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TMF Community General Meeting

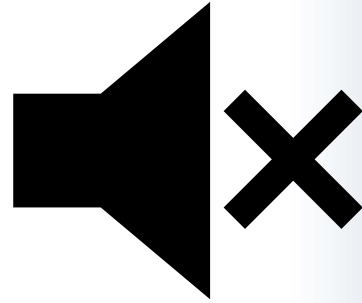
June 2, 2026 ROW / June 3, 2026 APAC





Housekeeping





You will remain on mute





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





Audio Issues?

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





The screenshot shows the CDISC website navigation. The top navigation bar includes links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events' (highlighted with a red box), and 'Membership'. Below the navigation bar, the breadcrumb trail reads 'Home / Events / Webinars / Webinars Public'. The main content area is titled 'Webinars - Public' and displays a grid of webinar recordings. The first two recordings are 'Pre-(admiral) Hackathon Workshop: Introduction to R for SAS Programmers' (dated Tue 17 2019) and 'COSA Spotlight for Q4: Dataset-JSON Hackathon Results' (dated Thu 8 DEC 2022). A right-hand sidebar menu lists 'Conferences' (2023 Europe, Japan, China, US, and Korea Interchange), 'Webinars' (Upcoming, Public Webinars Archive, and Members Only), and 'All Events' (Calendar, COSA, and Partner Events).



Webinar Recording

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



Agenda

1. Introduction
2. Recap of Milan
3. Upcoming interchange in Denver
4. Change Control Board
5. Update on V1
6. Updates from SubTeams:
 - ISF
 - Outreach
 - Metadata
7. Regional Community Updates:
 - Japan
 - China
 - France
8. Questions





Speakers

- Jamie Toth, Sr. Director, Global Trial Master File Management & Records, BeOneMedicines; TMF Steering Committee Member and Incoming Chair Elect
- Karen Roy, Consultant, CDISC; Phlexglobal; Outgoing Chair, TMF Steering Committee Member
- Joanne Malia, Sr. Director, Development Records Mgmt, Regeneron, TMF Steering Committee Member
- Kate Santoro, Sr. Director, Operational Excellence, Intellia Therapeutics
- Donna Dorozinsky, CEO, Just in Time, GCP, TMF Steering Committee Member
- Aaron Grant, Head of Innovation, Just in Time, GCP
- Yuto Kanda, Chugai Pharmaceutical Co., Lead of JP TMF community
- Jessica Ramdine, Sr. TMF Manager, Lead of France TMF Community





2026 CDISC Europe Interchange Recap

20 – 21 May | Milan, Italy



Milan!





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2026 Europe Interchange

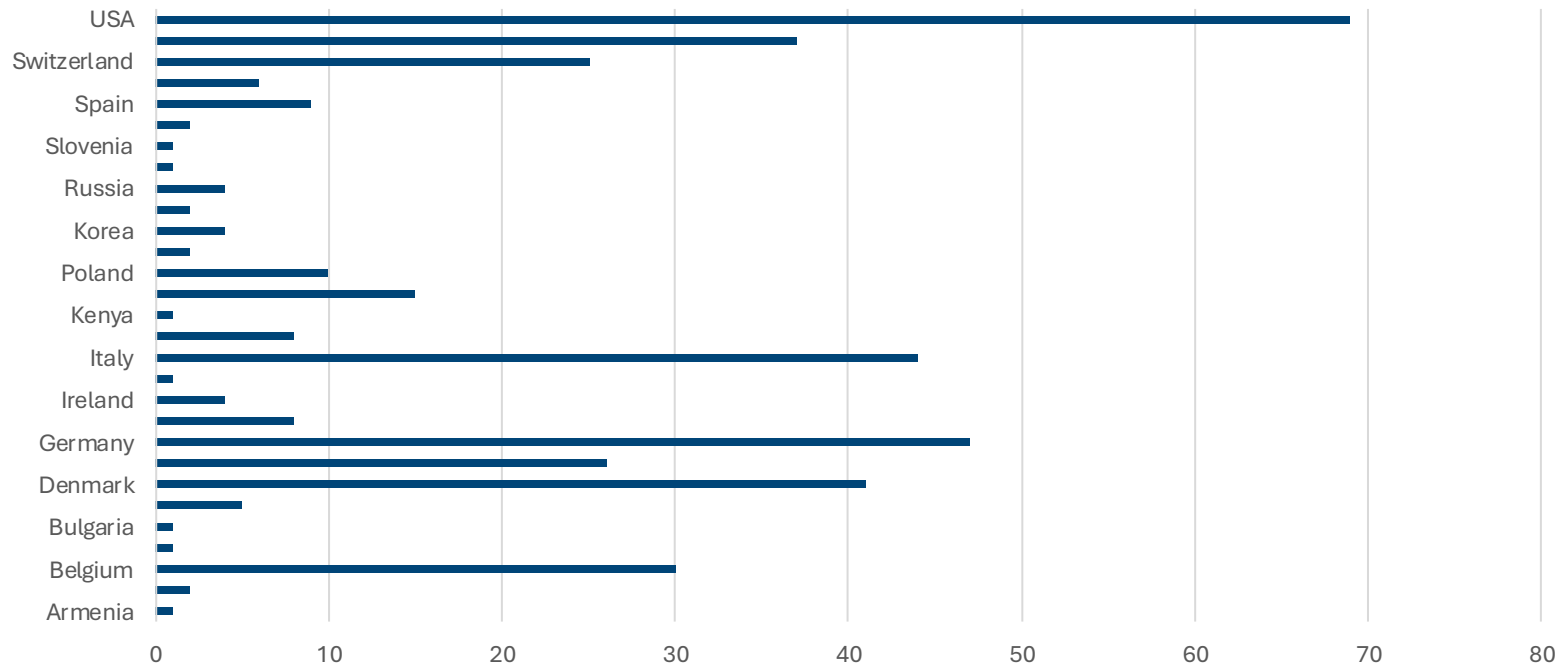






2026 Attendance

Attendance by Country



*Record Breaking
Year for EU
Attendance with
425 Registrants!*

*Representation
from 29 Countries
across 5
Continents! (6 more
countries than 2025)*



