



Trial Master File Reference Model

General Meeting

27 July 2020

Agenda

- ▶ Welcome
- ▶ Update on Membership
- ▶ Update on Initiatives
- ▶ Electronic communications
- ▶ Data Integrity update
- ▶ Next Meeting

Membership Update...

- ▶ 318 project team members (groups.io)
 - ▶ 1086 Mailing List Subscribers (tmfrefmodel.com)
 - ▶ LinkedIn group – 3,060 members
-
- ▶ 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

TMF RM Active Initiatives

Initiative	Deliverables / Activity
Sub-artifacts	<ul style="list-style-type: none">• A super-set of sub-artifacts for Companies to select and customise• Removal of the 'Alternative Name' column – any unique names have been added as sub-artifacts• Gone to CCB
Devices	<ul style="list-style-type: none">• Updated artifacts and sub-artifacts specific to Device studies
Real World Studies	<ul style="list-style-type: none">• The TMF Reference Model artifacts that are required for Real World studies
eMail	<ul style="list-style-type: none">• Document best practices for handling email. Deliverables to include: defining relevant correspondence; best filing practices, handling attachments and links; archiving
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



Trial Master File Reference Model

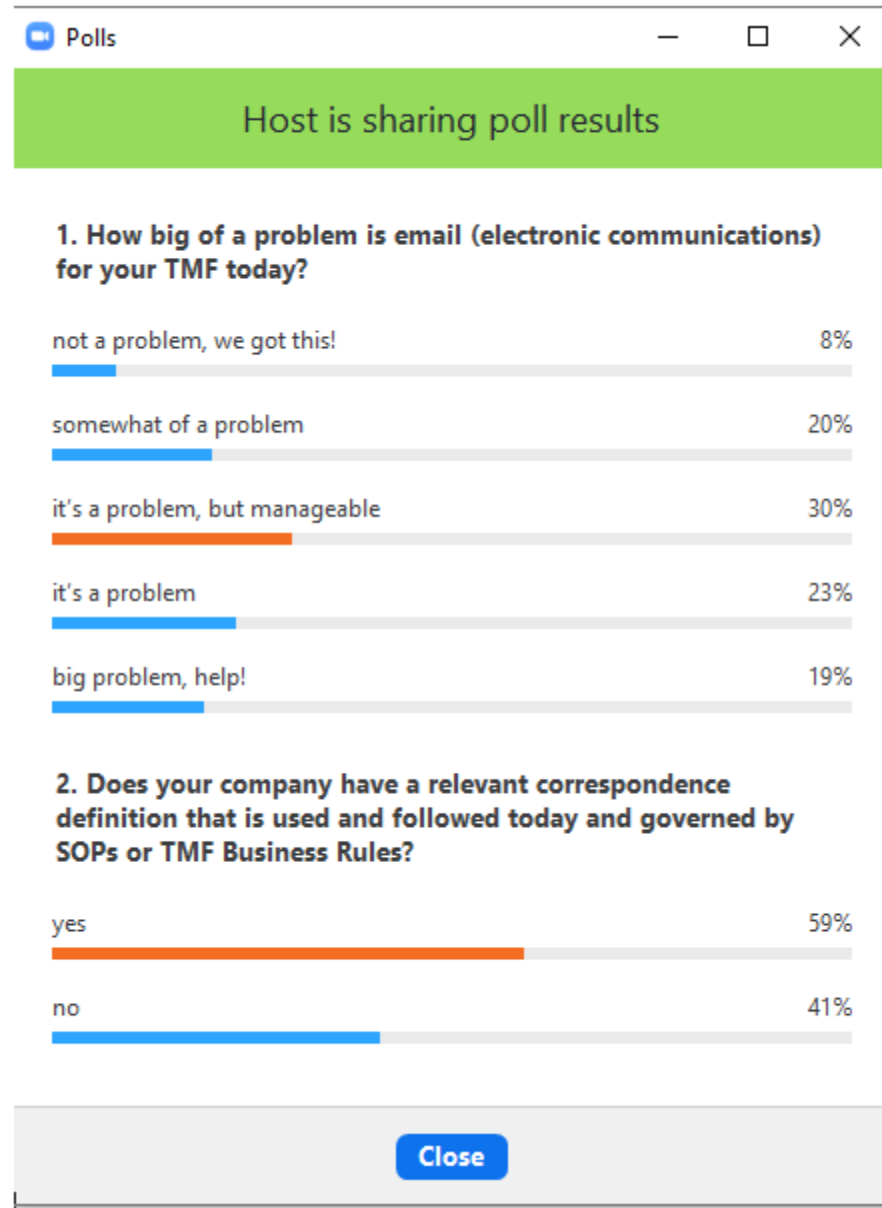
Electronic Communications SubGroup

Jamie Toth

Electronic Communications Subgroup Members

Team	
Name	Company
Jamie Toth	Daiichi Sankyo, Inc.
Jennifer Wilson	Syneos Health
Kathie Clark	Ennov
LoriAnn Verna	JustInTimeGCP
Mark Mercer	CGI
Mary Ann Brooks	Baxter
Russell Joyce	Heath Barrowcliff Consulting
Shah Ashraf	Transperfect
Tiffany Steward	Astellas
Cynthia Pinto	GSK
Dickson D'souza	IQVIA





Electronic Communications SubGroup

Working Group Lead: Jamie Toth, TMF Ref Model Steering Committee Member

Objectives:	Across the industry, the issues associated with electronic mail (e-mail) are widespread. These include how we define and manage "relevant communications" for a trial/study; ensuring it is retained and appropriately managed in an authoritative system; and produced during a health authority inspection in a manner that is aligned with the expectations of regulatory authorities.
