



Trial Master File Reference Model

General Meeting

23 September 2019

Agenda

- ▶ Welcome
- ▶ Membership Update
- ▶ Sub group Process
- ▶ Active Initiatives
- ▶ MHRA GCP Symposium
- ▶ IPQC TMF Inspection Readiness Conference
- ▶ Interactive discussions
- ▶ Upcoming Events

Since last meeting*...

- ▶ 10 new project team members – current total 299
- ▶ 25 new Mailing List Subscribers – current total 861
- ▶ 7 new Yahoo!Group Forum members – current total 609
 - 22 new discussion topics posted (53 messages)
- ▶ LinkedIn group – 2,862 members (63 new members)
 - 8 new discussion topics posted
- ▶ For details on all these different groups and how to get involved, see <http://tmfrefmodel.com/join>

TMF RM Subgroup Process

SUBGROUP PROPOSED

TMF RM member drafts subgroup charter (using the template), sends to SC [PMO tracker]

SC reviews and makes determination (approve, decline, requests more info)

Approved = SC liaison assigned, Subgroup IO established

How does the call for members work? Call out to Subscribers via MailChimp

ACTIVATING SUBGROUP

Lead accepts IO subgroup members

Lead sets up google drive or other collaborative platform for drafts/collaboration

Lead uses IO for meeting scheduling and communications

SUBGROUP GETS THE JOB DONE

Subgroup meets, confirms charter, establish cadence

Subgroup works on meeting group goal(s)

Lead sends regular updates to SC liaison [PMO tracker]

SUBGROUP COMPLETES EFFORT

Lead sends draft subgroup output to SC

SC reviews and takes action (approves or request revisions) or send to CC Board

When approved, output published on TMF RM Website [plus PMO tracker] and publicized at All Hands Meeting (Lead where possible)

SUBGROUP DISBANDS

Lead and team are copiously thanked and lauded

IO subgroup is closed by SC [PMO tracker]

Google drive is shuttered by the Lead

TMF Ref Model lives on!

Inputs:

Group Charter Template

TMF RM Groups IO membership

Outputs:

Subgroup product

PMO tracker

TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Investigator TMF Clarifications	Fran Ross	<ul style="list-style-type: none">Terminology position paper post Conference workshop	October 2019
Devices	Charlene Knape	<ul style="list-style-type: none">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	End 2019
Sub-artifacts	Karin Schneider	<ul style="list-style-type: none">Comprehensive revision of the 'sub-artifact' examples in column I→ Submit to Change Control Board	End of 2019

TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Annual Survey	David Ives	<ul style="list-style-type: none">Completed industry survey	October 2019
Observational Studies	Russell Joyce	<ul style="list-style-type: none">Focus changed to Non-Interventional Studies in general.Identified from TMF Ref Mod v3.0<ul style="list-style-type: none">10 Core artefacts98 Recommended artefactsFinal review due mid OctoberSubmit to Change Control Board by end of November 2019	End Nov 2019
J-GCP	Jamie Toth	<ul style="list-style-type: none">To be confirmed, pending review/understanding of JPMA deliverable	TBD
Exchange Mechanism	Paul Fenton	<ul style="list-style-type: none">See Over	Ongoing

eTMF Exchange Mechanism Standard

- ▶ Purpose: Facilitate eTMF content exchange.
- ▶ Meeting monthly
 - Business Roundtable:
 - Sponsors and CROs
 - Exchange Agreement Template
 - Vendor Roundtable:
 - eTMF vendors
 - Functional Requirements
- ▶ New release pending!
- ▶ Join us!
 - LinkedIn Group: “TMF Exchange Mechanism Standard”
<https://www.linkedin.com/groups/12136956/>
 - Business Roundtable
 1. TMF Reference Model Project Team
<https://tmfrefmodel.groups.io/g/main>
 2. Subgroup “Exchange Mechanism – Business Reviewers”
<https://tmfrefmodel.groups.io/g/Exchange-Business>

