



TMF Community General Meeting

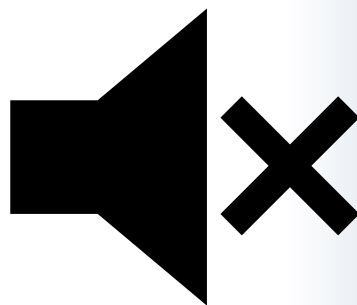
September 29, 2026 ROW / September 30, 2026
APAC





Housekeeping





You will remain on mute





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

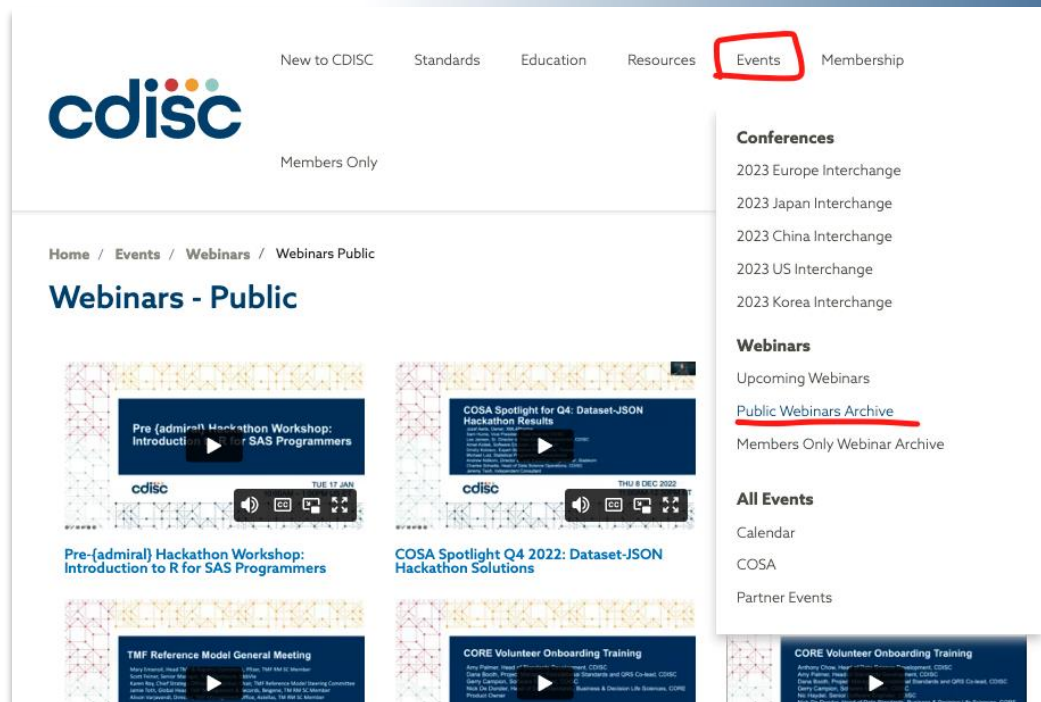




Audio Issues?

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





Webinar Recording

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



Agenda

- Intro & Housekeeping
- Thank you Joanne
- Interchange: Denver & Barcelona
- Risk Initiative
- Community Regional Updates:
 - China
 - France
 - Italy
 - Japan
- Change Control Board
- Standard Model V1 Update
- Implementation Guide
- Standard Model V1 Q&A
- Q&A & Closing





Speakers

- Paul Carter, CEO, Montrium; Chair, TMF Steering Committee
- Jason Weinstein, Associate Director TMF, Regeneron, TMF Steering Committee Member
- Rob Jones, Head of Clinical, Arithmostech, TMF Steering Committee Member
- Yuto Kanda, Chugai Pharmaceutical Co., Lead of Japan TMF Community
- Donatella Ballerini, Director TMF Strategy, Veeva
- Steph Viscomi, Sr. Director, Clinical Strategy & Operational Excellence, Kymera Therapeutics, TMF Steering Committee Member
- Kate Santoro, Sr. Director, Operational Excellence, Intellia Therapeutics
- Liz Farrell, Sr. Director, Compliance and TMF Oversight, Agios Pharmaceuticals, Inc., TMF Steering Committee Member
- Donna Dorozinsky, CEO, Just in Time, GCP, TMF Steering Committee Member





Thank
you



**Thank You
Joanne
Malia**



- 480 Registrants
- 150+ TMF Registrants
- 7 Sponsors, 19 Exhibitors
- THE place to hear about and discuss version1 of the Standard
- Excellent agenda covering AI, risk, partnerships and much more
- Register today under events on the CDISC website



cdisc.

