Trial Master File Reference Model

General Meeting

19th April 2021

Agenda

- Membership
- Steering Committee Voting
- Website Refresh
- 2020 Survey Output
- Future-proofing the TMF RM
- MHRA Stakeholders Meeting
- Forum feedback: Where do I file??
- Upcoming TMF Meetings
- Next Meeting

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Membership …

- 315 project team members (groups.io)
- 1,437 Mailing List Subscribers** (tmfrefmodel.com)
- 3,512 members of LinkedIn group
- For details on these different groups and how to get involved, see http://tmfrefmodel.com/join

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

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Steering Committee Voting

- 11 nominees who meet the criteria
  - Part of an initiative for the past year
- 330 potential voters (groups.io members)
  - 35% voted to date
  - Voting closes 11.45pm UK time / 6.45PM EST Monday 19th
  - LOOK IN YOUR SPAM FOR AN EMAIL FROM <invitations@mail.electionbuddy.com>

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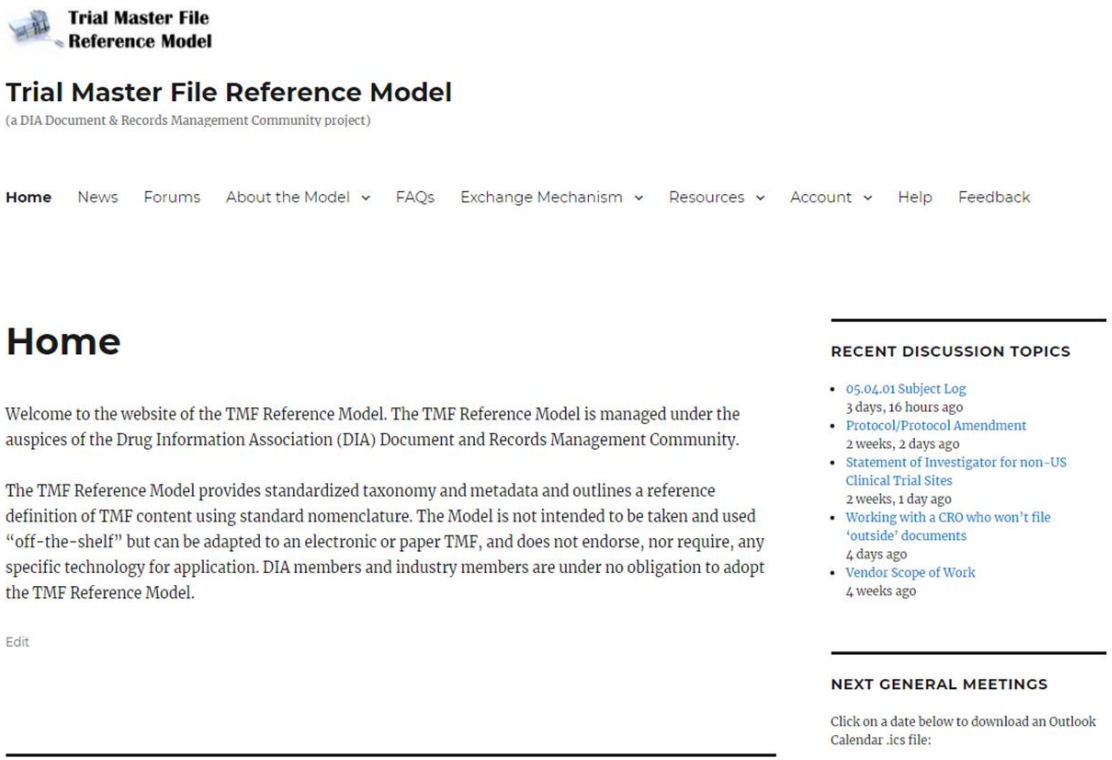
Website Refresh – We Need You!



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Website Content Team

- What information should the website hold?
- Can navigation be improved?
- How should information be presented?
- How can content be kept current?

- Initial task: refresh
- Ongoing: maintenance

- No requirement for technical know-how although appreciated…. changes will be implemented by Tech Admin

Request* to join team: https://tmfrefmodel.groups.io/g/website

* If you don't already have a groups.io account, you'll be asked to set a password and create an account

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Survey 2020: What do you want from the TMF RM?

