VEEVA 2014 PAPERLESS TMF SURVEY: AN INDUSTRY BENCHMARK

The *Veeva 2014 Paperless TMF Survey* explores the life sciences industry's progress toward paperless clinical trials by gathering the experiences and opinions of 252 Trial Master File (TMF) owners. The goal of the research is to understand the impact of growing eTMF adoption as well as the drivers, benefits, and barriers to going paperless. The survey examines the success factors for fully electronic trials and gives an industry-wide view of where organizations fall on the spectrum of paper-based to paperless TMFs.

Key Findings

- The types of eTMFs used vary broadly across a range of technologies, from simple file systems to purpose-built eTMF applications.
- Email and paper remain the dominant mechanisms for exchanging documents with external parties.
- More-advanced eTMF systems (content management systems and eTMF applications) deliver a greater number of benefits and higher TMF quality.
- Remote TMF access for auditors is expected to double by early 2015.
- Small organizations lag medium and large organizations in eTMF maturity.
- Organizations with more extensive use of metrics derive more benefits from using an eTMF.
- The top drivers motivating eTMF adoption are cost savings (56%), speeding study start-up (55%), improving monitoring (49%), and increasing inspection readiness (45%).
- The most frequently cited barriers to going paperless are cost of new technologies (38%), implementation time and services costs (33%), and regulatory requirements (28%).
- Integrating eTMF applications with other clinical systems is seen as vital to going paperless.

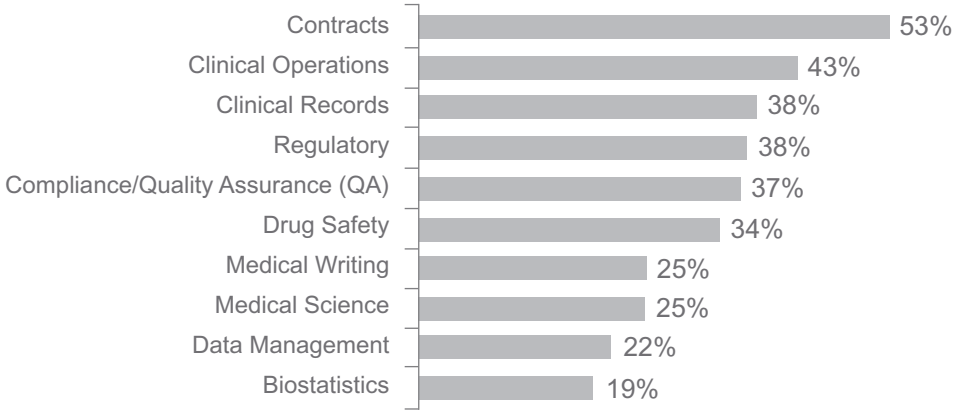
Usage of Paper and Types of Electronic Trial Master Files

Respondents were asked to estimate the extent to which different departments manage TMF documents on paper at any time during a document's lifecycle. Document-focused areas including legal/contracts (53%), clinical operations (43%), clinical records (38%), and regulatory (38%) reportedly manage most/all of their TMF documents on paper at some point during the document's lifecycle. These paper-heavy departments would benefit most from process-efficiency initiatives.

Conversely, data-driven areas of the business appear to use the least paper. Only 19% of biostatistics, 22% of data management, and 25% of medical science departments are reported managing most/all TMF documents on paper.

Percent with Most or All Documents Managed on Paper at Some Point

Base: Total respondents, N = 252



In each area, how many of your company's TMF docs are managed on paper at any point in their lifecycle? (Q.3)
Percent of respondents citing mostly paper or all paper.

Document exchange is another area in which the use of paper-based processes is prevalent. Results show that email (69%) and paper (57%) are the dominant means of exchanging trial documents between sponsors/CROs. Usage is relatively consistent across external parties, with no one party significantly more or less likely to interact via paper or email.

Methods for Exchanging TMF Documents with External Parties

Base: Total respondents

	Between sponsor/CRO	With investigator sites	With IRBs/IECs	With regulatory authorities
Paper shipments	57%	63%	58%	65%
Email	69%	68%	62%	58%
Portal	43%	37%	32%	30%
Fax	25%	26%	23%	19%
Cloud file share	30%	24%	16%	12%
Content mangement system	30%	21%	18%	17%
eTMF application	15%	10%	6%	8%

What methods does your team use to exchange TMF documents with external parties? Select all that apply per row. (Q2)

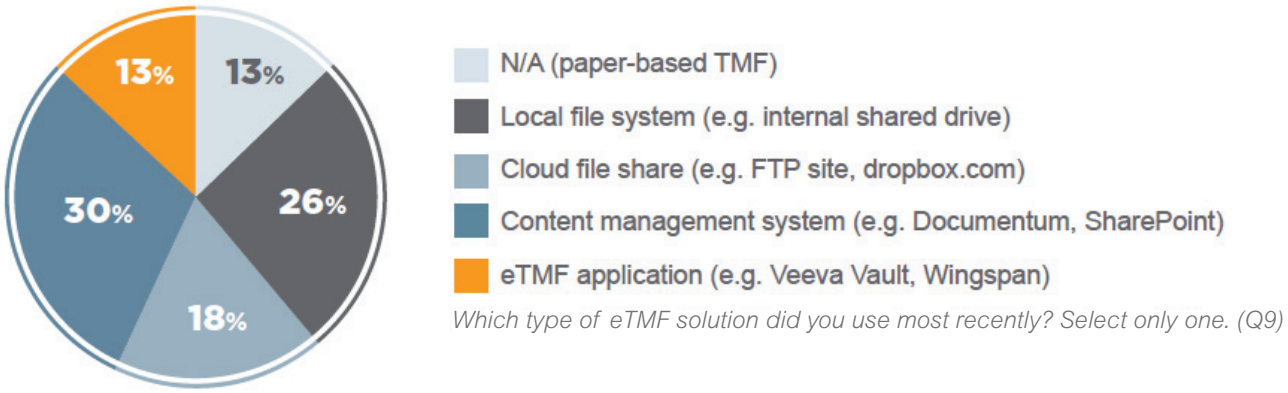
Email offers very little efficiency over paper and introduces many of the same challenges as paper shipments. Emailing documents as attachments, like exchanging paper, puts information outside of controlled processes, making it harder to track and manage documents efficiently. Often these documents are also printed for review and re-scanned into the system, creating a hybrid process.