2027 CDISC Europe Interchange

● ● ● ● Barcelona, Spain

Trainings 24–25 May
Main Conference 26–27 May

● DATE

26 – 27 May 2027

● FORMAT

In-Person

● AUDIENCE

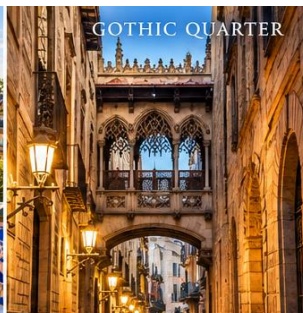
Sponsors, CROs, Standards
Volunteers, Data Managers



SAGRADA
FAMÍLIA



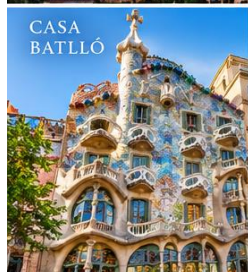
PARK GÜELL



GOthic QUARTER



LA RAMBLA



CASA
BATLLÓ



CASA MILÀ
LA PEDRERA



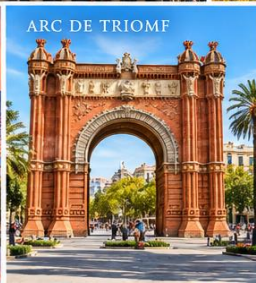
Barcelona



BARCELONETA
BEACH



MONTJUÏC
VIEWS



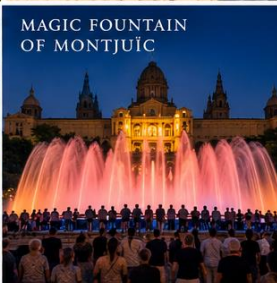
ARC DE TRIOMF



BARCELONA
CATHEDRAL



EL BORN



MAGIC FOUNTAIN
OF MONTJUÏC





Risk Initiative

Jason Weinstein





TMF Risk Initiative Update

Why it exists

- Regulators increasingly expect a “risk-based approach” to the TMF, but rarely define what that means in practice
- The initiative set out to give companies a practical definition and framework

What’s already available

- **TMF Risk Management White Paper:** personally reviewed by two regulators, with their comments incorporated
- **TMF Risk Assessment Tool:** Excel workbook to identify high-risk areas and records. Feedback welcomed.

What’s new

- **Risk-based TMF training is being finalized:** a 90-min educational teleconference with practical example / case study
- **Currently targeting November**



***Webinar coming in
November!***



Scan for the White Paper



Community Regional Updates

Rob Jones





Community Regional Updates

- Met twice with TMF Regional Groups
 - Introduced CDISC support: Wiki + Email List
- Agreed to quarterly regional meetings
- Developing a Regional Group Charter
 - Goal: support current and future regional groups
- Current groups: China, Denmark, France, Italy, Japan, Spain, UK



Regional Group Updates

- China TMF Community
 - Aug 14 CDISC China Day:
 - Presentation on AI use cases for TMF management
 - Official announcement of establishment for China TMF Community
 - 26 members as of today for China TMF Community



A community growing every day! ♥

SINCE OUR COMMUNITY LAUNCHED

≡ *May 2026* ≡

We're delighted to welcome

10 MEMBERS

FROM

FRANCE, BELGIUM & SWITZERLAND
(FRENCH-SPEAKING REGIONS) ♥



United by language, knowledge sharing & mutual support! ♥





KNOWLEDGE SHARING
practical experience



OPEN DISCUSSION
in French



IDEAS & PROJECTS
for the future



Building a strong French-speaking TMF community ♥

FROM **SOLO HEROES** TO A **TEAM**

≡ **THAT CHANGES THE GAME!** ♥

≡ **JOIN US!** ♥ ≡

GOALS



ALIGNMENT & SHARED UNDERSTANDING
Build a shared TMF language and align practices.



LEARNING & KNOWLEDGE SHARING
Learn together and share practical experience.



GREATER IMPACT ON PATIENTS & TRIALS
Turn insights into better trial delivery and patient outcomes.



SPONSOR-CRO COLLABORATION
Strengthen trust and ways of working across teams.





