



# **Trial Master File Reference Model**

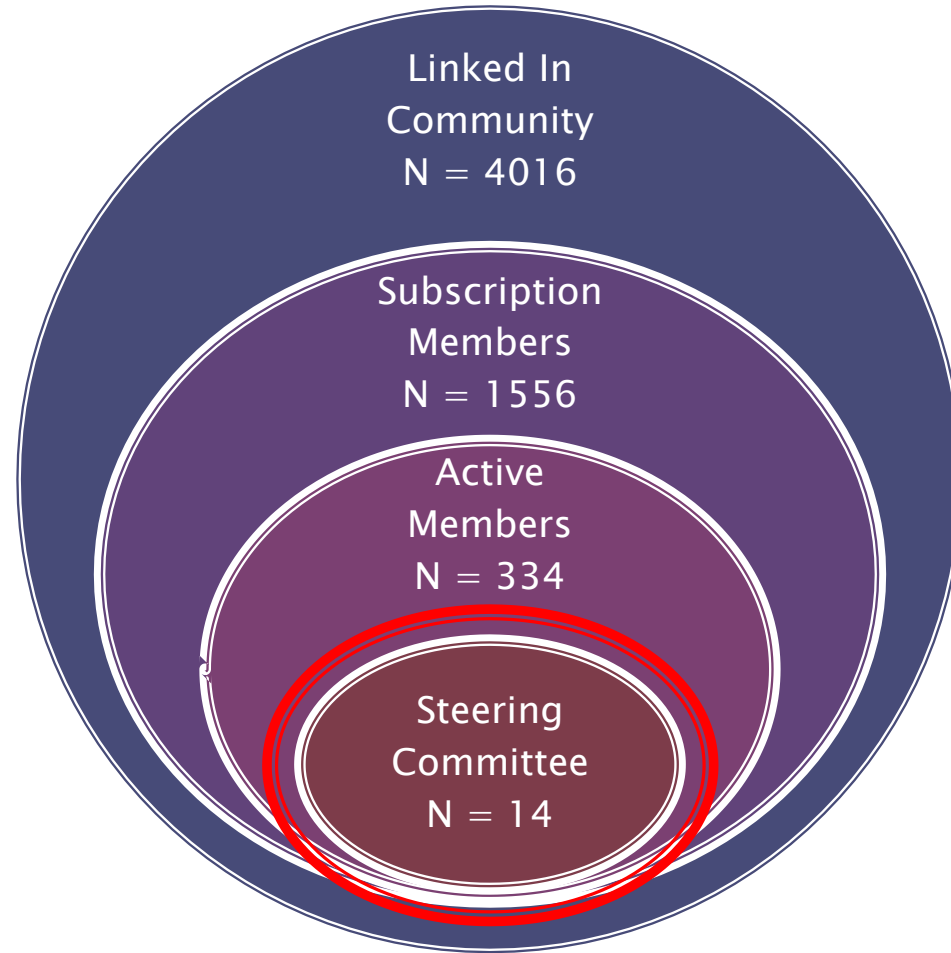
## **General Meeting**

14th March 2022

# Agenda

- ▶ TMF Reference Model Community
- ▶ New Steering Committee Member Introductions
- ▶ [www.tmfrefmodel.com](http://www.tmfrefmodel.com)
- ▶ CDISC Update
- ▶ MHRA GCP Meeting and Panel
- ▶ Upcoming TMF Meetings
- ▶ Next TMF RM Meeting

# The TMF Reference Model Community



# The TMF Reference Model Steering Committee

- ▶ Karen Roy, Phlexglobal, Chairperson of SC, Co-chair of the TMF RM
- ▶ Lisa Mulcahy, Mulcahy Consulting - Co-chair of the TMF RM
- ▶ Allison Varjavandi, Astellas, Meeting secretary
- ▶ Mary Emanoil, Pfizer
- ▶ Jamie Toth, BeiGene
- ▶ Kathy Clark, Ennov
- ▶ Todd Tullis, Veeva
- ▶ Paul Fenton, Montrium
- ▶ Donna Dorozinsky, Just in Time GCP
- ▶ Joanne Malia, Regeneron
- ▶ Gillian Gittens, TransPerfect
- ▶ JP Miceli, Advanced Clinical
- ▶ Dawn Niccum, Inseption
- ▶ Wendy Trimboli, Acadia

# Meet the New and Renewed Steering Committee



Dawn Niccum



Wendy Trimboli\*



JP Miceli



Allison Varjavandi\*



Mary Emanoil\*



Karen Roy\*





## Home

Welcome to the website of the TMF Reference Model. The TMF Reference Model was developed under the auspices of the Drug Information Association (DIA) Document and Records Management Community.