Types of eTMFs

Respondents were also asked which type of eTMF they used most recently. The findings reveal that no one type of eTMF is dominant. The data show adoption of diverse solutions ranging from local file systems all the way to eTMF applications. File systems provide access to a shared folder structure and online storage. Cloud file shares provide additional capabilities, the most important of which is easy access for external parties. An eTMF application is typically built on a content management platform and provides purpose-built functionality and configurations specific to TMF documents, along with process-driven content management functionality such as search, versioning, and workflow.

eTMF System Most Recently Used

Base: Responses from sponsor companies only, N = 135



Which type of eTMF solution did you use most recently? Select only one. (Q9)

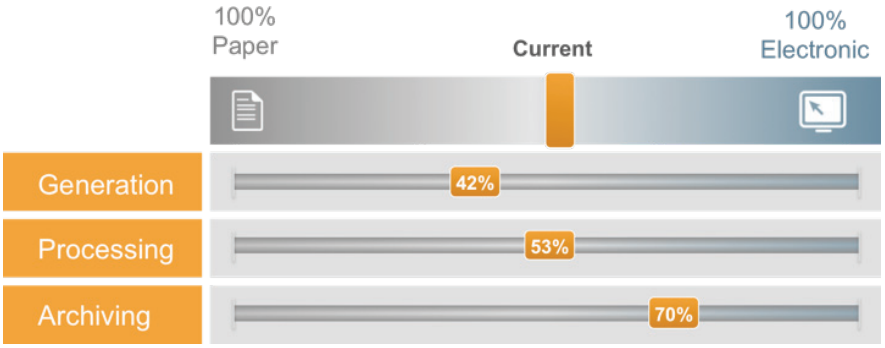
Half of sponsor-company respondents with an eTMF report using a file share, whether a local file system (26%) or a cloud file share (18%). Nearly one-third (30%) report using a content management system such as EMC Documentum or Microsoft SharePoint. Finally, roughly one in ten respondents (13%) report using an eTMF application such as Veeva Vault eTMF or Wingspan eTMF.

TMF Continuum

A significant number of paper TMF documents must be scanned, filed, and reconciled, as the majority of organizations (70%) mostly or always archive TMF documents electronically. In contrast, only 42% of organizations are creating electronic documents.

TMF Continuum

Base: Total respondents, N = 252



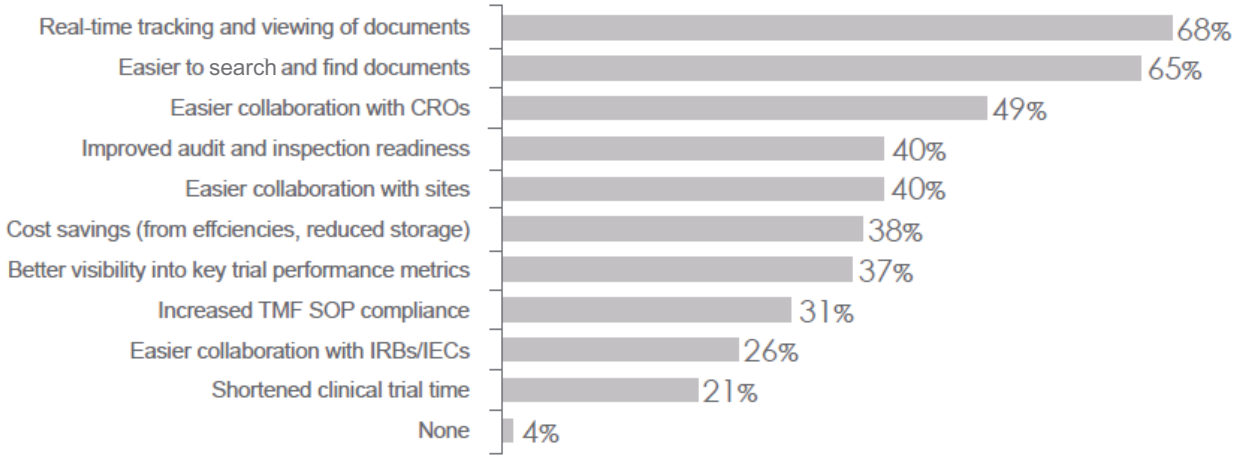
To what extent is your company currently doing any of the following with electronic TMF documents? (Q.8)
Percent of respondents indicating mostly or always electronic. Represents average across different external parties.

Reported Benefits of an eTMF

Respondents were asked to indicate which, if any, benefits they experience with the use of an eTMF. Real-time tracking and viewing (68%) and ease of locating documents (65%) are the two most frequently cited benefits across all types of eTMFs.

Benefits Attributed to an eTMF Solution

Base: Respondents reporting having an eTMF, N = 191

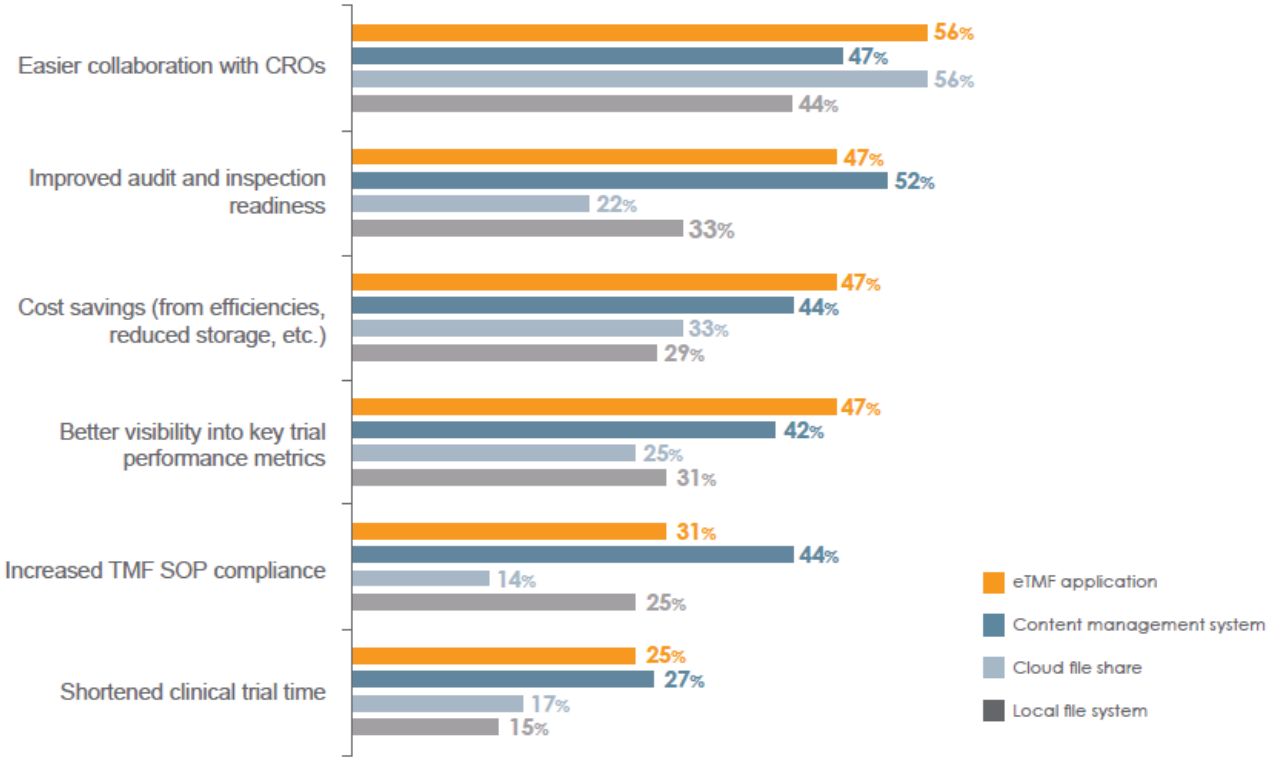


What benefits were achieved with your organization's implementation of the eTMF solution specified in Question 9? Select all that apply. (Q10)

Those using an eTMF application or a content management system achieve more benefits than those using a local or cloud file system (p=0.005). This is also true across most benefit areas measured; specifically improved inspection readiness, cost savings, better visibility, and SOP compliance (p<0.05).

