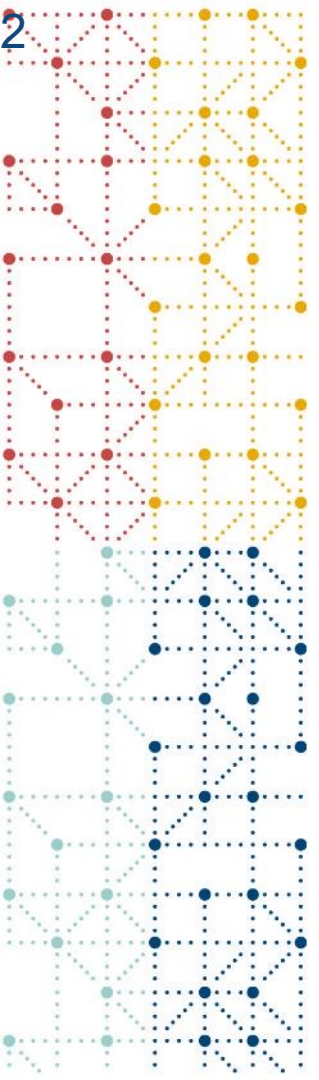




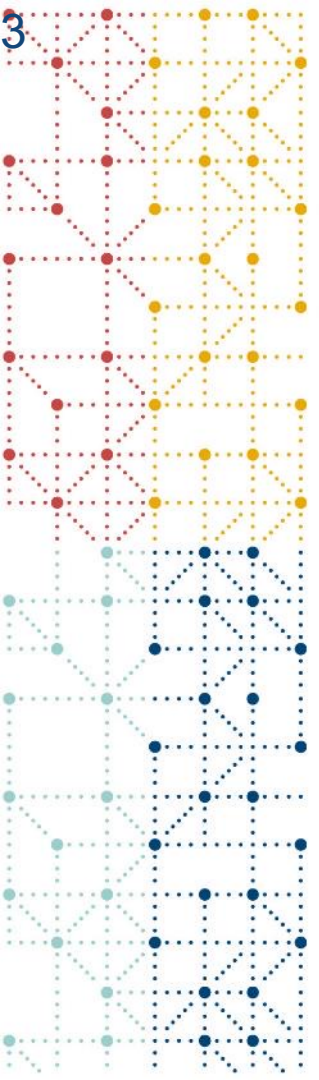
# The TMF Reference Model Group and CDISC Affiliation: What's Next?





## Today's Agenda

1. Housekeeping
2. Feature Presentation
3. Upcoming Learning Opportunities & Events



# Housekeeping

# Housekeeping



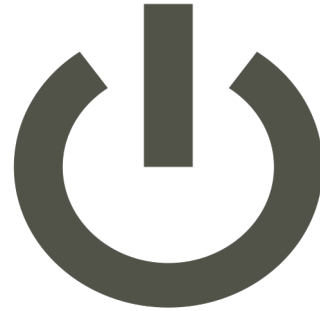
You will remain on **mute**

# 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



A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website



# The TMF Reference Model Group and CDISC Affiliation: What's Next?

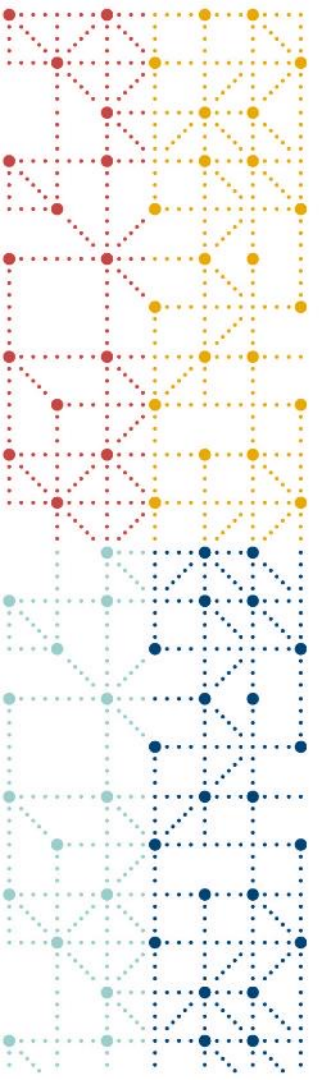
**cdisc**



# The TMF Reference Model Group and CDISC Affiliation: What's Next?

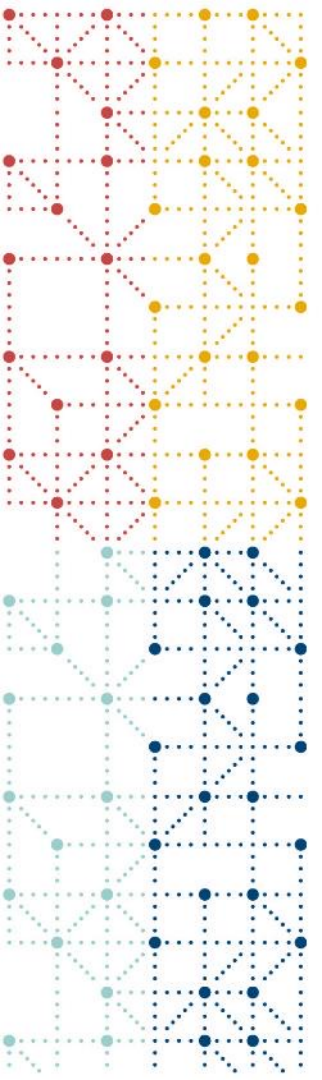


June 27<sup>th</sup>, 2022



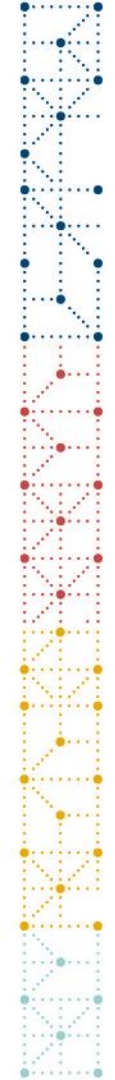
## Agenda

1. CDISC Intro – Dave Evans
2. History of the TMF RM – Karen Roy
3. What is a Standard – Bess LeRoy
4. TMF RM Standard – Joanne Malia
5. Exchange Mechanism – Paul Fenton
6. Implementation –Kathie Clark, Mary Emanoil
7. Volunteering – Amy Palmer
8. The Future– Dave Evans



