Veeva

Veeva 2020 Unified Clinical Operations Survey: Annual CRO Report

The Veeva 2020 Unified Clinical Operations Survey: Annual CRO Report examines contract research organizations' (CROs) progress toward modernizing clinical operations by gathering the experiences and opinions of CRO respondents around the globe. The annual research details the drivers, barriers, and benefits of a unified clinical operating model from a CRO perspective. It also tracks the industry's progress to unify clinical trial systems and processes and increase stakeholder engagement throughout study execution.

Executive Summary

Findings show CROs are driving the adoption of modern clinical applications to increase efficiency, quality, and speed in clinical trials.

Most (99%) CRO respondents report the need to unify clinical applications, and 90% say their organizations have, or plan to have, an initiative in place to do so.

Standalone, eClinical applications, including EDC (93%), eTMF (82%), and CTMS (73%), are now utilized by the majority of CROs as they steadily adopt function-specific technologies to improve study execution.

Most (98%) CRO respondents say they need to improve information sharing between study partners to reduce manual processes (78%), speed trials (61%), and improve collaboration (57%).

Consistent with the aim to streamline information sharing and speed trials, CRO respondents say reducing manual processes (53%) and faster collection of site essential documents (49%) are critical to improving study start-up.

CROs have made significant progress modernizing major clinical areas such as eTMF to improve TMF accuracy (70%), completeness (63%), and timeliness (55%).

Organizations that use purpose-built CTMS applications (58%) report better compliance with standards (67%), greater visibility (63%), and more effective monitoring (63%) compared to those using other methods to manage study execution.

The State of Unifying Clinical Trial Systems and Processes

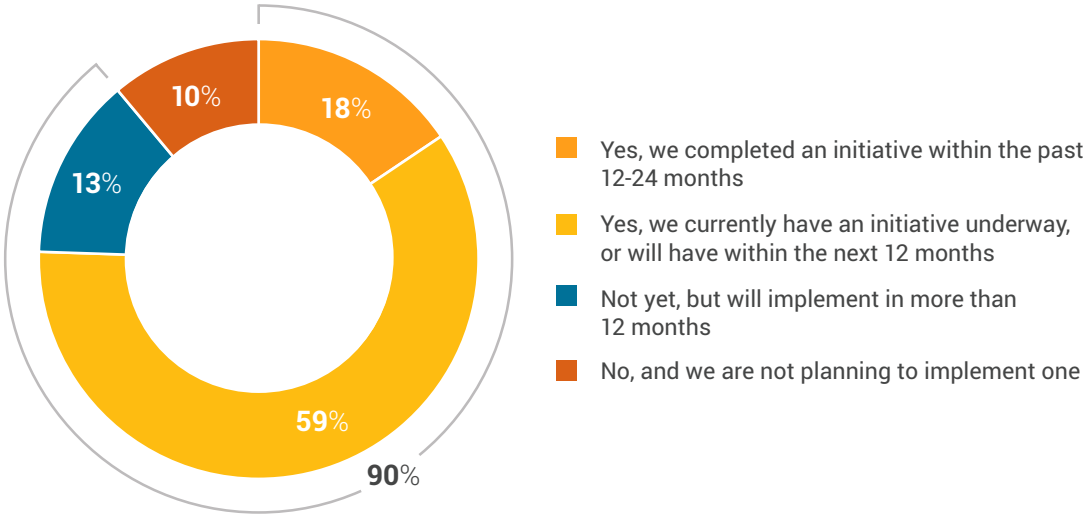
Clinical trial outsourcing is on the rise,[1] driven by the impact of COVID-19 on study operations, and the need for greater diversification and global capacity in research.[2]

As sponsors increase reliance on outsourcing partners to mitigate risk and speed trials, CROs require greater efficiency and more streamlined approaches to study execution.

Nearly all CRO respondents (99%) report the need to unify their clinical trial systems and processes. Of these respondents, 90% have, or plan to have, an initiative to unify their clinical application landscape.

The Number of Organizations with Unification Initiatives Underway

Base: Total CRO respondents, N=124



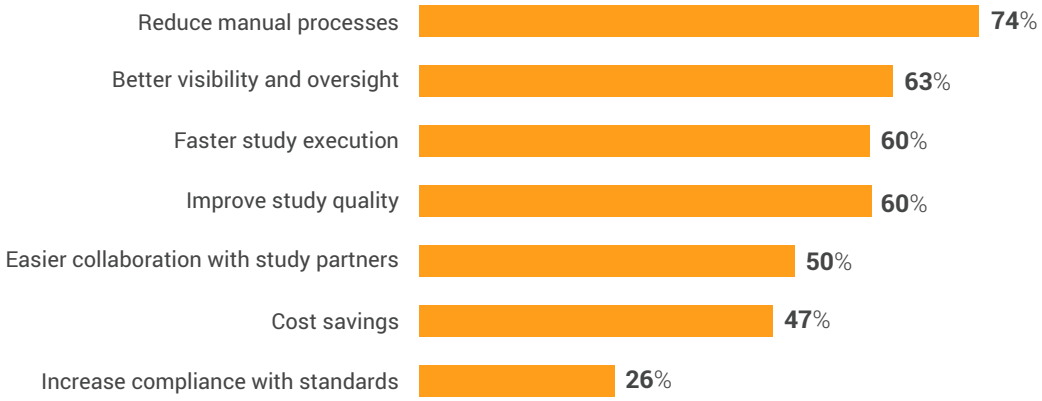
Does your organization have an initiative underway to better integrate/unify the clinical applications in Q3? (Q.5)

For more than half, the need to unify is driven by reduced manual processes (74%), better visibility and oversight (63%), faster study execution (60%), and improved study quality (60%).

