Trial Master File Reference Model

General Meeting

3 June 2019

Agenda

- Welcome
- Membership Update
- Steering Committee Update
- Active Initiatives
- MHRA StEM Summary
- HSRAA Summary
- Some more fun – Interactive discussions
- Upcoming Events

Since last meeting*…

▶ 20 new project team members – current total 289

▶ 26 new Mailing List Subscribers – current total 836

▶ 11 new Yahoo!Group Forum members – current total 602
  ◦ 8 new discussion topics posted (21 messages)

▶ LinkedIn group – 2,799 members (42 new members)
  ◦ 7 new discussion topics posted

▶ For details on all these different groups and how to get involved, see http://tmfrefmodel.com/join

* 1 April 2019

Steering Committee Update

- Successful committee members:
  - Karen Roy
  - Allison Varjavandi
  - Marie-Christine Poisson
  - Sholeh Ehdaivand (Introduction!)

- Technical Administrator: Eldin Rammell

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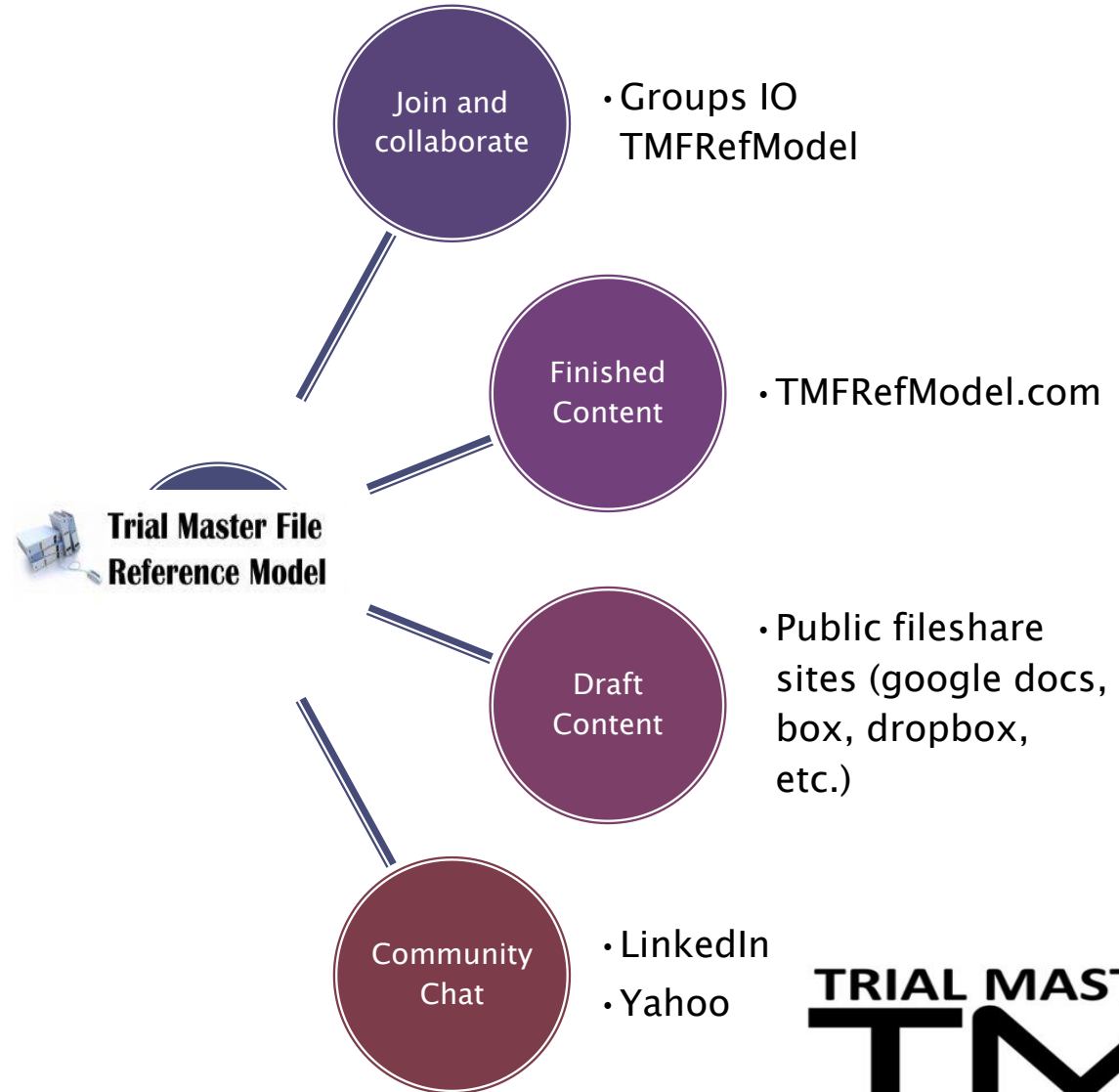# How do I access the TMF Reference Model???

