Trial Master File Reference Model

General Meeting

1 April 2019

While we are waiting for attendees to join and the host to start the meeting, all lines will be muted. Please stay on the call. You can unmute yourself when you want to talk!

Agenda

- Welcome
- Membership Update
- Sub-group / Initiatives update
- The FUN BIT
- Upcoming Industry meetings
- Meeting reminders (instructions at the back)

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Since last meeting*…

- 12 new project team members – current total 269
- 24 new Mailing List Subscribers – current total 810
- 6 new Yahoo!Group Forum members – current total 591
  - 5 new discussion topics posted (9 messages)
- LinkedIn group – 2,757 members (27 new members)
  - 2 new discussion topics posted

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

* 11 Feb 2019

TRIAL MASTER FILE TMF REFERENCE MODEL

Steering Committee Update

- Three-year term expires for:
  - Karen Roy
  - Eldin Rammell
  - Allison Varjavandi
  - Marie-Christine Poisson
- Self-nominations to: feedback@tmfrefmodel.com
  - Must have been registered on groups.io as a member for at least 12 months
  - Maximum 1 SC member per business entity/organization
  - Nomination closes April 12
- Voting by project members if >4 nominees

TRIAL MASTER FILE TMF REFERENCE MODEL

Technical Administrator [1 /2]

- Registration of new members, processing membership changes
- Responding to technical issues
- Configuring and maintaining IT platforms
- Publishing information from SC on website
- Optimization and development of IT tools by project team
- Reporting to SC, including statistics
- **NOT** a SC member role

TRIAL MASTER FILE TMF REFERENCE MODEL

Technical Administrator [2/2]

- Role description: see TMF Ref Model website
  - https://tmfrefmodel.com/about/tmf-reference-model-steering-committee/
- Activities carried out to date by Eldin Rammell
  - Eldin has developed the role description and has put himself forward to establish this as a new non-SC role **but**
  - The position is open for self-nomination from members (vote of members if >1 nominee) to kroy@phlexglobal.com
  - Nomination closes April 12

TRIAL MASTER FILE TMF REFERENCE MODEL

TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Investigator TMF Clarifications	Fran Ross	• Terminology position paper	Mid 2019
Document Status	Scott McCulloch	• White Paper summarising/referencing current regulatory positions on: certified copies; filing of originals; management of document versions	Mid 2019
Devices	Melonie Warfel	• 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	June 2019

TRIAL MASTER FILE TMF REFERENCE MODEL

TMF RM Active Initiatives

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

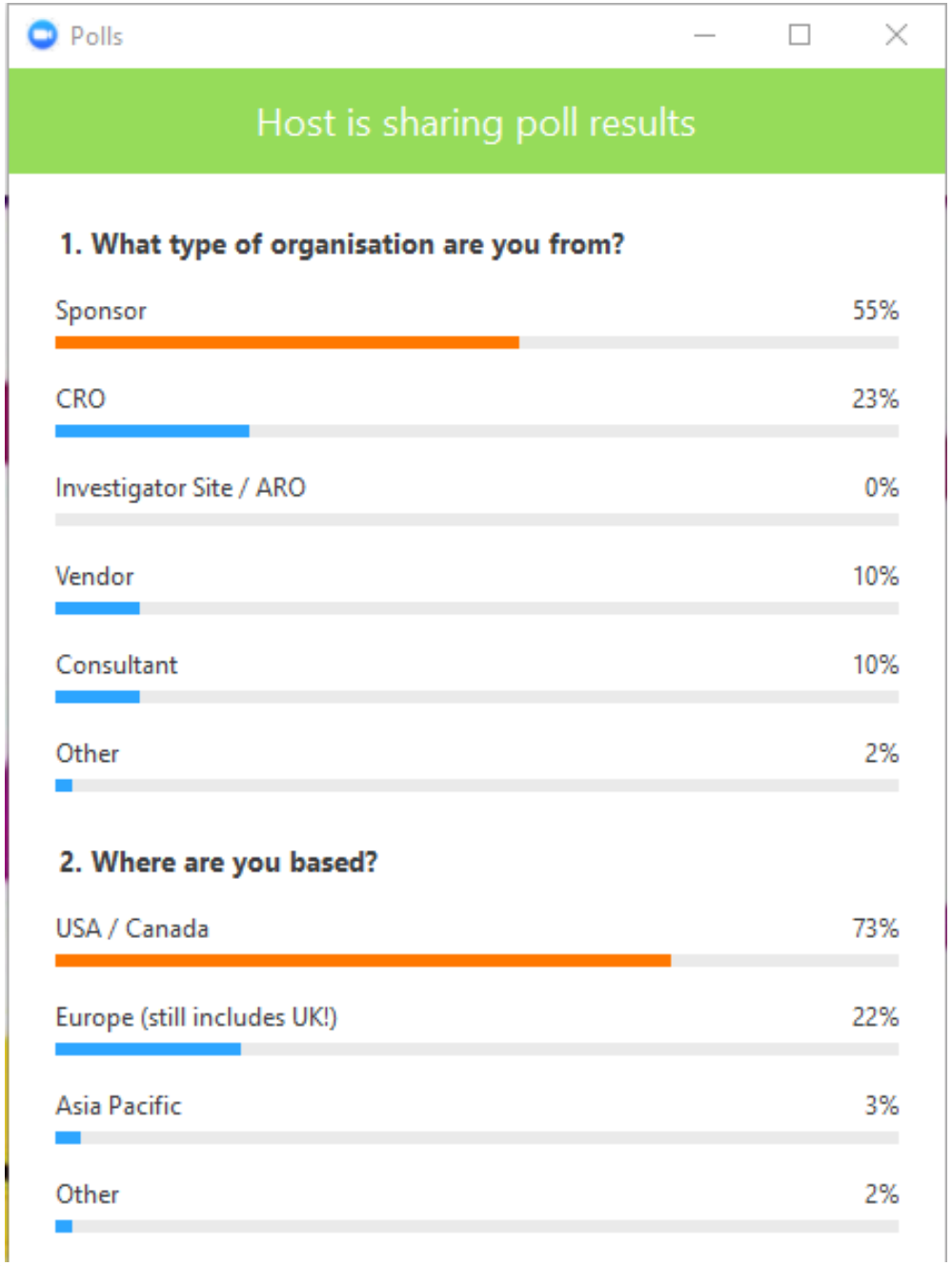
Observational Studies	Russell Joyce	• Focus on "Prospective Non-Interventional Study involving a Medicinal Product"
		• Identified from TMF Ref Mod v3.0
		  • 17 Core NIS artefacts
		  • 107 Recommended NIS artefacts
		• → Submit to Change Control Board
			End May 2019

