Veeva 2015 Paperless TMF Survey: Annual Report

REMOVING PAPER FROM THE PROCESS

The *Veeva 2015 Paperless TMF Survey* explores the life sciences industry's progress toward paperless clinical trials by gathering the experiences and opinions of Trial Master File (TMF) owners from around the globe. 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. Building off of last year's inaugural benchmark survey, which showed lagging technology adoption and extensive amounts of paper in clinical processes, the *Veeva 2015 Paperless TMF Survey* examines whether there has been a maturation in TMF processes and a reduction in paper documents.

Key Findings

- Over the past year, the use of paper has declined in key areas such as clinical operations where those managing "most or all" TMF documents on paper is down 12 percentage points from 43% to 31%.
- Sponsors and CROs use less paper and fax to exchange TMF documents today than one year ago. The use of paper dropped 10 percentage points to 47% and use of fax dropped 12 percentage points to 13%.
- One in four (24%) sponsors and CROs now utilize purpose-built eTMF applications to exchange TMF documents, up from 15% in 2014.
- While more than half of respondents (59%) are electronically archiving documents, fewer have fully digitized other key activities such as e-signature (21%), document creation (25%), and collaboration (30%).
- Those using purpose-built eTMF applications report improved audit and inspection readiness (61%) as a benefit of adoption more frequently than users of other types of eTMFs.
- Remote TMF access for auditors and inspectors is expected to double within the next two years to 65%.
- The use of metrics remains limited, despite evidence that organizations extensively leveraging TMF data achieve greater benefits with their eTMF.

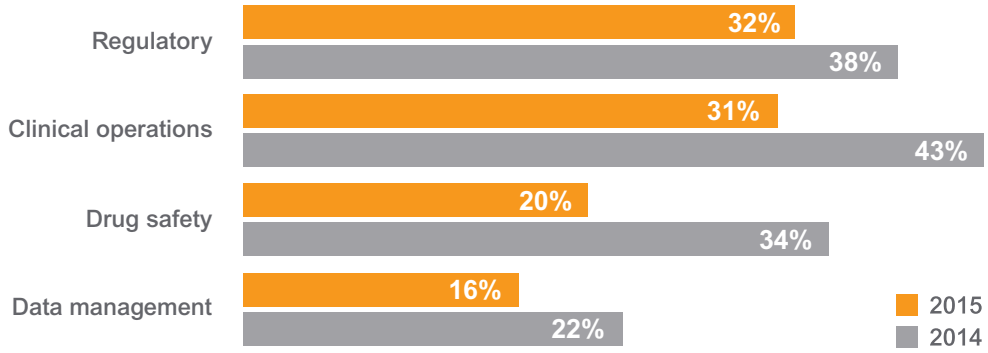
Usage of Paper and Digital Process Maturity

The use of paper has declined in key functional areas. The year-over-year estimates for clinical operations represent a significant drop – to less than a third (31%) managing most or all TMF documents on paper in 2015, down from 43% last year.

Drug safety also experienced a significant reduction in the amount of paper it manages; 20% manage most or all documents on paper this year, down from 34% in 2014.

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

Base 2015: Total respondents, N = 186
Base 2014: Total respondents, N = 252



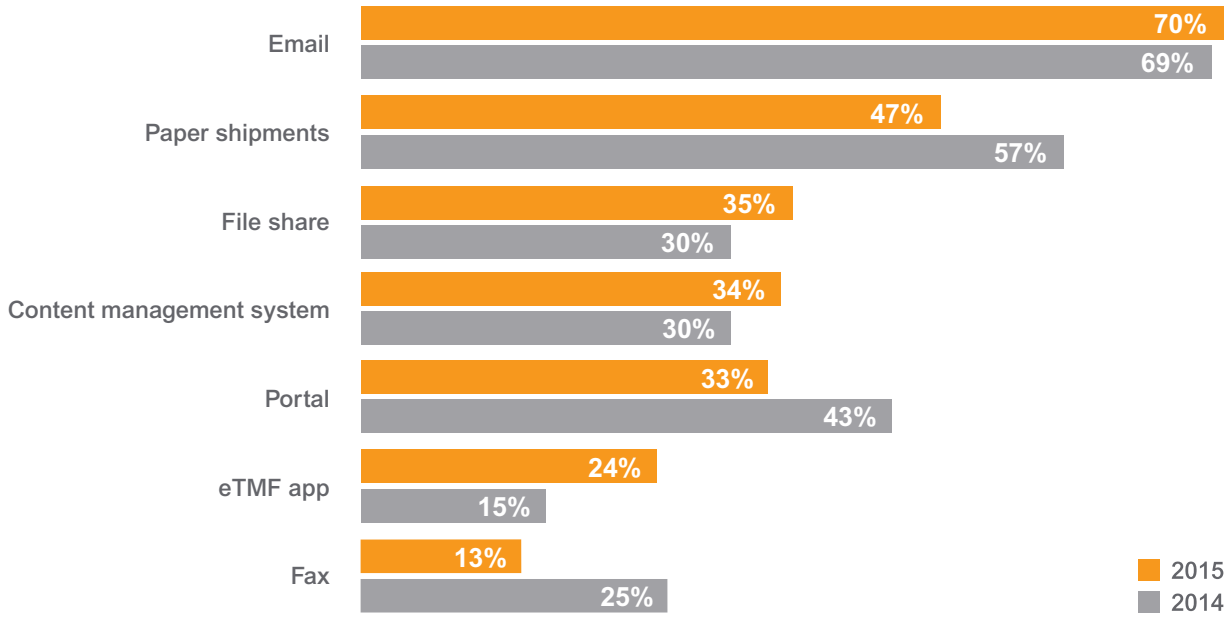
In each area, how many of your company's TMF documents are managed on paper at any point in their lifecycle? (Q.3)

Survey responses reflect significant declines in the use of paper and fax when exchanging documents between sponsors and CROs. Email remains the dominant method of exchanging TMF documents between sponsors and CROs (70% in 2015 vs. 69% in 2014). Paper, the second most common method of exchange, dropped significantly to 47% from 57%. Faxing documents saw the largest decline, now 13% versus 25% in 2014.