eMail SubGroup

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

Co-Lead: TBD

Objectives:	Across the industry, email is a constant problem for how we extrapolate what is relevant correspondence for a trial/study, ensuring it is transferred/held in an authoritative source/retained, and producible during a health authority inspection in a manner that is how the health authority wants to review it and viewable/accessible in the TMF.
Scope - In:	Agreements on position and recommendations for relevant email with a cross industry group ensuring that many viewpoints are incorporated (Sponsor, CRO, Vendor).
Scope - Out:	A technology tool for automation or agreeing to a technology tool.
Desired deliverables:	<ol style="list-style-type: none">1. Agreed on position for relevant correspondence, utilizing industry definitions as baseline and enhancing; tied back to the TMF Ref Model/Relevant Correspondence sections and how to handle common scenarios.2. Best practices/considerations for methods of transfer/filing in authoritative source/retaining long term.3. Best practices/considerations for producibility during a health authority inspection.4. Handling of attachments in email, as well as embedded links.
Action Plan & Timeline:	To be discussed/formulated once the group forms
Target End Date:	June 2020

Interested?

Accepting members now through 30-Sep-2019!

20 people will be accepted to the subgroup.

Looking for a mix of vendor, sites, independent, sponsor, CRO.

You need to be a TMF Reference Model Team Member to join the sub-group: sign-up here:

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

Once you are a member on groups.io, apply to join the sub-group here:

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

Questions? Send email to: jtoth@dsi.com / with Subject: email Subgroup

MHRA GCP Symposium 19-SEP-2019

- ▶ Specific to non-commercial trials.... >200 attendees
- ▶ Expectations and inspections more closely aligned with commercial trials
- ▶ eHRs (containing patient source data) have minimal standard & many systems not compliant with GCP expectations
 - especially important to consider how source data can be monitored
 - MHRA to publish further guidance (via blog)
- ▶ Wider use of eSystems at non-commercial sites: need to consider TMF implications e.g. ePrescribing

MHRA GCP Symposium 19-SEP-2019

- ▶ Investigator part of TMF Reference Model – need to accommodate broader scope of pre-protocol documents e.g. R&D review artifacts
- ▶ Oversight expectations for commercially-sponsored trials also applies to non-commercial
 - review of agreements; evidence of GCP compliance; monitoring of activities.... with evidence in the TMF
- ▶ Caution when using eSystems provided by commercial sponsor
 - Sites must have **independent** access to their data and to the system(s)... so cannot be controlled by the sponsor e.g. setting up user accounts



Trial Master File Reference Model



17-Sep to 18-Sep-2020
Pullman Brussels Centre Midi Hotel,
Brussels, Belgium



--RECAP--

High Level Overview:

Attendees:

75 attendees
50 companies
20 countries

Key themes:

1. Process – Process – Process !
2. Change management
3. eTMF and changing technology
4. Collaboration
5. Inspection readiness
6. Oversight
7. Optimization

Topics covered:

1. Compliance
2. Continuous Improvement Process
3. CRO perspective
4. Digital transformation
5. GDPR
6. Inspection readiness
7. Oversight
8. Technology
9. TMF Completeness

Key Takeaways:

- ▶ Expanded landscape includes both traditional and non-traditional players in the future, Data analytics to drive insight into the clinical trial process
- ▶ Importance of storyboards, including documenting out the Real time process for adjudication requested by FDA, and timeline for what transpired when a vendor went bankrupt and transitioning to a new vendor.
- ▶ TMF optimization of process when rolling out a new eTMF, and looking at pilot approach before a big migration.
- ▶ Ideas and methods to ensure collaboration, not just between sponsor/CRO, but also with internal stakeholders who have TMF accountability and ownership.
- ▶ How to be risk-busters and work collaboratively across functions to improve CRO oversight
- ▶ Implementing an eTMF at a small biotech and considerations, as well as resources and planning needed to be successful.
- ▶ Using a dedicated uploading pool and CTQ metrics for TMF success!
- ▶ Collaboration – having execution and enablement working together on sponsor TMFs and applying lessons learned to inspection readiness.
- ▶ Implementation tied to inspection readiness.
- ▶ Think less about docs and more about the data, and get back to GCP focus!
- ▶ Building your etmf stool, ensuring balance of people, process, technology with a CIP/PDCA model
- ▶ GDPR – It's not about consent! It's about PURPOSE and PROCESSING the data!
- ▶ Recent inspection findings and reg changes, and planning out your TMF reviews to avoid pitfalls AND TMF content review – review content in its context!
- ▶ Process harmonization, unified trainings, and challenges and lessons learned when taking etmf further to digitization