We are an R&D industry volunteer collaborative initiative, and welcome all interested participants!

We strive to make everything available to all (inclined to sunshine)

We rely on free-ware to accomplish our work (no money, honey)

We have been at it since 2009, and have tons of content (gots a lot)

To help you navigate the world of TMF RM...

Trial Master File Reference Model

Join and collaborate
- Groups IO TMFRefModel

Finished Content
- TMFRefModel.com

Draft Content
- Public fileshare sites (google docs, box, dropbox, etc.)

Community Chat
- LinkedIn
- Yahoo

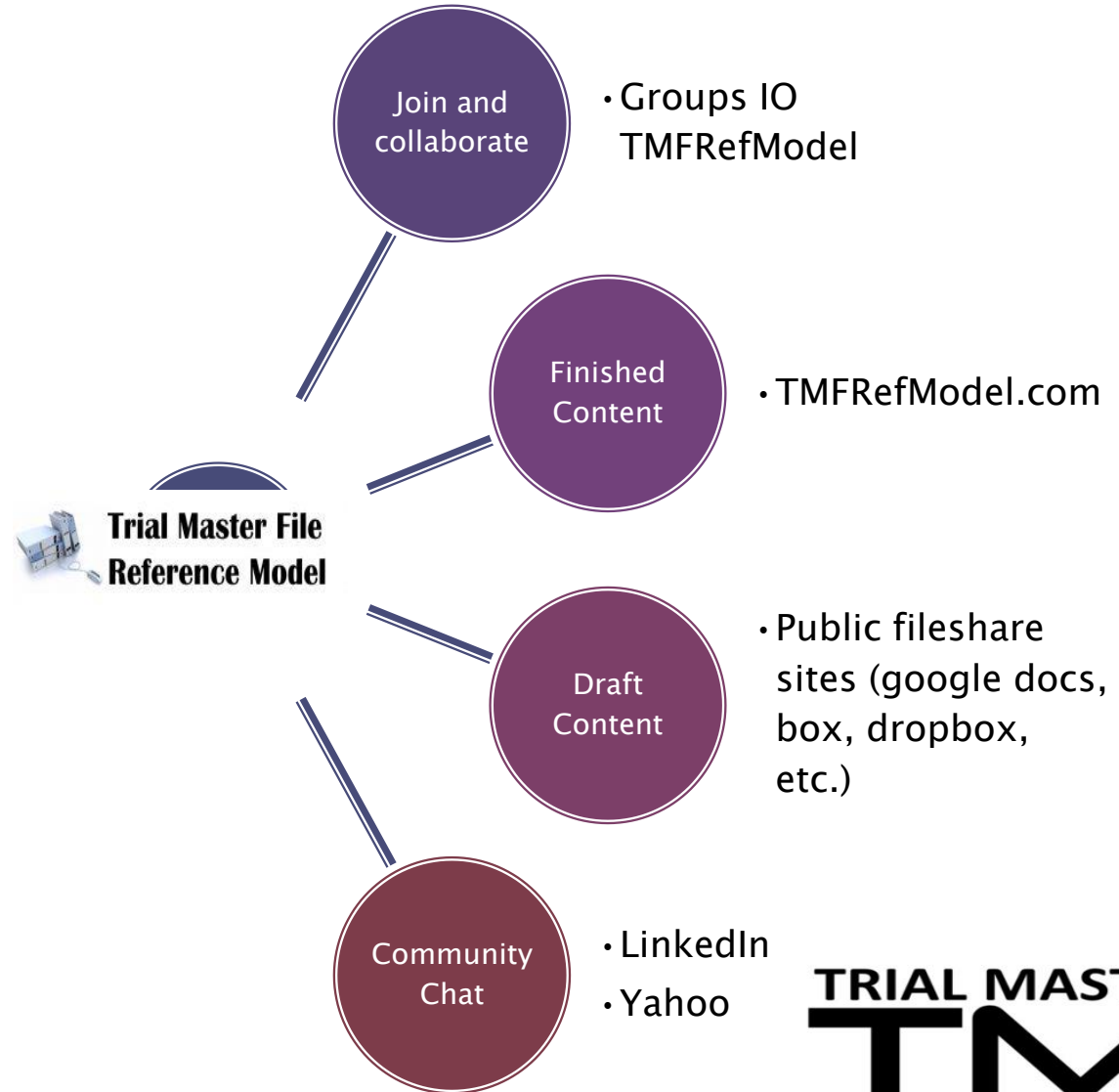**TRIAL MASTER FILE TMF REFERENCE MODEL**

