

Veeva 2018 Unified Clinical Operations Survey: Annual CRO Report

The *Veeva 2018 Unified Clinical Operations Survey: Annual CRO Report* examines contract research organizations' (CROs) progress in unifying clinical operations by gathering the experiences and opinions of CRO respondents from around the world. This annual research examines 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 streamline clinical systems and processes.

Executive Summary

Findings indicate CROs are driving the adoption of modern clinical applications to increase efficiency, streamline collaboration, and improve study quality.

- All CRO respondents report the need to unify their clinical applications, and 91% say their organizations have, or plan to have, an initiative in place to do so.
- All CROs surveyed also say they want to improve the use of CTMS in study operations. Top drivers are more proactive risk mitigation (74%), better study analytics and reporting (60%), and greater visibility (59%).
- CROs have made progress in modernizing trial processes with purpose-built applications like eTMF, driven by the need to be always inspection-ready (69%), automate document tracking and reporting (62%), and save costs (52%).
- Consistent with the aim to improve study execution, study start-up is a priority focus for CROs. Most (79%) have, or plan to have, programs to speed study start-up (66%), reduce spreadsheets and manual processes (45%), and improve collaboration with study partners (45%).
- CROs lead sponsors in adopting clinical trial applications, particularly in study start-up (33% vs. 17%, respectively) and CTMS (66% vs. 54%, respectively).

The Move to Unified Clinical Trial Systems and Processes

Outsourcing to clinical research organizations (CROs) has increased as sponsors seek to run trials faster, improve efficiency, and add specialized services. By 2020, sponsors are predicted to outsource 72% of clinical trials to CROs.¹

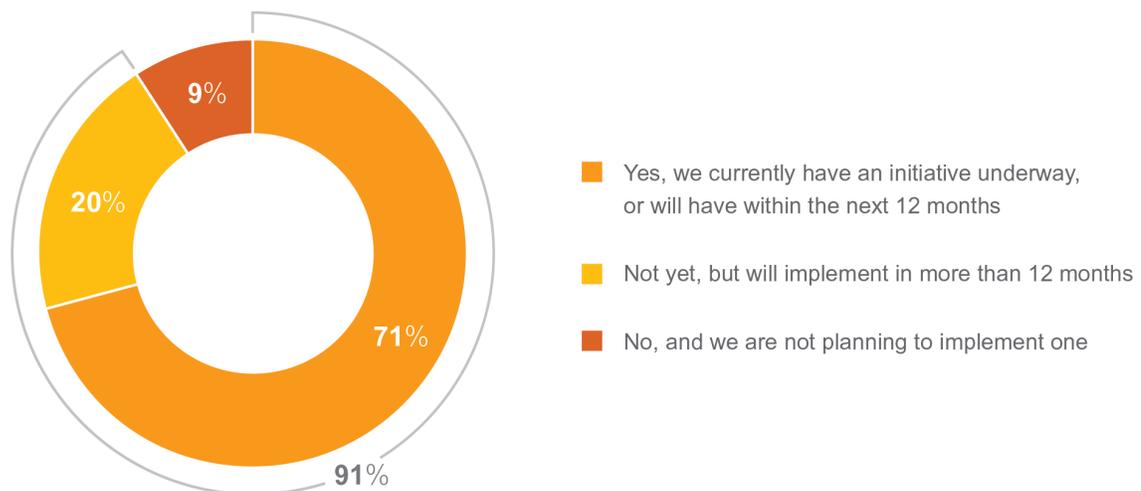
To drive operational efficiency, improve study quality, and contain costs, CROs have adopted function-specific clinical technologies. Standalone eclinical applications, including EDC, CTMS, and eTMF, are now the norm, with newer purpose-built applications like study start-up gaining traction.²

These systems were implemented by functional area, leading to application and process silos, which is now prompting an industrywide move to unify clinical operating environments.

All survey respondents (100%) report the need to unify their clinical trial systems and processes. Of these respondents, nine out of 10 (91%) CROs have, or plan to have, an initiative to unify their clinical application landscape.