Scope - In:	Positions and recommendations for relevant electronic communications with a cross industry group ensuring that a wide range of viewpoints are incorporated (Sponsor, CRO, Vendor, Consultant).
Scope - Out:	A technology tool for automation or specific technology tool(s) for managing e-mail.
Action Plan & Timeline:	Kick off held October 2019; 4 chapter sub-teams met and then came back together.

Overview of Guidance Document

- ▶ This is guidance!
- ▶ 21 pages, includes:
 - How to effectively file e-mail
 - Responsibility for filing e-mail
 - Subject lines
 - E-mail branching
 - Attachments
 - Use of embedded links
 - Unblinding e-mails
 - E-mail dates
 - Archiving
 - Regulations (17 citations)
 - Appendices (3) on repository options, preservation format options, and definitions



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1. How do you manage electronic communications today?

Store outside of eTMF (TMF) forever

Bring a .PST (outlook mailbox) into eTMF system at the end from personal accounts

Bring a .PST (outlook mailbox) into eTMF system at the end from study mailboxes

File emails separately into the artifact location within the eTMF on an ongoing basis

Print and file as paper

None of the above

2. For filing of emails, do you:

File as you go

File monthly

File at the end of a trial

3. Who is responsible for filing emails in the TMF?

The originator of the communication

The receiver of the communication

The originator of the communication unless they don't have access, and then the first receiver

The first person that files it

We file duplicates

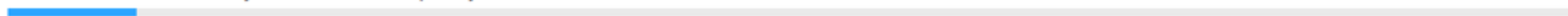
Who knows!!

4. How do you handle eMail attachments?

Always filed with the email



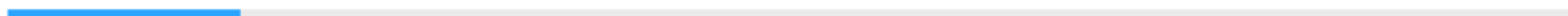
Never filed with the email – always detached and filed separately



Only filed separately if it doesn't already exist in the TMF



Who knows!



