Trial Master File Reference Model

General Meeting

26 October 2020

Agenda

- Welcome
- Update on Membership
- Update on Initiatives
  - Call for Initiatives!
- Version 3.2 of the TMF Reference Model
  - The 3.2 changes
  - The Sub-Artifact Group process
  - The Steering Committee review
  - Panel discussion
- Next Meeting

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Membership …

- 341 project team members (groups.io)
- 1,169 Mailing List Subscribers** (tmfrefmodel.com)
- 3,204 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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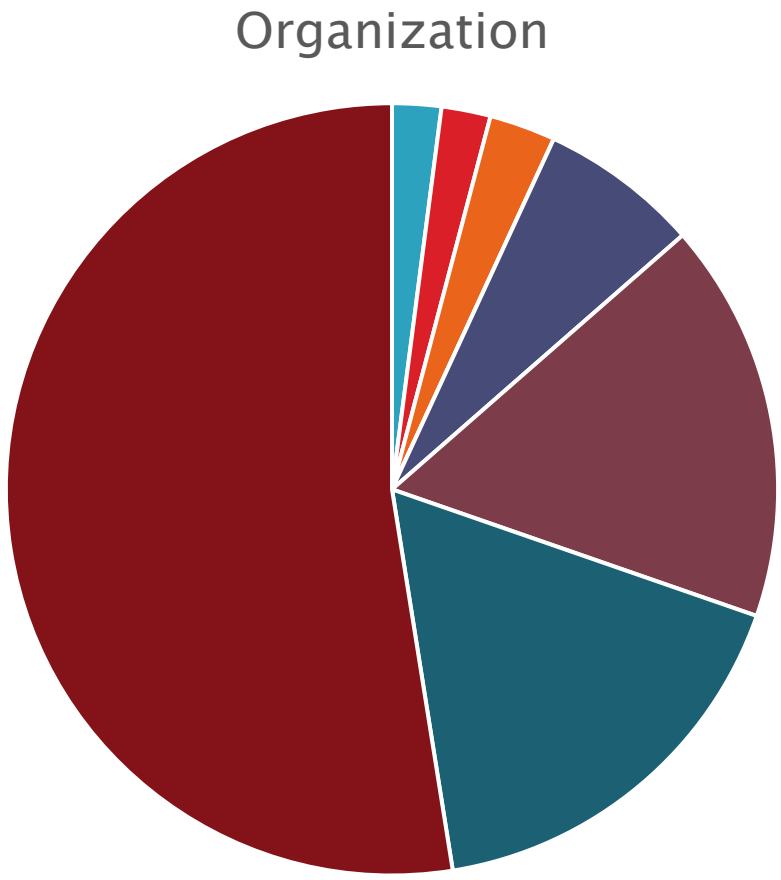
Membership



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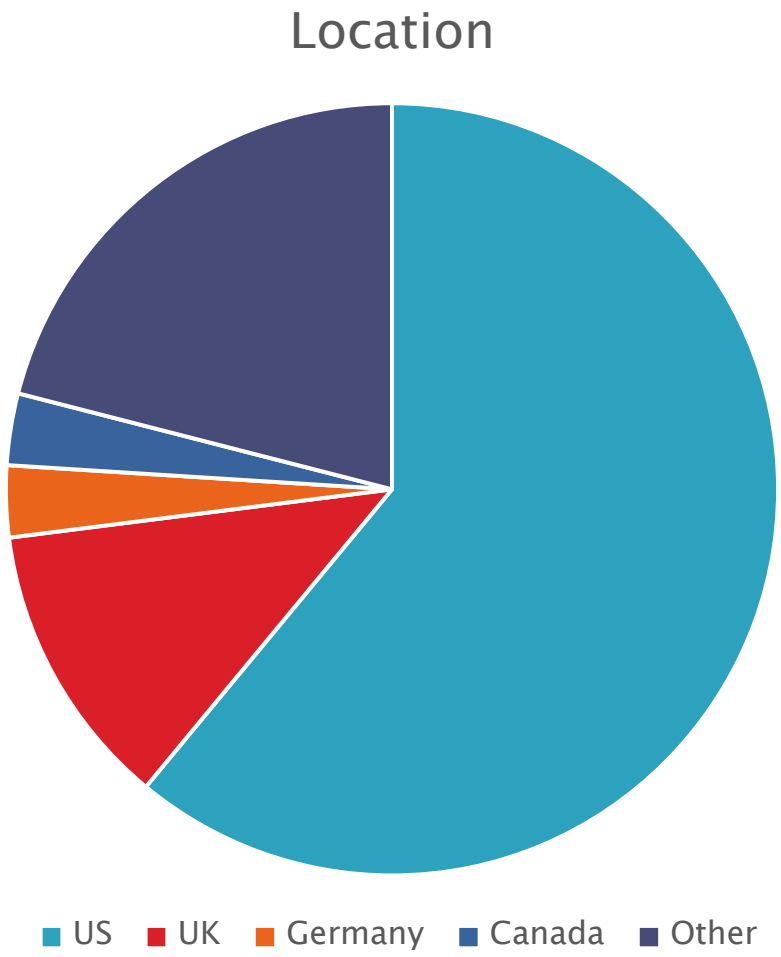
Membership



