Trial Master File Reference Model

General Meeting 24 April 2017

Agenda

- Welcome
- Update on the New members (Karen Roy)
- Steering Committee Update (Karen Roy)
- EMA draft TMF guidance for public consultation
- MHRA workshop (Andy Fisher)
- Exchange Mechanism
- Subteam updates
  - Inspection subgroup output (Kathie Clark)
  - Survey flash results (Jane Twitchen)
  - Presentation on sub-artifacts (Karin Schneider)
- EDMS Pocket guide
- Upcoming conferences

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New members

First name	Last name	Organisation	Country
Lena	Bowald	AstraZeneca	Sweden
Gerard	Bradley	Arivis	USA
Dominik	Budsky	PSI CRO	Czech Republic
Kathleen	Coleman	Bayer	Finland
Piyush	Dham	Covance	USA
Mai	Doan	Acceleron Pharma	USA
Carol	Dudek	Alnylam Pharmaceuticals	USA
Matthew	Duplin	Yale School of Medicine	USA
Susan	Geers-Meiners	CTI Clinical Trial & Consulting	USA
Jessica	Luhrsen	LMK Clinical Research	USA
Rich	Madden	LMK Clinical Research	USA
Luisa	Monica	LMK Clinical Research	USA

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New members

First name	Last name	Organisation	Country
Patricia	Mydlow	Just in Time GCP	USA
Tracy	Paster-Brown	Covance	USA
Heather	Prentice	Eli Lilly	USA
Igor	Proscurshim	Agenus Inc	USA
Yasheena	Smith-Mcneil	United Therapeutics	USA
Becky	Stacy	LMK Clinical Research	USA
Yogesh	Tambe	Quintiles IMS	India
Lisa	Watson	LMK Clinical Research	USA
Sheri	Webby	Health Sciences North Research Inst.	Canada
Lynne	Weston	Alnylam Pharmaceuticals	USA
Nour	Ziyadeh	Alnylam Pharmaceuticals	USA

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Steering Committee Update

- 5 positions available for nomination, current members include:
  - Fran Ross, Paragon – standing again
  - Jamie Toth, Daiichi-Sankyo – standing again
  - Karin Schneider, Janssen – not standing again
  - Lisa Mulcahy, Mulcahy Consulting – standing again
  - Todd Tullis, Veeva – standing again
- 4 new self nominations
  - Dorte Frejwald Christiansen, NNIT
  - Scott McCulloch, Biomarin
  - Heather Frankhouser, Janssen
  - David Ives, Vertex

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Steering Committee Update

- Martin Thorley resigned and replaced by Marie-Christine Poisson (Pfizer representative in accordance with the Charter, until Martin's term is finished)
  - Marie-Christine summary: I am currently the business process owner for TMF at Pfizer and have a passion for everything related to TMF! I bring about 30 years of experience in clinical trials, drug development, both from a pharma and vendor prospective where I have been monitor, study manager, project manager, GCP auditor. I have been a member of the TMF Reference Model since 2014 and have been involved in a couple of work streams.

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EMA Guidance

- Draft released 12th April 2017 for public consultation
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500225871&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

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MHRA Workshop – September

- 700 emails, nearly 100 responses in 3 days, with many very positive comments about a great way to help to helps bridge the gap between regulators and industry.
  - 27 yes definitely
  - 32 yes likely
  - 30 no unlikely – and most of these were from the USA
- Quite a few people wanted 2 people or more from their company to attend
- Quite a few people wanted webex as an option
- The new ICH E6 R2 came up a few times as a topic

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MHRA Workshop – September

- Andy Fisher presented.
- Please contact Andy directly if you wish to present or be involved in presenting
- Andrew.Fisher@mhra.gsi.gov.uk

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Exchange Mechanism Core Team Status

- Kathie Clark has joined the Exchange Mechanism Core Team as TMF RM Steering Committee Liaison.
- Other members of the Core Team include Paul Fenton, Elvin Thalund, Vivienne Yeap, Martin Snyder, and Ken Keefer
- Planning for a review of the draft Exchange Mechanism Specification by vendors.
- All Exchange Mechanism group members will meet with the Core Team on May 16.
- Identified roles to support the vendor review process.
- Asking for volunteers to fill these roles at the May 16 meeting.
- The Core Team will meet with the Reference Model Steering Committee on May 24 to report progress.

