Trial Master File Reference Model

General Meeting

13th September 2021

Agenda

▸ Membership
▸ Website update
▸ Future-proofing the TMF Reference Model
  ◦ Strategy on a Page process
  ◦ Process update
▸ Panel Discussion: Timeliness in the TMF
▸ Upcoming TMF Meetings
▸ Next Meeting

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Membership

- 324 project team members (groups.io)
- 1,547 Mailing List Subscribers** (tmfrefmodel.com)
- 3,689 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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No specific update on ICH E6R3

- Link to CTTI E6R3 **project**:
  - https://www.ctti-clinicaltrials.org/projects/informing-update-ich-e6
- Link to CTTI's webinar **overview and recordings**:
  - https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/meeting_report_of_key_themes_and_comments_june_2020_-_final_09152020.pdf
- Link to CTTI's webinar **coverage/synopsis**:
  - https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement

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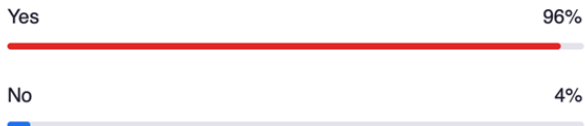**REFERENCE MODEL**

Trial Master File Reference Model

TMF RM Website Content Team

Website Polls

1. How much experience do you have working in TMF space?

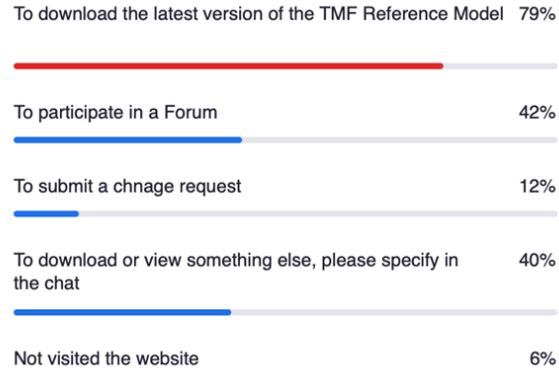|	
1–2 years: Beginner	12%
3-5 years: Intermediate	17%
5 -10 years: Intermediate to Expert	25%
10 + years: Expert	46%

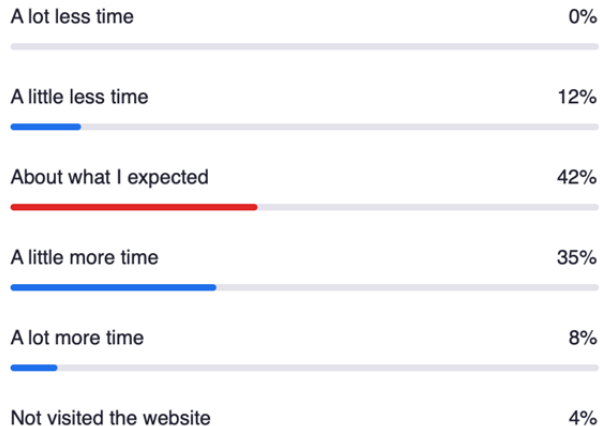**2. Have you ever visited the TMF RM Website?**