# CDISC Background

Dave Evans - President & CEO, CDISC



***Mission:*** To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- Global Non-profit Consensus-based Standards Development Organization
- 20 Years of Regulatory Clinical Data Standards Development and Implementation
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 545+ Member Organizations
- Widely Adopted and Freely Available Clinical Research Data Standards
- Mature Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Involved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry
- Addition of TMF Reference Model to CDISC Family of Standards



# CDISC – a look into this year

- **Standards Initiatives from Regulatory Agencies**
- **Ongoing Therapeutic Area Projects**
- **Ongoing Activities and Projects on RWD/RWE & Data Sharing**
- **Standards Implementation for Registries and Academic Use**
- **New Industry Projects are on schedule for delivery**
- **Continue to build upon CDISC Library and Biomedical Concepts**
- **Continue to add content to eCRF Portal and QRS Library**
- **Collaboration with other SDOs on emerging Industry Initiatives**
- **Expansion into additional areas of Clinical Information Standards**

# Strategic Benefits for the Clinical Research Community

- Expansion of scope of clinical information standards to trial design, trial administration, clinical operations, regulatory documentation
- CDISC serves as the hub for cross-industry standards initiatives and the TMF RM will be part of that direction
- Strategically, there is a natural progression to the development and governance of standards, so why reinvent the wheel when so much work has already been done
- Evolution organizationally to embrace governance of clinical research information standards, not just the clinical data from where it originated.
- Broadening the harmonization of clinical research information standardization.



# **Trial Master File Reference Model**

## **History of the TMF Reference Model**

Karen Roy

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

SVP of Clinical Marketing at Phlexglobal

## What *is* the Trial Master File?

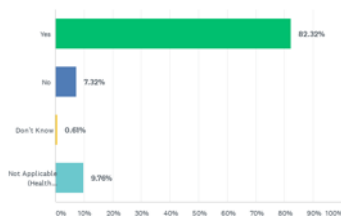
The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated [...]. It shall be readily available, and directly accessible upon request, to the Member States.

[EU Regulation 536/2014]

## What *is* the Trial Master File Reference Model?

A Standardised structure, contents and naming of these Essential documents

Q48 Is your organization using the TMF Reference Model?



Source: Annual TMF Ref Model Survey 2019  
From 247 Respondents

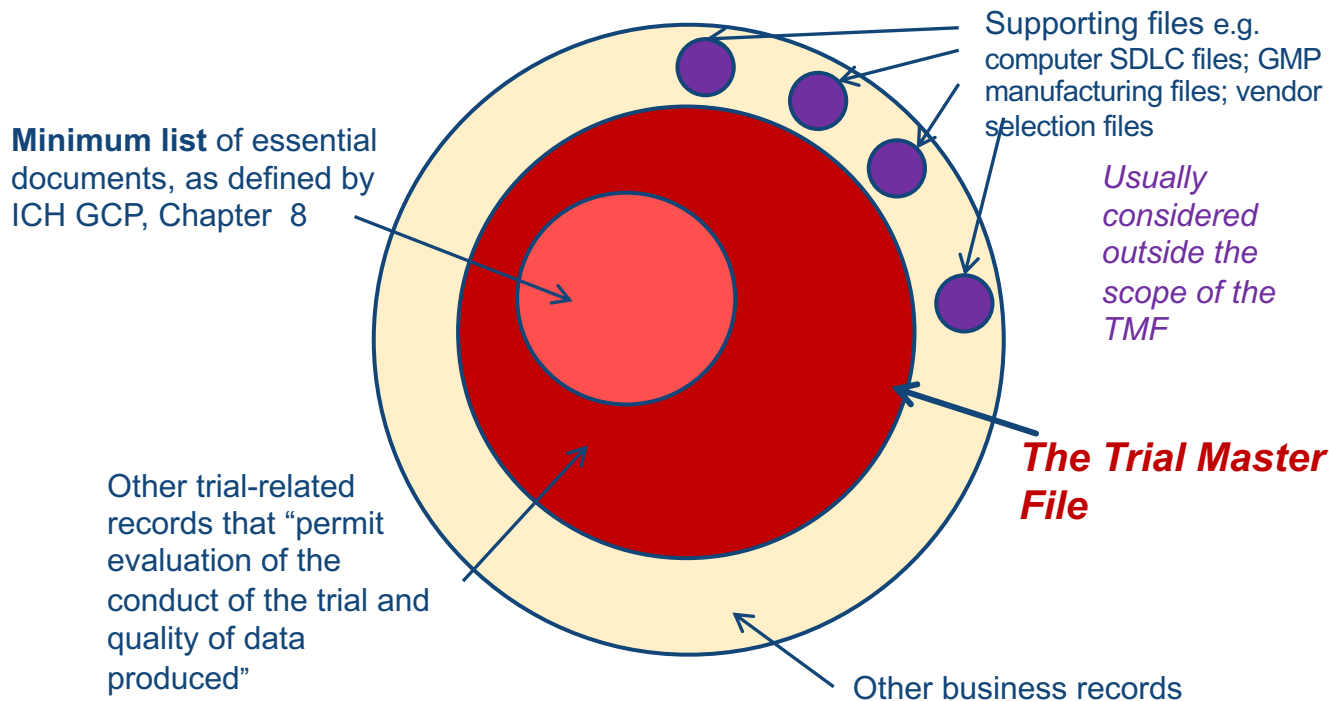




# Why a TMF Reference Model?

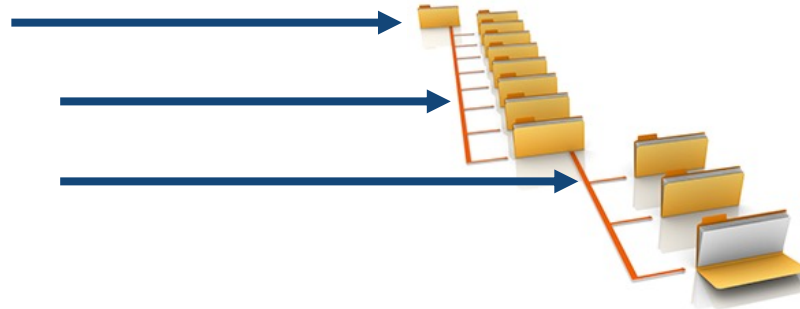
- ICH GCP Section 8.2 – 8.4
- “The **minimum** list of essential documents that has been developed.....”
- ICH GCP did **NOT** provide a comprehensive contents list for the TMF
  - Examples of missing documentation:
    - Electronic systems
    - Data management and statistical methodology
    - Safety monitoring
- Everyone had their own customised structure – Sponsors, CROs and third parties