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Activity Subgroups

Group	Lead
Metadata	Todd Tullis
Implementation toolkit / Upgrade User Guide	Mike Czaplicki Lisa Mulcahy **LOOKING FOR VOLUNTEERS!**
Dating conventions	Melissa Maberry ☑
Sub-artifacts	Karin Schneider
Inspection Preparation	Kathie Clark ☑
TMF Quality	Sholeh Ehdaivand ☑
Country specific artifacts	Eleanor Hewes
Milestones	Kathleen Kirby
Single Site Structure	Karen McCarthy Shau
Survey	Jane Twitchen ☑

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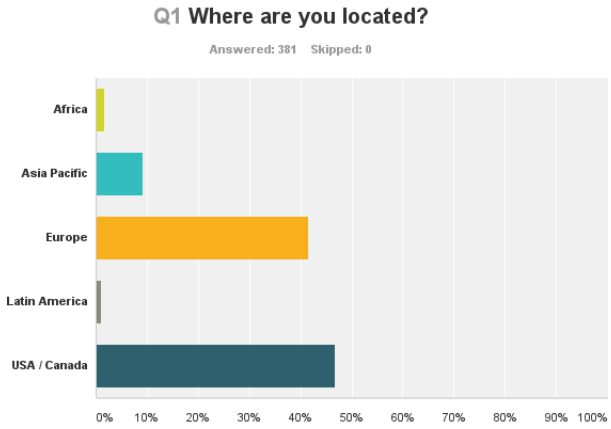
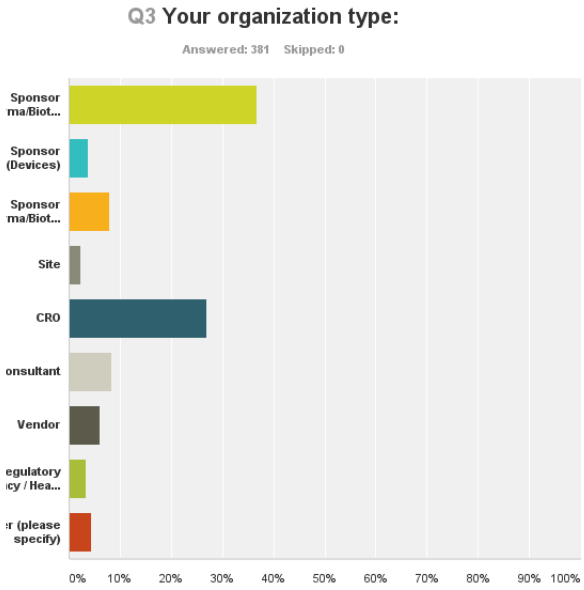
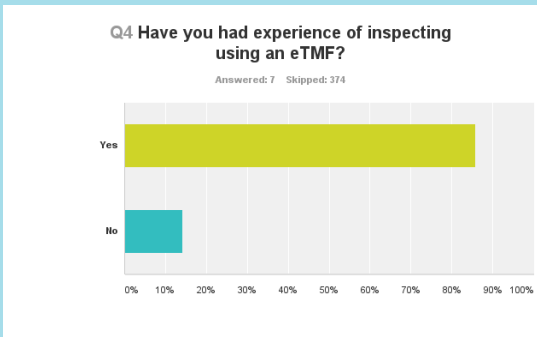
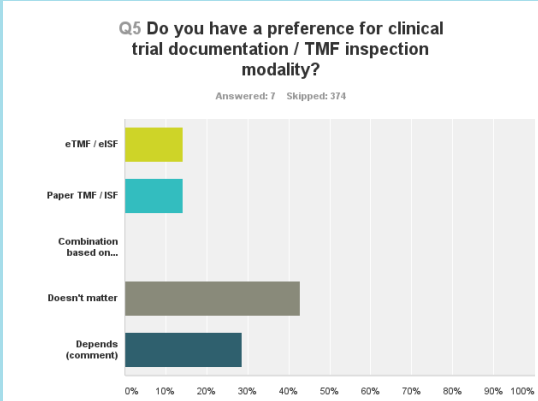
2017 Survey – Flash Results!