Yes	96%
No	4%

3. If so, how easy is it to navigate and find the information you are looking for in the TMF Reference Model Website?

Very easy	12%
Moderately easy, one you hunt around you can usually find what you are looking for	79%
Difficult - please put why in the chat!	6%
Not visited the website	4%
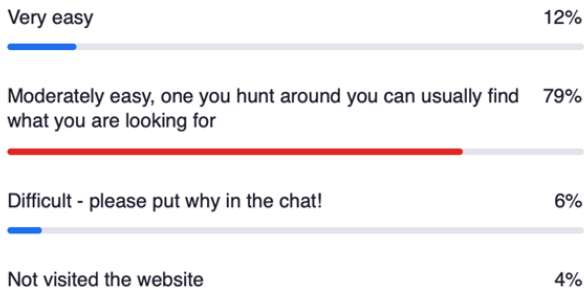
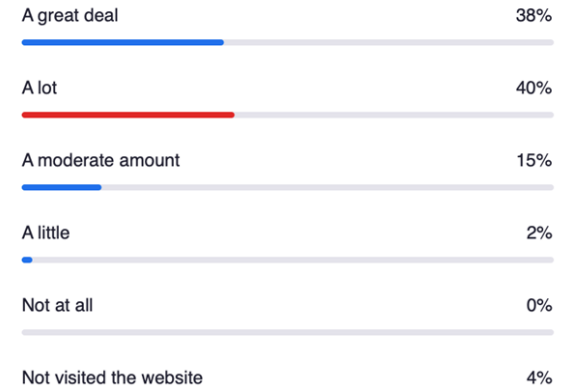**4. What specifically do visit the TMF Reference Model Website for? Multiple choice allowed(Multiple Choice)**

To download the latest version of the TMF Reference Model	79%
To participate in a Forum	42%
To submit a chnage request	12%
To download or view something else, please specify in the chat	40%
Not visited the website	6%

5. Did it take more or less time than you expected to find what you were looking for on the website?

A lot less time	0%
A little less time	12%
About what I expected	42%
A little more time	35%
A lot more time	8%
Not visited the website	4%

6. How visually appealing is the website?

Extremely appealing	0%
Very appealing	12%
Somewhat appealing	40%
Not so appealing	27%
Not at all appealing	17%
Not visited the website	4%

7. How much do you trust the information on the website?

A great deal	38%
A lot	40%
A moderate amount	15%
A little	2%
Not at all	0%
Not visited the website	4%

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Website Content Team Objectives

- 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

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Overview of the TMF RM Website

▸ Url: https://tmfrefmodel.com/

▸ Landing page/Home page:

Overview of the TMF RM Website

- Home page (continued)

Click on an event listed below to see details or to download a .ics file for your Outlook calendar

Upcoming Events

SEP
13 🔖 4:00 pm - 5:00 pm BST
TMF Reference Model General Meeting (Sep)

OCT
19 October 19 @ 8:00 am - October 21 @ 5:00 pm UTC+0
TMF Summit (In person)

NOV
3 November 3 @ 8:00 am - November 5 @ 5:00 pm UTC+0
Clinical Document World

View Calendar

NEXT GENERAL MEETINGS

Click on a date below to download an Outlook Calendar .ics file:

- September 13, 2021

RECENT POSTS

- Exchange Mechanism Standard Survey Results are Available
- EMS Survey Closes February 22
- CORRECTION TO MEETING INFORMATION
- TMF Reference Model User Guide – Revised
- Survey to aid industry adoption of eTMF Exchange Mechanism Standard

RELEVANT LINKS

- TMF Reference Model v3.2.0
- EDM Reference Model
- eTMF Exchange Mechanism Standard Presentation
- eTMF Exchange Mechanism Standard v1.0.1

Search …

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Overview of the TMF RM Website

- **News** – The news tab list the relevant news sequentially, i.e., newest to oldest
- **Forums** – List all the community forums. Currently, we have the following forums:

Forum Name	Topics	Posts
Future-proofing the TMF Reference Model	0	0
General Discussion Forum	51	129
Where do I file… ?	77	156
eMail Communications	2	3
Adopting the reference model	9	22
Archiving	5	25
TMF Management, Content, & Processing	28	71
Signatures	10	32
Project News	3	3

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Overview of the TMF RM Website

- **About the Model** menu link: from here you have the following options available:
  - Participate in Working Groups, Join A Team or it takes you to the Subscribers login page
  - TMF RM Steering Committee – This takes you to an information page regarding the steering committee
  - Intellectual Property Rights Policy
  - Change Requests – Here you can submit a change request to the Change Control Board by filling out a form. Type of feedback to submit are a 'General comment', 'Change existing artifact', and 'Proposal for new artifact'

