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.
Location of the 206 Survey Respondents

Higher % of US respondents and lower % in other regions this year than past survey.
Organization Breakdown of Respondents

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

- **2022**
- **2019**

- **2 from Regulatory Authority (US)**
- **5 organizations specified “ARO”**
Organization Size for Survey Respondents

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?

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

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?

- **All eTMF**: 53.70% in 2022, 41.50% in 2019
  - More companies using All eTMF
- **Combination of paper and eTMF**: 34% in 2022, 54% in 2019
  - Less companies using All Paper TMFs than in previous survey
- **All TMF in paper**: 0.50% in 2022, 3.50% in 2019
  - Historically paper TMFs, New Studies in eTMF and Electronic Systems other than eTMF
- **Other**: 3.40% in 2022, 0.50% in 2019

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
  - 2019: 24.90% (50)
  - 2022: 27.90% (56)
- It is an active repository but it is not used to support efficient and effective study management
  - 2019: 10.40% (21)
  - 2022: 23.90% (48)
- It is a project management tool used to support efficient and effective study management
  - 2019: 23.90% (48)
  - 2022: 27.90% (56)
- Currently viewed as an end state repository but we are working toward it being project management tool
  - 2019: 24.90% (50)
  - 2022: 23.90% (48)

Other (please specify)
- 2019: 3.50%
- 2022: 3.50%

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% (… in 2022, 34% (… in 2019
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.

2019

2022
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

- 39% Centrally
- 40% Disparately across functions
- 12% Combination of centrally and disparately
- 9% Other
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?

<table>
<thead>
<tr>
<th>Year</th>
<th>Yes, we retain all paper</th>
<th>Yes, we retain some paper</th>
<th>No, we do not retain any paper</th>
<th>Other (please specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>16.6%</td>
<td>24.8%</td>
<td>45.9%</td>
<td></td>
</tr>
<tr>
<td>2022</td>
<td>15.4%</td>
<td>30.3%</td>
<td>33.3%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

Retention of Wet Ink documents is a common answer.

Trending to retaining no paper.
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%
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

64% (114)
13% (23)
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...
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?

- **Other**: 11
- **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
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!
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, 18% No
- 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.

Here is a link to where you can locate these tools and templates: [https://tmfrefmodel.com/resources](https://tmfrefmodel.com/resources)
Thank You!