Benefits Attributed to an eTMF by eTMF Type

Base: Respondents reporting having an eTMF, N = 191



What benefits were achieved with your organization's implementation of the eTMF solution specified in Question 9? Select all that apply. (Q10)

Which type of eTMF solution did you use most recently? Select only one. (Q9)

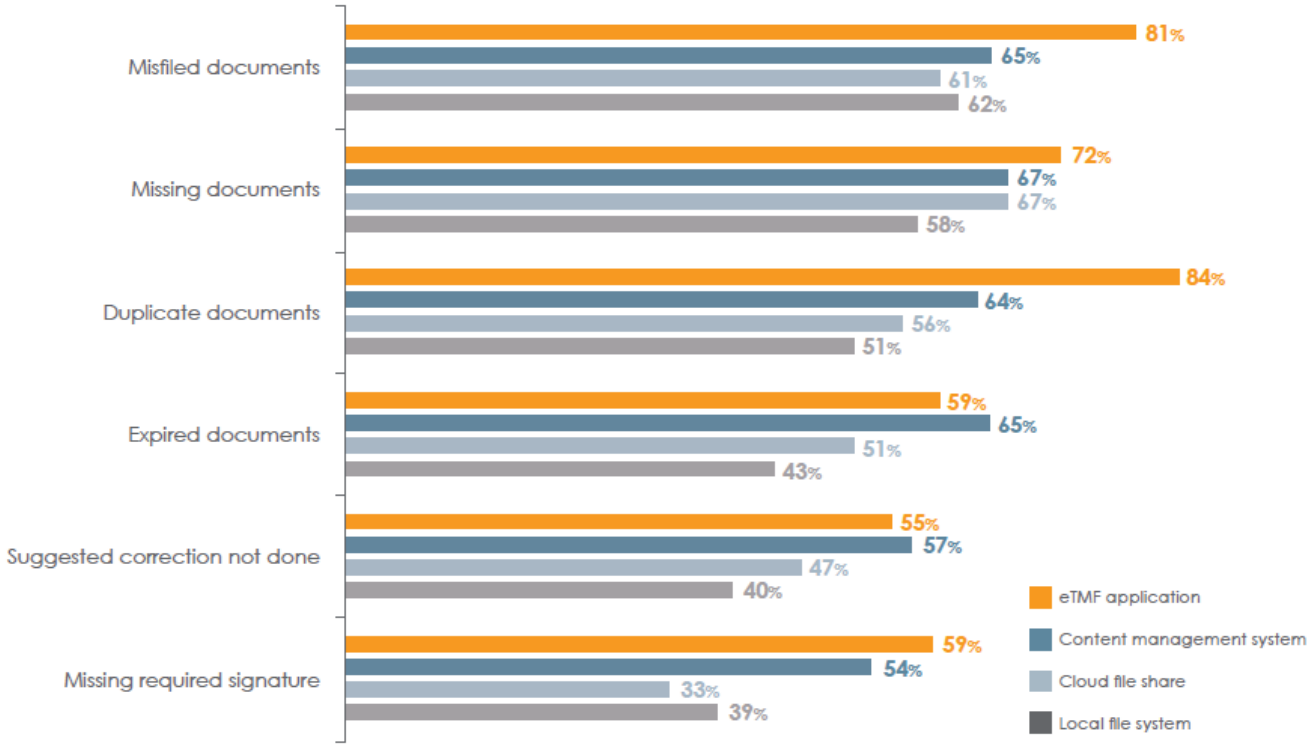
Improvements in Inspection Areas by Type of eTMF

The use of an eTMF application or content management system improves TMF quality in most inspection areas. Respondents using content management systems or eTMF applications report more "good" or "major" improvements in inspection areas than those using local or cloud file systems (mean of 4.7, compared to 3.7; p=0.014). Specifically, those who used eTMF applications or content management systems are more likely to report improvements in the following inspection areas (not shown): duplicate documents (70% vs 53%; p=0.046), expired documents (63% vs 46%; p=0.054), suggested corrections not done (56% vs 43%; p=0.070) and missing required signatures (55% vs 37%; p=0.028). The data also suggest those using an eTMF application experience the greatest improvements.

Improvements in Inspection Area by eTMF Type

(Percent rating improvements as good or major)

Base: Respondents reporting having an eTMF, N varies

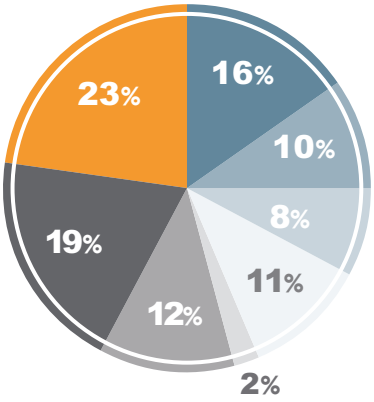


How much improvement, if any, did you observe in the following inspection areas after your organization implemented the eTMF solution specified in Question 9? (Q11)

Which type of eTMF solution did you use most recently? Select only one. (Q9)

Remote TMF Access

The number of organizations granting auditors remote access to the TMF is expected to almost double by 2015. Currently, 16% of respondents are providing auditors remote access to the TMF. This number is expected to climb to 32% within a year. An additional 12% of respondents indicate they would give remote access to their eTMF as soon as they have the technology.



