



Trial Master File Reference Model

General Meeting

11th January 2021

2021

Agenda

- ▶ History of the TMF Reference Model
- ▶ Current Status
- ▶ Overview of the Previous Deliverables
- ▶ Current Initiatives
 - Exchange Mechanism Specification
- ▶ TMF Survey Potential Initiatives
- ▶ Upcoming TMF Meetings
- ▶ Next Meeting

1. Which region are you based in?



2. What type of Company are you representing?



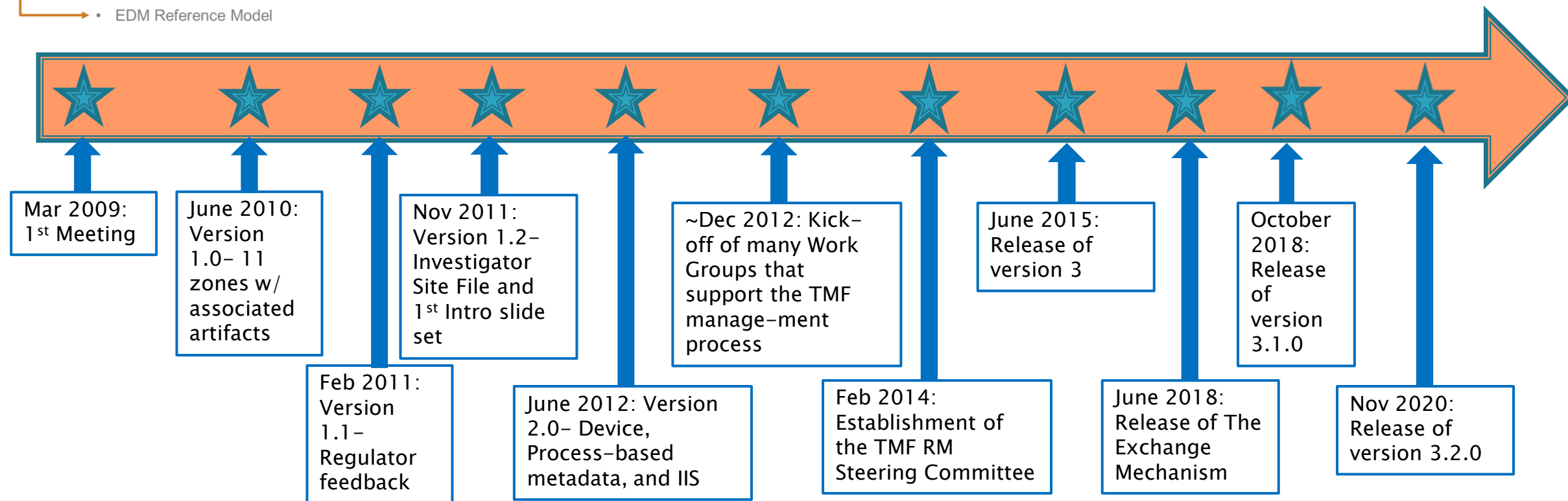
3. How many of these meetings have you



4. Do you / your company use a TMF Reference Model based TMF Structure?



How did we get here?



Purpose of the TMF Reference Model

Standard Contents

Industry opinion on
what is kept in a TMF

Standard Naming

Based on ICH E6 Sect. 8
& industry-accepted
terminology

Standard Structure

To support paper and
electronic systems

Standard Metadata

For eTMFs, minimum
metadata at system and
artifact level

Benefits Gained by Implementation

- ▶ Standardizes company content and structure and limits company customization
 - We all follow the same regulatory requirements
 - Inspectors are the same across companies
 - Company-specific requirements are often driven by tradition, legacy or personal opinion
- ▶ Simplifies engagement of CROs and other third parties
- ▶ Simplifies consolidation of disparate documents into a single TMF structure (in real time, at defined trial events and/or at study end)

How is it Managed?

