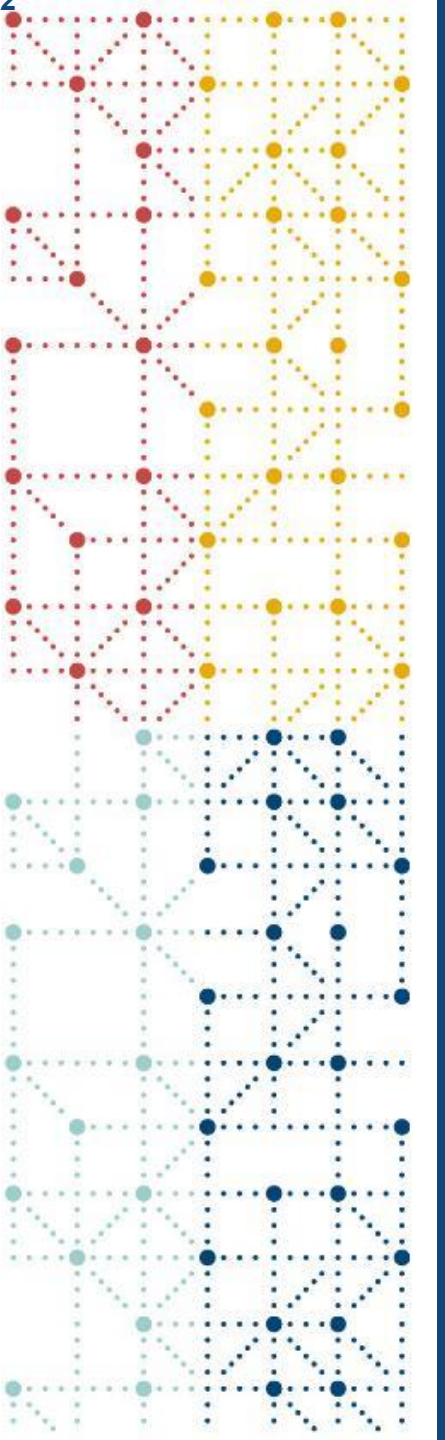
The TMF General Meeting March 2026

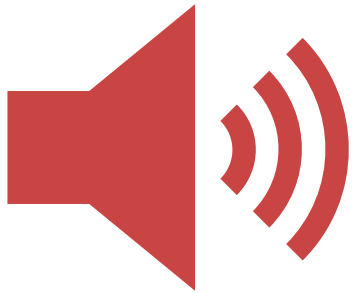
Presenters:

- Paul Carter, CEO, Montrium; Chair, TMF Steering Committee
- Donna Dorozinsky, CEO, Just in Time, GCP, TMF Steering Committee Member
- Yuto Kanda, Chugai Pharmaceutical Co., Lead of JP TMF community
- Dawn Niccum, Executive VP, Quality, inSeption Group
- Chad Scribner, Sr. TMF Consultant Inspection Readiness, Epista Life Science
- Albert Cheng, Clinical Research Project Manager, Massachusetts Eye and Ear Infirmary



Housekeeping

Housekeeping

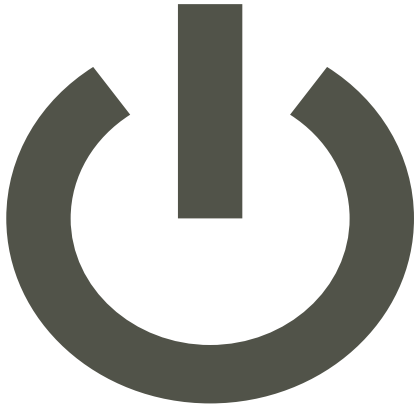


You will remain on **mute**

Housekeeping

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

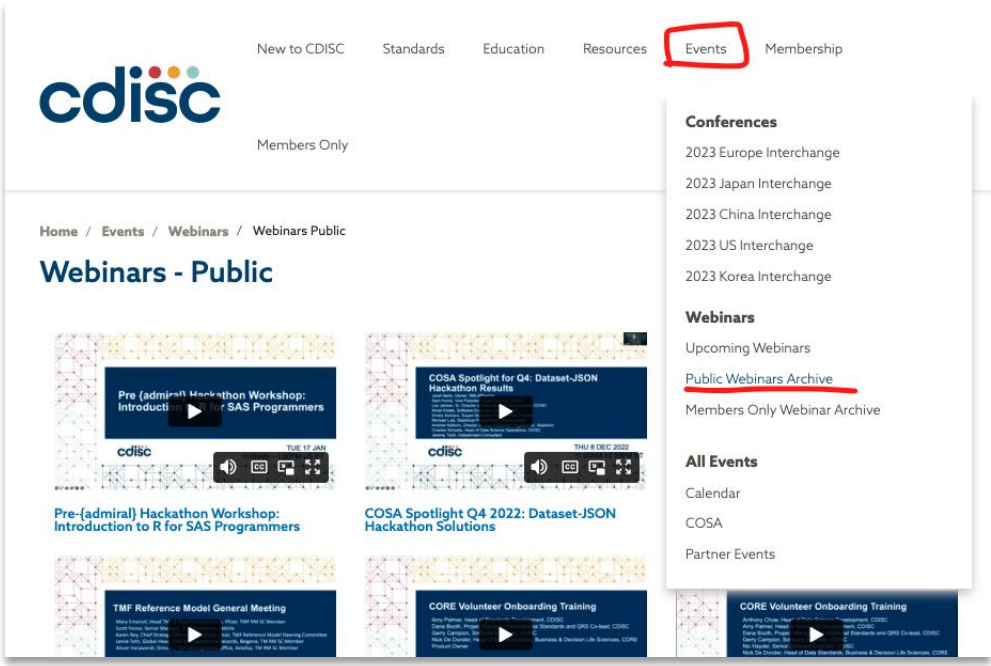
Housekeeping



Audio Issues?

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

Housekeeping

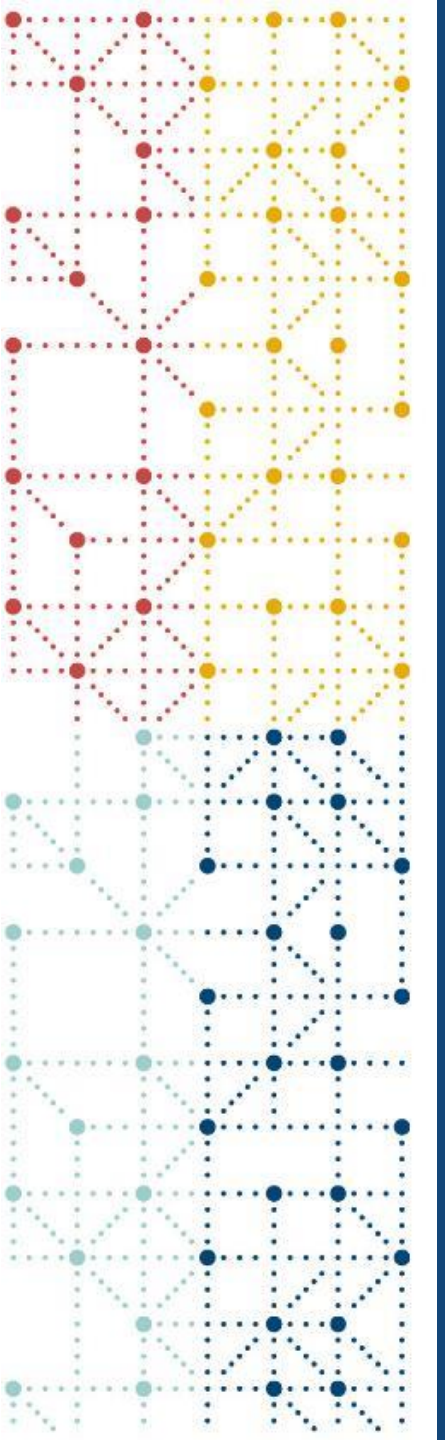


Webinar Recording

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

Agenda

- Opening Remarks/Introductions
- Steering Committee Elections
- Events & Interchange Update
- Update of TMF SM V1
- eClinical Systems
- JP TMF Community Update
- ISF RM V1 Release and Overview of Final Model
- TMF Outreach
- Risk Initiative
- Q&A



Opening Remarks/Introduction

Paul Carter, CEO, Montrium; Chair, TMF Steering Committee

Meeting Update

TMF Reference Model Meeting

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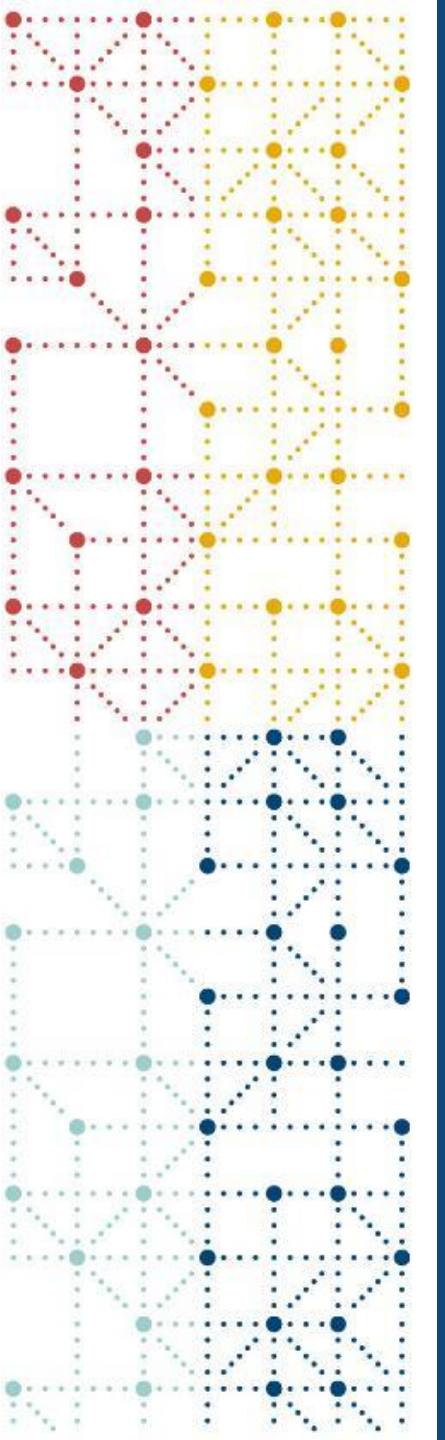
CDISC TMF Community Meeting

Reflects the expanding CDISC TMF community, and strengthens our focus on collaboration and TMF best practices

Same community. Same conversations. A refreshed name.