The Future is Connected: Standards and AI Powering Digital Transformation

MY highlights:

- Saving and improving lives by unlocking the full potential of existing drugs
- ICH E6 R3 – we are doing too much!
- TMF Standard V1
- Leveraging AI for risk assessment
- Empowering teams through AI and automation
- Capturing TMF clarity through a portfolio view
- The CDISC ISF Structure
- The eClinical zone
- TMF Interoperability
- Vendor panel on V1 implementation



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2026 Europe Interchange



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2026 Europe Interchange



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2026 Europe Interchange





2027 CDISC Europe Interchange

Barcelona, Spain | May 26-27 (Tentative)





*The Future is Connected:
Standards and AI Powering Digital Transformation*

2026 US Interchange

Main Conference: 5-6 October | Trainings & Workshops: 7-9 October

- Location: Denver Marriott Tech Center
- Main Conference: 5 – 6 October
- Evening Event: 5 October
- [Hotel Reservations](#)
- [Sponsor the Interchange](#)





Why do you **HAVE** to be in Denver?

- Your last chance to in-person discuss Standard V1 before it is released in 2027
- A huge focus on AI, not just how it is being used but the impact
- Inspection readiness, Risk management, Partnerships, Interoperability to name a few!



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Instructor-led training
in a virtual setting

**On Demand
Online Training**
























Self-paced
online training

Webinars



Industry hot topics
and best practices

 <p>Europe Interchange</p>	 <p>US Interchange</p>	 <p>2025 Event</p>	 <p>2025 Virtual Event</p>	 <p>India Day Training</p>	 <p>ARS Trainings</p>	 <p>Dataset-JSON Trainings</p>
 <p>China Day Trainings</p>	 <p>Newcomers Trainings</p>	 <p>CT Trainings</p>	 <p>SEND Trainings</p>	 <p>CDASH Trainings</p>	 <p>LHEA: Designing TRUE Research</p>	 <p>FREE TIG Training</p>
 <p>SDTM Trainings</p>	 <p>ADaM Trainings</p>	 <p>ODM Trainings</p>	 <p>Define-XML Trainings</p>	 <p>TMF Trainings</p>	 <p>TAUGs & Free Trainings</p>	 <p>Miscellaneous/ Other</p>

Training in Denver:



Fundamentals of TMF Management

The Critical Role of Data Managers,
Biostatisticians, and Programmers in
Achieving TMF Excellence



Change Control Board



TMF Standard Change Control Board



THE CDISC TMF COMMUNITY IS RESPONSIBLE FOR A VARIETY OF STANDARDS RELATING TO THE TMF; ONE OF WHICH IS PROMOTE THE TMF STANDARD.



TO MAINTAIN THIS PROPERLY, A CHANGE CONTROL BOARD HAS BEEN IN EXISTENCE FOR OVER TEN YEARS, AND THIS BOARD IS RESPONSIBLE FOR ENSURING THE ACCURACY AND CURRENCY OF THE STANDARD.

