Trial Master File Reference Model

General Meeting

18 November 2019

Agenda

- Welcome
- Membership Update
- IT Changes in Communication Tools
- Active Initiatives
  - Sub-artifact Group Deliverables
  - Exchange Mechanism Specification
- MAGI Update
- CRO Panel
- Upcoming Events

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Since last meeting*…

- 7 new project team members – current total 306
- 23 new Mailing List Subscribers – current total 858
- 6 new Yahoo!Group Forum members – current total 615
  - 3 new discussion topics posted (5 messages)
- LinkedIn group – 2,912 members (50 new members)
  - 9 new discussion topics posted

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

* 23 September 2019

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IT Update

- MailChimp no longer used for subscriber communications
  - All subscribers set up with a website account using email address used previously with MailChimp
  - Login: https://tmfrefmodel.com/login
  - Forgot your password? Click on “Forgot password” link
  - Need to update account info? https://tmfrefmodel.com/account

  - Emails will be sent out from the website to registered subscribers (after configuration of our SMTP mail settings)

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Next change

- Yahoo! is about to significantly reduce the functionality provided in its Yahoo!Groups tool
- New online discussion forum on our website as replacement
- After testing is complete, all Yahoo!Groups members will be set up with a website account, providing the ability to create and participate in our online discussions
- **NOTE:** To receive email alerts, you will need to login to the Forum and set notifications to “ON”

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Collaboration platform

MailChimp

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(a DIA Document & Records Management Community project)

Home | News | About the Model | FAQs | Exchange Mechanism | Resources | Login | Subscribe | Feedback

Groups.io

YAHOO! Groups

Home

Welcome to the website of the TMF Reference Model. The TMF Reference Model is managed under the auspices of the Drug Information Association (DIA) Document and Records Management Community.

The TMF Reference Model provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature. The Model is not intended to be taken and used "off-the-shelf" but can be adapted to an electronic or paper TMF, and does not endorse, nor require, any specific technology for application. DIA members and industry members are under no obligation to adopt the TMF Reference Model.

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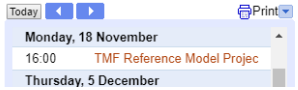
UPCOMING EVENTS

Click on 'Look for more' in the calendar or scroll down to view further events. Click on event for more details.



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TMF RM Active Initiatives

Initiative	Lead	Deliverables / Activity	Completion Goal
eMail	Jamie Toth	• 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	• 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	• Comprehensive revision of the 'sub-artifact' examples in column I • → Submit to Change Control Board	Early 2020

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Subartifacts

- Excellent work by the Sub-artifact group led by Karin Schneider and Daniel Bennett
- Extensive review by the Steering Committee
- Output will include:
  - A super-set of sub-artifacts for Companies to select and customise
  - Removal of the 'Alternative Name' column – any unique names have been added as sub-artifacts
  - Targeting early 2020

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TMF RM Active Initiatives

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

Observational Studies	Russell Joyce	• Focus changed to Non-Interventional Studies in general.
		• Identified from TMF Ref Mod v3.0
		  • 10 Core artefacts
		  • 98 Recommended artefacts
		  • Final review due mid October
		• Submit to Change Control Board by end of November 2019
			End Nov 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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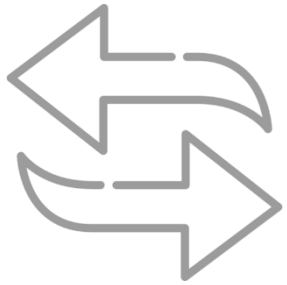
eTMF Exchange Mechanism Standard

Paul Fenton, Co-Chair eTMF-EMS Sub-Group



What is the eTMF-EMS

Electronic Trial Master File –
Exchange Mechanism Standard

- An extension of the TMF RM which focuses on the transfer of content, metadata, audit trail and eSig information
- A TMF metadata standard
- A mechanism for exchanging TMF content between systems
- A method for describing TMF artifacts which is comprehensible by both humans and machines

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eTMF-EMS – Where are we at?

- Specification and related files have been available for over one year
- Some vendors have started to implement the standard into their systems
- We launched two round tables:
  - Business Round Table – forum to work on business deliverables, notably Exchange Agreements, and to discuss implementation of the standard by sponsors and CROs
  - Vendor Round Table – forum to discuss technical implementation approaches and issues by software vendors
- No known actual use of the standard to date

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Challenges of not using a standard when exchanging TMF content?

