Trial Master File Reference Model

General Meeting

10 September 2018

Agenda

- Welcome
- Meeting details reminder
- TMF RM Community update
- Subgroup Activity
  - Sub-artifact
  - Exchange mechanism
  - Framework for destruction
- Version 3.1.0
- Upcoming Industry meetings

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Since last meeting…

- 10 new project team members
- 46 new Mailing List Subscribers (MailChimp)
- 14 new Yahoo!Group Forum members
  - 19 new discussion topics posted
- LinkedIn group – 2,629 members
  - 19 new discussion topics posted

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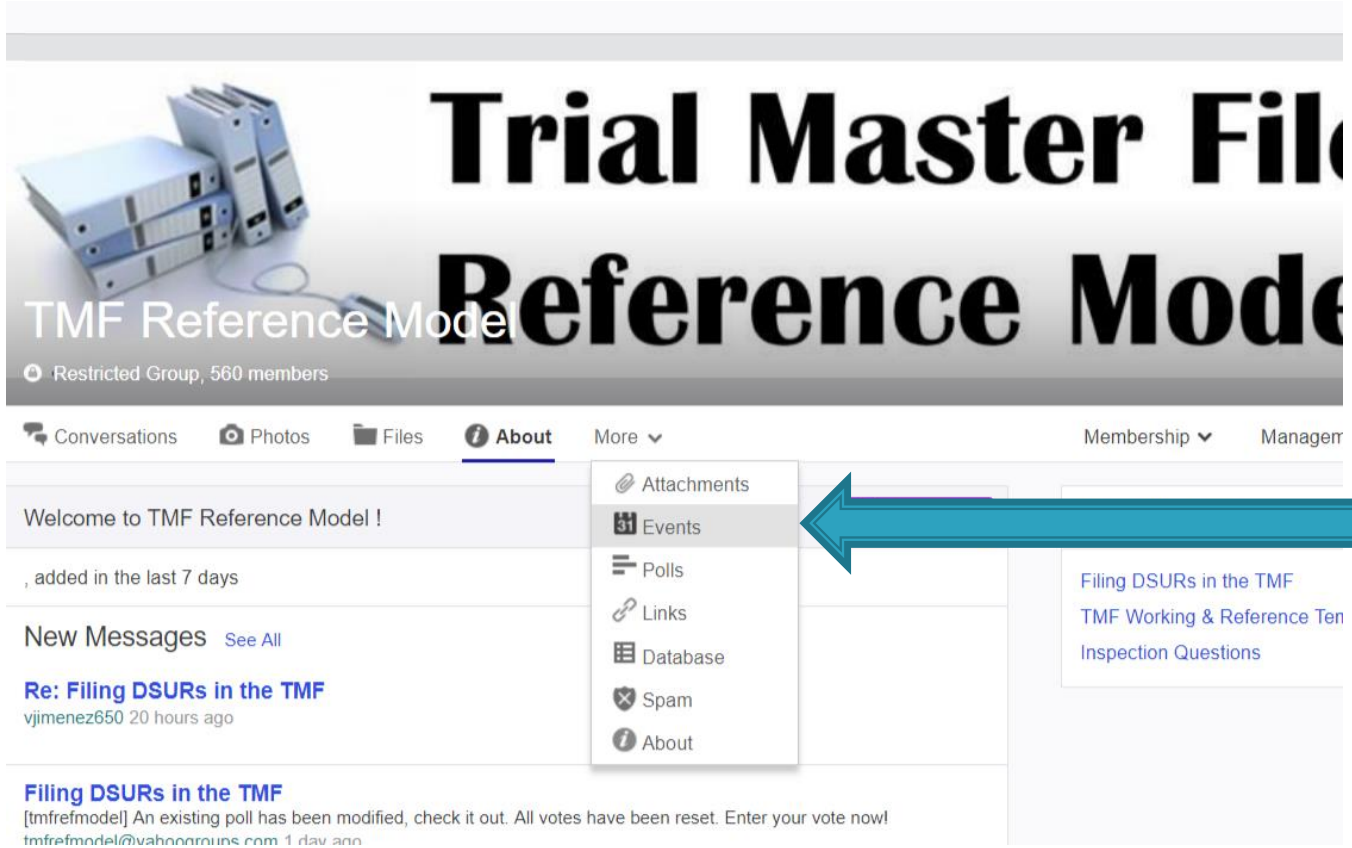
Meeting details

- Wondering where to find details of the next meeting?