The Number of Organizations with Unification Initiatives Underway

Base: CRO respondents, N=58



Does your organization have an initiative underway to better integrate/unify the clinical applications in Q3? (Q.6)

Better visibility is a top driver for unifying clinical applications for 77% of survey respondents. This may be, in part, due to the recent ICH E6 (R2) amendment requiring increased sponsor and CRO oversight during study execution.³

Over half of respondents cite faster study execution (67%), improved study quality (62%), and increased productivity (51%) among the primary reasons to unify their clinical applications.

¹ Businesswire.com. Research and Markets: The New 2015 Trends of Global Clinical Development Outsourcing. January 2015.

² Markets and Markets. eClinical Solutions Market. Global Forecast to 2020. 2016

³ Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). 2016

Top Drivers for Unified Clinical Operations

Base: Total respondents, N=180



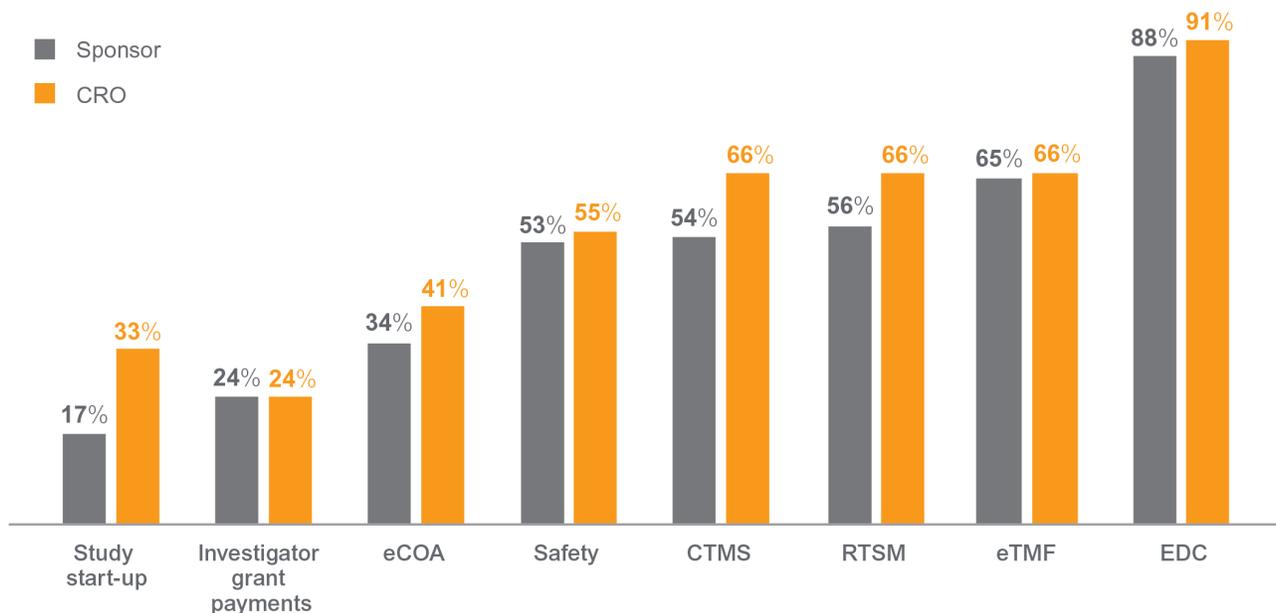
To the degree your organization needs to better integrate/unify the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.), what are the most important drivers? Select all that apply. (Q.5)

On average, CRO respondents use four third-party applications to manage clinical studies. The most commonly used applications are EDC (91%), eTMF (66%), RTSM (66%), and CTMS (66%).

According to research from Pfizer, Inc. and Trials & Training Consult⁴, CROs have increased investment in clinical technologies to improve efficiency. This survey supports this finding, with CROs leading sponsor companies in the adoption of clinical trial applications, particularly in study start-up (33% versus 17%, respectively) and CTMS (66% versus 54%, respectively).

Applications Used to Manage Clinical Studies, CRO versus Sponsor

Base: Total respondents. N=291



⁴ Pharmaoutsourcing.com. The Increasing Shift of Clinical Trials to CROs. May 2015.