[1] Buvailo, Andrii. The Evolving Pharma R&D Outsourcing Industry: A Bird's-eye View. BirorpharmaTrend.com. February 10, 2020.
[2] Brooks, Kristin. R&D Outsourcing Trends. Contract Pharma. October 14, 2020.

Top Drivers for Unified Clinical Operations

Base: Total CRO respondents, N=124



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.6)

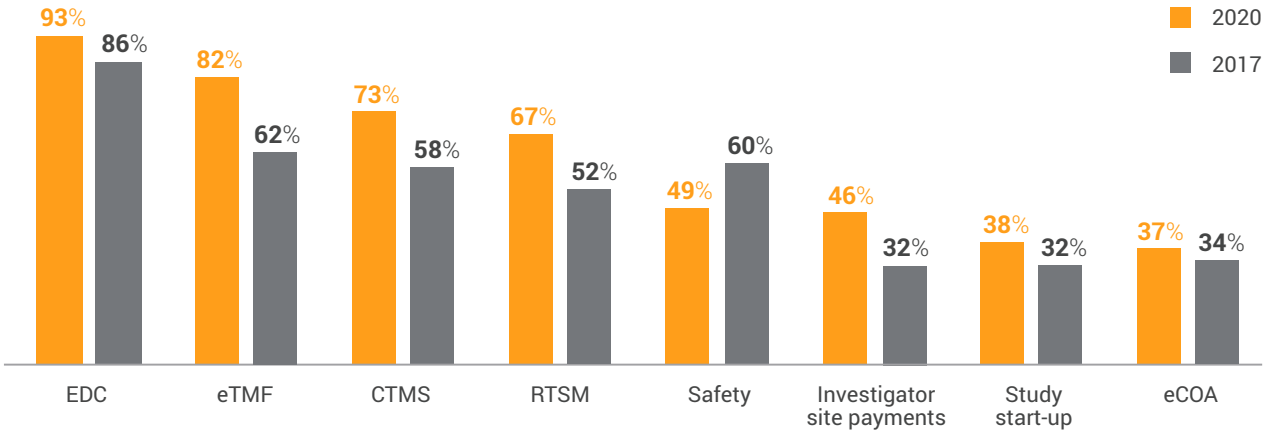
The Evolving Clinical Trial Landscape

Over the past several years, CROs have steadily adopted function-specific technologies to improve study execution. Highest is EDC, used by 93% of CROs surveyed. More than three-quarters (82%) have eTMF applications, up from 62% in 2017. Majorities also use CTMS (73%), an increase of 15-percentage points from 2017, as CROs aim to reduce costs and improve clinical trial performance.[3]

Roughly half (46%) now use site payment applications, up from 32% in 2017, and more than one-third (38%) use purpose-built study start-up applications. This is likely due to outsourcing site management activities, leading CROs to invest in technology to drive efficiencies.[4]

Applications Used to Manage Clinical Studies

Base: CRO Respondents, 2020 N=124, 2017 N=50



Does your organization utilize third-party applications to manage clinical studies? If yes, please indicate which are currently in use. Select all that apply. (Q.3)

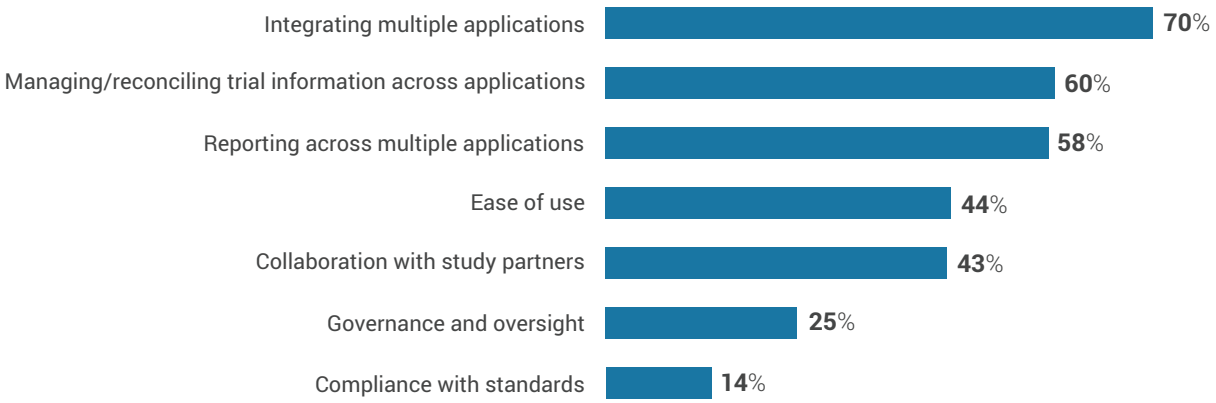
[3] Pharmaoutsourcing.com. The Increasing Shift of Clinical Trials to CROs. May 2015.
[4] Statnews.com. Clinical Trials Take a Long Time to Get Started. Here's How to Speed It Up. March 2018.

Nearly all (99%) CRO respondents say they have major challenges with their clinical applications. The top three challenges – integrating multiple applications (70%), managing trial information across applications (60%), and reporting across multiple applications (58%) – are likely the result of system and process silos.

More than one-third report issues with ease of use (44%) and a limited ability to support collaboration (43%). This may be due, in part, to the complexity of managing multiple clinical systems across trial processes and study partners.