TMF Ref Model community tips

Join IO and our public meetings

Get to know us by adding to the community chat

Join a subgroup and make a difference

Find a member and get support – we're happy to help!

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TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Investigator TMF Clarifications	Fran Ross	• Terminology position paper post IQPC Conference workshop	October 2019
Devices	Undergoing change	• Enhancements/updates to the TMF Reference Model to facilitate easier adoption for medical device and diagnostics trials. • → Submit to Change Control Board	Mid 2019
Sub-artifacts	Karin Schneider	• Comprehensive revision of the 'sub-artifact' examples in column I • → Submit to Change Control Board	September 2019

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TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Annual Survey	David Ives	• Completed industry survey	September 2019

Observational Studies	Russell Joyce	• Focus on "Prospective Non-Interventional Study involving a Medicinal Product"
		• Identified from TMF Ref Mod v3.0
		  • 12 Core NIS artefacts
		  • 98 Recommended NIS artefacts
		• → Submit to Change Control Board
			End June 2019

J-GCP	Jamie Toth	• To be confirmed, pending review/understanding of JPMA deliverable	TBD
Exchange Mechanism	Paul Fenton	• See Over	Ongoing

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eTMF Exchange Mechanism Standard

- eTMf Vendor Roundtable
  - Meeting monthly
  - Version 1.0, Release 19.1.5
  - Defining scope for testing
- Business Roundtable
  - Sponsors, CROs, system integrators
  - Meeting monthly
  - Exchange Agreement template
  - Feedback to Vendor Roundtable

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Framework for Destruction Survey

- New survey for the Framework for Destruction Group as a follow-up to the release to both inform and to gather information.
- Very short survey (takes 3-4 minutes)
- Please consider posting to your relevant social media contacts
- The link to the survey is:
  https://www.surveymonkey.com/r/Z9PB8J2
- Results will be posted to this website soon, likely in the early summer months.

MHRA Stakeholder Engagement Management Meeting (StEM)

- Review of audit trails resulting in increased time on inspections….. how can we make this review more efficient for inspectors?
- Still too much time getting access to systems at the start of the inspection. Aim to provide increased time for sponsors to prepare for inspections e.g. pre-inspection document requests
- Office Based Inspections (OBI) are part of the new programme
  - Day 1 = remote OBI
  - Post Inspection access to reduce the need for extended return visits
  - Office-based inspection (OBI) piloted successfully for 11 routine inspections. OBI requires that TMF content should "speak for itself"…. without explanation from study team

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MHRA Stakeholder Engagement Management Meeting (StEM) cont.

▸ AI / Machine Learning / Deep Learning is the next big revolution in clinical research
▸ Technology may also drive evolution to virtual trials..... no investigator, no sites
▸ Initial step in adoption of AI is "augmented intelligence".... still requires human activity but supported by AI
▸ Do we really have the ability to test AI algorithms to ensure they are accurate?
▸ MHRA Initiative to understand the impact of Artificial Intelligence

▸ Validation documentation providing an ongoing challenge in terms of time to review and retention procedures – do the Sponsor have to keep it all?
▸ MHRA confirms a risk-based approach to validation is acceptable, taking account of criticality of data, experience of vendor, type of system
▸ Need agreement with vendor for them to retain validation records for an appropriate length of time and make it available for inspection – must be stipulated in the contract between vendor and sponsor

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MHRA Stakeholder Engagement Management Meeting (StEM) cont.