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TMF RM Active Initiatives

Initiative	Deliverables / Activity
Sub-artifacts	• 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 • Being released as part of 3.2
Devices	• Updated artifacts and sub-artifacts specific to Device studies • Being finalised for release in 2021
Exchange Mechanism	• An extension of the TMF RM which focuses on the transfer of content, metadata, audit trail and eSig information

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eTMF-EMS Survey

- 10-12 minute survey on the implementation of the Exchange Mechanism Standard (EMS)
- Important for us to understand perceptions, barriers, value and intentions for the implementation of the EMS
- Results will be presented at the beginning of next year
- All are invited to respond to the survey and a link will be sent via email to the TMF Reference Model membership later on today
- Thank you for your input!

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TMF RM Active Initiatives

What new initiatives would you like us to consider?

- Must relate to TMF content!

Email kroy@phlexglobal.com

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Trial Master File Reference Model

Version 3.2

TMF Reference Model 3.2.0

Coming:

November 2, 2020

www.tmfrefmodel.com/resources

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Version 3.2.0

- Includes:
  - All approved requests submitted until June 2020
    - Requests received since June are in process of evaluation
  - One (1) new artifact
  - Four (4) changes to artifact names
  - One (1) change to filing level
  - Twenty two (22) Changes to Artifact Definition/Purpose, Milestones, Glossary, Model Overview and ICH Code
  - Sub-artifacts
    - *Alternate name was **retired and replaced by the new** Recommended Sub-Artifacts column. Individual companies may choose to retain this column for alternate names that may exist across divisions or with partners.*

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TMF Reference Model 3.2.0

- **Documentation Delivered**
  - TMF Reference Model Version 3.2.0
  - TMF Reference Model Version 3.2.0 Release Notes
    - Release on 2-NOV-2020
- **Change Requests 'By the Numbers'**
  - Total of 111 Change Requests Submitted since October 2015
    - 23 Approved and included in release 3.1.0
    - 25 Approved and included in release 3.2.0
    - 31 Rejected
    - 27 Open and will be considered for next release
    - 5 Deferred
      - Deferred to sub-teams, Steering Committee or next release

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TMF Reference Model 3.2.0

- One (1) new **artifact**
  - 06.05.04 Non-IP Storage Documentation

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TMF Reference Model 3.2.0

- Four (4) minor changes to **artifact name**
  - 04.01.02 IRB or IEC Approval …IRB / IEC Decision
  - 06.04.03 Maintenance Logs…Maintenance Logs ~~(Device)~~
  - 10.03.01 Database Specifications…Database Requirements
  - 10.04.03 Validation Documents…Validation Documentation

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- **Changes to Filing Level**
  - 01.01.08 Monitoring Plan; added TMF Level – Site Level Document

- **Trial Level Milestone/ Event**
  - 01.01.11 Debarment Statement; changed to #2 Clinical Infrastructure Ready