Biggest Challenges with Clinical Applications

Base: Total CRO respondents, N=124



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)

Streamlining Information Sharing

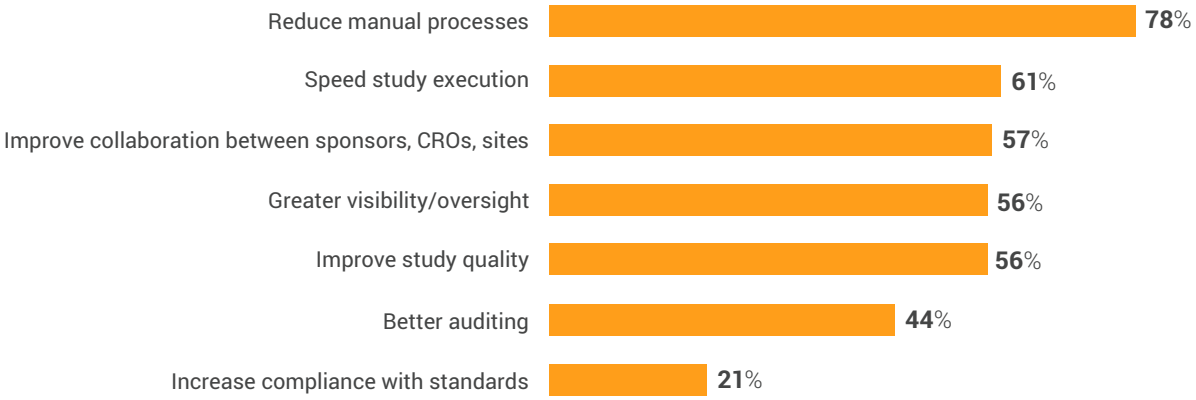
Clinical trials generate significant amounts of information that must be shared with study partners and filed in a timely manner to confirm the validity of trial conduct and improve compliance with regulatory requirements and study protocols.[5]

All CRO respondents report the need to simplify information exchange with study partners. The primary drivers are reduced manual processes (78%), faster study execution (61%), and improved collaboration (57%). More than half of CROs cite greater visibility (56%) and improved study quality (56%) as key drivers to streamline information sharing.

[5] Good Clinical Practice Network. Chapter 8: Essential Documents for the Conduct of a Clinical Trial.

Top Drivers to Streamline Information Exchange

Base: Total CRO respondents, N=124

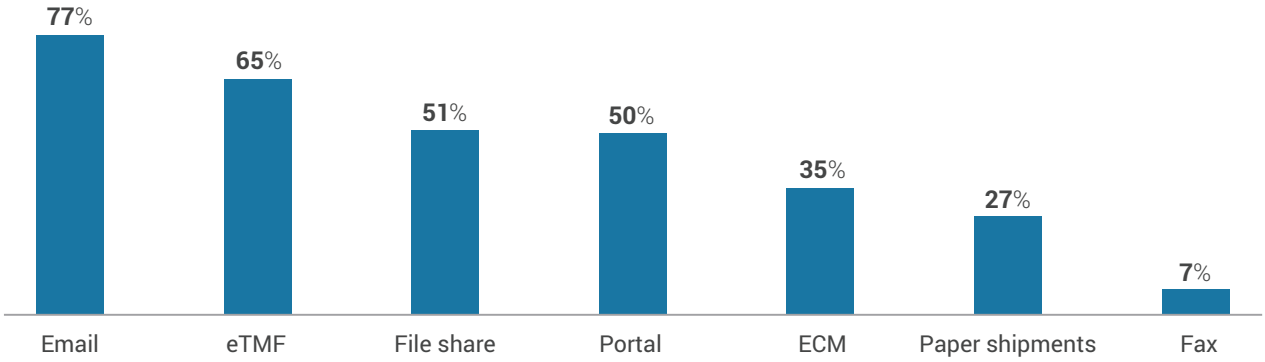


To the extent your organization needs to streamline/simplify information exchange with study partners, what are the primary drivers? Select all that apply. (Q.9)

Email is the predominant method used by CROs to exchange information with sponsors (77%), followed by eTMF (65%), file share (51%), and portals (50%).

Methods Used by CROs to Exchange Information with Sponsors

Base: Total CRO respondents, N=124



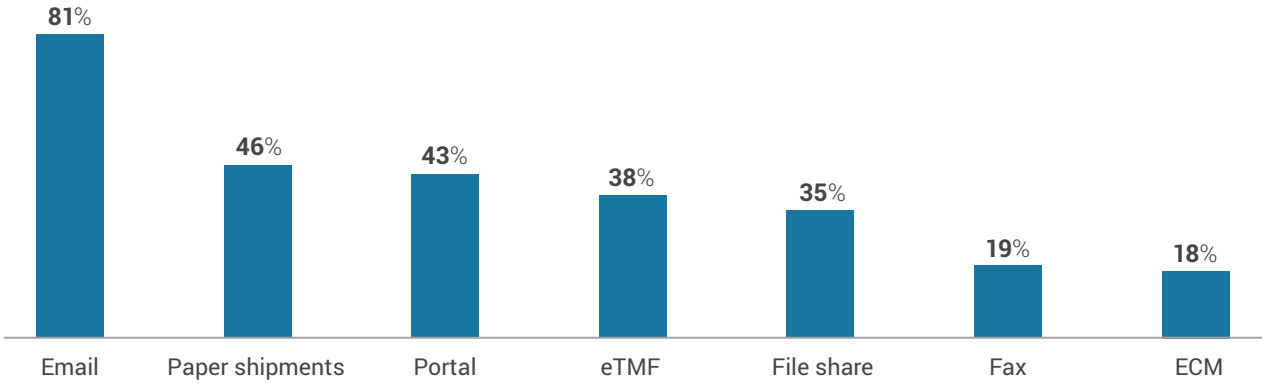
What methods does your organization use to exchange trial data and documents with study partners? Select all that apply. (Q.7)

The majority of CROs (81%) also use email as the primary method to manage information sharing with sites. Roughly half (46%) use paper shipments – likely because most sites store their regulatory binders on paper[6] – followed by portals (43%), eTMF (38%), and file share applications (35%).