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

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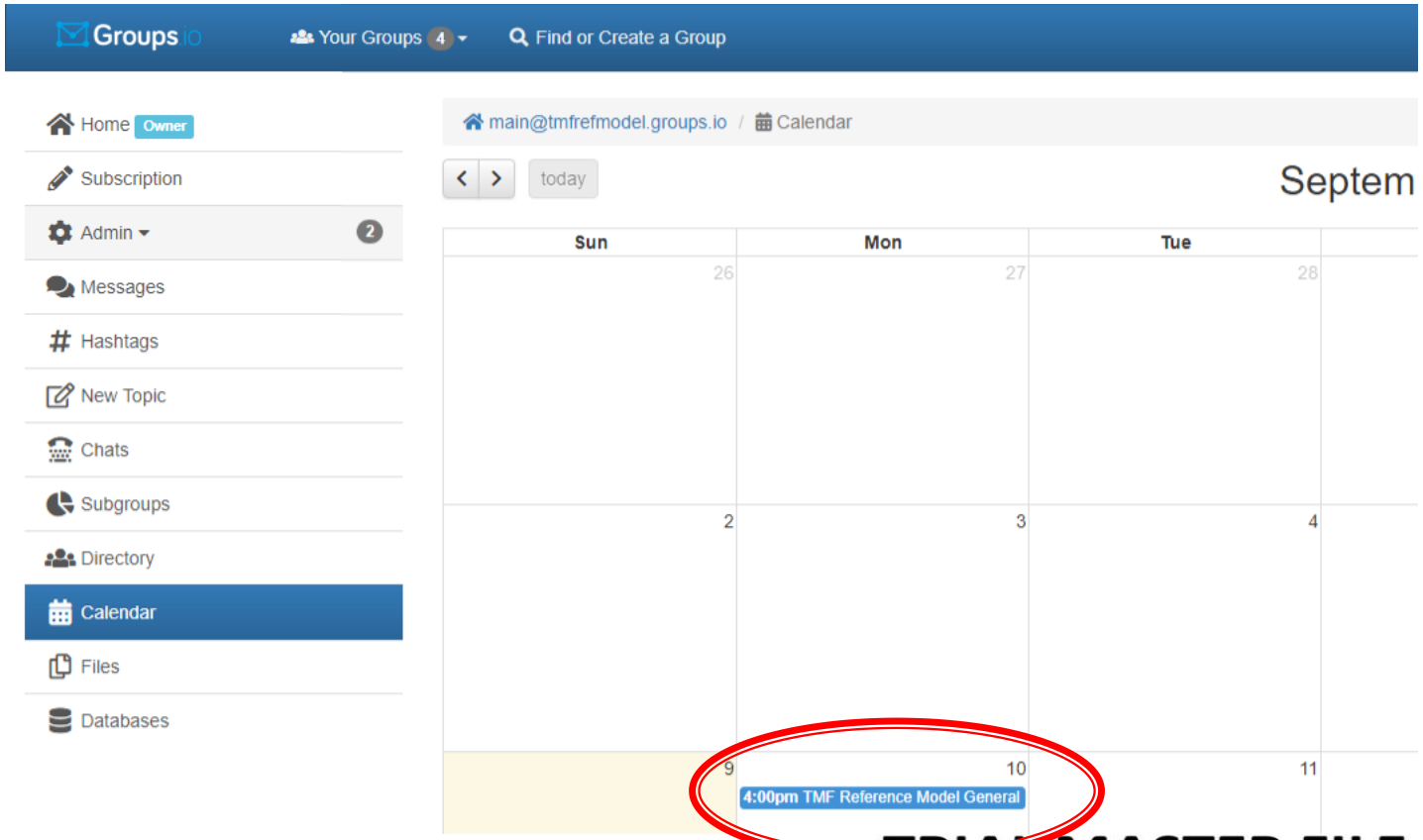
Meeting details