- Currently doing it now
- Within 6 months
- 6 to 11 months
- 1 to 2 years
- More than 2 years
- As soon as I have the technology to support
- Have no plans
- I don't know

When, if ever, does your organization plan to provide auditors with remote access to trial master file documents? Select one of the following. (Q12)

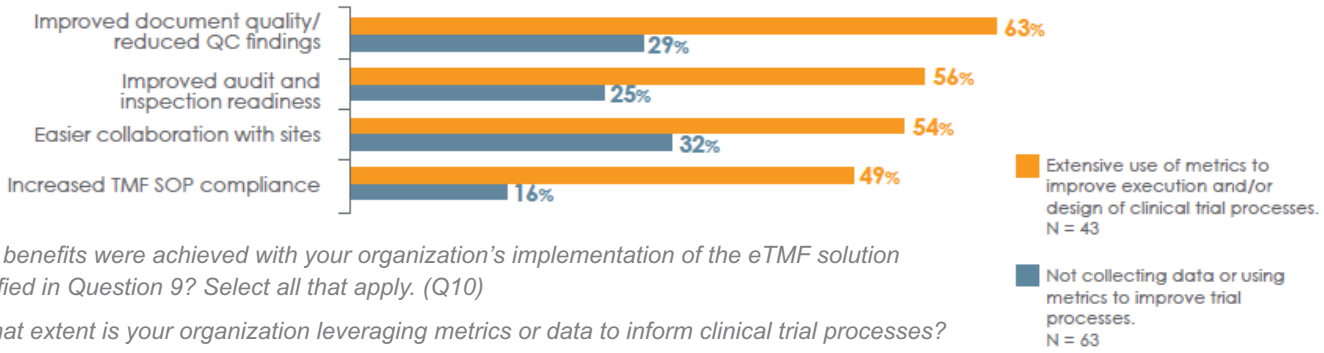
Use of Metrics and Impact on eTMF Benefits

Organizations that report extensively using metrics to improve execution and/or design of clinical trial processes realize a greater number of eTMF benefits than those that do not collect data or utilize metrics (mean number of benefits = 5.6 and 3.7, respectively; p=0.001).

eTMF Benefits Achieved by Level of Metrics Usage

(Those reporting no use compared to those reporting extensive use of metrics)

Base: Respondents reporting having an eTMF, N varies



What benefits were achieved with your organization's implementation of the eTMF solution specified in Question 9? Select all that apply. (Q10)

To what extent is your organization leveraging metrics or data to inform clinical trial processes? Select one. (Q13)

Findings are similar when examining improvements in TMF inspection areas. Those organizations using metrics extensively rate improvements as "good" or "major" more often than those that do not collect or use data (mean number of improvements rated good/major = 5.6 and 3.6, respectively; p=0.001).

eTMF Benefits and Inspection Area Improvements by Level of Metrics Usage

(Mean number of benefits and improvements rated good/major)

Base: Respondents reporting having an eTMF

	Mean number of eTMF benefits reported N =191	Inspection areas with good/mjor improvement N =187
Not collecting data	3.4	3.1
Collecting data but not using it to improve execution of trial	3.8	3.8
Using some metrics to improve execution of trial processes	4.7	4.2
Extensively using metrics to improve execution of trial processes	5.4	4.8
Extensively using metrics to improve execution and design of trial processes	5.9	6.2

What benefits were achieved with your organization's implementation of the eTMF solution specified in Question 9? Select all that apply. (Q10)

How much improvement, if any, did you observe in the following inspection areas after your organization implemented the eTMF solution specified in Question 9? (Q11)

To what extent is your organization leveraging metrics or data to inform clinical trial processes? Select one. (Q13)

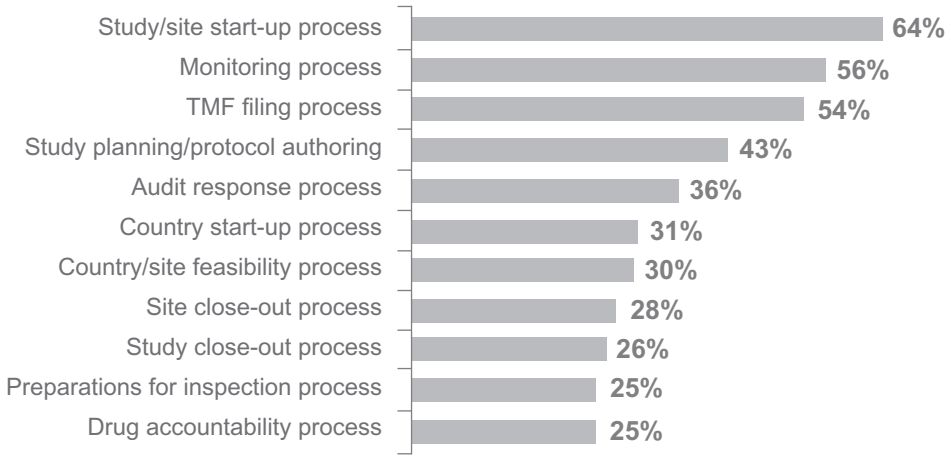
While the data show that using metrics to improve trial processes delivers benefits in TMF quality, the overall use of metrics is low. Twice the proportion of TMF owners report that their organization is not using metrics to improve trial processes (39%) compared to those organizations extensively leveraging metrics to improve execution and/or design of trial processes (20%).

Shortening Clinical Trials

Respondents were asked which processes could significantly shorten clinical development time if paperless. Study start-up (64%), monitoring (56%), and TMF filing (54%) are the most frequently cited processes.

Processes that Would Shorten Clinical Trials if Paperless

Base: Total respondents, N = 252

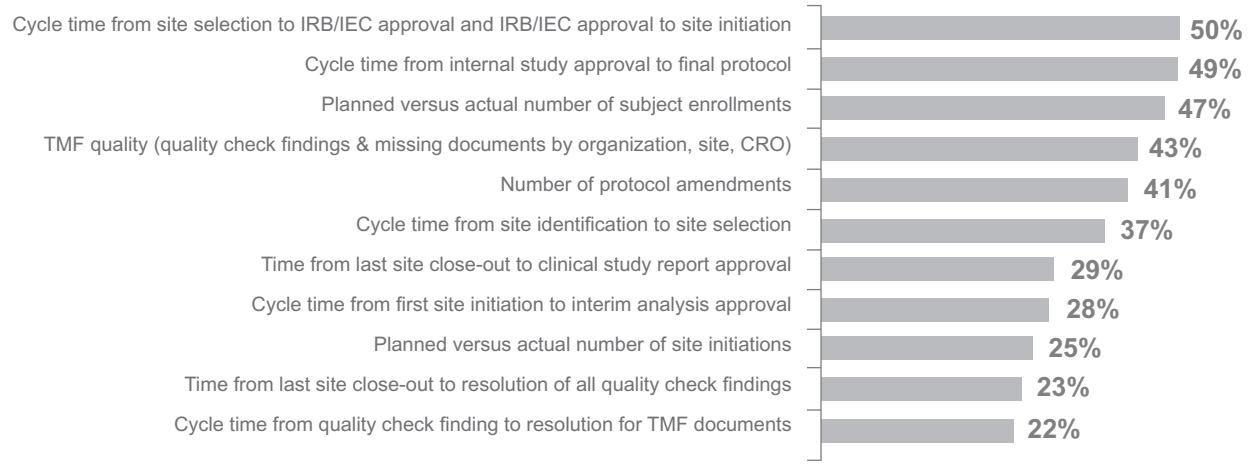


In your opinion, which of the following processes would significantly shorten clinical development times if it were paperless? Select up to five processes. (Q6)

Respondents were also asked which metrics would be the most useful to track in order to shorten clinical development time. Consistent with the belief that the start-up process would be quicker if paperless, the cycle time from site selection to IRB/IEC approval to site initiation and IRB/IEC approval to site initiation (50%) are seen as the most beneficial metrics. Cycle time from internal study approval to final protocol (49%) and planned versus actual number of subject enrollments (47%) are close behind.