In contrast, use of eTMF applications to exchange documents is increasing, and is now used by a quarter of sponsors and CROs (24%), up from 15% in 2014.

Methods for Exchanging TMF Documents Between Sponsors and CROs

Base 2015: Total respondents, N = 186
Base 2014: Total respondents, N = 252



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

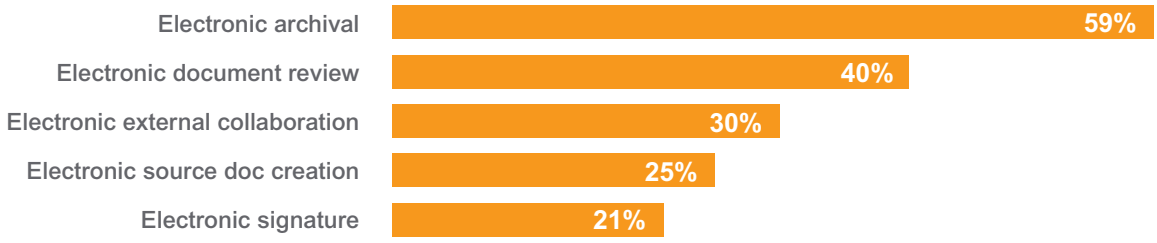
Use and Benefits of Electronic Processes

Respondents indicated which TMF processes their organization currently conducts electronically. More than half (59%) of respondents report "mostly or always" archiving TMF documents electronically.

Less than one-third of respondents, however, typically perform other key processes electronically: e-signature for documents (21%); source document creation (25%); and external collaboration (30%).

Activities Mostly or Always Done Electronically

Base: Total respondents, N = 186

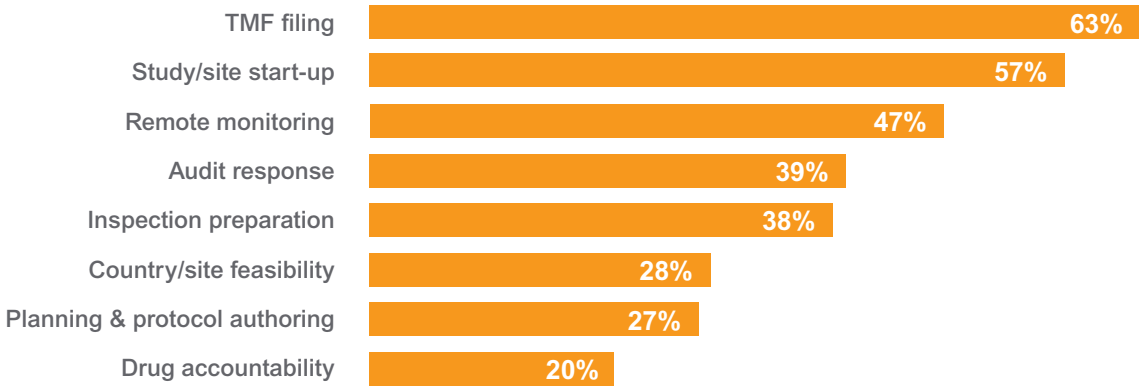


To what extent is your company currently doing the following [electronically] with TMF documents? (Q.8)

However, respondents do see significant benefit in moving to paperless processes. Nearly two-thirds (63%) say managing the TMF filing process in an eTMF would shorten clinical development time. More than half (57%) believe study/site start-up would speed development time if managed in an eTMF.

Would Shorten Development Time if Managed in an eTMF

Base: Total respondents, N = 186



In your opinion, which of the following processes would significantly shorten clinical development time if they were managed with an eTMF? Select up to four processes. (Q.6)

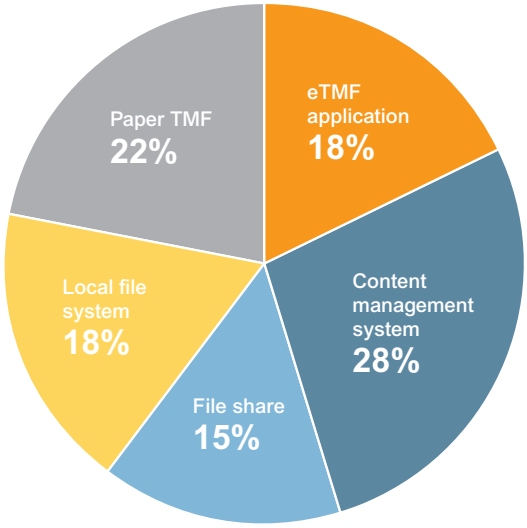
Types and Benefits of an eTMF

Historically, TMFs were categorized as either paper or electronic. This survey asks about the type of eTMF in use, recognizing the differences in system maturity. Local 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. Content management systems provide search, versioning, and workflow among other capabilities. An eTMF application is typically built on a content management system and provides purpose-built functionality and configurations specific to TMF documents.

eTMF adoption remains broadly distributed across the maturity spectrum. More than half (55%) of respondents report their TMF is little more than an archive (file share, local file system, paper). Nearly a third (28%) report using a content management system, and 18% an eTMF application, both of which can manage business processes.

eTMF System Currently in Use

Base 2015: Total respondents, N = 186



What type of eTMF solution do you currently use? Select only one. (Q.9)

Benefits of an eTMF

Respondents were asked to indicate which, if any, benefits relating to key clinical processes they experience with the use of an eTMF. In processes that impact TMF quality, eTMF applications have the greatest impact.

