Trial Master File Reference Model

General Meeting

7th June 2021

Agenda

▸ Membership
▸ Member Reminders
▸ Steering Committee Update
▸ Change Control Board Update
▸ Exchange Mechanism Specification Update
▸ ICH E6 R3 Update
▸ Management of Unblinding Documents (Panel)
▸ Upcoming TMF Meetings
▸ Next Meeting

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Membership

- 324 project team members (groups.io)
- 1,477 Mailing List Subscribers** (tmfrefmodel.com)
- 3,570 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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Emails

1. If you click on 'unsubscribe' to emails, you won't receive ANY further emails from us. If you don't want to receive any more emails, consider deleting your account (login, My Account, Delete Account

2. If your email changes (e.g. you move company), login, Edit Account to change your email address. We have >150 email delivery failures.

   - Check your other profile details too e.g. company name, country etc
   - Why not add a photo ☺

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Meeting details

- Wondering where to find details of the next meeting?

Trial Master File Reference Model
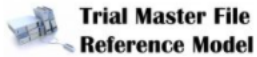
Trial Master File Reference Model
(a DIA Document & Records Management Community project)

Home   News   Forums   About the Model ⌄   FAQs   Exchange Mechanism ⌄   Resources ⌄   Account ⌄   Help   Change Requests

Home

Welcome to the website of the TMF Reference Model. The TMF Reference Model was developed 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.

Edit

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

RECENT DISCUSSION TOPICS

- Postmarketing Study TMF
  6 days, 20 hours ago
- TMF level
  1 week, 1 day ago
- Other information given to Subject
  2 weeks, 2 days ago
- Approval Date on IRB or IEC Approvals and Informed Consent
  2 weeks, 4 days ago
- Where to file DPIA and EMR
  3 weeks, 5 days ago

NEXT GENERAL MEETINGS

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

- April 19, 2021

On TMF Reference Model website, meeting dates are shown under "**Next General Meeting**". Click on a date to see the details and to download a calendar file compatible with Outlook and Google Calendars.
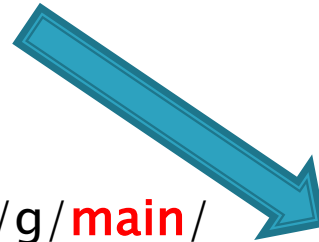
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Meeting details

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If you are registered 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**/

Steering Committee Update

▶ **New to the Committee:**

- Joanne Malia, Regeneron
- Gillian Gittens, Transperfect

▶ **Re-elected to the Committee:**

- Paul Fenton, Montrium
- Kathie Clark, Ennov
- Russell Joyce, Heath Barrowcliff Consulting

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Change Control Board and Zone Teams Update

- Chairs: Kelley Robinson (Odonate) and Leila Ponce (SeaGen)
- The CCB and SC are in the process of evaluating the zone team responsibilities in an effort to increase participation and clearly define roles and responsibilities
- A new zone team liaison is in the process of being identified
- Stay tuned for additional information and ways to participate

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Exchange Mechanism Standard Update

- Check out the recording of our latest Webinar: *"Will the Exchange Mechanism Standard help create a future of greater collaboration? Expert panelists David Ives, Virendra Alate, and Kathie Clark offer their perspectives as sponsor, CRO, and vendor in this recording of the webinar held by the Exchange Mechanism subgroup of the TMF Reference Model on May 27."*
- Recording can be found here: https://youtu.be/pQvuZEljYp8 or by going to the TMF Reference Model YouTube channel
- We will be organizing some follow up webinars so watch this space!
- Visit https://tmfrefmodel.com/ems to download the standard and find other resources!
- Reach out if you need advice how to implement!

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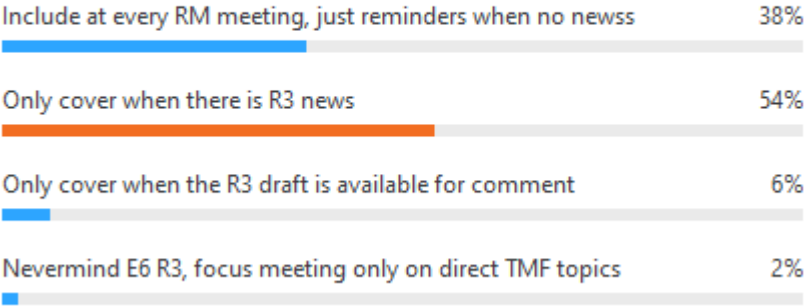**TMF**
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ICH E6R3
An overview of the overview