[6] TrialSiteNews.com. No Site Left Behind: Veeva Offers its SiteVault Free to Clinical Investigator Sites in their Quest to Bridge eTMF & eISF. October 2019.

Methods Used by CROs to Exchange Information with Sites

Base: Total CRO respondents, N=124



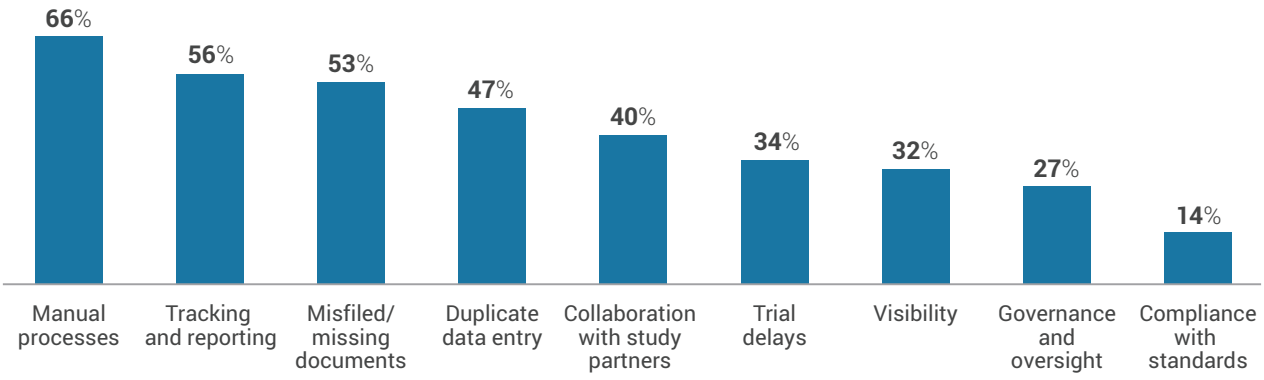
What methods does your organization use to exchange trial data and documents with study partners? Select all that apply. (Q.7)

Nearly all (99%) report significant challenges with the methods used to exchange information during clinical trials.

Managing information exchange using email and other traditional methods increases administrative effort, reduces efficiency, and limits visibility. These difficulties can contribute to reported challenges with manual processes (66%), tracking and reporting (56%), and misfiled/missing documents (53%).

Biggest Challenges with Information Exchange

Base: Total CRO respondents, N=124



What are the biggest challenges, if any, your organization faces in utilizing the methods of information exchange identified in Q6? Select all that apply. (Q.8)

Industrywide Focus on Improving Study Start-up

Study start-up is one of the most time-intensive areas within clinical drug development, accounting for 61% of total trial lifecycle times.[7] Cycle times can be significantly delayed due to paper-based processes, multiple document handoffs between study partners,[8] and manual methods of information exchange.

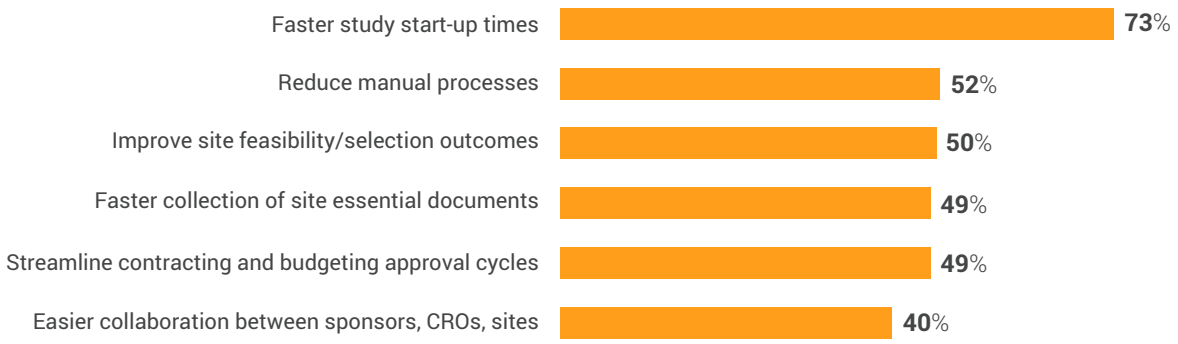
Findings show that study start-up is an area of significant potential to positively impact clinical trials, especially as organizations ramp up for post COVID-19 trial starts.[9]

All CRO respondents say they need to improve study start-up processes. The top drivers are faster start-up times (73%), reduced manual processes (52%), and improved site feasibility and selection outcomes (50%).

Roughly half (49%) say faster collection of site essential documents, and streamlined contracting and budgeting, will improve study start-up. More than one-third (40%) cite easier collaboration as a primary driver to improve study start-up, highlighting the importance of streamlining information sharing and collaboration to trial performance.

Drivers to Improve Study Start-up Processes

Base: Total CRO respondents, N=124



To the extent your organization needs to improve study start-up processes, what are the primary drivers? (Q.12)

Tufts Center for the Study of Drug Development (CSDD) research shows that the early stages of study start-up, like site contracting and budgeting, account for most of the cycle time in the start-up phase and take twice as long today than five years ago.[10]

As companies increasingly seek global approvals to improve study diversification during the COVID-19 pandemic,[11] challenges with country selection, initiation, and regulatory compliance add to these cycle times.