The TMF Reference Model provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature. The Model is not intended to be taken and used "off-the-shelf" but can be adapted to an electronic or paper TMF, and does not endorse, nor require, any specific technology for application. DIA members and industry members are under no obligation to adopt the TMF Reference Model.

## Latest News:

[Position Paper on CDISC Affiliation](#) February 8, 2022

### Upcoming General Meetings

MAR 3:00 pm - 4:00 pm UTC+0

**14** **TMF Reference Model General Meeting (Mar)**

[View Calendar](#)

[Click here download ics calendar link](#)

### Recent Discussion Topics

[ICH E8 8.2.12 and the use of "or".](#)

1 day, 18 hours ago

[ICH E8 8.3.3 Sponsor eTMF Requirement for](#)

[IRB Approvals for Revisions](#)

1 day, 18 hours ago

[ICH E8 8.3.3 "Where Required" Meaning](#)

1 day, 18 hours ago

### Recent Posts

[Position Paper on CDISC Affiliation](#)

[Update to Exchange Mechanism Standard Published](#)

[Exchange Mechanism Standard Survey Results are Available](#)

# Emails

1. If you click on 'unsubscribe' to emails, you won't receive **ANY** further emails from us. If you don't want to receive any more emails, consider deleting your account (login, My Account, Delete Account)
2. If your email changes (e.g. you move company), please update your email address (don't create new account!). We have **>150** email delivery failures.
  - Check your other profile details too e.g. company name, country etc
  - Why not add a photo 😊

# Subscriber info

- ▶ Login and click on **Account > My Account**
- ▶ Scroll down to **E-mail Address**, enter correct email address and click on **Update Account** button
  
- ▶ To change other settings e.g. Company name:
  - Click on **Account > My Profile**
  - Click on 'cog' icon and then **Edit Profile**
  - Correct Employer, Subscriber Type or Country
  - Click on **Update Profile**





# **Trial Master File Reference Model**

## **CDISC Transition**

Paul Fenton and Karen Roy

**cdisc**

# CDISC Position Paper



- ▶ Position Paper released 19<sup>th</sup> January and was available until 9<sup>th</sup> February.
- ▶ Comments received:
  - Position paper clearly articulates the need and rationale. I would like to know how affiliation with CDISC would work; who / how community contributions would be considered; how decisions would be made; how the alignment with DIA EDMS model would be kept; will work continue towards a common TMF document metadata standards
  - I agree wholeheartedly that dedicated support will be necessary to achieve two important objectives: (1) to continually align the RM with changing regulations and (2) to improve interoperability between systems that depend on data stored in TMF documents. Efforts toward these objectives would inevitably lag without committing to standardization. I support the decision to affiliate with CDISC. The RM and its metadata could complement the types of data CDISC has traditionally supported. Complementary standards could provide a foundation for developing systems that can share data more easily, improve productivity, and save time and money. I look forward to continuing in the development of RM standards. My current understanding is that anyone may participate as a volunteer, regardless if he or she is a member. My only concern would be if the organization were to impose any financial burden or restrictions on participation that may prohibit my involvement.

# CDISC Progress



- ▶ TMF RM Steering Committee voted with 100% agreement on 10<sup>th</sup> February 2022 to ratify decision to join CDISC
- ▶ Implementation team formed:
  - Paul Fenton, Joanne Malia, Mary Emanoil, Kathie Clark, Karen Roy
- ▶ Implementation plan drafted
- ▶ Weekly meetings with CDISC management implemented
- ▶ TMF RM SC to join a CDISC Board meeting in early April
- ▶ Decision to be formally announced at April CDISC meeting

# CDISC Implementation Plan

- ▶ Plan will lay out the steps required to integrate the TMF RM into CDISC
- ▶ We will focus on the following areas:
  - Community
  - Events
  - Standards and governance
  - Communications
  - Technology
- ▶ Plan is being drawn up jointly by the TMF RM SC and CDISC Management team
- ▶ Hope to have the final plan ready in April

# SC focus for CDISC



- ▶ All TMF Reference model materials (Primary reference model, guides and templates, EMS specification and schema) should remain downloadable for free by the TMF community.
- ▶ If the reference model is moved to the library (or other database tool) from the Excel spreadsheet we have today, then a read-only access should be available to the community to be able to consult the latest version of the TMF RM.
- ▶ All volunteers (current and future) should be able to participate in and contribute to the evolution of the TMF reference model without the need to maintain a paid membership.
- ▶ There will always be a community elected steering committee or similar body to represent the community and that drives the evolution of TMF standards and best practices. This committee will operate in accordance with the charters, policies and procedures of CDISC.

