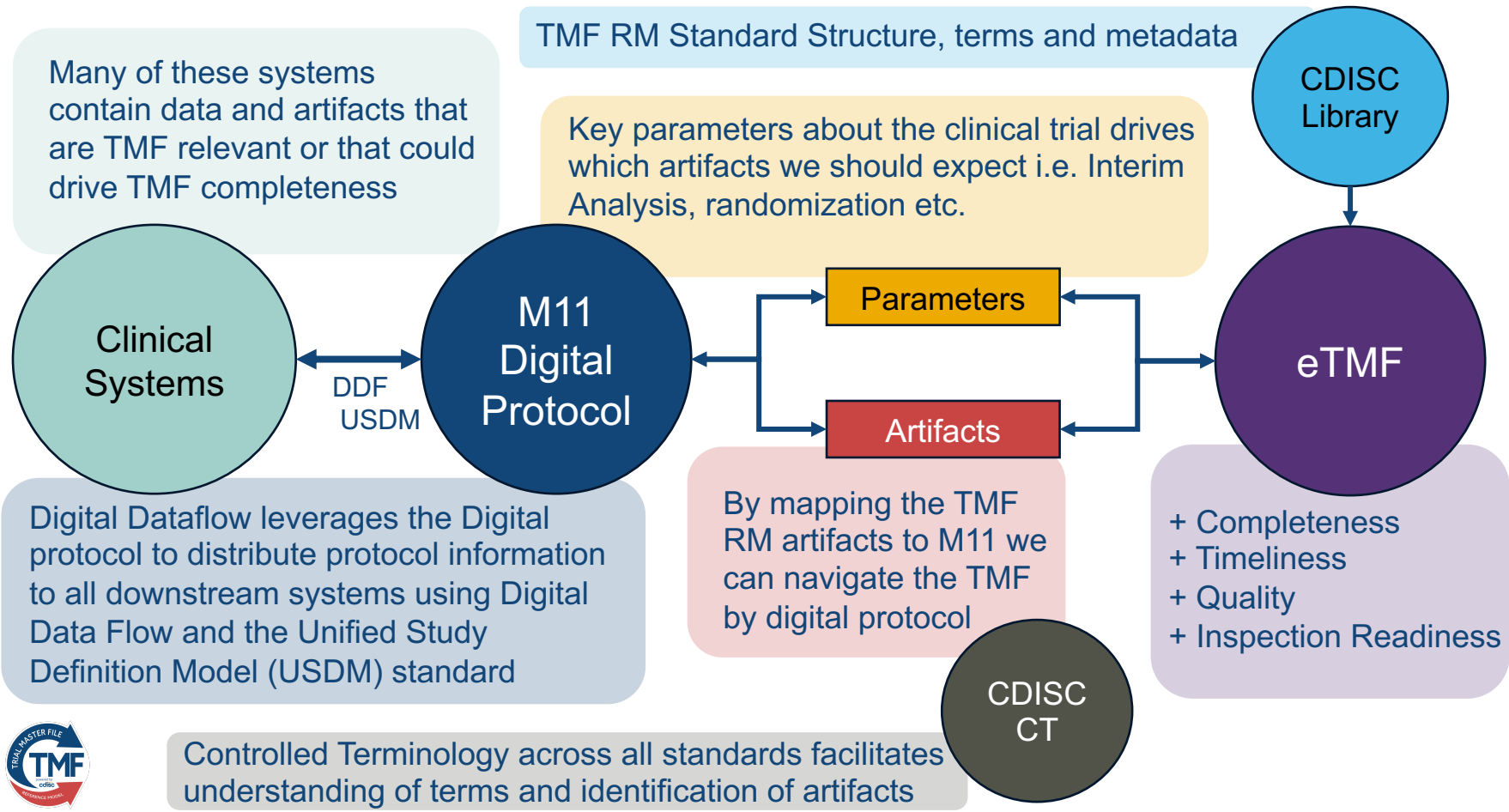


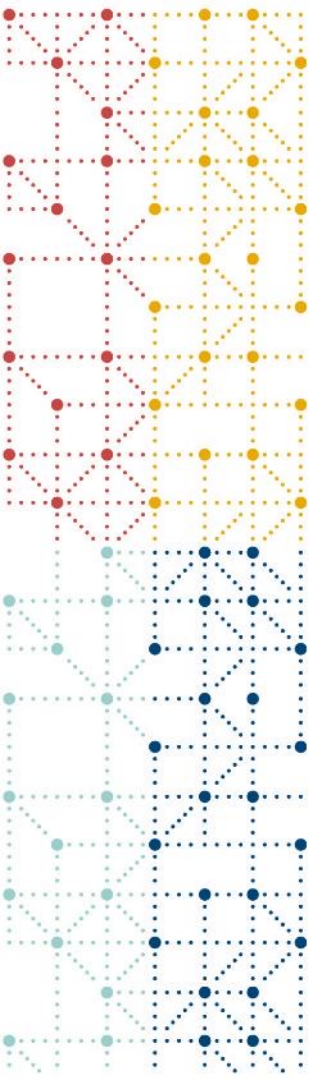


From Documents to Digital

Rob DiCicco

Using M11 and DDF to drive the eTMF





Upcoming Events

Upcoming Events

Conferences:

- **March** 18-20, 2024 - Savannah, Georgia: TMF US Summit
- **April** 24-25, 2024 – Berlin, Germany: CDISC EU TMF Interchange
- **September** 24-26, 2024 – Edinburgh, Scotland: HSRAA (Health Sciences Records & Archives Association) Annual Conference
- **October** 23-24, 2024 - Scottsdale, Arizona: CDISC US TMF Interchange

General Meetings in 2024:

- Tuesday, March 5th
- Tuesday, June 11th
- Tuesday, September 10th
- Tuesday, December 10th



Upcoming 2024 Events



2024 CDISC + TMF Europe Interchange

Location:
Berlin, Germany

Main Conference:
24-25 April 2024



2024 Japan Interchange

Location:
Tokyo, Japan

Main Conference:
12-13 June 2024



2024 Korea Interchange

Location:
Daegu, South
Korea

Main Conference:
August-September
2024 – stay tuned!



2024 China Interchange

Location:
Shanghai, China

Main Conference:
30-31 August



2024 CDISC + TMF US Interchange

Location:
Scottsdale,
Arizona

Main Conference:
23-24 October



Visit <https://www.cdisc.org/events> for more information!

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Opening for Questions (and hopefully Answers!)

Thank you

<https://www.cdisc.org/events/webinar/tmf-reference-model-general-meeting-q4>