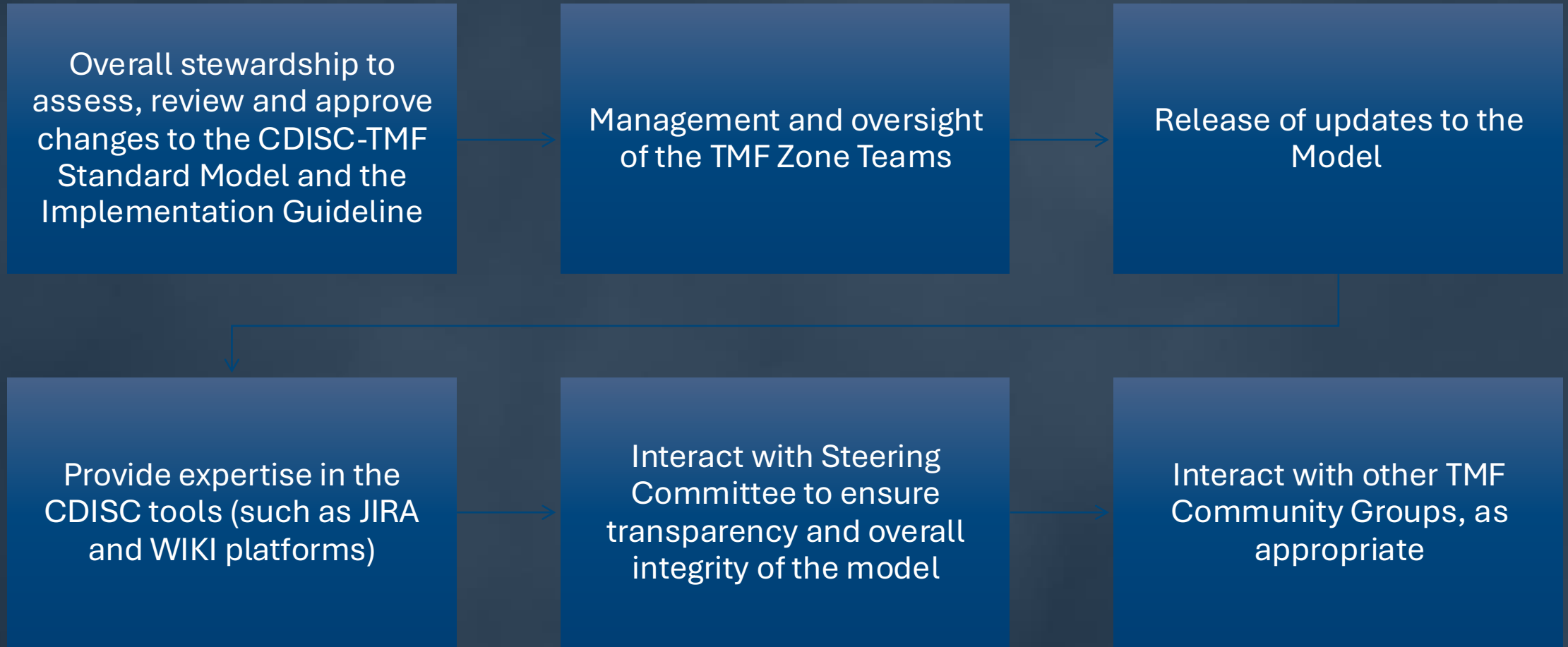


THE NEWLY DRAFTED CHARTER DESCRIBES ITS COMPOSITION AND RESPONSIBILITIES TO SUPPORT TMF STANDARD V1.0.

The expectation is that those in the CCB and zones will roll into the new structure, if they choose.



Role of the Change Control Board (CCB)





Qualifications of CCB Membership

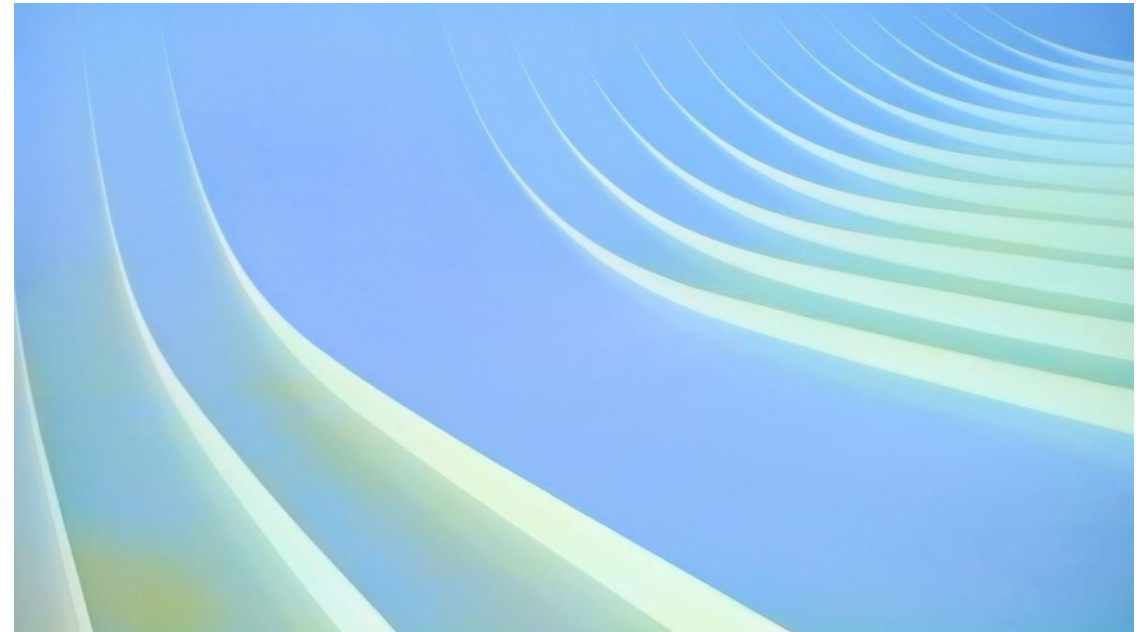
CCB Lead: Excellent working knowledge of all TMF Reference Zones; good communication and project management skills.

CCB Member: Willingness and availability to participate in CCB and individual Zone meetings (approximately 5 hours monthly)

Zone Lead: Excellent knowledge and understanding of the records within that particular Zone (approximately 5 hours monthly)

Zone Member: Working knowledge of the records within that particular Zone (approximately 1-3 hours monthly)

Definition of years in the industry in discussion and include “mentorship” option





Deliverables from the CCB

01

Version Releases of Standard Model
(based on the CDISC process for standards releases).

02

Release Notes
(explanation of release changes)

03

Implementation Guide
(recommendations of approaches and things to consider as releases are implemented)

Next Steps

Review of the CCB Charter by the TMF Steering Committee

Finalization

Elections (targeted this summer)



Updates on V1

Why V1 Matters

Where Are We Today?

What Has Been Decided/What Is Emerging?