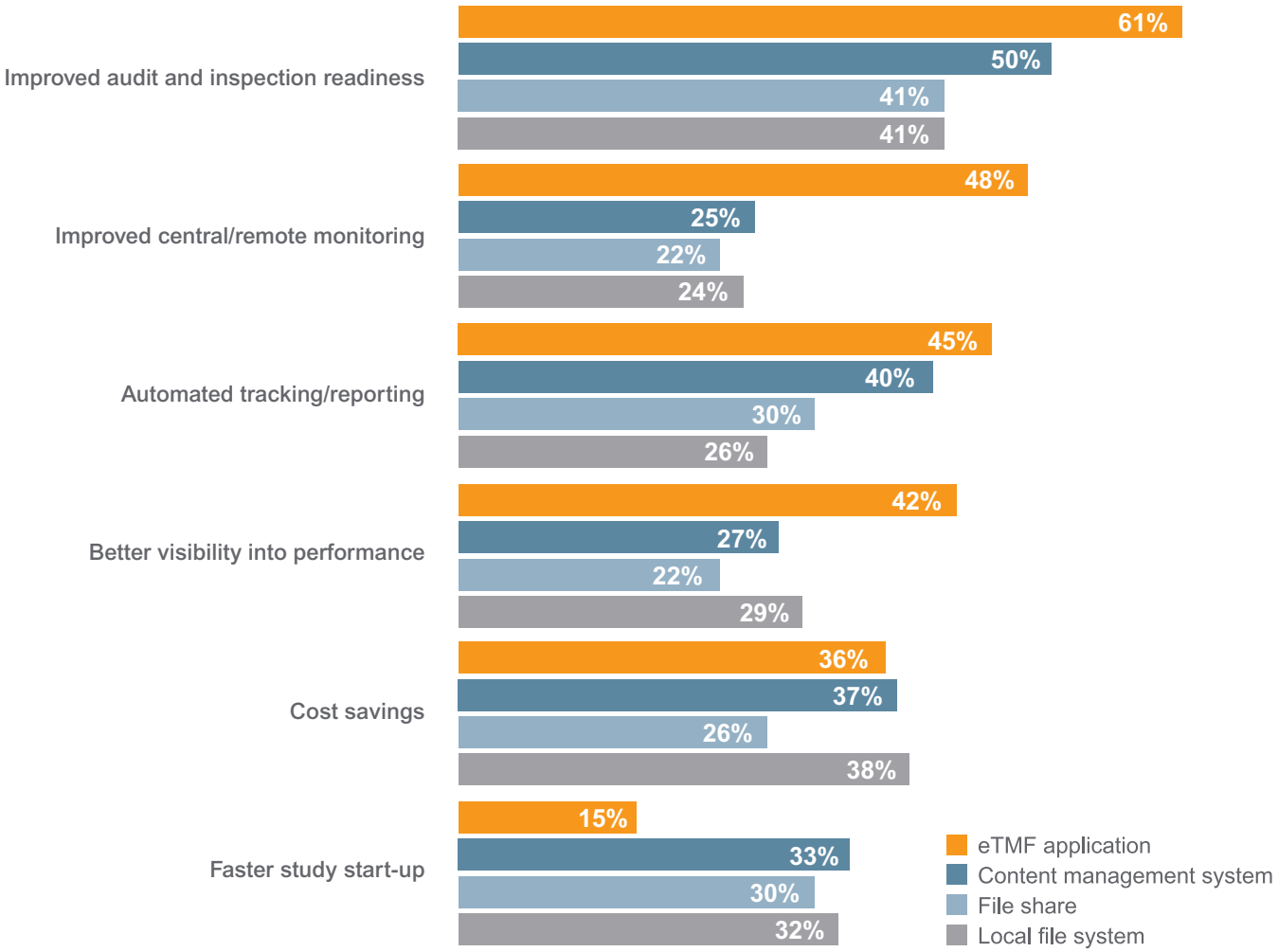
Almost two-thirds (61%) of respondents using an eTMF application report improved audit and inspection readiness after implementation. Half (50%) of content management system users also report audit and inspection readiness improvement.

By an almost two-to-one margin, those using an eTMF application (48%) report improved central/remote monitoring compared to other types of eTMFs. A quarter of respondents using a content management system (25%), cloud file share (22%), or local file system (24%) report improved central/remote monitoring.

In two other key categories that impact TMF quality – automated tracking/reporting of documents and better visibility into performance metrics – respondents using eTMF applications report the greatest improvements (45% and 42%, respectively).