Metrics Most Useful to Shorten Clinical Trials

Base: Total respondents, N = 252



Which of the following metrics are, or would be, the most useful in your efforts to shorten clinical trials? Please select up to five most useful metrics. (Q14)

Drivers and Barriers to Going Paperless

Costs and regulatory requirements are cited as the top barriers to going paperless. Thirty-eight percent (38%) of respondents cite the cost of new technology and 33% report cost of implementation as a major or insurmountable barrier. These numbers are influenced by the large proportion of survey respondents from small companies. When broken down by size of organization, small organizations are more than twice as likely to view the cost of implementation as a major or insurmountable barrier (45%) compared to medium (21%) and large (21%) organizations.

While roughly a third of respondents (38%) report cost as a significant barrier, an equal number (38%) attribute cost savings to their eTMF. Cost savings varies by type of eTMF – 29% of those using a local file share report cost savings, as compared to 47% of organizations using an eTMF application. Over half of the respondents (56%) cite cost savings as a top reason for moving to an eTMF.

Fewer respondents cite regulatory requirements and uncertainty around regulatory changes (28% and 19%, respectively) as major or insurmountable barriers. However, when broken down by size, small organizations (31%) are again more than twice as likely to see regulatory requirements as a major or insurmountable barrier than medium (10%) or large (14%) organizations.

Requirements from key clinical partners CROs (12%) and sites (16%) ranked at the bottom of TMF owner concerns.

Primary Barriers to Going Paperless (All)

(Percent rating each as a major barrier or a barrier that cannot be overcome)

Base: Total respondents, N = 252

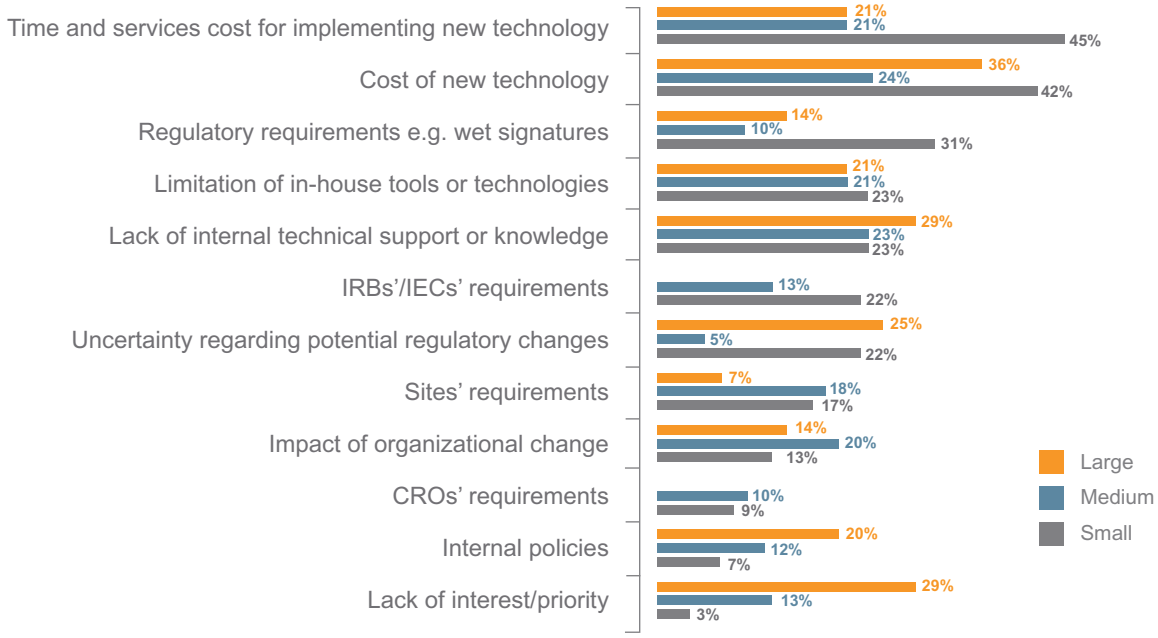
Answer options	Percent of respondents
Cost of new technology	38%
Cost of implementing new technology	33%
Regulatory requirements	28%
Lack of internal technical knowledge	26%
Limitation of in-house tools or technology	24%
Uncertainty regarding regulatory changes	19%
IRB's/IECs' requirements	19%
Impact of organizational change	17%

Rate the extent to which each of the following is a barrier to TMFs going paperless in your organization? (Q4)

Primary Barriers to Going Paperless (by Size)

(Percent rating each as a major barrier or a barrier that cannot be overcome)

Base: Total respondents, N varies



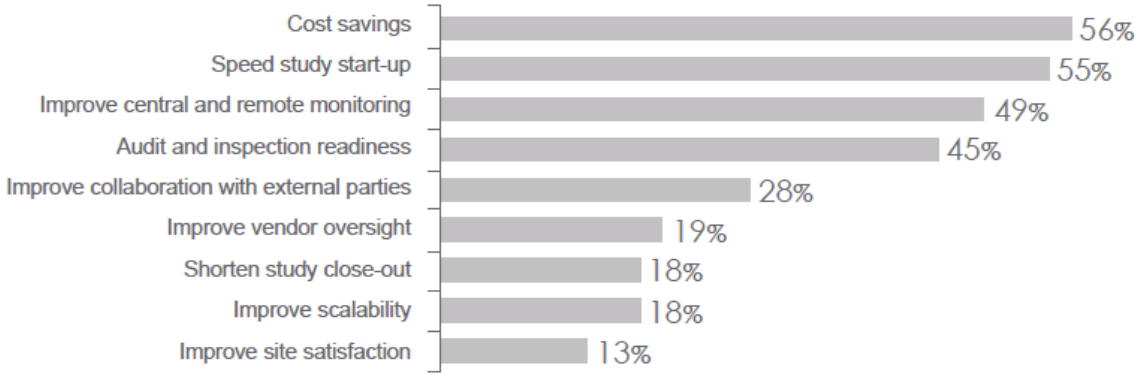
Rate the extent to which each of the following is a barrier to TMFs going paperless in your organization? (Q4)

Business Benefits Driving eTMF Adoption

In addition to cost savings (56%), other top reasons for moving to an eTMF include speeding study start-up (55%), improving monitoring (49%), and improving audit/inspection readiness (45%).

Top Drivers of eTMF Adoption

Base: Total respondents, N = 252



Which of the following business benefits are the most important in motivating your organization's adoption of electronic TMFs? Please select the top three benefits. (Q7)

A majority of sponsors also indicate that making start-up and monitoring processes paperless would significantly shorten clinical development times (64% and 56%, respectively).