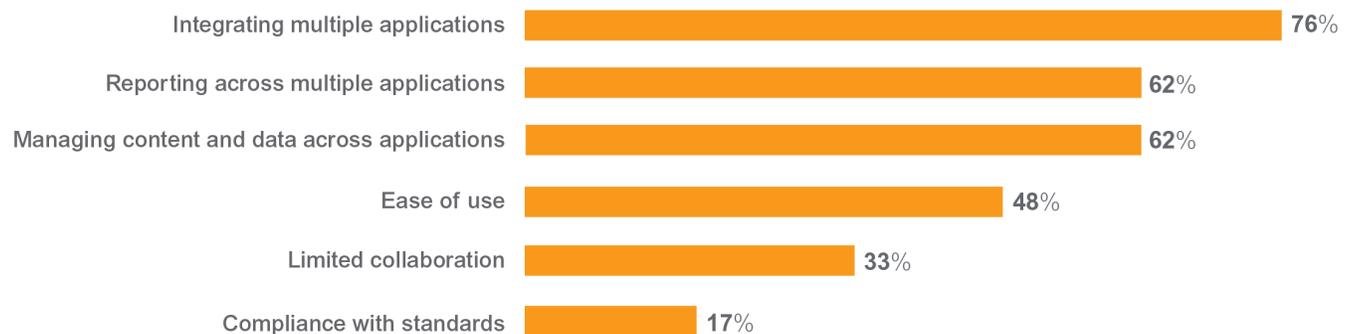
Does your organization utilize applications developed by third-party vendors in managing clinical studies? If yes, please indicate which are currently in use. (Q.3)

All CRO respondents (100%) have at least one major challenge with their clinical applications. The top system challenges are a direct result of clinical application silos and include integrating multiple applications (76%), managing content and data across applications (62%), and reporting across multiple applications (62%).

Collaboration is an issue for a third of CROs (33%), with almost a third (30%) of sponsors also listing this as a challenge.

Biggest Challenges with Clinical Applications

Base: CRO respondents, N=58



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)

Improving Clinical Trial Performance

ICH E6 (R2) GCP guidelines were amended in 2016 to keep pace with the scale and complexity of clinical trials and to ensure appropriate use of technology. Adherence requires improvements to clinical trial design, conduct, oversight, recording, and reporting. Sponsors and CROs in partnership must now document the rationale for their chosen strategy, including the use of systems and processes.

This heightened focus may contribute to respondents' desire to enable proactive risk identification and mitigation (74%), improve study analytics and reporting (60%), and enhance visibility (59%).

