PRELIMINARY FINDINGS

Veeva 2017 Unified Clinical Operations Survey

The *Veeva 2017 Unified Clinical Operations Survey* examines the life sciences industry's progress toward a unified clinical environment by gathering the experiences and opinions of 300 clinical operations professionals from around the globe. Evolved from the annual *Veeva Paperless TMF Survey*, this research examines the drivers, barriers, and benefits of a unified clinical operating model and tracks the industry's progress in its move to streamline clinical systems and processes.

Executive Summary

Findings indicate an industrywide drive toward a unified clinical model that is defined by end-to-end processes and systems, seamless collaboration among stakeholders, and greater insights across the clinical lifecycle to improve performance.

- Nearly all (99%) respondents report the need to unify their clinical applications, including CTMS, EDC, and eTMF. For more than half, this is driven by the need to speed study execution, improve study quality, ease collaboration, and achieve greater visibility.
- Respondents also cite significant challenges resulting from application and process silos. In looking at CTMS, half (49%) of sponsors say the challenge of integrating their eTMF application or EDC application with CTMS limits their organization's ability to improve clinical operations.
- The greater the number of separate applications used, the greater the number of challenges reported in study start-up ($p < .001$). Respondents who use two or more tools (76%) more frequently cite issues with site contracting and budgeting (60%), site identification (49%), and study planning during protocol design (40%).
- Consistent with the drive to streamline collaboration and implement end-to-end processes, sponsors are moving away from manual systems. One in three (31%) sponsors now use an eTMF application up from 13% in 2014. Only 16% of sponsors say their clinical operations departments use paper for most/all TMF documents, down from 41% in 2014. And half of document templates are now created electronically (52%), double the number from two years ago (25% in 2015).
- Reporting across multiple applications (60%) is among the biggest challenges organizations face when asked about their clinical solutions. Most sponsors (51%) report the need for better visibility and one-third say clinical data is tracked outside of their systems. Yet, organizations that extensively use data to improve clinical trial processes achieve greater benefits than those not leveraging data, including easier collaboration (50% to 25%, respectively), central and remote auditing (50% to 31%, respectively), and automated tracking and reporting of documents (54% to 38%, respectively).

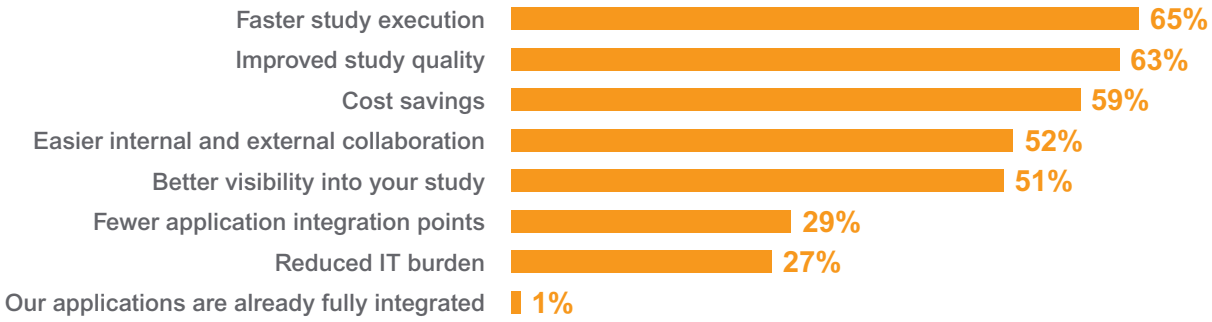
Drivers and Barriers to Unifying Clinical Systems and Processes

With the growing numbers of clinical trials[1] and increasing complexity across the clinical lifecycle, life sciences organizations are under tremendous pressure to increase study quality and execution. This has prompted industrywide recognition of the need for a unified clinical model that is defined by end-to-end processes and systems, seamless collaboration across the clinical ecosystem, and greater insights from metrics to increase performance.

Nearly all (99%) respondents report the need to unify their clinical applications. The top three most important drivers for unifying clinical applications are faster study execution (65%), improved study quality (63%), and cost savings (59%). Most (76%) say unifying their applications will drive improvements in three or more areas.

Top Drivers of Unification

Base: Total respondents, N=300



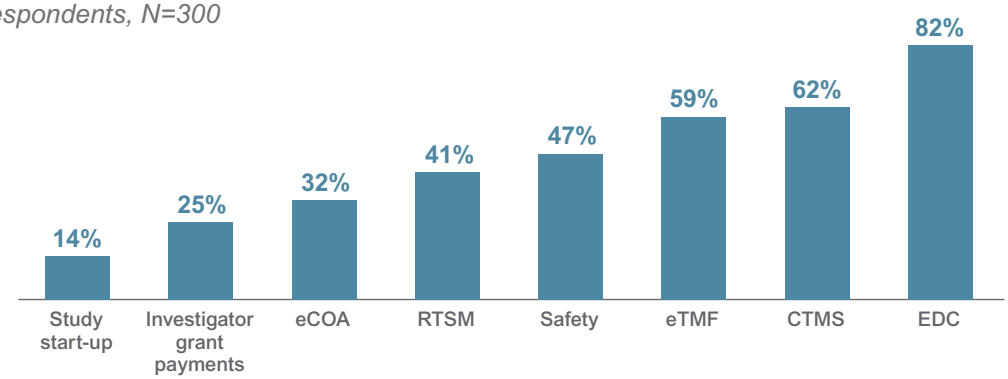
To the degree your organization needs to better integrate/unify the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.), what are the most important drivers? Select all that apply. (Q.5)

On average, respondents use four applications to manage their clinical studies and more than one-third (38%) use at least five applications. The most commonly used applications are EDC (81%), CTMS (59%), and eTMF (57%). Given EDC systems were among the first clinical applications introduced nearly 20 years ago, it's not surprising that they are the most prevalent applications in use today. Conversely, newer study start-up applications have not yet seen widespread adoption.