J-GCP	Jamie Toth	• To be confirmed, pending review/understanding of JPMA deliverable	TBD
Exchange Mechanism	Paul Fenton	• Initiation of Vendor Roundtable meetings • EMS Business Roundtable starting up in April, co-chaired by Kristen Bretzius and Fran. • First likely effort is an Exchange Agreement template.	Ongoing

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Lets have some fun!

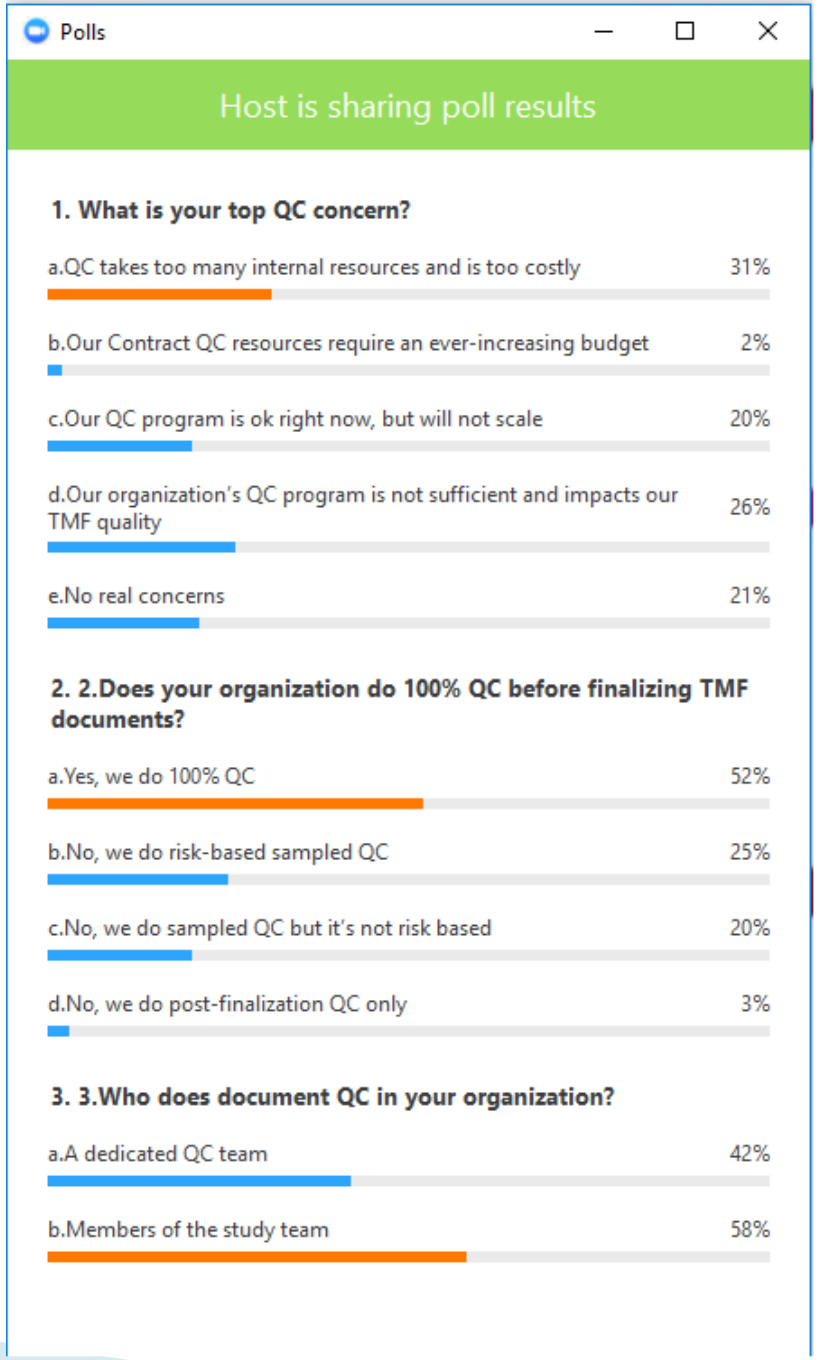
TRIAL MASTER FILE
TMF
REFERENCE MODEL



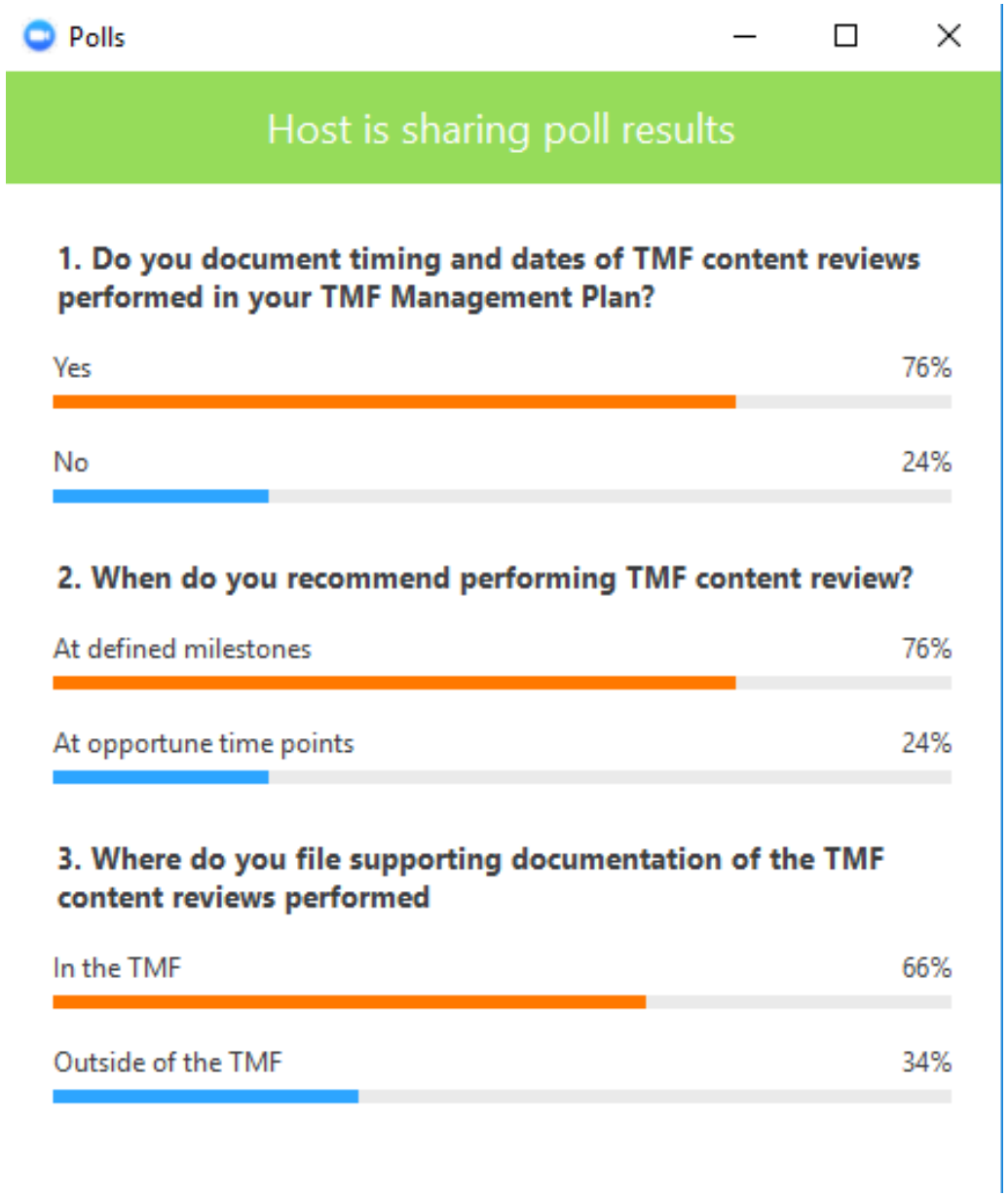
TRIAL MASTER FILE
TMF
REFERENCE MODEL

Quality Control

- Content would be the SM, ALCOAC would be QC team
- 100% of all documents submitted, yikes!!! where is the faith
- If you do QC post-finalization, it's too late to fix it