Benefits Attributed to an eTMF by Type of eTMF

Base: Respondents using an eTMF, N = 146



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

What type of eTMF solution do you currently use? Select only one. (Q.9)

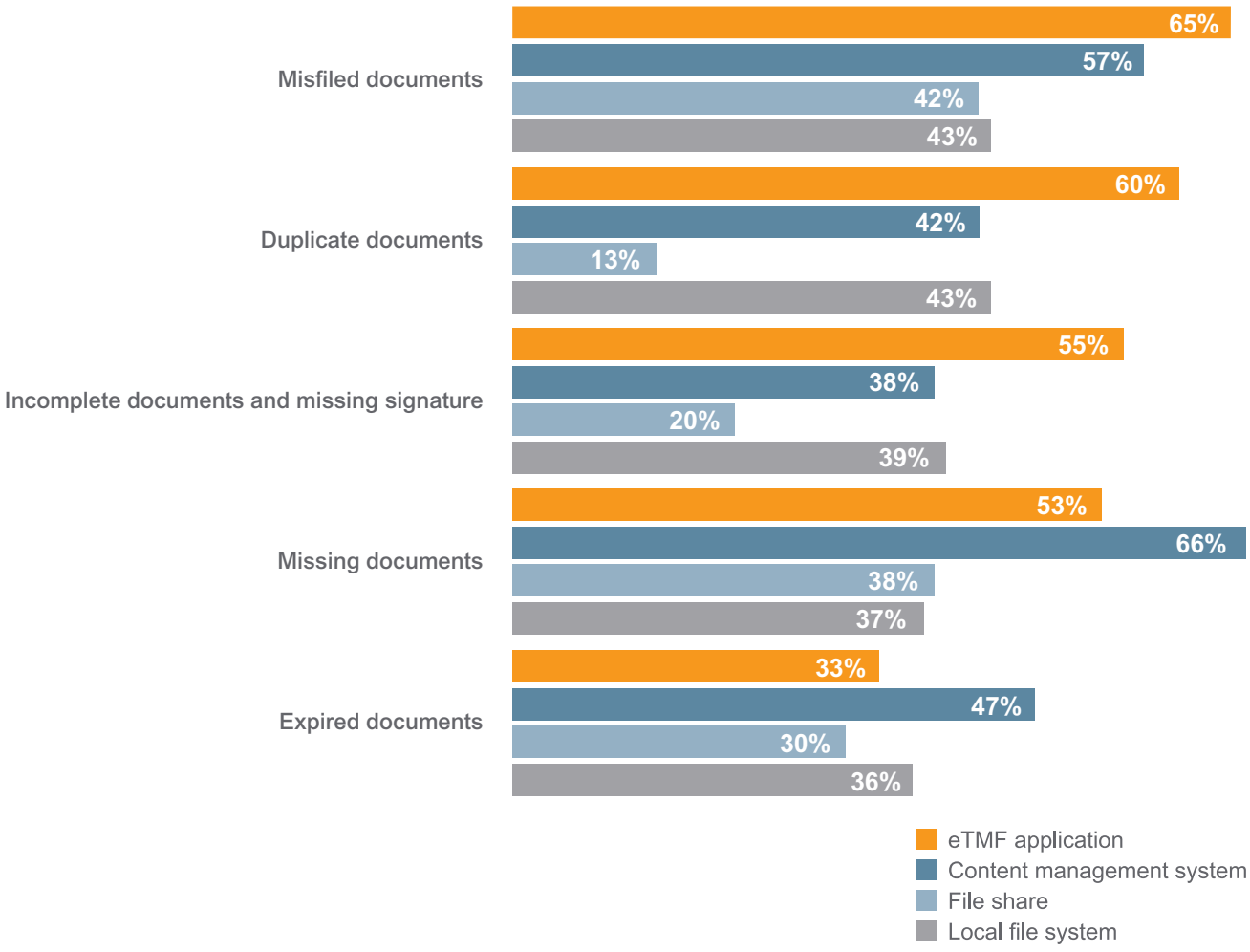
Improvements in Inspection Areas by Type of eTMF

The use of eTMF applications improves TMF quality in most inspection areas. Respondents who use eTMF applications indicate significant improvements in eliminating misfiled documents (65%) and duplicate documents (60%).

Very few of the cloud file share users achieved significant inspection area improvements. Approximately one in ten (13%) respondents using a cloud file share report significant improvement in eliminating duplicate documents. And two in ten (20%) cloud file share users report a significant improvement in reducing incomplete documents and missing signatures.

Significant Improvements in Inspection Area Achieved by Type of eTMF

Base: Respondents using an eTMF, N = 146



How much improvement, if any, did you observe in the following inspection areas after your organization implemented the eTMF solution specified in Question 9? (Q. 11)

What type of eTMF solution do you currently use? Select only one. (Q.9)

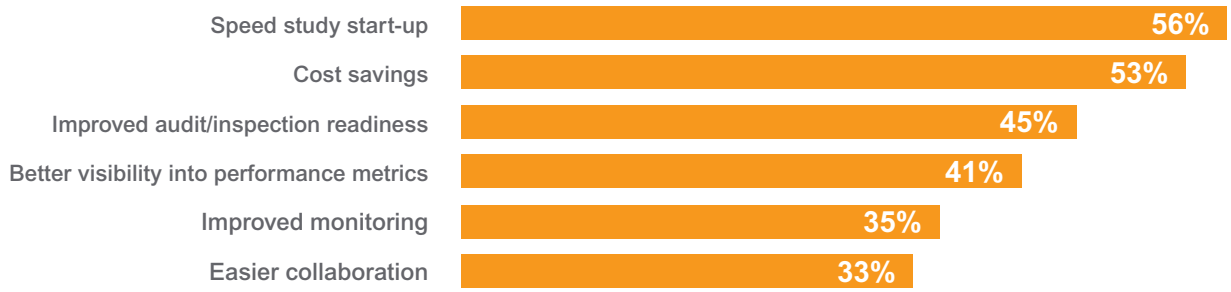
Drivers and Barriers to Going Paperless

Speeding study start-up (56%) and cost savings (53%) are the top drivers of eTMF adoption. Improved audit and inspection readiness (45%) also ranks high as a motivator.

