The TMF Reference Model
General Meeting 13-Oct-2022

Presenters:
- Mary Emanoil, Head TMF & Registry Operations, Pfizer, TMF RM SC Member
- Karen Roy, Chief Strategy Officer, Phlexglobal; Chair, TMF Reference Model Steering Committee
- Jamie Toth, Global Head, TMF Management & Records, Beigene, TM RM SC Member
- Alison Varjavandi, Director, TMF Management Office, Astellas, TM RM SC Member
- Scott Feiner, Senior Manager, Trial Disclosure, AbbVie
Introductions
Agenda

- Intros/Agenda – Mary Emanoil
- Membership Update – Karen Roy
- TMF Management Plan Template Update – Jamie Toth
- 2022 TMF RM Survey Report Out – Allison Varjavandi
- Special Topic: CTIS Update– Scott Feiner, Abbvie
- Upcoming Events: CDISC Interchange, EU TMF Summit – Mary Emanoil
Membership Update
The TMF RM Community move to CDISC

Linked In Community
N = 4366, managed by
TMF RM SC

Subscription Members
N = 1724

Volunteer Members
N = 324

Steering Committee
N = 14

Will migrate to CDISC list
N = 1724

Volunteer Onboarding
N = 120 so far

Steering Committee
N = 14

NO CHANGE
Volunteer Demographics

- CRO: 28%
- Sponsor: 11%
- Consultant: 3%
- Vendor: 52%
- Investigator: 6%
Special Interests of Volunteers

- TMF Subject Matter Experts: 87
- Zone Teams: 60
- Exchange mechanism: 38
- Survey working group: 24
- Website Content: 20
- Non interventional studies: 19
- Devices: 14
Registering as a Volunteer

1. Navigate to [https://www.cdisc.org/volunteer/tmf/form](https://www.cdisc.org/volunteer/tmf/form)
2. Review videos, CDISC policies, procedures, and CDISC and TMF charters
3. Provide contact information
4. Choose one or more TMF Volunteer Groups
5. Submit form
6. CDISC Volunteer Coordinator will begin onboarding process
Volunteer Onboarding

1. Volunteer Request
   - Volunteer completes form on CDISC website

2. Information Technology
   - Wiki Volunteer Contributor Access granted

3. Volunteer Administrator
   - Volunteer Record Creation:
     - Volunteer Tracker
     - Team Mail List

4. Communication To: Volunteer and Team Coordinator
TMF Management Plan Template

Presenter:
Jamie Toth, Sr. Director TMF Management & Records at BeiGene; Member, TMF Reference Model Steering Committee
Agenda

1. Members & Charter
2. Summary of Revisions
3. Status to Go-Live
Members & Charter
# Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jamie Toth - Workstream Lead</td>
<td>BeiGene</td>
</tr>
<tr>
<td>Marion Mays - Workstream CoLead, Subteam 2 Lead</td>
<td>Just in Time GCP</td>
</tr>
<tr>
<td>Gillian Gittens</td>
<td>TransPerfect</td>
</tr>
<tr>
<td>Mabel Ebot</td>
<td>Molecular Partners</td>
</tr>
<tr>
<td>Deb Oriez</td>
<td>Sarepta</td>
</tr>
<tr>
<td>Twanna Davis</td>
<td>FHI Clinical</td>
</tr>
<tr>
<td>Corunna Culver-Windham - Subteam 1 Lead</td>
<td>Relay Therapeutics</td>
</tr>
<tr>
<td>Debra Wells</td>
<td>Novartis</td>
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<tr>
<td>Donna Dorozinsky</td>
<td>Just in Time GCP</td>
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<tr>
<td>Dawn Niccum - Subteam 3 Lead</td>
<td>Inseption Group</td>
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<tr>
<td>Allison Grosik</td>
<td>Arcus Bio</td>
</tr>
</tbody>
</table>
**Charter**