[1] ClinicalTrials.gov. Total Number of Registered Studies. February 2017.

Applications Used to Manage Clinical Studies

Base: Total respondents, N=300



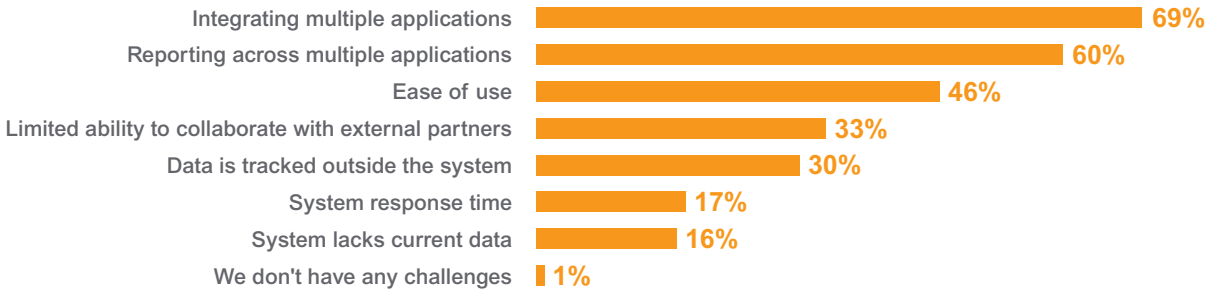
Does your organization utilize applications developed by third-party vendors in managing clinical studies? If yes, please indicate which are currently in use. (Q.3)

Nearly all respondents (99%) say they have at least one major challenge with their clinical applications and, over three-quarters (83%) reported two or more challenges. The top two issues – integrating multiple applications (69%) and reporting across applications (61%) – are a direct result of clinical application silos.

The next most often cited challenges point to clinical systems that are hard to use (46%) and lack the ability to support collaboration (33%). Application usability and accessibility issues may prompt users to work outside existing systems and could, in part, contribute to the difficulty some face with data being tracked outside of their system (30%).

Biggest Challenges with Clinical Applications

Base: Total respondents, N=300



What are the biggest challenges, if any, your organization faces in utilizing the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.)? Select all that apply. (Q.4)

Challenges in Managing Collaborative Clinical Processes

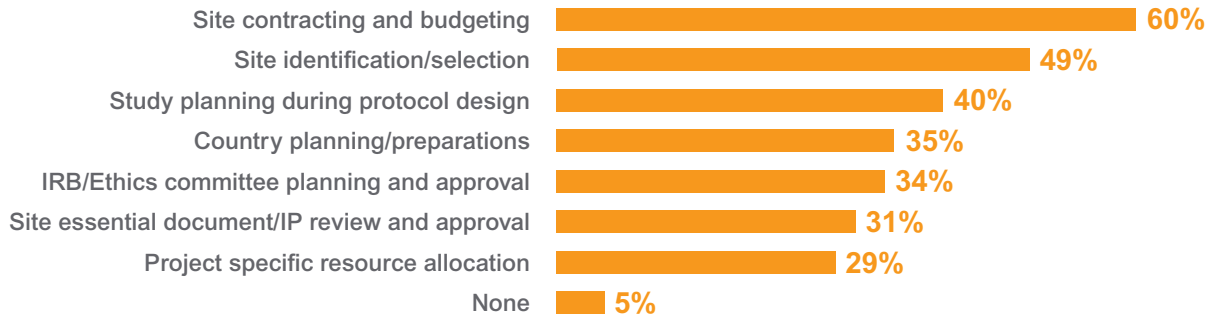
According to the Tufts Center for the Study of Drug Development, it takes one year, on average, to identify a site and activate it to conduct research.[2] Consistent with this research, 95% of sponsors report challenges with the study start-up process, an area that's heavily reliant on collaboration with external parties.

Further Tufts research found that the time from the pre-study visit to contract execution accounts for the majority of the study start-up cycle time.[3] Close to two-thirds (60%) of sponsors say site contracting and budgeting is one of the most challenging study start-up processes for their organization. Half (49%) report site identification/selection as the most challenging, followed by study planning during protocol design (40%).

Sponsors who report their current clinical applications limit their ability to collaborate with external partners more frequently report challenges with study start-up processes.

Most Challenging Study Start-up Processes

Base: Sponsor respondents, N=203, p<.05 and p<.01



What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.14)

Purpose-built study start-up applications are relatively nascent, used by only 9% of sponsors. The vast majority use spreadsheets (85%) to manage study start-up processes and roughly one-third or less use CTMS, eTMF, or internally developed applications or online survey tools.

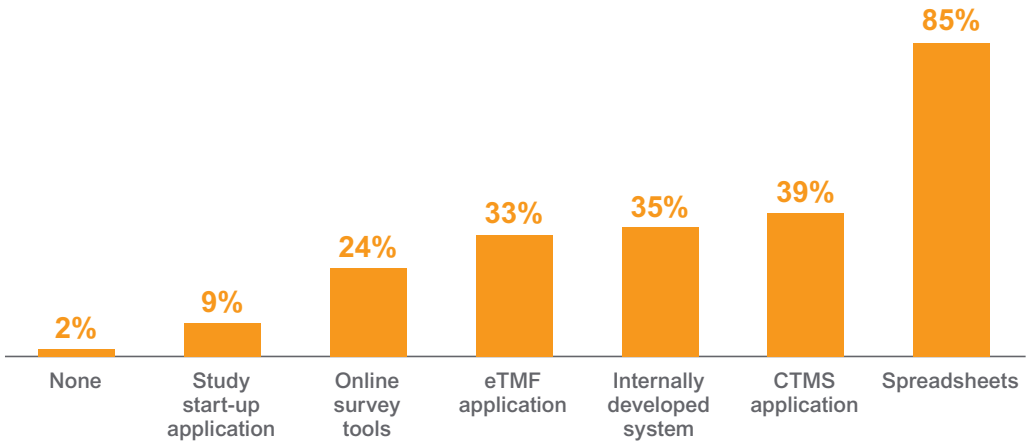
Those who use spreadsheets and multiple systems to manage study start-up processes also more frequently report issues with data being tracked outside their clinical systems.