Top Drivers to Improve Clinical Trial Performance

Base: CRO respondents, N=58

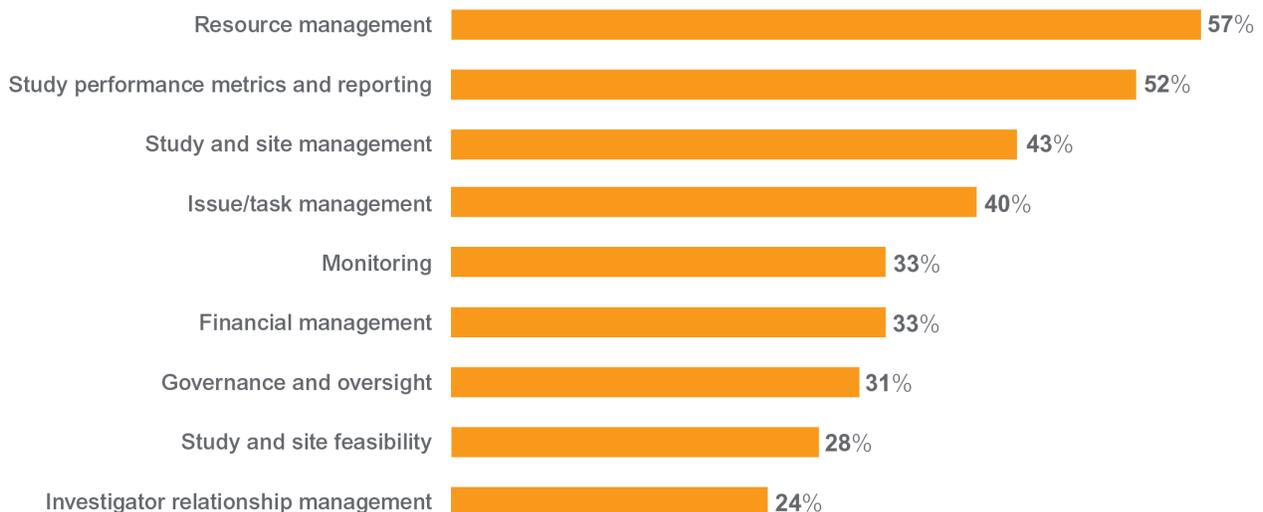


To the degree your organization needs to improve clinical trial management operations, what are the most important drivers? Select all that apply. (Q.9)

All CROs (100%) have challenges with core trial management processes, such as resource management (57%), study performance metrics and reporting (52%), and study and site management (43%).

Challenges with Clinical Trial Management Processes

Base: Total respondents using a CTMS system, N=38

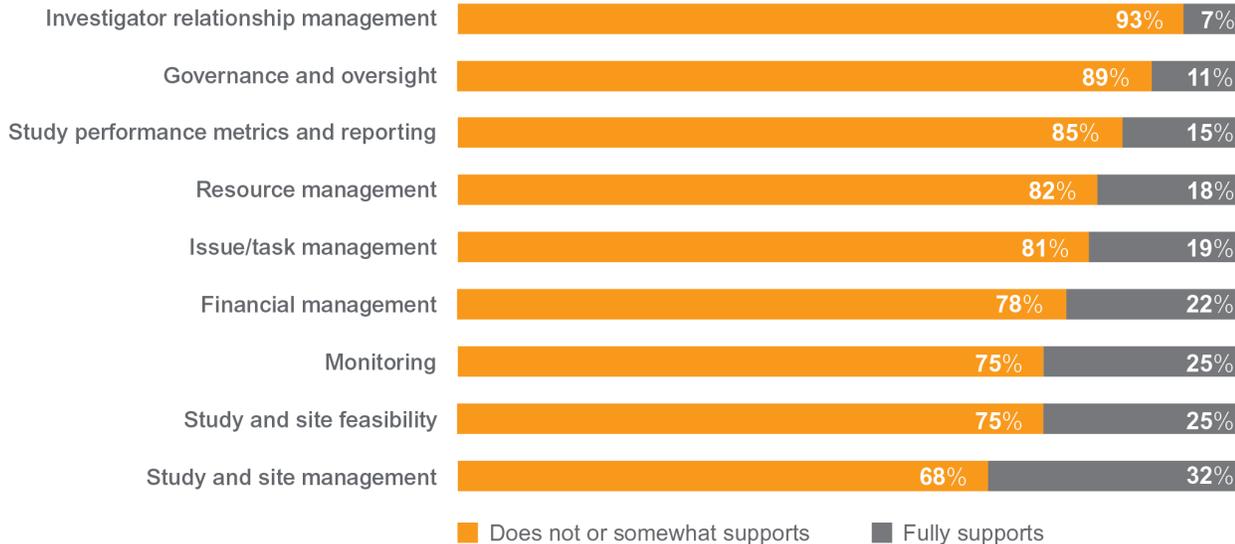


What are the most challenging, if any, clinical trial management processes for your organization? Check all that apply. (Q.7)

CTMS system issues are a limiting factor for 81% of CROs. The majority have CTMS applications that can't fully support a range of key functions including investigator relationship management (93%), governance and oversight (89%), and study performance metrics and reporting (85%). While resource management is a top challenge for CROs, less than a fifth of respondents (18%) report their organizations' CTMS systems adequately support this area.