Improving audit and inspection readiness is the fourth major driver of eTMF adoption. Shortly after the survey was conducted, the MHRA updated the definition of critical GCP inspection findings to include TMFs that are inaccessible or sufficiently incomplete that inspectors cannot fulfill their duties[1]. These changes may increase the importance of inspection readiness and TMF accessibility in future survey results.

Capabilities Needed to Go Paperless

The three capabilities most commonly cited as necessary for adoption of a paperless eTMF are digital/e-signatures (66%), electronic forms (65%), and secure access by external parties (62%). These results reflect the relatively low levels of adoption for these technologies in respondent organizations.

Capabilities Your Organization Needs for a Paperless TMF (All)

Base: Total resondents, N= 252

Answer options	Percent of respondents
Digital or e-signatures	66%
Electronic forms	65%
Secure access by external parties	62%
System compliance with 21 CFR Part 11, EU Annex 11, etc.	59%
Tracking and reporting	56%
Archival and export capabilities	47%
Integration with CTMS	47%
Integration with EDC	47%

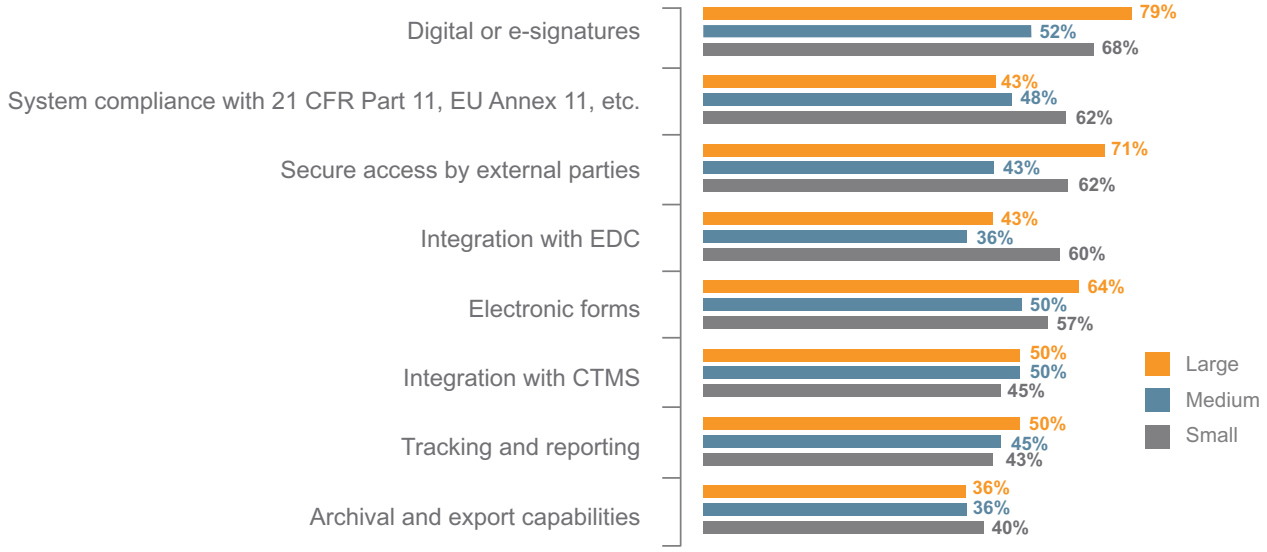
Which of these capabilities do you think your organization needs in order to move to paperless TMFs? Select all that apply. (Q5)

The relative ranking for required functionality varies by the type of eTMF currently in place within each organization. Companies using local or cloud file systems most frequently cite needing electronic forms (71% and 65% respectively) and digital/e-signature capabilities (68% and 65% respectively). By contrast, organizations using an eTMF application most frequently cite integrating a Clinical Trial Management System (CTMS) (76%) and Electronic Data Capture (EDC) (61%) with the eTMF as necessary for going paperless. Small organizations (60%) see integration with EDC systems as more important than medium (36%) or large (43%) organizations. There was no meaningful statistical deviation regarding CTMS integration based on size.

Secure access for external parties is among the top three most required capabilities for all respondents, except those currently maintaining a cloud TMF. These data highlight the importance of external access and the role of cloud in fulfilling partner access requirements.

Capabilities Your Organization Needs for a Paperless TMF (by Size)

Base: Total respondents, N varies



Which of these capabilities do you think your organization needs in order to move to paperless TMFs? Select all that apply. (Q5)

Conclusion

While paper is still extensively used when managing trial master file documents, eTMF adoption is on the rise. The *Veeva 2014 Paperless TMF Survey* reveals multiple stages of maturation for technology, processes, and metrics usage in the industry's move toward a paperless TMF. Those using more mature TMF technologies are seeing the greatest operational and business benefits from their eTMF.

Technology – The survey indicates that the type of eTMF utilized matters and significantly influences the level of benefits achieved. Not all eTMFs are created equal. The additional functionality and control that come with content management systems and eTMF applications appear to make a material difference in improving operating performance when compared to local or cloud-shared storage. Also, the voiced need for eTMF applications to integrate with other key clinical technology suggest an understanding of how these applications can be leveraged as strategic assets.

Process – Over half the respondents (56%) report electronic collaboration and document processing between sponsor and CRO partners (exchange, QC, review, and approval), but further probing into the definition of "electronic" suggests that the vast majority of these processes were carried out through email. When examining methods of TMF document exchange between sponsors and CROs, the survey found that 69% of respondents report using email, while 43% use a portal, and only 15% use an eTMF application.

Metrics – The more organizations use metrics to optimize trial processes, the more benefit they derive from their eTMF. Using metrics to improve trial processes impacts TMF quality. As the adoption of metrics expands, the industry will be better equipped to determine which metrics truly influence or predict outcomes.

Access – The need to grant remote access to the eTMF has been growing impressively over the last several years, and continues to climb rapidly with the number of organizations granting remote access doubling by 2015. It should be taken into account that the responses to this survey were collected prior to the MHRA announcing that incomplete and unavailable TMFs could now be considered a critical GCP finding. Given this, there is a high likelihood that the number of respondents granting remote access to the eTMF in 2015 may be even higher than the survey indicates.

Size of Organizations – Small organizations are less mature than their medium-sized and large-sized counterparts in adopting eTMF technology and processes. Much of their reticence seems tied to outdated perceptions surrounding cost and regulatory requirements. Paradoxically, the benefits achieved by eTMF applications could be a tremendous boon to small organizations that cannot afford the large content management systems often found in large organizations.

The results also show that barriers to becoming paperless are relatively low. None of the listed barriers were rated as “major” or “insurmountable” by a majority of respondents. The two leading barriers, cost and regulatory requirements, are rapidly diminishing due to changes in technology and regulations. According to Forrester Research, the implementation of cloud applications costs significantly less than implementing on-premise systems[2]. On the regulatory front, the FDA and MHRA have reduced signatory requirements to a handful of documents and instituted broad acceptance of electronic signatures[3].