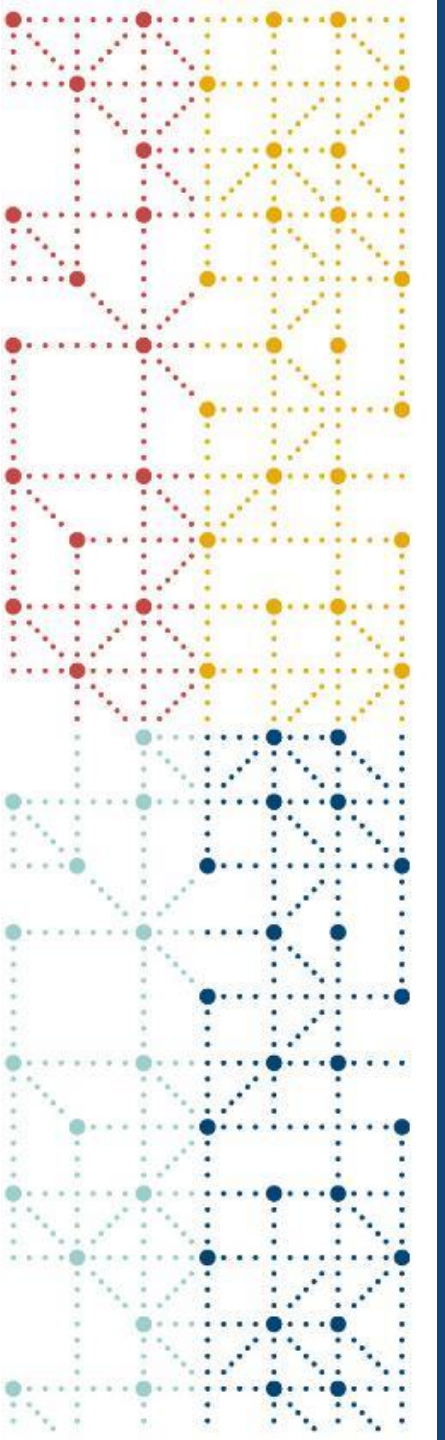
Steering Committee Elections

Paul Carter, CEO, Montrium; Chair, TMF Steering Committee

Steering Committee Elections

- Must be a CDISC Volunteer to vote
- Look for your ballot from ElectionBuddy
- If you do not see it, check your spam/junk folder
- Questions or issues? Email sstamper@cdisc.org

VOTING DEADLINE
March 20 • 5:00 PM EST



Events & Interchange Update

Paul Carter, CEO, Montrium; Chair, TMF Steering Committee

Virtual Training - 17th to 19th March 2026

Fundamentals of the TMF Reference Model

MILAN

Over 50 abstracts received!
Programme released
Exhibitions open (2 spaces left)
Early bird special ends 20th March 2026

https://www.cdisc.org/events/interchange/2026-cdisc-europe-interchange

WHY ATTEND MILAN?

- Torsten Stemmler, Head of GCP Inspection, BfArM
- TMF Standard Version 1 insights and implementation
- Broad TMF topics - Technology, Culture, Management
- TMF Management, Risk, Regulations, Interoperability
- Fundamentals of TMF Training
- Exciting Milan social event

DENVER

Call for abstracts open!

https://www.cdisc.org/events/interchange/2026-cdisc-us-interchange

INDIA CDISC DAY

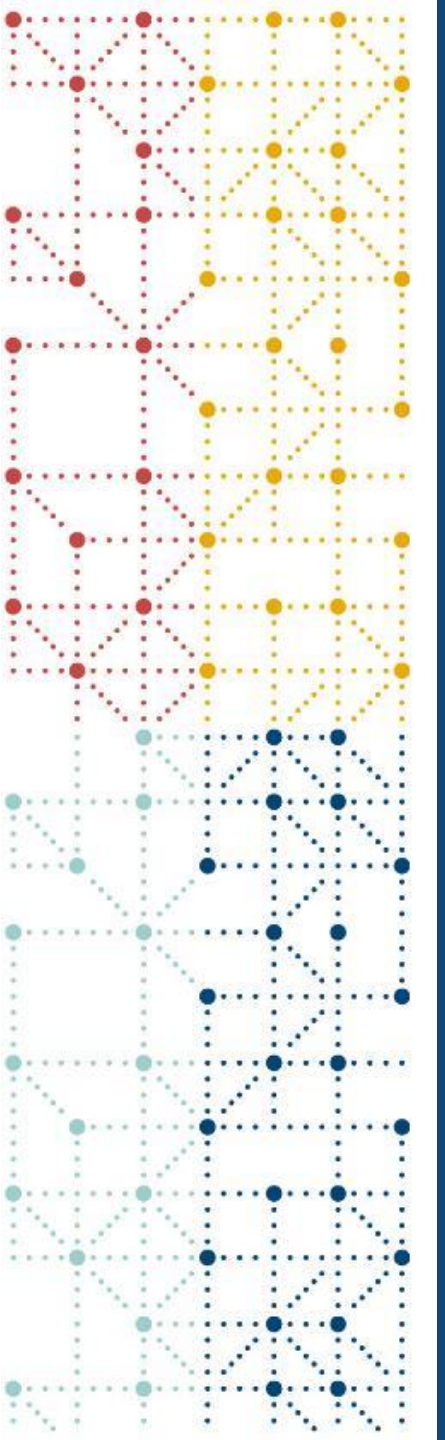
All the Insights, All the Impact, All in One Day!

1st event – In February, with Phuse

2nd event – Details to follow …. Host applications open

Other Relevant Conferences

- Institute of Clinical Research Conference, Birmingham, 13&14 April 2026
- https://fitwise.eventsair.com/the-institute-of-clinical-research-conference-2026/



Update of TMF SM V1

Donna Dorozinsky, CEO, Just in Time, GCP, TMF Steering Committee Member

Meet the TMF Standard Model Project Team

Paul Carter

Founder & CEO, Montrium

TMF SM V1 Association:
Chair of TMF Steering Committee
V1 Management Committee Member

Donna Dorozinsky

Founder & CEO, Just in Time GCP

TMF SM V1 Association:
Lead for the V1 Project

Gillian Gittens

Senior Director, Life Sciences
TransPerfect

TMF SM V1 Association:
Co-lead of the TMF SM V1 Triage Committee

Lisa Dotterweich Mulcahy

Owner & Principal Consultant,
Mulcahy Consulting, LLC

TMF SM V1 Association:
Co-lead of the TMF SM V1 Triage Committee

Steph Viscomi

Director, Clinical Documentation and TMF, Apellis Pharmaceuticals

TMF SM V1 Association:
V1 Project Management Team Member

Sydney Stamper

Associate Consultant, Just in Time GCP

TMF SM V1 Association:
V1 Project Management Team Member

Where are we to date….

Program levels are out of scope of the V1 Standard

Moving to a 4-level hierarchy that aligns with a tree view as an Excel file

Agreeing to retain reference numbering for historical artifacts

Retaining the Tree View

UI Numbers are carried over into V1 Standard with historical traceability preserved

Priority is getting a complete Record Type list that we can build on…..

Zone Teams are Active

COMMUNITY INPUT REVIEW COMPLETED

REVIEW OF V1 MANAGEMENT TEAM INPUT COMPLETED

R3 & EU CTR & UPDATES TO PURPOSE/DEFINITIONS

Working Group Activities

ICH E6(R3) Working Group – List of Record Types are with Zone Leads and WG is developing Purpose/Definitions for new Record Types

CSV Working Group – more to come

EU CTR Working Group – List of Record Types are with Zone Leads and WG is developing Purpose/Definitions for new Record Types

Working Group Activities

Metadata – Meeting regularly defining a core set of Metadata for V1. Representation from many different perspectives (big and small pharma / bio, CRO, vendor, etc).

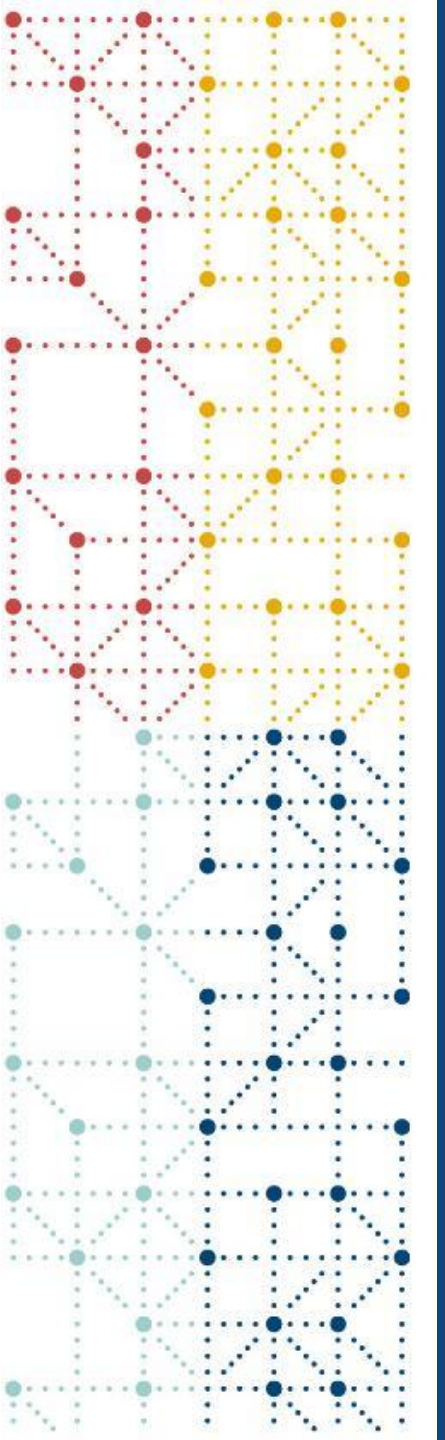
Vendors – Vendors have developed some key questions to support their product development that the Project Management Team is working to answer.

Devices – Working their way through the Model with plan to pull in new Record Types as they are agreed.

RDE – Finalizing current version that will be integrated into V1.