- Non-commercial GCP Symposium scheduled for 11 September 2019 in Manchester
- Joint FDA/MHRA commercial symposium March 2020 in London
- MHRA are testing their own portal for electronic exchange of documents between sponsor and MHRA
- Inspectorate blog is primary means of communicating important information…. subscribe to ensure you receive notification of updates

- Full minutes found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/804334/Minutes_of_the_Stakeholder_Engagement_Meeting_May_2019_Final.pdf

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HSRAA Conference Feedback

Health Sciences Records & Archives Association Annual Conference
Cardiff, UK – May 2019

## Summary

- Two Workshops held on Day 0 of Conference:
  - Implications of GDPR on Records Management
  - Data Integrity Expectations, Challenges, and Best Practices for GxP Compliance

- Two day conference theme was data integrity across all of GxP as it pertains to records, including ways that technology will look at improving records management in the future with AI and automation.
- Presentations:
  - Andy Fisher presented on Data and Compliance, which discussed the importance of both for records and archives as well as preservation of records, including emails.
  - Lisa Mulcahy presented update on Framework for Destruction of Paper.
- Other notable topics included:
  - An update from HARG, eArchiving GLP data and study data, Wearable Devices, AI and Machine Learning, and Automation.
  - Case studies on Quality, Knowledge Management, implementing an EDMS, considerations for EDMS vendor selection

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Lets have some more fun!

June 2019

Monday 3rd Jun 2019

- Demographics
- Getting the TMF right
- Destruction
- Archiving
- Interchange of TMFs
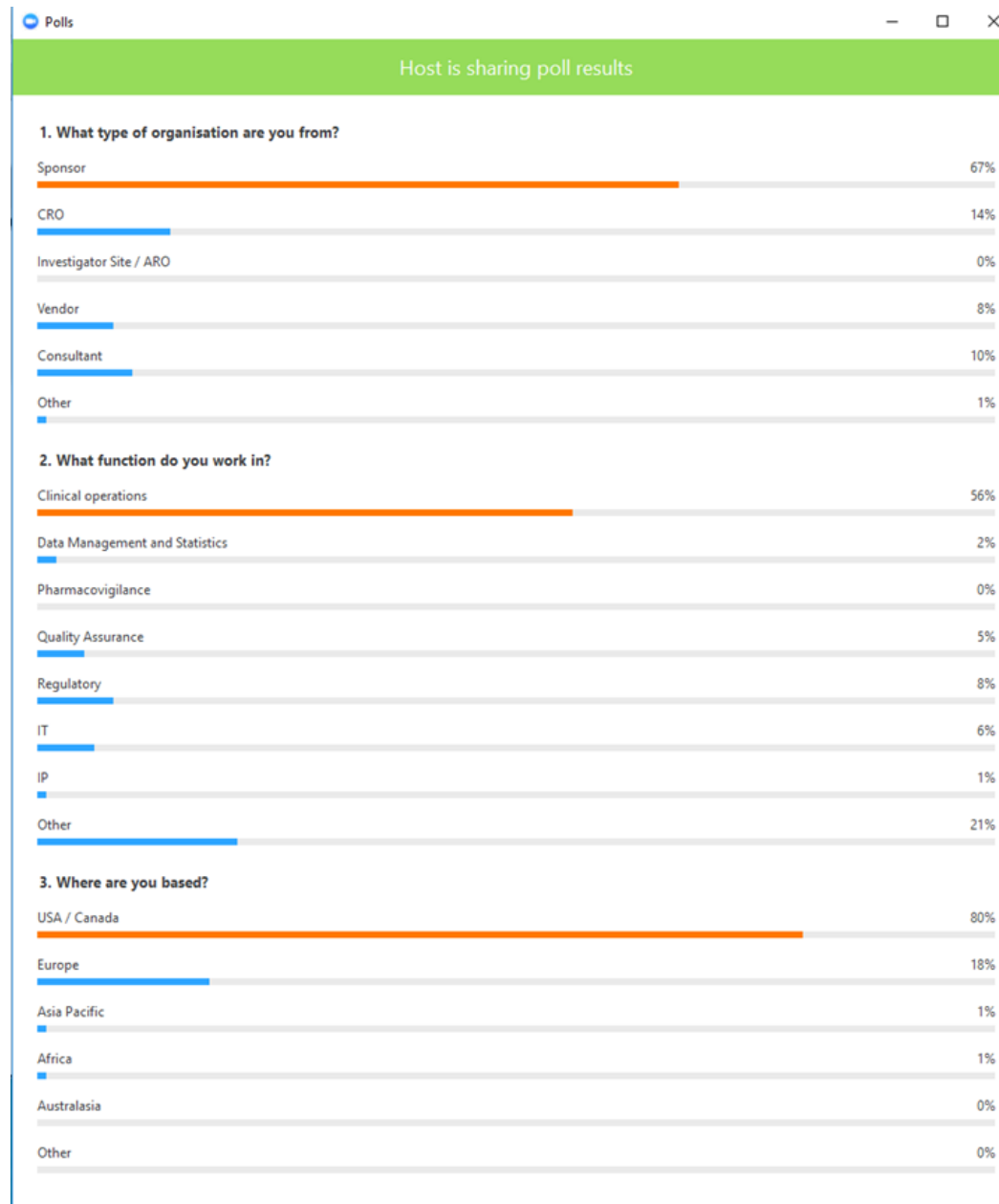
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Comments on Poll 2