- ▶ Governed under a formal charter
- ▶ 14 member Steering Committee
 - Chair
 - Meeting secretary
 - SC Charter – open for general review
- ▶ Independent website www.tmfrefmodel.com
 - Resources include Charter, deliverables, meeting slides, educational links, useful information and links
- ▶ Change Control Board

Who Manages it?

- ▶ 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, Daiichi-Sankyo
- ▶ Fran Ross, Advanced Clinical
- ▶ Kathy Clark, Ennov
- ▶ Todd Tullis, Veeva
- ▶ Wendy Trimboli, Acadia
- ▶ Paul Fenton, Montrium
- ▶ David Ives, Alexion
- ▶ Russell Joyce, Heath Barrowcliff Consulting
- ▶ Donna Dorozinsky, Just in Time GCP
- ▶ Sholeh Ehdaivand, LMK Clinical Research Consulting

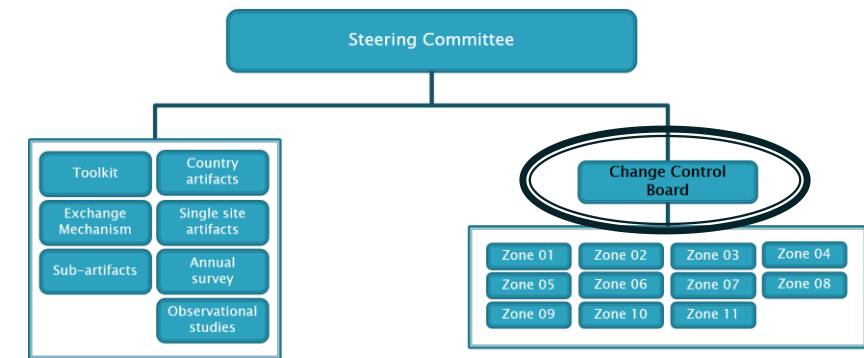
Who Controls the Versions?

► Change Control Board Structure

- 15 members
- Kelley Robinson, Odonate: Chair
- Joanne Malia, Regeneron: Deputy Chair

► Deliverables to Date

- Meeting twice a month since October 2017
- Created and finalized: Change Control Procedure, RACI and CR Tracker
- Reviewed and categorized all current change requests
- Triaging all change requests to Zone Teams



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

Who are the Members?

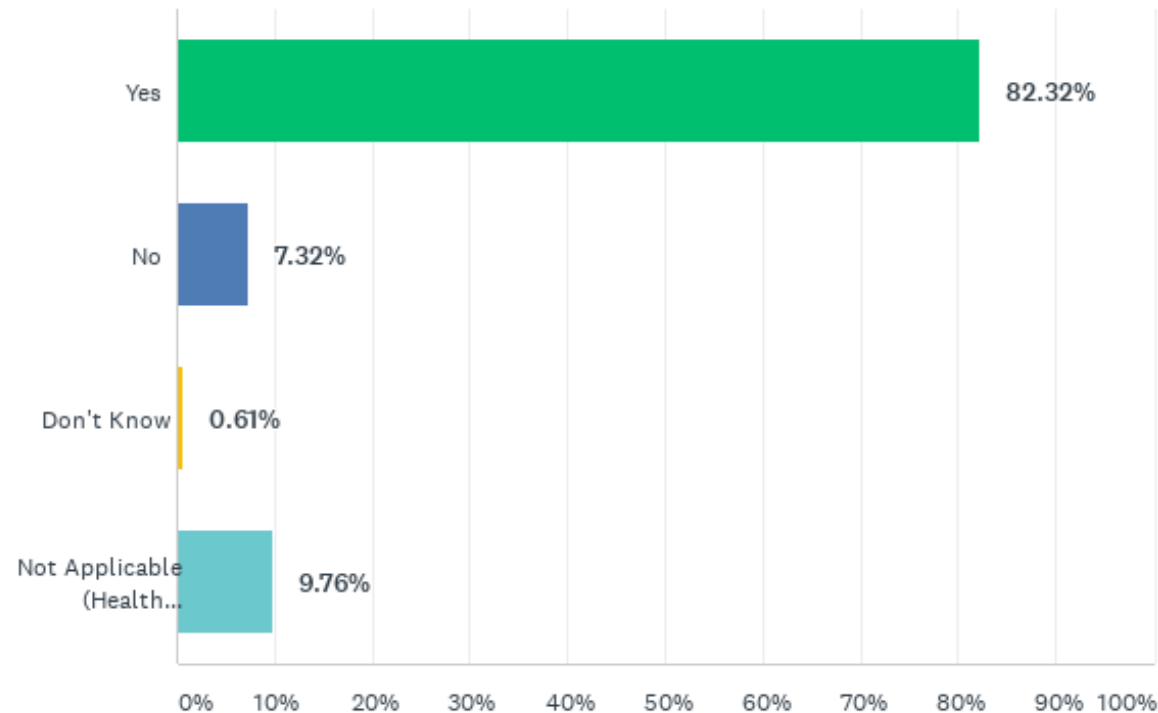
- ▶ 342 project team members (groups.io)
- ▶ 1,291 Mailing List Subscribers** (tmfrefmodel.com)
- ▶ 3,335 members of LinkedIn group
- ▶ For details on these different groups and how to get involved, see <http://tmfrefmodel.com/join>