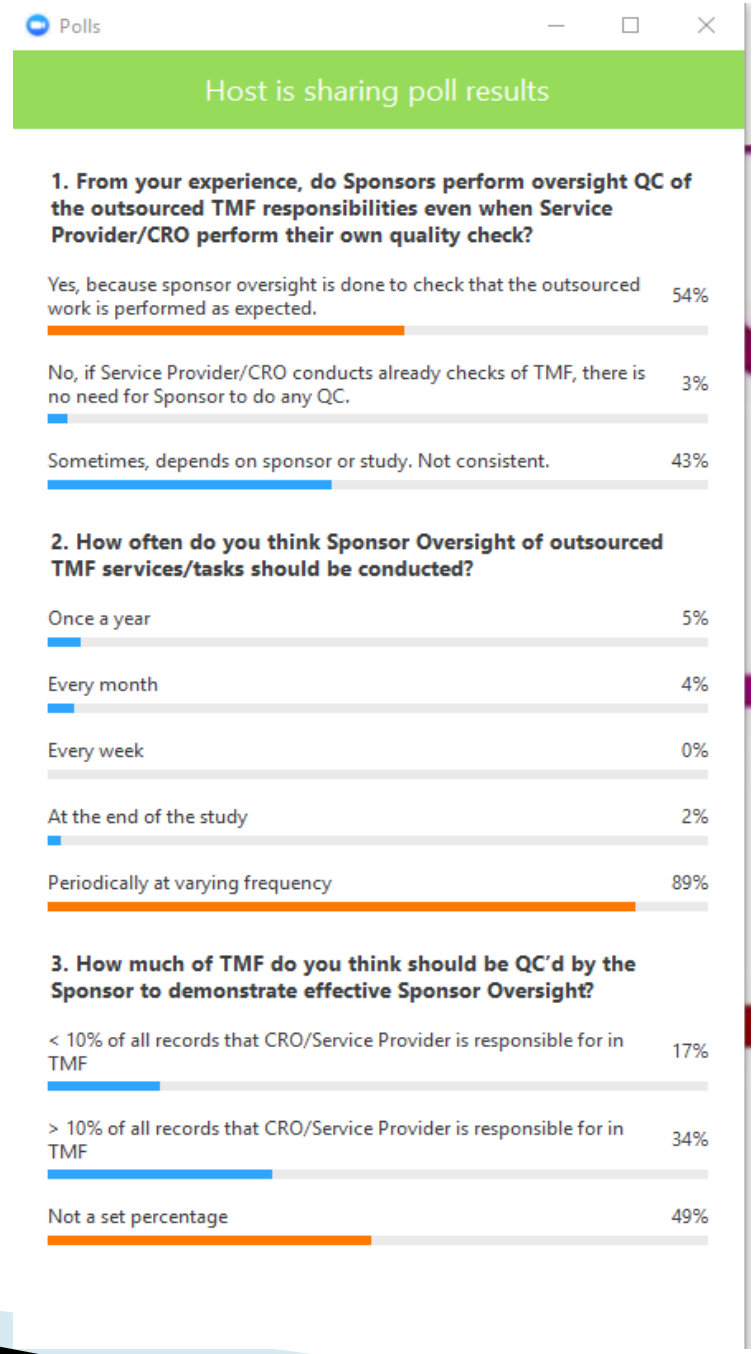
TRIAL MASTER FILE TMF REFERENCE MODEL



TRIAL MASTER FILE
TMF
REFERENCE MODEL

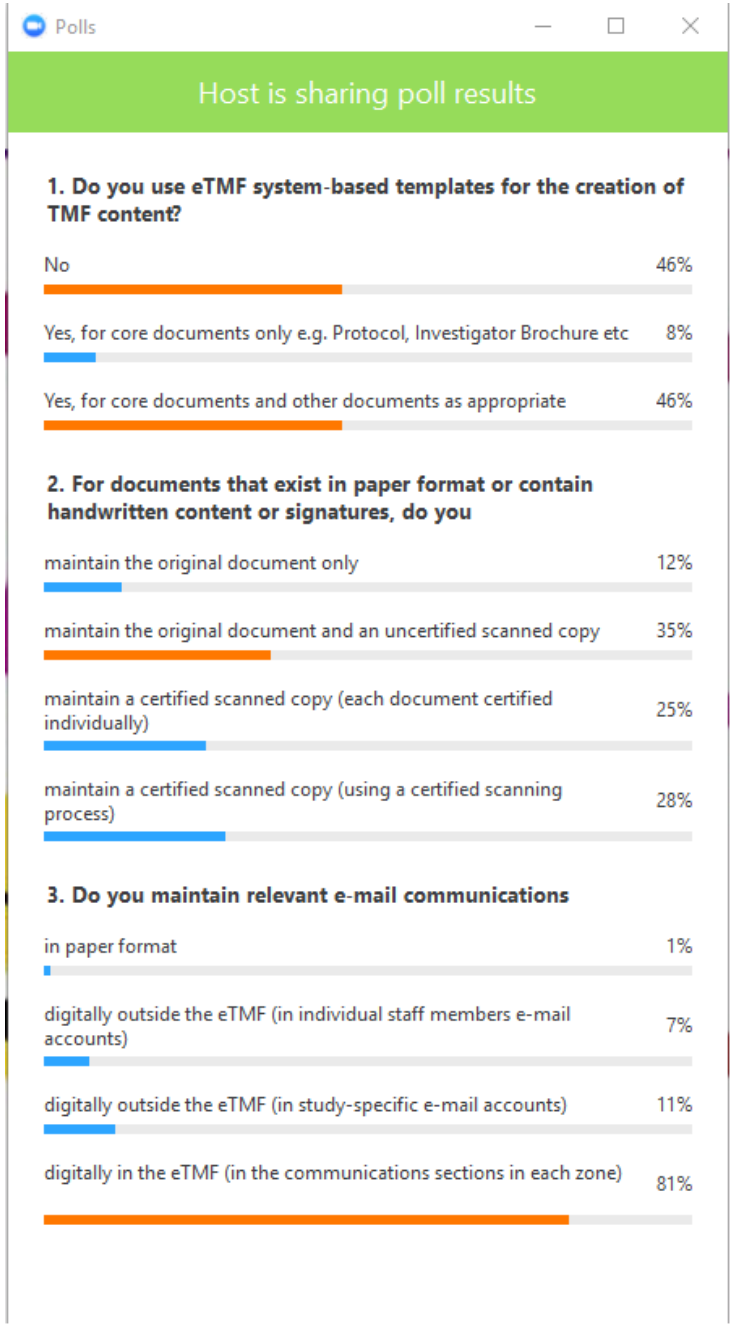
Content Review

- Only a certificate, not the findings...for the last question. we want to keep some information up our sleeve
- Agree, we only file certificate/ QC form, but not all the details of findings
- Same here - we document that we completed the review in the TMF, but the worksheets are stored outside the TMF.
- From a sponsor perspective, we file TMF review docs in TFM as part of sponsor oversight...maybe we shoudl switch to certificate only
- I'm surprised so many are filing the supporting documentation IN the TMF...
- We put a NTF in the TMF but the observations/ action items tracker are filed elsewhere.
- We require a attestation that the review/reconciliation has been completed.
- We put it in the TMF when all completed.
- We maintain a separate working file system with both.
- We have our CROs put in their logs and quality reviews
- I know that for some of our CRO clients, sponsors reqiure this
- Regarding number of people resourced for full TMF QC, how many are being put toward the effort?
- QC is not QA. We are keeping QC and QA data filed separate..
- Once a quarter .. Or at milestones
- Agreed, periodically = quarterly for me...
- It depends on the length of the trial
- We use a risk based approach based on enrollment for high enrolling sites and countries.
- Thanks.. quarterly or twice a year, depends on risks
- Sponsors are reviewing the entire TMF on a quarterly basis, wow, that's a lot of resources…
- Also depends on CRO performance
- but, should be on new documents as a routine so length of trial should be less impactful
- Yes - i think the performance/risk based is key
- Periodically = quarterly for me too, witht the percent QC'd being risk based
- Not set % = depends on CRO performance
- Phase 1 studies not quarerly, as they are too short
- Phase 1 early phase done at least once depending on duration of study