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- Nine (9) minor changes to **artifact definition/purpose**
  - 01.01.08 Monitoring Plan
  - 01.01.17: Vendor Management Plan
  - 01.04.04 Trial Team Evidence of Training
  - 02.01.04 Protocol Amendments
  - 04.01.02 IRB or IEC Decision
  - 06.04.03 Maintenance Logs
  - 10.03.01 Database Requirements
  - 10.04.02 Technical Design Document
  - 11.03.07 Final Analysis Raw Datasets

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- Four (4) **Glossary and model** clarifications
  - Glossary Zone 8; Central and Local Testing
  - Glossary SDTM definition
  - Model Overview: Row 5
  - Model Overview; Row 9

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- Eight (8) artifacts with **revised ICH codes**
  - 01.01.08 Monitoring Plan
  - 04.03.02 IRB or IEC Progress Report
  - 05.01.03 Feasibility Documentation
  - 05.01.04 Pre-Trial Monitoring Report
  - 05.01.05 Sites Evaluated but not Selected
  - 05.04.13 Subject Eligibility Verification Forms and Worksheets
  - 09.01.03 Ongoing Third Party Oversight
  - 11.03.10 Final Analysis Output

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Feedback and Change Requests

- If you have any feedback on the TMF Reference Model, including comments on existing artifacts, milestones, suggestions for additional artifacts or general comments about the TMF Reference Model, please use the link below to submit your feedback:

https://tmfrefmodel.com/feedback/

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TMF Reference Model 3.2.0

Recommended Sub-Artifact Set

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Sub-Artifact Group

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Thanks to Everyone in the Group

Karin Schneider - LEAD
Daniel Bennett - DEPUTY LEAD
Allison Grosik
Alyson Burch
Anne-Mette Vorney
Béatrice Chabot
Brian Harris
Charlene Knape
Clarie C. Mooney
David Ives
Debra Oriez
Dhara Patel
Dickson Dsouza
Donna Dorozinsky
Dorte Frejwald Christiansen
Eldin Rammell
Jason Weinstein
Jen Maier
John Kane

Kathie Clark
Kathleen Kirby
Kelly Rooney
Kristen Bretzius
Ksenia Chagan
Laurel-Ann Schrader
Liavaquino@gmail.com
Linda James
Lisa Mulcahy
Loretta Cipkus Dubray
Luisa Monica
Martin Hausten
Martin Thorley
Michele Atherton
Noreen Bouchard
Shah Ashraf
Sunil Joseph
Sunil Pawar
Susanne Prokscha
Wendy Trimboli

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We asked everyone for lists of sub-artifacts or lists of types of documents

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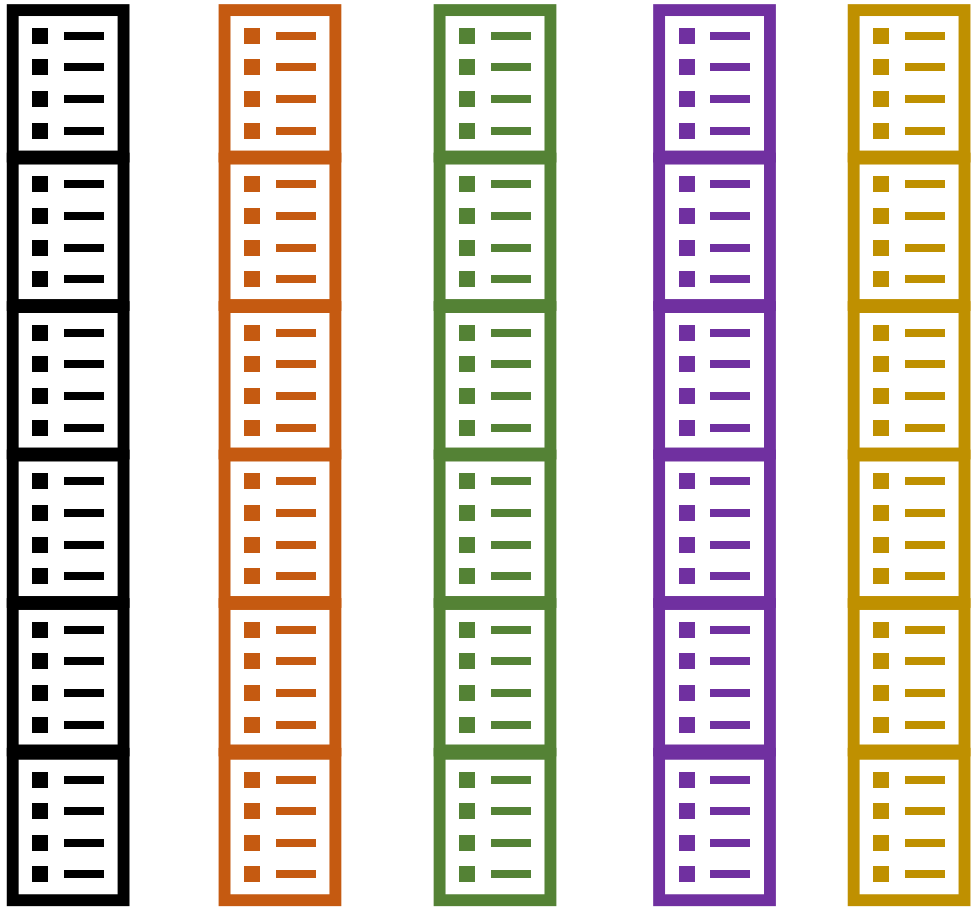
We received lots of lists about 1000 items long