While the reasons for moving to an eTMF remain largely unchanged from 2014, there is a marked decline in the importance of improving monitoring (35% today vs. 49% in 2014). Better visibility into performance metrics, which was not asked about in the 2014 survey, is considered a key driver for adopting an eTMF by 41% of respondents. Performance metrics can provide insight into site adherence to study protocols and standard operating procedures (SOPs), which play an important role in optimizing monitoring resources.

Top Drivers of eTMF Adoption

Base 2015: Total respondents, N = 186



Which of the following business benefits are the most important in motivating your organization's adoption of an eTMF? Please select the top three benefits. (Q.7)

While paper is prevalent in TMF processes, the barriers to going paperless are low. The cost of technology and implementation services (39%) is the greatest perceived barrier. About a third of respondents cite the limitation of in-house tools and technologies (36%) and the lack of internal support and knowledge (33%) as significant barriers.

The relatively low concern over regulatory requirements (25%) as a barrier to going paperless shows an industry in step with the global regulatory environment.

Significant Barriers to TMFs Going Paperless[1]

Base: Total respondents excluding "I don't know," N varies

To what extent is each of the following a barrier to TMFs going paperless in your organization? (Q.4)

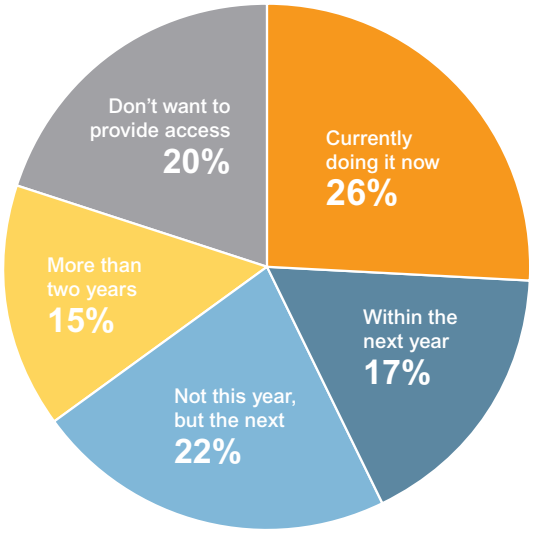
Remote TMF Access

A quarter (26%) of all respondents currently grant remote TMF access to auditors and inspectors. The April 2014 Medicines and Healthcare Products Regulatory Agency (MHRA) update on good clinical practice (GCP) critical findings has clarified regulatory expectations for inspection readiness and access to the trial master file. That update may contribute to projections that remote access will more than double to 65% within two years.

A majority (57%) of those using eTMF applications are already granting remote access to auditors, more than twice that of other eTMF types. Only 14% of cloud file share users are currently granting remote access, compared to 22% of local file system and 26% of content management system users.

Currently Granting Remote TMF Access

Base: Total respondents excluding "I don't know," N = 115



[1] In 2014 respondents reported cost of new technology (38%) and cost of implementing new technology (33%) as the two greatest barriers to TMFs going paperless. Changes to this question make year-over-year comparison difficult.

When, if ever, does your organization plan to provide auditors/inspectors with remote access to trial master file documents? (Q.12)

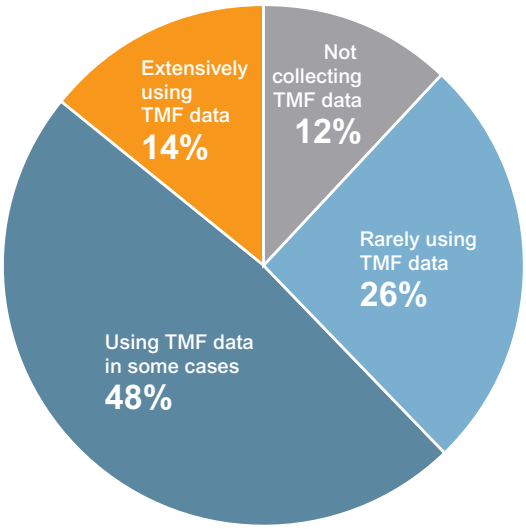
Use of Metrics and Impact on eTMF Benefits

Overall, the use of TMF data to improve trial processes is relatively low. Almost 40% either rarely use (26%) or do not collect (12%) TMF data. Nearly half of respondents (48%) leverage TMF data to improve trial processes in some cases, but only 14% are doing so extensively.

Despite this low use of TMF metrics, there is evidence of their benefits. Companies that use metrics extensively see greater benefit from their eTMFs than those who do not collect data, including improved inspection readiness (82% vs. 25%), improved remote monitoring (53% vs. 0%), and greater cost savings (53% vs. 17%).

