Agenda

- Welcome
- Membership Update
- Active Initiatives
- TMF Summit update
- A look forward
- Interactive polling – focus on Investigators
- Upcoming Events
Welcome to 2020

- How old are we??
Since last meeting*

- 6 new project team members (groups.io) – current total 312
- 928 Mailing List Subscribers** (tmfrefmodel.com)
  - 14 new discussion topics posted (51 responses, 1,849 hits)
- LinkedIn group – 2,937 members (25 new members)
  - 7 new discussion topics posted
- For details on these different groups and how to get involved, see http://tmfrefmodel.com/join

- Yahoo!Group Forum closed

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

* 18 November 2019
Collaboration platform

Next...
Does anyone have any experience with Phase 0 studies
Relevant communications
Site feasibility documentation
Filing site–specific SOPs
IBC TMF Filing
Phase 1 QC strategy
CSR filing options in eTMF
IP–related documents
Best practice: Wet–ink signatures and certified copies

DocuSign
TMF structuring trial, country and site levels
Does the investigator list get filed in the TMF?
TMF document naming conventions
Financial agreement in the TMF
Study level, site level, or both
Electronic TMF
## TMF RM Active Initiatives

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Lead</th>
<th>Deliverables / Activity</th>
<th>Completion Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>eMail</td>
<td>Jamie Toth</td>
<td>• Document best practices for handling email. Deliverables to include: defining relevant correspondence; best filing practices, handling attachments and links; archiving</td>
<td>June 2020</td>
</tr>
<tr>
<td>Devices</td>
<td>Joanne Bilmazes</td>
<td>• Since the review was completed, ISO have released the draft revised GCP standard. The team are now doing a comprehensive review of the standard to check for document requirements→ Submit to Change Control Board</td>
<td>Early 2020</td>
</tr>
</tbody>
</table>
| Sub–artifacts    | Karin Schneider| • 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 | Early 2020      |
## TMF RM Active Initiatives

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<tr>
<td>Annual Survey</td>
<td>David Ives</td>
<td>• Completed industry survey</td>
<td>Feb 2020</td>
</tr>
</tbody>
</table>
| Observational Studies     | Russell Joyce| • Focus changed to Non-Interventional Studies in general.  
• Identified from TMF Ref Mod v3.0  
  • 10 Core artefacts  
  • 98 Recommended artefacts  
• Final review due mid October                                                                                                               | End Dec 2019        |
| J-GCP                     | Jamie Toth   | • To be confirmed, pending review/understanding of JPMA deliverable                                                                                                                                                  | TBD                 |
| Exchange Mechanism        | Paul Fenton  | • See Over                                                                                                                                                                                                          | Ongoing             |
Real World Studies TMF Reference Model

Now finalized and submitted to the SC for review and approval.

Real World Studies are defined as “Human Research Studies whose design does not follow a traditional clinical trial framework” and may also be known as:

- Non-interventional studies
- Disease registry studies
- Natural history studies
- Post-market clinical follow up studies (medical device)
- Observational studies
- Non-IND studies

Based on the standard TMF Reference Model v3.1, the RWS Model comprises

- 11 Core artefacts
- 119 Recommended artefacts

Some zone, section, and artefact name changes to reflect RWS terminology

Considerable thanks to Stuart McCully, Tara Isherwood, Kath Firth, Jeff Kirsch, Shelley Brigstock, and Linda Rudolph without whose expertise, knowledge and commitment the RWS TMF Reference Model would not have been possible nor have come to fruition.
One last call to make sure your perspective is heard and get valuable insights and data! The survey closes this Friday February 7th

- [https://www.surveymonkey.com/r/2019TMF](https://www.surveymonkey.com/r/2019TMF)
What’s happened in 2020?
The withdrawal agreement foresees that following its departure from the EU on 31 January 2020, the UK will no longer participate in EU institutions and their decision-making. For EMA this means that as of 1 February 2020, no one who represents the UK, or is appointed or nominated by the UK can participate in meetings of EMA’s scientific committees, working parties or the Agency’s Management Board.
Poll

1. What group do you represent here today?
   - Sponsor: 49%
   - CRO: 30%
   - Vendor: 11%
   - Consultant: 16%
   - Regulator: 0%
   - Investigator site: 1%
   - Other: 2%

2. Has your Company changed anything regarding TMF as a result of Brexit?
   - Yes (be prepared to tell us!): 0%
   - No: 99%
   - I have no idea: 22%
   - N/A: 9%
Questions for TMF subject matter experts on a potential new ICH Topic – “eTMF (electronic Trial Master File) Metadata Harmonization”

Has anyone contributed?
TMF-related events coming up

- HSRAA Annual Conference, Windsor, UK, 22–24 Apr 2020
  - including Introduction to GCP Records Management Workshop
- SCOPE: Feb 18–21, Orlando
- RSIDM, Early Feb, North Bethesda MD
- DIA, Washington, June 2020 – a few TMF sessions plus a 10 year birthday party!
- IQPC TMF Conference Brussels 14–17 Sep
TMF RM General Meetings

- <30 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
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/