(RefMod V3.1 249 artifacts)

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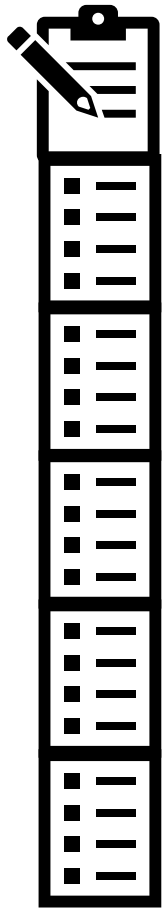
We combined them into a list about 5000 items long – exact duplicates were removed



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We went through zone by zone

- Removing obvious but non exact duplicates
- Identifying recurring questions and issues
- Starting to identify conventions for ‘sets’ of sub-artifacts

After each zone we reviewed with the wider team

And looked to implement some consistency

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What is a Sub-artifact?

It's a way of classifying different records that you might file in that location to achieve the same end.

An artifact achieves a point of compliance.

The sub-artifacts listed are ways that people have done this.

(*other ways are possible*)

The final arbiter was, 'would I ever want to see this on a report?'

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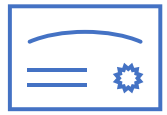
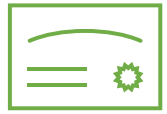
So what would you want to see on a report?

05.02.07 Site Staff Training Qualifications
Often many different types of documents– but sometimes…

…each person is to have a GCP certificate (or a series)



…each site is to have at least one IATA certificate



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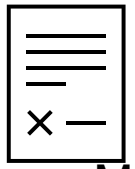
How did that work for ICFs?

02.02.03 Informed Consent Form

The sub-artifacts are

- ICF
- Addendum
- Review Checklist
- Summary of Changes

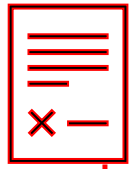
So type of ICF could be
a different metadata field


Main


Child


Pregnancy


Assent


Labs


Imaging

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Differences from previous

- Sub-artifacts are pragmatic rather than requirements
- Highly customisable
- Includes elements of evidence of QC as per GCP
  (Review and Approval)
- 612 sub-artifacts added

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What happened to alternate names?

Each company is supposed to *implement* the Reference Model.

Once you have done this and turned 'DIA Reference Model' into 'XYZPharma Model Index' why would you want a column of what other people might call their documents?

You should go through and put the *actual* names in there (if you want a column of document types / names).

This column made sense when the model was new and unfamiliar.