Organizations Using TMF Metrics to Improve Clinical Processes

Base: Total respondents excluding "I don't know," N = 155

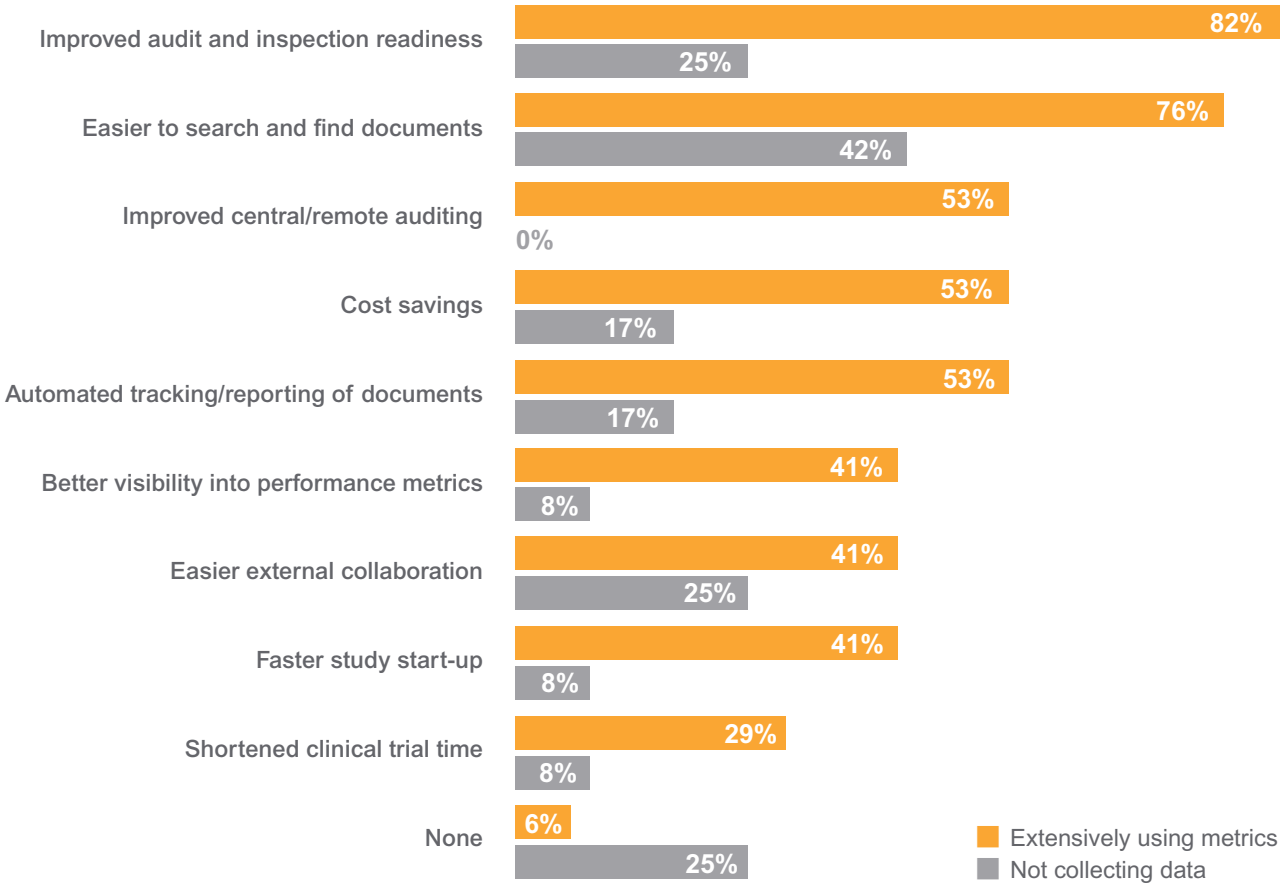


To what extent is your organization leveraging TMF operational data (e.g., time from initial review to approval) to improve trial processes? (Q.13)

eTMF Benefits Achieved by Level of Metrics Usage

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

Base: Respondents using an eTMF excluding "I don't know," N = 126



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

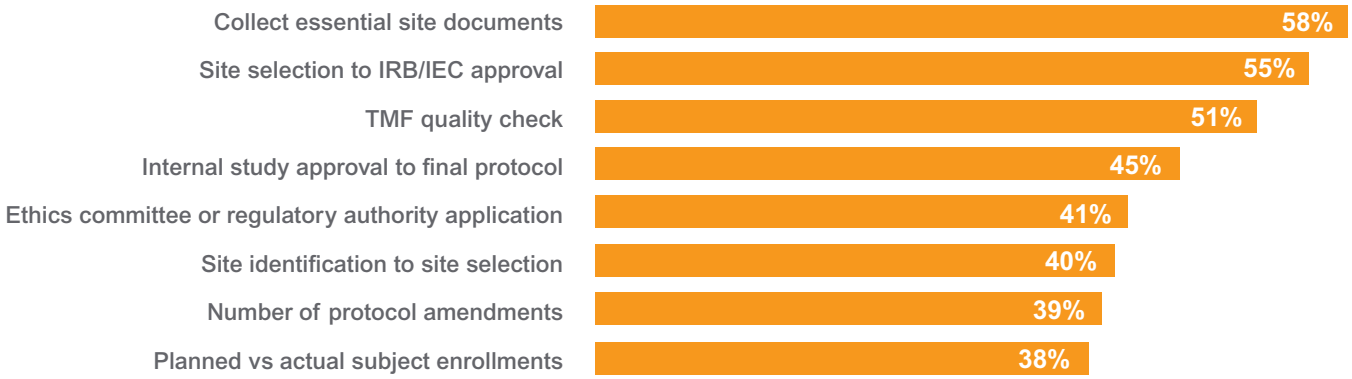
What type of eTMF solution do you currently use? Select only one. (Q.9)

To what extent is your organization leveraging TMF operational data (e.g., time from initial review to approval) to improve trial processes? (Q.13)

When asked what were the most useful metrics to shorten trial time, those associated with study start-up led the way. More than half of respondents say access to information about the cycle time to collect essential site documents (58%) and site selection to Institutional Review Board (IRB) approval (55%) would be the most useful metrics in shortening trials. This aligns with the 57% of respondents indicating that managing the study/site start-up process in an eTMF would shorten development time (Q.6).