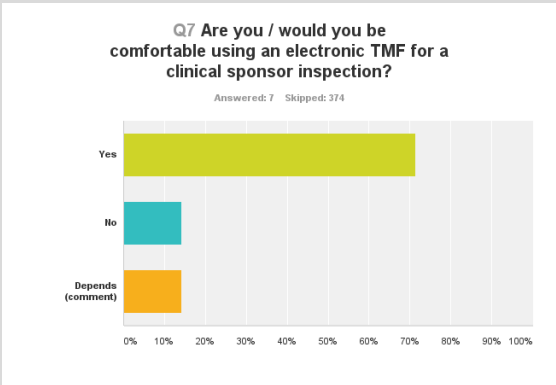
- 381 people took the survey
  - 205 took the 2015 (previous) survey
  - Highest before, 271 in 2013











Inspection Subgroup Deliverable

- Kathie Clark presented
- Output on wwwtmfrefmodel.com

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Artifact Subtype – Status

- Core team established (15 volunteers)
- Small group met in April
- Agreed on current definition, reserving the right to refine as we are collecting examples
- Agreed on process and next steps

Proposed Process

Task	Timeline/Logistics
1. Engage zone review teams from v3 to identify all artifacts that could have "subtypes"(partly done as part of v3 design effort) - other collection methods? 2. Populate "May Include" column with examples (Example help test the definition) 3. Working recommendation; best practice; Additional guidance where there is flexibility in the level of interpretation –also applies to artifacts itself (may result in other changes, e.g. aliases, artifact, description) 4. Communication strategy (to collect feedback and promote update)	3 months to gather feedback? Working recommendation and communication strategy: subteam?
The list can be modified by the TMF group members at any time and will be subject to review as the model goes through revisions; changes are published as category 3 changes (according to the release model) Steering Committee Change Control roll "subtype" changes into the TMF release schedule as subversions indicating minor releases with no direct model impact: V 3.0: approved major revision of the RM v 3.1 approved minor revision of the RM V 3.01 vocabulary update; subtype or alias's added; no other RM impact	Steering Committee manages, feedback through Reference Model Community Site
4. As part of the general RM review, the list is reviewed as well	With RM release schedule and process

TMF Feedback

- Trial Master File Reference Model

Trial Master File Reference Model

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Trial Master File Reference Model

Version 3.0 of the Trial Master File Reference Model is HERE!

rammellel
June 16, 2015

Building on the most widely leveraged standardized reference in TMF management today – with version 2.0 used by more than a hundred life science sponsors, CROs and technology vendors – version 3.0 of the TMF Reference Model (released at the DIA Annual Meeting in Washington, DC on June 16th) incorporates feedback from this extensive industry use to enhance content clarity. Highlights of V 3.0 include:

- Updated artifacts – Additions, deletions, consolidations
- Updated zones – Zones have been reassessed for logical artifact inclusion – E.g. local labs
- Updated definitions – That more accurately describe the TMF RM components
- Sub-artifact examples – assists with mapping to and understanding purpose of artifacts
- TMF Reference Model User Guide – Provides step-by-step process for mapping your organization's TMF to the TMF RM

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Artifact Subtype – ASK

- Need Zone leads for 1, 3, 4, 6, 7, 8, 9,10, or 11
  - Linda James: Can lead or assist in zones 1, 2, 4, 5, 6, 8 or 9
  - Dorte Frejwald Christiansen lead Zone 2
  - Kristen Bretzius contributing company examples to all zones, leading Zone 5
  - Brian Harris: assist in Zone 10 & 11
- Companies willing to share what they may have collected for their internal use when mapping to the TMF RM