[2] Lamberti, MJ, Chakravarthy, R, Getz, KA. Assessing Practices & Inefficiencies with Site Selection, Study Start-Up, and Site Activation. Applied Clinical Trials, August 2016

[3] Lamberti, MJ, Brothers C, Manak D, Getz, KA. Benchmarking the study initiation process. Therapeutic Innovation & Regulatory Science, 47(1) 101-109. 2013.Applied Clinical Trials, August 2016.

Tools Used to Manage Study Start-up Processes

Base: Sponsor respondents, N=203

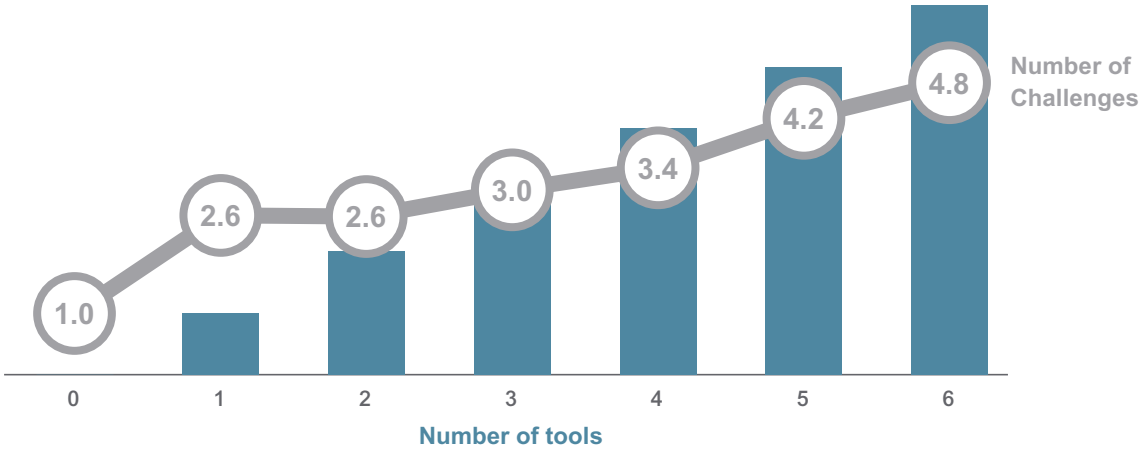


What tools do you use to manage study start-up processes? Select all that apply. (Q.15)

The more tools a sponsor uses to support the study start-up processes, the more challenges they report having in study start-up (p<.001). On average, sponsors use two tools to manage the study start-up process and have an average of three challenges.

Number of Challenges with Study Start-up Processes by Number of Tools Used

Base: Sponsor respondents, N=203



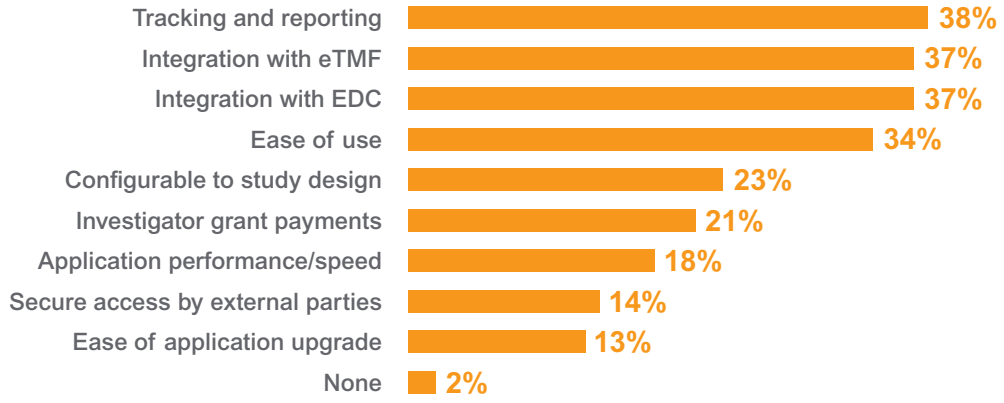
What tools do you use to manage study start-up processes? Select all that apply. (Q.15)
What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.14)

Impact of CTMS Applications on Clinical Operations

Highlighting the importance of CTMS applications to clinical operations, life sciences organizations are expected to increase their CTMS investments by almost 15% each year through 2020 driven by rising demand for data and site collection solutions and the availability of new CTMS applications.[4] Nearly all sponsors (98%) say challenges with their current CTMS application limit their ability to improve clinical operations. Tracking and reporting (38%) and integrating either an eTMF application (37%) or an EDC application (37%) are the most frequently cited shortcomings.

Challenges with CTMS Applications that Limit Ability to Improve Clinical Operations

Base: Sponsor respondents, N=203



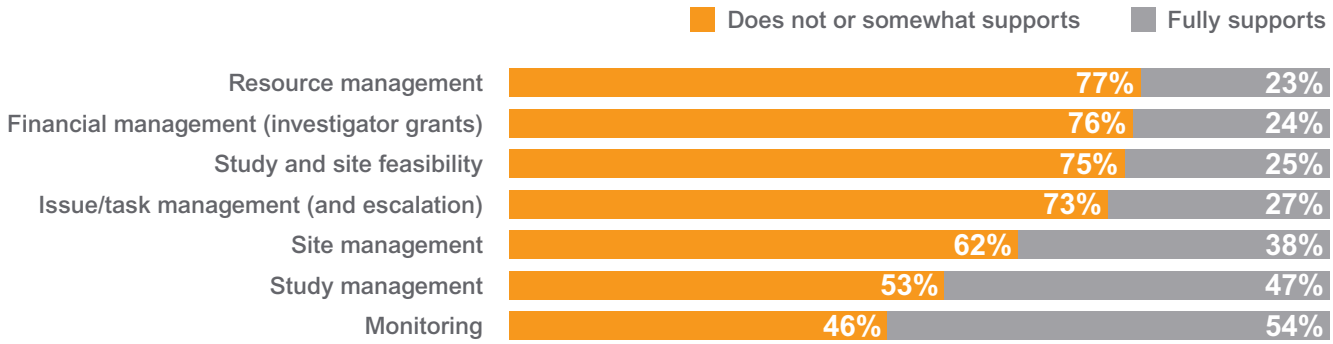
What challenges, if any, do you have with your organization's CTMS application that limit your ability to improve clinical operations? Select all that apply. (Q.7)

In addition, sponsors report significant deficiencies with their CTMS applications including an inability to fully support key functions like resource management (77%), study and site feasibility (76%), financial management (75%), and issue/task management (73%). Monitoring is the only process a majority of sponsors (54%) say their CTMS application fully supports.