Most Useful Metrics to Shorten Trial Time

Base: Total respondents, N = 186



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. (Q.14)

Conclusion

The *Veeva 2015 Paperless TMF Survey* was conducted to analyze the maturity of TMF technologies, processes, and metrics, which are fundamental to achieving the industry-wide goal of a paperless TMF. Since 2014, there were measurable advances made in the move away from paper, and those using more mature TMF technology continue to see the greatest operational and business benefits.

Technology – The 2015 survey results demonstrate there is wide variation in the technologies used to manage eTMFs, and the type of eTMF used impacts the benefits achieved. Those using eTMF applications are more likely to report improved inspection readiness, central monitoring, automated tracking and reporting, and better visibility into performance. Respondents expect these types of process improvements, which are inherent with paperless TMFs, to ultimately shorten clinical development times.

Process Improvement and Removal of Paper – There has been measurable progress toward removing paper from TMF processes. The predominant use of paper in clinical operations and drug safety decreased significantly as did the exchange of documents between CROs and sponsors. These are encouraging indicators of progress, but there is still much to be done as manual and paper processes remain in force.

Inspection Readiness and Quality – Survey respondents report improved TMF quality with the use of an eTMF. The most significant improvements reported by those using an eTMF application are in the reduction of the number of missing signatures, misfiled documents, and duplicate documents.

Remote access for inspectors to the TMF is becoming a key component of inspection readiness. And, eTMF application users are setting the bar for remote access, reflecting global, state-of-the-art inspection practices.

Return on Investment – More than half of survey respondents report that cost savings and faster study start-up processes are key motivators for adopting an eTMF, yet approximately a third cite the cost of eTMF systems and implementation services as a significant barrier to going paperless. This dichotomy points to the need for careful return on investment (ROI) analysis by organizations evaluating and selecting eTMF systems.

Meaningful return on investment analysis will require collecting and evaluating performance metrics. The survey finding that few respondents are extensively using TMF data to improve trial process may signal a challenge to rigorous ROI analysis. However, as the industry expands the use of technology to gather and analyze operational and performance metrics, these challenges can be overcome.

Survey Methods

The survey consisted of 13 questions, many of which included sub-questions 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. The survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and the first 50 respondents were offered a $5 gift card. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

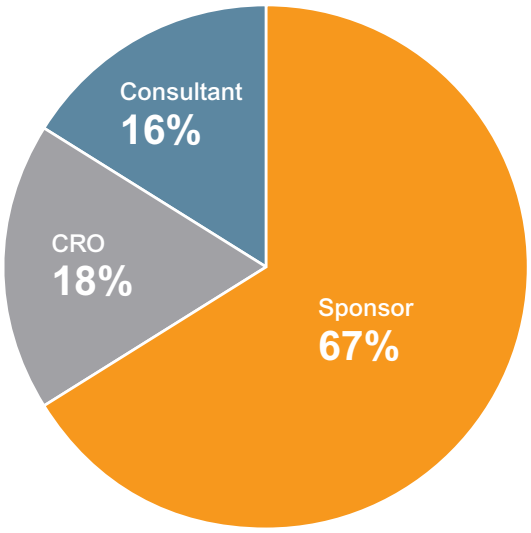
Survey Respondents

Of the more than 200,000 individuals invited to take the survey, a total of 2,257 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. More than 175 unverified responses were eliminated, yielding 186 qualified survey responses. More than half of the respondents were from sponsor companies in the United States.

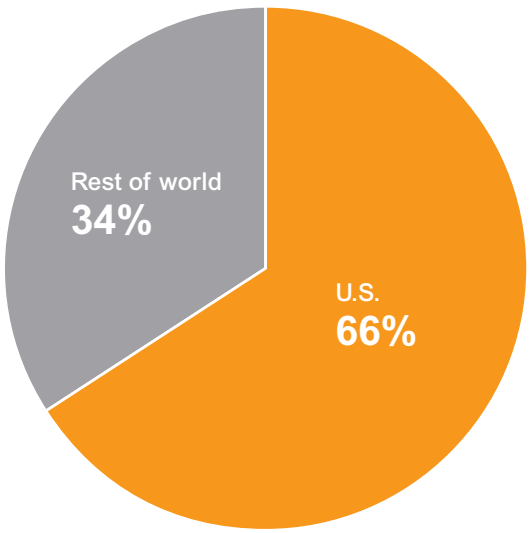
Survey Respondent Demographics

Base: Total respondents, N=186

Type of Organization



Geographic Location



Contact

For more information about this study, please contact us at eTMFsurvey@veeva.com.