- 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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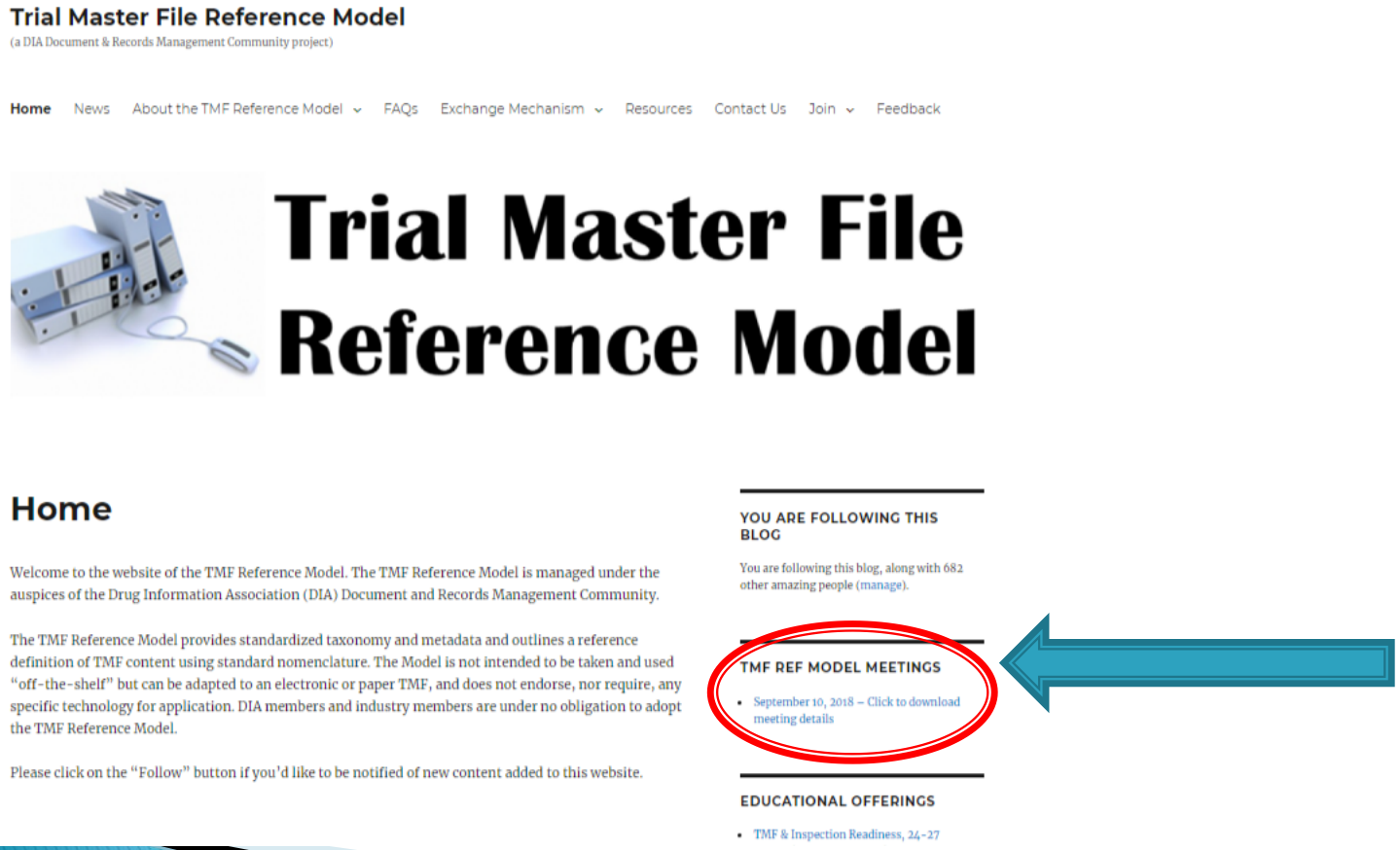

On TMF Reference Model website, click on calendar link. This downloads a .ics file that you can import into your Outlook/Google calendar