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Steering Committee Review Process

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Role of Steering Committee in v3.2

- MAR 2019: Began review & revision of the subteam's output
- MAR 2020: Submitted all model revisions for sub-artifacts to Change Control Board

- *Lessons Learned:*
  - Steering Committee will seek to more carefully identify & provide guidance to subteams (at kickoff and ongoing)
  - Change Control Board owns approval for all subteam outputs that affect the structure of the TMF RM [CCB charter updated MAY 2020]

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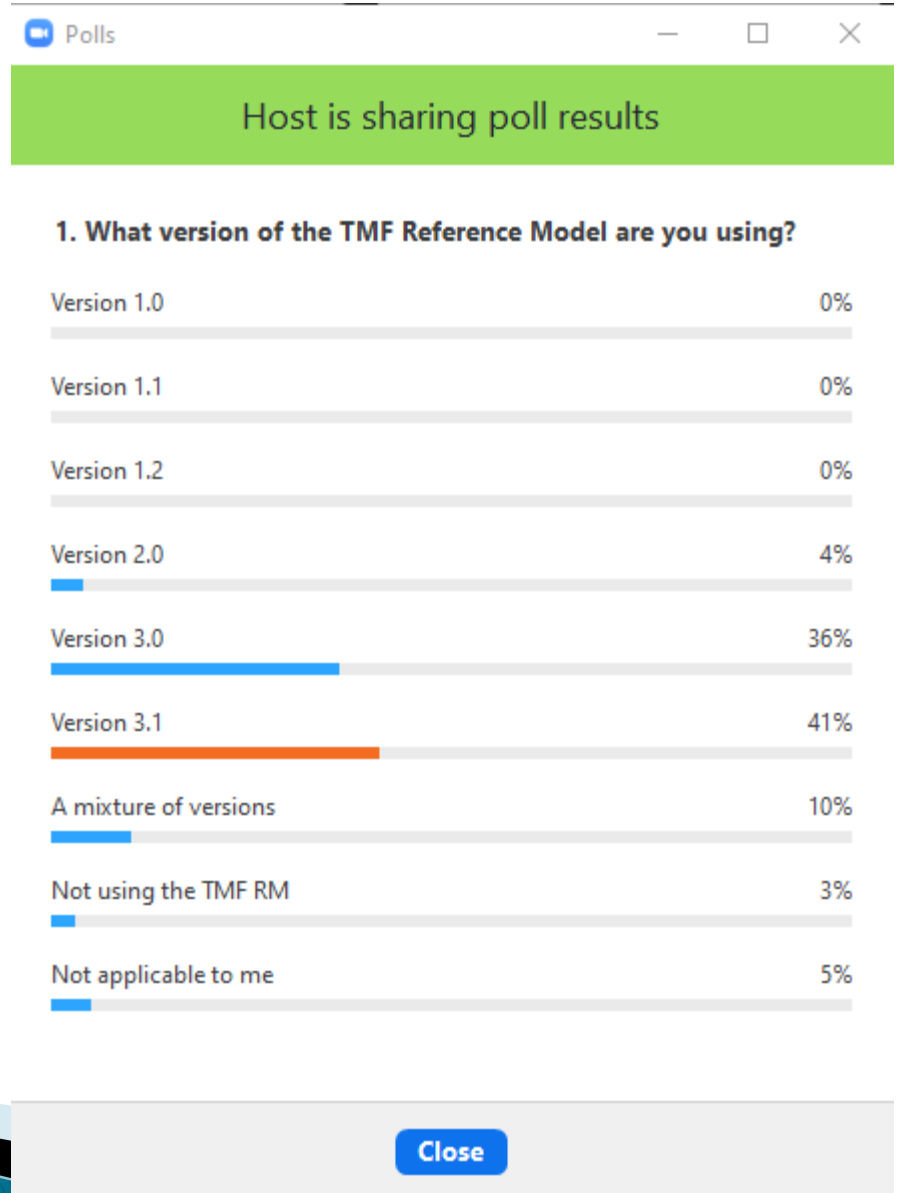
TMF RM version Poll



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Panel
Considerations for Implementation

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TMF-related events coming up*

Events page on website (under Resources menu)