- Findings do not immediately go to 100%, there are algorithms for sampling plus risk based assessment of sections
- We set a threshold, but it will change if we find issues.
- We generate an error rate from the review and do a trend analysis to determine if more needs to be done.
- Risk based on a number of factors
- We're still at 100%
- It's based on at risk documents initially. then make modifications based on findings
- Document review would be a pass/fail rate, 25% of first 100 documents, if more than 25% fail, then keep going with review…i.e. another 25%
- We review critical sections and then make decision if go further
- I think it increases depending on issues identified--but have never seen it increase to a FULL 100%...
- 10% then increase if issues; also if too many errors, go back to CRO to take a better look at their QC review
- Thanks all! We are still doing 100% as sponsor (on top of CRO review) - trying to update this process
- What algorithms are being used for ...sampling plus risk based assessment of sections?
- Quarterly - Trial Level 100% key documents; Country Level 100% key documents of 10% active countries; Site Level 100% of 10% active sites
- I have also see, square root of N (sites) +1, then 75% pass rate is required. If fail, then continue review in cycles



TRIAL MASTER FILE
TMF
REFERENCE MODEL

- Email Communications…Specific Outlook mailboxes and standard format of subject lines
- For the document templates, it depends on Sponsor preference and comfort with creating documents in the system.
- Love the third question and a big topic of discussion with some of my clients…some specific rules on email inbox's with codes in the 'subject lines' which automatically files the documents, then the inbox is reviewed by the team on an annual basis.
- We keep patient safety communications directly in the TMF, but a majority of communications are digitally filed outside the TMF.
- Those using BOTS – share with us!
- BOTS = smart algorithms
- Challenging to find anything when kept outside TMF in separate electronic location.