Processes Supported by CTMS Applications

Base: CRO respondents, N=58



To what degree does your organization's CTMS application support the clinical trial management process identified in question 7? Check only one box per row. (Q.8)

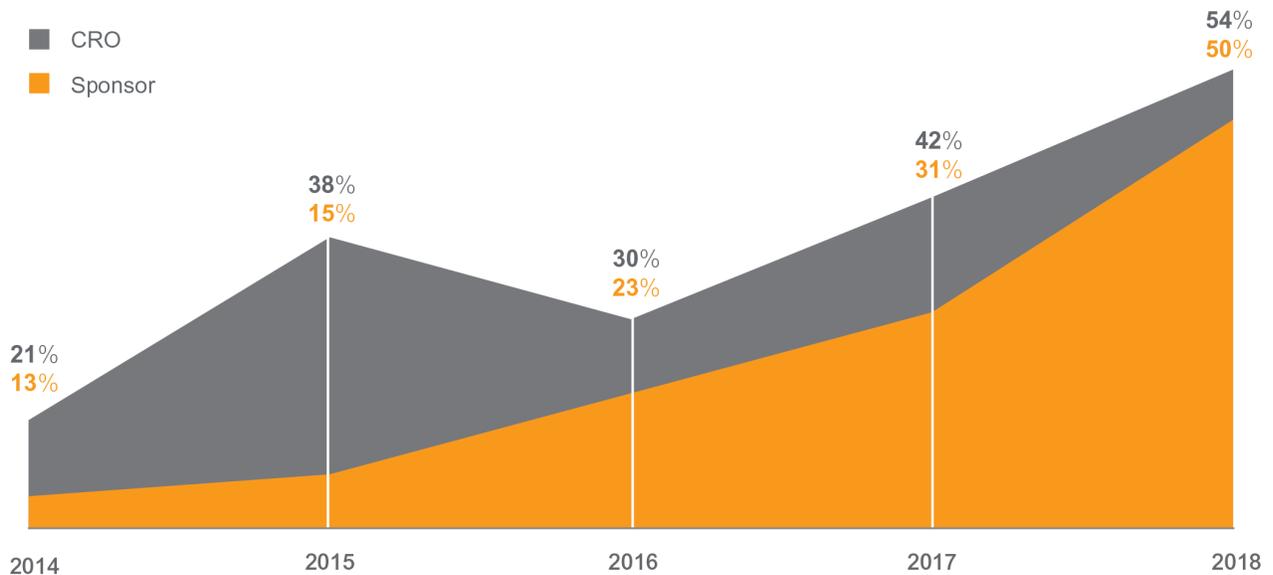
Industrywide Move to More Active TMF Management

With the focus to improve clinical operations, organizations are looking for more advanced, purpose-built systems and rapidly moving away from general-purpose content management solutions and file stores.

The number of CROs now using an eTMF application has more than doubled since 2014. More than half (54%) of CROs now use a purpose-built eTMF application versus a fifth (21%) in 2014, and 42% in 2017. This is consistent with sponsor adoption, with purpose-built eTMF usage quadrupling from 13% to 50% since 2014.

eTMF Application Use 2014-2018

Base: CRO and sponsor respondents, 2018, N=291, 2017 N=253, 2016 N=180, 2015 N=186, 2014 N=161

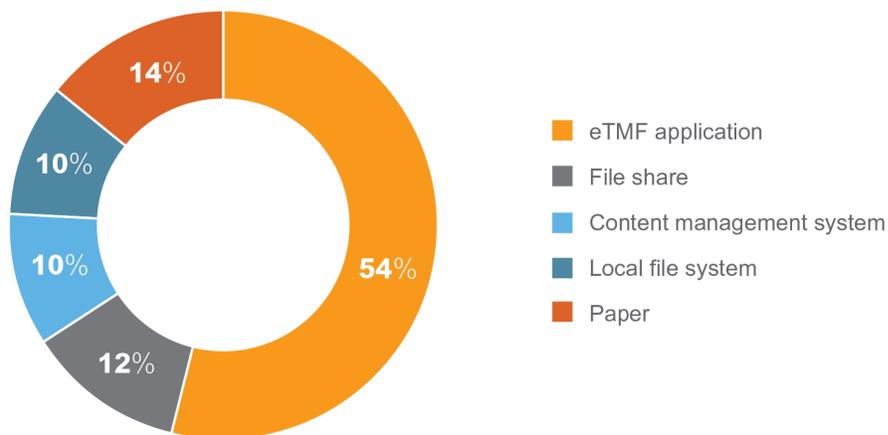


What type of eTMF solution do you currently use? Select only one. (Q. 11)

The increase in the use of eTMF applications since 2017 is matched by a 16% decline in the use of content management systems, signaling a shift away from general-purpose methods – typically used in ‘passive’ TMFs.