What is Left to Do

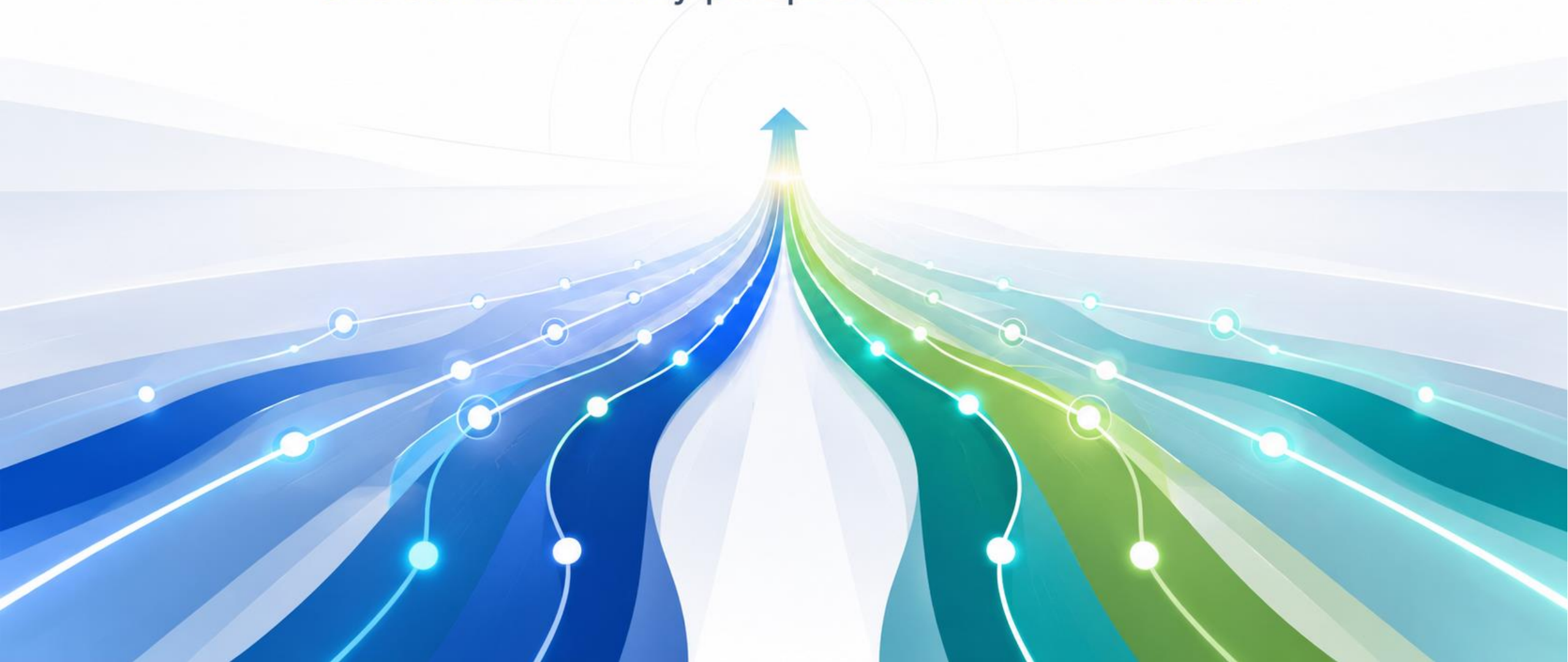
Timeline

Closing



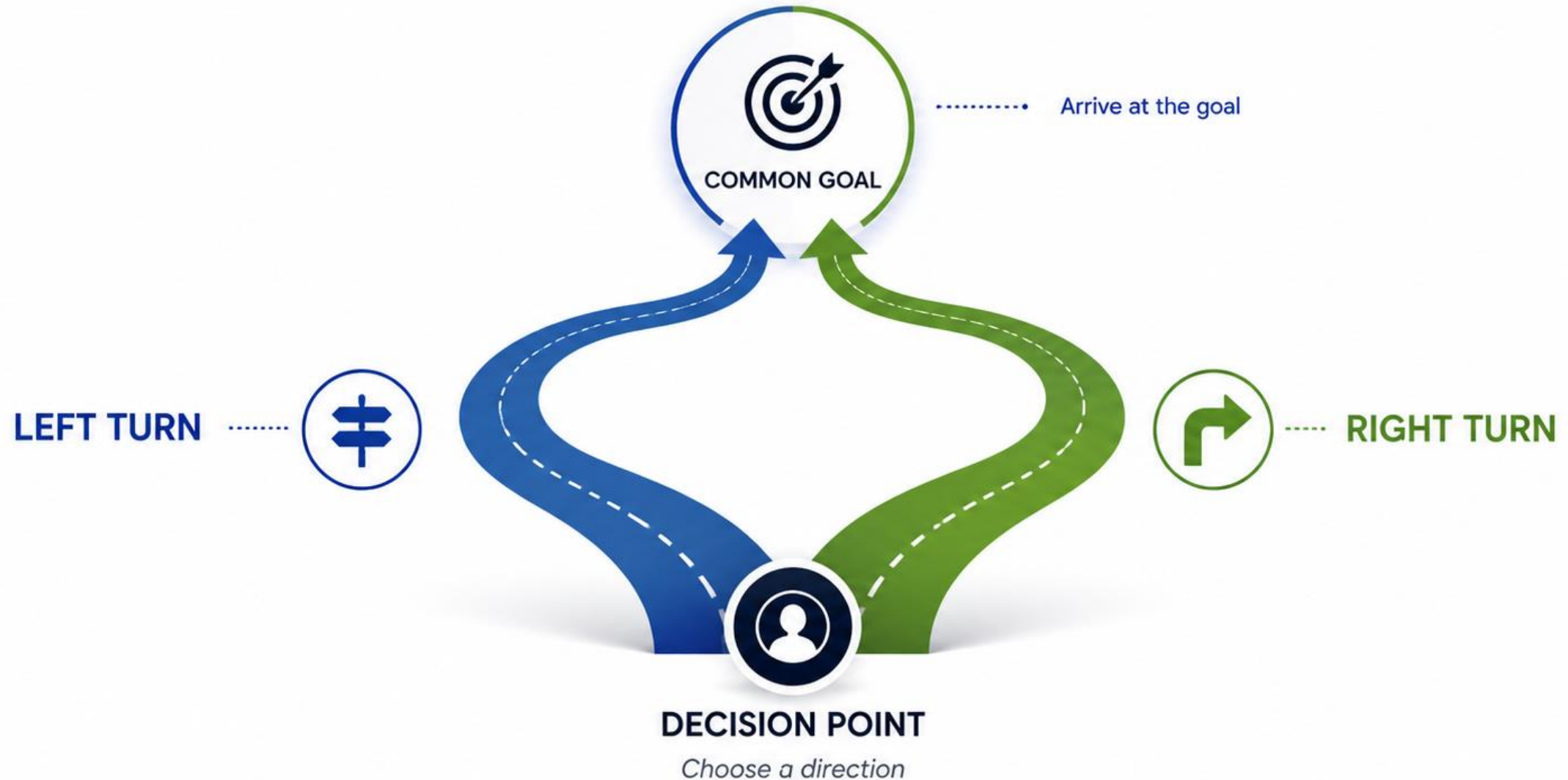
We Are Building This Together

One standard. Many perspectives. A shared future.



Right Turn / Left Turn

Different choices can still lead to the same objective.



V1 Is More Than an Update

It is a shift toward a more consistent, connected, and future-ready TMF Standard.



Guiding Principles



Solve real
problems



Avoid unnecessary
change



Build for the
digital future



Create consistency
across the
TMF Standard



Where Are We Today?



Additional Guiding Principles that are Driving Decisions



- We want decisions to solve problems not just be a different way of doing it.
- We are being careful not to make decisions that create new problems or create new gaps.
- Sometimes it's either left or right and we just need to pick one.



Current Activities

- Zone reviews are complete
- ISF, Device, & RWE has provided their revisions
- Management team is going zone by zone to create consistencies and review responses to build the final draft of Record Types.
- Combining ISF, Device, and RWE into the Standard Model
 - Identifying inconsistencies in Record Type Naming
 - Identifying new Record Types from the 3 other sub-models that need to be added



What Has Been Decided/What Is Emerging?





Where are we with decisions impacting V1?

- Addition of new Zone – eClinical Systems
- Eliminating Core vs Recommended
 - This has become increasingly challenging to explain the difference between the two
 - As we bring together the subsets of ISF, RWE, & Device it becomes even more challenging
 - Changes as regulations change
 - Limited value to the standard model
- Move from term **Vendor** to **Service Provider** across the Standard Model
- Keeping the Standard to 3 levels by combining Section & Artifact to create Record Groups



What Will This Look Like?

- 12 Zones

- Undetermined Number of Record Groups

- Record Types



Where Are We With Record Groups