TRIAL MASTER FILE TMF REFERENCE MODEL

TMF-related events coming up

- MAGI Clinical Research, Boston, USA, 5-8 May
- HSRAA Conference, Cardiff, UK 8-10 May
  - Andy Fisher speaking
- DIA Annual Conference, San Diego, 24-26 June
- IQPC TMF Conference, Brussels, Belgium,17-19 Sep
- TMF Summit, London, UK, 1-3 Oct
- SCRS Global Site Solutions Summit, Florida, USA , 11-13 Oct

TRIAL MASTER FILE
TMF
REFERENCE MODEL

TMF RM General Meetings

- 3 June 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

TRIAL MASTER FILE
TMF
REFERENCE MODEL

QUESTIONS?

Join the TMF Reference Model Yahoo! Discussion Group
https://groups.yahoo.com/neo/groups/tmfrefmodel/info

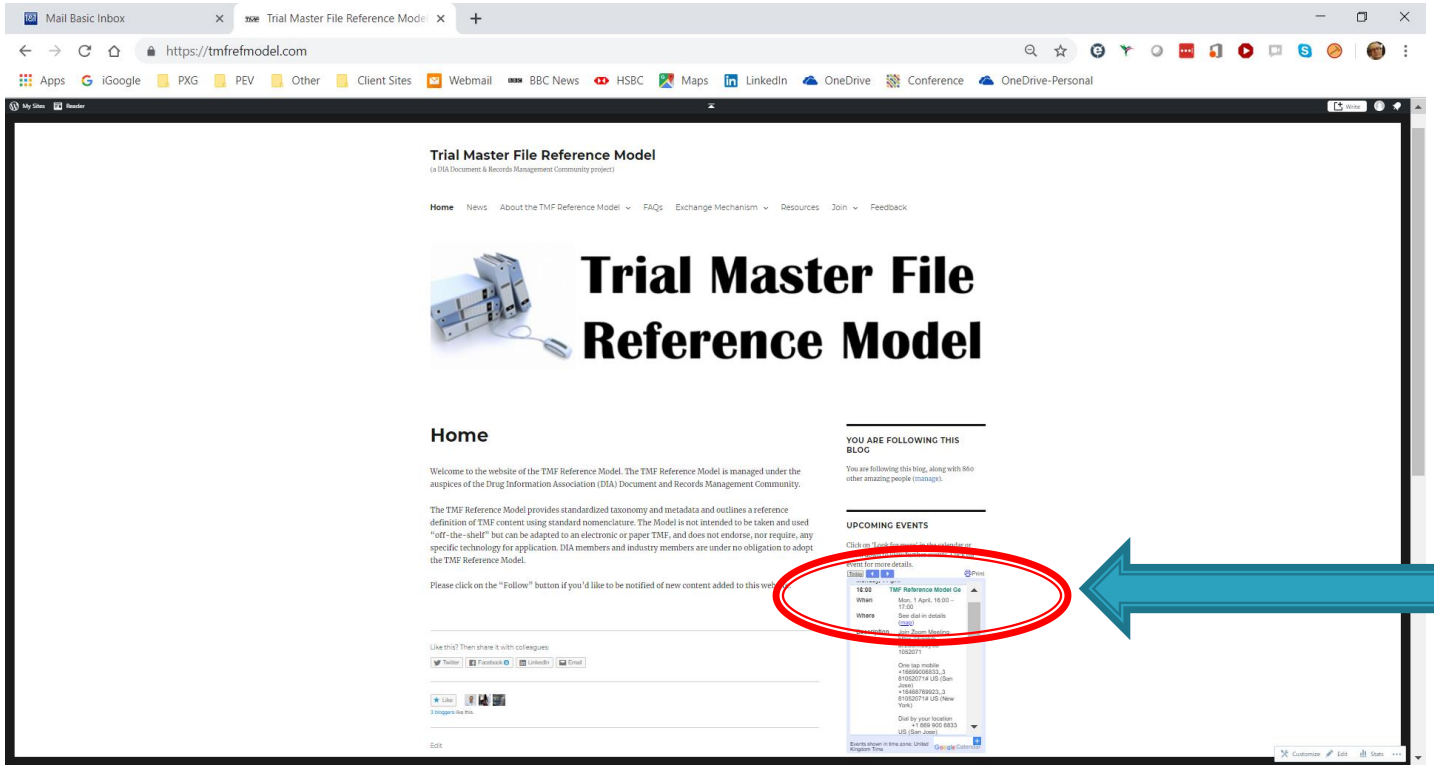
- Knowledge sharing
- Networking
- Too Much Fun!

Join the TMF Reference Model Project Team
(but be prepared to work!)
http://tmfrefmodel.com/join

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Meeting details

- Wondering where to find details of the next meeting?