TMF System Used

Base: CRO respondents, N=58



What type of eTMF solution do you currently use? Select only one. (Q. 11)

Organizations that use purpose-built eTMF applications have greater visibility into TMF status and report fewer challenges with TMF tracking and reporting, collaboration with study partners, and maintaining compliance with standards.

The Path to Active TMF

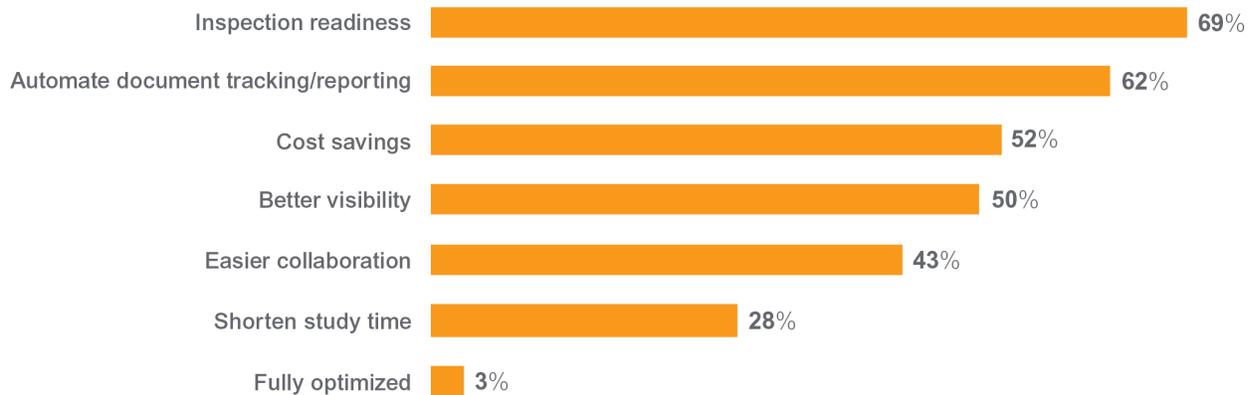
In a 'passive' TMF operating model, documents are uploaded and archived at the end of a trial, rather than in real-time as the process is executed. As a result, the underlying processes associated with documentation are mostly managed outside of the TMF system.

Conversely, in an 'active' TMF operating model, documents are created, reviewed, and accessed by all study partners in real-time as the TMF is being generated. Designed specifically to manage TMF documents and unify end-to-end processes, 'active', purpose-built eTMF solutions have a significant, positive impact on inspection-readiness and trial performance. Automated document exchange and tracking replace iterative paper-based processes, study progress is made visible to all stakeholders, and centralized oversight and use of metrics enable a constant state of inspection readiness.⁵

This model and the emergence of modern systems to support it are helping drive change in the industry. CROs are now looking to optimize TMF processes to improve inspection readiness (69%), automate tracking and reporting (62%), and achieve cost savings (52%).

Top Drivers of eTMF Optimization

Base: CRO respondents, N=58



To the extent that your organization needs to optimize TMF processes, what are the main drivers? Select all that apply. (Q.13)

While cost savings was highlighted by CROs as a key driver to optimize TMF processes, less than a third of sponsors (30%) raised this as a motivator. The CRO industry is focused on delivering value at a competitive price, while sponsors are typically more focused on productivity and finding ways to execute trials more efficiently.⁶

⁵ Veeva 2017 Clinical Operations Survey, Benefits of an eTMF by Type of eTMF (Q.13).

