



Trial Master File Reference Model

General Meeting

19 March 2018

Agenda

- ▶ Welcome
- ▶ Steering Committee Update – Reminder to Vote!
- ▶ TMF RM Community
- ▶ ICH Update
- ▶ Implementation and User guide
- ▶ Change Control Board
- ▶ Exchange mechanism
- ▶ Other Subgroup activity update
- ▶ MHRA Data Integrity
- ▶ Upcoming industry mtgs
- ▶ If time allows, a presentation on TMF Management: “Engaging People to be Part of the TMF Solution” by Lisa Mulcahy

Steering Committee Update

- ▶ Voting for 3 vacancies closes EOB on Friday March 23
 - Kristen Bretzius, PSI, USA (CRO)
 - Kathie Clark, IQVIA, USA (Vendor)
 - David Ives, Vertex, USA (BioPharma)
 - Russell Joyce, Heath Barrowcliff Consulting, UK (Consultant)
 - Jackie Morrill, LMK Clinical Research Consulting, USA (Consultant)
- ▶ Voting open to groups.io members (active project team)
 - Approx. 35% of eligible members have participated
- ▶ Final reminder from SurveyMonkey will be sent after this meeting.... look out for your personal link

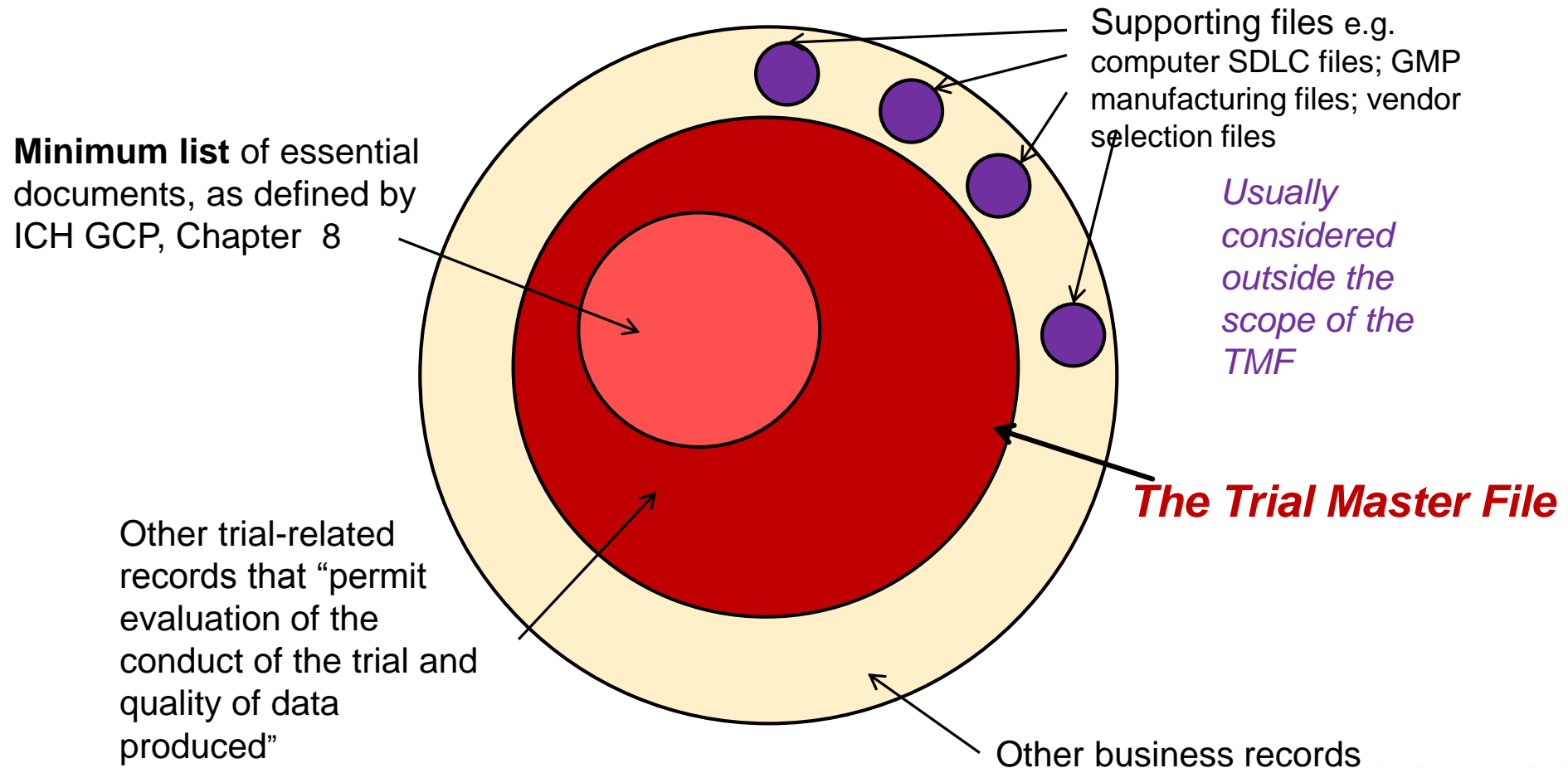
TMF RM Community in numbers

- ▶ Project Team Members: 260
 - ▶ Subscribers (join from website homepage): 712
 - ▶ Discussion Board (Yahoo! Groups): 540
 - ▶ LinkedIn Group: 2,463
-
- ▶ Approx. 10 new subscribers join each month

Why a TMF Reference Model?

- ▶ ICH GCP Section 8.2 – 8.4
- ▶ “The **minimum** list of essential documents - those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements.
- ▶ ICH GCP does **not** provide a comprehensive contents list for the TMF
 - Examples of missing documentation:
 - Electronic systems
 - Data management and statistical methodology
 - Safety monitoring

Defining the TMF Reference Model



An ICH Opportunity!

- ▶ Invitation to present TMF Reference Model and Exchange Mechanism to ICH M2 Expert working Group
- ▶ USA, Japan and EU
- ▶ What do we want from it??

New User and Implementation Guides

Now Available

TMF Tools:

- [TMF Reference Model User Guide](#): Introduction to the model, understanding its structure, and how to use it (v1.0 Approved 16-March-2018) **NEW**
- [TMF Reference Model Implementation Guidance](#): Provides a framework for implementing the model in your organization (v1.0 Approved 14-March-2018) **NEW**

Trial Master File Reference Model

(a DRA Document & Records Management Community project)