- DGE Electronic Trial Master File Forum, New Jersey & Virtual, 26-27 Oct
- VIRTUAL FierceLive / Questex / Exl European TMF Summit, 2nd to 6th November
- e-Mail (Electronic) Communications Guidance Workshop will be a 1-1.5 hour webinar held in January 2021, date/time TBD.
- IQPC TMF & GCP Inspection Readiness, Bruges, Belgium RE-SCHEDULED TO APRIL 2021

* COVID-19 dependent

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TMF RM General Meetings

- <7th December>
- 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
(but be prepared to work!)
https://tmfrefmodel.groups.io/g/main

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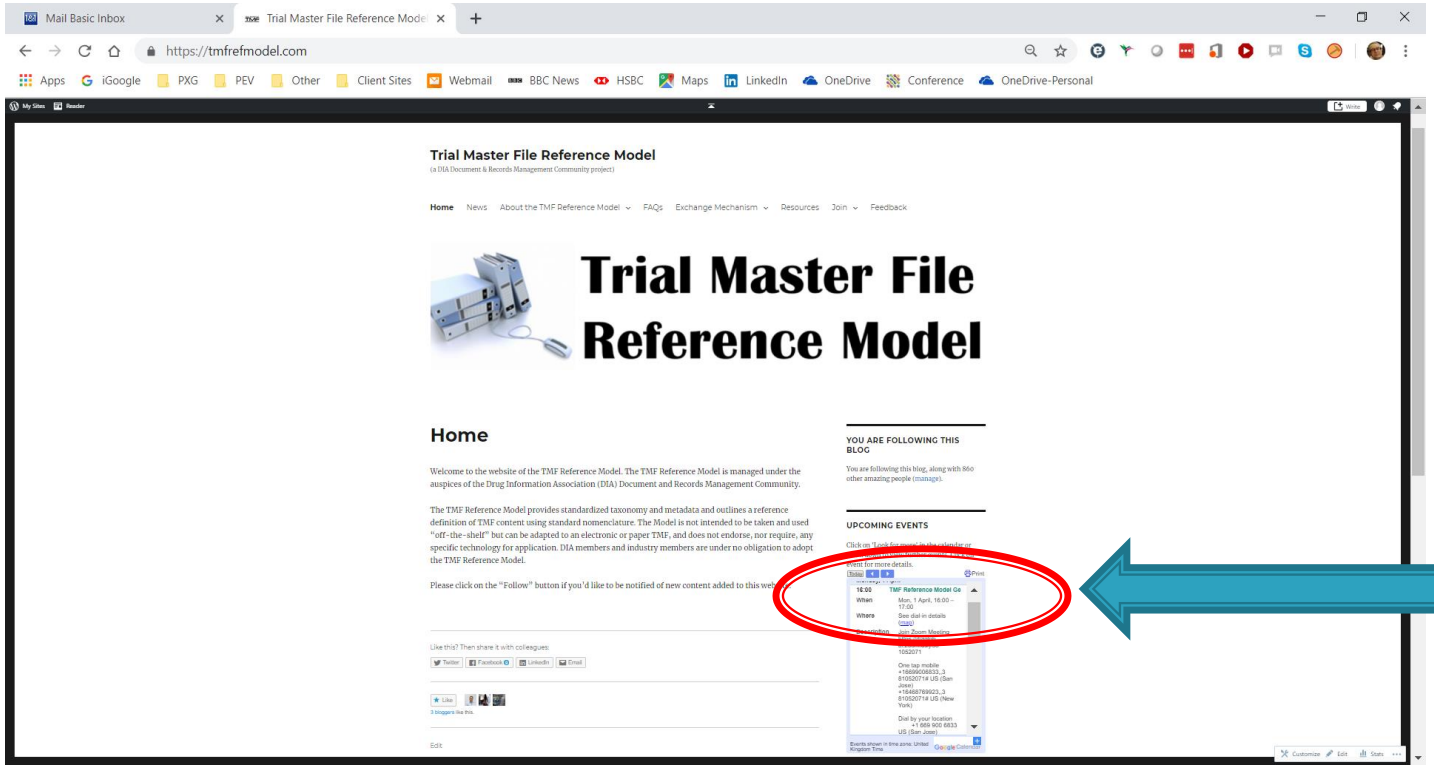
Meeting details