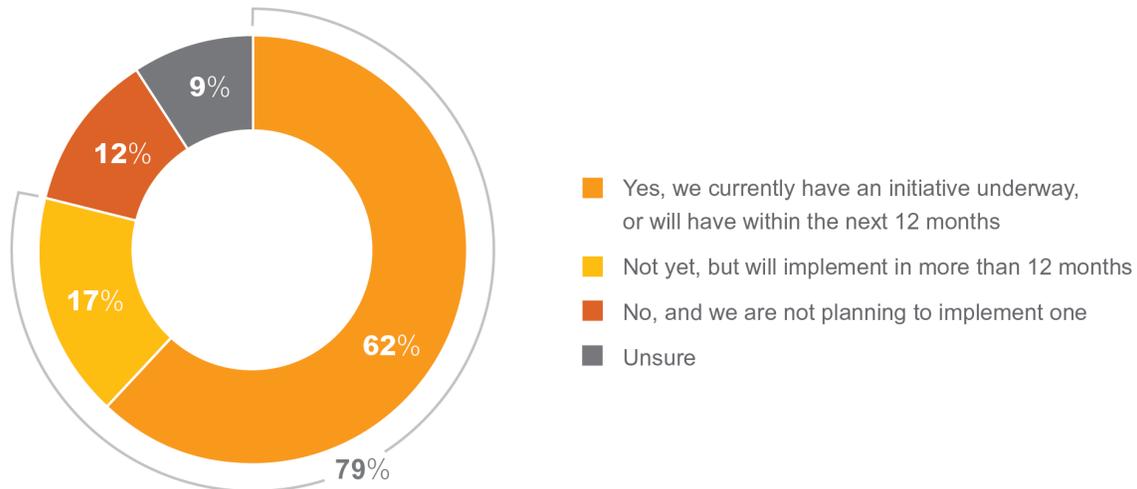
⁶ Outsourcing-pharma.com. Sponsors: Efficiency more Important than CRO Margins. February 2016

Focus on Streamlining Study Start-up

The survey data shows that almost four out of five (79%) CROs have an initiative underway, or will within the next year or more, to improve study start-up processes.

Study Start-up Improvement Initiatives

Base: CRO respondents, N=58



Does your organization have an initiative underway to improve study start-up processes? (Q.15)

Trials are slow and costly to sponsors. It is estimated that 70% of studies run more than one month behind schedule⁷, costing sponsors between \$600,000 and \$8 million per day of delay.⁸

With about 11% of sites failing to enroll a single patient, and a further 37% not meeting enrollment targets, poor site selection can increase the cost of trials by at least 20%.⁷

To address these challenges, sponsors often outsource study start-up to CROs. As a result, CROs seek further efficiencies⁹ and are more likely than pharma or biotechs to invest in technology to speed critical business processes and accelerate time to first patient.

Consistent with these findings, a majority (66%) cite faster study start-up times as one of the most important drivers for improving study start-up processes, followed by reducing spreadsheets and manual processes (45%), easier collaboration (45%), and improving site feasibility and site selection outcomes (45%).

⁷ Temkar P. Accelerating Study Start-Up: The Key to Avoiding Trial Delays. *Clinical Researcher*, February 2017

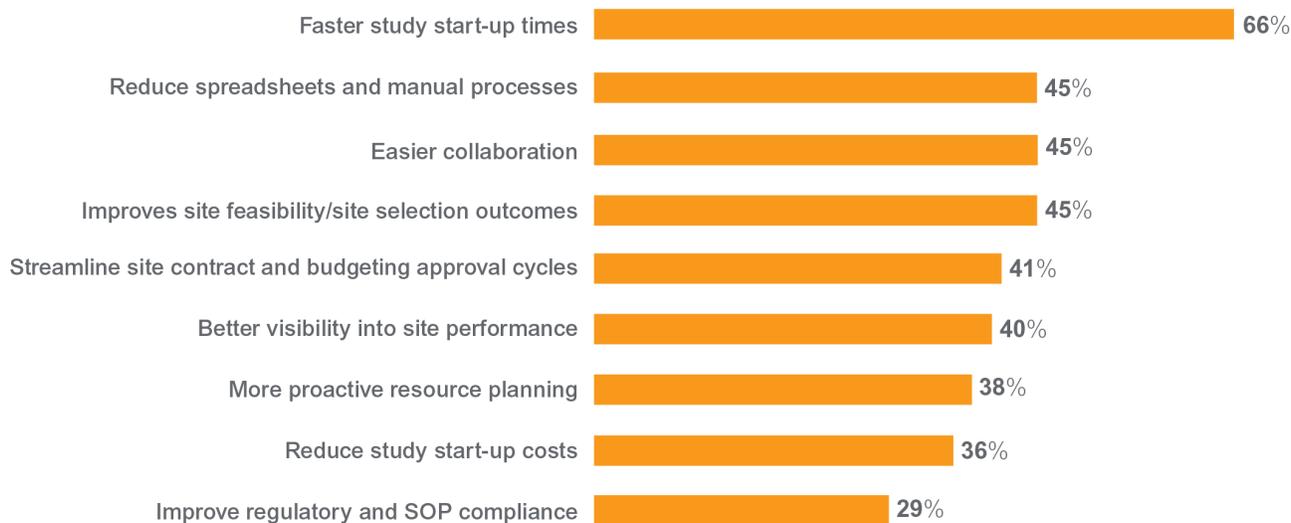
⁸ Lamberti MJ, Wilkinson M, Harper B, Morgan C, Getz KA. Assessing Study Start-up Practices, Performance, and Perceptions Among Sponsors and Contract Research Organizations, *Therapeutic Innovation & Regulatory Science*, DOI: 10.1177/2168479017751403 tirs.sagepub.com