Italy Update

The Community is growing fast, new members joined in August and September so now we are **43 people!!!**

Current challenge: how to share documents and quick updates in a more effective way (avoiding emails).

BIG NEWS: AIFA will meet the Italian TMF Community in Rome (date to be defined)!!!

Next virtual meeting planned for **12 November 2026**: agenda is ready and lots of interesting topic will be discussed.



*Chiesi, Veeva, SGS, Dompe,
ClinChoice, Ibsa, GCP Service,
Evotec, Bracco, Italfarmaco,
Grunenthal, JSB, FIDIA*

If you are Italian and TMF is part of your job, join the Community! Write to donatella.ballerini@veeva.com or contact me on LinkedIn



Italian
TMF
COMMUNITY
CONNECT • SHARE • EVOLVE

Japan Update

1. JP community's internal F2F workshop finished on 10 June.

- Key topics covered
 - EU interchange feedback
 - TMF reference model analysis
 - ICH-E6(R3) vs TMF Management



We talked a lot,
as usual!

2. JP community site reps members including Yuto did presentation about TMF/ISF RM in JP conference for sites in Sep, we've got 160+ audiences in the room.

3. Yuto and Mai will present JP TMF community outputs in US interchange.



CDISC TMF Change Control Board

Q3 GENERAL MEETING | 2026

What is the TMF CDISC Change Control Board (CCB)?

A cross-functional, multi-stakeholder committee that governs changes to the CDISC TMF Standard Model.



Governing Body

STEWARD | REVIEW | APPROVE



Oversight

Provide governance for the CDISC TMF Standard Model.



Review & Approve

Evaluate and decide on requested changes.



Oversee Zone Teams

Provide guidance and oversight of Zone Teams and their deliverables.



Community Volunteers

PEOPLE | COLLABORATION | IMPACT



13 Members

Representing a broad range of expertise across the TMF community.



Monthly Meetings

Regular cadence to review, discuss and decide on change requests.



Management & Oversight

Coordinate and oversee Zone Teams to ensure alignment and progress.



Upcoming Election

3 additional members



Enabling a consistent, transparent, and community-driven process
to evolve the TMF Standard Model for greater global impact.

Change Control Board: A Brief History

From community-led change control to formal standards governance.



The role has evolved — the purpose remains the same:

protect the integrity of the TMF Standard while enabling thoughtful change.

CCB Purpose

Maintain the integrity. Enable continued progress.



The main responsibility of the CCB is to ensure the **overall integrity** of the *CDISC TMF Standard Model*.

The CCB ensures that changes:



Are Reviewed and Approved

Evaluate change requests for impact, feasibility and alignment.



Maintain Alignment

Ensure consistency with the Standard Model, principles and scope.



Enable Implementation

Oversee coordination with Zone Teams and support adoption planning.



Support Continuous Improvement

Facilitate an open, transparent process that enables the TMF Standard to evolve.



Upon release of V1 of the CDISC TMF Standard Model in **April 2027**, all subsequent changes will go through the CCB for review, approval and implementation before they are adopted and formally released in new versions of the CDISC TMF Standard Model in alignment with the **TMF Implementation Guide**.

Change Control Board (CCB)

Committee Structure & Members



Change Control Board (CCB)

13 Members



Kate Santoro

Chair

Sponsor



We are looking for 3 additional members

Seeking Site, CRO and/or Sponsor representation to ensure diverse perspectives and broad industry input.

Sponsor

Site & CRO

Open Position

CCB Responsibilities

Driving a transparent, consistent and community-led change process.



Triage Changes

Review and assess change requests.



Oversee Zone Teams

Provide oversight and guidance.



Define Updates

Set scope and prioritization for approved changes.



Release Model Versions

Approve inclusion of changes in new versions.



Model Deliverables

Ensure related deliverables are updated and released.



Industry Alignment

Promote alignment with regulatory expectations and industry needs.



Enable thoughtful change. Maintain integrity. Drive global impact.

The CCB ensures the CDISC TMF Standard Model evolves in a controlled, transparent and collaborative manner.

CCB: Roles and Responsibilities

Defined ownership to support effective governance and delivery.



CCB Chair

- Elected by CCB members for a 2-year term.
- Leads CCB governance and meetings; ensures alignment with the TMF Steering Committee.



CCB Administrator

- Manages meeting logistics, minutes and action tracking.
- Maintains CCB documentation and tools (e.g., JIRA, Confluence/Wiki).