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Meeting details

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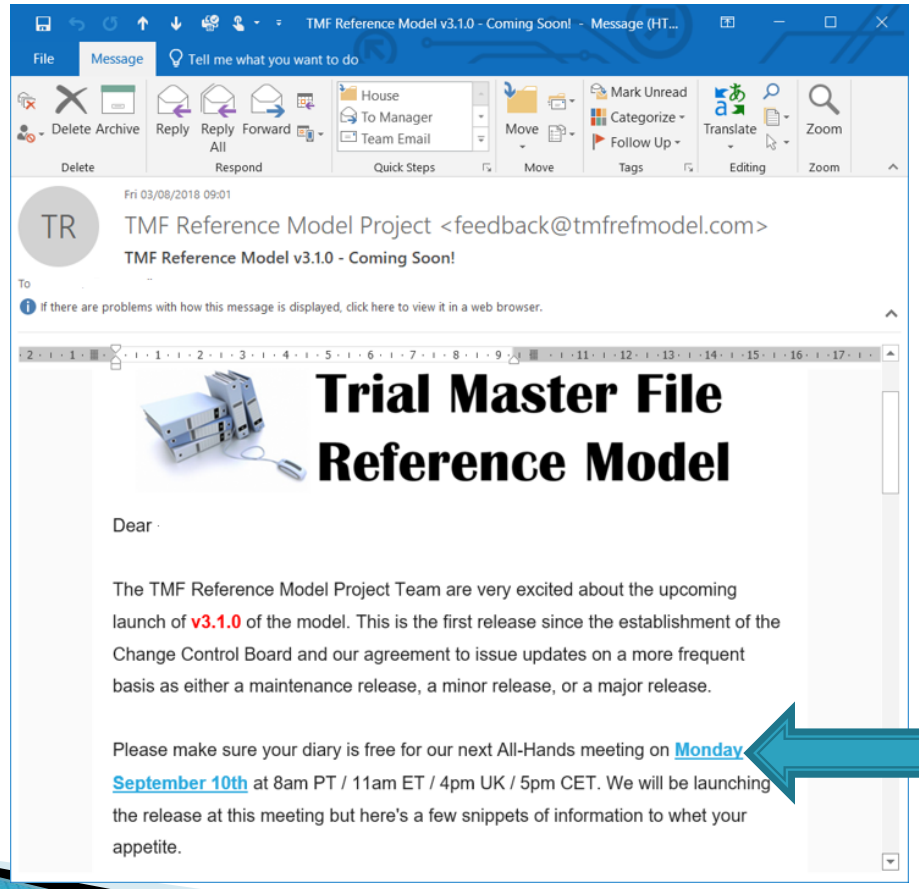

In Reference Model emails, click to download calendar file (.ics) for import into your Outlook/Google calendar

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Activity of Subgroups

Group	Lead
Non-Interventional Studies	Russell Joyce
Sub-artifacts	Karin Schneider
Country specific artifacts	Eleanor Hewes
Device Studies	Melonie Warfel
Survey 2019	David Ives
J-GCP	Sub group
Framework for the Destruction of Paper	Lisa Mulcahy
Exchange Mechanism	Paul Fenton / Elvin Thalund / Ken Keefer
Change Control Board	Kelley Robinson / Joanne Malia

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Sub-artifacts Team Update

- 11 zone teams have been identifying sub-artifacts
- Five zones have sub-artifacts identified and whole-team reviews completed (01, 02, 03, 07 and 11)
- Six zones have sub-artifacts identified and are scheduled for review by the whole team (04, 05, 06, 08, 09 and 10)
- Two requests:
  - Existing team members to make time to complete their review
  - New members welcome to zone teams…. zone teams to also review relevant Change Requests

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Devices

- 10 Members with 3-4 active participants
- Small group – reviewing the Zones and documenting recommendations as a team
- Zones 1-6 reviewed with comments
- Zone 6 recap and Zone 7 meeting Sept.13th 11:00-12:00 EST
- Meetings scheduled every 4th Thursday through end of year
- If interested please join the group!