<table>
<thead>
<tr>
<th>Brief description of project &amp; objectives:</th>
<th>Objective: Review the template published in 2018 and incorporate changes due to regulations, technology, pandemic needs. Template must still be: a <em>cross-industry usable, simplistic TMF Management Plan template</em>. <em>Guidance provided on how to deal with variations depending on study size, phase, type.</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope - In:</td>
<td>Template to be used for all clinical research study/trial types.</td>
</tr>
<tr>
<td>Scope - Out:</td>
<td>Development of an SOP. Processes already created within a given company around the TMF.</td>
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</tbody>
</table>
| Desired deliverables: | • An updated, simplistic Plan template that can be used within any company, where company specifics can be added.  
• Guidance on Plan usage and any variations and how to adapt Plan. |
| Target end date: | 15-Dec-2022 |
| Status: | • First meeting held 03-Mar-2022; 3 mini teams formed to work on Subteam 1 – Sections 0-4, Subteam 2 – Section 5 – 8, Subteam 3 – Sections 9-12. Teams had 3 months to work on suggested updates.  
• Biweekly meetings scheduled March to Oct 2022.  
• Beginning in July 2022, brought the 3 drafts together to finalize master draft.  
• 25-Aug provided to TMF Ref Model SC for comment.  
• As of 10-Oct, SC had ~46 comments and we have 11 left to review/reconcile. |
Summary of Revisions
Summary of Revisions – High Level

- Updated instructions, added additional instructions throughout.
- Re-arranged the order of the sections, i.e. Transfer/archive is section 11 now.
- Added in tables for SOPs, training, vendor responsibilities.
- Created activities table, removed RACI.
- Created subsections for TMF Review documentation, Archiving at Sponsor or CRO/Vendor and Retention and Destruction.
- Created table for Legal Holds section.
- Added Transfer Agreement language into section 11.
<table>
<thead>
<tr>
<th>Section #</th>
<th>Section Topic</th>
<th>Page #</th>
<th>Revisions Made</th>
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<tr>
<td>0</td>
<td>Instructions</td>
<td>1</td>
<td>Updated instructions for intention and the font written in</td>
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<tr>
<td>0</td>
<td>Table of Contents</td>
<td>2</td>
<td>Re-arranged the order for better flow</td>
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<tr>
<td>3</td>
<td>Definitions and Abbreviations</td>
<td>5</td>
<td>Added additional instructional text</td>
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<tr>
<td>4</td>
<td>Introduction</td>
<td>6</td>
<td>Reworded section, ensure boxes were clickable</td>
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<td>5</td>
<td>Applicable SOPs</td>
<td>7</td>
<td>Added tables for both Sponsor and CRO SOPs</td>
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<td>5.1</td>
<td>Sponsor Specific</td>
<td>7</td>
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<tr>
<td>5.2</td>
<td>Vendor/CRO Specific</td>
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<tr>
<td>6</td>
<td>TMF Training</td>
<td>8</td>
<td>Reworded section, added table for type of training by Role</td>
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<tr>
<td>7</td>
<td>TMF Oversight &amp; Access Arrangements</td>
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<td>7.1</td>
<td>Responsibilities</td>
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<td>Removed the RACI, added an Activity table to state what is doing what at Sponsor or CRO (or other vendor)</td>
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<td>8</td>
<td>TMF Content</td>
<td>12</td>
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<tr>
<td>8.1</td>
<td>TMF Format, Structure/Content Map/Specifications</td>
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<td>Minor wording changes and major change by adding in table by vendor type</td>
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<td>8.2</td>
<td>Authoritative Sources</td>
<td>15</td>
<td>Minor wording changes</td>
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<td>8.3</td>
<td>E-Signatures, Originals, Wet Inks, and Raised Seals</td>
<td>15</td>
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<td>Relevant Correspondence</td>
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<td>Unblinded Records</td>
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<td>9</td>
<td>Conducting TMF Reviews</td>
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<td>Wording changes</td>
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<td>TMF Review Documentation</td>
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<td>Section added</td>
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<td>Record and TMF Disposition</td>
<td>19</td>
<td>Updated instructions</td>
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<td>Archiving</td>
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<td>Added TMF Transfer Agreement info into instructional text; added column to table for type of Documentation</td>
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Status to Go-Live
Status to Go-Live – Jan 2022 to present