Pre populated forms/templates to decrease duplication of info, Less trackers

More functional area accountability

An EDC style TMF

Standards around milestone based quality reviews for sponsors

Timeliness and completeness are co-related though

Completeness factor - Until eTMF is a value add part of project management completeness will remain a struggle people don't live in their TMF most project teams live in Sharepoint or share drives because...

Documents can reside in other locations...there isnt a regulation that states it must all be in one place. as long as your 'tmf map' states that, and the content is mapped appropriately.

Completeness would be better if more artefacts were created within the TMF

And what if we had audit findings if the auditors found those documents in other systems :-)

Using templates in the TMF system and creating artefacts from there where possible

some eTMF applications are a full lifecycle document management system, therefore the review and approval is done in that system...it's a relatively new concept but becoming more and more common.

our documents are created in the system, content is reviewed and approved, and then upon finalization automatically become visible in the eTMF if they are considered TMF docjuments

It's a move away from people thinking of the TMF as an "archive"

We (the people on this call ;) are always seeking out ways to drive active ownership/engagement from the cross-functional trial team, who are the people closest to the conduct of these processes and activities/events that comprise a TMF (either a central system or set of mapped locations)... Only their buy-in and mindset shift will give us confidence in our Completeness reports, that they are still current in terms of measuring what's captured with what's expected to be captured at a given moment/milestone of the trial.

The systems help...but it's the companies AWARENESS and dedication to TMF management.