Addendum

Q.1 *Please indicate your role and level of responsibility for a trial master file (TMF) in your organization.*

Answer Options	Response Percent	Response Count
Consultant	15.6%	29
CRO	17.7%	33
Sponsor	66.7%	124
I am the primary person responsible	23.7%	44
I am one of the several people responsible	76.3%	142

Q.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	File Share (e.g., FTP site, Box, Dropbox, virtual data room)	Enterprise Content Management (ECM) system (e.g., SharePoint, Documentum)	eTMF Application (e.g., NextDocs, Veeva Systems, Wingspan, etc.)	Response Count
Investigator sites	41	106	128	38	52	36	28	186
IRBs/IECs	32	94	115	25	27	25	14	186
Regulatory authorities	42	109	102	27	31	30	19	186
Sponsors/CROs	62	87	130	24	66	64	44	186

Q.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 or Little on Paper	Some on Paper	Most to All on Paper	I Don't Know/ Does Not Apply	Response Count
Clinical operations	27	96	57	6	186
Data management	74	78	29	5	186
Drug safety	46	88	38	14	186
Regulatory	32	88	60	6	186
Clinical trial records	81	68	32	5	186

Q.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	Moderate Barrier	Significant Barrier	I Don't Know/ Does Not Apply	Response Count
Regulatory requirements, e.g. wet signatures	47	89	46	4	186
Cost of technology and/ or implementation services	31	78	70	7	186
Lack of internal support or knowledge	38	83	60	5	186
Limitation of in-house tools or technologies	42	74	66	4	186
Impact of organizational change	56	87	38	5	186
Lack of interest/priority	86	63	33	4	186

Q.5 *Which capability(ies) listed is your organization currently missing and would be required by your organization in order to move to paperless TMFs? Select all that apply.*

Answer Options	Response Percent	Response Count
Electronic forms	37.6%	70
Digital or eSignatures	52.2%	97
Secure access by external parties	44.1%	82
System compliance with 21 CFR Part 11, EU Annex 11, etc.	39.8%	74
Tracking and reporting	44.1%	82
Archival and export capabilities	33.3%	62
Integration with CTMS	46.2%	86
Integration with EDC	47.3%	88
None – we are fully paperless today	8.6%	16

Q.6 *In your opinion, which of the following processes would significantly shorten clinical development time if they were managed with an eTMF? Select up to four processes.*

Answer Options	Response Percent	Response Count
Study planning/protocol authoring process	27.4%	51
Country/site feasibility process	28.0%	52
Study/site start-up process	57.0%	106
TMF filing process	62.9%	117
Remote monitoring process	47.3%	88
Inspection preparation activities	37.6%	70
Audit response process	39.2%	73
Drug accountability process	19.9%	37

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

Answer Options	Response Percent	Response Count
Improved audit and inspection readiness	45.2%	84
Cost savings	53.2%	99
Speed study start-up	56.5%	105
Better visibility into key trial performance metrics	41.4%	77
Easier collaboration with external parties	32.8%	61
Improved central and remote monitoring	34.9%	65

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

Answer Options	Mostly or Always Doing	Sometimes Doing	Not or Rarely Doing	Does Not Apply	Response Count
Electronic archival of documents	109	51	25	1	186
Electronic signature of documents	39	82	62	3	186
Electronic collaboration (exchange, QC, review, approval) with external partners	56	97	31	2	186
Remote document review	75	84	25	2	186
Electronic creation of source documents	46	87	49	4	186

Q.9 *What type of eTMF solution do you currently use? Select only one.*

Answer Options	Response Percent	Response Count
Local file system	18.3%	34
File share (e.g., Box, Dropbox, FTP site)	14.5%	27
Content management system (e.g., Documentum, SharePoint)	28.0%	52
eTMF application (e.g., NextDocs, Veeva Vault, Wingspan)	17.7%	33
I am currently using a paper TMF	21.5%	40

Q.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
Faster study start-up	22.0%	41
Easier collaboration with external parties	31.7%	59
Easier to search and find documents	51.1%	95
Improved audit and inspection readiness	38.2%	71
Automated tracking and reporting of documents	28.5%	53
Better visibility into key trial performance metrics	23.7%	44
Shortened clinical trial time	10.2%	19
Cost savings (from efficiencies, reduced storage, etc.)	27.4%	51
Improved central and remote auditing	23.1%	43
None	7.0%	13

Q.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	Significant Improvement	I Don't Know	Response Count
Missing documents	10	55	68	10	133
Misfiled documents	14	49	71	9	134
Incomplete documents and missing required signature	15	63	49	16	127
Expired documents	16	63	49	15	128
Duplicate documents	15	63	54	11	132

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

Answer Options	Response Percent	Response Count
Currently doing it now	16.1%	30
Within the coming year	10.8%	20
Not this year, but the following	13.4%	25
More than two years	9.1%	17
Do not want to provide access	12.4%	23
I don't know	38.2%	71

Q.13 *To what extent is your organization leveraging TMF operational data (e.g., time from initial review to approval) to improve trial processes? Select one of the following.*

Answer Options	Response Percent	Response Count
Not collecting data	9.7%	18
Rarely using data	22.0%	41
Using data in some cases	39.8%	74
Extensively using data	11.8%	22
I don't know	16.7%	31

Q.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	44.6%	83
Number of protocol amendments	39.2%	73
Cycle time from site identification to site selection	39.8%	74
Cycle time from site selection to IRB/IEC approval	54.8%	102
Planned versus actual number of subject enrollments	38.2%	71
TMF quality (quality check findings and missing documents by organization, site, CRO)	50.5%	94
Cycle time to collect all essential site documents	57.5%	107
Cycle time to prepare an ethics committee or regulatory authority application	40.9%	76