- Industry often uses the TMF RM as a baseline for identifying artifacts however the RM does not cover metadata, audit trail or signature information
- Metadata often needs to mapped from one standard to another when being imported into the sponsor or CROs eTMF – this is time consuming and expensive
- Transfers of content tend to be infrequent due to the effort required to import and reconcile content, making oversight more challenging
- Automation is possible but tends to require development effort in the source and destination systems to properly integrate them

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We have the solution to these challenges…

- Sponsors and CROs should identify pilots that they could implement to test the eTMF-EMS
- They should work with vendors to provide an incentive for vendors to implement functionality that would allow for the generation and reception of eTMF-EMS Exchange Files and content
- Sponsor and CRO stakeholders should join in the business roundtable to share experiences and approaches and get involved in the Exchange Agreement Template development
- Vendors should work with clients to implement compatibility for eTMF-EMS and get involved with the vendor community to evolve the eTMF-EMS and exchange experiences of implementation

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Benefits of implementation

- Significant reduction in time and cost to transfer TMF artifacts from one organization to another
- Possibility to maintain a full up to date shadow copy of the TMF in each organizations eTMF system
- Significant improvement in oversight and management of completeness
- Better traceability of artifacts after transfer

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Future Opportunities

- Transfer of activity logs with artifacts
- Exchange of study event information
- Expansion of metadata standard to include more operational information
- Transfer of data-only artifacts

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For further information

- Main website: https://tmfrefmodel.com/ems
- LinkedIn Group: “TMF Exchange Mechanism Standard” https://www.linkedin.com/groups/12136956/
- Business Roundtable

  Subgroup “Exchange Mechanism – Business Reviewers” https://tmfrefmodel.groups.io/g/Exchange-Business
- Vendor Roundtable

  Subgroup “Exchange Mechanism – Vendor Reviewers” https://tmfrefmodel.groups.io/g/Exchange-Vendor

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WE NEED YOU!

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MAGI ISF Model Initiative

- Over 100 sites participating in the initiative
- Working Group Session at MAGI West (28-30 October 2019)
- Working Draft developed by sites, CROs, pharma/biotech, vendors, and consultants
- Currently being piloted
- Feedback will be incorporated into next draft (mid-December 2019)

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CRO Panel

Molly Brock, Senior Director Clinical Operations, PRA Health Sciences

Michelle Ingraham, Manager Information Governance & Compliance, PPD

JP Miceli, Associate Director of Document Management, Advanced Clinical

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2019 TMF SURVEY

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- Survey Launching this week!
- Please take the survey and share with your friends! This valuable information helps us all understand the current TMF landscape and gives valuable input to shape what the TMF Reference Model focuses on.

Thank you!

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TMF-related events coming up

- Training: Setting up and Managing the Trial Master File, UK, 5 Dec (see calendar on website for more details)
- ExL TMF Summit, Orlando, USA, 21 – 23 Jan 2020
- HSRAA Annual Conference, Windsor, UK, 22-24 Apr 2020

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TMF RM General Meetings

- 3 Feb 2020
- 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 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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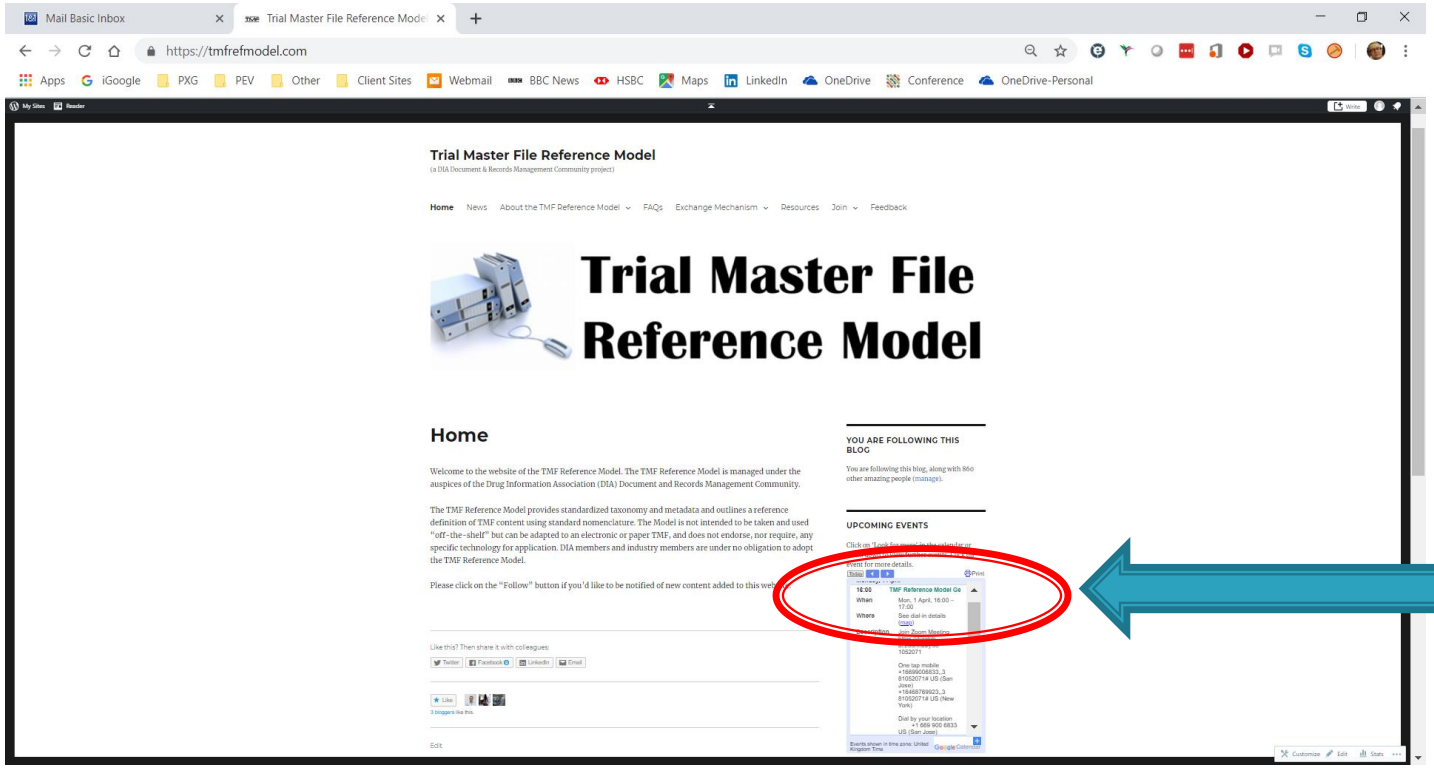
Meeting details