# Defining the TMF Reference Model



# Structure and Content of the Model

- Data held in a simple Excel spreadsheet
  - Easy for non-technical people to use!
- Hierarchical structure
  - 11 Zones
  - 48 Sections
  - 249 Artifacts



***607 Sub-Artifacts***

# Development of the TMF Reference Model

DIA DEVELOP  
INNOVATE  
ADVANCE

Document & Records Management  
Community

Multiple releases including

Regulator feedback,  
Investigator Site Files,  
Devices, Process based  
metadata. Workgroups  
established

Separated from DIA



2014 to 2021



cdisc

Forward to Compliance

2009 to 2010

Initial meeting in 2009  
with first version being  
released in 2010

2011 to 2013



Formalization with a  
Steering Committee.  
**Release of the  
Exchange Mechanism  
Specification** and  
Version 3

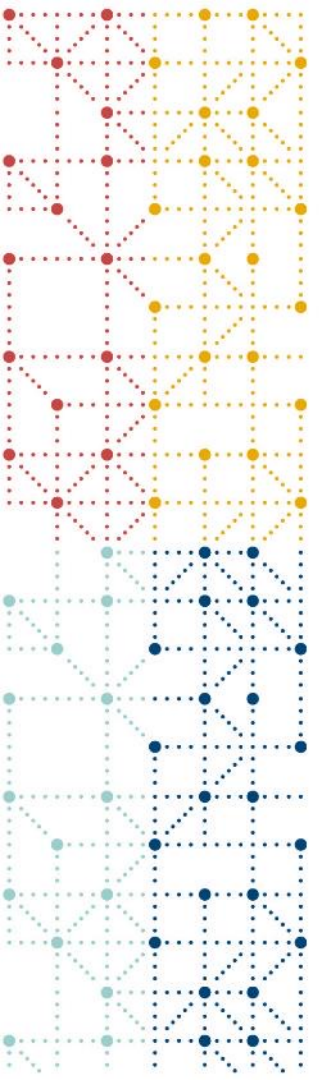
2022 onwards



cdisc

# Strategy Pillars for the Future





# What is a Standard

Bess LeRoy

Head of Standards Development

CDISC

# What is a Standard?

## Webster's Dictionary

- “**something established by authority**, custom, or general consent as a model or example”
- “the type, model, or example commonly or **generally accepted** or adhered to; criterion set for usages or practices: moral *standards*”
- “**a level of excellence**, attainment, etc. regarded as a measure of adequacy”, e.g., the *standard* of care

# Flavors of Standards in Clinical Research

Clinical Concepts and Tools

Data Exchange

Electronic Data

Terminology

Electronic Data Metadata

Templates

Content / Documents / Artifacts

SOPs / Processes





# Consensus Based Standards

## Consensus

- Consensus is defined as general agreement but not necessarily unanimity

## Openness

- Processes are open and transparent
- Interested parties are provided meaningful opportunities to participate in standards development



# Consensus Based Standards

## Balance

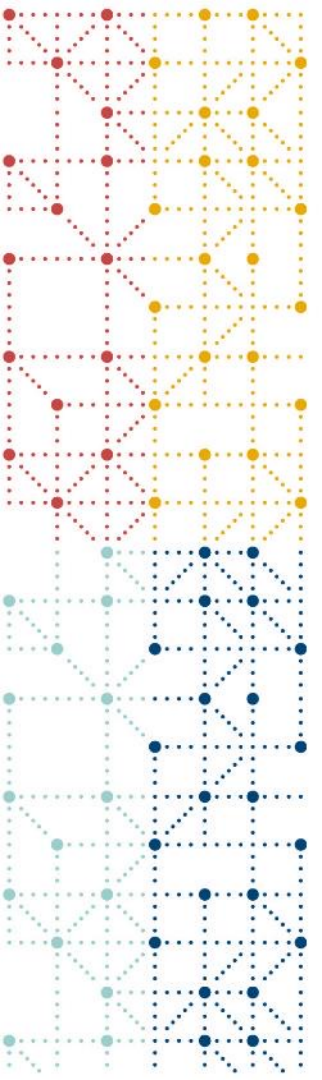
- There should be meaningful involvement from a broad range of parties, with no single interest dominating the decision-making

## Due Process

- Due process shall include documented and publicly available policies and procedures

## Appeals Process

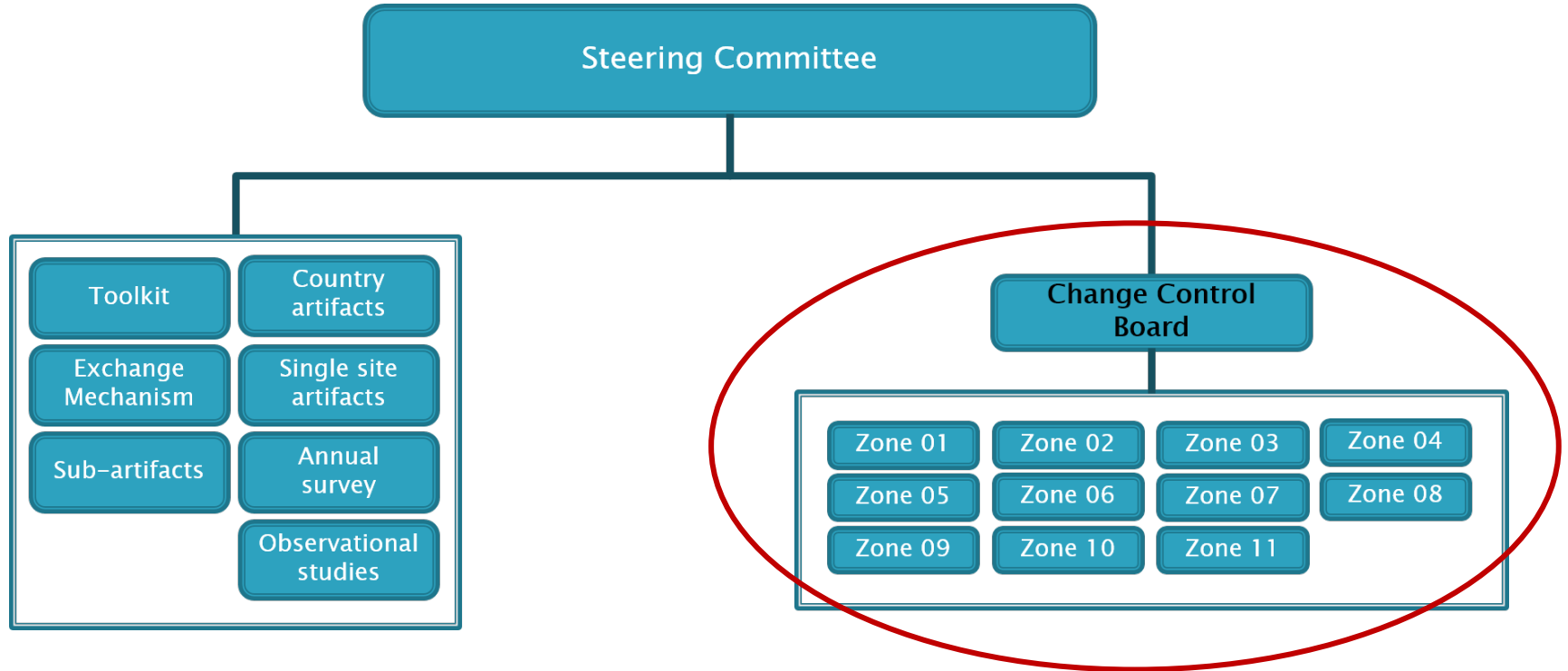
- An appeals process shall be available for the impartial handling of procedural appeals