Next Steps

- Finalizing Record Types
- Updates to Purpose/Definitions with new Purpose/Definitions for new Record Types
- Aligning Metadata to Record Types
- Building Record Groups to connect Record Types
- Providing draft structure to Vendors to support their technology development



eClinical Systems

Donna Dorozinsky, CEO, Just in Time, GCP, TMF Steering Committee Member

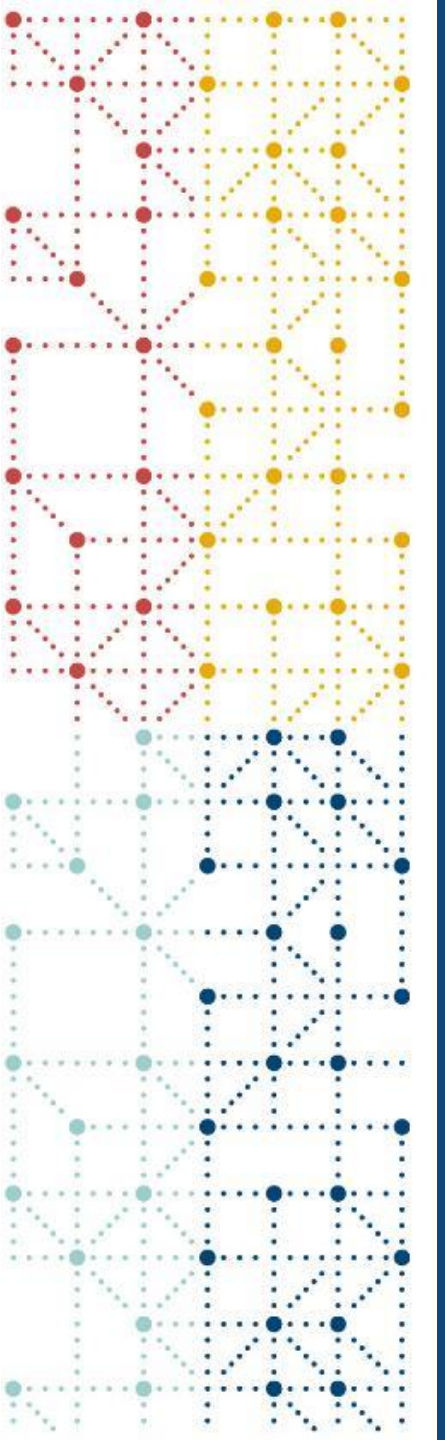
The TMF Zone We've ALL Been Waiting For 🎉

🤖 What used to hide in mysterious IT folders and vendor portals is now front and center in TMF SM.

✨ CSV artifacts now have VIP status: validation plans, risk assessments, executed test scripts—all inspection ready!

🚀 As trials go digital, Zone 12 gives us the structure, confidence, and ALCOA++magic we've needed.

🎬 Get ready for TMF stories that finally include the systems behind the science.

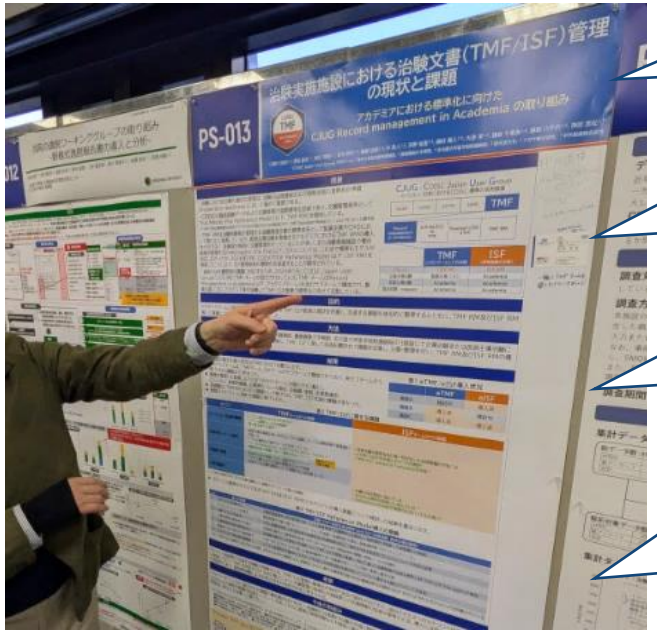


JP TMF Community Update

Yuto Kanda, Chugai Pharmaceutical Co., Lead of JP TMF community

Poster session finished!

- **Academia team** from the community presented a poster in one of the biggest clinical trial conference in Japan in 20-21Feb
  - Annual conference of JSCTR (Japan Society of Clinical Trial & Research)
- Title :
  JP Clinical Sites' challenges for managing TMFs and ISFs
- Thank you for those who came to poster booth!



My site is still doing paper TMF…

Each sponsor name their document by their own rule. It should be consistent.

I didn't know that CDISC has TMF RM

I want to join the the JP community to **discuss with other sites** and to **learn more about the ISF RM!**

A panel discussion planned in EU interchange

An international panel discussion is planned during the EU interchange to highlight values of to have local community(ies).

Date and time : 20May, 3-3:30pm local time (session 3 track E)

Title : **Value of Local TMF Communities**

Panelists :

Italy

Donatella Ballerini

Denmark

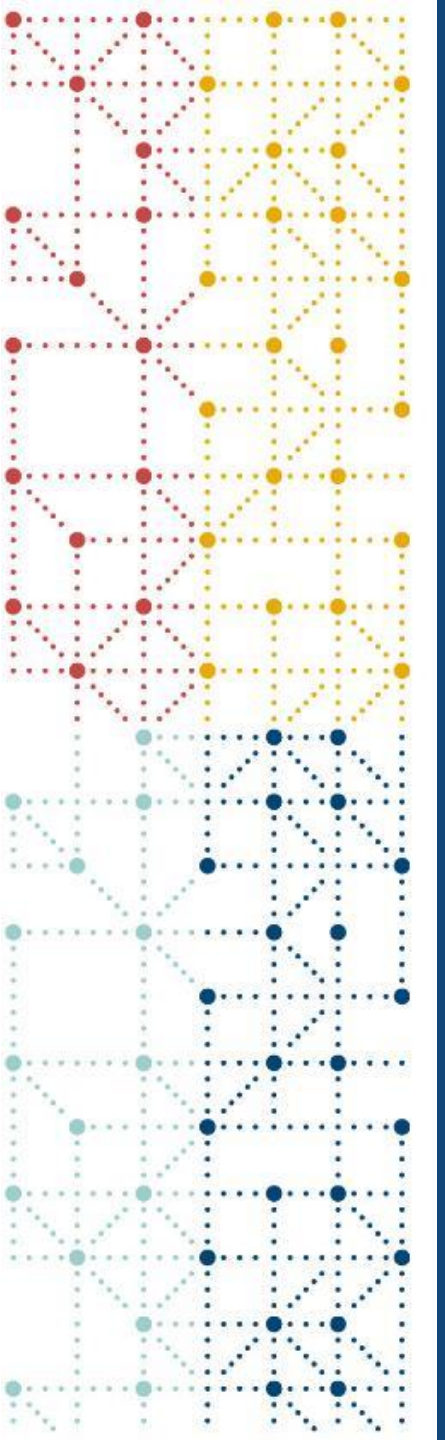
Karla Navera Andersen

Nina Louise Arberg

Japan

Yuto Kanda

See you in Milan!



ISF RM V1 Release & Overview of Final Model

Dawn Niccum, Executive VP, Quality, inSeption Group

Timeline

We are here

2024

Team forms/initial drafts created

February - December

2025

CDISC Review

January - July

Public Review

July - September

Ratification of public comments

September - November

CDISC Final Review

November – January 2026

2026

CDISC Final Review

From November 2025-January 2026

Public Launch

February 6, 2026

2026

Webinars, trainings, comms, etc.

February – December 2026

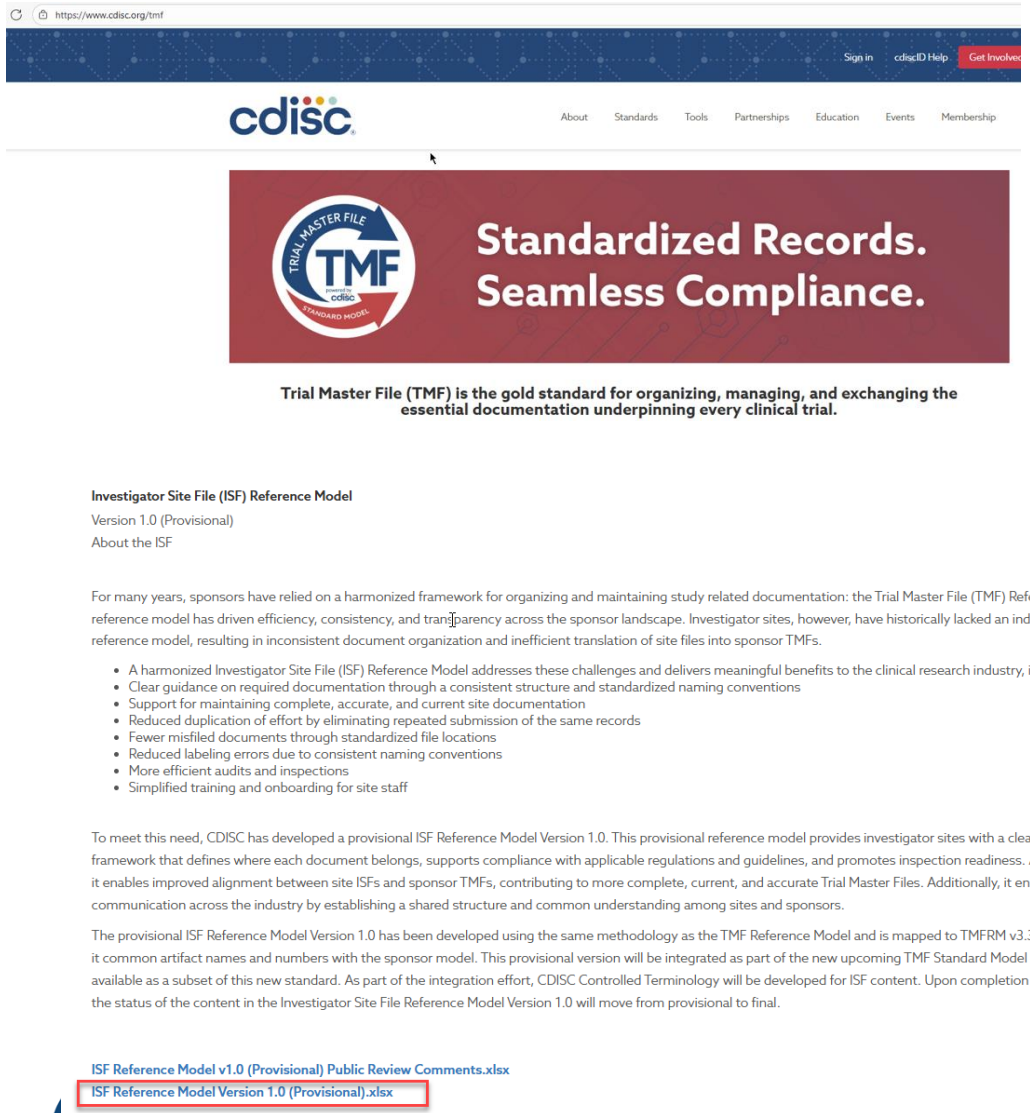
2027

TMFSMV1

Inclusion of ISF RM 1 into TMFSMV1

Outreach has been ongoing with presentations & updates at various conferences, webinars, since 2024

ISF RM Location



Go to the bottom of the page and click TMF Resources and select Investigator Site File - ISF

The ISF Page will display. The model is available **via a link at the bottom of the page.**

ISF RM Release 1.0

ISF Structure Overview

The ISF Zone Map visually represents the **14 zones** of the ISF structure, supporting comprehensive trial management.
Currently an Excel File with columns A – L.