Home News About the TMF Reference Model FAQs Exchange Mechanism Resources Contact Us Join Feedback

Trial Master File Reference Model

Current Version of TMF Reference

- [TMF Reference Model v3.0](#), Released 16-JUN-2015, Excel Spreadsheet
- Mindjet File for TMF-RM v3.0 (.mmmap format - requires Mindjet licence to open file) - available to TMF Reference Model Project Team members via Yahoo!Group document library due to WordPress restrictions
- [MindMap PDF File for TMF-RM v3.0](#) (.pdf format - requires Acrobat Reader and Adobe Flash)
- [TMF Reference Model v3 Presentation](#) - Overview of the Reference Model
- [TMF Reference Model User Guide](#) - Guide for Implementing the TMF Reference Model
- [TMF Reference Model Process Maps](#): Used in development of Reference Model to align TMF artifacts to trial processes
- [The Evolution of the TMF Reference Model v3.0](#): Recording of webinar delivered in July 2015

TMF Tools:

- [TMF Reference Model User Guide](#): Introduction to the model, understanding its structure, and how to use it (v1.0 Approved 16-March-2018) **NEW**
- [TMF Reference Model Implementation Guidance](#): Provides a framework for implementing the model in your organization (v1.0 Approved 14-March-2018) **NEW**
- [TMF Plan Template](#): Suggested structure and outline for a Trial Master File Plan (v1.0 Approved 23-February 2018) **NEW**
- [TMF Plan Template Feedback](#): Click on [LINK](#) to provide feedback on the TMF Plan **NEW**
- [Milestones / Events](#): Suggested latest milestones or events by which each artifact should be filed (v1.1 Approved 31-January-2018) **NEW/UPDATE**

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EDUCATIONAL OFFERINGS

- [TMF and Clinical Operations Quality Excellence](#), Berlin, Germany, 19-21 March 2018 Agenda includes presentation on the TMF Reference Model and supporting tools. Also an update on the Exchange Mechanism.
- [ISRAA \(formerly Scientific Archivists Group\) Conference](#), 26/27 April 2018, Brighton, UK...incl. TMF Essentials Workshop
- [4th European Clinical Trials Inspection Roundtable](#), London, UK, May 2018 from Ed. Events
- [TMF & Inspection Roundtable](#), 24-27 September 2018, Amsterdam

SUBSCRIBE

TRIAL MASTER FILE
TMF
REFERENCE MODEL

Example pages below...