# Clinical Trial Regulation Impact

- ▶ The new Clinical Trials Regulation (EU) 536/2014 has raised questions about possible new document types for the TMF and how they might be filed and managed.
- ▶ All-hands workshop on 7th April at 9am EST / 2pm GMT.
- ▶ We will present an initial view on the documents and possible mappings and to consider any potential impact on the Reference Model. This will then be fed back to the Change Control Board for formal assessment within their Zone teams.
- ▶ **IMPORTANT NOTE:** This workshop is intended solely for participants who will actively contribute thoughts and opinions.
- ▶ [https://us06web.zoom.us/meeting/register/tZwrceCpqTMiHtKDA-k4A\\_bydzUOvAPpSd\\_h](https://us06web.zoom.us/meeting/register/tZwrceCpqTMiHtKDA-k4A_bydzUOvAPpSd_h)



# MHRA/FDA/HC GCP Seminar Reflections Panel

- ▶ Karen Roy
- ▶ Fran Ross
- ▶ Mary Emanoil
- ▶ Joanne Malia
- ▶ Donna Dorozinsky
- ▶ Lisa Mulcahy

# TMF Plan Template Workstream

Brief description of project & objectives:	Review the template published in 2018 and incorporate changes due to regulations, technology, pandemic needs. Template will be cross-industry usable, simplistic TMF Management Plan template. Guidance provided on how to deal with variations depending on study size, phase, type.
Kick Off	03-Mar-2022
Team	Jamie Toth – Workstream Lead, Marion Mays – Co-Lead 14 people across Industry (pharma, biotech, vendor, consulting) 3 Subteams (12 sections, each reviewing 4 sections)
Target Draft Date	15-Dec-2022

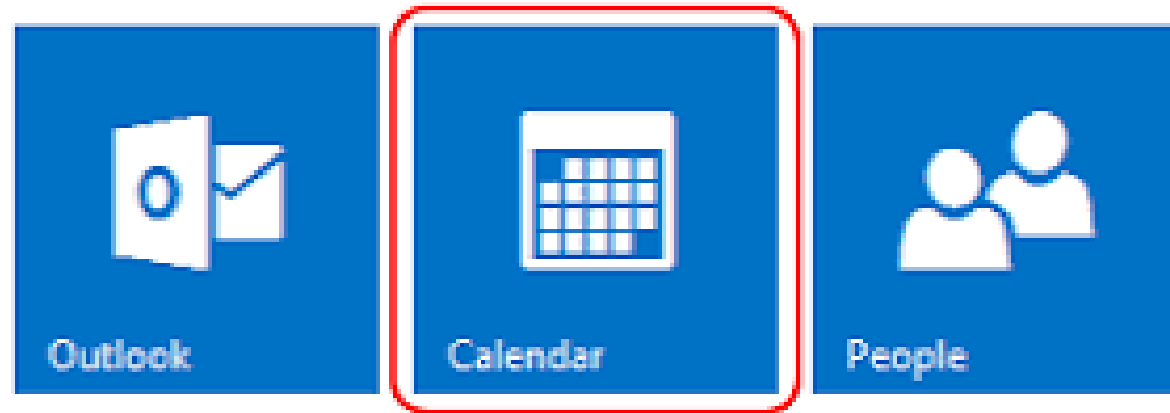
# TMF-related events coming up\*

*\*Events page on website (under Resources menu)*

Conference	When	Location
Clinical Trial Regulation Impact	April 7, 2022	Virtual
Association for GXP Excellence	May 1-4, 2022	San Antonio, TX, USA
Fierce Pharma TMF Summit Keynote is Dave Evans, CEO, CDISC	May 2-4, 2022	New Orleans, LA, USA
8th Clinical Trials Strategic Summit	May 4-5, 2022	Boston, MA, USA
HSRAA Conference	Sep 21-23, 2022	Manchester, UK
Hanson Wade Trial Master Files & Inspection Readiness	End of September 2022	Boston, MA, USA
Fierce Pharma TMF Summit	Early November 2022	London, UK

# TMF RM General Meetings

- ▶ 9<sup>th</sup> May 22
- ▶ Add to your calendar NOW or download the calendar file (.ics file) from our [homepage](#)
- ▶ Outlook Meeting Request no longer distributed