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<th>JAN</th>
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<th>MAR</th>
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<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
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<td>Gather volunteers</td>
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<td>Biweekly Meetings &amp; Subteam 1, 2, 3 Meetings</td>
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<td>3 drafts came together and review/reconciliation</td>
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<td>Final review with SC</td>
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<td>Anticipated Go-Live!</td>
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Kick off Meeting

By 15-Nov-2022
Next Steps
Next Steps

✓ Version 1.0 to Version 2.0 comparison document.
✓ Listing of Revisions Made.
✓ Creation of feedback form for SC for ease of reconciliation and uploading into CDISC WIKI in future.

• Finish Reconciliation of all SC feedback (11 comments to go!) on 14-Oct.
• Review final reconciled version with SC on 19-Oct or 02-Nov.
• Share to industry via upcoming conferences (EU TMF Summit) and social media!
Thank You!

Questions?

Jamie.Toth@beigene.com use subject CDISC TMF Plan Template
TMF Survey Report Out

Allison Varjavandi
TMF Reference Model Survey

• Thank you to everyone who contributed to the Survey conducted June 2022!

• Many of the comments collected through the survey will be communicated to the Steering Committee and Change Control Board to determine where there is opportunity for enhancement to tools, model etc.

• Today, we will share some interesting takeaways we learned from the survey results.
Higher % of US respondents and lower % in other regions this year than past survey.
Organization Breakdown of Respondents

- **Vendor**: 7% (15) in 2022, 7% (15) in 2019
- **Sponsor**: 52% (105) in 2022, 7% (15) in 2019
- **Site**: 1% (3) in 2022, 1% (2) in 2019
- **Regulatory Agency/Health Authority**: 2 from Regulatory Authority (US) in 2022, 1% (2) in 2019
- **Other**: 5% (11) in 2022, 1% (2) in 2019
- **CRO**: 25% (51) in 2022, 7% (15) in 2019
- **Consultant**: 7% (15) in 2022, 7% (15) in 2019

- **2022** vs. **2019**
87 individuals who completed survey were from larger organizations and 100 individuals were from companies less than 1,000 employees.
How did you hear about TMF Reference Model?

- Organisation already used the TMF Reference Model: 92%
- Heard at conference / meeting: 27%
- Referred by colleague: 34%
- Other (please specify): 23%
- When searching for TMF information: 25%

Common answer for “Other” was using since Reference Model first introduced.
Organizations using TMF Reference Model

96% (178)

This has increased from 82% in 2019
In which format is your organization's TMF?

- **Combination of paper and eTMF**: 34% (54%)
- **All TMF in paper**: 0.50% (3.50%)
- **All eTMF**: 41.50% (53.70%)
- **Other**: 3.40% (0.50%)

**2022 vs 2019**:
- Less companies using All Paper TMFs than in previous survey.
- More companies using All eTMF.
- Common answers for “Other” was Historically paper TMFs, New Studies in eTMF and Electronic Systems other than eTMF.
Overall, what is your organizational view of TMF?

- **It is an end state repository for finalised documents to meet compliance**: 23.90% (48) in 2022, 27.90% (56) in 2019
- **It is an active repository but it is not used to support efficient and effective study management**: 10.40% (21) in 2022, 24.90% (50) in 2019
- **It is a project management tool used to support efficient and effective study management**: 27.90% (56) in 2022
- **Currently viewed as an end state repository but we are working toward it being project management tool**: 0.00% in 2022, 24.90% (50) in 2019
- **Other (please specify)**: 3.50% in 2022

This is trending in the right direction!
If you are a Sponsor, do you utilize your own eTMF or do you use CRO's eTMF?

- Use our own eTMF solution and require CRO to use our eTMF
- Use our own eTMF solution only for sponsor-generated records and CRO eTMF for CRO / site-generated records
- We don't have an eTMF so use the CRO eTMF
Has your organization adopted the Model without any change?

- Adopted with changes:
  - 74% (128) in 2022
  - 66% (84) in 2019

- Adopted without changes:
  - 26%...
  - 34%...
How many document types or artifacts are identified in your index / table of contents? In other words, how many unique document types or artifacts?