- Way of organizing like records in a more meaningful way, but still retaining the option of a tree view
- Record Groups may exist across zones
- Driven by ICH E6 R3, but keeping in mind industry terminology

Sample of Record Groups Under Consideration



- **Trial Management** – Study Plans
- **Quality Assurance** – Audits, QA Plans, CAPAs
- **Risk Management** – Risk Management Plans, Data, Reports
- **Agreements** – Contracts & Agreements
- **Investigator Site Monitoring** – Investigator Site Monitoring Plan, All MVR, All Confirmation Letters, All Follow-up Reports, evidence of review of Monitoring Visit reports.
- **Resources** – Trial Team lists, transitions, (non-qualifications and training records)

Examples



Trial Management

- TMF Plan
- TMF Quality Review
- Clinical Development Plan
- Project Management Plan
- Communication Plan
- Publication Policy
- TORO
- etc

Agreements

- Committee Member Confidentiality Disclosure Agreement
- Data Privacy Agreement
- Site Clinical Trial Agreement
- Clinical Trial Agreement with Investigator
- Investigator Agreement
- Service Provider Agreement
- etc

Qualifications and Training

- All CVs across all zones
- Trial Team Training Log
- Trial Team Training Certificate
- Investigator Affiliation Form
- Investigator Biographical Sketch
- Investigator CV
- Site Training Material
- Quick Reference Guide
- etc



What Is Left To Do?





What's Next

- Finalization of Record Types and organizing them into Record Groups
- Decision on how this will all be supported by Metadata
- Draft Standard Model structure to vendors
- Public Review
- Controlled Terminology

Timeline





The Future Will Not Be Built by Chance

- **Consistency** so evidence can be understood.
- **Interoperability** so information can move.
- **Digital readiness** so the TMF can support the future.
- **Regulatory alignment** so trust can scale.
- **Community ownership** so the standard reflects the industry it serves.



*Standards do not limit progress.
They make progress scalable*





Stay engaged.

Ask the hard questions.

Help us solve real problems.