[4] Markets and Markets. eClinical Solutions Market, Global Forecast to 2020. 2016.

Processes Supported by CTMS Applications

Respondents: Sponsor respondents, N=203



To what degree does your organization's CTMS application support the following processes? Check only one box per row. (Q.6)

eTMF Adoption and Maturity

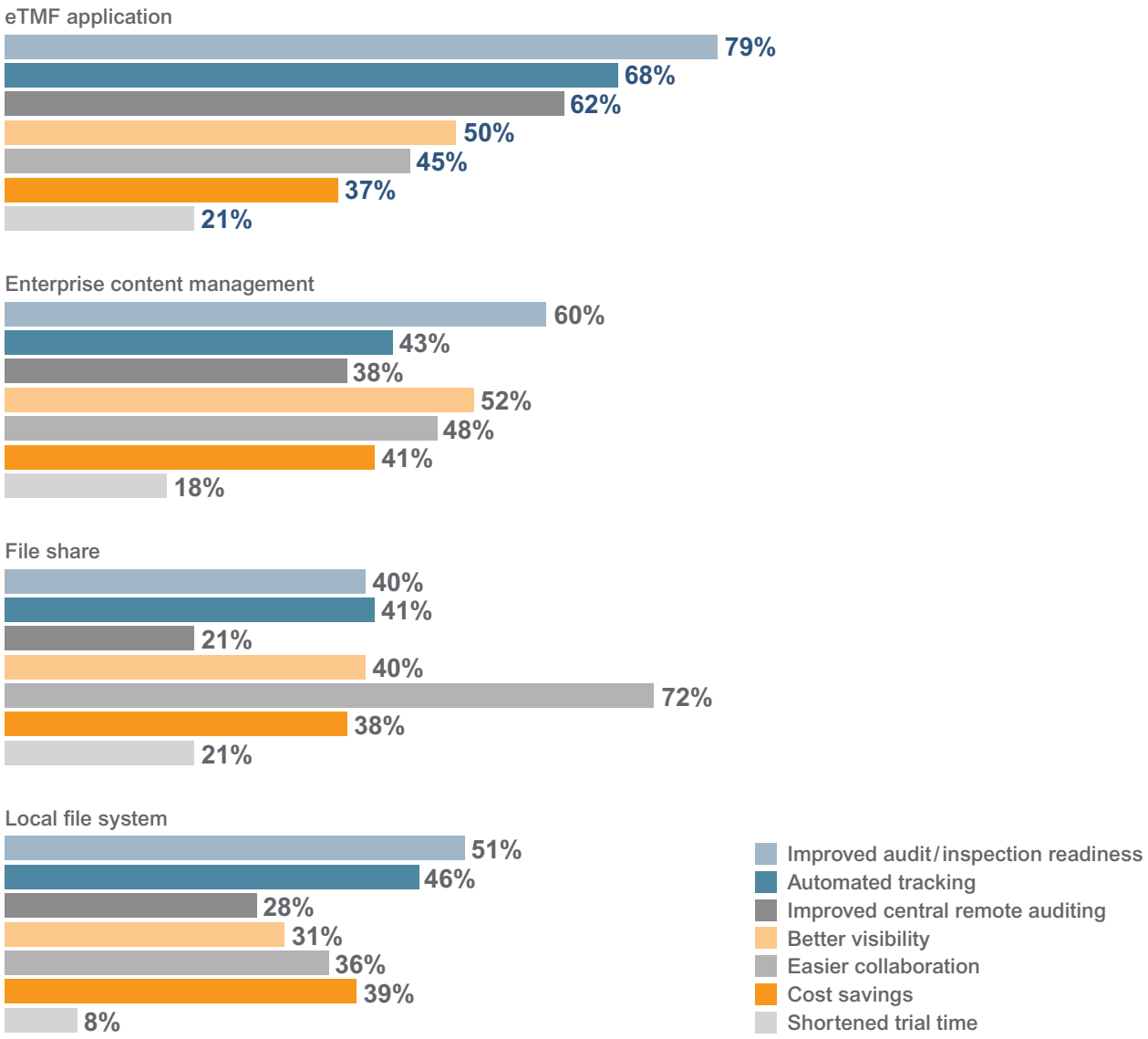
eTMFs are among the applications most frequently used to manage clinical studies, after EDC and CTMS. Types of eTMF applications used range from more general-purpose content management systems to purpose-built applications. Those not leveraging applications most often utilize other types of 'eTMF systems' like local or cloud file shares or paper.

The least mature solutions, such as local file systems and cloud file shares, provide simple storage and archival of TMF documents and are typically referred to as 'passive' TMFs. Content management systems are slightly more mature, but often have limited accessibility and are not designed for TMF processes. The most mature solutions are purpose-built eTMF applications. Designed specifically to manage TMF documents and unify end-to-end processes, these 'active' solutions manage information and processes in real-time as the TMF is being generated.

Sponsors find active eTMF applications have a significant, positive impact on inspection-readiness and improve activities key to unifying clinical operations, including automated tracking and reporting of documents (68%), central and remote auditing (62%), and visibility into key study performance metrics (50%). Automation, centralized oversight, visibility, and use of metrics drive efficiencies and collaboration that help clinical operations teams better manage the increasing volume and complexity of modern clinical trials.

