Trial Master File Reference Model

TMF Reference Model 2019 Survey Overview

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Overview of Respondents

307 Respondents

58% – US
27% – EU
8% – Asia Pacific
5% – Canada
1% – Africa
1% – Latin America
<1% – Middle East

55% – Sponsor
23% – CRO
9% – Vendor
8% – Consultant
3% – Other
1% – Site
Has your organization adopted the Model as is, without any change?

- Yes, adopted as is: 32.4%
- No, adapted with changes: 61.8%
- Other (please specify): 5.9%
There continues to be a trending increase in unique artifacts although the number of respondents within the 201–400 range remains consistent with prior years.
What format is your TMF of record?

- All TMF in paper: 3.5%
- All eTMF: 41.5%
- Combination of paper and eTMF: 54.5%
- Other (please comment): 0.5%

150% increase in all eTMF operations since the last survey!
How does your organization approach certified copy requirements?

- We do not have a certified copy procedure: 40.5%
- We have a certified copy procedure that applies to any document filed to the TMF that was not created in the TMF: 30.0%
- We have a certified copy procedure that applies only when an original is irreversibly replaced: 29.5%
How does your organization manage draft documents in the TMF as part of your change control process?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>We do not retain any draft documents in the TMF</td>
<td>43%</td>
</tr>
<tr>
<td>We would only retain draft documents if the final was missing</td>
<td>7%</td>
</tr>
<tr>
<td>We maintain evidence of change control in other systems e.g. collaboration tools</td>
<td>17%</td>
</tr>
<tr>
<td>Our eTMF is a collaboration tool and maintains drafts of many documents as minor versions</td>
<td>18%</td>
</tr>
<tr>
<td>Our eTMF is a collaboration tool but minor versions are purged once a document is finalized.</td>
<td>7%</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>10%</td>
</tr>
</tbody>
</table>

Still relatively few utilize eTMF for collaboration.
Overall what is your organizational view of TMF? (please select the one that most closely aligns)

- It is an end state repository for documents to meet compliance: 25.0%
- It is a project management tool that is used to support efficient and effective study management: 18.0%
- Currently viewed as an end state repository but we are working toward it being project management tool: 32.5%
- It is an active repository but it is not used to support efficient and effective study management: 21.5%
- Other (please specify): 3.0%

Majority still working toward eTMF being supportive of study management
Do you retain paper content scanned into your eTMF?

- Yes, we retain all paper: 45.9%
- Yes, we retain some paper: 24.8%
- No, we do not retain any paper: 12.7%
- Other (please specify): 16.6%

Majority still retaining some paper.
The primary reasons listed for not filing blinded records in eTMF was related to not comfortable with risk and system security or workflows.
COVID-19 Impact will continue to accelerate the shift.
Do you require inspectors to complete training prior to issuing credentials?

80.5% Yes, 19.5% No
Please share some insight regarding the types of findings you have received following an Audit/Inspection using your eTMF or (select all that apply)

- Not Applicable (no findings or findings not yet received): 22.99%
- Finding regarding TMF Completeness: 55.17%
- Finding regarding TMF Timeliness (i.e. non contemporaneous TMF): 42.53%
- Finding regarding TMF Quality (document content): 22.99%
- Finding regarding eTMF Quality (e.g. metadata or formatting): 22.99%
- Finding regarding eTMF System navigation: 12.64%
- Finding regarding eTMF System access: 3.45%
- Finding regarding eTMF System training: 3.45%
- Finding regarding TMF Filing Structure used: 10.34%
- Finding regarding CRO Oversight: 29.89%
- Other (please comment): 13.79%
Have you undergone a joint inspection with a partner (sponsor/CRO) where both organizations were equally subject of the inspection?

- No: 58.62% (51)
- Yes: 41.38% (36)
Is eTMF data or metrics used by your Risk Based Monitoring (RBM) program?

- 19.5%: Yes, our RBM program uses data / metrics from eTMF
- 24.8%: Not currently, but will in the future
- 26.6%: We do not use eTMF data / metrics for RBM
- 27.5%: We do not have a RBM program
- 1.8%: Other (please specify)
Do you measure metrics on CRO performance too?

- Yes: 52.3% (56)
- N/A - I am not a sponsor or do not use CROs: 24.3% (26)
- No: 23.4% (25)
Questions?