Structured ISF Zones

14 zones cover various documentation categories such as planning, regulatory, and site materials.

ISF Zone Combined #/Name	Count of ISF Artifact Type
ISF_01_Planning and Procedures	23
ISF_02_Study Library	12
ISF_03_Participant Materials	7
ISF_04_Regulatory Submissions	3
ISF_05_IRB or IEC	7
ISF_06_Other Committees	3
ISF_07_Site Documentation	21
ISF_08_IP or Device Documentation	16
ISF_09_Trial Supply Documentation	4
ISF_10_Testing Facility Documentation	10
ISF_11_Monitoring Logs and Reports	6
ISF_12_Safety Events, Logs, and Reports	6
ISF_13_Study and/or Participant Data and Logs	6
ISF_14_Correspondence and Notes to File	2
Grand Total	**126**

126 Artifacts
- 89 Core
- 37 Recommended

ISF Reference Model-Structure Overview

Zones

Section

Artifacts

Subartifacts

ISF RM Metadata (12 columns)

A. ISF Zone Combined #/Name
B. ISF Zone Number
C. ISF Zone Name
D. ISF Section Combined #/Name
E. ISF Section Number
F. ISF Section Name
G. ISF Artifact Combined #/NameISF
H. Artifact Number
I. ISF Artifact Type
J. ISF Subartifact Name
K. TMF Artifact Group
L. ISF Inclusion

How ISF Reference Model Is Delivered

Excel Spreadsheet Format Format

Delivered as a comprehensive Excel workbook

Powerful Functionality

- Searching
- Sorting
- Filtering
- Pivoting

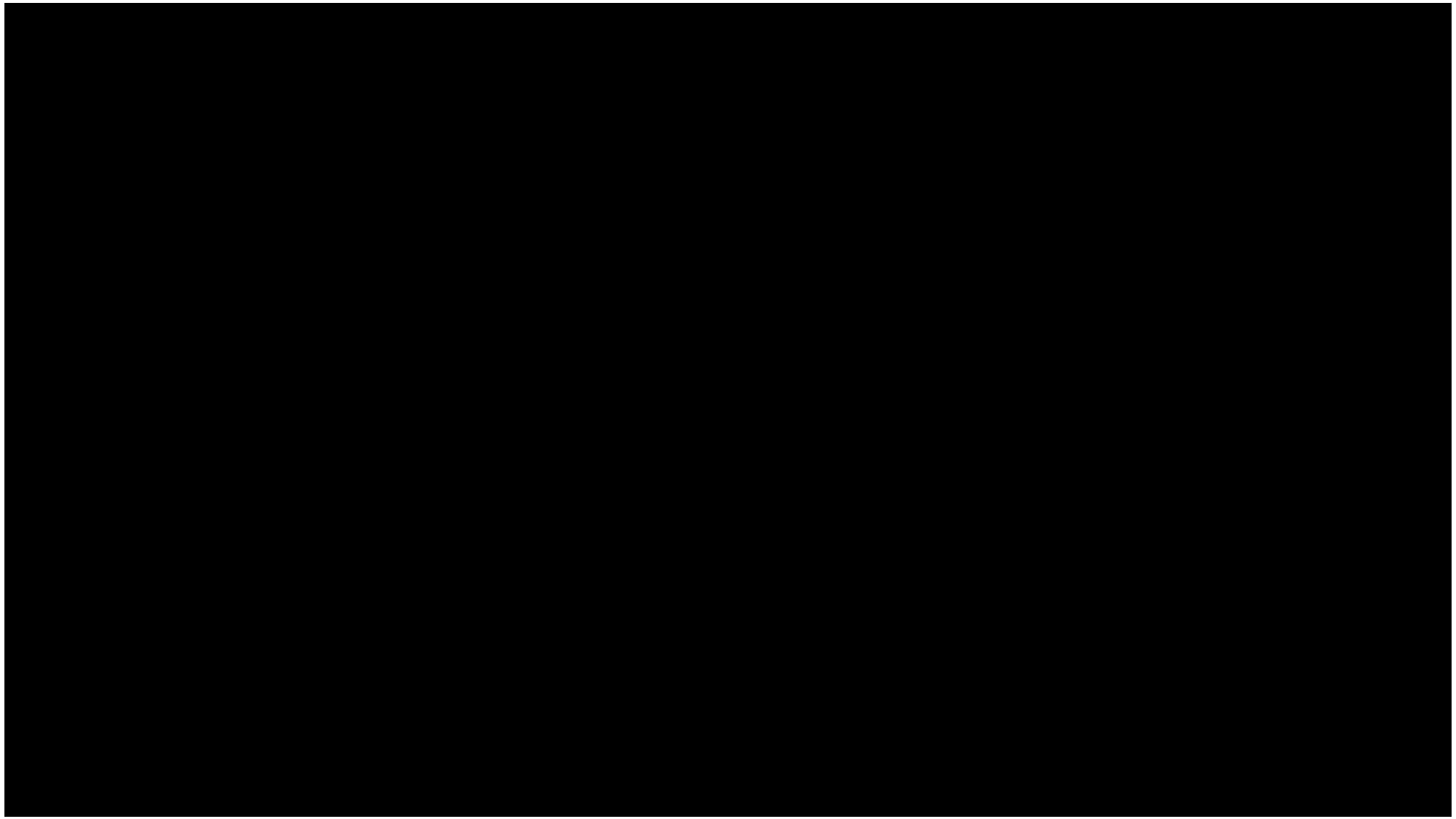
Flexible Implementation

- Paper ISFs
- Electronic ISFs (eISF systems)

ISF Reference Model

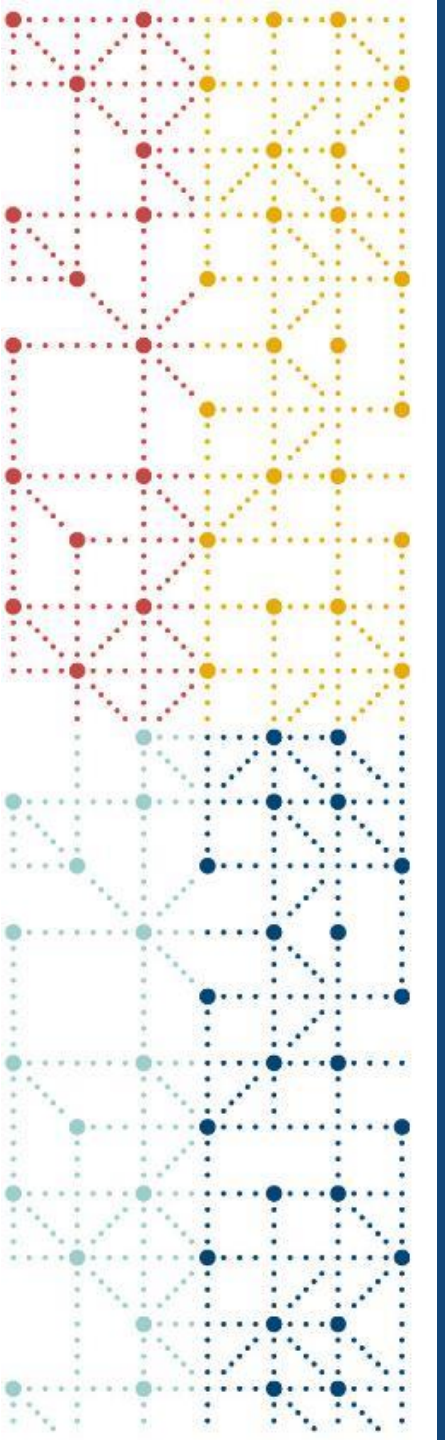
	A	B	C	D	E	F	G	H	I
1	ISF Zone Combined #/Name	ISF Zone Number	ISF Zone Name	ISF Section Combined #/Name	ISF Section Number	ISF Section Name	ISF Artifact Combined #/Name	ISF Artifact Number	ISF Artifact Type
2	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.01_ISF Plan	ISF_01.01	ISF Plan	ISF_01.01.01_ISF/eISF Index	ISF_01.01.01	ISF/eISF Index
3	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.02_Feasibility	ISF_01.02	Feasibility	ISF_01.02.01_Feasibility Documentation	ISF_01.02.01	Feasibility Documentation
4	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.03_Site Selection and Activation	ISF_01.03	Site Selection and Activation	ISF_01.03.01_Site Activation Document	ISF_01.03.01	Site Activation Document
5	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.04_Recruitment	ISF_01.04	Recruitment	ISF_01.04.01_Recruitment Plan	ISF_01.04.01	Recruitment Plan
6	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.01_Informed Consent Plan	ISF_01.05.01	Informed Consent Plan
7	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.02_IP or Device Instructions for Handling	ISF_01.05.02	IP or Device Instructions for Handling
8	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.03_IP or Device Labeling Plan	ISF_01.05.03	IP or Device Labeling Plan
9	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.04_IP or Device Transfer Documentation	ISF_01.05.04	IP or Device Transfer Documentation
10	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.05_IP or Device Recall Plan	ISF_01.05.05	IP or Device Recall Plan
11	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.06_Unblinding Plan	ISF_01.05.06	Unblinding Plan
12	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.07_IRT User Manual	ISF_01.05.07	IRT User Manual
13	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.08_Trial Supply Plan	ISF_01.05.08	Trial Supply Plan
14	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.09_Operational Procedure Manual	ISF_01.05.09	Operational Procedure Manual
15	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.10_Other Plan	ISF_01.05.10	Other Plan
16	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.11_Safety Manual	ISF_01.05.11	Safety Manual
17	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.12_Site Policies or Procedures	ISF_01.05.12	Site Policies or Procedures
18	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.12_Site Policies or Procedures	ISF_01.05.12	Site Policies or Procedures
19	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.13_Manual	ISF_01.05.13	Manual
20	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.14_Source Data Agreement	ISF_01.05.14	Source Data Agreement
21	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.15_Data Entry Guideline	ISF_01.05.15	Data Entry Guideline
22	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.16_Sample Case Report Fo	1.05.16	Sample Case Report Form

ISF Demo



Stay Tuned: What's Next for ISF RM

- ISF User/Implementation Guide
- ISF Reference Model v2 planned to be released with TMF Standard Model v1 in early 2027
- More comprehensive training in the model is been planned!