Benefits of an eTMF by Type of eTMF

Base: Sponsor respondents, N=203

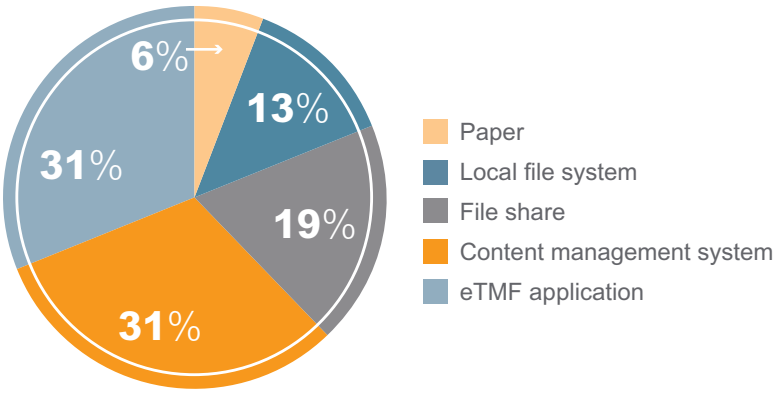


What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

This research shows there has been a major move away from 'passive' systems to 'active' eTMF solutions as one in three sponsors (31%) now use a purpose-built eTMF application, more than double the number reported in 2014 (13%).

eTMF System Used

Base: Sponsor respondents, N=203

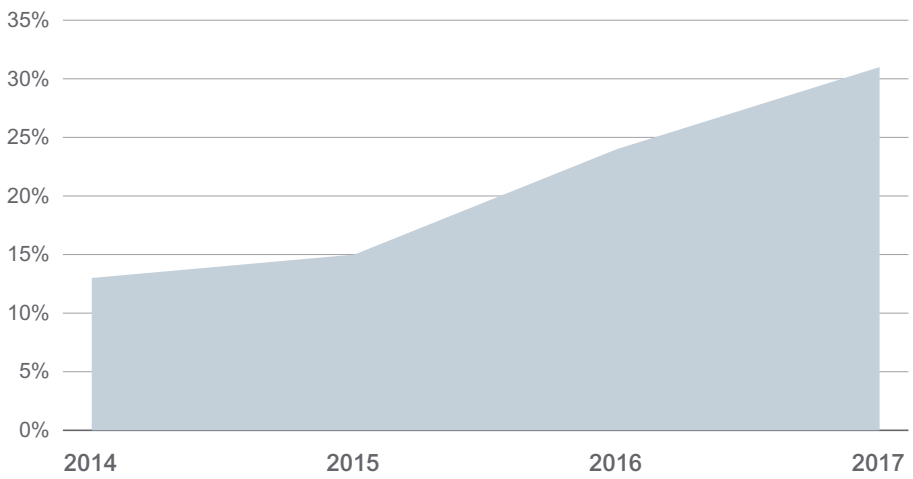


What type of eTMF solution do you currently use? Select only one. (Q.12)

Sponsors say a major driver of eTMF adoption is improving audit and inspection readiness. The increase in the use of eTMF applications since 2014 coincided with the MHRA's 2014 update to its definition of critical GCP inspection findings to include trial master files that are inaccessible or sufficiently incomplete such that inspectors cannot fulfill their duties.[5]

eTMF Application Use 2014-2017

Base: Sponsor respondents, 2017 N=203, 2016 N=137, 2015 N=124, 2014 N=135



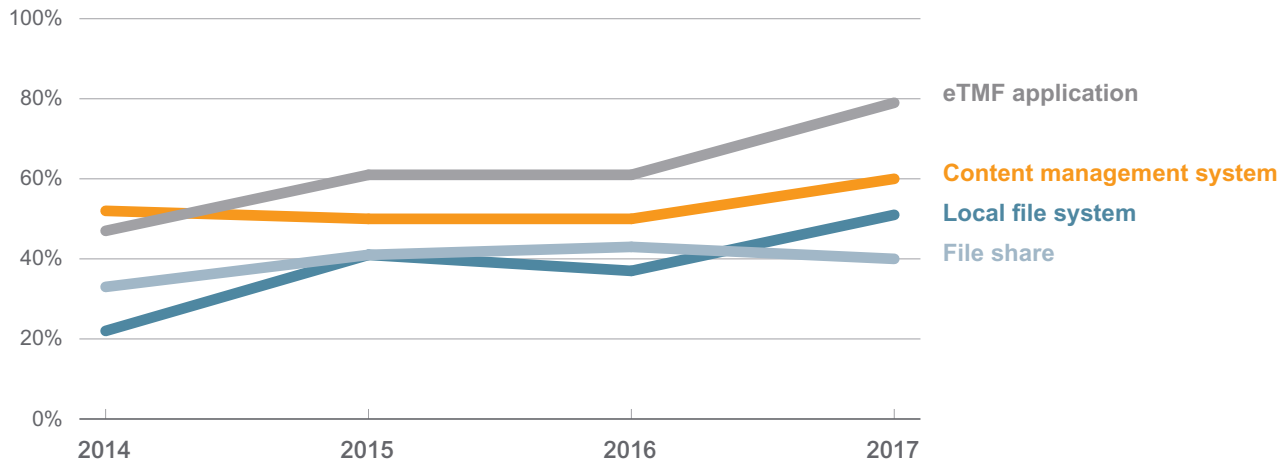
What type of eTMF solution do you currently use? Select only one. (Q.12)

More than three-quarters (79%) of sponsors report improvements in inspection readiness after implementing an active eTMF application, compared to 47% in 2014.