More than two-thirds (68%) say site contracting and budgeting is their most challenging study start-up process, followed by site identification, feasibility, selection (52%).

Site essential document collection is an issue for more than one-third of CRO respondents (46%). This may be due, in part, to the prevalence of email and paper shipments to exchange trial documents with sites.

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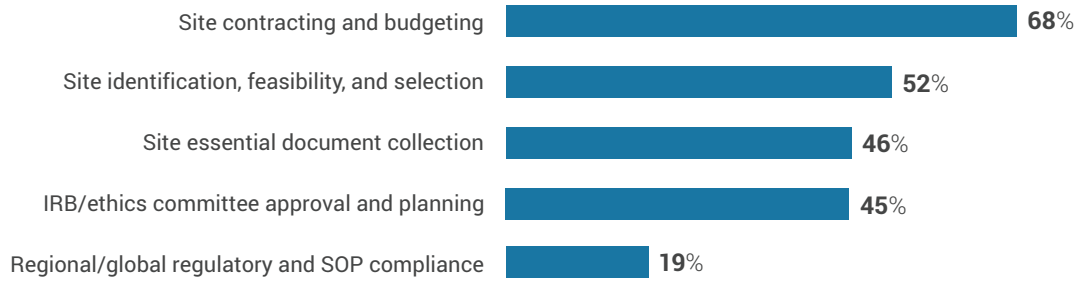
7 Lamberti, Mary Jo. Tufts Center for the Study of Drug Development Impact Report. March 2018.
8 Applied Clinical Trials. The Need and Opportunity for a New Paradigm in Clinical Trial Execution. June 2018.
9 Informa PharmaIntelligence. COVID-19 and the impact on the clinical trial space. May 2020.
10 Lamberti MJ, Wilkinson M, Harper B, Morgan C, Getz KA. Assessing Study Start-up Practices, Performance, and Perceptions Among Sponsors and Contract Research Organizations, Therapeutic Innovation & Regulatory Science, DOI: 10.1177/2168479017751403 tirs. sagepub.com
11 Informa PharmaIntelligence. COVID-19 and the impact on the clinical trial space. May 2020.

Biggest Challenges with Study Start-up Processes

Base: Total CRO respondents, N=124



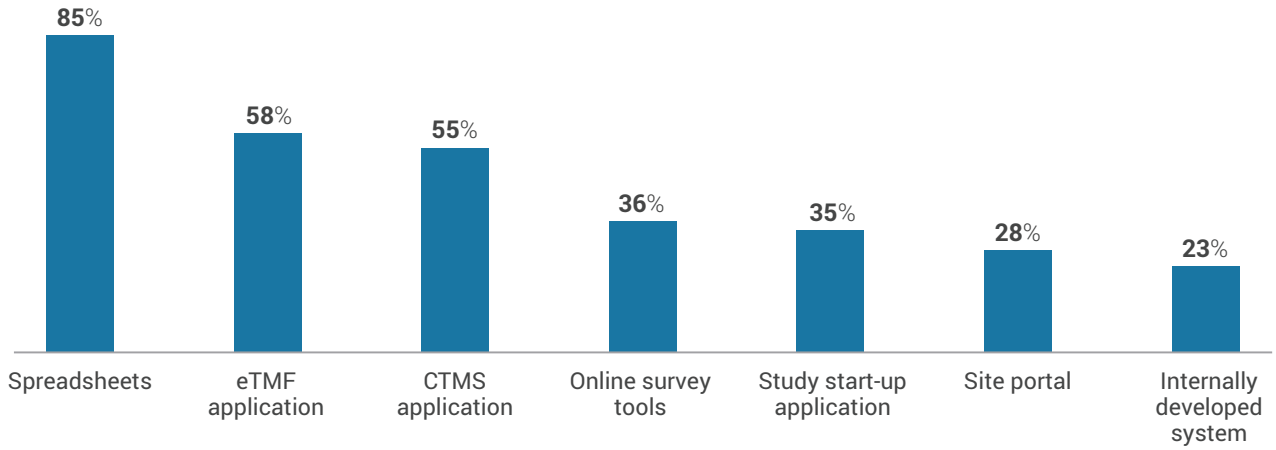
To the extent your organization needs to improve study start-up processes, what are the primary drivers? (Q.12)

Majorities (85%) use spreadsheets to manage study start-up processes. More than half use eTMF (58%) and CTMS (55%) applications, followed by online survey tools (36%).

Significantly more CROs than sponsors use newer, purpose-built study start-up applications (35% versus 21%, respectively). Most likely due, in part, to the outsourcing of study start-up activities, leading CROs to invest in technology to speed processes and drive efficiencies.[12]

Tools Used to Manage Study Start-up

Base: Total CRO respondents, N=124



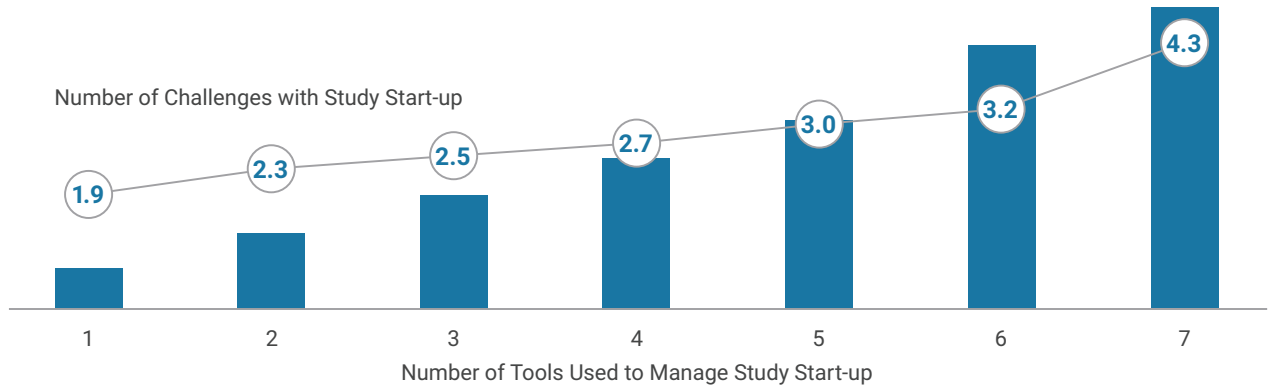
What tools do you use to manage study start-up processes? Select all that apply. (Q.10)

