



Trial Master File Reference Model

General Meeting

03Feb2020

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??

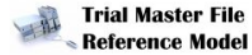
10

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

Collaboration platform



Trial Master File Reference Model

(a DIA Document & Records Management Community project)

Home News **Forum** About the Model ▾ FAQs Exchange Mechanism ▾ Resources Login Subscribe Feedback



General Discussion Forum

[Home](#) > [Forums](#) > General Discussion Forum

This forum has 16 topics, 51 replies, and was last updated 2 hours, 23 minutes ago by Maria Lopez.

Viewing 16 topics - 1 through 15 (of 17 total)

Topic	Voices	Posts	Last Post
General Meetings Started by: Eldin Rammell	1	1	2 months, 2 weeks ago Eldin Rammell
Use of the discussion forum Started by: Eldin Rammell	1	1	2 months, 2 weeks ago Eldin Rammell
Site feasibility documentation Started by: Maria Lopez	1	1	2 hours, 23 minutes ago Maria Lopez
Best Practice: Wet-Ink Signatures & Certified Copies Started by: Katie Kelly	6	10	4 days, 3 hours ago Kathie Clark



RECENT DISCUSSION TOPICS

- Site feasibility documentation
2 hours, 23 minutes ago
- Filing Site-Specific SOPs
5 days, 23 hours ago
- IBC TMF Filing
2 weeks, 3 days ago
- Phase 1 QC strategy?
4 days, 12 hours ago
- CSR Filing Options in eTMF
2 weeks, 6 days ago

UPCOMING EVENTS

Next....



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Very active discussions!

- ▶ 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

Initiative	Lead	Deliverables / Activity	Completion Goal
eMail	Jamie Toth	<ul style="list-style-type: none">Document best practices for handling email. Deliverables to include: defining relevant correspondence; best filing practices, handling attachments and links; archiving	June 2020
Devices	Joanne Bilmazes	<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	Early 2020
Sub-artifacts	Karin Schneider	<ul style="list-style-type: none">A super-set of sub-artifacts for Companies to select and customiseRemoval of the 'Alternative Name' column – any unique names have been added as sub-artifacts	Early 2020

TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
Annual Survey	David Ives	<ul style="list-style-type: none">Completed industry survey	Feb 2020
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 October	End Dec 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

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.

TMF Survey Update

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>



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What's happened in 2020?