[5] Medicines and Healthcare products Regulatory Agency. The Medicines for Human Use (Clinical Trials) Amendment Regulations. Regulation 31A 1-3. 2014

Improvements in Inspection Readiness by Type of eTMF, 2014-2017

Base: Sponsor respondents, 2017 N=203, 2016 N=137, 2015 N=124, 2014 N=135



What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

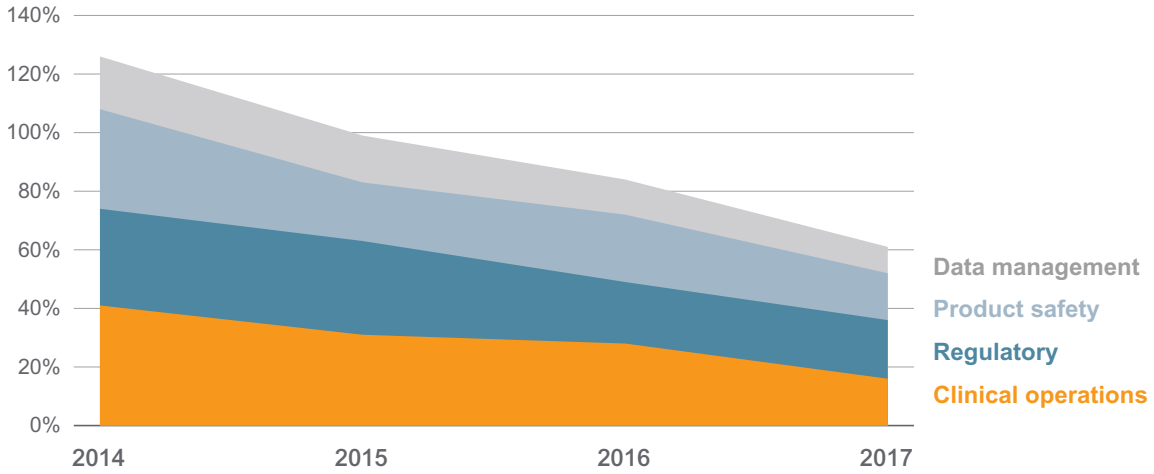
The Move Away from Manual Systems and Processes

Consistent with the drive to streamline collaboration and improve visibility, sponsors have significantly decreased their use of paper over the past four years. Across almost all functional areas measured, the number of TMF documents managed on paper is down by at least half among sponsor companies since 2014.

Clinical operations departments led the way, with just 16% of sponsors now reporting that most to all TMF documents managed by clinical operations departments are on paper, a 25 percentage point drop since 2014. Given more than half of the documents in the trial master file are managed by clinical operations, underscores the potential impact of this reduction. Product safety followed, with sponsors reporting an 18 percentage point drop since 2014 in the number of most to all TMF documents managed on paper.

Most to All Documents Managed on Paper at Some Point in Their Lifecycle

Base: Sponsor respondents, 2017 N=203, 2016 N=137, 2015 N=124, 2014 N=135



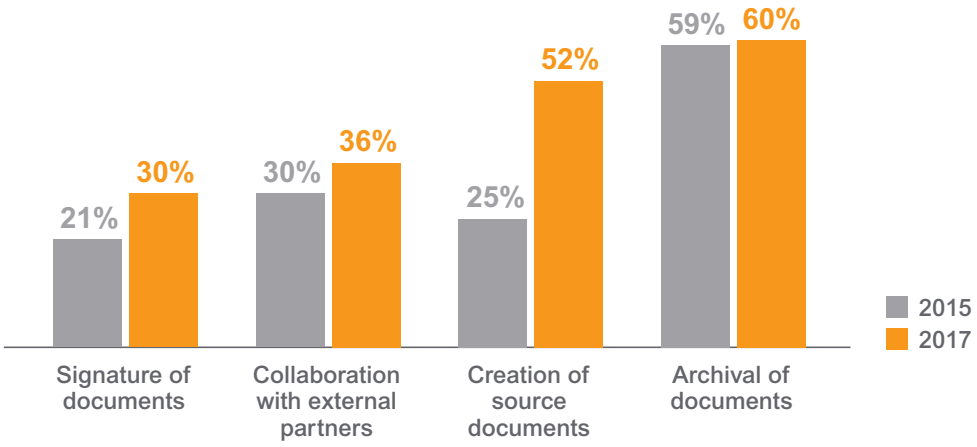
In each of the following areas, how many of your organization's TMF documents are managed on paper at any point during their lifecycle? Select only one box per row. (Q.9)

Correspondingly, decreases in the use of paper to manage TMF documents were matched by increases in more automated methods including the electronic creation of source document templates, which has doubled since first reported in 2015 (52% in 2017 versus 25% in 2015). Over the same period, the use of electronic signature for documents grew nine percentage points to 30%.

A majority of sponsors (60%) electronically archive TMF documents and one in three (36%) are leveraging electronic collaboration, both of these areas remained at similar levels as 2015.

Activities Mostly or Always Done Electronically

Base: Sponsor respondents, 2017 N=203, 2015 N=124



To what extent is your organization currently doing any of the following with TMF documents? Check only one box per row. (Q.11)

Collaboration with External Partners

ContractPharma's 2016 *Outsourcing Survey* found increasing demand for outsourcing and nearly all life sciences companies surveyed view their relationship with their contract service providers as a true partnership.[6] Integrating service partners and providing easy access to unified clinical systems is necessary to execute true end-to-end processes.