1	Introduction to the TMF Reference Model	4
1.1	Goal of TMF Reference Model	4
1.2	History of TMF Reference Model	4
1.3	How to contribute to the TMF Reference Model	4
2	Introduction to the User Guide	5
2.1	Goal of the User Guide	5
3	Structure of the TMF Reference Model	5
3.1	TMF Zones, Sections and Artifacts	5
3.1.1	Zones and Sections	6
3.1.2	Artifacts	7
4	Navigating the TMF Reference Model Excel Spreadsheet	8
4.1	TMF Reference Model Workbook	8
4.1.1	TMF Numbering – Zones, Section & Artifacts	9
4.1.2	TMF Descriptions – Alternative names, Definition & Sub-artifacts	10
4.1.3	TMF Inclusion – Core vs. Recommended	11
4.1.4	ICH Code and EDM RM Artifact	11
4.1.5	Unique ID Number	12
4.1.6	Sponsor/Investigator Filing Accountability	12
4.1.7	Investigator Initiated Studies	13
4.1.8	Process Based Metadata	14
4.1.9	TMF (Filing) Levels	14
4.2	TMF Mark-up Tab	15
4.3	TMF Model Overview Tab	16
4.4	Introductions and Glossary Tab	17
4.5	Computer System Validation Tab	18
5	Navigate the TMF RM using filter and sort functions	19
5.1	Filtering the TMF Workbook	19
5.2	Sorting	20

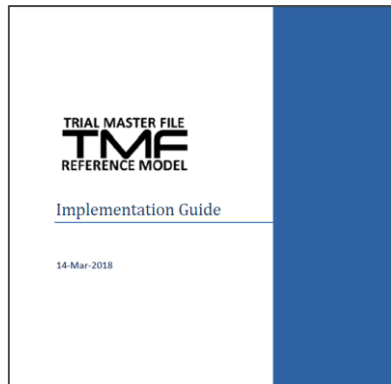
Mark-up Mapping Explanation of differences between Version 2.0 and Version 3.0	Model overview Explanation of the History of the TMF Reference Model and how artifacts work	Instructions and Glossary Provides a description of columns and abbreviations	Computer System Validation Options CSV artifacts
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Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Core or Recommended inclusion
02	Central Trial Documents	02.01	Product and Trial Documentation	02.01.04	Protocol Amendment	Core
02	Central Trial Documents	02.01	Product and Trial Documentation	02.01.05	Financial Disclosure Summary	Recommended

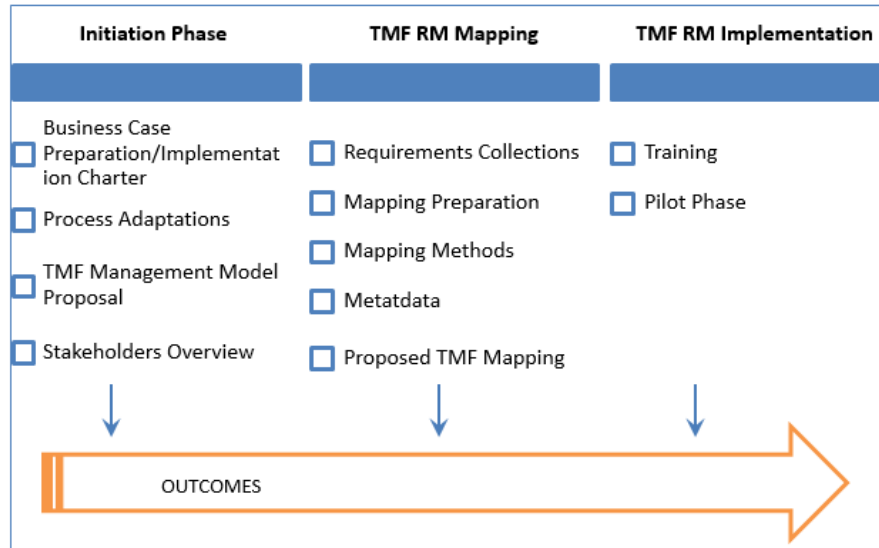
Implementation Guide

Provides a framework for implementing the TMF Reference Model

Example pages below...



