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

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Deliverables / Activity</th>
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| Sub-artifacts               | • 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                     | • Updated artifacts and sub-artifacts specific to Device studies                                                                                         |
| Real World Studies          | • The TMF Reference Model artifacts that are required for Real World studies                                                                             |
| eMail                       | • Document best practices for handling email. Deliverables to include: defining relevant correspondence; best filing practices, handling attachments and links; archiving |
| Exchange Mechanism          | • 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

<table>
<thead>
<tr>
<th>Team</th>
<th>Name</th>
<th>Company</th>
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<tbody>
<tr>
<td></td>
<td>Jamie Toth</td>
<td>Daiichi Sankyo, Inc.</td>
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<td></td>
<td>Jennifer Wilson</td>
<td>Syneos Health</td>
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<td></td>
<td>Kathie Clark</td>
<td>Ennov</td>
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<td></td>
<td>LoriAnn Verna</td>
<td>JustInTimeGCP</td>
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<td></td>
<td>Mark Mercer</td>
<td>CGI</td>
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<td></td>
<td>Mary Ann Brooks</td>
<td>Baxter</td>
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<td></td>
<td>Russell Joyce</td>
<td>Heath Barrowcliff Consulting</td>
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<td></td>
<td>Shah Ashraf</td>
<td>Transperfect</td>
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<td></td>
<td>Tiffany Steward</td>
<td>Astellas</td>
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<td></td>
<td>Cynthia Pinto</td>
<td>GSK</td>
</tr>
<tr>
<td></td>
<td>Dickson D’souza</td>
<td>IQVIA</td>
</tr>
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1. How big of a problem is email (electronic communications) for your TMF today?

- not a problem, we got this! 8%
- somewhat of a problem 20%
- it’s a problem, but manageable 30%
- it’s a problem 23%
- big problem, help! 19%

2. Does your company have a relevant correspondence definition that is used and followed today and governed by SOPs or TMF Business Rules?

- yes 59%
- no 41%
### Electronic Communications SubGroup

<table>
<thead>
<tr>
<th>Working Group Lead: Jamie Toth, TMF Ref Model Steering Committee Member</th>
</tr>
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<tbody>
<tr>
<td><strong>Objectives:</strong> Across the industry, the issues associated with electronic mail (e-mail) are widespread. These include how we define and manage &quot;relevant communications&quot; 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.</td>
</tr>
<tr>
<td><strong>Scope - In:</strong> 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).</td>
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<tr>
<td><strong>Scope - Out:</strong> A technology tool for automation or specific technology tool(s) for managing e-mail.</td>
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<tr>
<td><strong>Action Plan &amp; Timeline:</strong> Kick off held October 2019; 4 chapter sub-teams met and then came back together.</td>
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</table>
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
1. How do you manage electronic communications today?
- Store outside of eTMF (TMF) forever
- Bring x:PTT (outlook mailbox) into eTMF system at the end from personal accounts
- File x:PTT (outlook mailbox) into eTMF system at the end from study mailbox
- 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
- Based on an October 2018 MHRA–FDA Joint Meeting

- Hit a paywall? US residents can request copy from author
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 October
- 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
<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.
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/