** Make sure webadmin@tmfrefmodel.com
is on your email whitelist

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Usage of the Reference Model

Q48 Is your organization using the TMF Reference Model?



Source: DIA Annual Ref Model Survey 2019

Deliverables to Date

TMF Tools:

- [TMF Reference Model User Guide](#): Introduction to the model, understanding its structure, and how to use it (v1.0 Approved 16-March-2018) **NEW**
- [TMF Reference Model Implementation Guidance](#): Provides a framework for implementing the model in your organization (v1.0 Approved 14-March-2018) **NEW**
- [TMF Plan Template](#): Suggested structure and outline for a Trial Master File Plan (v1.0 Approved 23-February 2018) **NEW**
- [TMF Plan Template Feedback](#): Click on [LINK](#) to provide feedback on the TMF Plan **NEW**
- [Milestones / Events](#): Suggested latest milestones or events by which each artifact should be filed (v1.1 Approved 31-January-2018) **REVISED**
- [Date Conventions](#): Suggested date convention to use for each artifact (Approved 15-Feb-2017)
- [Date Conventions Guidance](#): Guidance notes to be used with Date Conventions spreadsheet (Approved 15-Feb-2017)
- [TMF Quality Control](#): Toolkit to help prepare a TMF quality control programme (Approved 12-Oct-2016)
- [TMF Quality Control Presentation](#): Powerpoint slides presented to group meeting November 7, 2016
- [Inspection Readiness](#): Toolkit to help prepare TMF for regulatory inspections (Approved 09-Nov-2016)
- [Inspection Readiness Presentation](#): Powerpoint slides presented to group meeting January 9, 2017
- [eTMF Selection – Request for Proposal Template](#) (co-authored by Scientific Archivists Group, TMF Reference Model and Pocket EDMS, March 2017)
- [Inspection FAQs](#): Common inspection questions with answers, and regulatory resource list (Approved 15-Mar-2017)
- [Metrics 101](#) – How to Implement a TMF Metrics Program (PDF File)
- [Metrics 101](#) – How to Implement a TMF Metrics Program (PPT File)
- [Metrics Definitions](#) – Recommended Metrics for your TMF Metrics Program (XLS File)



Trial Master File Reference Model

(a DIA Document & Records Management Community project)

[Home](#) [News](#) [Forums](#) [About the Model](#) [FAQs](#) [Exchange Mechanism](#) [Resources](#) [Account](#) [Help](#) [Feedback](#)

Home

Welcome to the website of the TMF Reference Model. The TMF Reference Model is managed 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.