Moving Forward

The data suggests four major changes are necessary to deliver on the full potential of a paperless TMF:

1. Deploying eTMFs that are more than electronic archives.
2. Replacing established but inefficient email and paper workflows with an integrated electronic model.
3. Expanding the use of metrics in trial operations.
4. Providing remote access to the eTMF.

With these changes in place, organizations can create a paperless operating model that achieves the goals of cost savings, faster study start-up, improved monitoring, and TMF inspection readiness.

Survey Methods

The survey consisted of fourteen questions, many of which included subquestions with response matrices. Survey questions were designed for individuals with knowledge of TMF document processes and with partial or full responsibility for a TMF within their organization. An external expert in survey design reviewed the survey for objectivity and lack of bias. The survey was piloted with a small group of respondents for feedback on question clarity before it was introduced. The survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and the first fifty responders were offered a $5 Starbucks gift card. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

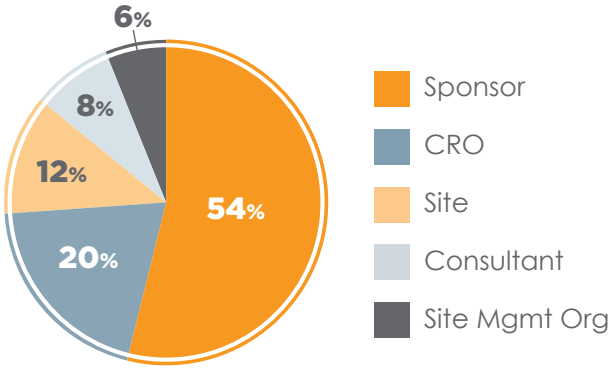
Survey Respondents

Of the 170,000 individuals invited to take the survey, a total of 2,103 surveys were initiated, the majority of which were terminated based on a qualification question gauging the level of responsibility for a TMF in their organization. Over 150 unverified responses were eliminated, yielding 252 qualified survey responses. As a result, we believe this represents the largest and most rigorously qualified survey sample of TMF stakeholders.

Over half of the respondents were from the United States. The majority of respondents were from small or medium-sized organizations – 64% indicated that their organization had 15 or fewer active trials.

Survey Respondents by Type of Organization

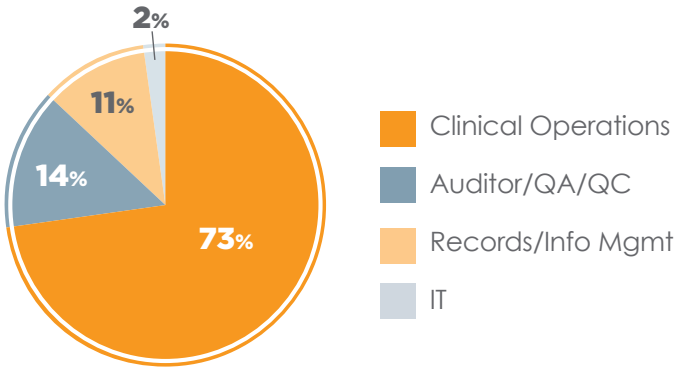
Base: Total respondents, N = 252



Select the best description for your organization. Select one. (Q15)

Survey Respondents by Functional Area

Base: Total respondents, N = 252



Which of the following best describes your functional area within your organization? Select one. (Q16)

Contact

For more information about the study, please visit http://www.veeva.com/tmfsurvey-2014 or contact us at eTMFsurvey@veeva.com.

[1] MHRA, 25 April 2014, Accessed from the MHRA website: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/News/CON408249

[2] Forrester, The ROI Of Software-As-A-Service, Liz Herbert and Jon Erickson.

[3] Lisa Mulcahy presentation, "Designing Efficient Processes for TMF Content when Outsourcing Clinical Trials," March 2014.

[4] Survey questions and answer options were reviewed for clarity and lack-of-bias by Geoff Feinberg, Research Director, Yale University, Yale Project on Climate Change Communication. Former Vice President, GfK Roper, GfK Custom Research North America.

Addendum

Veeva 2014 Paperless TMF Survey: An Industry Benchmark

1. Are you one of the primary people responsible for a trial master file (TMF) within your organization? Select one of the following.

Answer Options	Response Percent	Response Count
Yes, I am the primary person responsible	29.8%	75
Yes, I am one of the several people responsible	70.2%	177
No	0.0%	0

2. What methods does your team use to exchange TMF documents with external parties? Select all that apply per row.

Answer Options	Portal	Paper shipments (e.g. FedEx, UPS, etc.)	Email	Fax	Cloud file share (e.g. FTP site, Box, Dropbox, virtual data room)	Enterprise Content Management (ECM) system (e.g. SharePoint, Documentum, etc.)	eTMF application (e.g. NextDocs, Veeva Systems, Wingspan, etc.)	Response Count
Investigator Sites	94	158	170	65	60	52	24	252
IRBs/IECs	81	147	157	58	40	45	15	252
Regulatory Authorities	75	163	147	49	29	42	21	252
Sponsors/CROs	108	143	173	64	76	75	38	252

3. In each of the following areas, how many of your company's TMF documents are managed on paper at any point during their lifecycle? Select only one box per row.

Answer Options	None	Some Paper	Mostly Paper	All Paper	I Don't Know/ Does Not Apply	Response Count
Clinical Operations	13	125	87	21	6	252
Data Management	53	136	47	8	8	252
Drug Safety	28	128	71	14	11	252
Contracts	10	103	83	51	5	252
Biostatistics	68	115	41	8	20	252
Clinical Records	27	116	75	22	12	252
Medical Science	32	123	56	7	34	252
Medical Writing	45	114	52	12	29	252
Compliance/Quality Assurance (QA)	28	121	72	20	11	252
Regulatory	23	126	70	25	8	252

4. To what extent is each of the following a barrier to TMFs going paperless in your organization? Select only one box per row.

Answer Options	Not A Barrier At All	Not Much Of A Barrier	Moderate Barrier	Major Barrier	Barrier That Cannot Be Overcome	I Don't Know/ Does Not Apply	Response Count
Internal policies	66	85	65	30	3	3	252
Regulatory requirements e.g. wet signatures	18	59	99	62	9	5	252
Uncertainty regarding potential regulatory changes	23	82	86	47	0	14	252
CROs' requirements	51	85	76	27	3	10	252
Sites' requirements	39	72	90	34	4	13	252
IRBs'/IECs' requirements	31	81	82	40	6	12	252
Limitation of in-house tools or technologies	35	70	79	56	5	7	252
Cost of new technology	27	52	73	85	10	5	252
Time and services cost for implementing new technology	24	55	85	76	7	5	252
Lack of internal technical support or knowledge	34	68	82	60	6	2	252
Impact of organizational change	34	82	89	40	3	4	252
Lack of interest/priority	54	84	79	29	0	6	252

5. Which of these capabilities do you think your organization needs in order to move to paperless TMFs? Select all that apply.