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Device Zone Review Example

TMF Reference Model	TMF RM Website	Version 3.0

Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Alternate names (artifact also commonly known as)	Definition / Purpose
06	IP and Trial Supplies	06.01	IP Documentation	06.01.01	IP Supply Plan	Trial Medication Plan Clinical Trial Material Distribution Plan IP Supply and Packaging Plan	To describe the following as they pertain to the IP: 1) quantity and packaging of active, placebo and/or if applicable, comparator or rescue supplies needed to fulfill the requirements of the trial protocol over the life of the trial, as well as blinding plan (if applicable) and 2) acceptable storage temperatures and conditions, storage times, reconstitution fluids and procedures and devices for product infusion. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.02	IP Instructions for Handling	Pharmacy Manual Device User Manual IP Manual IP Labeling and Packageing	To instruct on how the IP should be handled during transit and stored upon arrival at the distribution center, depot and/or trial site. Should address expectations for adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects and return of unused IP to the sponsor (or their delegate) If appropriate to the trial, includes preparation of the IP leading to administration and administration instructions.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.03	IP Sample Label		A sample of each IP label type (for every pack and every language) to be used in the trial; approval status must be clear. All stages of label text development are included within this artifact.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.04	IP Shipment Documentation		To record details of the shipment process including approval , requests, dispatch, tracking and receipts to/from a distribution center, depot and/or trial site.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.05	IP Accountability Documentation	Inventory Documentation IP Accountability Records	To document records of the allocation of IP to/from a distribution center, depot, trial site and/or site to subject and the reconciliation of IP prior to return to the sponsor.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.06	IP Transfer Documentation. Clarify reaoson for review (is it the "distribution/depot"?		To document the transfer of IP between depots and sites (within or across protocols). Examples include sponsor approval for transfer and evidence of consultation with Qualified Person (QP).
06	IP and Trial Supplies	06.01	IP Documentation	06.01.07	IP Re-labeling DocumentationClarify reaoson for review (is it the "distribution/depot"?		To document the plan for the re-labeling process to occur at the distribution center, depot and/or site and confirmation records that the re-labeling occurred.
06	IP and Trial Supplies	06.01	IP Documentation	06.01.08	IP Recall DocumentationClarify reaoson for review (is it the "distribution/depot"?		To document the plan for the recall process for the IP to occur at a distribution center, depot and/or site; will include confirmation records that the recall occurred.

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Framework for the Destruction of Paper – Update

All parameters have been (mostly reviewed). There have been removal, splitting and combining, and addition of parameters. Ramping way up is the Implementation / Toolkit Team

TTL Leader name(s):	**Curran Murphy and Liz Farrell** **Support by: Fran Ross and Russell Joyce**
TT progress to date:	Team has been reviewing the proposed tools to support the Framework. There are 8 tools that have been proposed to date. The team has approved the following tools for creation: 1)**Paper Destruction Decision Tree** and 2)**Paper Destruction Policy Template**; and is responsible for 3)**reviewing/revising the current Process Maps** after the Framework has been refreshed (Process Maps are being removed from the Framework document and placed into Appendix for the update)
Still to come:	Continuing Work: • Assign responsible person & sub-team personnel for creation of approved tools (work already being done!) • Continue discussions to decide if additional tools will be created (reviewing/discussing 6 additional proposed tools)

Project Timeline

Very Simply…

Project Task	Date Due
Call for Volunteers	January – February 2018
Project Kick-off	March 1, 2018
Survey Team	February – April/May 2018
Topic Team Activities	March – September 2018
Editing Team	October – November 2018
Implementation Team	May – November, December 2018 and beyond
Presentation of Results	October 2018 – May 2019
Survey Team	Additional surveys being considered in January & June 2019

Beyond the Parameters – The Editing Team

Other Parts of the Framework that need to be reviewed/revised

Now that parameter review has been (mostly) completed, the work to publish the document is ramping up. Need volunteers to take small and larger tasks to review/check

- Cross parameter review to ensure consistency and completeness
- Reference check and categorization of references (standards, regulations, guidances, etc.). Consistency in how written.
- Textual consistency across the entire document
  - Defining what and how – ex. document dates
- URL link checking
  - Including the entry of last date checked
- Glossary information confirmation
- Update Opening page and Appreciation page
- Develop feedback mechanism/feedback form

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Publication/Presentation Planning

- Publication/presentation planning is in full swing!
- Please forward any appropriate meetings in which we could promote this effort or sub-topic(s).
  - If in doubt, please propose the meeting! So far we have:
    - Electronic Data and Document Management – The Next Industrial Revolution; 28-29 November 2018, Barcelona, Spain
    - DIA Global Forum – DRM Community
    - TMF Summits – Oct'18 (London, UK) & Jan'19 (Orlando, FL USA)
    - Regulatory Submissions & Document Management Forum (Feb'19)
    - Submitted to DIA EU meeting (Feb '19)
    - HSRAA Annual Meeting (May '19)
    - DIA DRM Community and others – All Hands Meetings (Jan – June '19)
- Send all meetings/suggestions to: Lisa Mulcahy, mulcahyconsulting@comcast.net so it can be considered