Overview of the TMF RM Website

- **FAQs** – list commonly asked questions
- **Exchange Mechanism** – Link to the following:
  - EMS News
  - EMS Roundtables
- **Resources** – Link to the following:
  - Resources
  - Resources Archive
  - Events
- **Login** – link to the log in page
- **Help** – basic information on how to use the website
- **Subscribe** – the page that allows you to join and subscribe to the TMF RM

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Overview of the TMF RM Website

- **Change Requests** – provides instructions regarding change requests and takes you to the TMF RM Feedback Form.
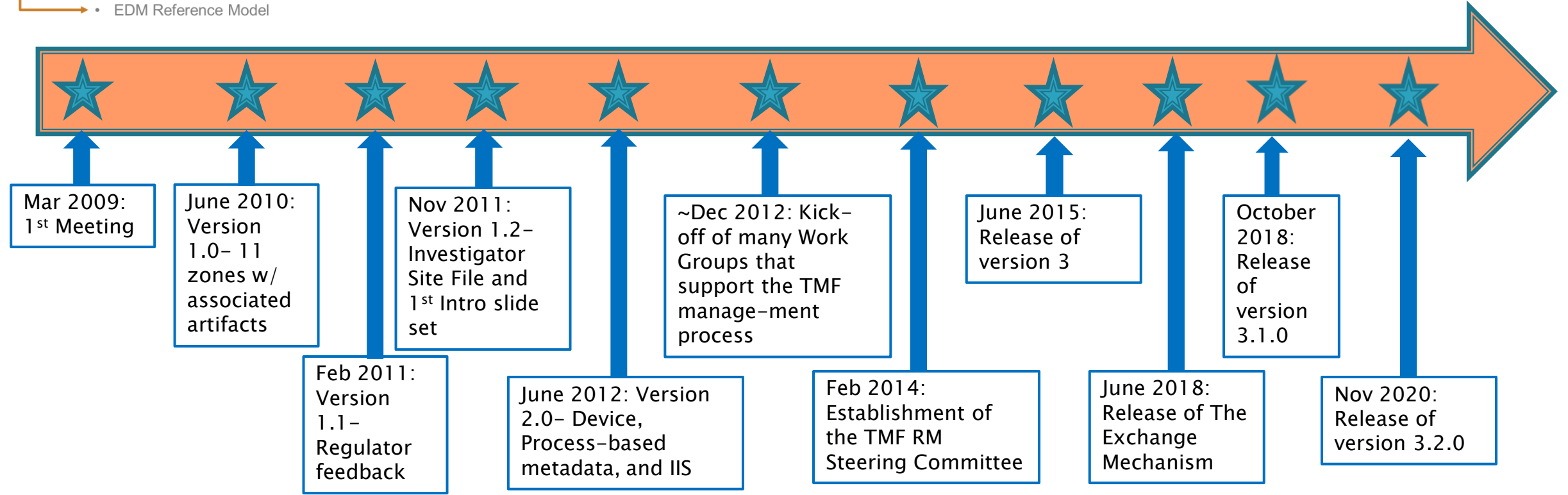
Trial Master File Reference Model

Future-proofing the TMF Reference Model

Karen Roy

Key Messages Reminder

- 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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Strategy on a page

Fran Ross

Why SOAP?

- The Strategy on a Page exercise delivers:
  - Agreement on the organization's goals and strategy
- The outcomes of this effort can include:
  - Increased community and stakeholder alignment
  - Clarity for future directions
  - Speed on action for current activities
  - Wise deployment of resources and time
  - Effective communications and marketing
  - Clarity for goal setting and reporting

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TMF RM Steering Committee SOAP plan

Three Pillars : Refine our goal into three or four main initiatives.

Success Criteria : Specify what success looks like for each goal.

Mission : Create a mission statement to sum up our strategy in one sentence.

