

Veeva 2019 Unified Clinical Operations Survey: Annual CRO Report

The Veeva 2019 Unified Clinical Operations Survey Report: Annual CRO Report examines contract research organizations' (CROs) progress toward a unified clinical operating environment by gathering the experiences and opinions of CRO respondents from around the world. This 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 in its move to unify clinical systems and processes and align stakeholders throughout study execution.

Executive Summary

Findings show CROs are leading the adoption of modern clinical applications to increase efficiency, enhance collaboration, and improve trial performance.

- The majority of CROs now use standalone, eClinical applications for EDC (93%), eTMF (77%), RTSM (71%), and CTMS (70%) as they steadily adopt function-specific technologies to support clinical trials.
- All CRO respondents (100%) report the need to unify clinical applications. Main drivers are better visibility and oversight (74%), faster trials (68%), and easier stakeholder collaboration (63%).
- Consistent with the aim to improve collaboration, 100% of respondents say they want to improve methods of information exchange between study partners. Primary reasons include reduced manual processes (77%), streamlined collaboration (65%), and improved study quality (64%).
- All CROs surveyed (100%) also report challenges with study start-up, and 78% rely on manual spreadsheets to manage this area.
- CROs have made progress modernizing clinical systems and processes in areas such as eTMF to ensure a constant state of inspection readiness (60%) and increase visibility into TMF status (58%).
- Most CRO respondents (96%) want to improve the use of CTMS in clinical operations. Top drivers are better analytics and reporting (68%), proactive risk mitigation (62%), and improved integration with other eClinical applications (57%).

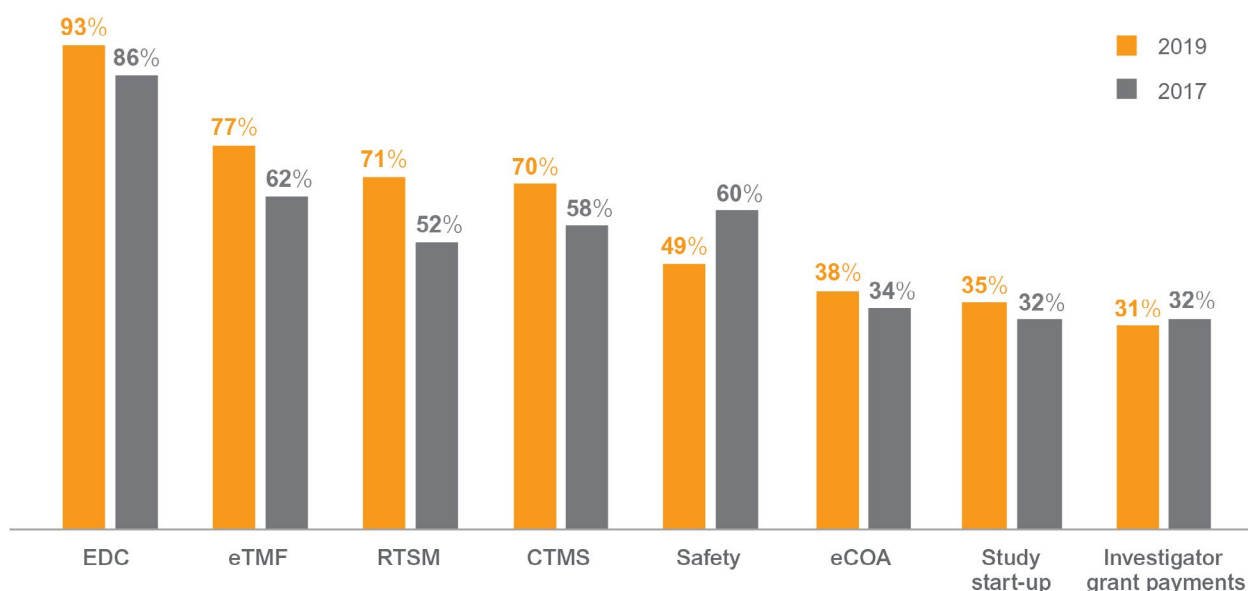
The State of Unifying Clinical Systems, Processes, and Stakeholder Collaboration

The contract research organization (CRO) industry continues to grow, with sponsors outsourcing their trials for greater speed and efficiency. In 2018, the value of the global CRO market was estimated to be \$37 billion¹ and is forecasted to grow annually by 8.2%.²

Over the past several years, CROs have steadily adopted function-specific technologies to improve study execution. Highest is EDC, used by 93% of CROs. More than three-quarters (77%) have eTMF applications, up from 62% in 2017. RTSM applications (71%) increased 19 percentage points, likely due to rising protocol design complexity.³ The majority of CROs also use CTMS (70%), an increase of 12 percentage points as CROs aim to reduce costs and improve study quality.

Applications Used to Manage Clinical Studies

Base: CRO respondents, 2019 N=115, 2017 N=50



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

¹ 2017 CRO Market Size Projections 2016-2021, ISR Reports, 2017.

² Contract Research Organization (CRO) Services Market Forecasts to 2024, Researchandmarkets.com, 2024.

³ Getz KA, Campo RA. New Benchmarks Characterizing Growth in Protocol Design Complexity. Therapeutic Innovation & Regulatory Science. 2017.