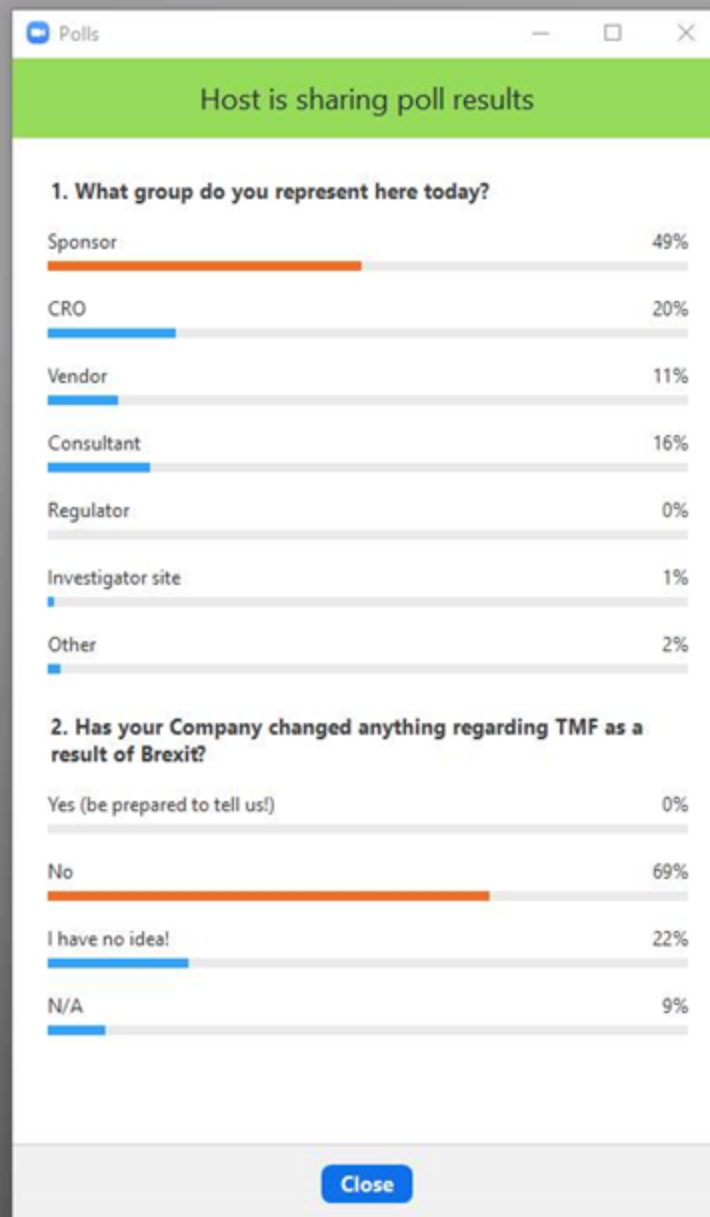


UK withdrawal from the EU on 31 January 2020 [Share](#)

Press release 31/01/2020

- ▶ 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

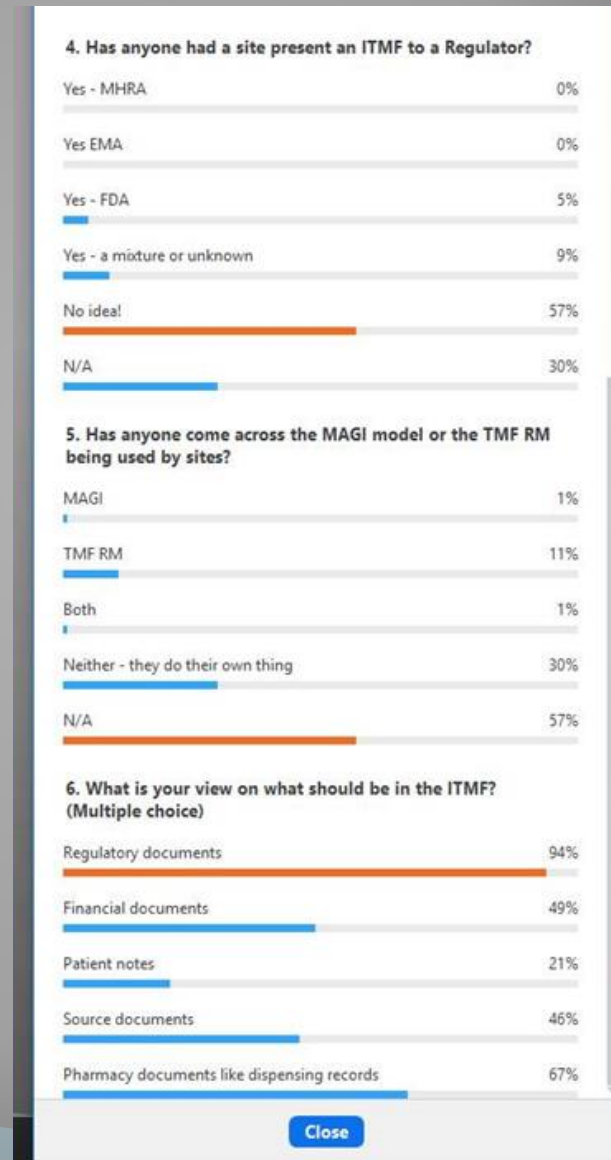
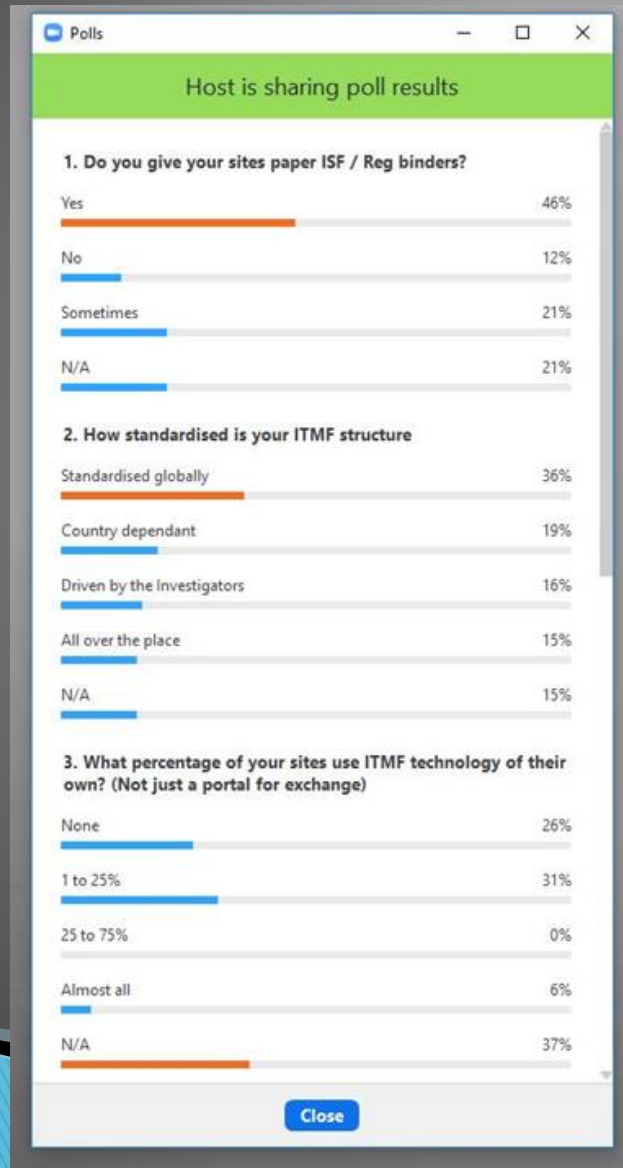