Present: Present to you, the stakeholders, and the community for feedback

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Visualising SOAP

Top of pillar = mission statement

Pillar's top = three main objectives

Pillar middles = objective's three success factors

Base = more about the mission, more details on success factors, or any detail that supports objectives, adds color and insights

Objective

Success looks like

Success looks like

Success looks like

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Strategy on a Page Progress

Karen Roy

SOAP Progress to Date

- Survey to capture the SC thoughts on:
  - Offering
    - What do we deliver? How valuable is our offering? What won't we do? What haven't we accomplished?
  - Purpose
    - Why do we exist? What do we do better? What has hampered us? What are our limits?
  - Customers
    - Who are our customers? Who are the VIP customers? Who haven't we served? Who won't we serve?
  - Goals
    - What are our goals
  - Success
    - What does success look like? What does failure look like?
- Workshop 1 to discuss survey responses and consolidate goals
- Workshop 2 to agree the principles of the main objectives
- Survey to vote on top success factors

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Pillar 1 – Evolution

A new way of managing the TMFRM with the ability to incorporate all other models and look further than documents to include data

ANSWER CHOICES ▼	RESPONSES ▼	
▼ Extensible TMF classification scheme (ability to expand model easily such as sub-artifacts, metadata etc.)	76.92%	10
▼ Interoperable TMF classification scheme / All inclusive taxonomy: ISF, devices, RWE, Functional Medicines, different phases etc.	76.92%	10
▼ Better, more malleable tools (DB etc.,) to manage, map and distribute TMF RM Standard	46.15%	6
▼ Accurate and flexible model for clinical trial master file records	30.77%	4
▼ Evolved to include documentation arising from adoption of technology in clinical trials (process Zone 12 - CSV documents)	30.77%	4
▼ Adapting to changing content collection methods - collection of data not documents	23.08%	3
▼ Expansion of the standard to encompass clustering, processes, TMF Health etc..	7.69%	1
▼ Gaining eTMF vendor commitment to implement evolving TMF RM output	7.69%	1
Total Respondents: 13		

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Pillar 2 – Community

Continuity, good future vision and leadership to be fed into through engagement of community.

ANSWER CHOICES	RESPONSES	
Robust, transparent, dedicated RM Steering Committee leadership / Drive membership to assume leadership roles to ensure future proofing for SC and preservation of the TMF RM	69.23%	9
Future focused charter and vision/mission	53.85%	7
Active Working Groups / Drive membership so less are consumers and more are contributors	53.85%	7
Community focus, community driven, community first / Community continues to be engaged and drive evolution	38.46%	5
Ongoing connections to related industry consortia	23.08%	3
Improved website with forums and social media channels to raise awareness / Established communication mechanisms including opportunities to volunteer/engage	23.08%	3
Establish monetary source to support initiatives / Members who are willing to pay for membership	23.08%	3
Included other stakeholders such as investigator sites and SMOs	7.69%	1
Links with National Health Services especially for Investigator Led Studies	7.69%	1
Continuing to raise awareness of the Ref Model	0.00%	0
Model training and education programme responsive to the evolving clinical trial landscape / Process for member qualification	0.00%	0
Total Respondents: 13		

Pillar 3 – Formalization

Align and engage with Regulators, formal process for changes and management, be the defacto standard

ANSWER CHOICES	RESPONSES	
Engagement with the Regulators and other Industry bodies/ Endorsement by Regulatory Authorities / Industry Specific Bodies e.g. ICH / Demonstration to the Regulatory Authorities the Ref Model is produced by TMF expert representation from the industry	76.92%	10
The defacto industry standard TMF structure, with global adoption	38.46%	5
Officially ratified and governed standard with formal rules / Affiliation with Standards Authority	38.46%	5
Accurate and strong RM Change Control Board	30.77%	4
Industry adoption of the Exchange Mechanism Standard - interoperability	30.77%	4
Alignment to health authority requires and desires	30.77%	4
Industry consensus of the TMF management through technology and process	30.77%	4
Governed by a Legal Entity (either by establishing the TMF RM as a legal entity or joining an existing one) / Operational and Financial support	23.08%	3
Standard used for Remote Inspections	0.00%	0
Total Respondents: 13		