- 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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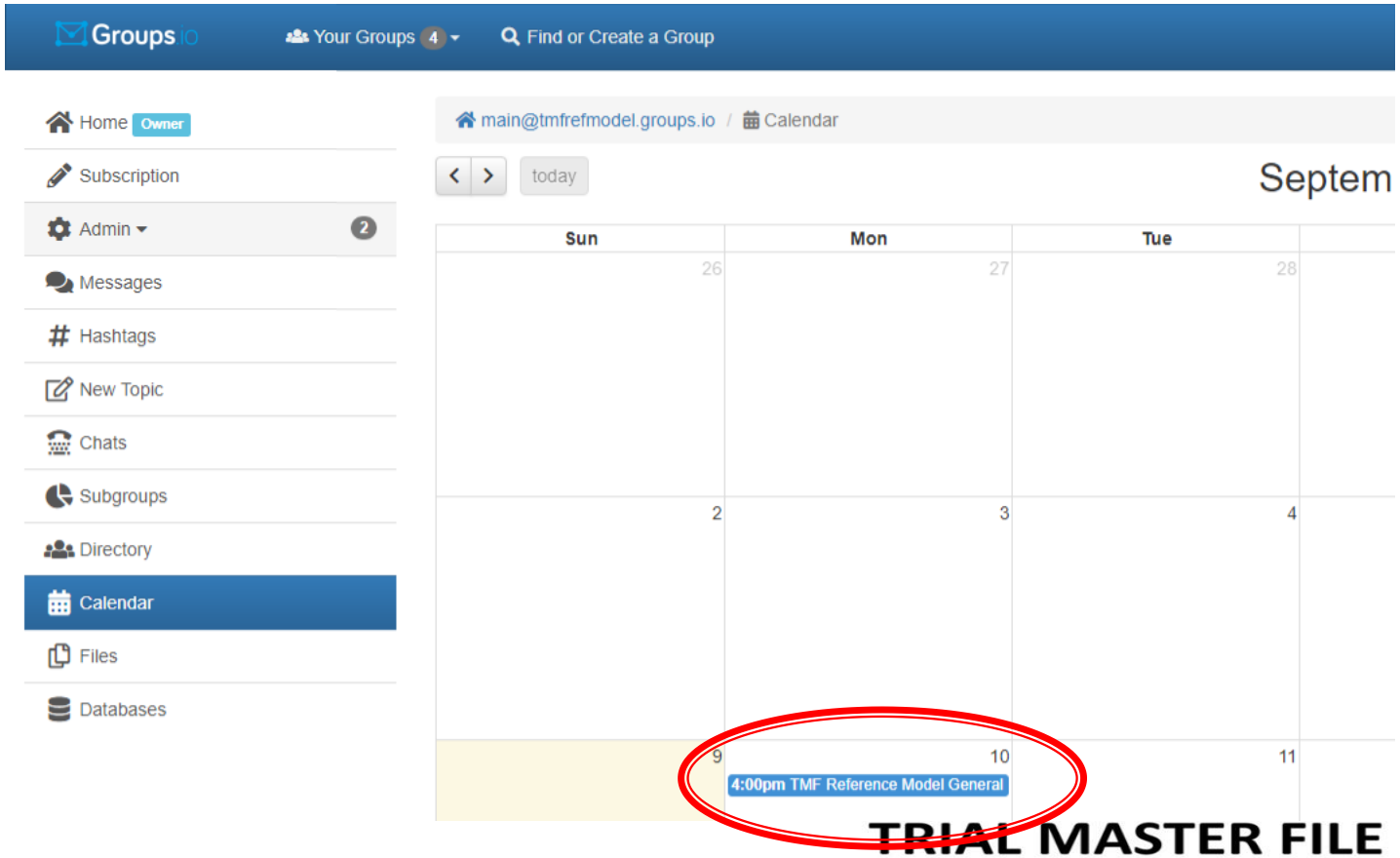
Meeting details

- 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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