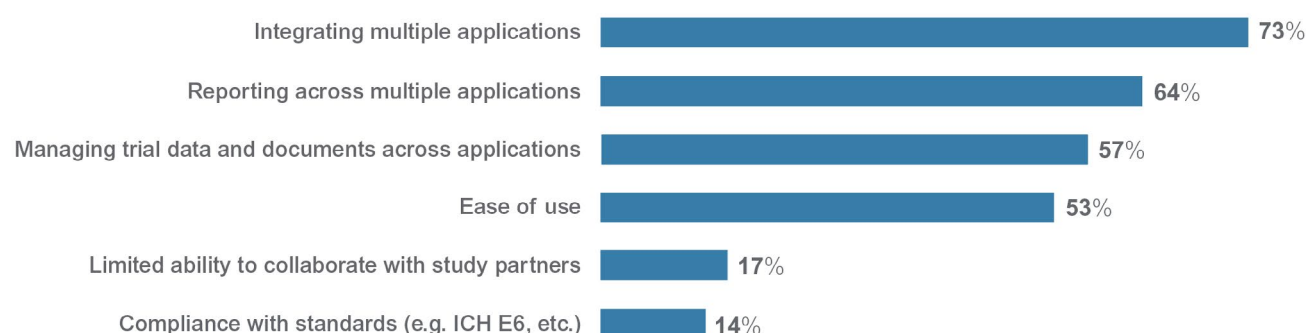
Drivers and Barriers to Unifying Clinical Systems and Processes

All CRO respondents (100%) say they have at least one major challenge with their clinical applications.

The top two issues – integrating multiple applications (73%) and reporting across multiple applications (64%) – are the direct result of clinical application silos.

Biggest Challenges with Clinical Applications

Base: CRO respondents, N=115

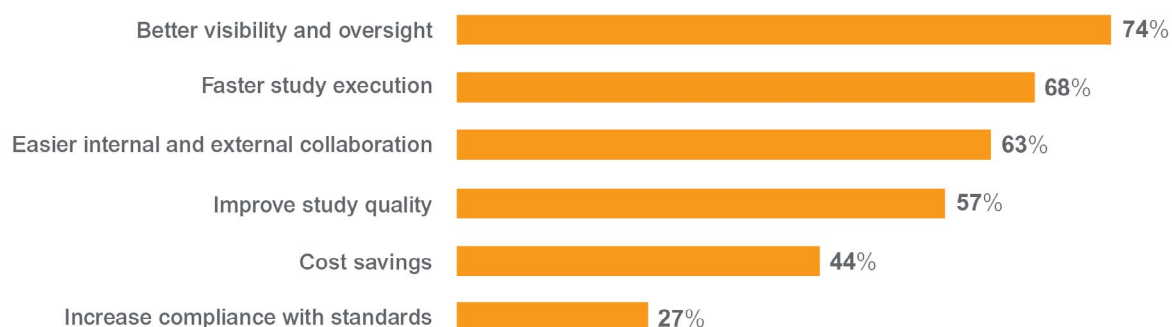


What are the biggest challenges, if any, your organization faces in utilizing the clinical applications identified in question 3? (e.g., CTMS, EDC, eTMF, etc.) Select all that apply.

With the focus to improve trial operations, 100% of CRO respondents say they need to unify their clinical trial systems and processes. For more than half, the need to unify is driven by better visibility and oversight (74%), faster study execution (68%), easier collaboration (63%), and improved study quality (57%).

Top Drivers for Unifying Clinical Applications

Base: CRO respondents, N=115



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.

Information Exchange in Clinical Trials

By next year, it is estimated that the majority (72%) of clinical trials will be run by CROs.⁴ As sponsors increasingly contract the specialized services of multiple CROs in a single study, information sharing is difficult because of the many different processes and systems used across stakeholders.⁵

All CRO respondents (100%) report the need to simplify information exchange with study partners. The primary drivers are reducing manual processes (77%), improving collaboration (65%), improving study quality, and speeding study execution (64%). More than half of CROs cite better central and remote auditing versus a third of sponsors (54% versus 38%, respectively). This is likely, in part, due to difficulty tracking information that is managed outside of controlled systems and processes.