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eTMF-EMS Updates

Webinars

- Monthly webinars started end of August and will be held monthly
- Next webinar is Technical and will be held October 9th at 10am EST – Invites will be sent
- Next business webinar to be held November 8th 10am EST

Piloting the EMS

- Looking for sponsors/CROs/vendors who are willing to text the EMS in a pilot

Our website

- Submit your questions, suggested topics for webinars or put forward your organization for a pilot at https://tmfrefmodel.com/ems/

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Change Control Board – Version 3.1.0

- CCB Membership Update
- Deliverables – Review of TMF Reference Model Version 3.1.0!
- CCB ‘By the Numbers’
- Feedback and Change Requests
- Call for Volunteers

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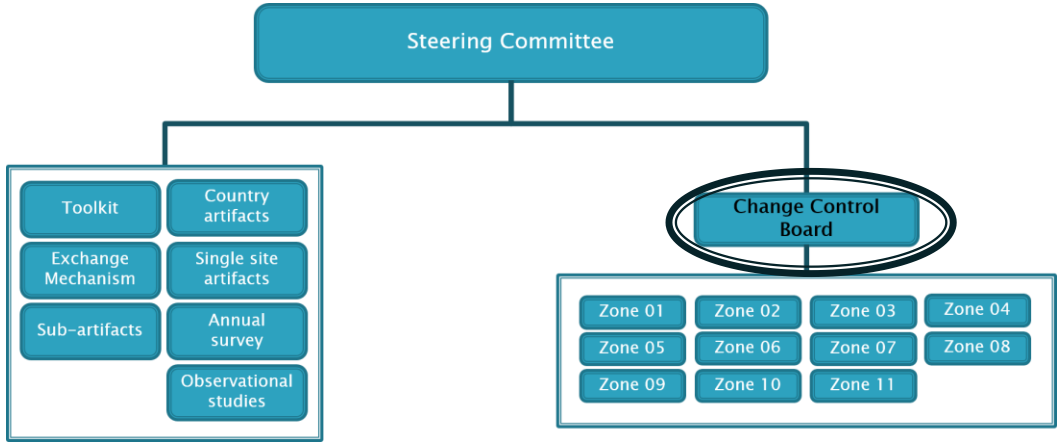
CCB Membership Update

- 14 Members
  - Kelley Robinson, Odonate Therapeutics: *Chair*
  - Joanne Malia, Regeneron: *Deputy Chair*
  - Gift Chareka, UCSF: *Exchange Team Liaison*
  - Eldin Rammell, Rammell Consulting: *Steering Committee Liaison*
  - Cynthia H. Squires, UCB Biosciences
  - Kristen Bretzius, PSI CRO
  - Melissa Maberry, Veeva Systems
  - Marion Mays, Phlexglobal, Inc.
  - Katherine M. Santoro, Alkermes, Inc.
  - Claire Mooney, Phlexglobal, Inc.
- New Members – Welcome!
  - Craig Picinich, BioClinica
  - Laurel-Ann Schrader, TransPerfect
  - JP Miceli, Advanced Clinical
  - Kaylin Tribble, Arivis



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TMF Reference Model 3.1.0

- **Documentation Delivered**
  - TMF Reference Model Version 3.1.0
  - TMF Reference Model Version 3.1.0 Release Notes
    - Released on 10-Sep-2018 for preview
    - Effective as of 10-Oct-2018
    - https://tmfrefmodel.com/resources/
- **Change Requests 'By the Numbers'**
  - Total of 64 Change Requests Submitted since October 2015
    - 23 Approved and included in release 3.1.0
    - 18 Rejected
    - 21 Deferred
      - Deferred to sub-teams, Steering Committee or next release

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TMF Reference Model 3.1.0

- Added deliverables already approved
  - Suggested dating conventions for each artifact (Feb 2017)
  - Recommended milestones/events (Jan 2018)
    - Also scheduled for assessment during 2019 to take account of industry feedback

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TMF Reference Model 3.1.0

- Four minor changes to artifact name
  - 03.01.02 Regulatory Approval Notification…. Regulatory Approval Decision
  - 03.02.02 Import or Export License…. Import or Export Documentation
  - 03.03.01 Notification to Regulatory Authority of Safety or Trial Information…. Notification of Safety or Trial Information
  - 10.03.10 Data QC or QA Plan and Results…. Data Review Documentation