- 201-400
- 401-600
- 601-800
- 801+
- Fewer than 200

We do not have a standard content list / index

This could indicate there may be need for a subcommittee to create an Index template that can be shared for use.
Factors Impacting Electronically Transferred TMF Content between Systems/Organizations

- IR: Concerns of Document and Data Integrity: 25.5%
- Mapping Complexity: 33.9%
- Lack of Technical Expertise: 11.5%
- Lack of Resources: 13.9%
- Budget Constraints: 6.1%
- Data Quality: 9.1%
How TMF is Managed In or Across the or Organization

- Centrally: 39%
- Disparately across functions: 12%
- Combination of centrally and disparately: 40%
- Other: 9%
Does your Organization have a TMF Plan for each Study?

- Yes: 83.6%
- No, but looking to create one: 11.3%
- No: 5.1%
Do you routinely capture / retain relevant e-mail communications in the eTMF?

Yes: 88.1%
No: 11.9%
Do you Retain Paper Content Scanned into your TMF?

- **2019**
  - Yes, we retain all paper: 12.7%
  - Yes, we retain some paper: 24.8%
  - No, we do not retain any paper: 45.9%
  - Other: 16.6%

- **2022**
  - Yes, we retain all paper: 9.0%
  - Yes, we retain some paper: 30.3%
  - No, we do not retain any paper: 33.3%
  - Other: 15.4%

Trending to retaining no paper.

Retention of Wet Ink documents is a common answer.
Which type of certified (true) copy policy does your organization promote?

- Other
- We do not have a certified copy procedure
- We have a certified copy procedure that applies only when an original is irreversibly replaced

This had decreased significantly since 2019 when it was at 40.5%
Does your Organization Author Documents in the eTMF?

- **No, and no plans to do so**: 29.7% (52)
- **No, but planning to do this in the future**: 26.3%, (46)
- **Yes, but only for a few record types**: 20.6%, (36)
- **Yes, this is routinely done in our eTMF**: 23.4%, (41)

70% currently author in eTMF at some level or are planning to do so in future and about 30% do not and have no plans to author in future.
Who is accountable for assessing the TMF completeness at your organization?

- All contributing functions
- A central group
- Partnering organizations (e.g., CRO, Site)
- Other
About 72% are tracking and utilizing metrics or are implementing a metrics program. This is slightly higher than 69% in 2019.
Do you measure metrics on CRO performance?

Yes: 64.9% (64.9...)

No: 35.1% (47)
How do you archive records in your eTMF?

- Other
- We archive directly in the eTMF solution
- We do not currently archive the TMF
- We migrate records from eTMF to another system for long-term archiving

78% of respondents follow a formal TMF Archive process outlined in their company SOPs.
How do you archive TMF content kept outside of the primary TMF?

- **We archive in the system outside of the TMF**: 52
- **We do not currently archive outside the TMF**: 47
- **We migrate records to another system for long-term archiving**: 27
- **We migrate records to the eTMF long-term archiving**: 31

Other: 11
Would you be willing to contribute to ongoing development of the TMF Reference Model?

There remains a high percentage of you willing to contribute to ongoing development of the TMF Ref Model!

- Yes: 166, 85%
- No: 29, 15%

No  Yes
Use of TMF RM Tools/Templates

Have you used these tools?

- TMF Reference Model Implementation Guide: 65% Yes, 36% No
- eTMF Selection Request for Proposal Template: 79% Yes, 21% No
- TMF Reference Model Exchange Mechanism Standard: 82% Yes
- TMF Reference Model Email Communication Guidance: 46% Yes, 54% No
- Real-World Studies Document Index: 77% Yes, 23% No

Why not? Most common response was they didn’t know it existed. A few commented they didn’t have a need to use it and few didn’t know or were not responsible for that part of the business.
Thank You!
CTIS
Scott Feiner, Abbvie
Upcoming Events
Upcoming Events

• 26-27 October; Austin, TX: CDISC 2022 US Interchange
• 14-16 November; London: Fierce European TMF Summit
Thank You!