[Edit](#)

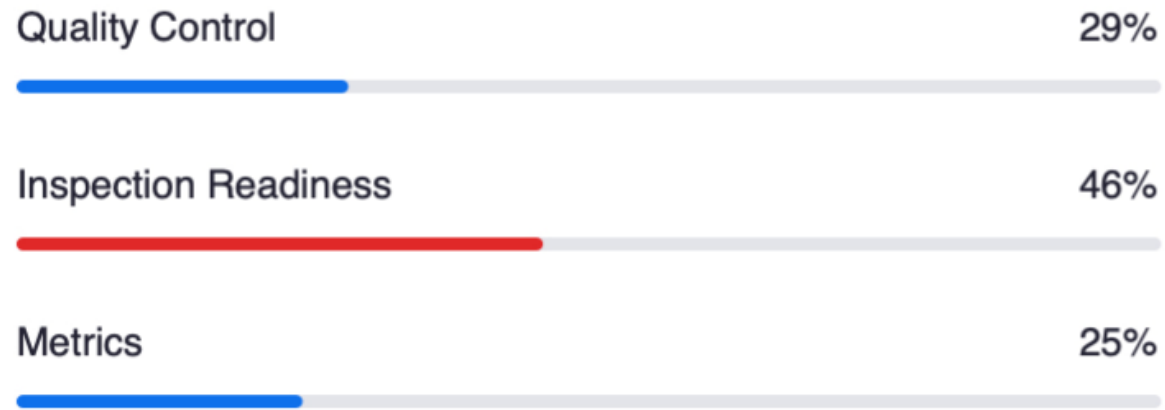
RECENT DISCUSSION TOPICS

- [05.04.01 Subject Log](#)
3 days, 16 hours ago
- [Protocol/Protocol Amendment](#)
2 weeks, 2 days ago
- [Statement of Investigator for non-US Clinical Trial Sites](#)
2 weeks, 1 day ago
- [Working with a CRO who won't file 'outside' documents](#)
4 days ago
- [Vendor Scope of Work](#)
4 weeks ago

NEXT GENERAL MEETINGS

Click on a date below to download an Outlook Calendar .ics file:

1. Which refresh would be the most interesting / useful to you?



TMF RM Active Initiatives

Initiative	Deliverables / Activity
Devices	<ul style="list-style-type: none">• Updated artifacts and sub-artifacts specific to Device studies• Being finalised for release in 2021
Exchange Mechanism	<ul style="list-style-type: none">• An extension of the TMF RM which focuses on the transfer of content, metadata, audit trail and eSig information

