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
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
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.
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/
Meeting details

Wondering where to find details of the next meeting?

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

Wondering where to find details of the next meeting?

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Interventional Studies</td>
<td>Russell Joyce</td>
</tr>
<tr>
<td>Sub-artifacts</td>
<td>Karin Schneider</td>
</tr>
<tr>
<td>Country specific artifacts</td>
<td>Eleanor Hewes</td>
</tr>
<tr>
<td>Device Studies</td>
<td>Melonie Warfel</td>
</tr>
<tr>
<td>Survey 2019</td>
<td>David Ives</td>
</tr>
<tr>
<td>J-GCP</td>
<td>Sub group</td>
</tr>
<tr>
<td>Framework for the Destruction of Paper</td>
<td>Lisa Mulcahy</td>
</tr>
<tr>
<td>Exchange Mechanism</td>
<td>Paul Fenton / Elvin Thalund / Ken Keefer</td>
</tr>
<tr>
<td>Change Control Board</td>
<td>Kelley Robinson / Joanne Malia</td>
</tr>
</tbody>
</table>
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
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!
<table>
<thead>
<tr>
<th>Zone #</th>
<th>Zone Name</th>
<th>Section #</th>
<th>Section Name</th>
<th>Artifact #</th>
<th>Artifact name</th>
<th>Alternate names (artifact also commonly known as)</th>
<th>Definition / Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.01</td>
<td>P Supply Plan</td>
<td>Trial Medication Plan Clinical Trial Material Distribution Plan IP Supply and Packaging Plan</td>
<td>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.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.02</td>
<td>P Instructions for Handling</td>
<td>Pharmacy Manual Device User Manual IP Manual IP Labeling and Packaging</td>
<td>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.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.03</td>
<td>P Sample Label</td>
<td></td>
<td>Examples 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 among label artifacts.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.04</td>
<td>P Shipment Documentation</td>
<td></td>
<td>To record details of the shipment process including approval, requests, dispatch, tracking and receipts from a distribution center, depot and/or trial site.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.05</td>
<td>P Accountability Documentation</td>
<td>Inventory Documentation IP Accountability Records</td>
<td>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.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.06</td>
<td>P Accountability Documentation</td>
<td></td>
<td>To document the transfer of IP between depot sites (within or across protocols). Examples include sponsor approval for transfer and evidence of consultation with Qualified Person (QP).</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.07</td>
<td>P Accountability Documentation</td>
<td></td>
<td>To document the plan for the re-labelling process to occur at the distribution center, depot and/or site and confirmation records that the re-labelling occurred.</td>
</tr>
<tr>
<td>06</td>
<td>IP and Trial Supplies</td>
<td>06.01</td>
<td>IP Documentation</td>
<td>06.01.08</td>
<td>P Recall Documentation</td>
<td></td>
<td>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.</td>
</tr>
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</table>
## 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

<table>
<thead>
<tr>
<th>TTL Leader name(s):</th>
<th>Curran Murphy and Liz Farrell</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Support by: Fran Ross and Russell Joyce</td>
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</tbody>
</table>

| 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) |

<table>
<thead>
<tr>
<th>Still to come:</th>
<th>Continuing Work:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Assign responsible person &amp; sub-team personnel for creation of approved tools (work already being done!)</td>
</tr>
<tr>
<td></td>
<td>• Continue discussions to decide if additional tools will be created (reviewing/discussing 6 additional proposed tools)</td>
</tr>
</tbody>
</table>
# Project Timeline

Very Simply…

<table>
<thead>
<tr>
<th>Project Task</th>
<th>Date Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call for Volunteers</td>
<td>January – February 2018</td>
</tr>
<tr>
<td>Project Kick-off</td>
<td>March 1, 2018</td>
</tr>
<tr>
<td>Survey Team</td>
<td>February – April/May 2018</td>
</tr>
<tr>
<td>Topic Team Activities</td>
<td>March – September 2018</td>
</tr>
<tr>
<td>Editing Team</td>
<td>October – November 2018</td>
</tr>
<tr>
<td>Implementation Team</td>
<td>May – November, December 2018 and beyond</td>
</tr>
<tr>
<td>Presentation of Results</td>
<td>October 2018 – May 2019</td>
</tr>
<tr>
<td>Survey Team</td>
<td>Additional surveys being considered in January &amp; June 2019</td>
</tr>
</tbody>
</table>
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
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.
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/
CCB Membership Update
Deliverables – Review of TMF Reference Model Version 3.1.0!
CCB ‘By the Numbers’
Feedback and Change Requests
Call for Volunteers
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
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
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
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
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
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
Two artifacts with revised ICH codes
- To correct a typographical error
  - 02.01.02 Protocol
  - 02.01.04 Protocol Amendment
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
Two artifacts with additional alternate names
- To correct a typographical error
- 03.01.02 Regulatory Authority Decision
- 03.02.02 Import or Export Documentation
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/
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.
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
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
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
eTMF Conferences coming up

- IQPC, TMF and Inspection Readiness, 24th to 27th September, Amsterdam [https://trialmasterfile.iqpc.co.uk/](https://trialmasterfile.iqpc.co.uk/)
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
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