# Managing the TMF Reference Model

Joanne Malia - Director, Clinical Documentation Management,  
Regeneron Pharmaceuticals, Inc.; Member, TMF Reference Model  
Steering Committee

# TMF Reference Model Change Overview/Framework



# Who Controls the Versions?

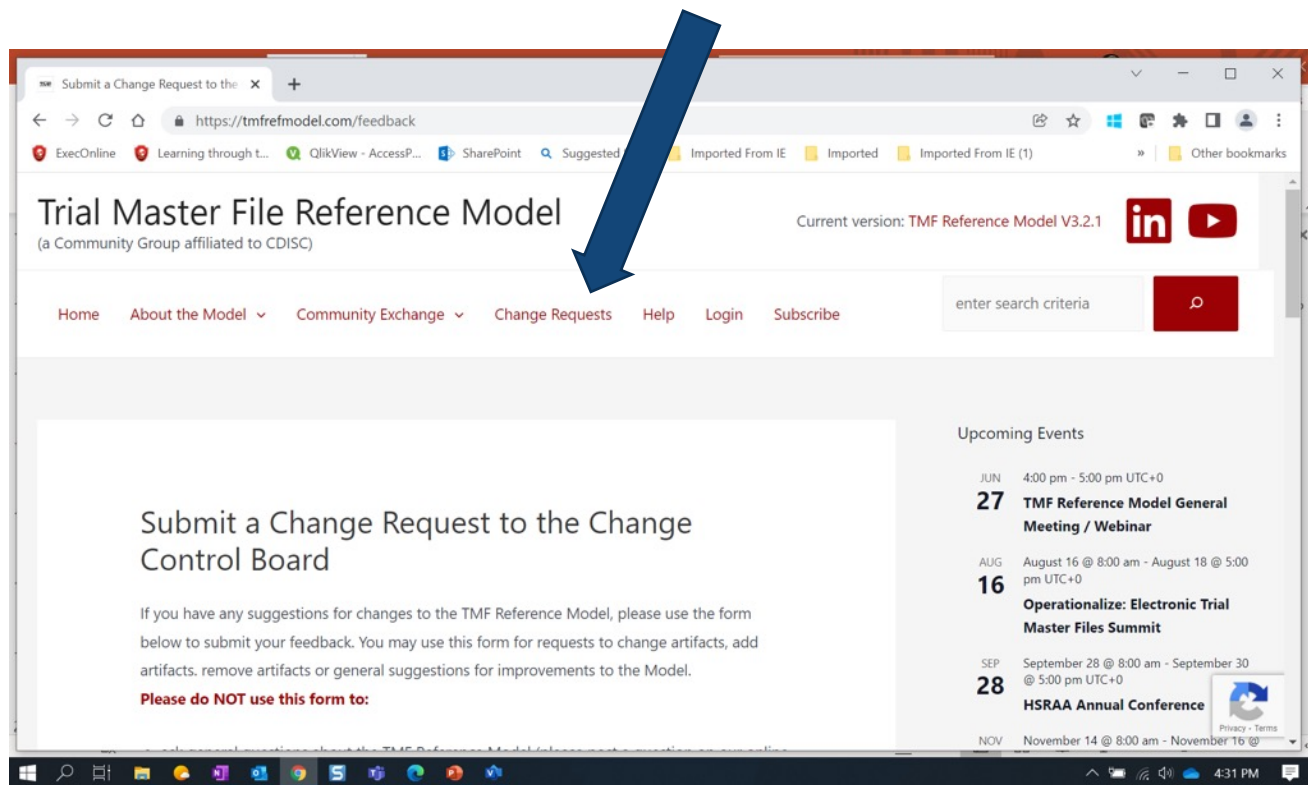
- **Change Control Board Structure**

- Kelley Robinson, Sention Therapeutics: Chair
- Leila Ponce, Seagen Pharmaceuticals: Deputy Chair and Zone Team Liaison

- **Deliverables**

- Meeting monthly
- Change Control Procedure, RACI and CR Tracker
- Reviewing and categorising all current change requests
- Triaging all change requests to Zone Teams
- Delivery of new versions in concert with Steering Committee