*Help us avoid unnecessary
complexity.*

*Help us build something that is
practical, inspectable, digital-ready,
and durable.*





SubTeam Updates

- ISF
- Outreach
- Metadata



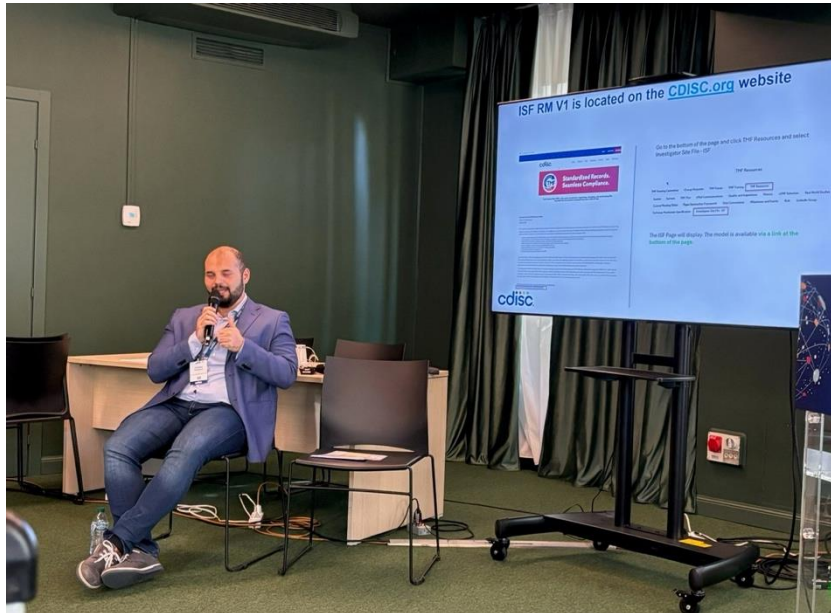


ISF SubTeam

Co-leads – Matt Lowery, Aryn Knight

TMF SC Liaisons – Jamie Toth, Dawn Niccum

- Presented in Milan with a Site and shared the Site perspective!



Vincenzo Mercurio, PhD, Trial Office Coordinator, Ufficio Ricerche Cliniche - Dipartimento di Oncematologia, IRCCS San Raffaele Scientific Institute

Currently working on:

- ISF User Guide
- ISF Plan Template
- Planning more webinars and potentially Office Hours!





Outreach SubTeam

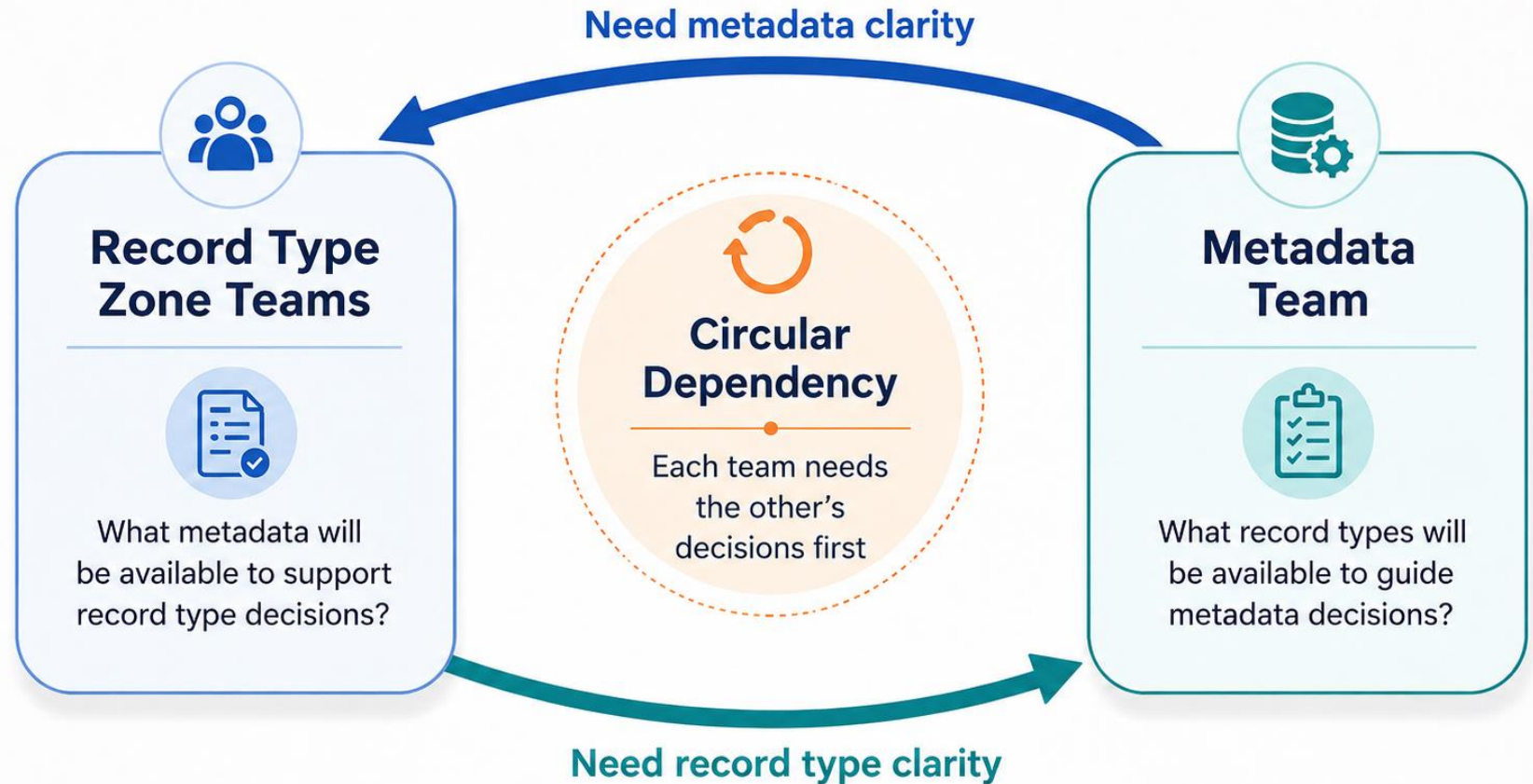
Tri-leads – Jennifer Christofferen, Anusha Rameshbabu, Sean Mahoney
TMF SC Liaison – Jamie Toth