Lets get chatting!!



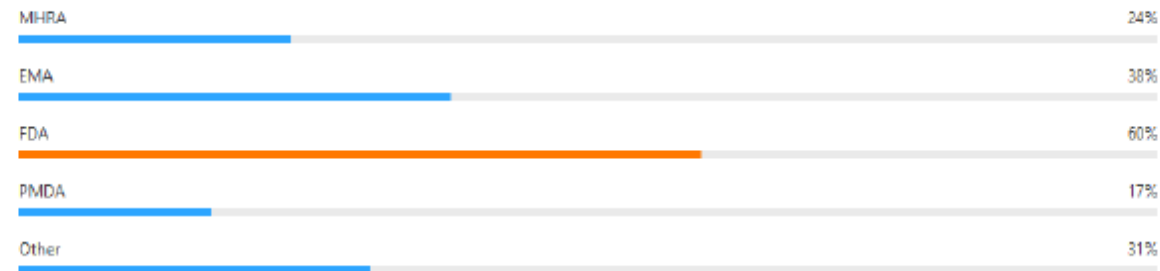
1. Who do you work for?



2. Where are you based?



1. What Inspections have you had in the past 12 months (Multiple choice)



2. Have you had an office based inspection?



3. Is yes was inspector access to the eTMF closed immediately after the OBI, immediately after the site-based inspection, or kept open beyond the end of the site-based inspection.