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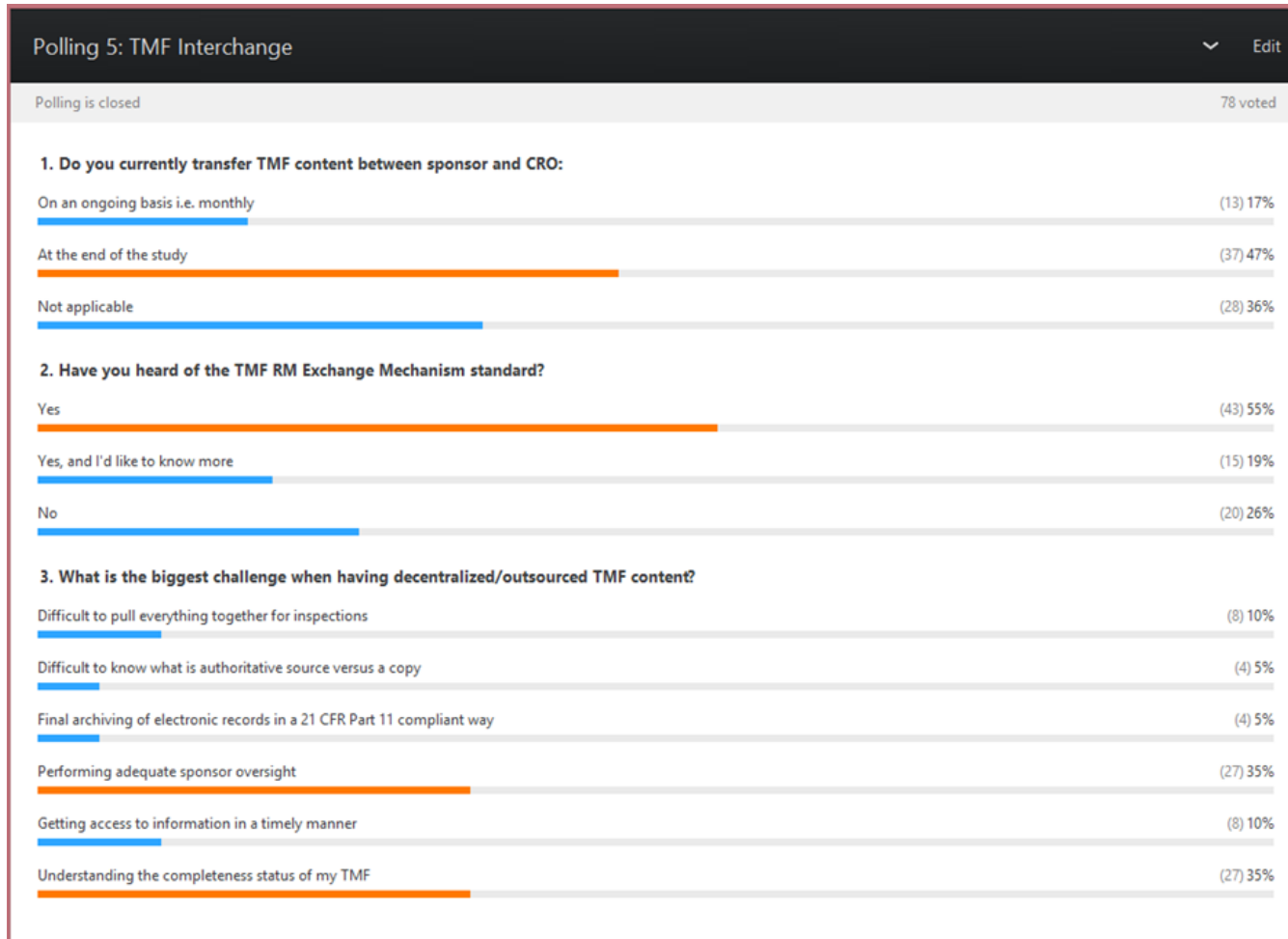
If you are using multiple eTMF's its really difficult to agree on who files what...everyone wants a copy of the central trial documents in their TMF...even though they are filed (probably) in the sponsor TMF...so yes, difficult to make the agreement.

Exchange mechanism will also help with eArchiving..... mitigating technology obsolescence

TMF-related events coming up

- DIA Annual Conference, San Diego, 24-26 June
- TMF and Document Management, Anaheim, CA, USA 10 -12 Sep
- IQPC TMF & Inspection Readiness Conference, Brussels, Belgium,16-19 Sep
- ExL TMF Summit, London, UK, 1-3 Oct
- SCRS Global Site Solutions Summit, Florida, USA , 11-13 Oct