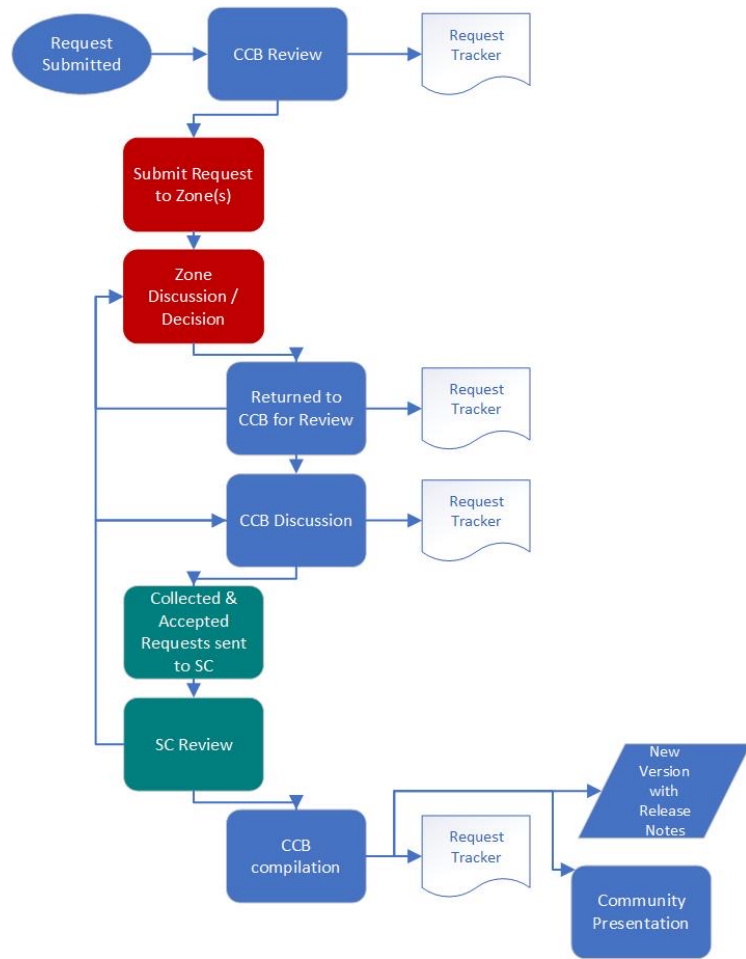
# To Request a Change



The screenshot shows a web browser window with the URL <https://tmfrefmodel.com/feedback>. The page title is "Trial Master File Reference Model (a Community Group affiliated to CDISC)". The current version is "TMF Reference Model V3.2.1". The navigation menu includes "Home", "About the Model", "Community Exchange", "Change Requests", "Help", "Login", and "Subscribe". A blue arrow points to the "Change Requests" link. Below the navigation is a search bar with the text "enter search criteria". The main content area features a heading "Submit a Change Request to the Change Control Board" and a paragraph: "If you have any suggestions for changes to the TMF Reference Model, please use the form below to submit your feedback. You may use this form for requests to change artifacts, add artifacts. remove artifacts or general suggestions for improvements to the Model. Please do NOT use this form to:". On the right side, there is a section for "Upcoming Events" with a table of dates and event titles.

Month	Date	Event
JUN	4:00 pm - 5:00 pm UTC+0	27 TMF Reference Model General Meeting / Webinar
AUG	August 16 @ 8:00 am - August 18 @ 5:00 pm UTC+0	16 Operationalize: Electronic Trial Master Files Summit
SEP	September 28 @ 8:00 am - September 30 @ 5:00 pm UTC+0	28 HSRAA Annual Conference
NOV	November 14 @ 8:00 am - November 16 @ 8:00 am UTC+0	

# Change Request Process

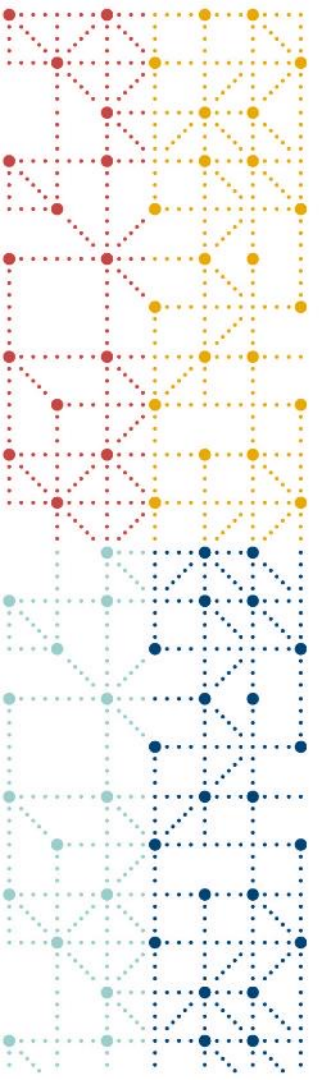


# Version Definition

- Maintenance release e.g. v3.0.1
  - e.g. minor typographic changes, clarification, sub-artifacts
- Minor release e.g. v3.1
  - Substantial change in content but no compatibility issues e.g. additional optional column (milestones)
- Major release e.g. v4.0
  - Change likely to have compatibility issues with prior version e.g. addition/removal of artifacts

Current version is  
3.2.1





# Exchange Mechanism

Paul Fenton – President and CEO, Montrium; Member, TMF Reference Model Steering Committee