Zone Representatives

- Attend Zone Team meetings as the CCB liaison.
- Escalate key issues and provide input on change proposals.



TMF Standard Model Manager

- Oversees the physical model, including versioning and governance.
- Ensures consistency across components (Record Groups, Record Types, metadata, etc.).



Initiatives Manager

- Manages metadata changes to the model.
- Works with impacted Working Groups and tracks change requests to resolution.



Release Notes / Implementation Guide Owner

- Maintains release notes for all model versions.
- Develops and maintains the Implementation Guide.

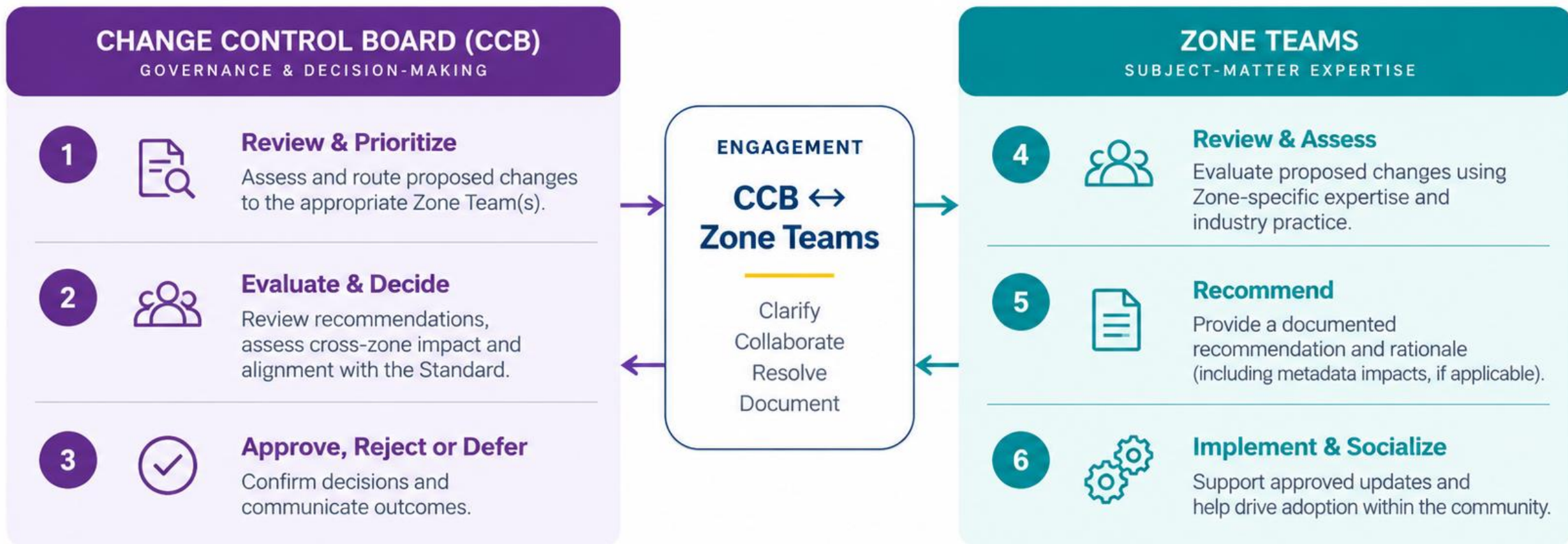


Shared Goal

Enable thoughtful change. Maintain integrity. Drive global impact.

CCB & Zone Team Engagement

Working together to evaluate, decide and deliver changes to the TMF Standard Model.



Shared Outcome

Well-informed, transparent change decisions that keep the TMF Standard Model accurate, consistent and fit for purpose.