TMF Outreach

Dawn Niccum, Executive VP, Quality, inSeption Group

Outreach Team Charter

Brief description of community & objectives:	To gather intel on opportunities for outreach, promoting awareness, understanding, and consistent use of the CDISC TMF Resources and Workstream products. To create content as needed and review content for sharing out to the industry.
Scope - In:	Communications related to CDISC TMF initiatives and working groups/subteams.
Scope - Out:	Non-CDISC initiatives, unless presenting at those initiatives; a Conference

Desired deliverables:	• Complete listing of events where CDISC TMF should be providing assets for.
	• Produce ready-to-use assets for priority events (e.g., one-pagers/QR).
	• Ensure all materials align to TMF SM V1 / ISF and pass Marketing review; translations are completed as required.
	• Channel / Platforms to use strategy
	  • Define platform mix per region (e.g., LinkedIn; WhatsApp (Japan), WeChat China).
	  • Create a message bank and visual templates for reuse.
	• Measurement & learning
	  • Track outputs (assets created, events supported) and outcomes (traffic, registrations).
	  • Retrospective after each major event.

Target end date:	Ongoing
Status:	•29-Jan-2026 Kick Off Meeting held with 19 team members. •26-Feb-2026 Second meeting for alignment of team members on subteams

Accomplishments to date

- Tri-leads identified: Jennifer Christofferson, Sean Mahoney, Anusha Rameshbabu
- Three subteams formed with ~10 volunteers on each:

Subteam	Goal	Lead
Tools for Communication	Establish Methods and Vehicles for communication. Examples: QR codes, dedicated web pages…	Jennifer
Communication Pathways	Determine pathways for Outreach Examples: Digital platforms, industry organizational outreach (ACRP, ACDM…)	Sean
Response Analysis	To anayze results of Outreach Example: Platform based response, data driven approaches	Anusha

Risk Initiative

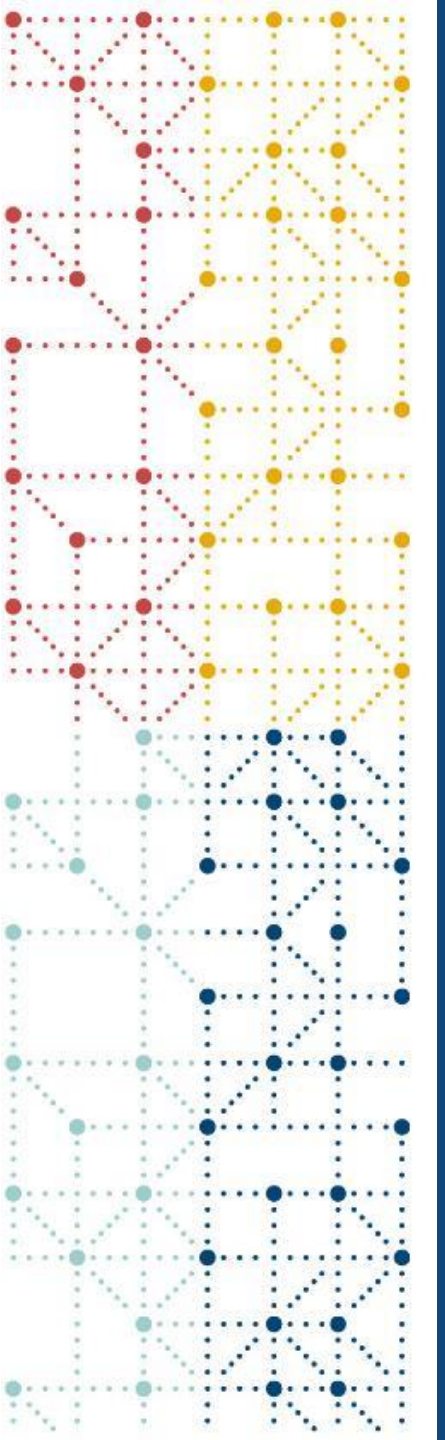
Introductions: Joanne Malia, Sr. Director, Development Records Mgmt, Regeneron, TMF Steering Committee Member

Presented by: Chad Scribner & Albert Cheng

Chad Scribner, Sr. TMF Consultant Inspection Readiness, Epista Life Science

Albert Cheng, Clinical Research Project Manager, Massachusetts Eye and Ear Infirmary

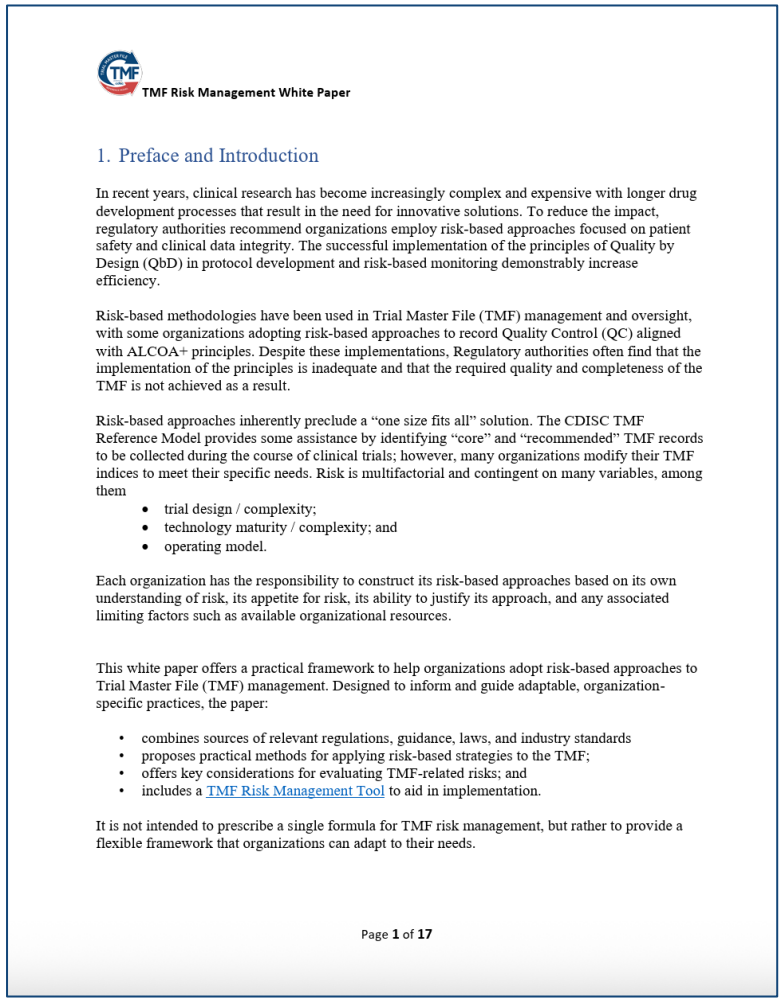
Have your phone/Tablet/QTR code scanners ready



TMF Risk Management White Paper

Risk-based TMF Training Design

White Paper



TMF Risk Management White Paper

1. Preface and Introduction

In recent years, clinical research has become increasingly complex and expensive with longer drug development processes that result in the need for innovative solutions. To reduce the impact, regulatory authorities recommend organizations employ risk-based approaches focused on patient safety and clinical data integrity. The successful implementation of the principles of Quality by Design (QbD) in protocol development and risk-based monitoring demonstrably increase efficiency.

Risk-based methodologies have been used in Trial Master File (TMF) management and oversight, with some organizations adopting risk-based approaches to record Quality Control (QC) aligned with ALCOA+ principles. Despite these implementations, Regulatory authorities often find that the implementation of the principles is inadequate and that the required quality and completeness of the TMF is not achieved as a result.

Risk-based approaches inherently preclude a "one size fits all" solution. The CDISC TMF Reference Model provides some assistance by identifying "core" and "recommended" TMF records to be collected during the course of clinical trials; however, many organizations modify their TMF indices to meet their specific needs. Risk is multifactorial and contingent on many variables, among them

- trial design / complexity;
- technology maturity / complexity; and
- operating model.

Each organization has the responsibility to construct its risk-based approaches based on its own understanding of risk, its appetite for risk, its ability to justify its approach, and any associated limiting factors such as available organizational resources.

This white paper offers a practical framework to help organizations adopt risk-based approaches to Trial Master File (TMF) management. Designed to inform and guide adaptable, organization-specific practices, the paper:

- combines sources of relevant regulations, guidance, laws, and industry standards
- proposes practical methods for applying risk-based strategies to the TMF;
- offers key considerations for evaluating TMF-related risks; and
- includes a TMF Risk Management Tool to aid in implementation.

It is not intended to prescribe a single formula for TMF risk management, but rather to provide a flexible framework that organizations can adapt to their needs.

Page 1 of 17

TMF Risk Management White Paper
https://www.cdisc.org/sites/default/files/2025-06/2025-05-30_TMF_Risk_Initiative_White_Paper_v1.2_0.pdf

TMF White Paper

- Practical framework for risk-based TMF management

- Protocol-specific flexible process, NOT on-size fits all
  - Endpoints, Study Phase, Countries & Sites
  - Service providers
  - Computerized systems, Processes

- Focus of risk assessment:
  - Patient rights, well-being, safety or dignity
  - Regulatory expectations for data integrity
  - “Essentiality” as stipulated in ICH GCP E6 (R3)
  - The evidential value and quality of records
  - The completeness of the TMF