The more tools used to manage study start-up, the more challenges CRO respondents say they have with this process (r=.32, p<.001). On average, respondents use three tools to manage start-up activities and have two challenges.

[12] Statnews.com. Clinical Trials Take a Long Time to Get Started. Here's How to Speed It Up. March 2018.

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

Base: Total CRO respondents, N=124



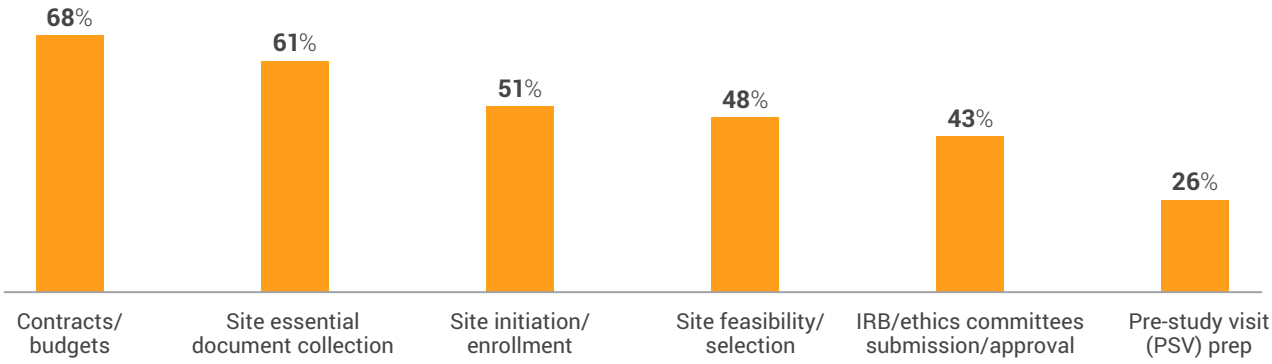
What tools do you use to manage study start-up processes? Select all that apply. (Q.10)
What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.11)

The predominant use of spreadsheets and other general-purpose methods increases manual effort, as these tools are not purpose-built to manage study start-up processes.

More than half of survey respondents say automating key study start-up processes, like contracts and budgets (68%), site essential document collection (61%), and site initiation and enrollment (51%), will improve trial quality and speed study start-up.

Automating Study Start-up Processes

Base: Total CRO respondents, N=124



Which of the following processes, if better automated, would improve trial quality and speed? Select all that apply. (Q.13)

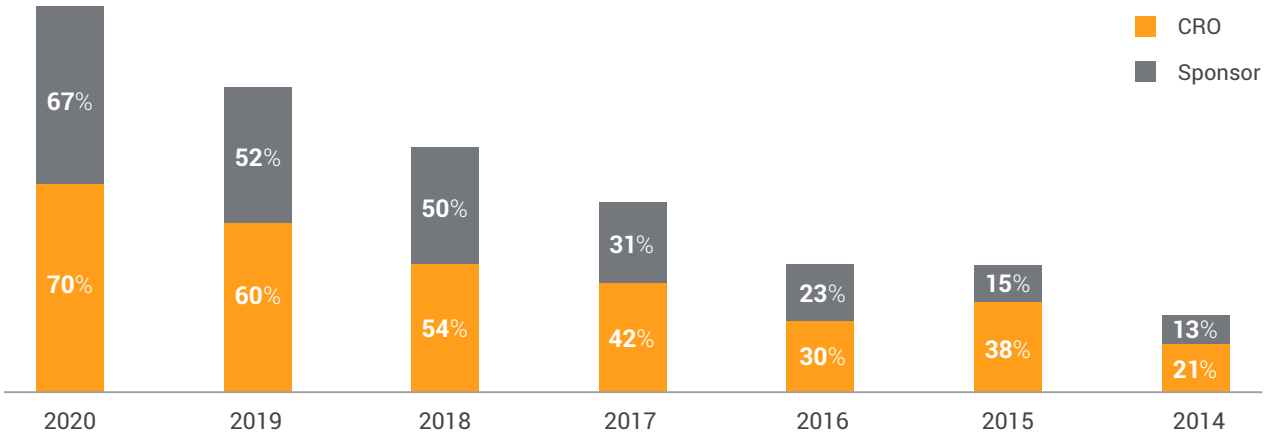
Active TMF Management and Oversight

Findings indicate positive change is underway as CROs modernize trial processes with the adoption of purpose-built eTMF applications, which can help to ensure a constant state of inspection readiness, reduce compliance risk, and increase operational efficiency.