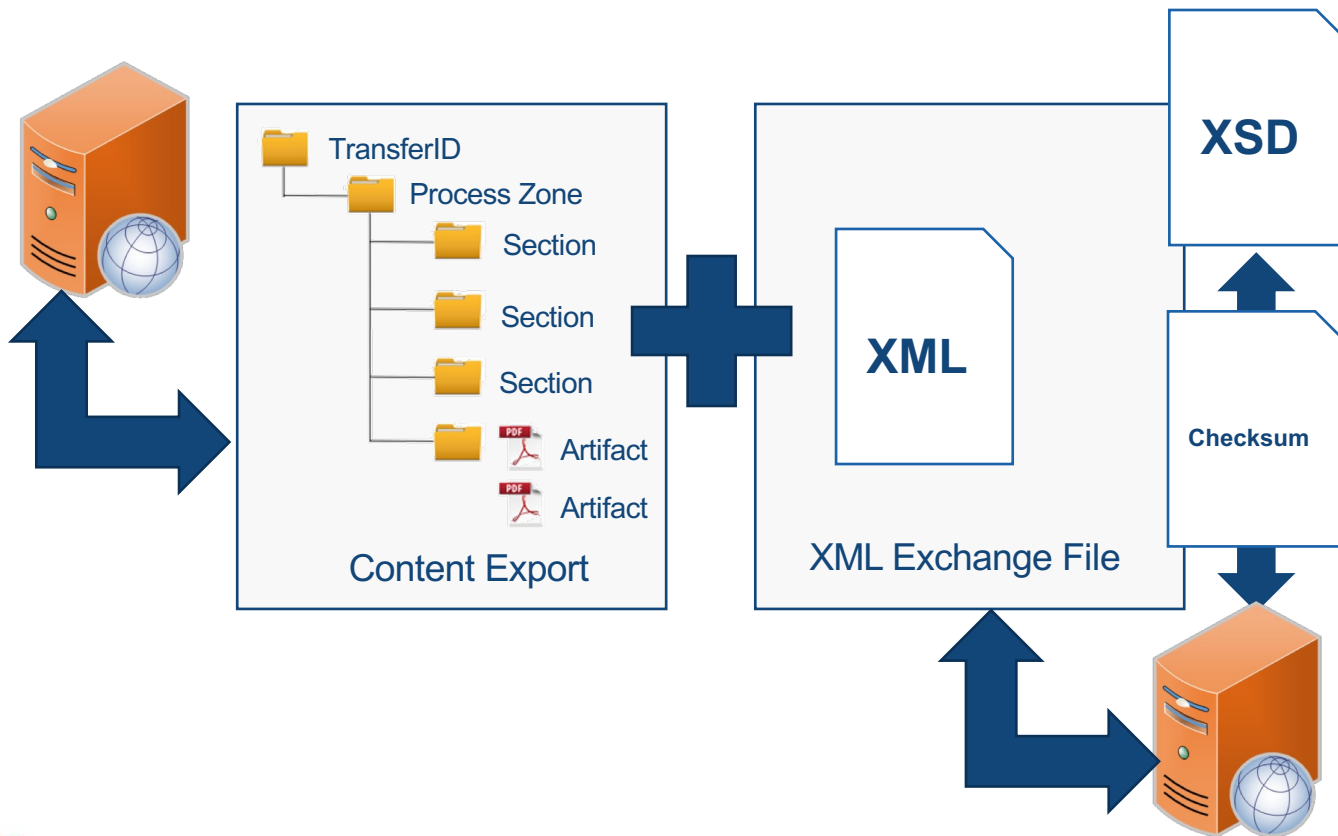
# What is the eTMF-EMS

## Electronic Trial Master File – Exchange Mechanism Standard



- An extension of the TMF RM which focuses on the transfer of content, metadata, audit trail and eSig information
- A TMF metadata standard
- A mechanism for exchanging TMF content between systems
- A method for describing TMF artifacts which is comprehensible by both humans and machines

# How it works





## How could it be used?

- **Final eTMF transfer** to sponsor from CRO for archiving
- **Interim transfer of eTMF content** to central eTMF or other trial management system
- **Migration of eTMF content** following **merger and acquisition**
- **Migration of eTMF content** following **upgrade** or change of eTMF system
- **Long term archiving** of eTMF content and associated metadata



## Where are we with EMS?

- Version 1 of the specification and schema was launched
- Some vendors have started to implement
- Uptake has not been as strong as we had hoped
- We need to re-engage with the sponsor, CRO and vendor community to drive adoption
- We need guidance on how to evolve the EMS moving forward - this is where CDISC can help!



## Implementation

Kathie Clark - Product Director, CTMS and eTMF, Ennov; Member, TMF Reference Model Steering Committee

Mary Emanoil – Head TMF & Registry Operations, Pfizer; Member, TMF Reference Model Steering Committee

# Implementation/Transition Approach

## Overview

- Core team defined for transition
  - Members from both CDISC and TMF Reference Model Steering Committee
  - Weekly meetings to define, prioritize and report on activities
- Implementation Plan created
  - Goals & Objectives - Short Term and Long Term
  - Governance
  - TMF Reference Model Maintenance & Rollover
  - Sub-teams
  - Communications

## Short Term Goals

- Maintain forward momentum of TMF activities without disruption
- Develop standards governance and formalization plan for TMF under CDISC
- Develop TMF Marketing and Communication Plan
- Develop membership framework for TMF in CDISC
- Load all TMF Models into CDISC Library



# CDISC Implementation Areas

- Membership – Karen Roy, Sheila Leaman, Amy Palmer
- Communications – Kathie Clark, Rhonda Facile
- Events – Mary Emanoil, Sheila Leaman
- Standards – Joanne Malia, Peter Van Reusel, Bess LeRoy
- Technology – Paul Fenton, Sam Hume



# CDISC Implementation Progress

## Completed

- Memorandum of Understanding signed on 6-Apr-2022
- Presentation at CDISC Board Meeting on 8-Apr-2022
- [CDISC Press Release](#) 27-Apr-2022
- TMF Summit Keynote 03-May-2022

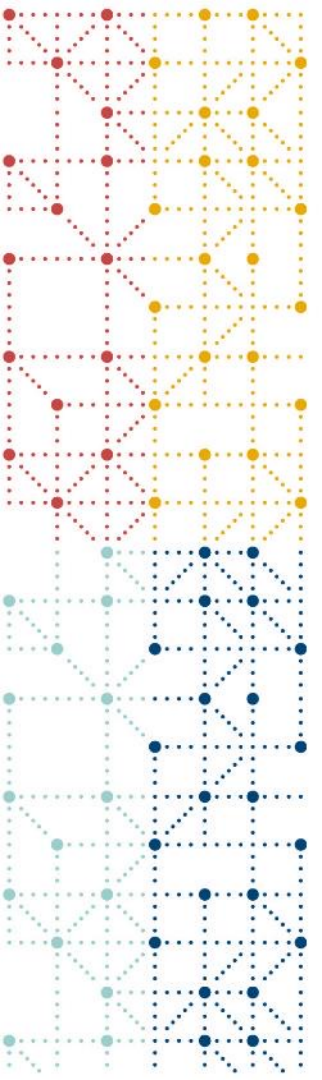
## Upcoming

- Volunteer transition
- Charter updates
- Final implementation plans for
  - Model governance
  - Technology
  - Website content
  - Events



# Coming Soon—CDISC Tools for TMF RM

- Wiki
  - Team Collaboration And Development Space
  - Repository Of Draft Standards / Mechanism For Public Review
  - Project Status Updates
- Jira
  - Issue tracking tool
  - Supports comment resolution
  - Integrates with the Wiki
- Knowledge Base and FAQs
  - Curated articles and FAQs