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TMF RM General Meetings

- **23 September 2019**
- 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

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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
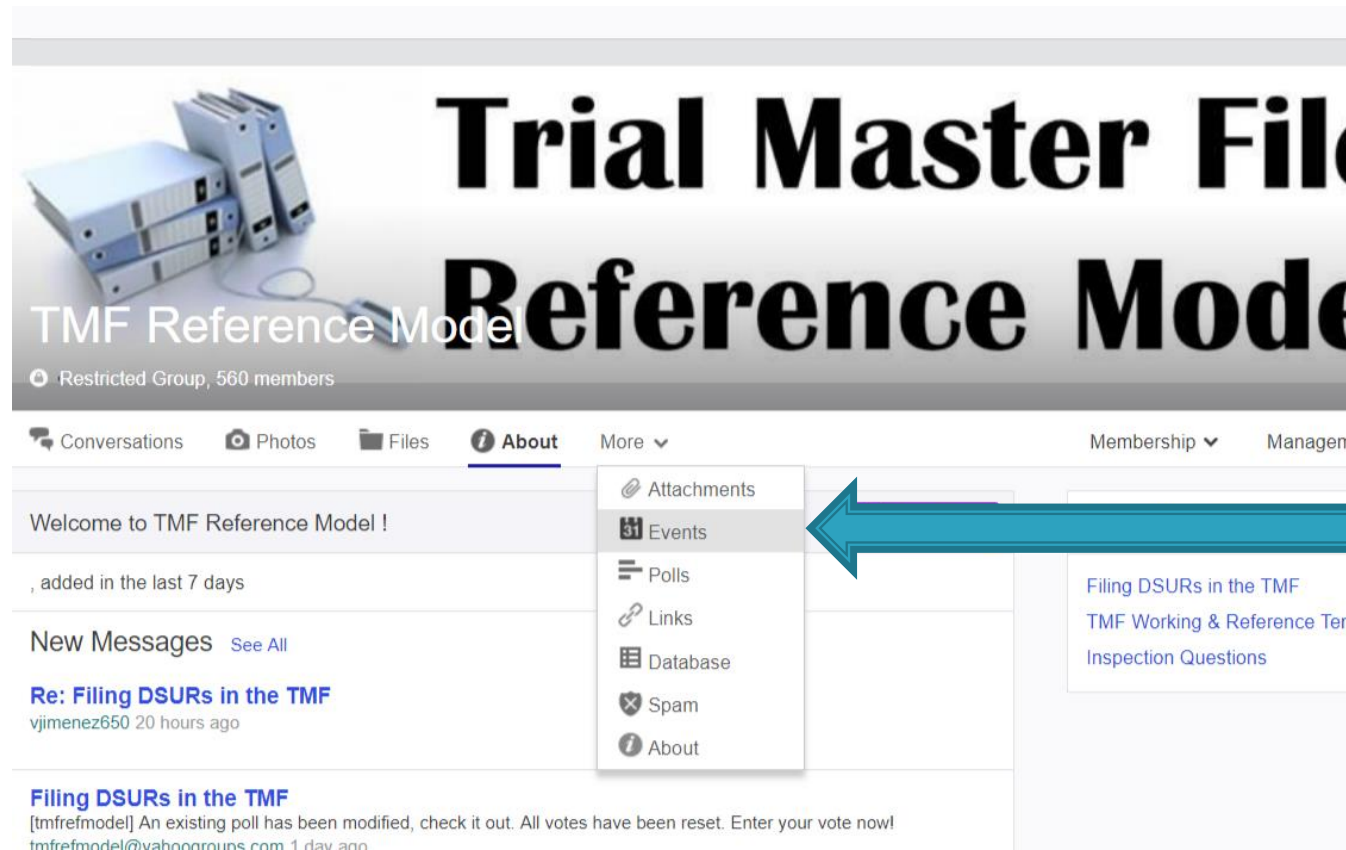
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Meeting details

▶ Wondering where to find details of the next meeting?
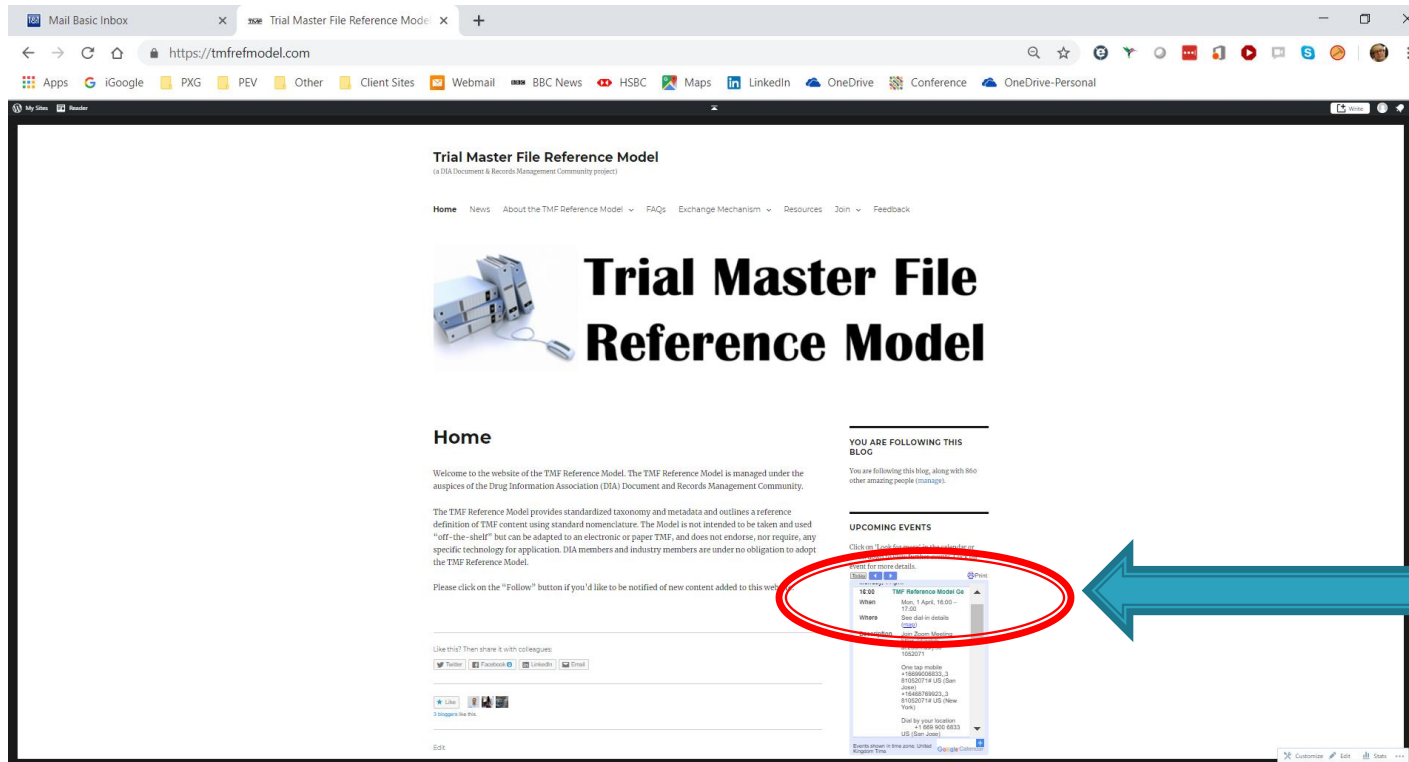
On TMF Reference Model website, click on calendar to see meeting details. Click 'Copy to my calendar' to add to your Outlook / Google calendar.