Fran Ross

I reviewed E6 hard when revision two came out — 26%

I read ICH regs once a month or more — 12%

I know Too Many Facts about ICH E6 — 10%

2. How aware is the TMF RM community of E6R3?

I attended both live webinars of E6 revision 3 — 4%

I attended one live webinar for E6 R3 — 16%

I watched the webinar recording(s) — 7%

I reviewed E6 R3 urls / links — 18%

I've done multiples of the above — 3%

Not yet, on my to-do list — 39%

All news to me — 12%

1. How often should TMF RM include E6 R3 in our meetings?

Include at every RM meeting, just reminders when no newss — 38%

Only cover when there is R3 news — 54%

Only cover when the R3 draft is available for comment — 6%

Nevermind E6 R3, focus meeting only on direct TMF topics — 2%

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ICH E6R3

- ICH EWG is hard at work updating GCP
  - E6 is GCP *topic number six*
  - As you know, E6 Section 8 = Essential Documents (aka TMF)
  - R3 is revision three
- ICH = **International Committee on Harmonization**
- EWG = ICH's **Expert Working Group**
  - Global inspectors and their Health Authority coworkers
- GCP = **Good Clinical Practice**
  - Not perfect clinical practice (PCP? Not!)
- E6 revision 3 is being crafted / drafted **now**

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CTTI's ICH E6 Revision 3 Overview

- In collab with CTTI, ICH EWG held public webinars
  - "Stakeholder Engagement on ICH E6 Guideline for GCP"
- ICH E6 is one of the most impactful guidelines on clinical trial conduct that affects a variety of stakeholders
  - Everyone in our trial universe
- Webinars described <u>here</u> is *part* of layered ICH engagement program

- **Intent = capture experiences of all affected stakeholders**
- **Chime in, discuss, share at work – now is the time**

> "The EWG highlighted that they are working on comprehensive principles that will remain relevant as technologies evolve and clinical trial design advances."

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ICH E6R3 – Stakeholder Engagement

▸ EWG intends to capture **all** the divergent perspectives
  ◦ Across trial *participation, conduct, management, and coordination*
▸ EWG wants E6(R3) to reflect **all** trial stakeholders
  ◦ HumanHeroes, Medical Pros, Site Trialists, Sponsor Trialists (and Sponsor's Vendors), Health Authorities, Trial.orgs (PhRMA, CTTI, TransCelerate, etc.)
▸ First ever public webinars May 18 and 19, 2021
  ◦ Different panels each day, broad perspectives
  ◦ Thanks pandemic – originally was f2f mtg
▸ E6R3 **formal draft** will come out for **formal public comment**
  ◦ Finger in the wind – perhaps early / mid 2022?

▸ **DIAL IN – SHARE – CHIME IN – WATCH OUT more public interactions to follow**

"Engagement is at the heart of the E6 revision process."

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Dig into CTTI's coverage of 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

- CTTI overview states "June 4 and 5" – they make mistakes too!

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Bear in mind...

Our Global Regulators and the Awesome Inspectors...

Are funded by your tax dollars

Are humans just like you

QR source: https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/meeting_report_of_key_themes_and_comments_june_2020_-_final_09152020.pdf 07June2021

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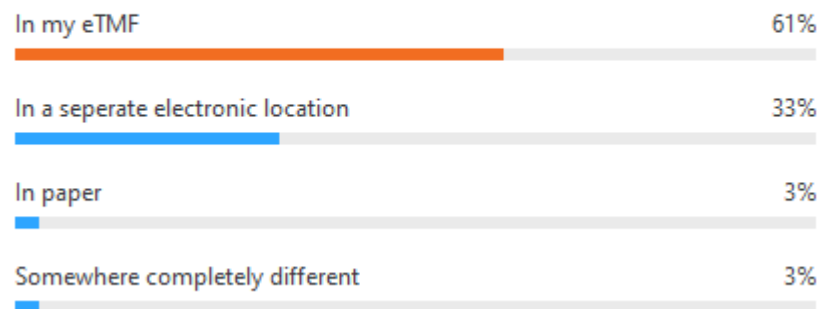**TMF**
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Too Many Famous Acronyms

- CTTI = clinical trials transformation initiative
- FDA = USofA health authority
- ICH = International Committee on Harmonization
  - For medicines, keeping the #humanHeroes safe
  - UK, EU, PanAmerican, AsiaPac…many countries adopt ICH as regulations
- E6R3 = Efficacy topic six, revision three
  - Drafting **now**
- EWG = Expert Working Group
  - Lots of inspectors and their HA friends
- QbD and RM = Quality by Design and Risk Management
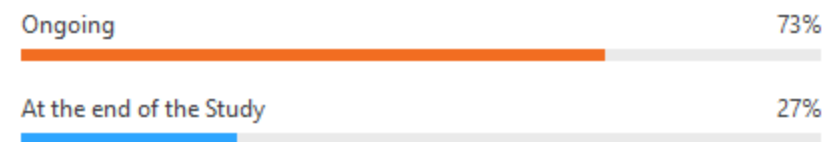
ICH E6 materials = hard work, so worth it

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How do I manage Unblinded Documents?

Panel: Mary Emanoil, Paul Fenton, Allison Varjavandi

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1. Where do you store your unblinded TMF documents?

In my eTMF	61%
In a seperate electronic location	33%
In paper	3%
Somewhere completely different	3%

1. If you store your unblinded documents in your eTMF, when do you add the documents?

Ongoing	73%
At the end of the Study	27%

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ICH E6 R2 "1.10 Blinding/Masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s)."