# Volunteering

Amy Palmer

Head of Standards Development

CDISC



# Registering as a Volunteer



Navigate  
to <https://www.cdisc.org/volunteer/tmf/form>



Review videos, CDISC policies,  
procedures, and CDISC and TMF charters



Provide contact information



Choose one or more TMF Volunteer  
Groups

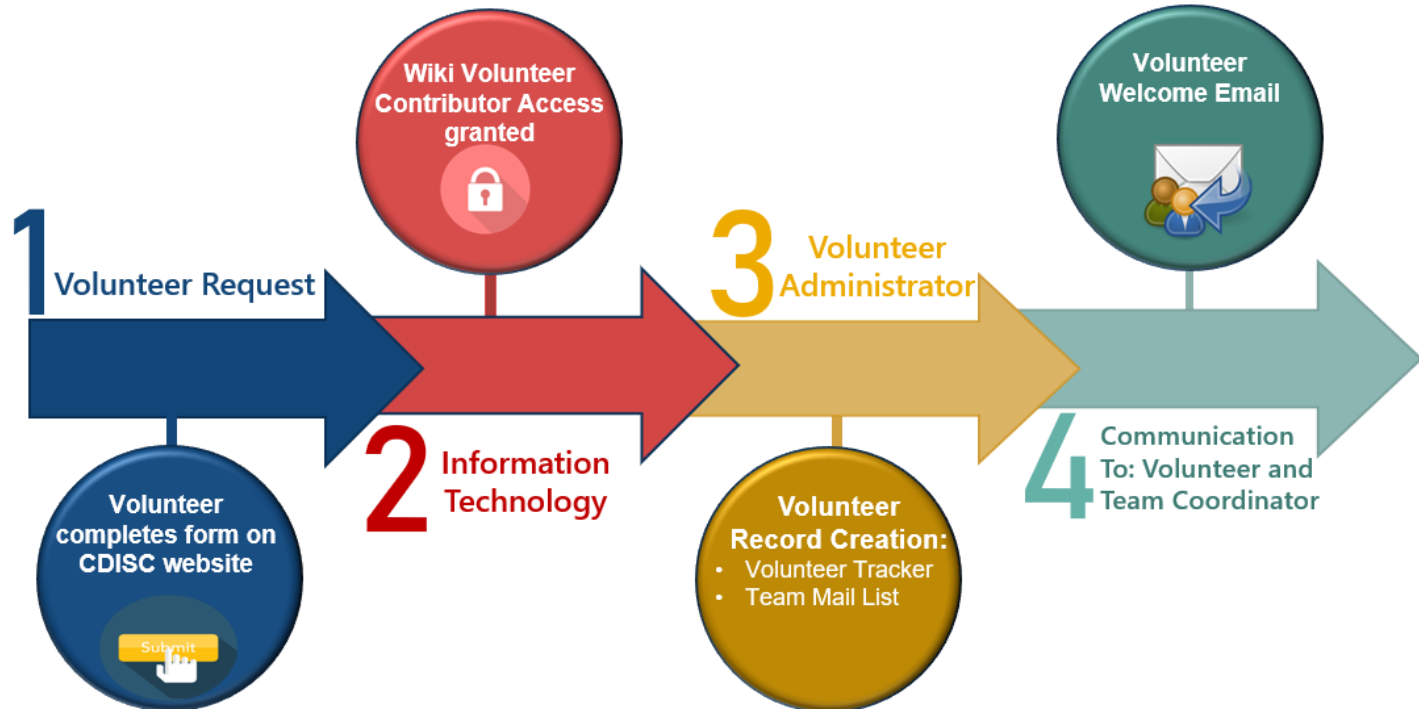


Submit form



CDISC Volunteer Coordinator will begin  
onboarding process

# Volunteer Onboarding



# CDISC MEMBERSHIP

## Become a Member!

Join nearly 500 member organizations that contribute to bringing clarity to data.

## Already a Member?

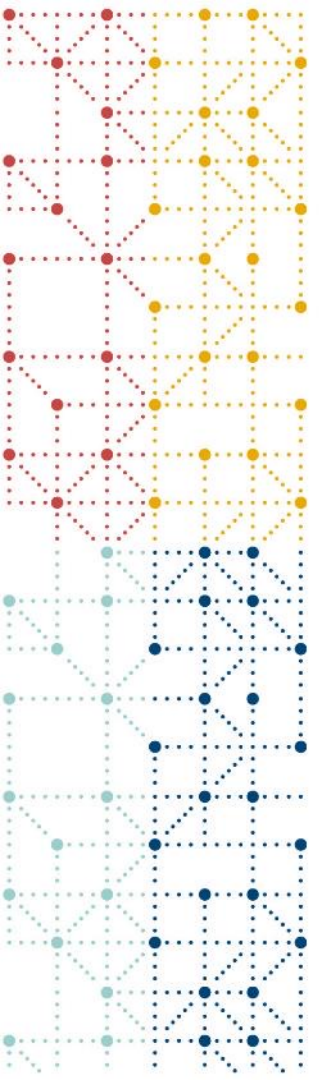
Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.

JOIN US



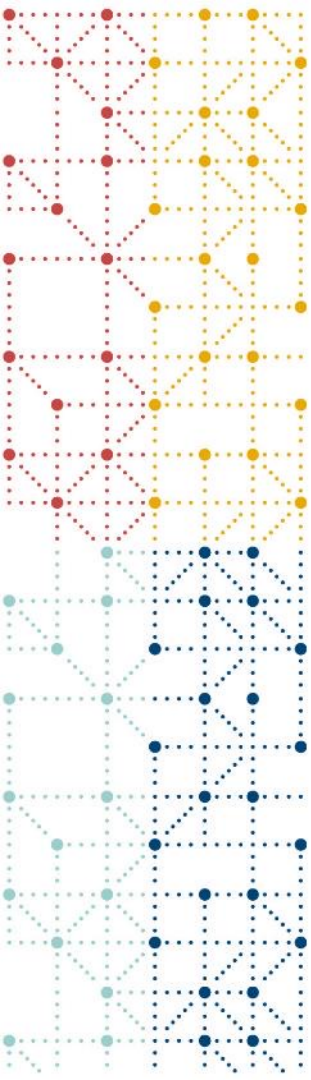
Email: [membership@cdisc.org](mailto:membership@cdisc.org)





# The Future

Dave Evans - President & CEO, CDISC



**Thank You!**

**cdisc**



# July

Asia



Virtual Training Event

*Regional discounts will appear at checkout.*

# September

US



Virtual Training Event

- Information available at: [www.cdisc.org](http://www.cdisc.org)
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)