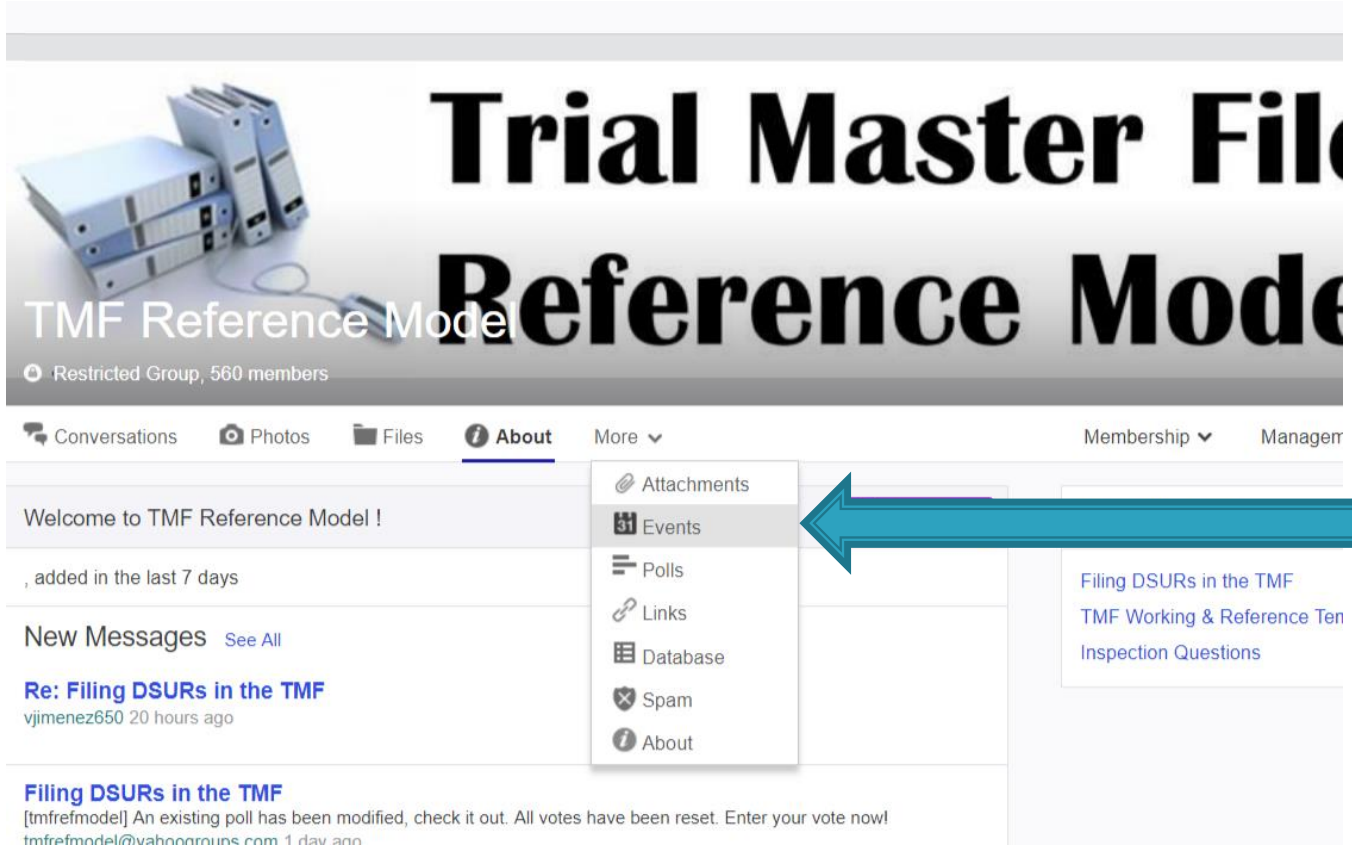


On TMF Reference Model website, click on calendar to see meeting details. Click 'Copy to my calendar' to add to your Outlook / Google calendar.