Top Drivers to Streamline Information Exchange

Base: CRO respondents, N=115



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

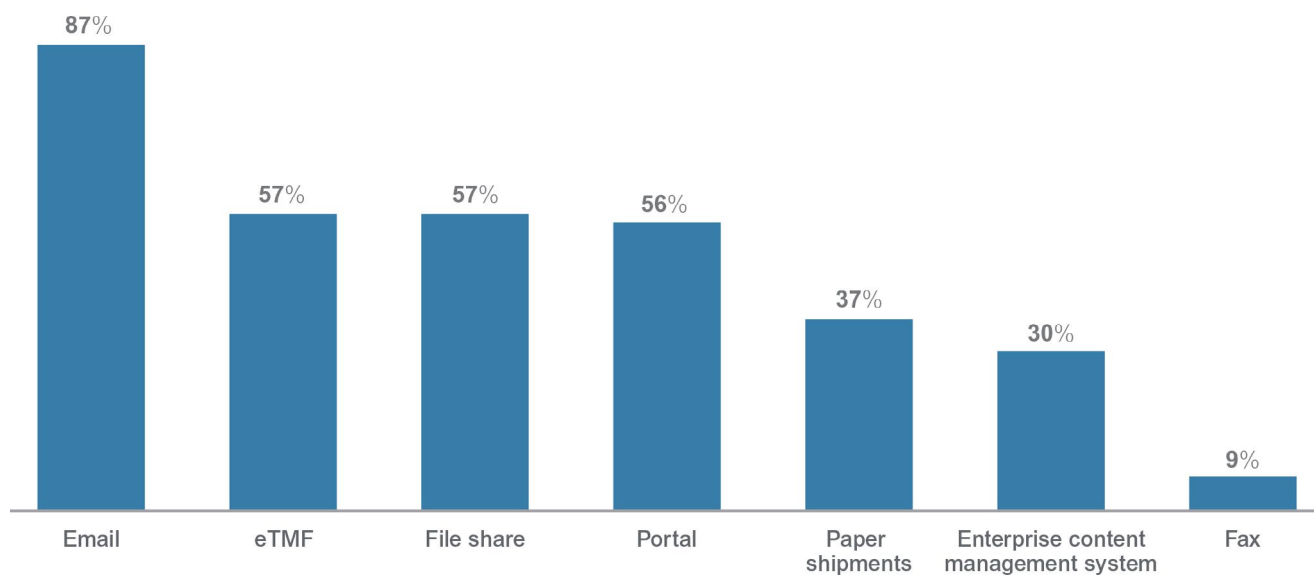
CROs use, on average, three methods to exchange trial data and documents with study partners, with 48% using four or more methods. Email is the predominant method used by CROs to exchange information with sponsors (87%), followed by eTMF and file share (57%), and portals (56%).

⁴ PharmaVoice. Clinical Solutions: Clinical Services Market Poised For Growth. June 2015.

⁵ DIA Global Forum. The Next Big Step Toward a Collaborative Clinical Ecosystem. October 2018.

Methods Used by CROs to Exchange Information with Sponsors

Base: CRO respondents, N=115



*What methods does your organization use to exchange trial data and documents with study partners?
Select all that apply per row.*

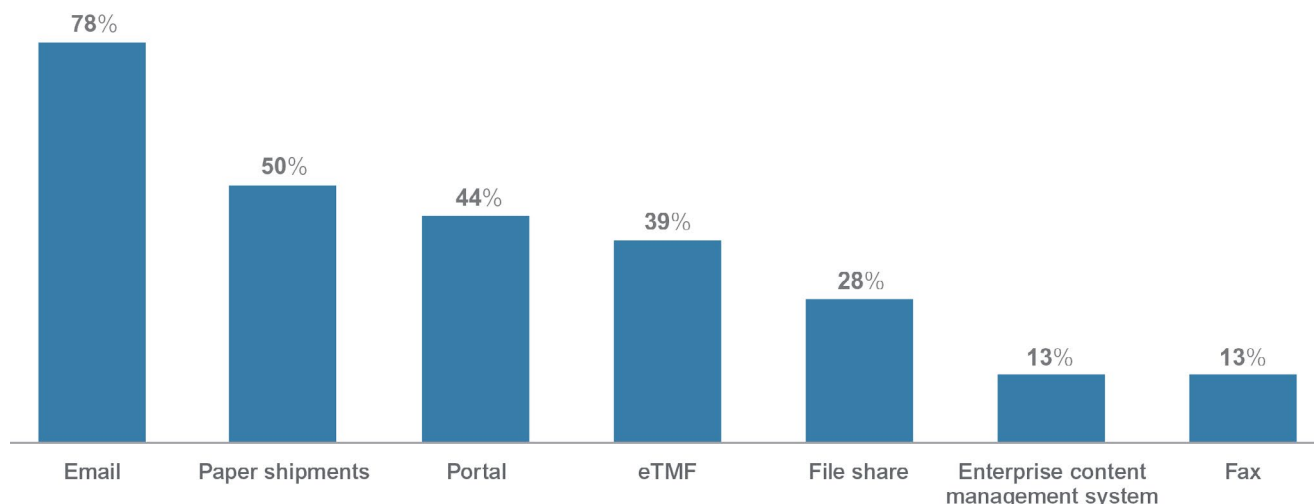
CROs use different methods to exchange information with sites, adding further complexity in data sharing and collaboration.

Half of CROs (50%) use paper shipments to manage information with sites – most likely due to the fact most sites still store their regulatory binders on paper⁶ – followed by portals (44%), and eTMF (39%). Manual methods of information exchange are highly inefficient and likely explains why CROs cite reducing manual processes as a top driver.