V1 Implementation Guide: Purpose

Bridging the Standard and real-world application

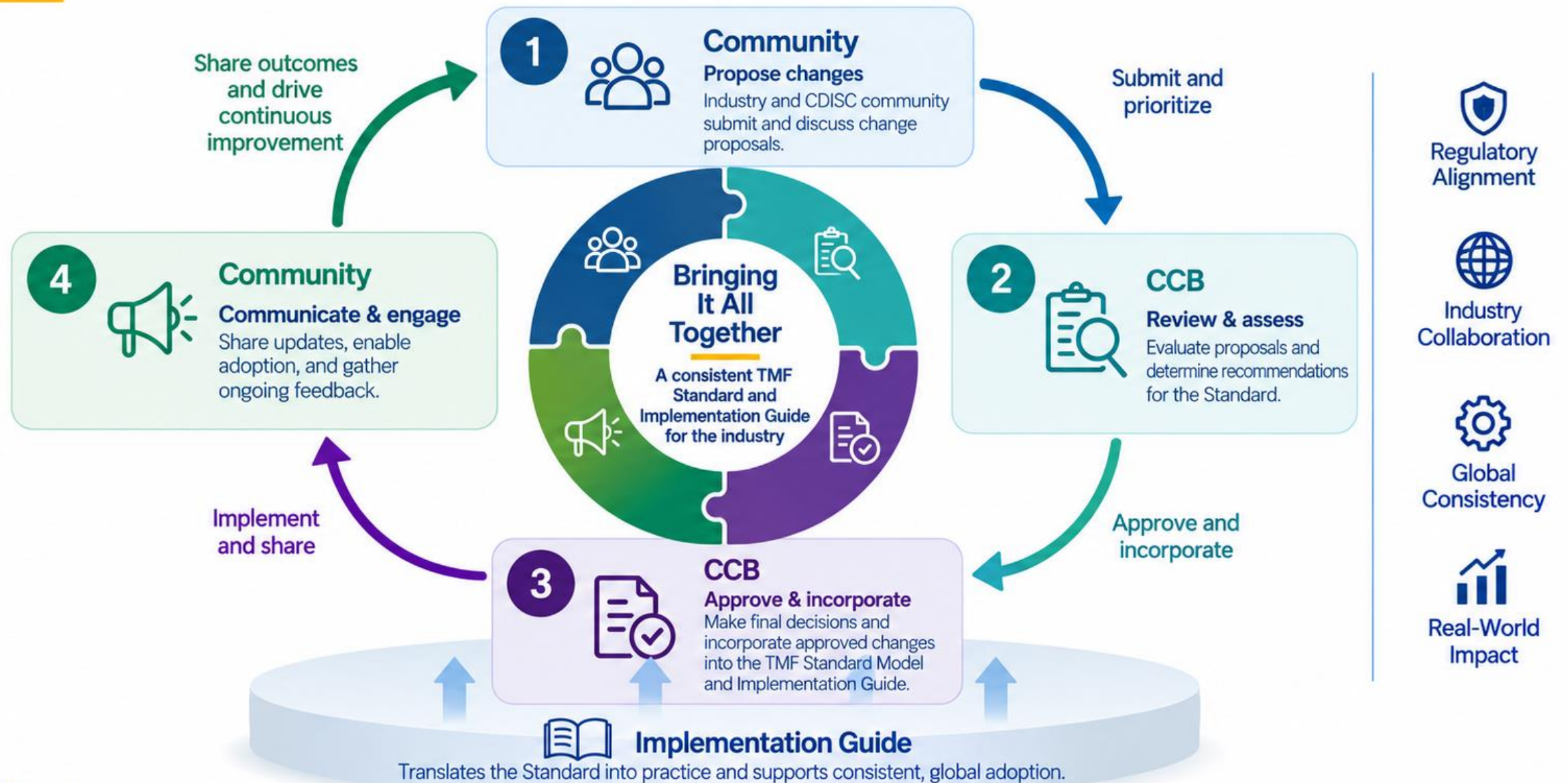
The **Implementation Guide** explains how the TMF Standard Model V1 is intended to be understood and applied by organizations and technology providers. It provides context for the structure of the Standard, key concepts and design principles, and practical guidance for consistent implementation while preserving flexibility across different organizational processes and technology environments.



*From Standard to Practice.
A Stronger, More Connected TMF.*

CCB & TMF Community Collaboration

From ideas to impact. Bringing it all together.



CCB Elections

Get Involved. Help Shape What's Next.

SAME MISSION. NEW LEADERSHIP. A STRONGER TOMORROW.

WHAT'S NEXT

CCB Elections



October Elections

New members and Chair elected.



3 New Members

Bring your perspective.



Interested?

Submit a short bio.

Building
on Our
Momentum

UPCOMING

Future CCB



Established Leadership

13 dedicated members.



Driving Progress

Advancing the TMF Standard Model together.



Lasting Impact

A strong foundation for what's next.



Interested in joining the CCB?

More details coming soon.

CCB Elections

A transparent process to maintain strong CCB leadership and engagement.