The number of CRO respondents using an eTMF application has more than tripled since 2014, with 70% of CROs now using a purpose-built eTMF application, versus 21% in 2014.

eTMF Application Use 2014 – 2020

Base: Total respondents, 2020 N=524, 2019 N=461, 2018 N=291, 2017 N=253, 2016 N=180, 2015 N=186, 2014 N=161

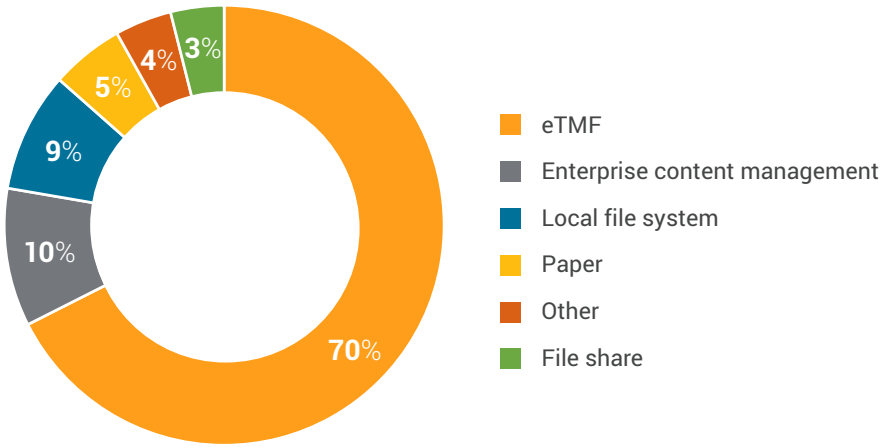


What type of TMF solution do you currently use? Check one box per row. (Q.14)

The growth in eTMF adoption comes as CROs increasingly move away from general purpose methods to manage TMF processes. Today, only 10% use content management systems for TMF management, versus 31% in 2017.

TMF System Used

Base: Total CRO respondents, N=124



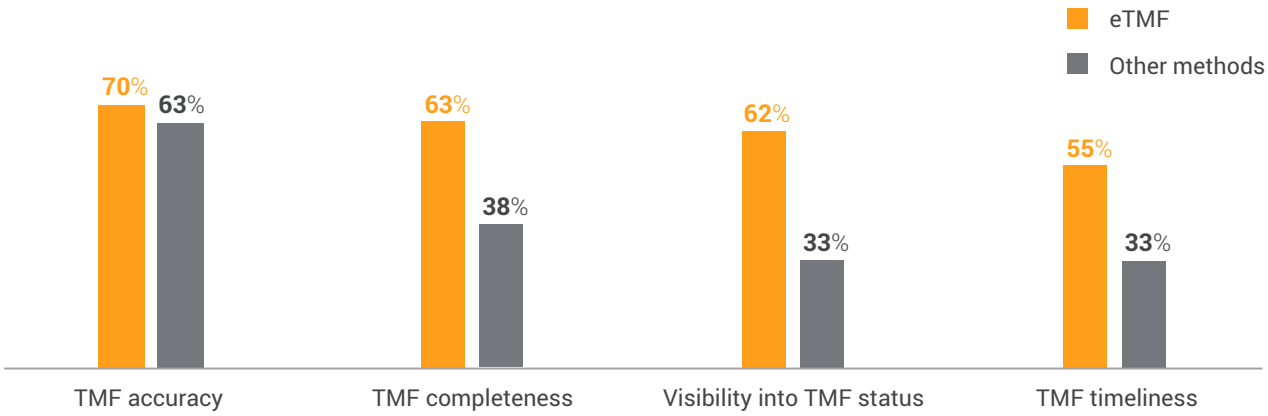
What type of TMF solution do you currently use? Check one box per row. (Q.14)

The data suggests the move to modern purpose-built eTMF applications is enabling more 'active' trial management. Likely because these newer applications automate processes and manage documents in real-time as they are created, versus acting as static repositories to store and archive document upon completion.

Those using purpose-built eTMF applications report a significant, positive impact on TMF inspection readiness metrics compared to those using other methods, including TMF accuracy (70% versus 63%, respectively), TMF completeness (63% versus 38%, respectively), visibility into TMF status (62% versus 33%, respectively), and TMF timeliness (55% versus 33%, respectively).

Effectiveness of TMF Solutions

Base: Total CRO respondents, N=124



How effective is your organization's TMF in the following areas? Check one box per row. (Q.15)

Modernizing Clinical Trial Management

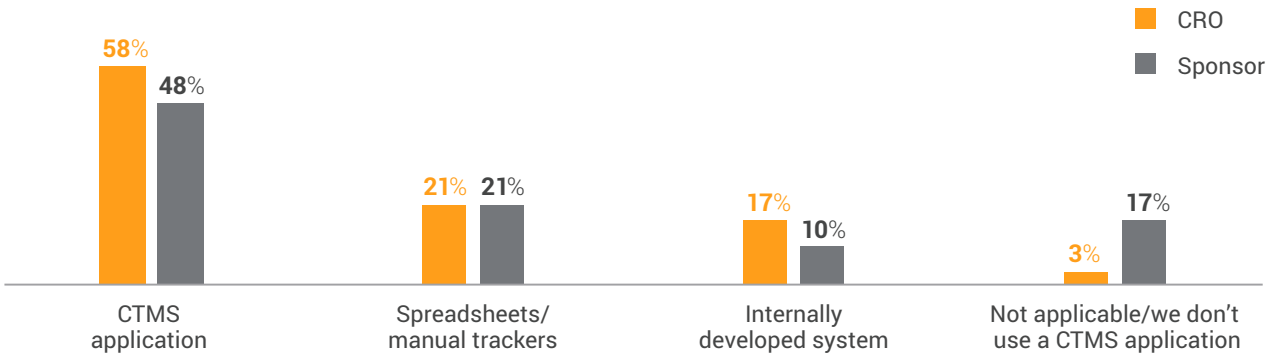
Life sciences organizations are expected to increase their CTMS investments by 13% annually through 2026, driven by the rising complexity of clinical trials and the mounting pressures of COVID-19 on end-to-end trial management.[13]

CROs lead sponsors in their adoption of purpose-built CTMS applications (58% versus 48%, respectively). Less than a quarter of CROs use spreadsheets and manual trackers (21%) and internally developed systems (17%) to manage clinical studies.