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: CRO respondents, N=115



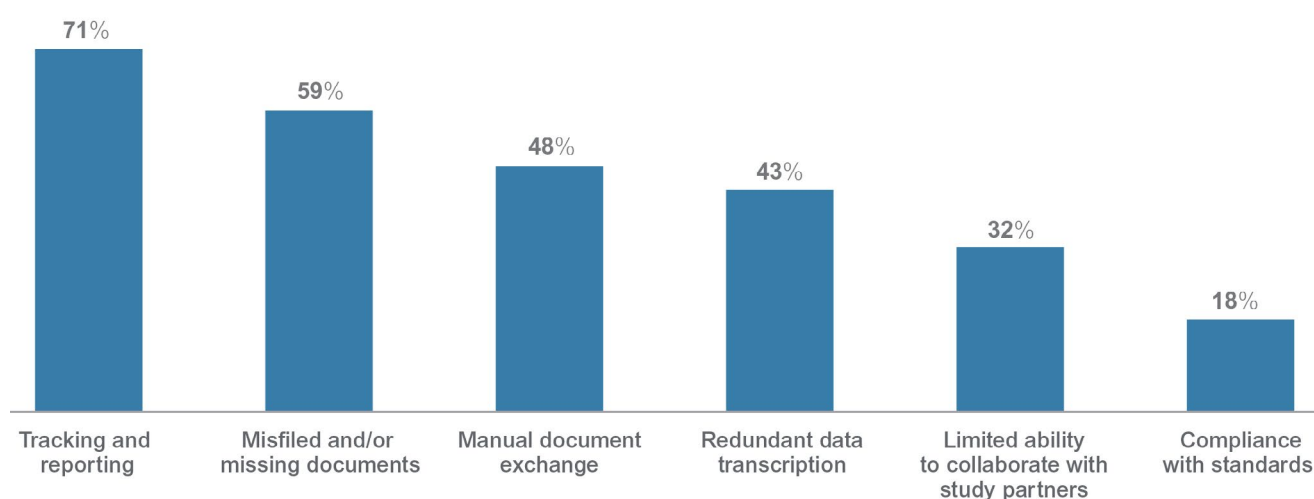
What methods does your organization use to exchange trial data and documents with study partners? Select all that apply per row.

The majority (96%) of respondents say they have significant challenges with the methods used to exchange information during clinical trials.

Collecting data in different systems increases manual effort, causes duplicate entry, and limits visibility. These difficulties can contribute to issues CRO respondents have with tracking and reporting (71%), misfiled or missing documents (59%), and manual document exchange (48%).

Biggest Challenges with Information Exchange

Base: CRO respondents, N=115



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

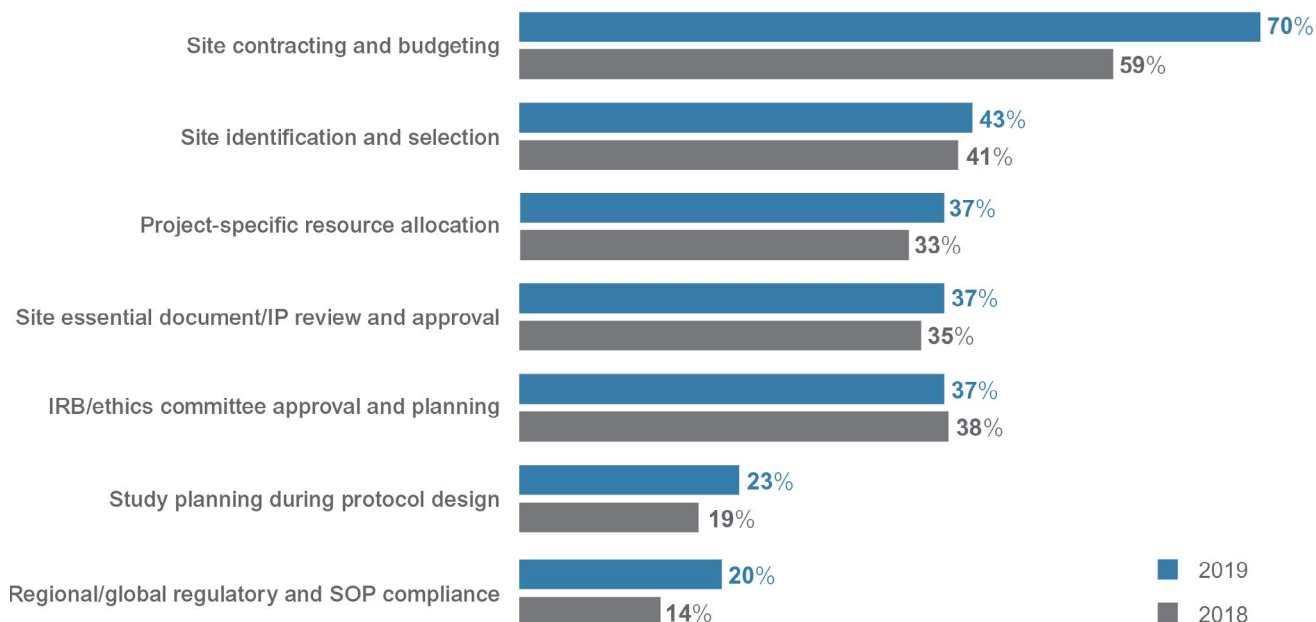
Accelerating Study Start-up

The resource-intensive study start-up phase of clinical trials is no faster today than a decade ago.⁷ Most trials (86%) experience delays in meeting start-up timelines, costing sponsors up to \$2M per month.⁸ To address these challenges, sponsors often outsource study start-up to CROs.