David Ives

Survey 2020 TMF Process Requests

- Overall TMF management and oversight
- eTMF implementation
- Archiving requirements
- Country specific guidelines
- Naming conventions
- Certified copies
- Specific document workflows
- Using CRO eTMF systems and end of study transfers
- TMF RM Training

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Survey 2020 TMF Content Requests

- Study Types Coverage
- Investigator Site File
- Expanding the model for filing of records related to digital solutions / wearable devices, etc.
- Clinical and Regulatory – overlap between TMF and CTA submission documents
- Clustering and relationship between artifacts
- Metadata – definitive set of minimum metadata per artifact
- Making the model a Standard
- Simplification of the structure and presentation

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Future-proofing the TMF Reference Model

Karen Roy and Paul Fenton

Key Messages

- We are by the Industry for the Industry
- The TMF RM is owned by the members of the Team
- The TMF RM is freely available
- We are in control of the TMF Reference Model
- After more than a decade, we want to ensure the TMF RM is future-proof
- We are transparent
- We want the members to guide the future – opening communication pathways like surveys

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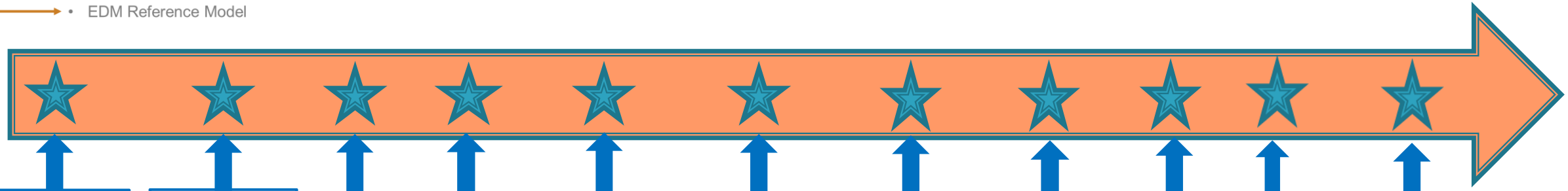
How did we get here?

DIA DEVELOP INNOVATE ADVANCE

DIA Communities

Document & Records Management Community

- EDM Reference Model



Mar 2009: 1st Meeting

June 2010: Version 1.0- 11 zones w/ associated artifacts

Feb 2011: Version 1.1- Regulator feedback

Nov 2011: Version 1.2- Investigator Site File and 1st Intro slide set

June 2012: Version 2.0- Device, Process-based metadata, and IIS

~Dec 2012: Kick-off of many Work Groups that support the TMF manage-ment process

Feb 2014: Establishment of the TMF RM Steering Committee

June 2015: Release of version 3

June 2018: Release of The Exchange Mechanism

October 2018: Release of version 3.1.0

Nov 2020: Release of version 3.2.0

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We need to show sustainability ….

We need to remain current …

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Future of TMF Reference Model

As a steering committee we have been discussing the following:

- **Evolution of the model:** We need additional tools to Excel to be able to manage the RM if we are to introduce new initiatives such as mapping to other models, more comprehensive metadata, clustering and relationship between artifacts etc.
- **Standardization:** We need to encourage establishment and adoption of the TMF RM Exchange Mechanism as an industry standard
- **Regulatory Requirements:** We need to have a stronger voice with regulators
- **Governance and Funding:** We need to ensure the long-term perennity of the model and find ways of funding initiatives

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Future of TMF Reference Model

- Over the coming months we will be looking for the TMF RM communities feedback on how we shape the future
- This could be:
  - Do nothing and leave things as they are
  - Find ways of funding new initiatives and tools as well as formalizing the TMF RM organization
  - Look to partner or associate ourselves to other standard setting bodies
  - Other ways of future proofing the work that has been done by the community
- **Watch this space!**
  - We are committed to transparency – Survey to follow soon

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MHRA Stakeholders Meeting

Russell Joyce

Inspections in 2020

- Remote since March 2020
  - Precedent already in place with Office Based Inspections
  - High risk and Covid inspections prioritised
  - More than 30 remote Inspections have been done, some had critical findings
  - Inspections often took longer, so scope narrowed directed by risk
- Accessing systems across the board a challenge
  - TMF was usually least trouble
- Industry surveyed on MHRA approach
  - Generally well received
- The future?
  - Critical and Covid 19 support inspections on site only, rest remote
  - 29th March onwards – continue with limited on-site
  - Overseas and NHS inspections paused
  - Remote bioequivalence studies and Investigator inspections planned

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Other TMF-Related Discussions

- eConsent
  - Appropriateness, access, and back-up
- Source Data Verification
  - Re-monitoring on site after remote SDV depends on circumstances and may require assessment. Only repeat if no confidence in the remote monitoring
  - Redacting data for remote monitoring: Personal identifiers should not leave the site but they don't want a huge burden on Investigator site.
- Electronic Health Record guidance
  - New stakeholder and patient engagement group created
  - Will consider access, access control, sponsor training, functionality requirements
- ICH E6 (R3)
  - Principles and annex 1 to be signed off by end 2021 and implemented by end of 2022
- New UK guidance on TMF scheduled Dec 2021
  - Includes 25 year storage requirement

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Forum Feedback

Where do I file???