5. Are emails reviewed as part of the periodic Quality Review?

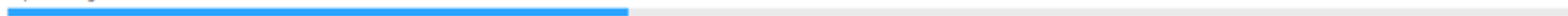
Yes, always, who knows what may be hiding there



No, any relevant document should be filed in the correct artifact



A percentage is checked



6. How do you archive your emails?

They are in PDF format in the eTMF, the native files are deleted



We never ever delete any native format emails just in case



We keep native format for a retention period then delete



Next Steps

- ▶ Finalizing the guidance by Wednesday!
- ▶ Publication on tmfrefmodel.com for Friday, 31-Jul-2020!

MHRA–FDA Joint Paper on Data Integrity

- ▶ 30 Jun 2020: Announced on [MHRA Inspectorate Blog](https://mhrainspectorate.blog.gov.uk/2020/06/30/mhra-and-fda-joint-paper-data-integrity-in-global-clinical-trials/)
- ▶ <https://mhrainspectorate.blog.gov.uk/2020/06/30/mhra-and-fda-joint-paper-data-integrity-in-global-clinical-trials/>
- ▶ Based on an October 2018 MHRA–FDA Joint Meeting



- ▶ Hit a paywall? US residents can request copy from author

Summary for TMF = Nothing new here

- ▶ Primary concern is clinical trial data, and consideration for restricted (unblinded) data
- ▶ Such data are considered part of the TMF, whether or not they are stored in an eTMF system with other study records
- ▶ Reinforce the importance of clear governance for these data

TMF-related events coming up*

NEW Events page on website (under Resources menu)

- ▶ Clinical Document World, Virtual Event, 8–11 September
- ▶ FierceLive / Questex / Exl European TMF Summit, London, UK 19–21 October
- ▶ Electronic Trial Master File Forum, New Jersey & Virtual, 20–21 Oct
- ▶ AGxP San Antonio, TX – 8–11 November
- ▶ IQPC TMF & GCP Inspection Readiness, Bruges, Belgium RE-SCHEDULED TO APRIL 2021