All CRO respondents (100%) report challenges with the study start-up process. Site contracting and budgeting accounts for most of the cycle time and takes twice as long today than five years ago.⁹ Most CROs (70%) say site contracting and budgeting are their most challenging study start-up processes, up 11 percentage points since 2018.

Biggest Challenges with Study Start-up Processes

Base: CRO respondents, 2019 N=115, 2018 N=58



What are the most challenging study-start up processes, if any, that limit your organization's ability to speed clinical trials? Select all that apply.

For most, faster study start-up time (80%), streamlined site contracting and budgeting (65%), and reducing spreadsheets and manual processes (60%) are the primary drivers to improve study start-up.

More than half (55%) say easier collaboration with sponsors and sites is key to improve study start-up, highlighting the importance of collaboration in driving speed and efficiency.

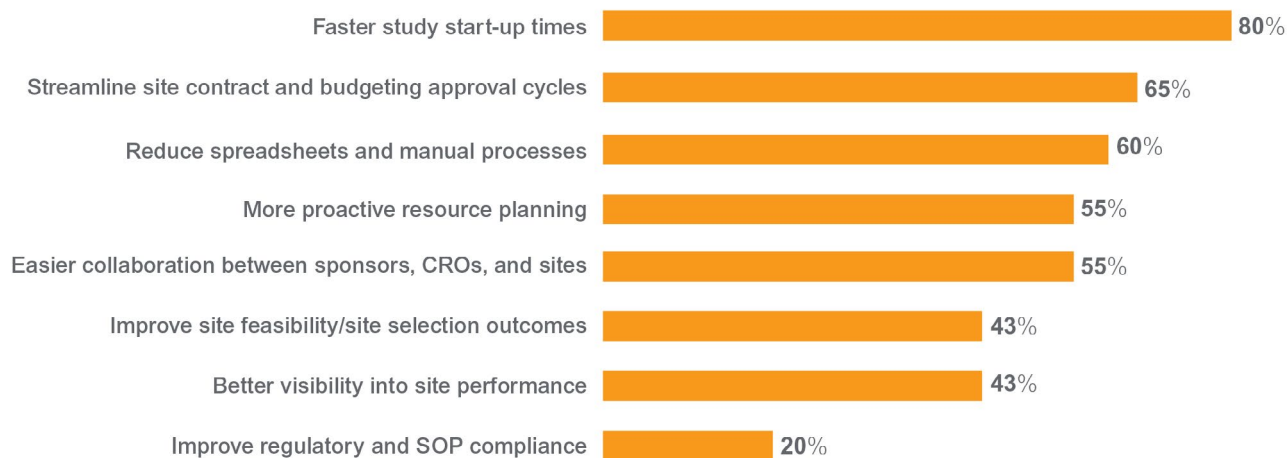
⁷ 2017 CRO Market Size Projections 2016-2021, ISR Reports, 2017. Lamberti, MJ, Chakravarthy, R Getz, KA. Assessing Practices & Inefficiencies with Site Selection, Study Start-Up, and Site Activation. Applied Clinical Trials, August 2016.

⁸ NCBI. Brianna M Krafcik, Gheorghe Doros, Mariana A Malikova. A single center analysis of factors influencing study start-up timelines in clinical trials. July 2017.

⁹ BioSpace. Site Contracts from Weeks to Months: Results from KMR Group's Site Contracts Study. August 2016.

Top Drivers to Improve Study Start-up Processes

Base: CRO respondents using a study start-up application, N=40



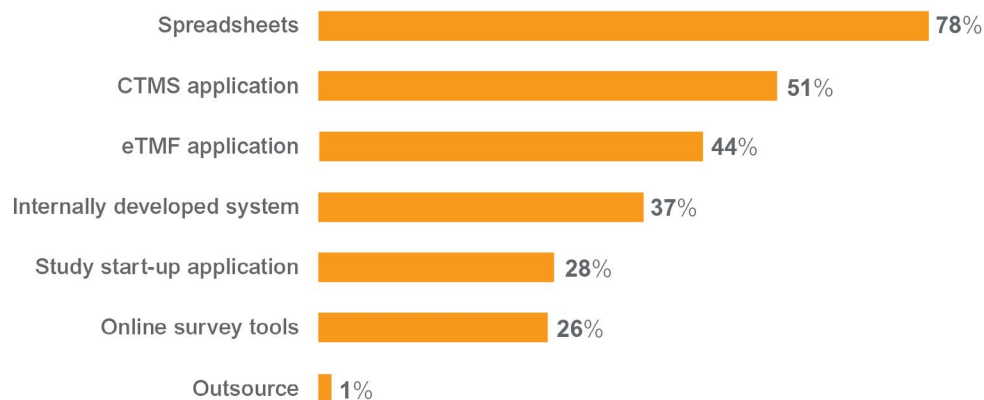
To the extent that your organization needs to improve study start-up processes, what are the primary drivers? Select all that apply.

Most CROs (78%) use spreadsheets to manage study start-up. Half (51%) use CTMS, followed by eTMF (44%), and internally developed applications (37%).