BLEND  
ED LEARNING



VIRTUAL  
TRAINING



CLASSROOM  
TRAINING



PRIVATE  
TRAINING

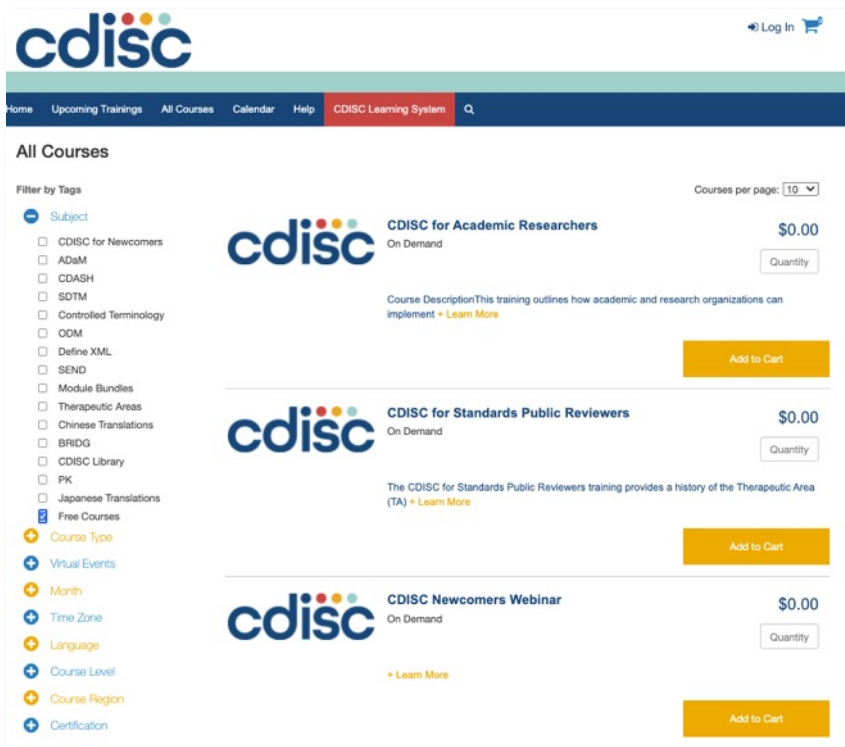


WEBINARS



WORKSHOPS

# Free CDISC Courses



The screenshot displays the CDISC Learning System interface. At the top, the CDISC logo is on the left, and a 'Log In' button with a shopping cart icon is on the right. A navigation bar below the logo contains links for 'Home', 'Upcoming Trainings', 'All Courses', 'Calendar', 'Help', and 'CDISC Learning System'. The main content area is titled 'All Courses' and features a 'Filter by Tags' section on the left with expandable categories: Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The 'Subject' category is expanded, showing a list of checkboxes for various topics like 'CDISC for Newcomers', 'ADaM', 'CDASH', 'SDTM', 'Controlled Terminology', 'ODM', 'Define XML', 'SEND', 'Module Bundles', 'Therapeutic Areas', 'Chinese Translations', 'BRIDG', 'CDISC Library', 'PK', and 'Japanese Translations'. The 'Free Courses' category is selected. The main area displays three course cards, each with the CDISC logo, title, 'On Demand' status, '\$0.00' price, a 'Quantity' input field, and an 'Add to Cart' button. The first course is 'CDISC for Academic Researchers', the second is 'CDISC for Standards Public Reviews', and the third is 'CDISC Newcomers Webinar'. Each card includes a brief description and a '+ Learn More' link.

cdisc

Log In

Home Upcoming Trainings All Courses Calendar Help CDISC Learning System

### All Courses

Filter by Tags Courses per page: 10

- Subject
  - CDISC for Newcomers
  - ADaM
  - CDASH
  - SDTM
  - Controlled Terminology
  - ODM
  - Define XML
  - SEND
  - Module Bundles
  - Therapeutic Areas
  - Chinese Translations
  - BRIDG
  - CDISC Library
  - PK
  - Japanese Translations
  - Free Courses
- Course Type
- Virtual Events
- Month
- Time Zone
- Language
- Course Level
- Course Region
- Certification

**cdisc** **CDISC for Academic Researchers** **\$0.00**  
On Demand  
Quantity  
Add to Cart  
Course Description This training outlines how academic and research organizations can implement + Learn More

**cdisc** **CDISC for Standards Public Reviews** **\$0.00**  
On Demand  
Quantity  
Add to Cart  
The CDISC for Standards Public Reviews training provides a history of the Therapeutic Area (TA) + Learn More

**cdisc** **CDISC Newcomers Webinar** **\$0.00**  
On Demand  
Quantity  
Add to Cart  
+ Learn More

[Http://learnstore.cdisc.org](http://learnstore.cdisc.org)

# Upcoming Webinars

Date	Title
28 JUN	Controlled Terminology Updates: P50 Publication / P51 Public Review
30 JUN	COSA Spotlight for Q2
7 JUL	Developing Standards for Cell and Gene Therapy Product Monitoring
12 JUL	Pediatrics User Guide Public Review
8 SEP	QRS Office Hours
15 SEP	Genomics Findings Office Hours
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public review

# 2022 CHINA INTERCHANGE

CDISC VIRTUAL CONFERENCE

29-30 JULY

2022

US

INTERCHANGE

26-27 OCTOBER | AUSTIN, TX

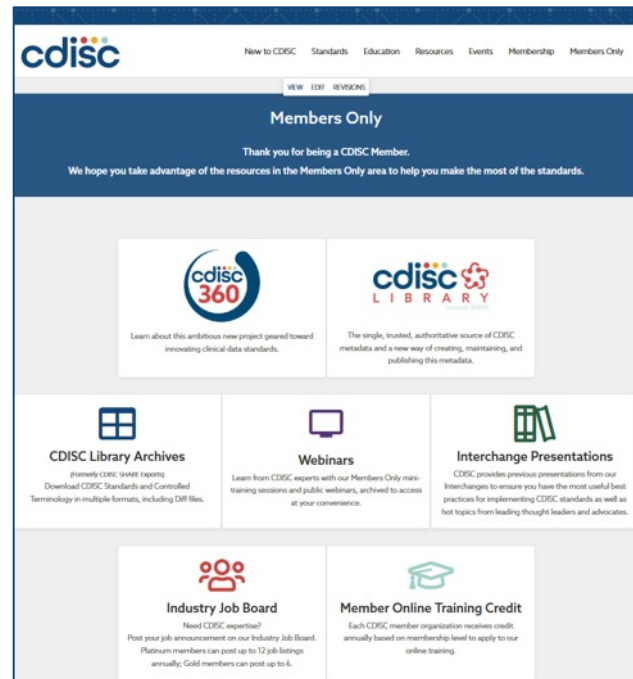


WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

# Why 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
- To gain visibility in the marketplace



The screenshot displays the CDISC website's 'Members Only' section. At the top, the CDISC logo is on the left, and navigation links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only' are on the right. Below the navigation is a 'VIEW EDIT REVISIONS' link. The main heading is 'Members Only' with a sub-heading 'Thank you for being a CDISC Member.' and a message: 'We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.'

The content is organized into several tiles:

- cdisc 360:** Learn about this ambitious new project geared toward renovating clinical data standards.
- cdisc LIBRARY:** The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing the metadata.
- CDISC Library Archives:** Browse CDISC credit reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars:** Learn from CDISC experts with our Members Only 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.
- Industry Job Board:** Need CDISC expertise? 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 MEMBERSHIP

## Become a Member!

Join nearly 500 member organizations that contribute to bringing clarity to data.

## Already a Member?

Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.



JOIN US

Email: [membership@cdisc.org](mailto:membership@cdisc.org)



# Thank you!



Contact the Events inbox:  
[events@cdisc.org](mailto:events@cdisc.org)



Contact Education inbox:  
[training@cdisc.org](mailto:training@cdisc.org)



Contact Bernard directly:  
[bklinke@cdisc.org](mailto:bklinke@cdisc.org)