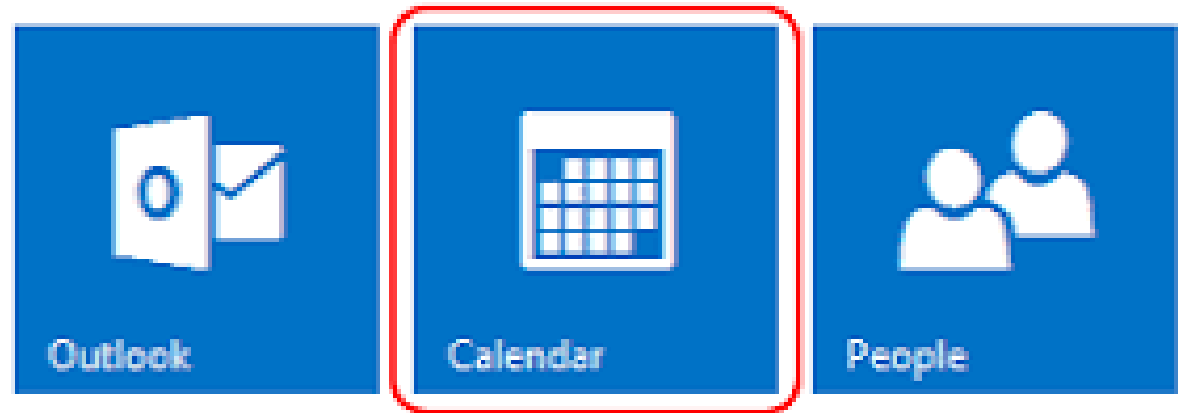
* COVID-19 dependent

Open Q&A Session



TMF RM General Meetings

- ▶ <21st September>
- ▶ 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>

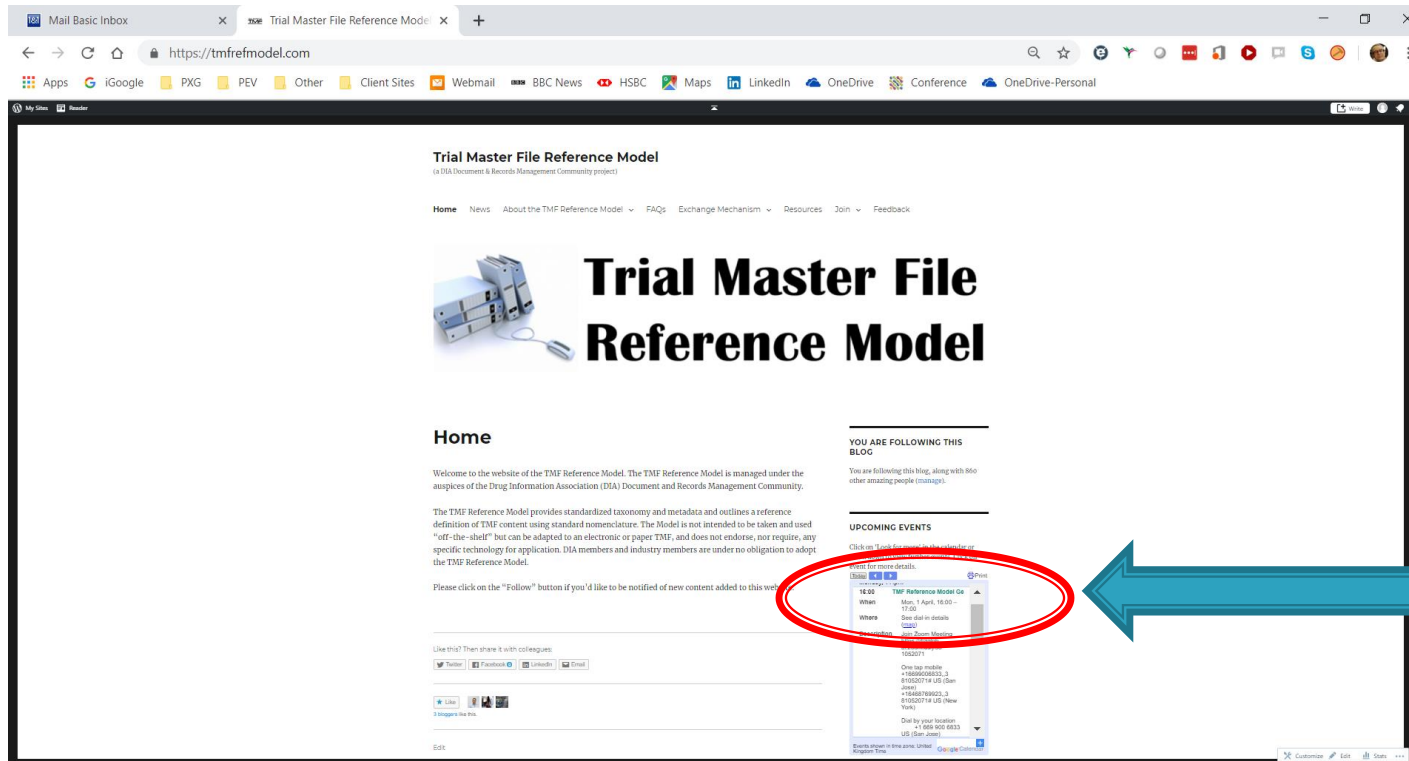
- Knowledge sharing
- Networking
- Too Much Fun!

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

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



The screenshot shows the Groups.io interface for the group 'main@tmfrefmodel.groups.io'. The left sidebar contains navigation links: Home (Owner), Subscription, Admin (2), Messages, Hashtags, New Topic, Chats, Subgroups, Directory, Calendar (highlighted), Files, and Databases. The main area displays a calendar for 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.

Sun	Mon	Tue
26	27	28
2	3	4
9 4:00pm TMF Reference Model General	10 4:00pm TMF Reference Model General	11

TRIAL MASTER FILE
TMF
REFERENCE MODEL