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TMF-related events coming up*

**Events page on website (under Resources menu)*

- Fierce TMF Summit, Virtual, May 2021
- Clinical Document World, Inspection Readiness, Virtual, May 2021
- HSRAA, Virtual, September 2021
- Fierce TMF Summit, In Person, October 2021
- Clinical Document World, New Jersey, November 2021

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TMF RM General Meetings

- <7th June>
- Add to your calendar NOW or download the calendar file (.ics file) from our homepage
- Outlook Meeting Request no longer distributed

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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

(be prepared to work! – we can't do this without YOU)

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

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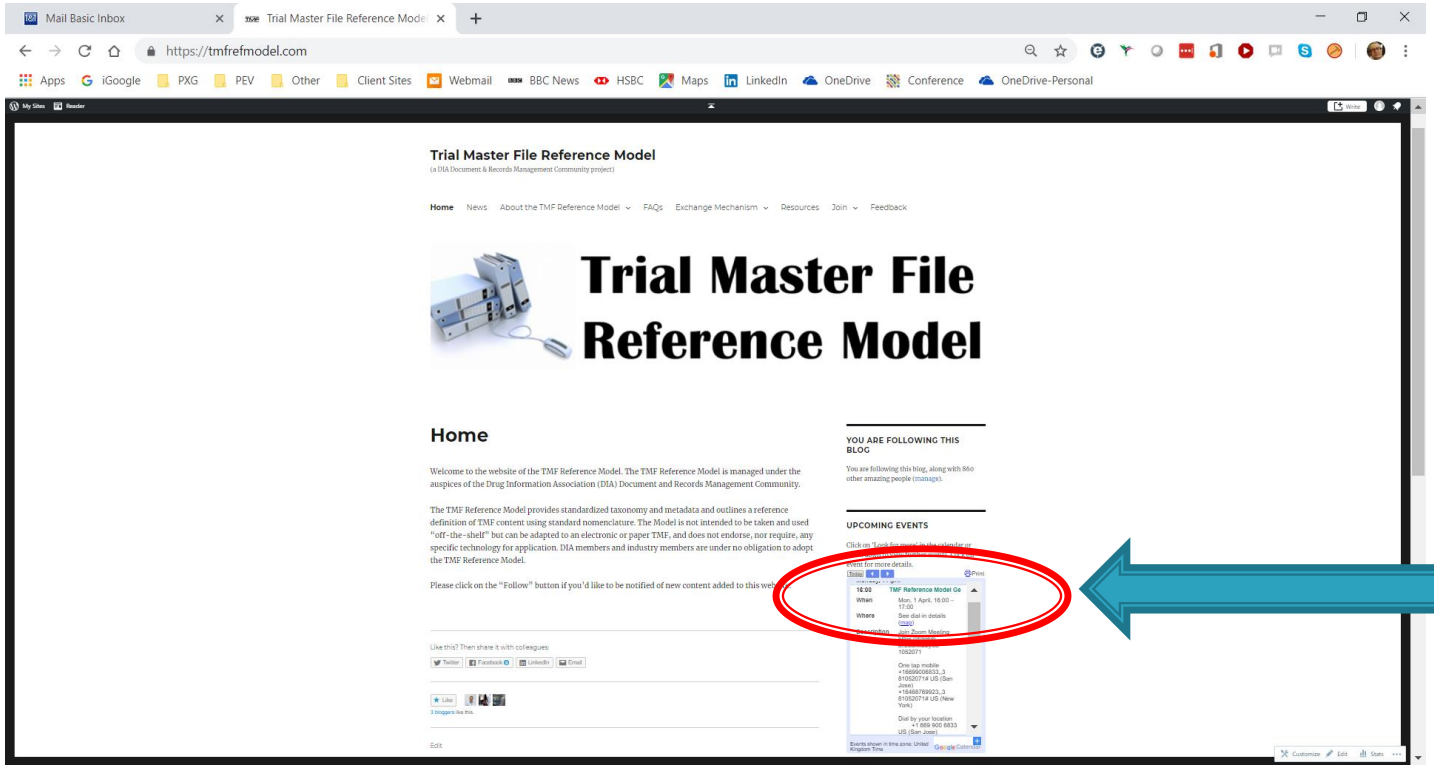
Meeting details