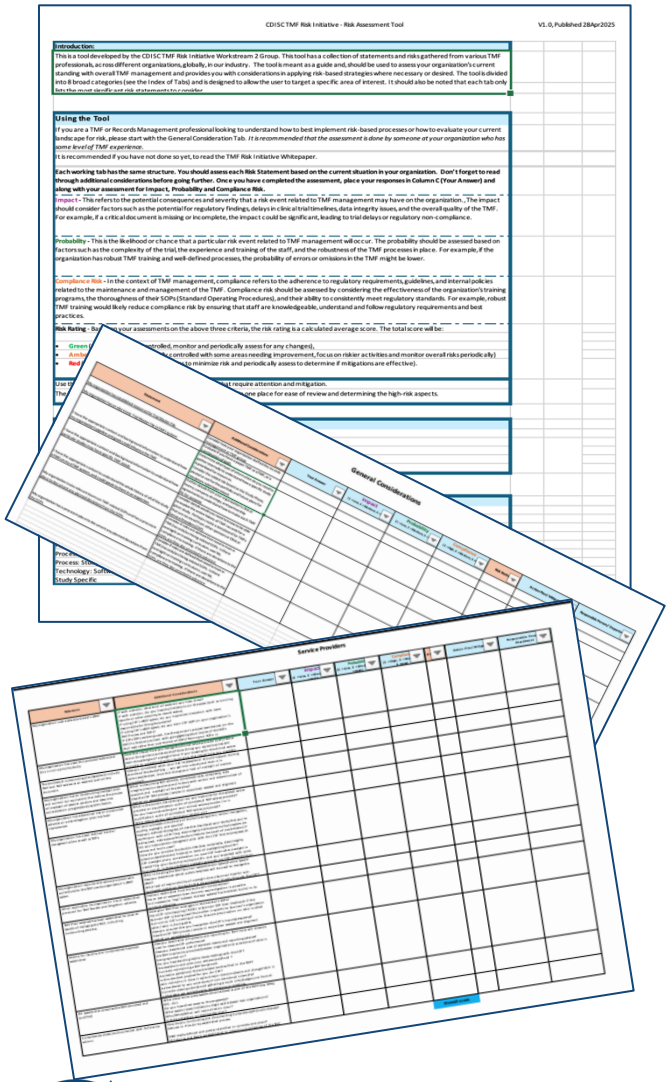
TMF White Paper

- Considerations for People, Processes, Technology

- TMF Risk Management – all ‘levels’ of the TMF across all TMF repositories
  - Organisational risks – TMF Resources
  - Trial-level risks
  - Country-level risks
  - Site-level risks

- Risk control considerations
  - System capabilities & process controls
  - Proportionality & quality tolerance thresholds
  - Quality control, reports & analytics

The TMF Tool



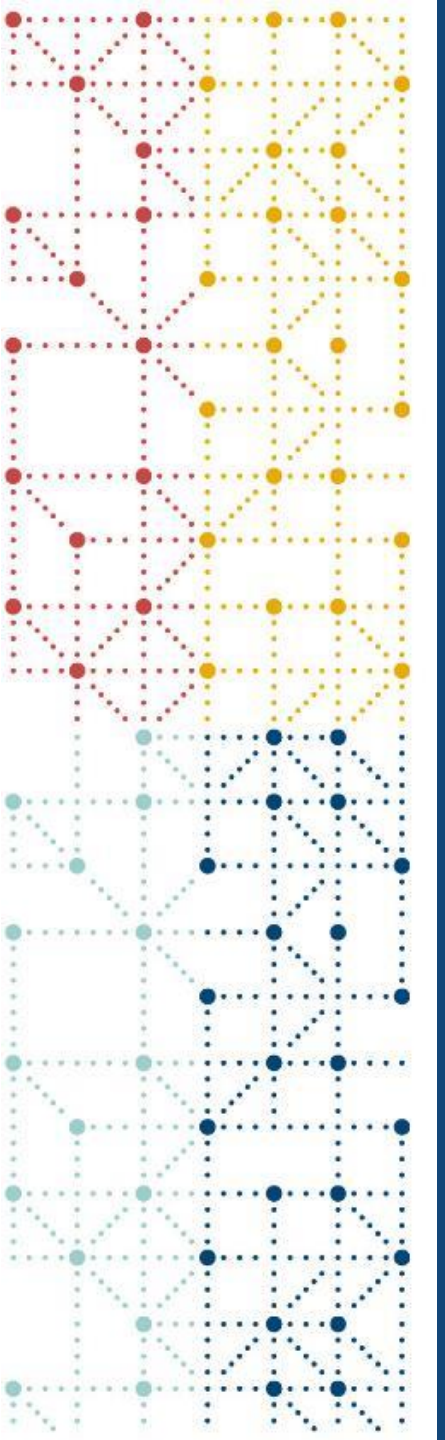
Excel Workbook with Multiple Tabs

- General Considerations - Resources & TMF Process
- Study-specific considerations
- Service Providers - Governance & Oversight
- Internal Resources - Organisation, Governance, Performance Measures
- Study Start-up Phase Risk Assessment – Trial-specific procedures & the TMF Plan
- Quality Checks – Reviewing the TMF & TMF QC strategy
- Study Close-out & Archiving – Orderly shut-down processes & related risks e.g. migration, protection
- Software Checklist

Identifies the high-risk areas within a file & high-risk records

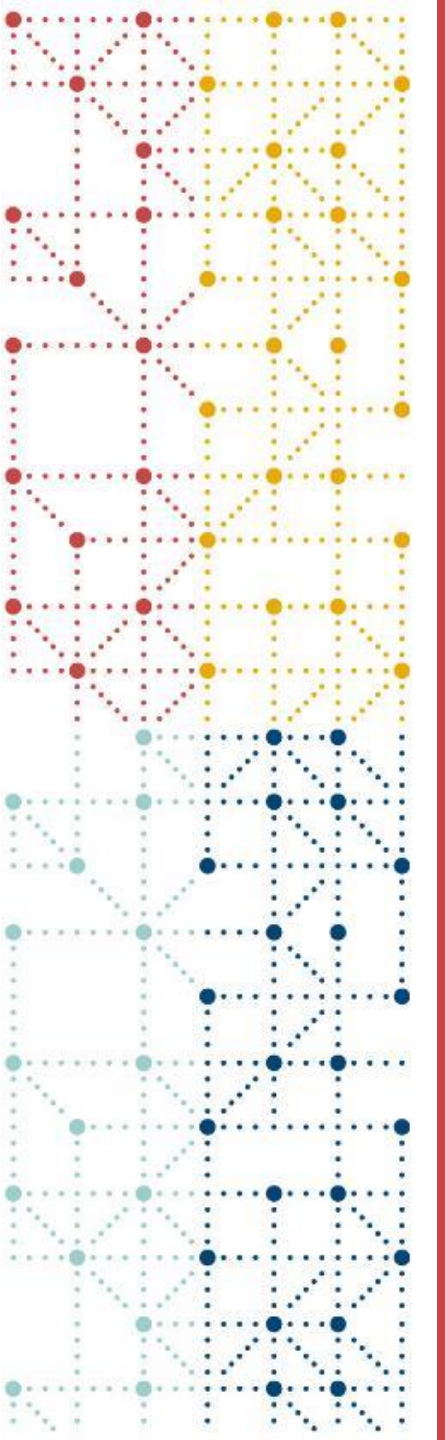
Version 1 – Please provide feedback for tool development

TMF Tool Demo



Planned Training Overview

Training format & content



TMF Training Agenda - Proposal

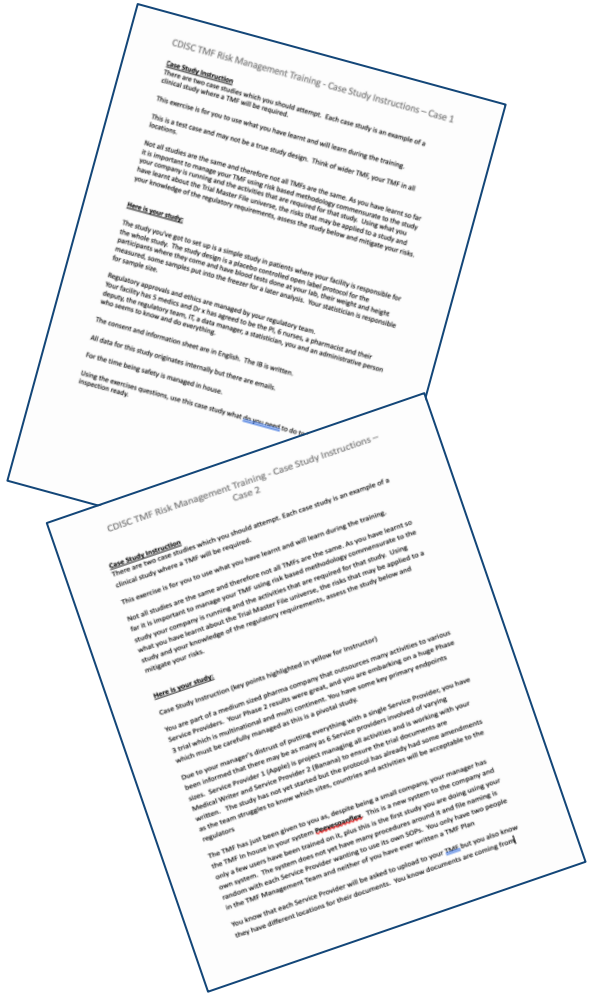
1. Planned Training Overview
2. Outline Module Content
3. Summary