1



CCB Member Requirements

- At least 10 years of industry experience
- Strong working knowledge of TMF Zones



2



Submit for Candidacy

- Community members submit a brief bio and statement of interest
- Details and submission instructions will be shared in October



3



Elections

- Elections held in October
- New members and Chair announced following the election



Strong leadership. Broad engagement. Continued progress.

A transparent election process that supports the ongoing evolution of the TMF Standard Model.

CCB Elections Timeline & How to Submit for Candidacy

October is election month.



How to Submit for Candidacy



1 Prepare

Draft a brief bio and statement of interest.



2 Submit

Send your bio and statement by the deadline (per Call for Candidates).



3 Confirm

You will receive confirmation of receipt and eligibility review.

Key Points



Open to current CCB members only



3 new members elected each cycle



Elections held in October



Full details, eligibility criteria and submission instructions provided in the Call for Candidates.



Your participation strengthens the TMF community.

Consider putting your name forward!

Thank You!

Interested in making an impact?

See us at CDISC for more information.



Learn More

About CCB roles
and opportunities



Ask Questions

Meet the team
at CDISC



Consider Your Candidacy

We look forward
to seeing you!



Different Perspectives. Greater Impact.

Together, we advance the TMF Standard Model.

cdisc
INTERCHANGE

OCTOBER 5 – 7, 2026
DENVER, CO

*We look forward
to seeing you as a
CCB candidate!*



V1 Standard Update

Donna Dorozinsky



We Set Out to Build a Standard for the Next Era of the TMF



Two Goals

1. Establish a framework for controlling the evidence of compliance with ICH E6(R3)
2. Build a Standard designed for the digital era

From Records Management to Evidence Control

Records Management —————> Evidence Control



- **Then:** What **documents** should be in the TMF?
- **Now:** What **evidence** do we need to demonstrate what happened, what was evaluated, what was decided, and that the study was appropriately controlled?

The record is the evidence – not necessarily a document



The challenge was not simply adding or removing Artifacts and Sub-artifacts.

We had to establish consistent principles for:

- ✓ What is a Record Type?
- ✓ When are two records actually the same evidence?
- ✓ When does different context require metadata rather than another Record Type?
- ✓ How do we represent evidence across modern systems and study models?
- ✓ How do we create something usable across organizations—not just one way of working?

V1 Has Been Built by Our Community

200+ contributors. Different perspectives. One Standard.

Aaron Grant
Abbey Diaz
Adeola Latona
Alan Cohen
Albert Cheng
Amanda Zenere
Amélie Rivet
Amruta Patil
Aneta Kocourkova
Angela Moore
Angela Porter Badcock
Ann Ackley-Fifer
Anne-Noëlle Charles
April Funicella
April Mattison-Wolfe
Aryn Knight
Avani Amin
Ayesha Khan
Bandana Sharma Chapagain
Beata Glogowska
Beatriz Sevilla-Jensen
Becky Dion
Bhagawathy Sarma
Bhavleen Arora
Birgit Bentele
Bradley Russell
Brian Lyons
Bridget Patrick
Brittany Walker
C. Lewiski

Carey Smoak
Carla Calitri
Carol Radwanski
Caroline Bay
Caroline Tientcheu Mbieleu
Casey Jackson
Cat Hall
Catherine Molin
Celia Carter
Chad Scribner
Chandni Patel
Chantelle Watts
Charles Fortier
Charles Pattrell
Chasity M Kinder
Christina Connors
Christina Mantzioros
Christine Ignacio
Christine Morris
Christine Pierce
Clare Whitehouse
Courtney Marissa Igne
CShea
Curran Murphy
Dagmar Schadler
David Ives
Dawn Niccum
Deb Oriez
Deborah Castellana
Deepthi Annakula

Denise Moak
Diana Cieraad
Dietmar Rescheleit
Dipak Chaudhari
Donna Dorozinsky
Elaine Shikaze
Eleanor Hewes
Elisa Young
Elvin Thalund
Erin Gainey
Eva Matheu Nijssen
Evgenia Delyagina
Fatoumata Camara
Gabriela Iordache
Gabriele Theiner-Loskarn
Gagandeep Kaur
German Diaz
Gillian Gittens
Giusi Aiavolasit
Heather Scuderi
Hema Ahuja
Hendrik Bödige
Hugh O'Neill
Imy Chiu
Isabella Smith
Isabelle Martella
Joanne Bilmazes
Jackie Morrill
Jake McDonald
Jamie Toth