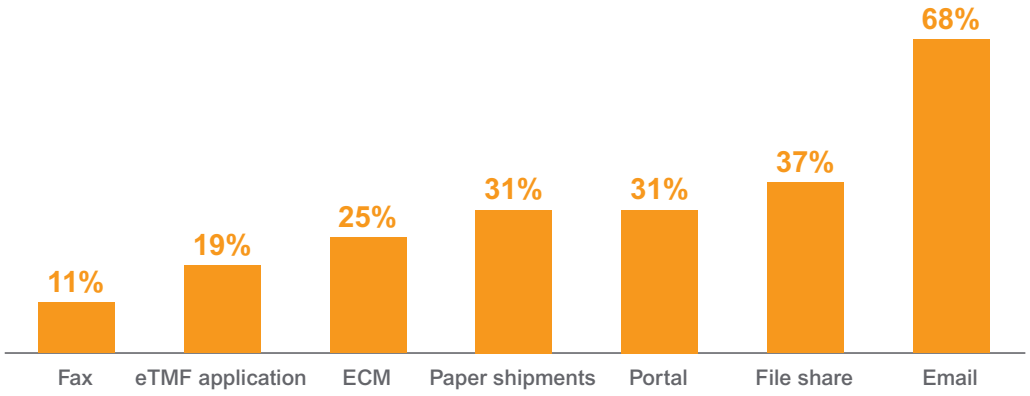
Moving to a unified clinical environment to remove organizational silos, however, requires collaborative processes and technology. One out of three sponsors (33%) say the limited ability to collaborate with external partners is one of the biggest issues with their current clinical applications.

More than two-thirds of sponsors (68%) use email to exchange TMF documents with CROs. Emailing documents as attachments puts information outside of controlled processes, making it harder to track and collaborate efficiently.

The transition to modern cloud-based eTMF applications is making partner collaboration easier according to almost half (45%) of sponsors surveyed. It is also enabling more sponsors to exchange documents with CROs electronically.

Methods to Exchange TMF Documents Between Sponsors and CROs

Base: Sponsor respondents, N=203



What methods does your organization use to exchange TMF documents with external parties? Select all that apply per row. (Q.8)

Use of Data to Improve Study Processes

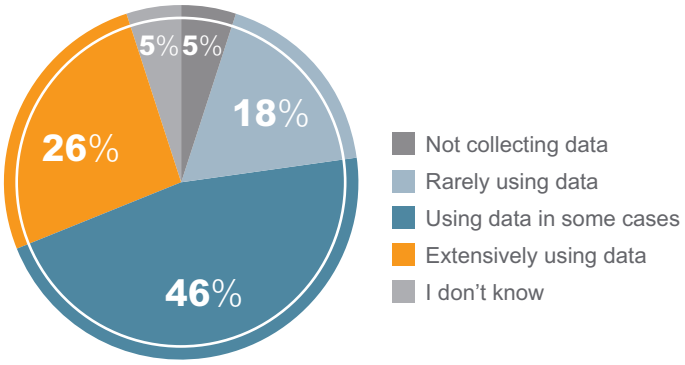
Reporting across multiple applications (60%) is one of the biggest challenges organizations face when asked about their clinical landscape. In addition, for half of respondents (51%) better study visibility is one of the most important drivers for unifying their clinical applications.

Metrics can help identify trends to drive process improvements across an individual study or a portfolio of studies. Yet, one in four (23%) are not using or rarely use data to improve study processes, roughly half (46%) only use it in some cases.

[6] ContractPharma. 2016 Annual Outsourcing Survey, May 2016.

Organizations Using Data to Improve Study Processes

Base: Total respondents, 2017 N=300

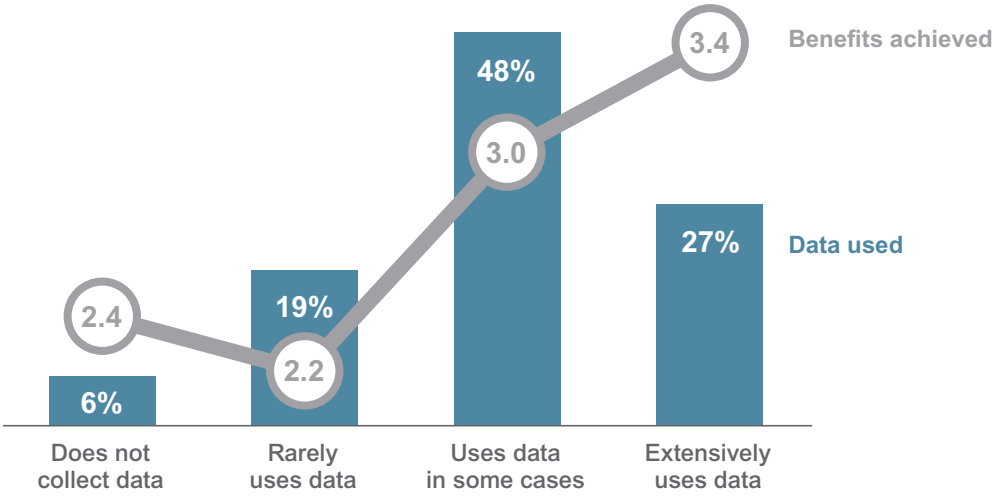


To what extent is your organization leveraging data (e.g., time from initial review to approval) to improve study processes? Select one of the following. (Q.16)

Organizations that extensively utilize data to improve study processes realize more benefits from their clinical applications. Those who leverage data extensively report a higher number of benefits than those who rarely, sometimes or do not leverage data (3.4 vs 2.7, p = .016).

Number of eTMF Benefits Achieved by Amount of Data Used

Base: Total respondents, 2017 N=300



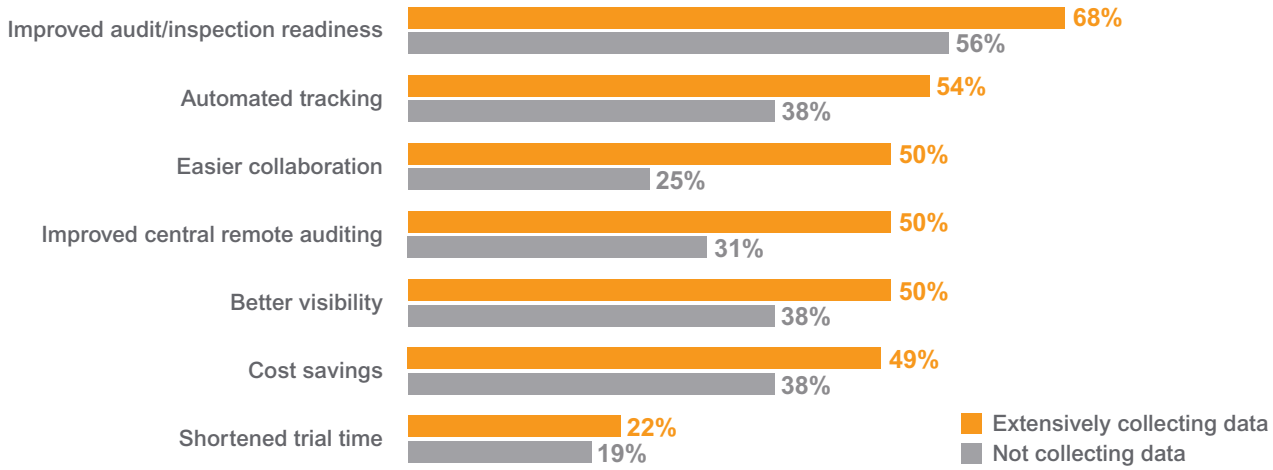
To what extent is your organization leveraging data (e.g., time from initial review to approval) to improve study processes? Select one of the following. (Q.16)