4 TMF RM Implementation Process Overview



5.2.9.2 Suggested Deliverables List

Check list	Deliverables/Documentation
<input type="checkbox"/>	Mapping document that shows current vs. new classification (keep these unless you plan on re-filing all documents from closed studies) Objectives: company TMF version control procedures and TMF harmonization mapping structure across all studies
<input type="checkbox"/>	Map the Artifact to your functional areas – determine who the “content owner” is. Objectives: Stakeholders Management Engagement
<input type="checkbox"/>	Map the Artifacts to the system/location in which they will reside. Objectives: TMF Master Model, study specific TMF Model, and transfer of essential documentation collection duties
<input type="checkbox"/>	Update of internal SOPs as appropriate Objectives: company QA platform maintenance and sustainability
<input type="checkbox"/>	Project Update communication/newsletter to keep all stakeholders and potential users up-to-date on the project status and timelines. Objectives: TMF Stakeholders Communication
<input type="checkbox"/>	Training (including Work Instructions and tip sheets) for all users on classification, changes made from last filing model and practices and impacted processes. Objectives: company QA/TMF platform maintenance and sustainability
<input type="checkbox"/>	Transition plan between the previous Organization TMF Model and the new one. Plan for migration of current studies, if applicable. Determine if some studies will remain in the current structure based on timing, or other factors, and what studies will be migrated to the new model. Objectives: Change Management for TMF RM Implementation

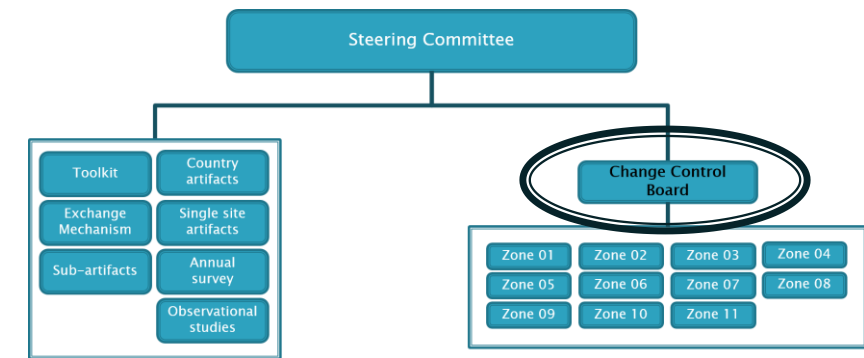
Change Control Board

► Change Control Board Structure

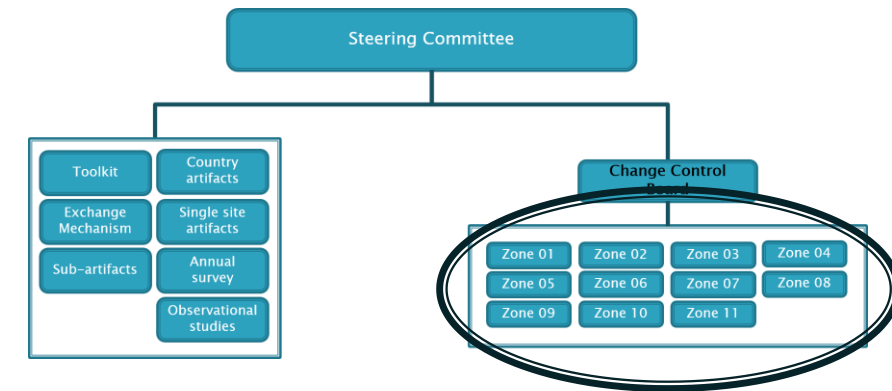
- 15 members – no additional members needed
- Kelley Robinson, Pfizer: Chair
- Joanne Malia, Regeneron: Deputy Chair
- Gift Chareka, UCSF: Exchange Team Liaison
- Eldin Rammell: Steering Committee Liaison

► Deliverables to Date

- Currently meeting once a month
- Change requests have been sent to Zone teams
- Eight recommendations have been submitted to the Steering Committee for final review
- Submit requests here: <https://tmfrefmodel.com/feedback>



Change Control – Zones



▶ Role

- Groups of subject matter experts who are constituted to review proposed changes to the TMF Reference Model and make recommendations to the Change Control Board on their acceptance or rejection

▶ Zone Team Structure

- SMEs still needed for all zones
- ▶ Please consider joining a zone – time commitment is on average 1 hour a month

Exchange mechanism update

- Exchange Mechanism
 - XML standard to support data transfer between eTMF systems
- Comments received from both vendors and business reviewers
- Currently working on responding to comments and integrating changes
- Aim to submit updated version 0.4 to steering committee for ratification in April/May
- Aim to release version 1.0. of the eTMF-EMS in June
- Testing of the standard will happen after release of v1.0. and we may release a minor update after the testing period
- Sponsors and CROs interested in testing version 0.4, please contact the EMS team by submitting the form at <https://tmfrefmodel.com/ems/>