4. What was the biggest challenge in responding to the Inspectors



5. Was there a big focus on Audit Trails



6. Was archiving a topic of questioning?



1. Follow-up letters: 05.04.12 - do you keep them separate to the monitoring visit report?

yes 59%



Response	Percentage
yes	59%
no	41%

no 41%

2. Site Evaluated Not Selected: 05.01.05 - do you store this information?

Yes 85%



Response	Percentage
Yes	85%
No	15%

No 15%

3. Affiliation Form: 05.02.04 - do you collect this form?

Yes 29%



Response	Percentage
Yes	29%
No	71%

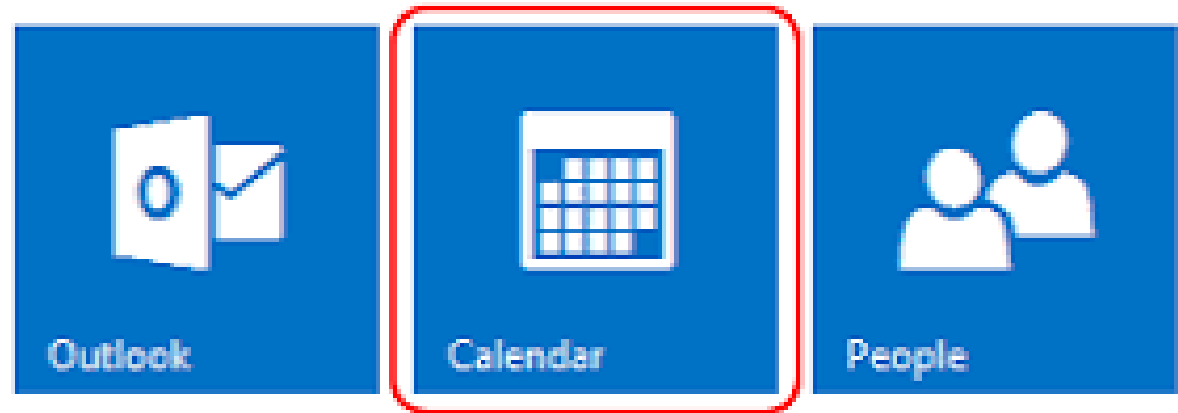
No 71%

TMF-related events coming up

- ▶ ExL TMF Summit, London, UK, 1–3 Oct
- ▶ SCRS Global Site Solutions Summit, Florida, USA , 11–13 Oct
- ▶ MAGI Clinical Research, Las Vegas, 28–30 Oct
- ▶ ExL TMF Summit, Orlando, USA, 21 – 23 Jan

TMF RM General Meetings

- ▶ <18 Nov>
- ▶ Add to your calendar NOW or download the calendar file (.ics file) when you receive the meeting notification from MailChimp or from our [homepage](#)
- ▶ Outlook Meeting Request no longer distributed



QUESTIONS?

Join the TMF Reference Model Yahoo! Discussion Group

<https://groups.yahoo.com/neo/groups/tmfrefmodel/info>

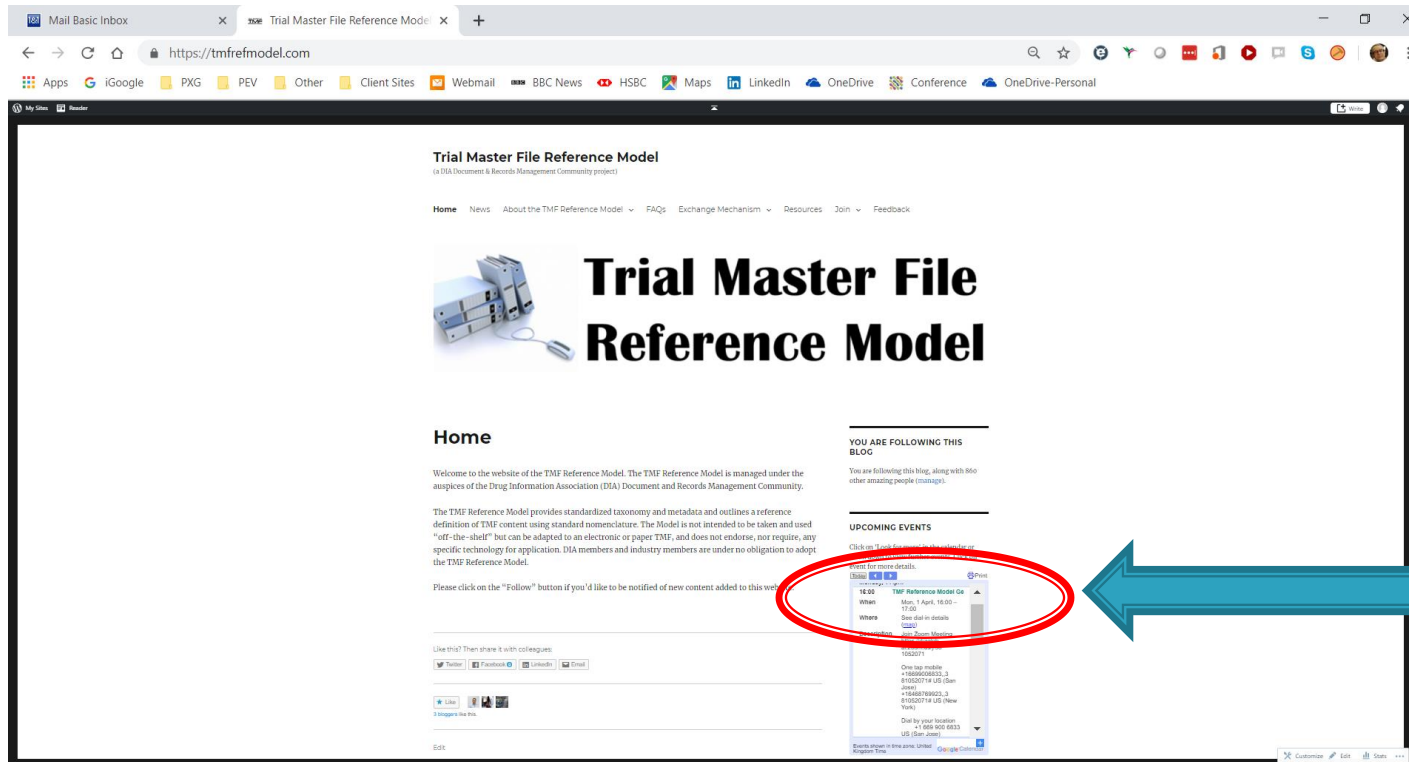
- Knowledge sharing
- Networking
- Too Much Fun!