TRIAL MASTER FILE TMF REFERENCE MODEL

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

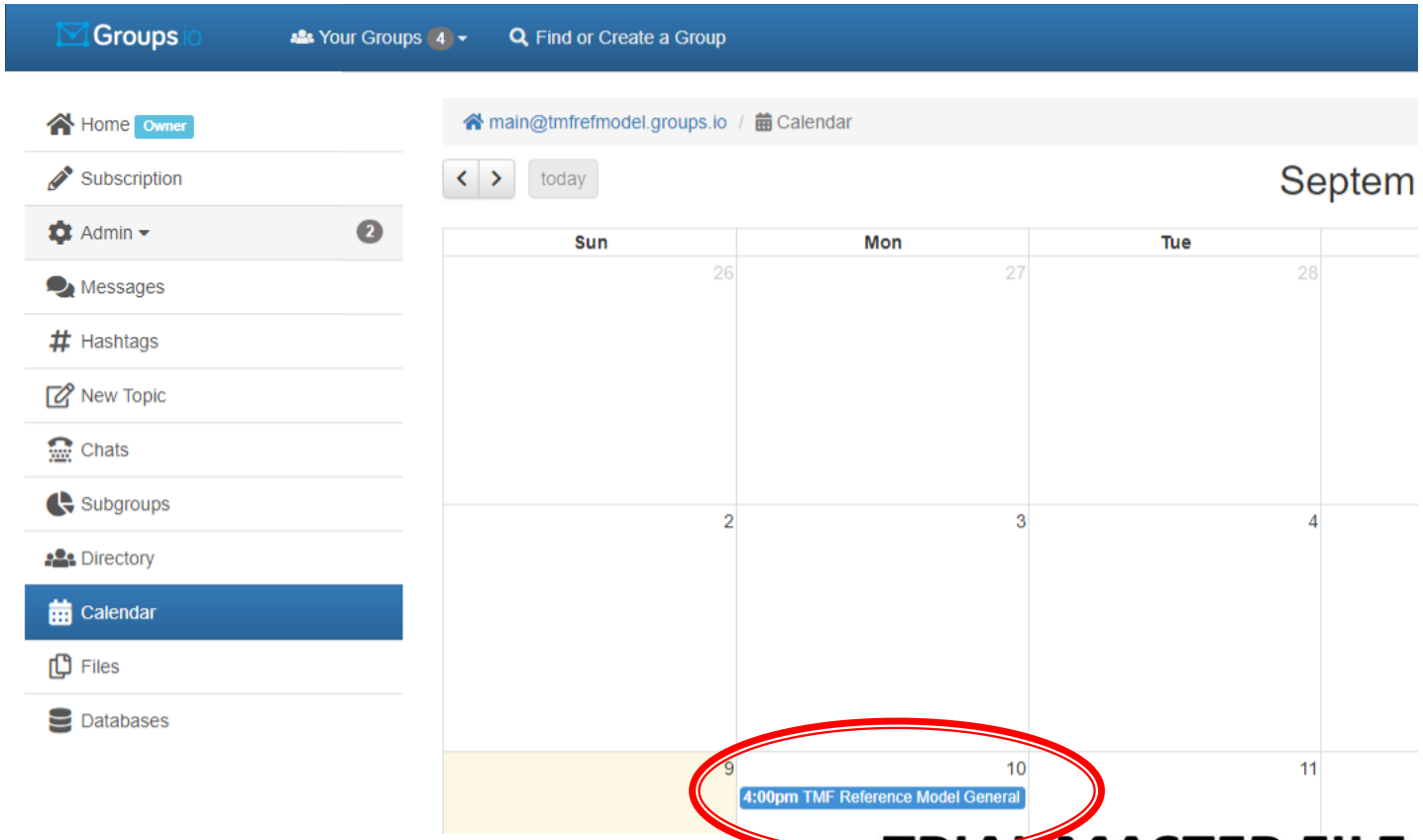
TRIAL MASTER FILE
TMF
REFERENCE MODEL

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

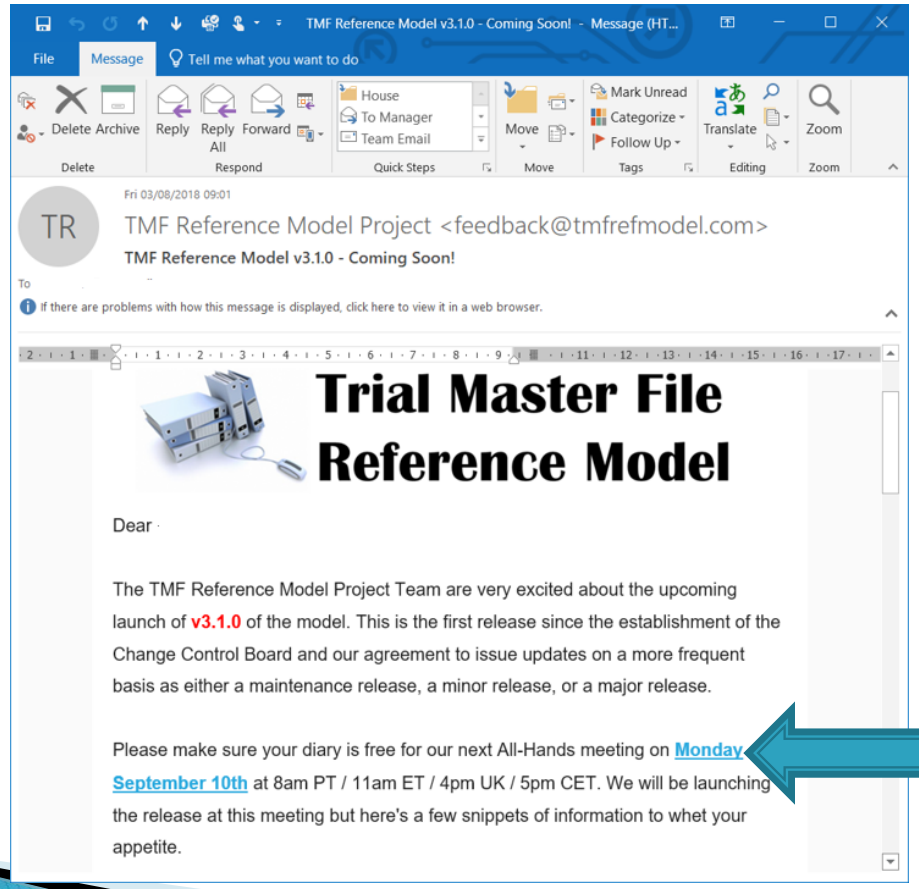
https://tmfrefmodel.groups.io/g/**main**/



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
TMF
REFERENCE MODEL