- 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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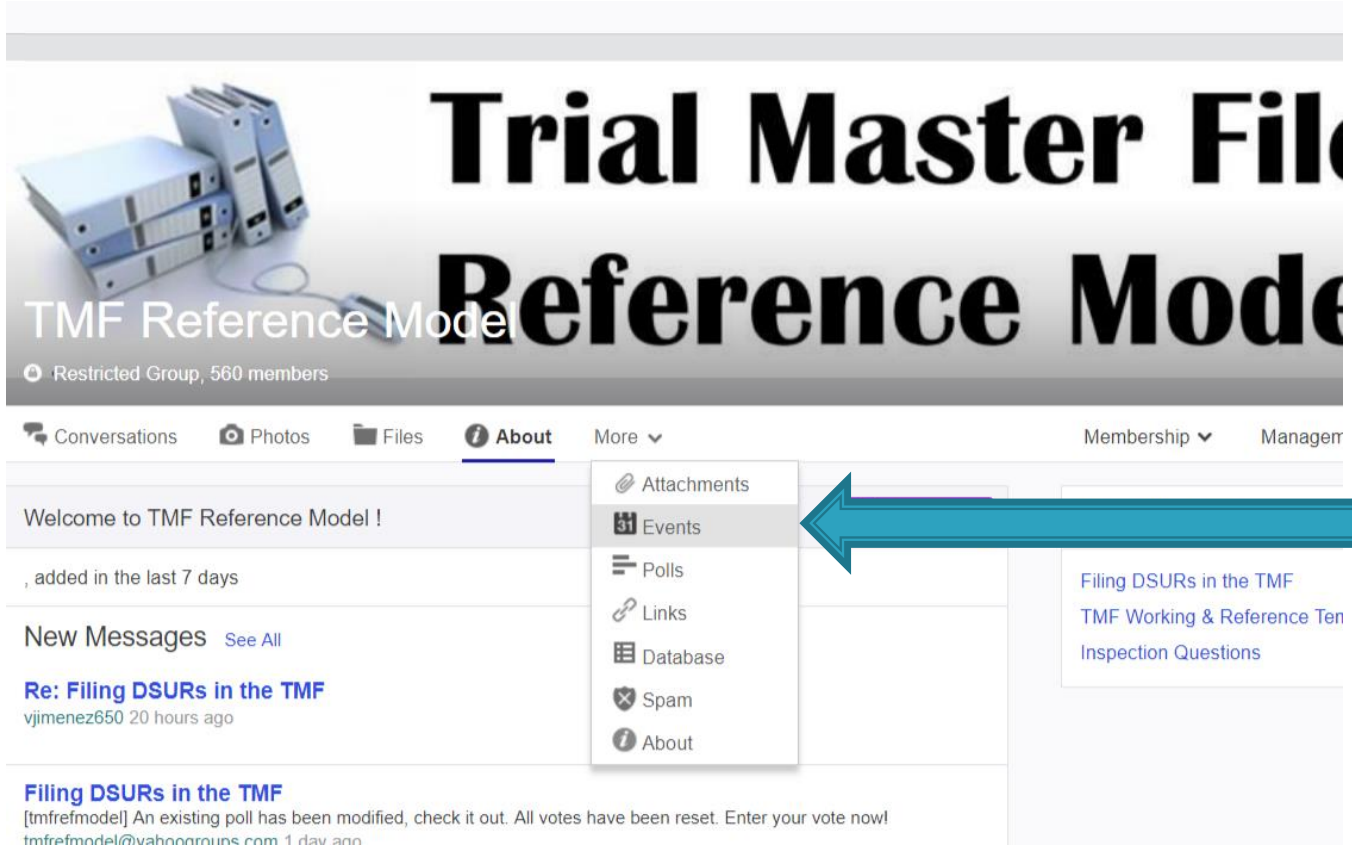