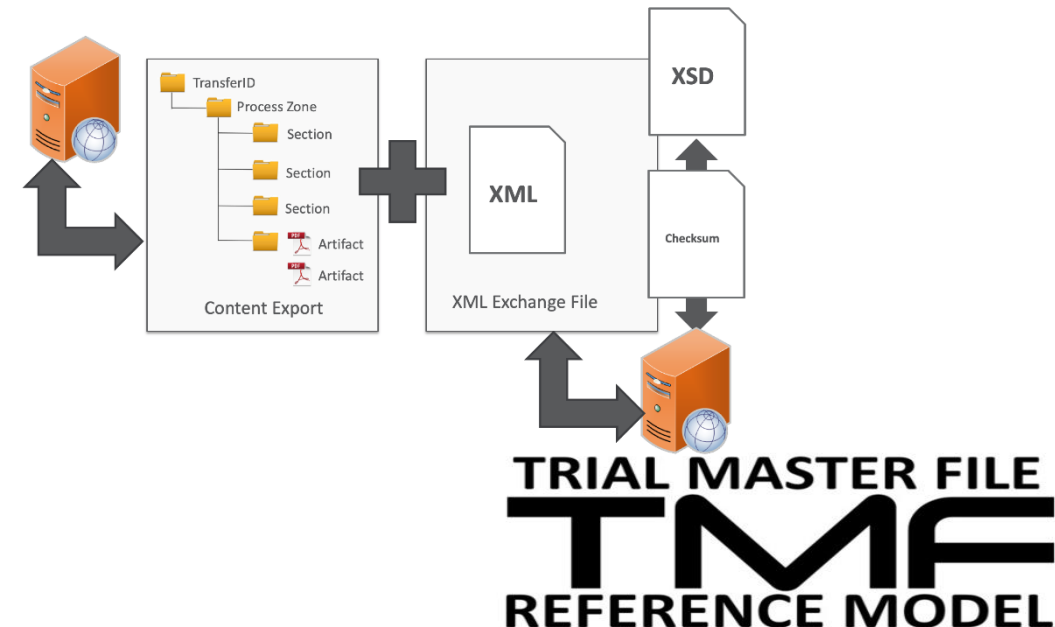
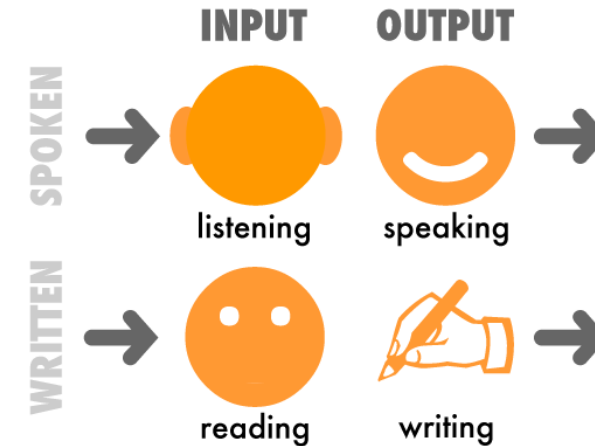
eTMF Exchange Mechanism Standard (EMS) survey!

- If you have time please take the survey now, just go to the <https://tmfrefmodel.com/>
- Yes, the exchange mechanism is a technical standard, but it is also a common business language

What does the eTMF Exchange Mechanism provide?

Human vs system-based communication

- ▶ **Mechanism**
 - Mouth->ears or hands->eyes
- ▶ **Common language**
 - English (to communicate outside native language)
- ▶ **Shared protocol**
 - Soundwaves or pen and paper
- ▶ **Mechanism**
 - APIs and/or standard parser (TMF EMS¹)
- ▶ **Common language**
 - The TMF Reference Model¹
- ▶ **Shared protocol**
 - XML (TMF EMS¹)



What part of business can benefit from the EMS?

Do you collaborate?

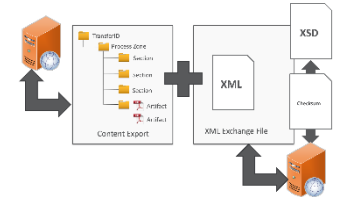
- Sponsor and CRO, Study sites, IRB/EC, Lab's...

How can this be done efficiently

- Ensure quality from the provider (Quality by Design) and be able to transfer the documented quality.
 - Issues caught early are easier and cheaper to fix.
 - The customer does not have to recheck the work. Only risk-based sampling.
- Oversight – monitor the quality in real-time
 - Establish vendor oversight with minimal effort and as fast as possible.

The eTMF Exchange Mechanism Standard (EMS) can preserve and transfer GCP between collaborators!

- When established the EMS can easier be used by other collaborators.
- You should receive an email from TMF RM, or please go to the <https://tmfrefmodel.com/>



TMF RM New Initiatives

2019 Survey suggested a number of new initiative themes:

- ▶ TMF RM Training Course
- ▶ Study Types coverage
- ▶ Clinical and Regulatory – overlap between TMF and CTA submission documents
- ▶ Investigator Site File
- ▶ Clustering and relationship between artifacts
- ▶ Metadata – definitive set of minimum metadata per artifact
- ▶ **Other ideas??**

1. Which theme is of most potential interest/ usefulness to you?



Q & A time

- ▶ Correspondence: Regarding the new media use for TMF
Correspondence and how to manage it. The use of media to help communication last year escalated dramatically (e.g. TEAMS, ZOOM etc). Obviously some of these communications need to be filed as important correspondence for TMF. With TEAMS, whilst you can file an individual message via email, you can't file a "string" conversation.
- Do the Team have any suggestions as to how to manage this type of correspondence for TMF?