Activity Other Subgroups

Group	Lead
Implementation toolkit / Upgrade User Guide	Mike Czaplicki
Sub-artifacts	Karin Schneider
Country specific artifacts	Eleanor Hewes
Device Studies	Melonie Warfel
J-GCP	Sub group
Exchange Mechanism	Paul Fenton / Elvin Thalund
Change Control Board	Kelley Robinson / Joanne Malia

Data Integrity

- ▶ Final guidance on GxP data integrity requirements published by MHRA (March 1)
 - <https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity>
- ▶ Based on ALCOA principles – provides additional detailed guidance on interpretation
- ▶ Not a one-size-fits-all approach e.g.
 - DIRA – data integrity risk assessment
- ▶ Data integrity by design – start at design/procurement
- ▶ Helpful definitions, incl. ‘true copy’ and ‘audit trails’
- ▶ Data migration and retention, incl. obsolescence

Frame for the Destruction of Paper Review and Update Project

- ▶ Kicked off with a Full Team Meeting on 1 March 2018.
- ▶ 8 Sub-teams: Project, Survey, Regulatory, Records Management, Quality, Technology, Legal, and Implementation Toolkit
 - 68 members to date – @ ½ from TMF perspective. Not too late to join! Contact Lisa Mulcahy to be part of the project at mulcahyconsulting@comcast.net

Project Task	Date Due
Call for Volunteers	January – February 2018
Project Kick-off	March 1 2018
Survey Team	February – March 2018
Topic Team Activities	March - September 2018
Implementation Team	April/May – October 2018
Presentation of Results	October 2018 – February 2019

TMF Management – Related Presentation

- ▶ If there is time...

Engaging People to be
Part of the **TMF** Solution

Lisa Mulcahy, Mulcahy Consulting, LLC

mulcahyconsulting@comcast.net

TMF RM General Meeting – 19 MARCH 2018

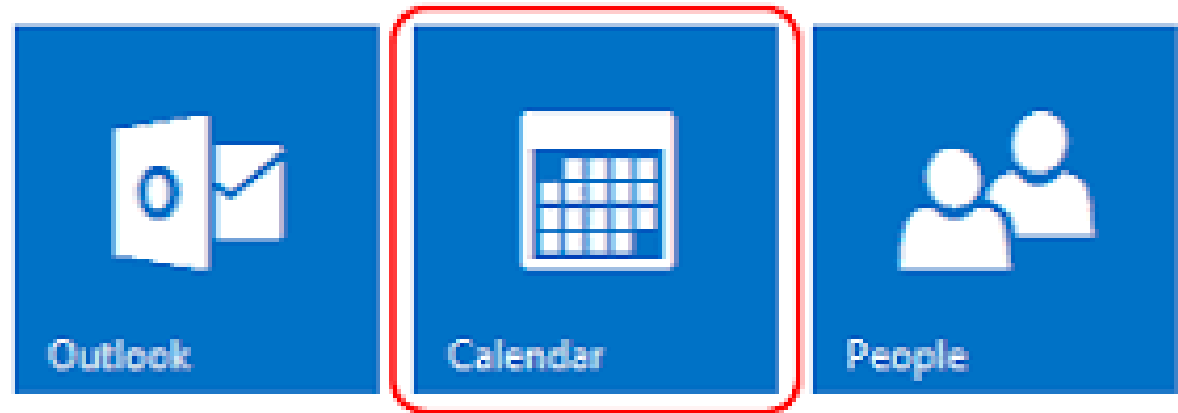
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eTMF Conferences coming up

- ▶ Health Sciences Records & Archives Association Conference, Brighton, UK, April 2018 (formerly Scientific Archivists Group)
- ▶ EXL TMF Institute, Boston, July 11–12, 2018
<http://tmfsummit.com/institute>
- ▶ 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, Abstracts are open.
<http://www.diaglobal.org/en/conference-listing/meetings/2018/11/edm-2018-clinical-and-regulatory-operational-excellence-forum>

TMF RM General Meetings

- ▶ 14-May
- ▶ Add to your calendar NOW or download the calendar file (.ics file) when you receive the meeting notification from MailChimp
- ▶ Outlook Meeting Request no longer distributed



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>