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TMF Reference Model 3.1.0

- Eight minor changes to artifact definition/purpose
  - 01.05.04 Filenote
  - 02.01.01 Investigator's Brochure
  - 03.01.01 Regulatory Submission
  - 03.03.01 Notification of Safety or Study Information
  - 06.01.06 IP Transfer Documentation
  - 08.02.05 Record of Retained Samples
  - 11.03.02 Analysis QC Documentation
  - 11.03.09 Final Analysis Datasets

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TMF Reference Model 3.1.0

- Sub-artifacts added for three artifacts
  - 10.03.09 Dictionary Coding
  - 10.03.10 Data QC or QA Plan and Results
  - 02.03.01 Clinical Study Report

- Further sub-artifacts currently under development by sub-artifact team…. for release in 2019

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TMF Reference Model 3.1.0

- Two artifacts with revised ICH codes
  - To correct a typographical error
  - 02.01.02 Protocol
  - 02.01.04 Protocol Amendment

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TMF Reference Model 3.1.0

- Three artifacts with additional filing level
  - Added study-level:
    - 03.01.01 Regulatory Submission
    - 03.01.02 Regulatory Approval Notification
  - Added site level:
    - 06.03.02 IP Unblinding Plan

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TMF Reference Model 3.1.0

- Two artifacts with additional alternate names
  - To correct a typographical error
  - 03.01.02 Regulatory Authority Decision
  - 03.02.02 Import or Export Documentation

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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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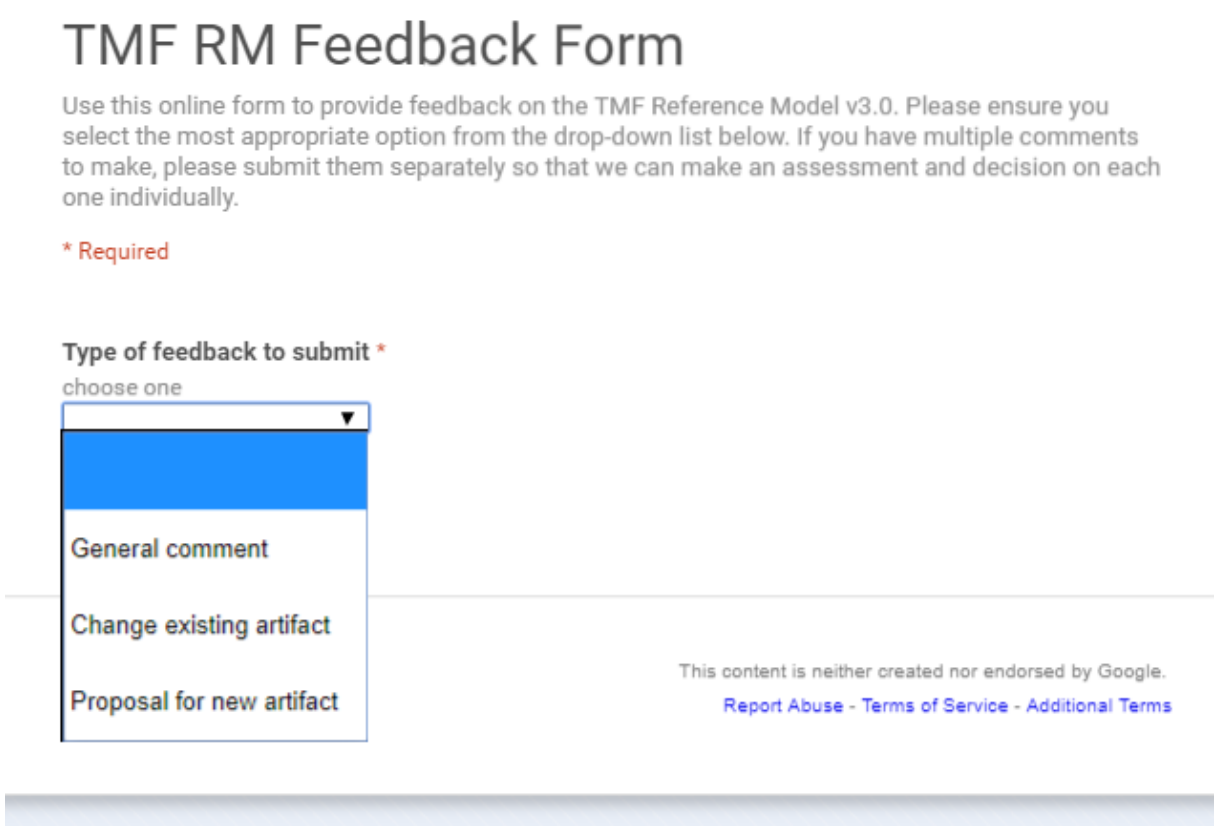
Feedback and Change Requests