Answer Options	Response Percent	Response Count
Electronic forms	65.1%	164
Digital or e-signatures	66.3%	167
Secure access by external parties	61.5%	155
System compliance with 21 CFR Part 11, EU Annex 11, etc.	59.1%	149
Tracking and reporting	55.6%	140
Archival and export capabilities	46.8%	118
Integration with CTMS	46.8%	118
Integration with EDC	46.8%	118
None - we are fully paperless today	4.0%	10
Other (please specify)	5.6%	14

6. In your opinion, which of the following processes would significantly shorten clinical development times if it were paperless? Select up to five processes.

Answer Options	Response Percent	Response Count
Study planning/protocol authoring process	42.9%	108
Country/site feasibility process	30.2%	76
Study/site start-up process	63.9%	161
Country start-up process	31.0%	78
TMF filing process	53.6%	135
Monitoring process	56.0%	141
Preparations for inspection process	25.0%	63
Audit response process	35.7%	90
Drug accountability process	25.0%	64
Site close-out process	27.8%	70
Study close-out process	26.2%	66

7. Which of the following business benefits are the most important in motivating your organization's adoption of electronic TMFs? Please select the top three benefits.

Answer Options	Response Percent	Response Count
Audit and inspection readiness	45.2%	114
Cost savings	56.3%	142
Speed study start-up	54.8%	138
Improve central and remote monitoring	49.2%	124
Improve scalability	17.5%	44
Improve collaboration with external parties	28.2%	71
Improve vendor oversight	18.7%	47
Improve site satisfaction	12.7%	32
Shorten study close-out	17.5%	44

8. To what extent is your company currently doing any of the following with TMF documents? Check only one box per row.

Answer Options	Always Doing	Mostly Doing	Sometimes Doing	Not Doing	Does Not Apply	Response Count
Electronic archival of documents	75	102	49	22	4	252
Electronic collaboration (exchange, QC, review, approval) on documents by internal staff	48	108	68	24	4	252
Electronic collaboration (exchange, QC, review, approval) on documents with CRO partners or sponsor clients	38	102	78	26	8	252
Electronic collaboration (exchange, QC, review, approval) on documents with sites	31	89	85	38	9	252
Electronic collaboration (exchange, QC, review, approval) on documents with IRBs/IECs	31	84	82	42	13	252
Electronic creation of source documents by internal staff	47	86	77	26	16	252
Electronic creation of source documents by sites	28	65	83	52	24	252
Electronic creation of source documents by CRO partners or sponsor clients	26	81	89	40	16	252
Electronic creation of source documents by IRBs/IECs	21	66	73	66	26	252

9. What type of eTMF solution did you use most recently? Select only one.

Answer Options	Response Percent	Response Count
Local file system	25.0%	63
Cloud file share (e.g. Box, Dropbox, FTP site)	15.9%	40
Content management system (e.g. Documentum, SharePoint)	28.6%	72
eTMF application (e.g. NextDocs, Veeva Vault, Wingspan)	13.1%	33
Not applicable - we currently maintain a paper-based TMF	17.5%	44

10. What benefits were achieved with your organization's implementation of the eTMF solution specified in Question 9? Select all that apply.

Answer Options	Response Percent	Response Count
Real-time tracking and viewing of documents	54.4%	137
Easier collaboration with CROs	40.5%	102
Easier collaboration with sites	32.5%	82
Easier collaboration with IRBs/IECs	21.5%	54
Easier to search and find documents	52.0%	131
Improved document quality/reduced QC findings	35.3%	89
Increased TMF SOP compliance	25.0%	63
Improved audit and inspection readiness	31.7%	80
Shortened clinical trial time	18.7%	47
Better visibility into key trial performance metrics	29.4%	74
Cost savings (from efficiencies, reduced storage, etc.)	31.7%	80
None	3.6%	9
We have not implemented an eTMF solution	20.6%	52

11. How much improvement, if any, did you observe in the following inspection areas after your organization implemented the eTMF solution specified in Question 9? Select only one box per row.

Answer Options	No Improvement	Minor Improvement	Good Improvement	Major Improvement	I Don't Know	Does Not Apply - No eTMF Solution	Response Count
Missing documents	18	41	75	60	11	47	252
Misfiled documents	19	36	78	60	12	47	252
Incomplete documents	19	62	64	46	14	47	252
Expired documents	20	53	76	39	15	49	252
Missing required signature	27	62	58	42	15	48	252
Duplicate documents	22	41	85	45	11	48	252
Suggested correction not done	17	59	72	32	20	52	252

12. When, if ever, does your organization plan to provide auditors with remote access to trial master file documents? Select one of the following.

Answer Options	Response Percent	Response Count
Currently doing it now	15.5%	39
Within 6 months	9.5%	24
6 to 11 months	7.9%	20
1 to 2 years	10.7%	27
More than 2 years	2.4%	6
As soon as I have the technology to support it	11.9%	30
Have no plans	19.4%	49
I don't know	22.6%	57

13. To what extent is your organization leveraging metrics or data to inform clinical trial processes? Select one of the following.

Answer Options	Response Percent	Response Count
Not collecting data	15.5%	39
Collecting data but not using it to improve execution of trial processes	23.0%	58
Using some metrics to improve execution of trial processes	41.7%	105
Extensively using metrics to improve execution of trial processes	11.1%	28
Extensively using metrics to improve execution and design of trial processes	8.7%	22

14. Which of the following metrics are, or would be, the most useful in your efforts to shorten clinical trials? Please select up to five most useful metrics.

Answer Options	Response Percent	Response Count
Cycle time from internal study approval to final protocol	49.2%	124
Number of protocol amendments	40.9%	103
Cycle time from site identification to site selection	36.9%	93
Cycle time from site selection to IRB/IEC approval and from IRB/IEC approval to site initiation	49.6%	125
Planned versus actual number of site initiations	25.0%	63
Planned versus actual number of subject enrollments	47.2%	119
TMF quality (quality check findings and missing documents by organization, site, CRO)	42.9%	108
Cycle time from quality check finding to resolution for TMF documents	21.8%	55
Cycle time from first site initiation to interim analysis approval	27.8%	70
Time from last site close-out to clinical study report approval	28.6%	72
Time from last site close-out to resolution of all quality check findings	23.4%	59

15. Select the best description for your organization. Select one of the following:

Answer Options	Response Percent	Response Count
Sponsor	53.6%	135
CRO	20.2%	51
Consultant	8.3%	21
Site	12.3%	31
Site Management Organization	5.6%	14

16. Which of the following best describes your functional area within your organization? Select one of the following:

Answer Options	Response Percent	Response Count
Clinical Operations	73.4%	185
Records / Information Management	11.1%	28
Auditor / Quality Assurance (QA) / Quality Control (QC)	13.5%	34
IT	2.0%	5