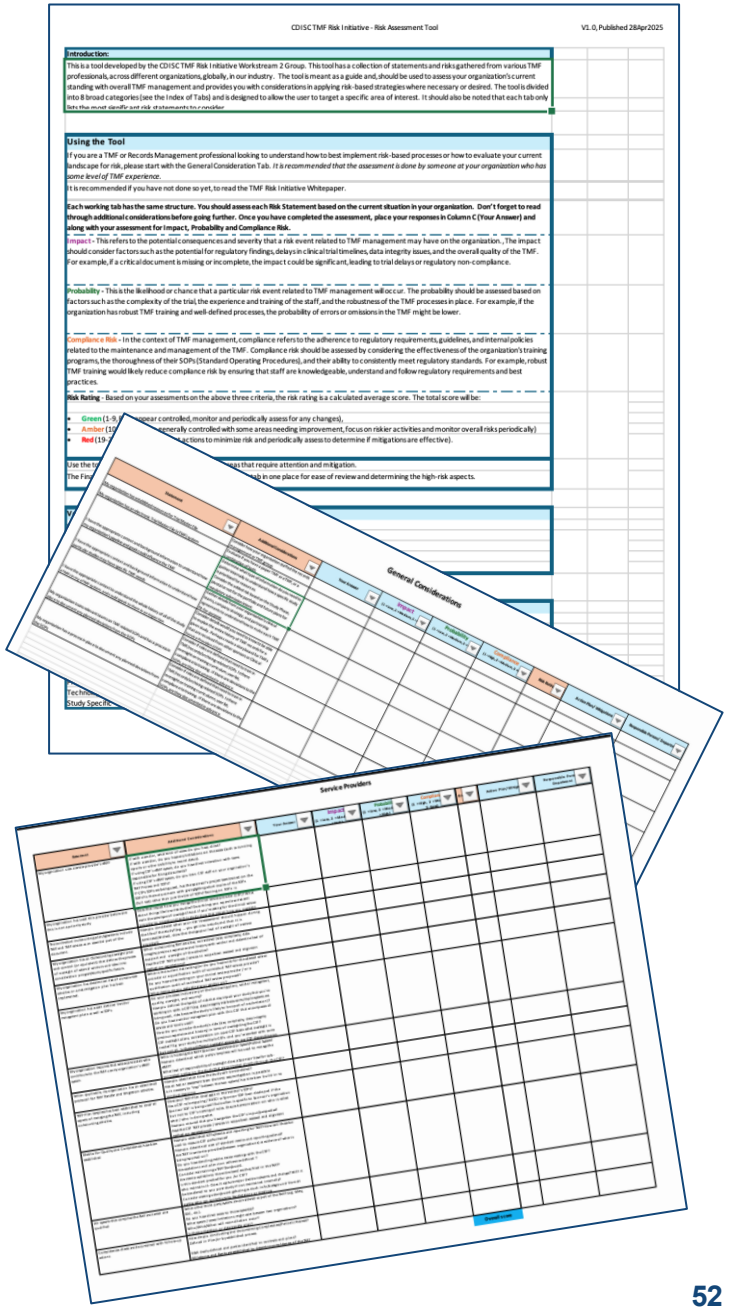
Risk-based TMF Training Design

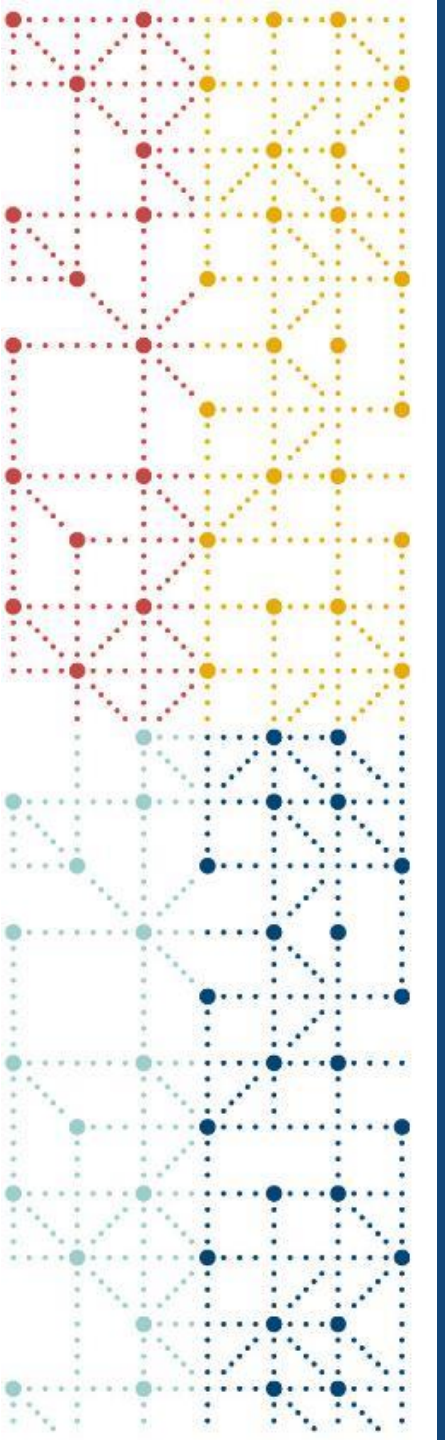
Module 1:
Introduction to TMF & Risk Management Principles

Module 2:
Risk Identification & Evaluation in TMF Management

Module 3:
TMF Continuous Improvement & Risk Monitoring







Outline Module Content

Module Objectives

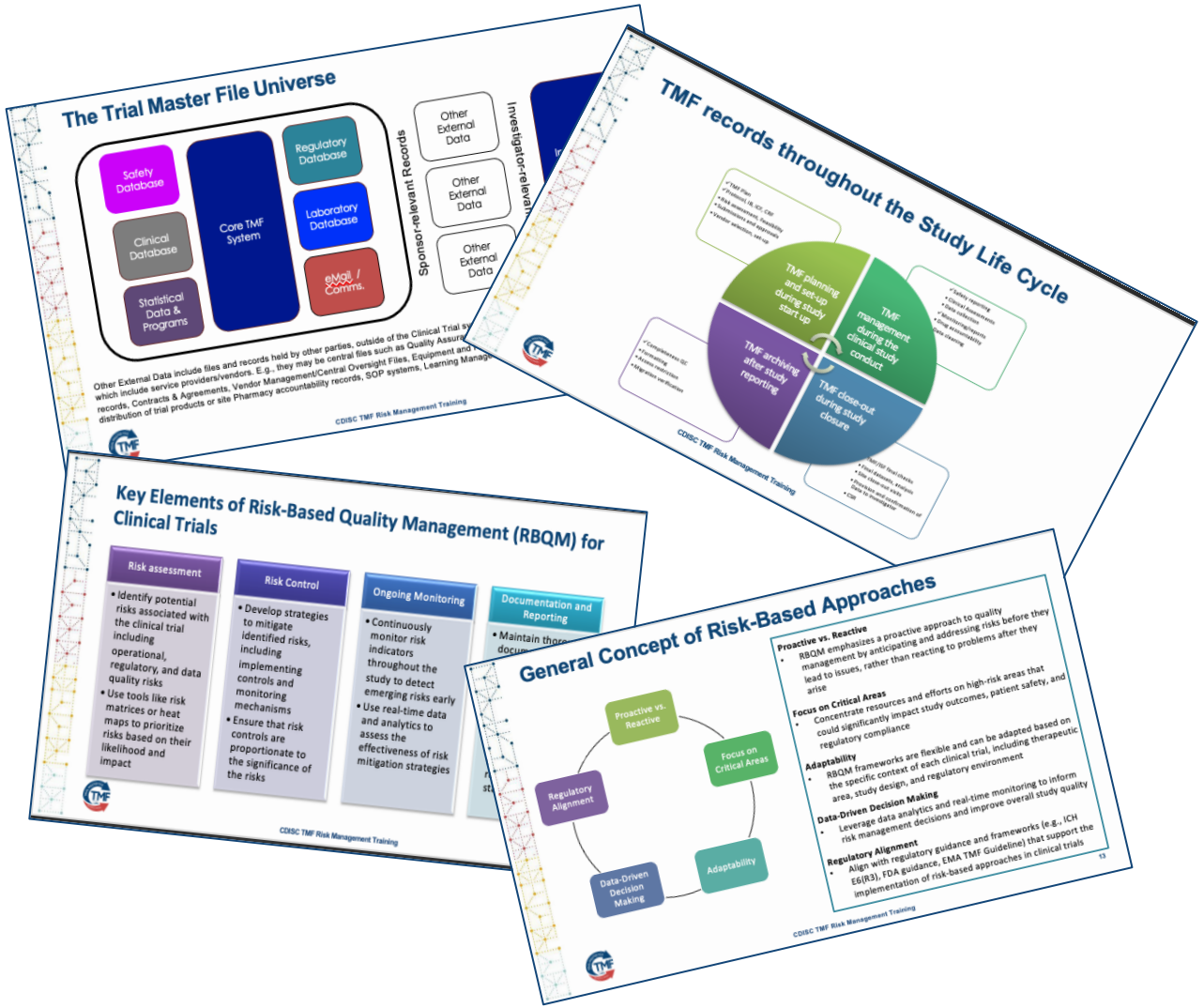
Module 1
- Purpose & significance of the Clinical Trial TMF
- Risk-based approaches & regulatory expectations
- Introduction to risk-managed TMFs

Module 2
- Identification of TMF risks at differing TMF levels
- Importance & role of critical to quality factors (critical data & processes)

Module 3
- Continuous improvement practices for TMF risks
- The importance of oversight – monitoring TMF processes & effectiveness of risk management strategies

Module 1:
Risk Identification & Evaluation in TMF Management

- ICH GCP E6(R3) & TMF records – ‘TMF Universe’
- Risk-based approaches: ICH E8(R1) CtQ for the TMF
- The TMF & study life-cycle
- Risk-based Quality Management (RBQM) for Clinical Trials
- Case Studies – introduction to fundamental trial differences, low/high intervention studies, risk variance

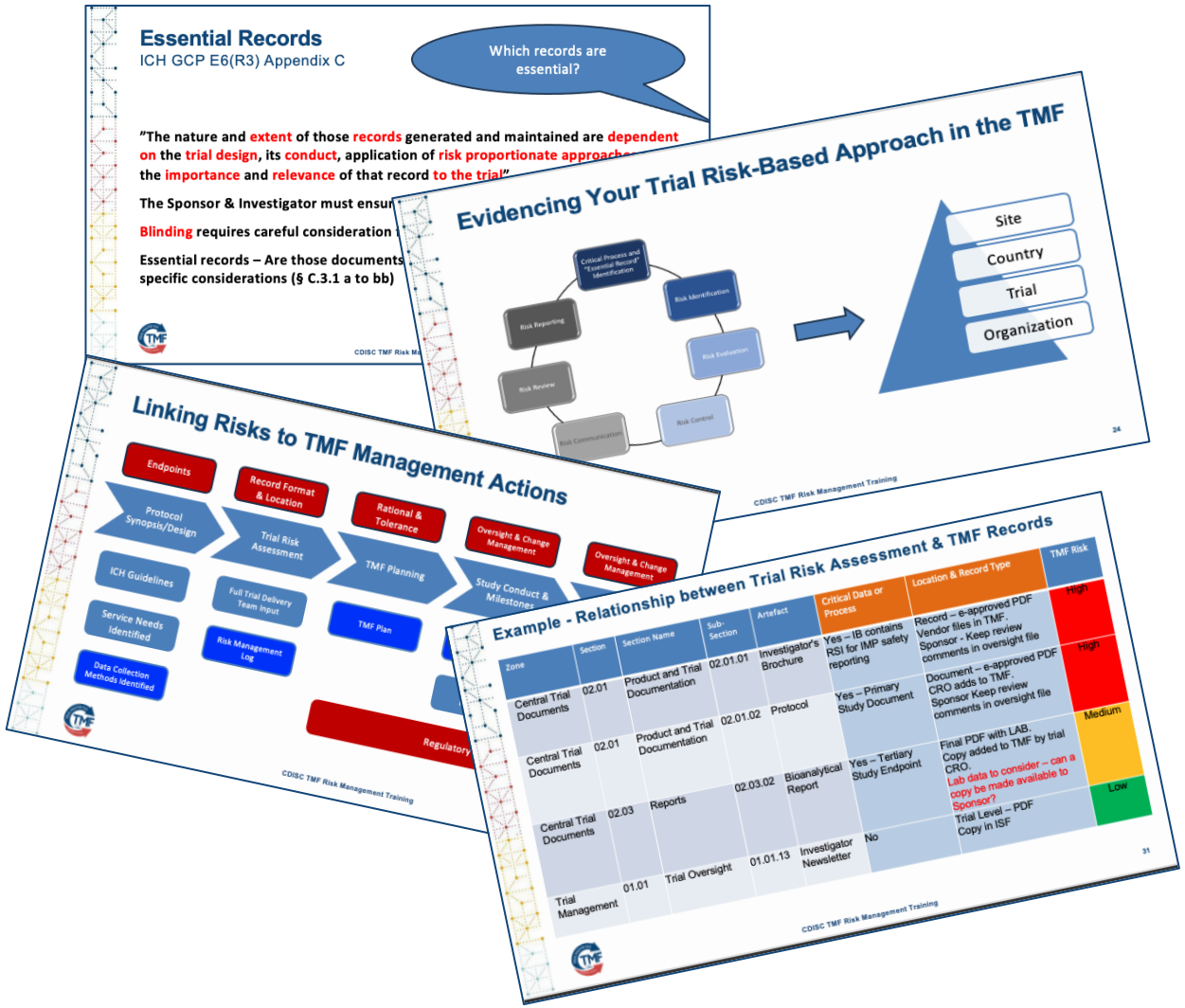


Module 2:
Risk Identification & Evaluation in TMF Management

- TMF management methodologies, critical data & critical processes
- TMF risks: organizational, trial, country and site-level risks
- Risk management & thresholds proportionate to risks