Significantly more CROs than sponsors use newer, purpose-built study start-up applications (28% versus 12%, respectively). This is likely due, in part, to the outsourcing of site management activities, leading CROs to invest in technology to drive efficiencies.¹⁰

Tools Used to Manage Study Start-up Processes

Base: CRO respondents, N=115



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

¹⁰ Statnews.com. Clinical Trials Take a Long Time to Get Started. Here's How to Speed It Up. March 2018.

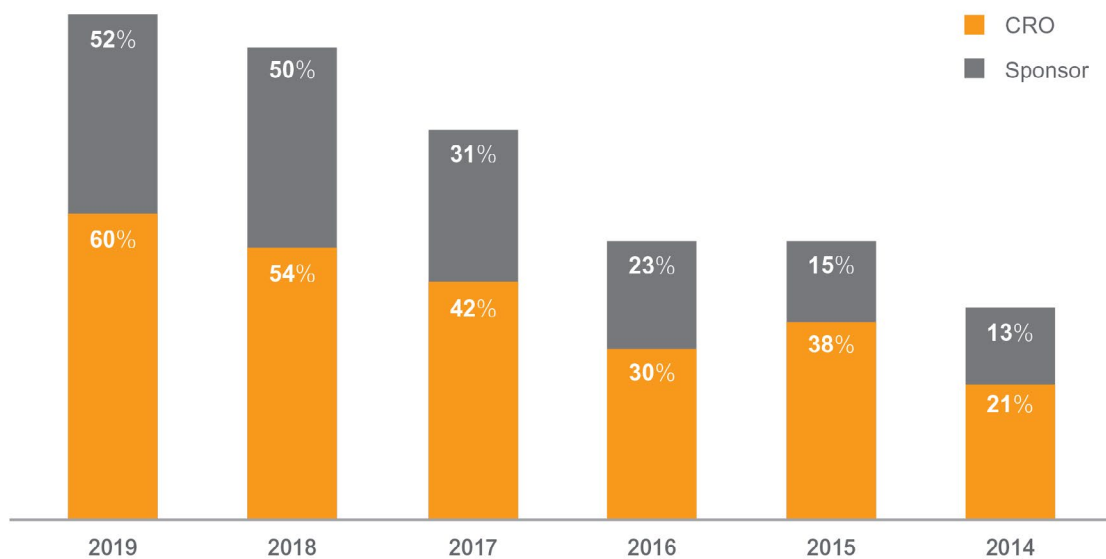
Active TMF Management and Oversight

Over the past five years, CROs have made significant progress modernizing trial processes with the adoption of purpose-built eTMF applications which can help ensure a constant state of inspection readiness, increase visibility and oversight, and improve collaboration.¹¹

The number of CRO respondents using an eTMF application has tripled since 2014, with 60% of CROs now use a purpose-built eTMF application, versus 21% in 2014.

eTMF Application Use 2014-2019

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



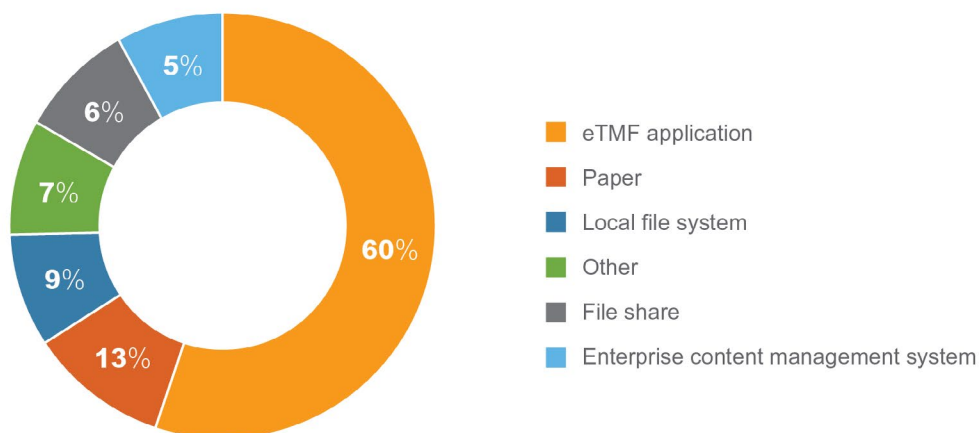
What type of TMF solution do you currently use? Select only one.

The increase in the use of purpose-built eTMF applications is matched by a sharp decline in the use of content management systems, signaling a shift away from general-purpose methods to manage TMF processes. Today, only 5% of CRO respondents use content management systems for TMF management, versus 26% in 2017.

¹¹ Veeva 2018 Unified Clinical Operations Survey. Top Drivers to Optimize TMF Processes (Q.13).