TMF-related events coming up*

Events page on website (under Resources menu)

- ▶ e-Mail (Electronic) Communications Guidance Workshop, 15 January 2021 – Zoom details on the next slide

#TMFisTooMuchFunEmailCommunicationsMoreFun

- ▶ Clinical Document World, Virtual, 24 to 26 Feb
- ▶ Fierce TMF Summit, April 2021?
- ▶ IQPC TMF & GCP Inspection Readiness?

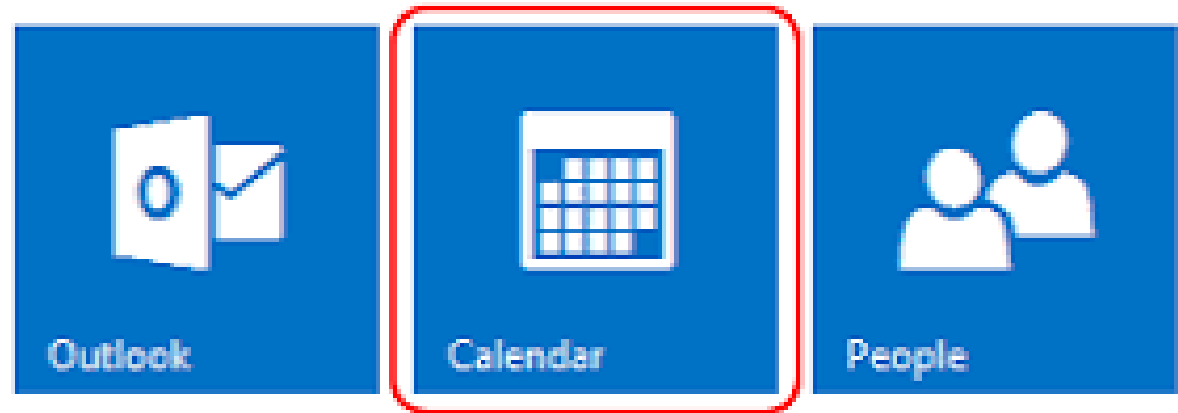
* COVID-19 dependent

e-Mail (Electronic) Communications Guidance Workshop

- ▶ Join Zoom Meeting
<https://zoom.us/j/93846023917?pwd=ZkMrc2lsWFY3SGFzSXc5M2Z1Q3RMQT09>
- ▶ Meeting ID: 938 4602 3917
Passcode: TMFRM
One tap mobile
+19292056099,,93846023917#,,,,,0#,,727732# US (New York)
+12532158782,,93846023917#,,,,,0#,,727732# US (Tacoma)
- ▶ Dial by your location
+1 929 205 6099 US (New York)
+1 253 215 8782 US (Tacoma)
+1 301 715 8592 US (Washington D.C)
+1 312 626 6799 US (Chicago)
+1 346 248 7799 US (Houston)
+1 669 900 6833 US (San Jose)
Meeting ID: 938 4602 3917
Passcode: 727732
Find your local number: <https://zoom.us/u/aelyvJ7OKE>