[13] COVID-19 Impact Over the Clinical Trial Management Market. Pharmaweb.com. September 2020.

Type of CTMS Solution Used

Base: Total respondents, N=524



What type of CTMS solution do you use? Select only one. (Q.17)

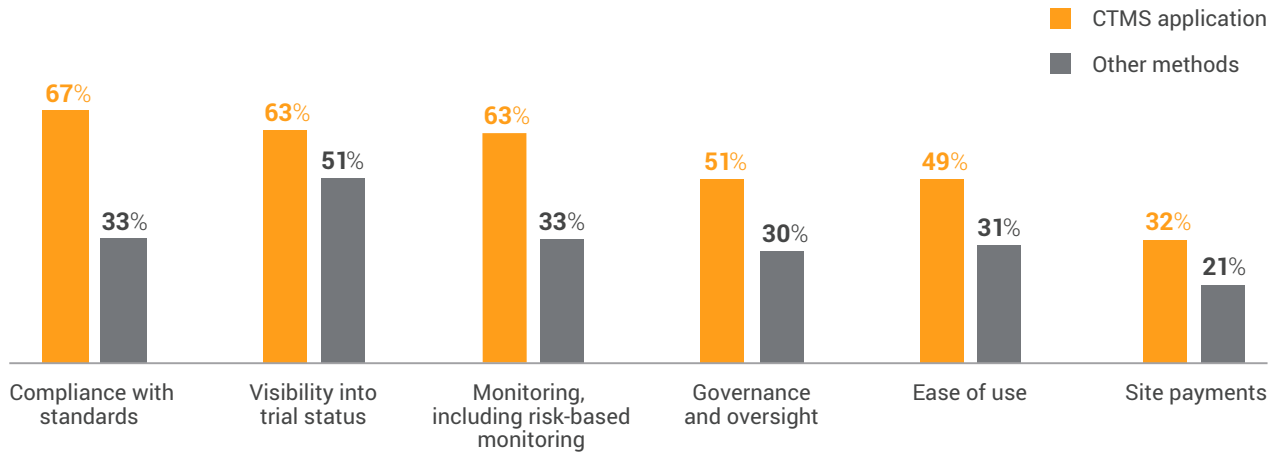
For CROs – who are highly focused on driving operational efficiencies – findings show that purpose-built CTMS applications are the most effective tool for managing end-to-end clinical trial processes compared with manual trackers and internally developed systems.

Major areas of advantage include compliance with standards (67% versus 33%, respectively), visibility into trial status (63% versus 51%), monitoring (63% versus 33%, respectively), and governance and oversight (51% versus 30%, respectively).

Roughly half cite ease of use (49%) as an area of advantage versus other methods (31%), highlighting the importance of usability in driving operational efficiency.

Effectiveness of CTMS Solutions

Base: Total CRO respondents, N=124



How effective is your organization's CTMS solution? Select only one. (Q.17)

Conclusion

This research shows that unifying clinical operations is a top priority for improving the quality and speed of clinical trials.

While CROs have made progress towards that goal, COVID-19 has accelerated efforts to adopt new and more effective business models that drive trial performance.[14]

As CROs take action to address the critical need to speed study execution, this research underscores the impact of:

- **Rapid, collaborative information sharing:** There is a tremendous opportunity to simplify information sharing between sponsors, CROs, and sites during clinical trials. Unified processes and systems streamline (and where possible, automate) the flow of trial information for improved efficiency and collaboration. Manual handoffs and administrative tasks are reduced, allowing CROs to focus on trial execution and study quality.
- **Optimizing study start-up processes:** Study start-up is one of the clinical areas with the most potential to improve trial efficiency and execution. Encouragingly, adoption of study start-up applications is on the rise and is reducing cycle times by automating and streamlining start-up activities – bringing a higher level of predictability, quality, and speed to clinical trials.
- **Increasing study quality and compliance:** CROs have made significant progress unifying and modernizing TMF processes for active TMF management and oversight. Documents are managed in real-time as the TMF is generated and a constant state of inspection readiness is achieved, leading to significant improvements in visibility and regulatory compliance.
- **Real-time, end-to-end visibility and oversight:** Positive change is underway as the CRO industry modernizes its clinical trial management systems on a unified platform to effectively manage and optimize trials. Full visibility across clinical trial processes enables greater oversight and better decision-making for faster, higher-quality trial execution.

CROs see tremendous opportunity to improve operational efficiency and deliver high-quality outsourced services by unifying their clinical trial environments. The resulting gains will allow CROs to work smarter and more cost-effectively to improve study execution, simplify information sharing and collaboration – and ultimately, accelerate clinical research.

[14] U.S. Food and Drug Administration. Statement by FDA Commissioner Dr. Hahn on COVID-19. June 1, 2020.

Survey Methods

The survey consisted of 19 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, Applied Clinical Trials, PharmaFocus, and Veeva Systems. Completion of the survey was voluntary. Respondents received a $5 or $10 Amazon gift card and were offered a summary of survey results. No other compensation was offered or provided.

Survey Respondents

Of the approximately 370,000 individuals invited to take the survey, a total of 4,626 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 435 unverified responses were eliminated, yielding 524 qualified responses.

Survey Respondent Demographics

Base: Total respondents, N=524