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

<http://tmfrefmodel.com/join>

Meeting details

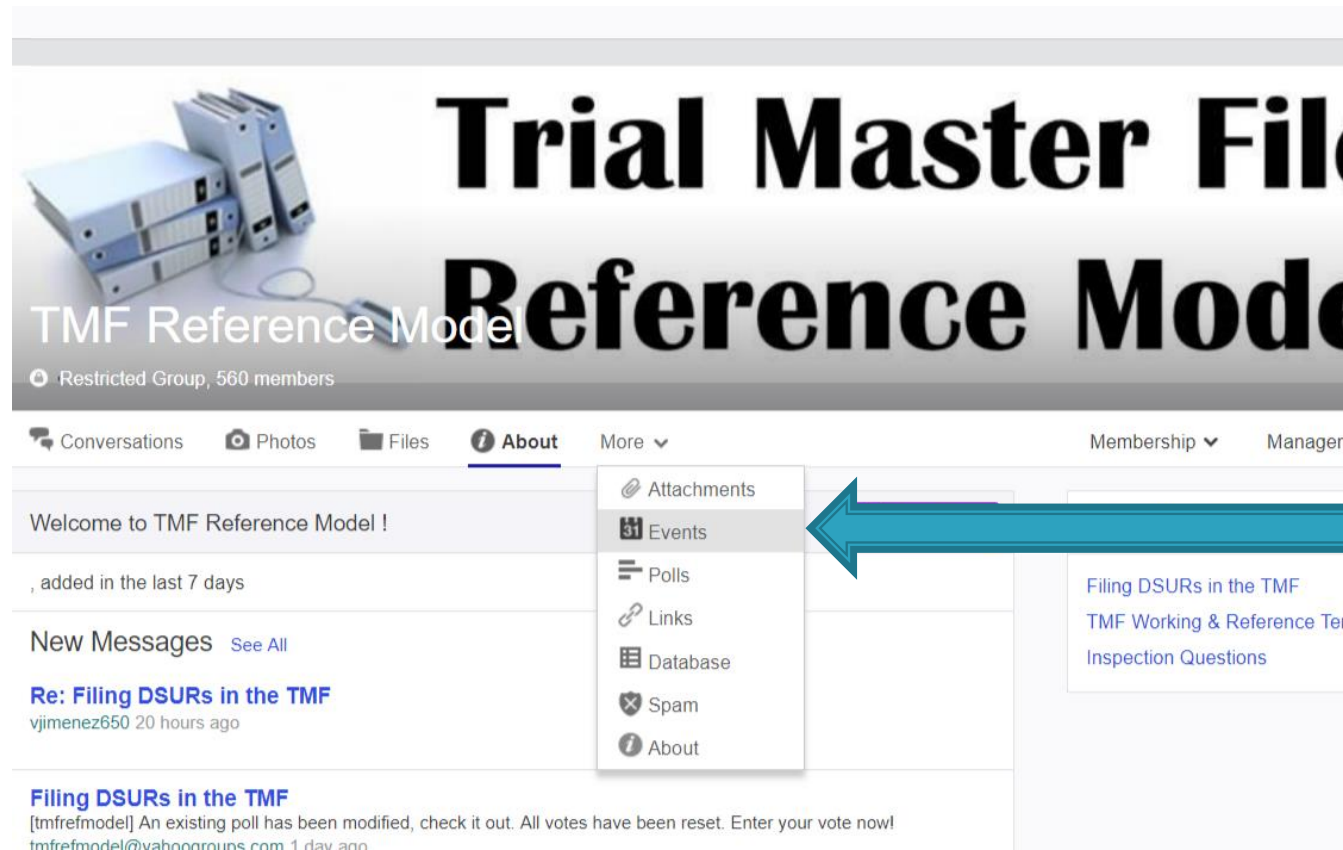
- ▶ Wondering where to find details of the next meeting?