Comments in the discussion:

- Each function is responsible for filing and the timing may be different based on the information.
- We manage it through our User Role Setup. We restrict which study members can see blinded and unblinded documents, which can see only blinded.
- We have an unblinded role and everything they create is restricted by default, but at the time of creation they can choose to lift the restriction if the document doesn't need restricted access.
- We have the unblinded user upload and the QC reviewer confirms it is indeed an unblinded document. it's also good for the QC reviewer to confirm the blinder users are not uploading unblinded documents
- Our Biometrics team adds PWD protected unblinded documents in eTMF to enable sharing with specific users, this has a different risk obviously
- One way we mitigate the impact of over sharing of sensitive documents like unblinding information, is to have a strict audit trail of "views" or readership built in to our TMF. So if things go wrong we always know who has accessed information (tends to be just a few) vs those who have not (the vast majority).
- We have a small TMF Team and they all have access to Unblinded docs to QC

TMF-related events coming up*

Events page on website (under Resources menu)

▸ HSRAA, Virtual, September 2021

▸ Fierce TMF Summit, New Orleans, October 2021

▸ Clinical Document World, New Jersey, November 2021

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TMF RM General Meetings

- <19th July>
- 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?

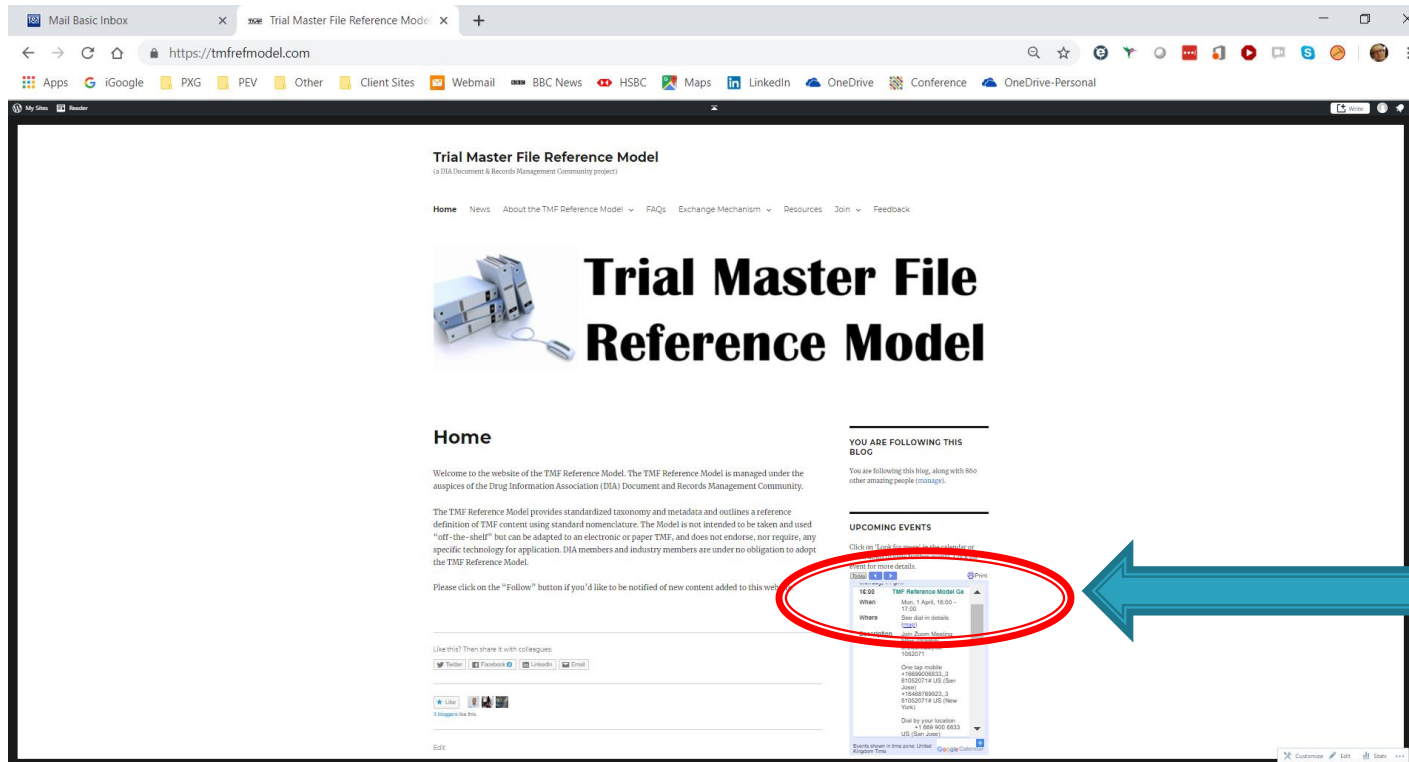Join the TMF Reference Model Discussion Group
https://tmfrefmodel.com/register

- 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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