What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

In addition, eTMF users extensively using data report the largest improvements in all of the areas surveyed, including audit and inspection readiness. The most notable with regard to not using and extensively using data include the ease of collaboration (50% versus 25%;), central and remote auditing (50% versus 31%), and automated tracking and reporting of documents (54% versus 38%).

eTMF Benefits Achieved by Level of Metrics Usage

Base: Total respondents with an eTMF, 2017 N varies



To what extent is your organization leveraging data (e.g., time from initial review to approval) to improve study processes? Select one of the following. (Q.16) What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

Conclusion

There is industrywide recognition that a move to a unified clinical model is necessary to address the growing need to improve the quality and speed of study execution. Clinical leaders are looking to achieve higher levels of performance across their study portfolio by implementing end-to-end processes and systems, streamlining collaboration, and leveraging insights from across the full trial lifecycle.

The majority of challenges sponsors face today in managing clinical trials stem from the siloed nature of their processes and applications. Some of the most prevalent applications in use today, such as EDC and CTMS, are based upon first-generation technology so they lack the core functionality, modern architectures, and usability required to enable true end-to-end processes and visibility.

This research finds that the organizations that adopt modern, purpose-built applications, like 'active' eTMFs, report fewer challenges and see greater benefits to their studies. And when unified, these applications enable life sciences organizations to establish repeatable, collaborative processes, and increase oversight and accuracy by consistently leveraging insights across their clinical portfolio.

Unified systems and processes – There is universal agreement that organizations need to unify their clinical landscape and most see significant benefits in doing so, including improved study execution, quality, cost, collaboration, and visibility. The business impacts of having disconnected systems and processes are also clear. And the greater the number of different clinical applications an organization uses, the greater the negative impacts, particularly with complex processes such as study start-up.

Modern information systems – CTMS applications are not keeping up with the demands of today's clinical trials. Most sponsors report their CTMS only partially supports many key clinical operations processes and deficiencies prompt the need for manual tracking and reporting. Adoption of modern, active eTMF applications, however, is on the rise and sponsors report greater benefits from the technology's ability to improve study tracking, visibility, and inspection readiness.

Collaborative clinical ecosystem – Most sponsors use an average of three to five different applications, each supporting a discrete area, creating silos that prevent effective collaboration. Further compounding this challenge, a majority of sponsors email documents as attachments putting information outside of controlled processes. Those who adopt end-to-end systems, such as active eTMF applications, report easier collaboration with their external partners and are less reliant on manual processes.

Insights from measurement – The amount of data collected and the extent to which it is leveraged has a direct impact on improvements to clinical operations efficiency. Organizations using the most amount of data report the greatest number of improvements in audit readiness, collaboration, and monitoring activities.

Survey Methods

The survey consisted of 16 questions, many of which included sub-questions with response matrices. Survey questions were designed for individuals with knowledge of clinical operations processes and with partial or full responsibility for clinical operations within their organization. The survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and a $5 donation was made to Doctors Without Borders for each valid completion of the full survey. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

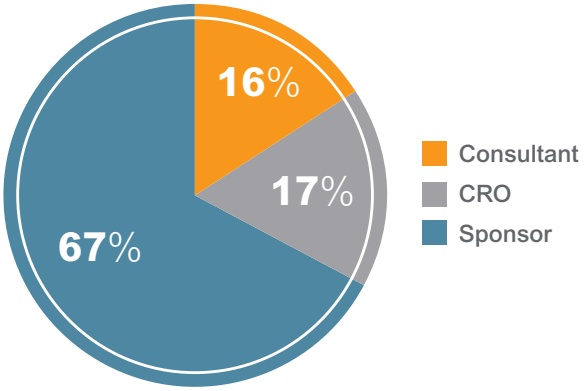
Survey Respondents

Of the approximately 300,000 individuals invited to take the survey, a total of 1,081 surveys were initiated, the majority of which were terminated based on a qualification question gauging the level of responsibility for clinical in their organization. More than 600 unverified responses were eliminated, yielding 300 qualified survey responses. Almost half of the respondents were from sponsor companies in the United States.

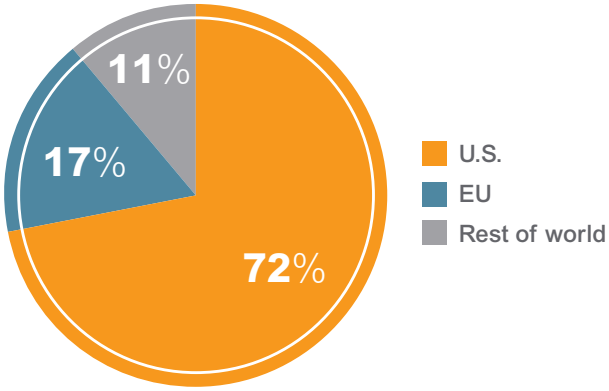
Survey Respondent Demographics

Base: Total respondents, N=300

Type of organization



Geographic location



Contact

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