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 Yahoo!Groups, click on Events to show group calendar. Click on an event to see dial-in details

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/>



Groups.io Your Groups 4 Find or Create a Group

main@tmfrefmodel.groups.io / Calendar

< > today

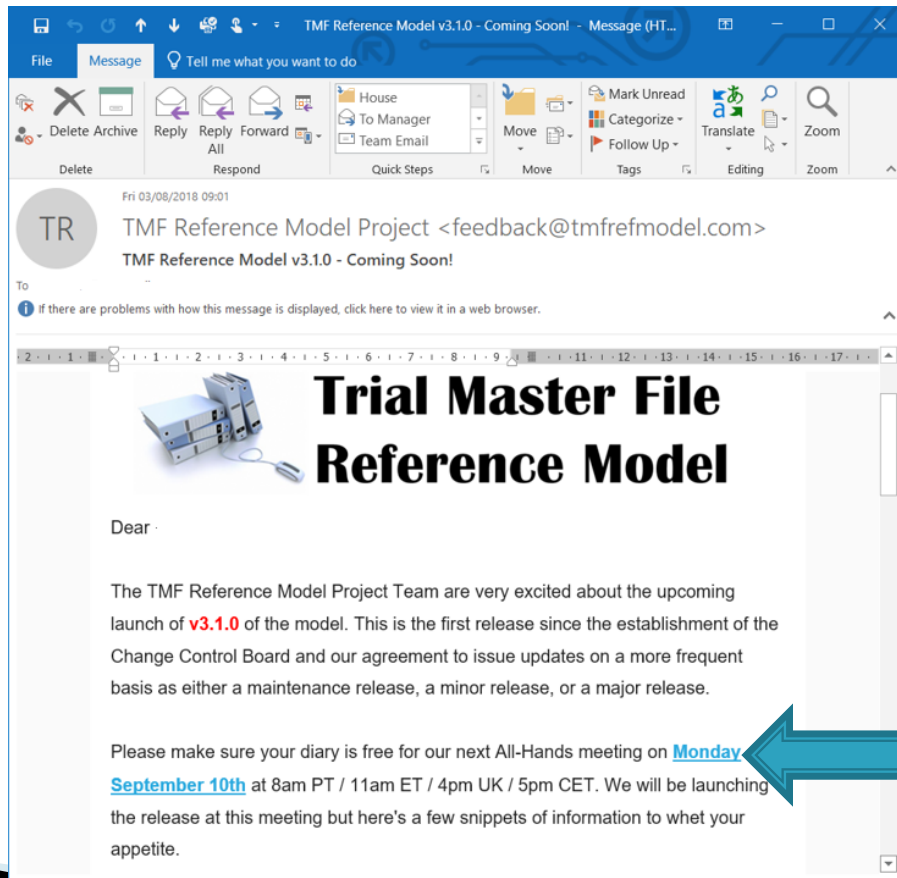
Septem

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

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Meeting details

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



In Reference Model emails, click to download calendar file (.ics) for import into your Outlook/Google calendar

TRIAL MASTER FILE
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