Artifact Subtype – Next steps

- Task of the Zone Leads
  - Collect subtypes from companies, your organization, v3 effort others..
  - Help vetting examples at team review meeting
  - Timeframe: 3 months collecting and vetting

Definitions

Definition			
Artifact	**"May Include" (Subtype)**	Component	Alias
The primary section for general document type based on industry standards with specific characteristics and purpose; ideally, it represents one content object but in some cases it may relate to a group of objects **Example:** RMP, Debarment Statement, ICF	A subtype is a specific type of artifact where the artifact describes a group of documents; In the Reference Model the column for "subtype" has been renamed to: "May include"; This column contains a list of examples; The list is not required to be standardized and is not subject to the same rigor/control as the pertinent parts of the RM, e.g. artifact, process zone.... It can be company specific It is not required to be technically an extension of the reference model (attribute) but could be; Interoperability is still enabled on the artifact level It is meant to be used instructional to help with the proper classification of specific content into the Ref Model that is not explicitly called out as an artifact; Working recommendation (guidance), not a standard **Example:** 1. Artifact: 04.03 – Trial Management – Meetings – Investigators Meeting Material – Subtypes may include, but are not limited to: Agenda, Minutes, Attendance Sheet, Presentation Materials, Questions and Answers, Recordings, etc. 2. Artifact: Insurance Subtype: Insurance Policy, Insurance Certificate	Granular part of an artifact which when combined with other items will make a whole business object; managed as distinct content object but only has relevance in the context of the artifact which it is part of **Example:** 1. Artifact: Submission Components: Cover letter, proof of postage, cioms, proof of delivery, submission checklist 2. Artifact: Clinical Study Report Component: Cover page, signature page, confidentiality statement, body of report	Synonym/alternate name/other language name; basically the same meaning as the artifact itself just a different label **Example:** Artifact: Clinical Study Report Alias: Clinical Trial Report, Study Report, Studienbericht Artifact: Meeting Material Alias: Meeting Document, Documentation for a meeting

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Contributing Team Members

Noreen Bouchard (Astellas)

Laurel-Ann Schrader (Ardeabio now Transperfect)

Brian Harris (Medimmune)

Kathie Clark (Wingspan)

Clarie C. Mooney (Quintiles)

Sunil Joseph (IronwoodPharma)

Jen Maier (Biogen)

Karin Schneider (Janssen) – Lead

Daniel Bennett (Phlexglobal) – joined Aug 2016

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New Team Members for phase II

- Donna Dorozinsky (Justintimegcp)
- Dorte Frejwald Christiansen (NNIT)
- David Ives (Vertex)
- Linda James (Alnylam, earlier with: Biogen)
- Eldin Rammell (Rammell Consulting)
- Kristen Bretzius (PSI)

EDMS Pocket Guide

- Pocket EDMS version 6.0 that includes user requirements for eTMF released.
- It is now available at www.tmfrefmodel.com/resources under TMF tools
- A big thanks to the GCP-Scientific Archivists Group (SAG) for their tremendous work in putting together the eTMF requirements.
- Jamie Toth has provided strong leadership to developing the specifications, which has been followed closely to better understand the needs.

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eTMF Conferences coming up

- ACRP Meeting, 28 Apr, Seattle, USA
- DIA Chicago, June
- DIA Operational Excellence Forum, Berlin 12 to 14 September
- EXL TMF Summit, Japan, September
- IQPC TMF Conference, September, Amsterdam
- EXL TMF Summit, London, October

- Plus Inspection Readiness, Quality forums etc.

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TMF RM General Meetings

- 12-Jun
- 11-Sep

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QUESTIONS?

Join the TMF Reference Model
Yahoo! Group

http://tmfrefmodel.com/join

- Knowledge sharing
- Networking
- Too Much Fun!

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