TMF RM General Meetings

- ▶ <1st March>
- ▶ 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>

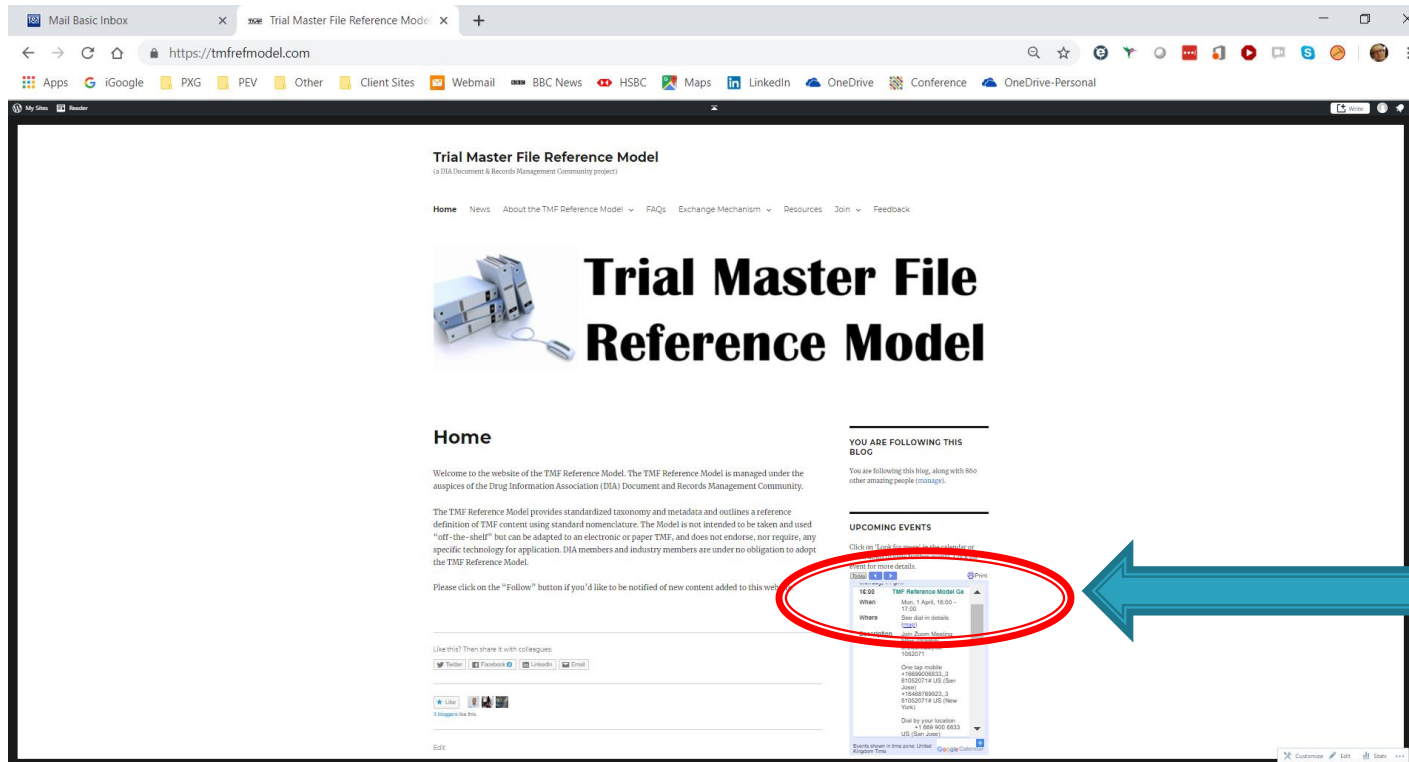
- Knowledge sharing
- Networking
- Too Much Fun!

Join the TMF Reference Model Project Team
(but be prepared to work!)

<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. On the left is a sidebar with navigation links: Home (Owner), Subscription, Admin (2), Messages, Hashtags, New Topic, Chats, Subgroups, Directory, Calendar (highlighted in blue), Files, and Databases. The main area displays a calendar for the month of September. The calendar grid shows dates from 26 to 11. An event titled '4:00pm TMF Reference Model General' is scheduled for September 9th and 10th, highlighted with a red oval. The top navigation bar includes the Groups.io logo, 'Your Groups 4', and a search bar.

TRIAL MASTER FILE
TMF
REFERENCE MODEL

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