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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

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Meeting details

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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**/

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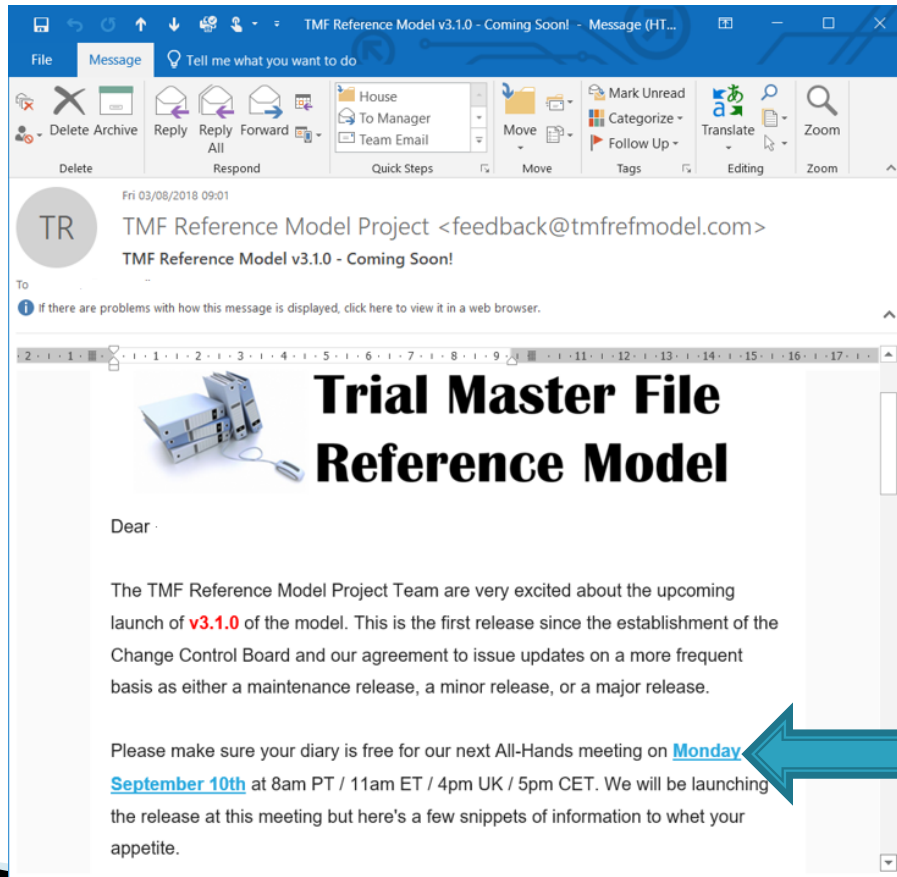
In Reference Model emails, click to download calendar file (.ics) for import into your Outlook/Google calendar