- ▶ Questions for TMF subject matter experts on a potential new ICH Topic – “eTMF (electronic Trial Master File) Metadata Harmonization”
- ▶ *Has anyone contributed?*

TMF Summit Update



Investigator TMF Poll



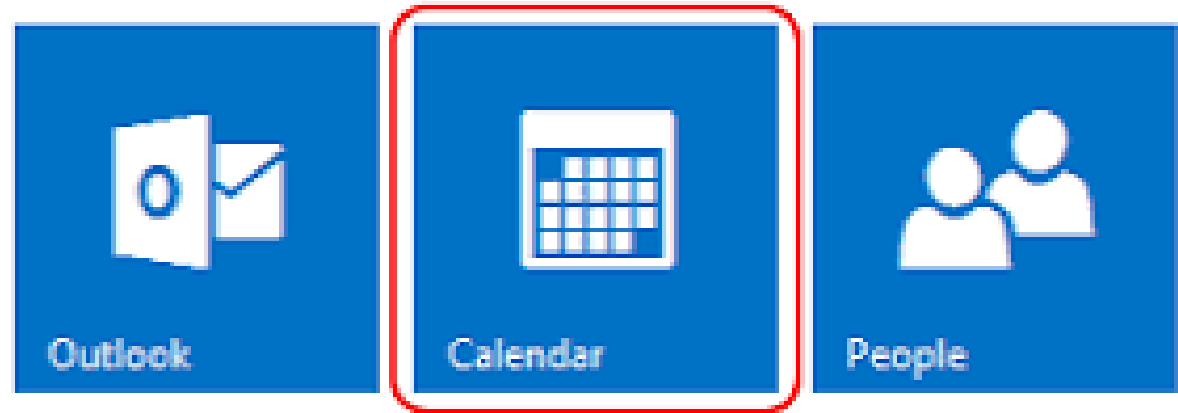
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TMF-related events coming up