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Pillar 4 – Expansion

Go beyond just strictly TMF RM focus. Information and expertise sharing

ANSWER CHOICES	RESPONSES	
Shared experiences and suggestions for best practices, inspections, archiving etc	69.23%	9
Standard metrics for TMF completeness, TMF timeliness and TMF quality / Industry-wide benchmarking using the standard performance measures / eTMF Vendor adoption of standard metrics	61.54%	8
Expand activities/deliverables from just providing the spreadsheet and change the name to reflect this	61.54%	8
RM Community Derived Templates, White Papers, Education / Knowledge initiatives and tools beyond the spreadsheet	46.15%	6
Supports to align with the Regulations, Guidances, etc.	46.15%	6
Determined industry resolution to TMF issues in accordance with Regulators	15.38%	2
Total Respondents: 13		

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The TMF Reference Model is Yours!

- Survey to follow

- Volunteers to contribute ideas

- Get involved

Timeliness Polls

1. Do you measure timeliness?

Yes	60%
No	18%
I'm a vendor	4%
I'm a consultant so I advise on it	18%

2. How do you measure timeliness?

Document Date to Finalization	36%
Receipt Date to Finalization	42%
Due Date	7%
I don't measure timeliness	16%
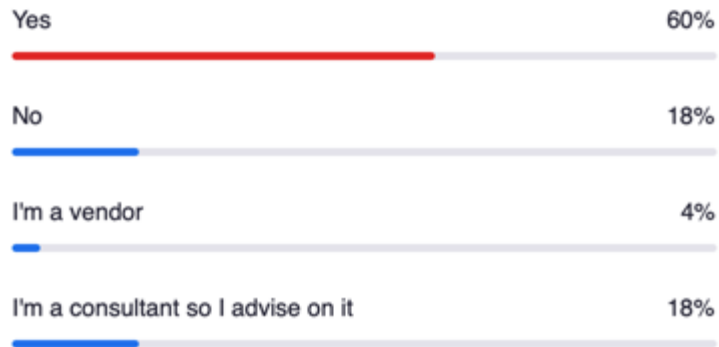
3. What are the biggest challenges you face in measuring timeliness?(Multiple Choice)

Some Document Dates will naturally be outside a timeliness window (e.g., CVs)	64%
Document submitters do not understand the concept of Receipt Date	40%
Due Dates may not always be at the necessary level of granularity	38%
Other - write in the chat!	20%

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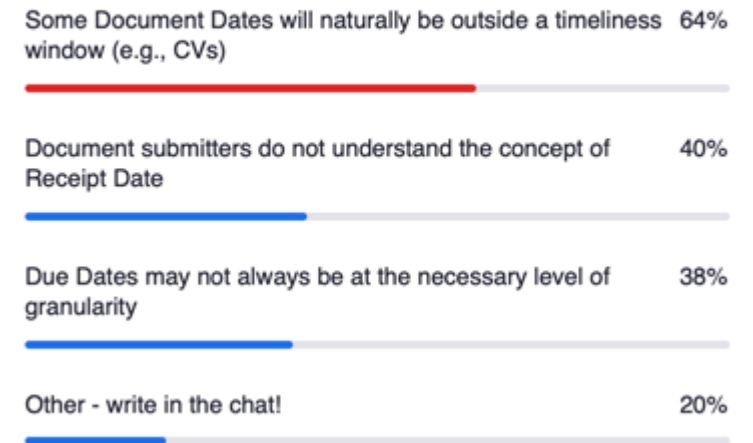
TMF-related events coming up*

*Events page on website (under Resources menu)

▸ HSRAA, Virtual, September 2021

▸ Fierce TMF Summit, NEW ORLEANS AND VIRTUAL, October 2021

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TMF RM General Meetings

▸ <15th November>

▸ 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.

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**/