# QUESTIONS?

Join the TMF Reference Model Discussion Group

<https://tmfrefmodel.com/register>

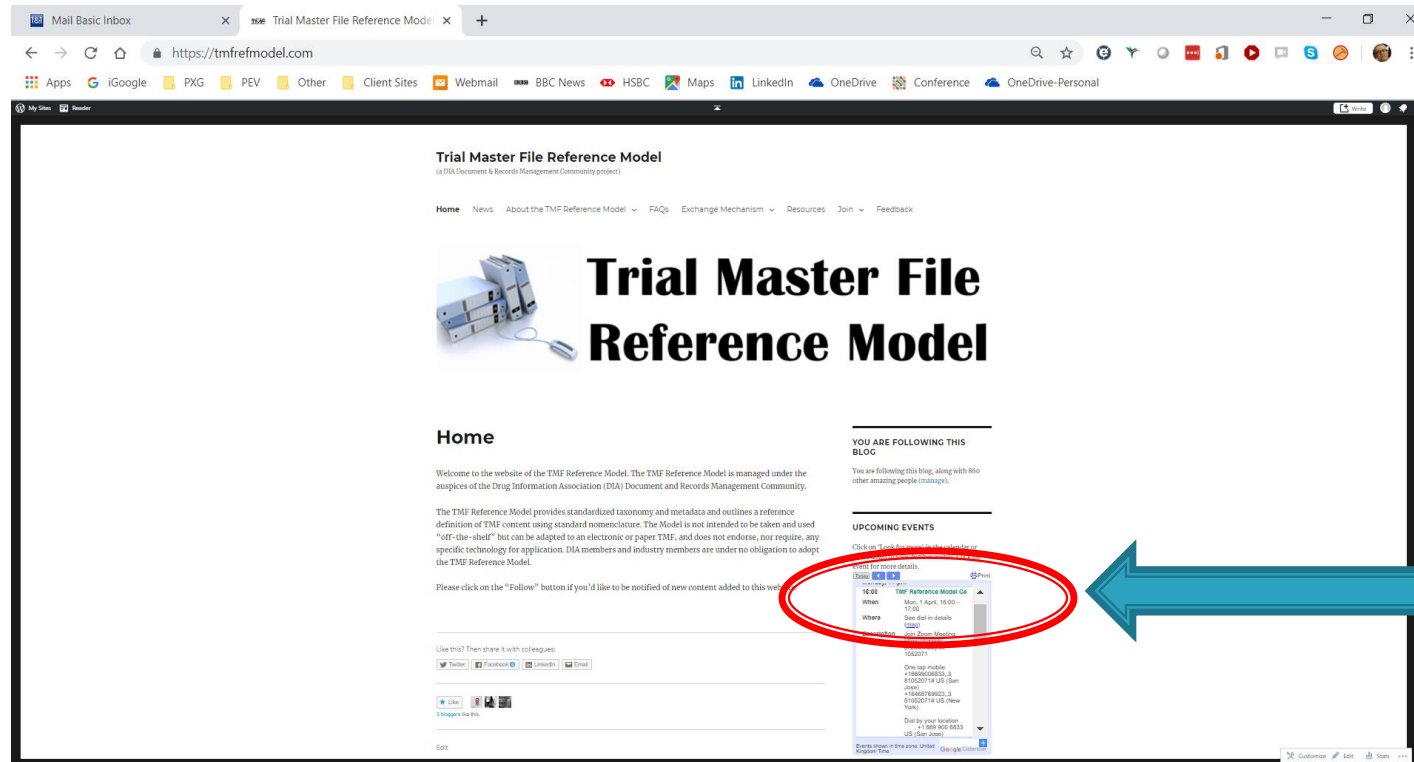
- Knowledge sharing
- Networking
- Too Much Fun!

Join the TMF Reference Model Project Team  
(be prepared to work! – we can't do this without YOU)

<https://tmfrefmodel.groups.io/g/main>

# Meeting details

- ▶ Wondering where to find details of the next meeting?



On TMF Reference Model website, click on calendar to see meeting details. Click 'Copy to my calendar' to add to your Outlook / Google calendar.



# Meeting details

- ▶ Wondering where to find details of the next meeting?

On Groups.io, click on Calendar to show group calendar. Click on an event to see dial-in details



The screenshot shows the Groups.io interface for the group 'main@tmfrefmodel.groups.io'. The left sidebar contains a navigation menu with items: Home (Owner), Subscription, Admin (2), Messages, Hashtags, New Topic, Chats, Subgroups, Directory, Calendar (highlighted), Files, and Databases. The main content area displays a calendar for September. The calendar grid shows dates from 26 to 11. A meeting titled '4:00pm TMF Reference Model General' is scheduled for September 9th at 4:00pm and is circled in red.

<https://tmfrefmodel.groups.io/g/main/>