TMF System Used

Base: Total respondents, N=115



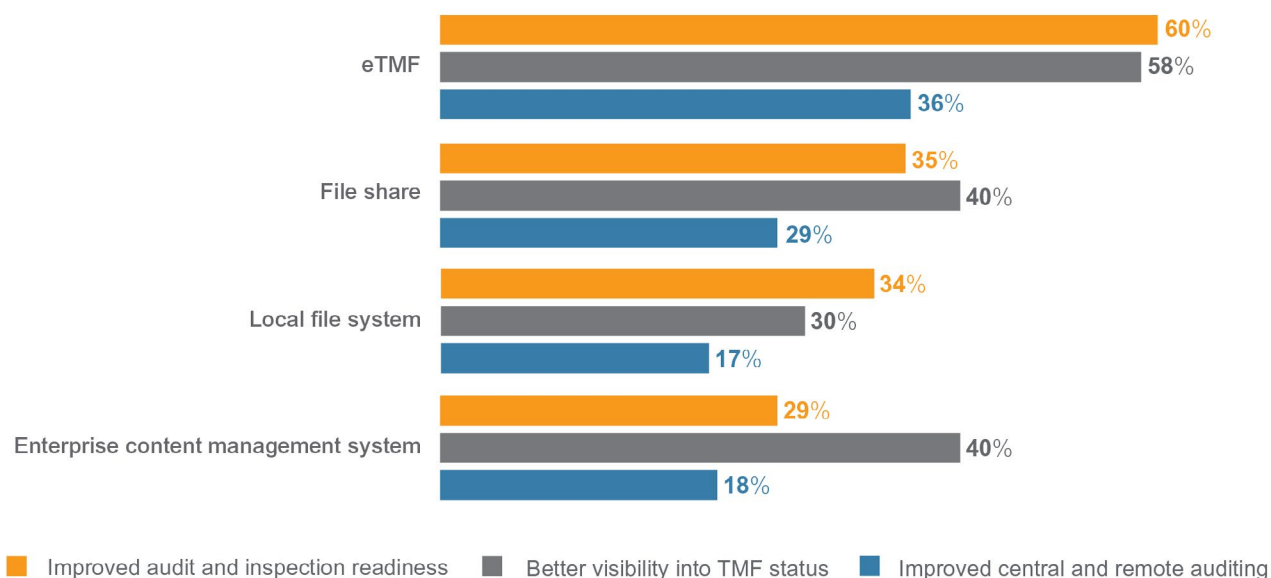
What type of TMF solution do you currently use? Select only one.

Findings indicate the move from TMFs which act as static repositories to store and archive documents upon completion, to modern purpose-built eTMF applications is enabling more ‘active’ trial management. Likely because these newer applications automate processes and manage documents as they are created and reviewed, ensuring the TMF is maintained in a constant state of inspection readiness.

Those using purpose-built eTMF applications report a significant, positive impact on inspection-readiness (60%), increased visibility into TMF status (58%), and centralized auditing (36%). They also report fewer challenges complying with standards (8% for purpose-built TMF users versus 31% using other methods) and TMF tracking and reporting (47% versus 64%, respectively).

Benefits of a TMF by Type of TMF

Base: Total respondents, N=461



What benefits has your organization achieved with the TMF solution specified in Q11? Select all that apply.

Improving Clinical Trial Performance

CTMS applications enable a centralized view of study progress, requiring interoperability with other clinical systems to support timely decision making, oversight, and streamlined communication among stakeholders.¹²

CROs lead sponsors in their adoption of CTMS applications (70% versus 57%, respectively). For CROs – who are highly focused on driving efficiencies – collaborative CTMS applications offer improved oversight and a real-time view of progress while lowering operating costs.¹³

Nearly all CROs (94%) say they have at least one major challenge with their CTMS application that limits operational efficiency and 74% have two or more challenges.

Integrating CTMS applications with other clinical systems (68%) and study performance and metrics (53%) are the most commonly reported challenges.

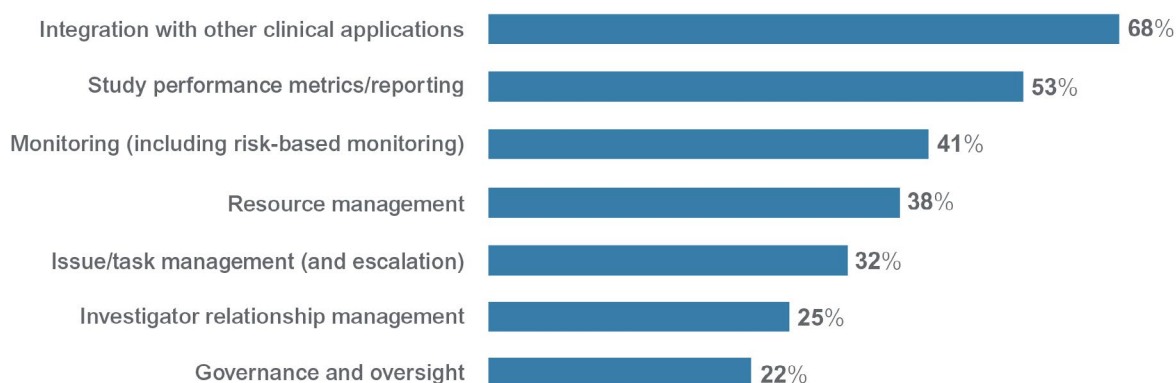
One-third say CTMS application issues limit the efficiency of key trial processes, including monitoring (41%), resource management (38%), and issue and task management (32%).

¹² First Analysis Securities Corporation. eClinical Solutions: Streamlining the Introduction of New Drugs and Medical Technology. January 2018.