Use online form for:

- Making a suggestion for a general enhancement to the Reference Model
- Suggesting a change to any metadata for an existing artifact
- Suggesting a new artifact

Select the appropriate option and only make ONE suggestion per form submitted please.

Do not send general queries using this form.

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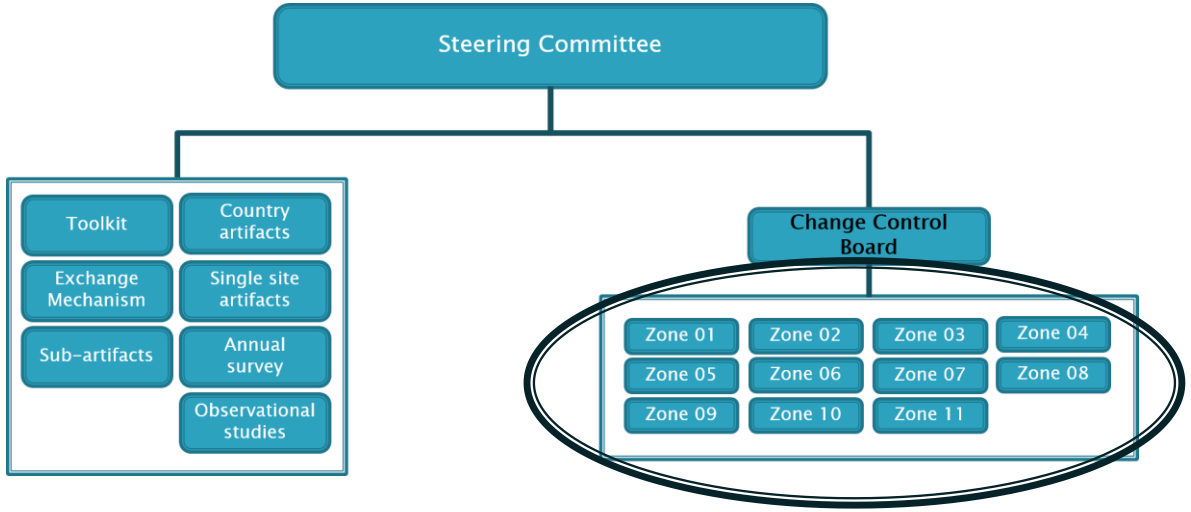
Get Involved!



- Have a passion for the TMF? Are you an expert in a particular area? We are always looking for new members to join the zone teams!

- Follow the instructions on the Join page or contact any member of the CCB team

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TMF RM Version 3.1.0

What is the Impact?

- Release notes give all details to assess impact
- Minor release so minimal impact on overall structure
- Artifact names may change BUT the artifact numbers do not change
- Includes process aspects such as milestones and dating conventions – very customised by Sponsors / CROs

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Future Releases

- Minor/Maintenance release anticipated in 1Q 2019
- Major release anticipated later in 2019 to incorporate deliverables from the following sub-teams:
  - Sub-artifact
  - Observational and Device

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eTMF Conferences coming up

- IQPC, TMF and Inspection Readiness, 24th to 27th September, Amsterdam https://trialmasterfile.iqpc.co.uk/
- EXL TMF Summit, London, 15th to 17th October http://tmfsummit.com/europe
- DIA Clinical and Regulatory Operational Excellence, Barcelona, 28th to 29th November 2018. http://www.diaglobal.org/en/conference-listing/meetings/2018/11/edm-2018-clinical-and-regulatory-operational-excellence-forum

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TMF RM General Meetings

- 12-Nov
- Add to your calendar NOW or download the calendar file (.ics file) when you receive the meeting notification from MailChimp or 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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