On Yahoo!Groups, click on Events to show group calendar. Click on an event to see dial-in details

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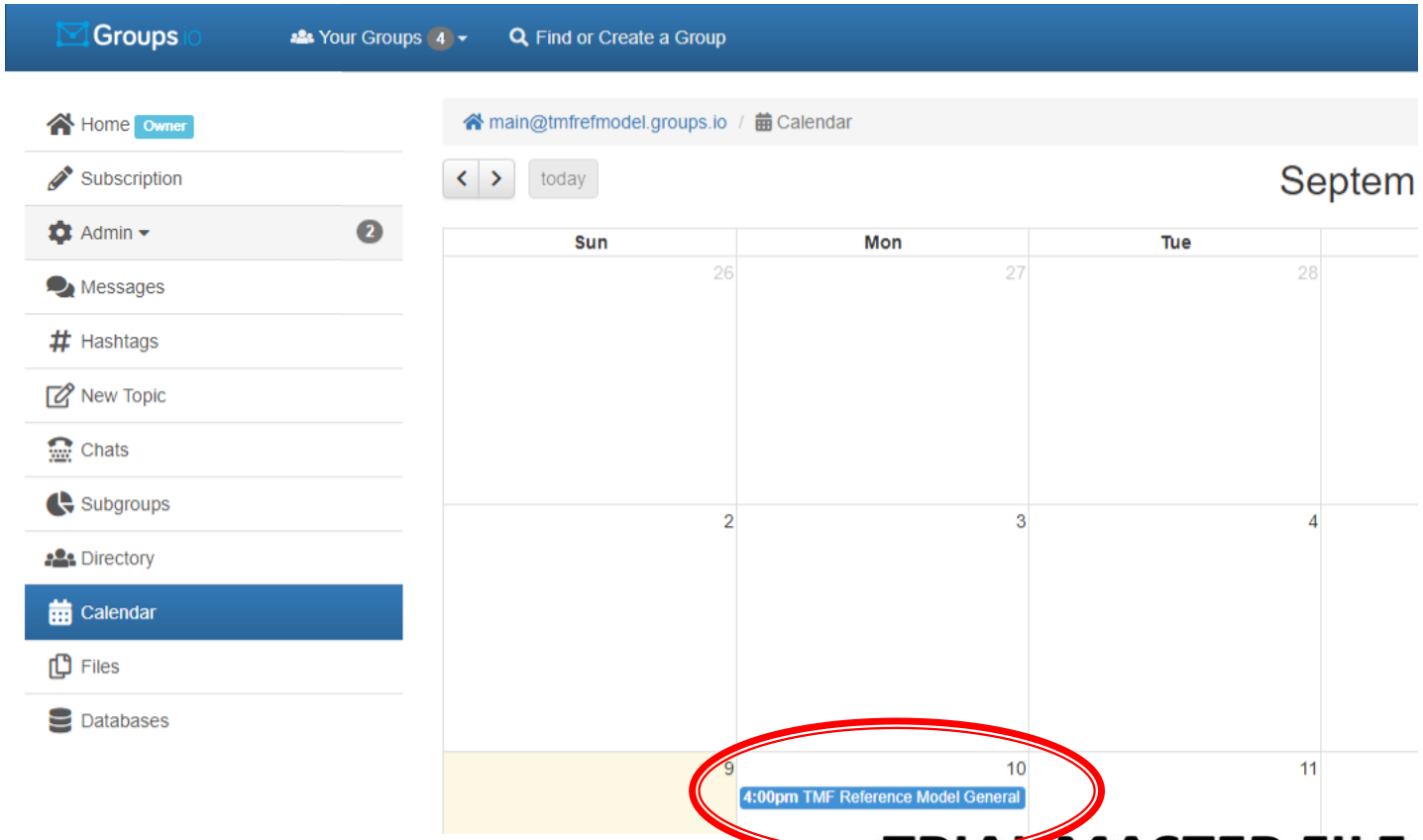

On Groups.io, click on Calendar to show group calendar. Click on an event to see dial-in details

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

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