- The team of ~30 has been meeting since February
- The team has compiled a comprehensive list of tools and strategies for effectively communicating updates to our audience.
- Some of the key options include: video vignettes, QR code drops, elevator pitches, industry marketing materials, office hours, quick-hit updates, survey trivia questions, an AI Q&A repository, workshops at major meetings, and training champions to help spread targeted messages.



Metadata Challenge for V1

- Getting Record Type list right in V1 is critical
- Record Type list needs metadata and vice versa (Circular Relationship)
- Metadata creates challenges to migration and adoption for vendors and others



Challenge: Mutual dependency delays progress and decision-making



Metadata Plans for V1

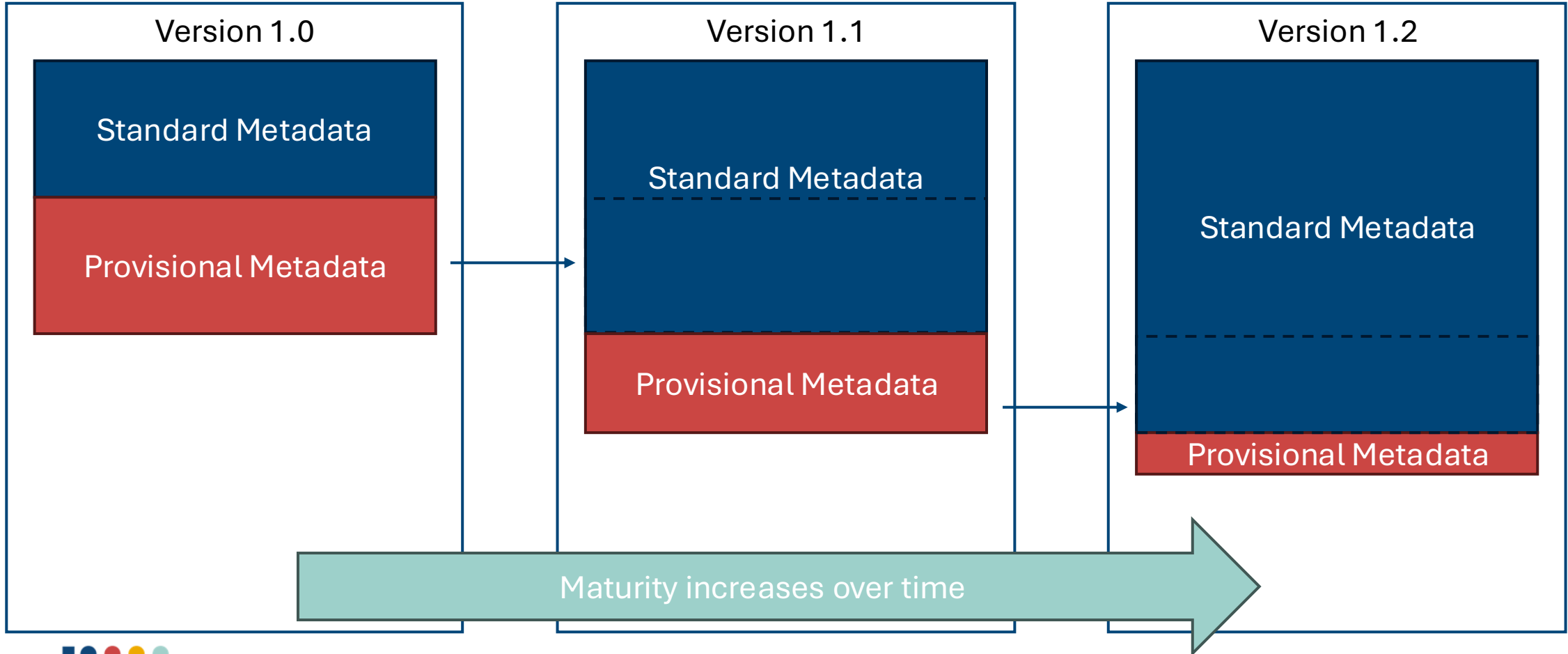
Standard Metadata

- **Only Metadata that applies to All Records**
- Simple Explanation of Scope for V1
- Easy to draw lines. Most Vendors already support all of these fields in some way
- Clear scope of Required we can publish and give out as draft to the industry without relying on Record Type list finalization
- Proposed “Standard” Metadata for V1

Provisional Metadata at a lower level

- Additional Metadata beyond standard scope
- Suggested for V1
- Conceded guidance and time for feedback during v1
- **Will generally become standard in v1.1**
- Each CDISC release will make provisional from last round required in next release and a new set of provisional fields will be defined