Exercise

- Case study risks, tolerance thresholds,
- The TMF Plan & trial team training

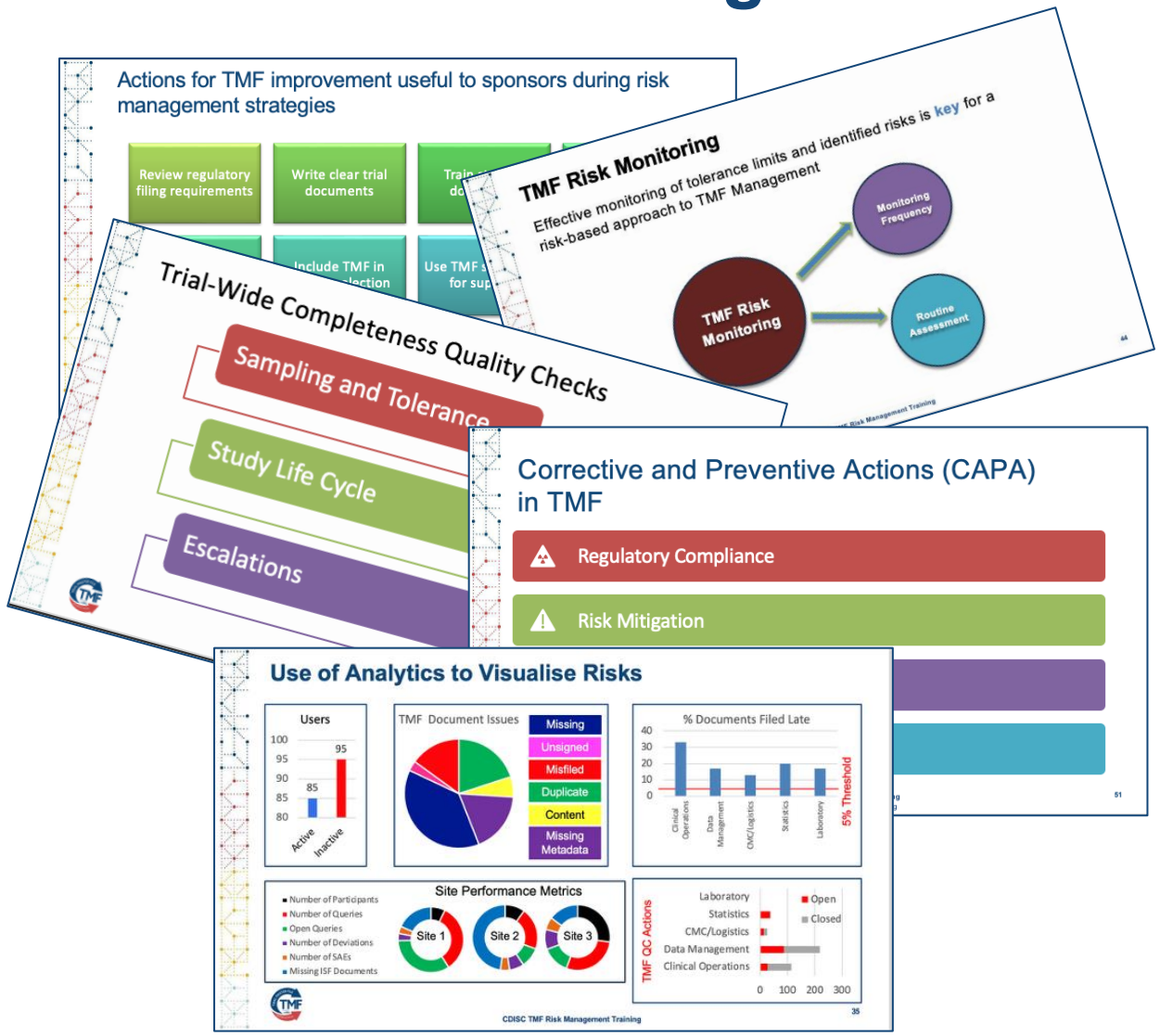


Module 3:
TMF Continuous Improvement & Risk Monitoring

- Sponsor risk management strategies for TMF improvement
- Significance of routine TMF review
- Document-level quality checks & trial-wide completeness assessments
- Importance of corrective & preventative actions (CAPA) in TMF management

Exercise

- TMF risk monitoring tools & techniques



Case Studies

- No TMF is the same
- Group exercises will compare a **higher** & **lower** intervention trial, with emphasis on the differences in the focus of the TMF (including all its repositories, not just the central paper or eTMF file)
- The case studies will exemplify **differences** in:
  - TMF set-up, oversight & archiving
  - The people & processes for managing the TMF Universe
  - Risk proportionate mitigation & control activities for the TMF
- Case studies allow for practical examples & sharing of experience
- Current status: drafted Trial synopses, model answers, facilitators notes

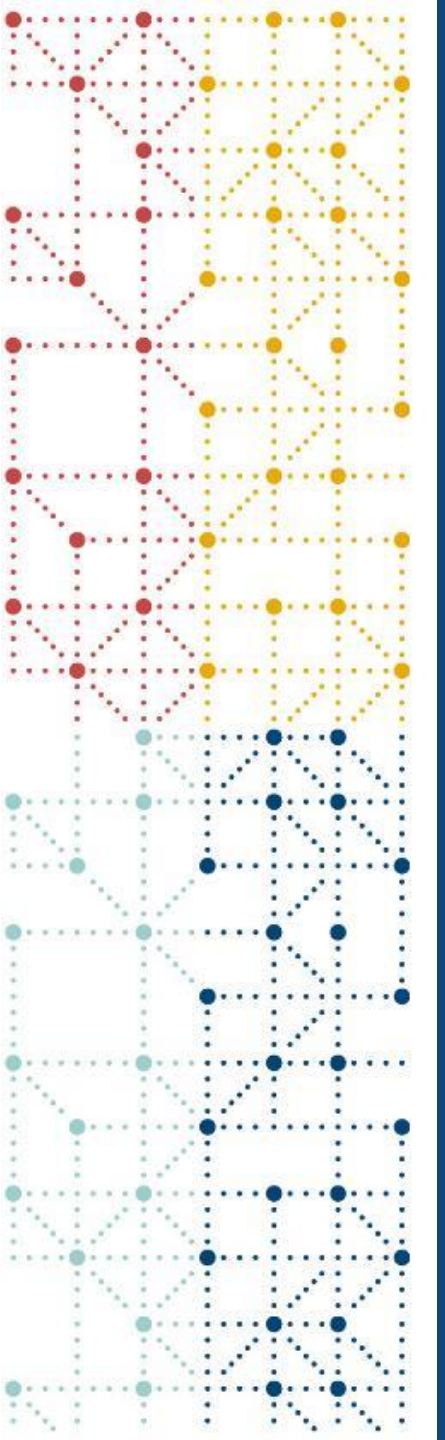
Case Studies

example points to consider

Organisation Level	Country Level
Staff/Functions	Number of Countries
TMF	No. Laboratories
	Translations
TMF Management	**Site Level**
Staff	Number of Sites
Procedures	Staff experience
File-naming	e-Systems use

Trial Level
Phase & Design
No. Participants
Type of Participant
Primary Endpoint(s)
Secondary Endpoint(s)
Safety Endpoint(s)
Exploratory Endpoint(s)
Investigational Product
Treatment & Duration
Third Parties
Systems

- **Protocol synopsis**
- Risk identification
- Risk control
- Risk management tools
- Oversight of TMF using risk proportionate approach…
- Minimise missing & low-quality records that matter
- Maximise focus on records of highest importance to:
  - Legal compliance
  - Participant safety
  - Trial results
  - GCP



Risk Initiative Summary

Poll

Please complete the poll when requested.

Have your phone/Tablet/QTR code scanners ready

Thank You!

There were a lot of fantastic people involved in creating the Training Modules, TMF Case Studies and the TMF Tool. The major contributors were:

- Albert Cheng, Clinical Research Project Manager, Massachusetts Eye and Ear Infirmary
- Martina Duevel, Systems Excellence Project Leader, Bayer AG
- Jennifer Eberhardt, Executive Director, Operational Excellence, Sarepta Therapeutics
- Mabel Ebot, TMF-Manager, Molecular Partners AG
- Sarah Hitching, TMF Consultant, Hedian Records Management
- Karen Hue, QA Director, NMD Pharma
- Tonia Huggins, Director Business Systems & Ops Mgmt - TMF, Daiichi Sankyo
- Ramya Iyer, Senior TMF Manager, Regeneron
- Vidya Jayapalan, Senior Manager, Statistical Programming, Takeda Pharmaceuticals
- Joanne Malia, Senior Director, Development Records Management, Regeneron
- April Mattison-Wolfe, Senior Manager, Technical Services, TransPerfect
- Louise Mawer, Director, Mirabilitas
- Marion Mays, Principal Consultant, Jerion Consulting Group
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- Chad Scribner, Sr. TMF Consultant Inspection Readiness, Epista Life Science
- Suzanne Turner, Consultant, ICE Consulting, LLC
- Zhigang Xu, TMF Supervisor, BioNTech SE

Any questions please contactJoanne Malia joanne.malia@regeneron.com

Questions?

Thank You!!!