- ▶ 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>

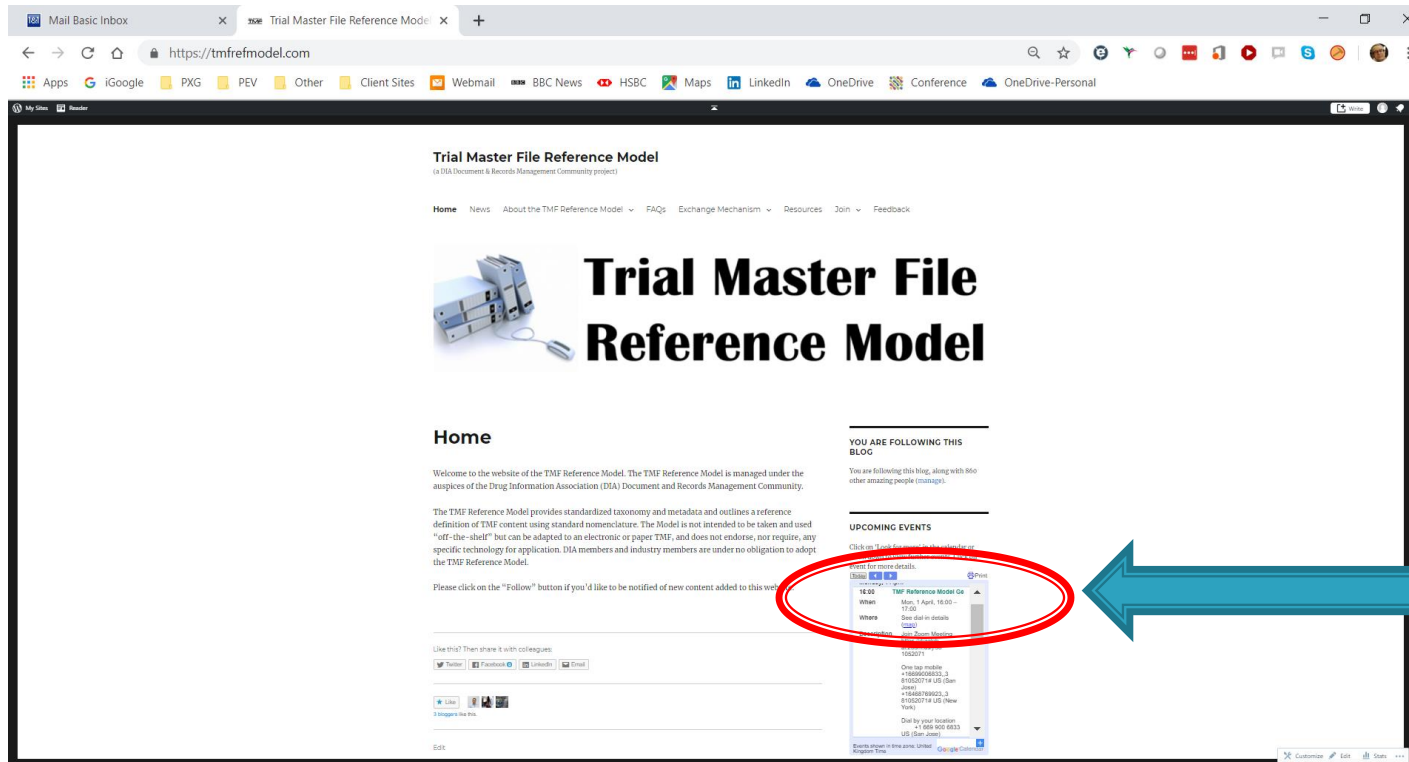
- Knowledge sharing
- Networking
- Too Much Fun!

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

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

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 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

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