Provisional Metadata Lifecycle





Next Steps for Metadata Team

- Define Standard Metadata (Currently in Review)
 - Guidance rules for what's a record type vs metadata (Currently in Review)
 - Used to standardize record type decisions for V1
 - Define “Provisional” Metadata for V1
- NOTE: This decision means metadata needed to fully define Record Types will NOT be available in V1 but will be defined in a future release. This tradeoff will most likely be necessary. We will flag in record type definitions that metadata will be needed to differentiate and will become part of the model at a later date.**



Regional Community Updates

- Japan
- China
- France





JP community update

- A panel discussion finished successfully in EU interchange about the **value of local TMF communities** involving reps from Italy and Denmark.
- JP community's F2F workshop will be held on 10 June, the community members look forward to having Too Much Fun in person soon!
- We are open to any questions to launch new local communities, feel free to reach-out via LinkedIn.



Yuto's Tips and Tricks to launch TMF community→

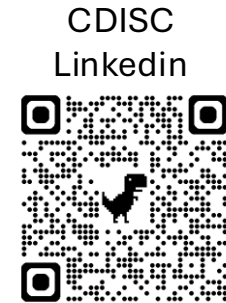




China community update

- China TMF community is in its process of establishment so that local TMFers can share their ideas, best practices, challenges, solutions, developments and innovation.

@CN TMFers,
Let's follow CDISC Linkedin and CDISC Wechat!



- Latest updates about TMFSM V1 and key highlights from the EU interchange will be presented in **China CDISC day(14Aug)**.
 - Again @CN TMFers, you cannot miss this great event!
<https://www.cdisc.org/events/interchange/2026-cdisc-china-day>



France community update

4 KEY OUTCOMES

1. Alignment & Understanding

Regulatory requirements & ICH GCP E6(R3) in French to remove language barriers

2. Shared Learning & Growth

Best practices, knowledge sharing, skill development

3. Greater Impact on Patients & Trials

Better traceability, better decisions, stronger protection

4. Sponsor & CRO Collaboration

Aligned expectations, harmonized practices, more efficiency



Call-out posted to kick off a French TMF community!



Jessica RAMDINE • You

Senior TMF Manager | TMF Strategy & Operations Leader | Clinical Research Expe...
4d • Edited

📣 Appel à tous les TMFers francophones !

Et si le TMF se jouait enfin en équipe ?

Lisez l'article ➡ https://lnkd.in/db_SCwtk

#TMFCollectif #OneTMF #WeAreTMF #TMFStrongerTogether #TMFers #ClinicalResearch #Pharma #CRO #ClinicalTrials #Quality #Networking #France #Community #Collaboration

Show translation

📣 Appel à tous les TMFers francophones !

Jessica RAMDINE

👍👍👍 Hélène Raptis and 14 others

5 comments • 4 reposts





ONE COMMUNITY
ONE PURPOSE

**TOGETHER,
WE POWER**

**TMF EXCELLENCE
FOR PATIENTS**

DRIVE QUALITY
PROTECT PATIENTS

OUR ENERGY
OUR KNOWLEDGE
OUR COMMITMENT

SHARE EXPERIENCES
BEST PRACTICES

LEARN TOGETHER
GROW TOGETHER

OUR COMMUNITY
OUR IMPACT
OUR FUTURE

**TMF COMMUNITY
FRANCE**

BUILDING THE FUTURE. **TOGETHER.**

100%
PERSONAL &
NON-COMMERCIAL
INITIATIVE

ONE GOAL
QUALITY & COMPLIANCE

ONE MISSION
PATIENT SAFETY

ONE FORCE
COLLECTIVE INTELLIGENCE

ONE IMPACT
BETTER TRIALS, BETTER CARE

FROM SOLO HEROES TO A COMMUNITY THAT **CHANGES THE GAME.** ❤️

WHY A TMF COMMUNITY IN FRANCE?

- Because we face the same challenges.**
Let's stop being solo heroes.
- Because other countries already do it.**
Italy. Japan. Denmark.
Now it's our turn!
- Because together, we can go further.**
Share, align, learn, improve.
- Because patients deserve the best.**
Quality TMF, safe trials, real impact.

4 KEY OUTCOMES OF THIS INITIATIVE

- ALIGNMENT & UNDERSTANDING**
Meet regulatory requirements and ICH GCP E6 R3 in French to break down the language barrier.
- SHARED LEARNING & GROWTH**
Exchange best practices, return on experience and develop skills.
- BETTER IMPACT ON PATIENTS & STUDIES**
Better traceability, better decisions, better protection for patients.
- COLLABORATION WITH SPONSORS & CROs**
Aligned expectations, harmonized practices, more efficiency together.

READY TO MAKE THE DIFFERENCE **TOGETHER?**

2 SIMPLE REQUIREMENTS TO JOIN:

- 1** You are French or Francophone.
- 2** You are a TMF'er, passionate or just curious.



JOIN US!

- Comment or send us a message
- sarah_neglo@hotmail.fr
- jramdine@gmail.com

Upcoming 2026 Events



China CDISC
Day

14 August
Shanghai

India CDISC
Day

22 August
Chennai

TechniCon

9 September
Virtual

CDISC-SCDM
Japan Event

4-5 November
Tokyo

Korea CDISC
Day

Q4 2026
Seoul



Questions?





Thank You!