Janina Babiarz
Jason Weinstein
Jay Rehm
Jay Smith
Jeanine Hembd
Jenn Stamper
Jennifer Arters
Jennifer Christofferson
Jennifer Escobar
Jennifer Flowers
Jennifer Peacock
Jennifer Pisaniello
Jessica Hogan
Jessica Vicari
Jim Horstmann
Jo Oliver
Joanne Malia
Joe Coffie
John Saviski
Joshua Conrad
Kamala Novak
K. Bosman Smith
K. Kell
Karen Hue
Karen Roy
Karin Schneider
Karine Renard
Kate Santoro
Katelyn Nugent
Katelyn Richmond

V1 Has Been Built by Our Community

200+ contributors. Different perspectives. One Standard.

Katherine Kearney
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Kathleen P. Clark
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Katie Sousa
Kelley Robinson
Kelly Rooney
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Kristin Rittmann
LaTanya Andrews
Laura Wiggins
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L. A. Green
L. Naranjo
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Monika Thielen
Nakema Glanton
Neharika Ramani
Nejat P.
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Nick Hargaden
Nicki Ferraro
Nicki Tiekan
Niki Phan
Nikita Helen Lewis
Nirmal (Nimz) Chana
Nisi Nazim
Olga Radyushkina
P. B. Martin
Padma Channa

Paige Mucha
Pallavi Tadimeti
Pam Dellea-Giltner
Paul Carter
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Pavan Kumar Dronamraju
Pawel Tadeusz Podsiadlo
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Princess Barcelona-Martin
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Ramya Iyer
Rashad Lewis
Rebecca Halbur
Rebecca Reel
Remon Hollander
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Ricky Lakhani
Rob Jones
Robert Bokuniewicz
S. Dodd
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S. Parsa
S. Yadlapalli
Sandra Cleveland
Sarah Hitching
Sarah Ruiz
Sarah Wilmschen-Tober
Sean Mahoney
Shounak Damle

Silvinia Poindexter
Soraya Halligan
Steph Viscomi
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Surendra Manuri
Susan Geers-Meiners
Susan Pietropaolo
Susie Beasley
Suzanne Turner
Sydney Stamper
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T. Pathareddy
Tara Morris
Tawny Bowen
Timothy Galvin
Tingting (Jackie) Fu
Tiziana Valentini
Todd Tyner
Tonia Huggins
Vanessa Gonzalez Vivero
Vanessa Tarraga
Vidya Jayapalan
Vinay Bhanu
Vipul Bamanya
Vittoria Sparacio
Vladislav Nikitin
Wshshan
Y. Timmons
Yen Phan
Yixuan (Iris) Wang
Zameer Abida



The Structure is Taking Shape

- July 2026: Vendors received an early draft of Zones, Record Groups, Record Types
- Mid-October 2026 – Community Review of the TMF Structure
- End October – Community Review of Implementation Guide
- Up Next to complete by end of year
 - Finalizing the metadata
 - CDISC Definitions
 - Public review of definitions with metadata included
- April, 2027 Release of TMF Standard Model V1 with Implementation Guide

October Is the Structural Draft — Not the Finished Standard



You WILL see:

Zones → Record Groups → Record Types → Purpose/Descriptions → Study/Country/Site → Subsets

You will NOT yet see:

Fully defined metadata & CDISC Definitions



A Standard Built for What Comes Next

**Common
language**

**Consistent
structure**

**Evidence-
focused**

**Digital-
ready**

**Designed to
evolve**

**We are not simply updating the TMF Reference Model.
We are building the foundation for how our industry controls study
evidence in a digital era.**



Implementation Guide

Liz Farrell



TMF SM Implementation Guide

- **What the Implementation Guide is:**

- Across CDISC, an implementation guide directs the organization, structure, and format of the standard and offers standard solutions to implementation issues

A technical companion

- To the Standard Model itself

The rules and principles

- For how the standard is intended to be used

The rationale

- Behind design decisions, and how the model should be interpreted

Baseline rules

- Supporting consistent implementation across the community



TMF SM Implementation Guide

- **Where we are**

- Working group is in place
- First draft of the Implementation Guide is under review
- Revisions are in progress

- **What comes next**

- TMF SM v1 to be released for public review
- Implementation Guide to be released shortly after



SM V1 Q&A





Questions?





Thank You!