¹³ Applied Clinical Trials Online. CTMS: Maximizing Your Global Clinical Trials. March 2014.

Biggest Challenges with CTMS Applications

Base: CRO respondents using a CTMS application, N=81



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.

Likely due to the significance and prevalence of challenges, nearly all (96%) say they need to improve the use of CTMS in trial operations. Better analytics and reporting (68%), proactive risk identification and mitigation (62%), and improving integration with other clinical systems (57%) are among the top reasons to improve.

Easier internal and external collaboration is also a driver for 51% of CROs, underscoring the importance of streamlining communication and information sharing during study execution.

Top Drivers to Improve Clinical Trial Performance

Base: CRO respondents using a CTMS system, N=81



To the degree your organization needs to improve the use of CTMS in clinical trial operations, what are the most important drivers? Select all that apply.

Conclusion

This research shows that unifying clinical operations and improving stakeholder collaboration are top priorities for CROs. While there is work to do, CROs have made strides in moving toward unified clinical operating models which is having a significant, measurable impact in:

- **Streamlining information exchange and collaboration:** Improving information exchange is one of the greatest areas of opportunity for enhancing how CROs work with sponsors and sites throughout the trial process. Unified systems and processes streamline stakeholder collaboration and communication. The exchange of trial information is simplified and real-time study progress is visible to all, driving stakeholder alignment and improving trial performance.
- **Speeding study start-up:** Study start-up is a major area of focus for CROs. As a result, the adoption of purpose-built applications is on the rise and is reducing cycle times by eliminating manual processes and streamlining communication – delivering a higher level, of predictability, quality, and speed to clinical trials.
- **Increasing study quality and compliance:** CROs are unifying and modernizing TMF processes for active TMF management and oversight. Documents are managed in real-time as the TMF is generated, ensuring a constant state of inspection readiness, significant gains in compliance and visibility, and process improvements that streamline the entire study process.
- **Eliminating silos:** There is tremendous opportunity to reduce system and process fragmentation which limits trial performance and slows execution. Modern clinical trial management systems on a unified platform eliminate silos, improve visibility, and enable centralized monitoring and oversight to manage and optimize trials.

CROs operate in a highly competitive marketplace and, as a result, are focused on efficient operations and delivering differentiated services to study partners. A unified clinical environment is essential for CROs to transform clinical operations to achieve gains in efficiency, quality, and visibility. This modern operating model allows CROs to rethink how studies are conducted and to deliver more effective trials, resulting in enhanced performance, simplified collaboration, and faster time to market.

Survey Methods

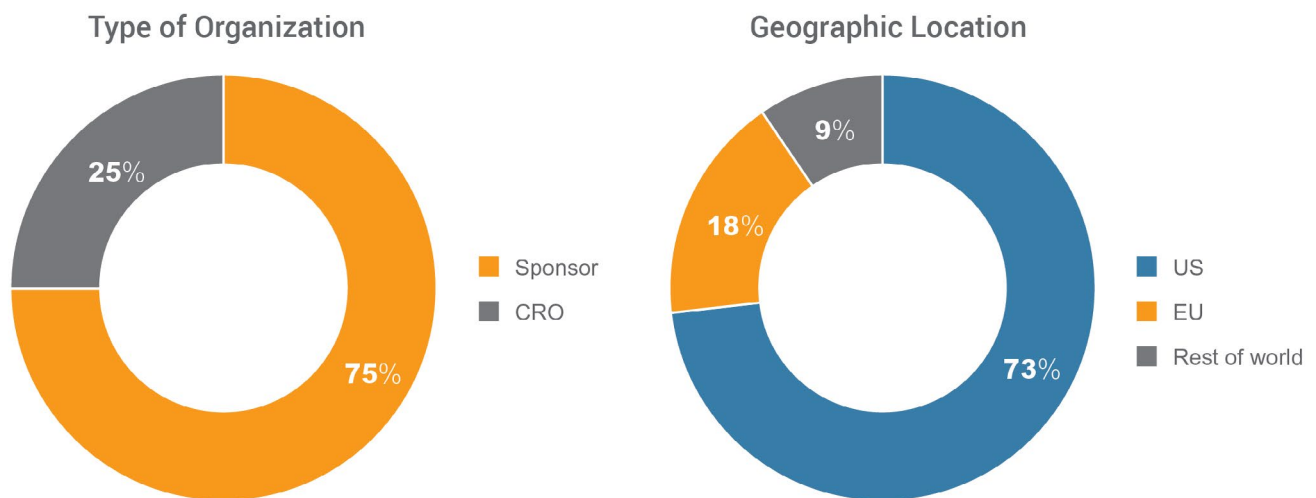
The survey consisted of 16 questions, many of which included sub-questions with response matrices. Survey questions were designed for individuals with knowledge of clinical operations processes and with partial or full responsibility for clinical operations within their organization. The survey was commissioned by Veeva Systems and conducted by Fierce Markets, Applied Clinical Trials, 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 270,020 individuals invited to take the survey, a total of 2,484 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 830 unverified responses were eliminated, yielding 461 qualified responses.

Survey Respondent Demographics

Base: Total respondents, N=461



Contact

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