- 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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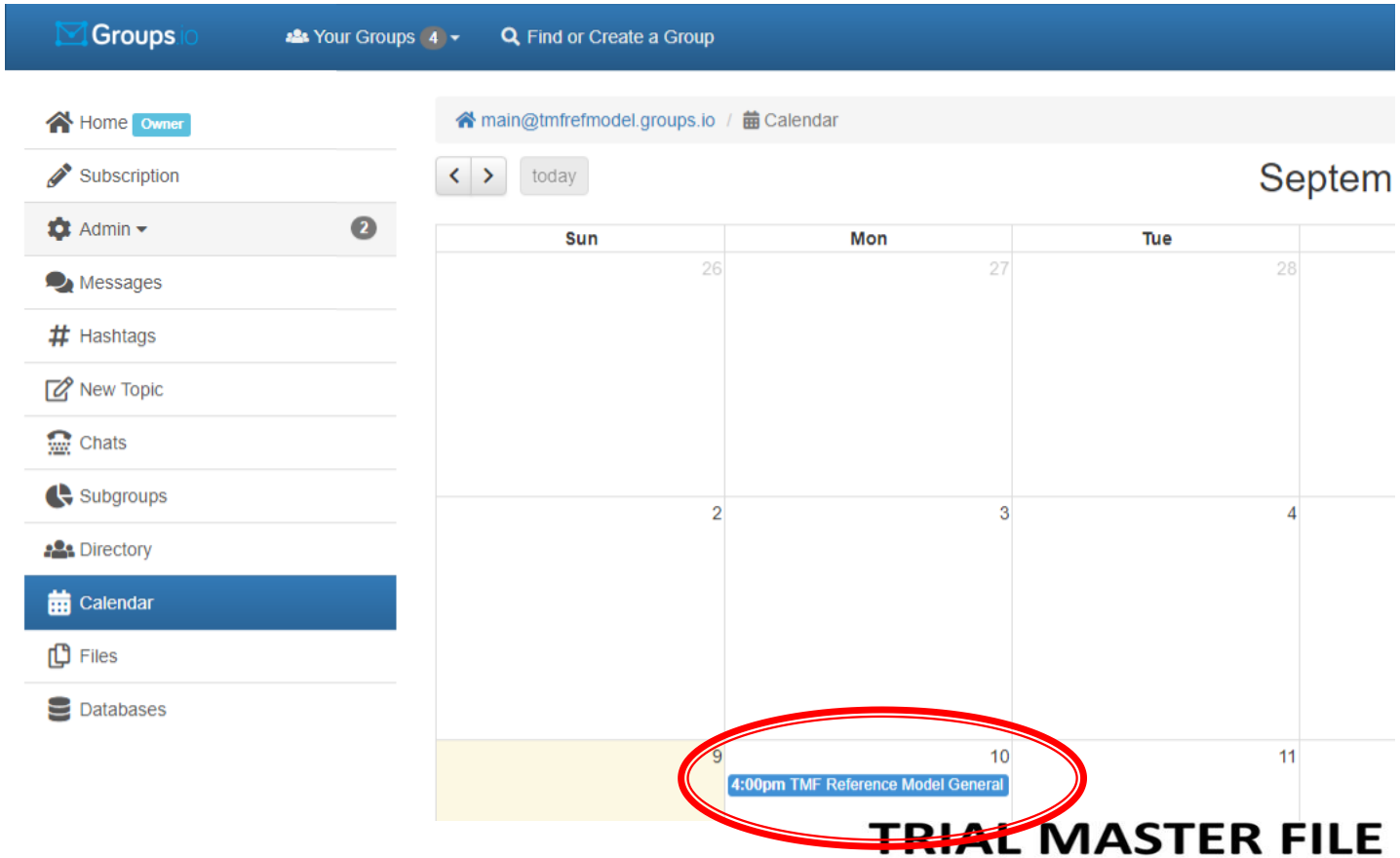
Meeting details

- Wondering where to find details of the next meeting?

On 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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