⁹ Statnews.com. Clinical Trials Take a Long Time to Get Started. Here's How to Speed It Up. March 2018.

As a result of increased outsourcing, collaboration between CROs and sponsors is essential. Similarly to last year's Unified Clinical Survey CRO Report¹⁰ findings, there continues to be room for improvement in collaboration with almost half of CROs (45%) and a third of sponsors (33%) highlighting its importance.

Top Drivers to Improve Study Start-up Processes

Base: CRO respondents, N=58



To the extent your organization has a study start-up improvement initiative underway, what are the most important drivers? (Q.16)

Tufts CSDD research shows that the initial stages of the site initiation process, like site contracting and budgeting, account for most of the cycle times. As more global trials are conducted, challenges with country selection, initiation, and regulatory compliance add to these cycle times.¹¹

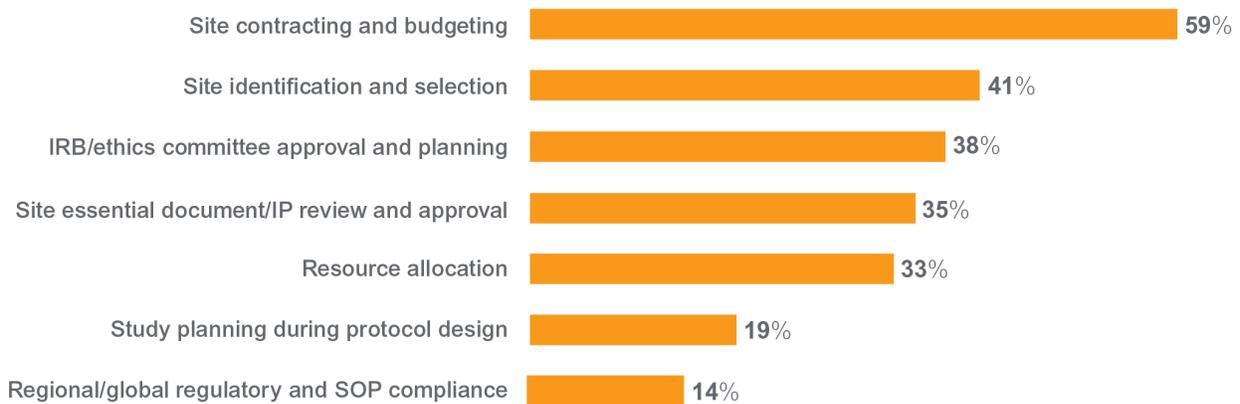
Correspondingly, more than half of respondents (59%) report site contract and budgeting among the most challenging study start-up processes that limit their organization's ability to speed clinical trials, followed by site identification and selection (41%), and IRB/ethics committee planning and approval (38%).

¹⁰ Veeva 2017 Unified Clinical Operations Survey: Annual CRO Report. September 2017.

¹¹ Temkar P. Accelerating Study Start-up: The Key to Avoiding Trial Delays. *Clinical Researcher*. February 2017.

Biggest Challenges with Study Start-up Processes

Base: CRO respondents, N = 58



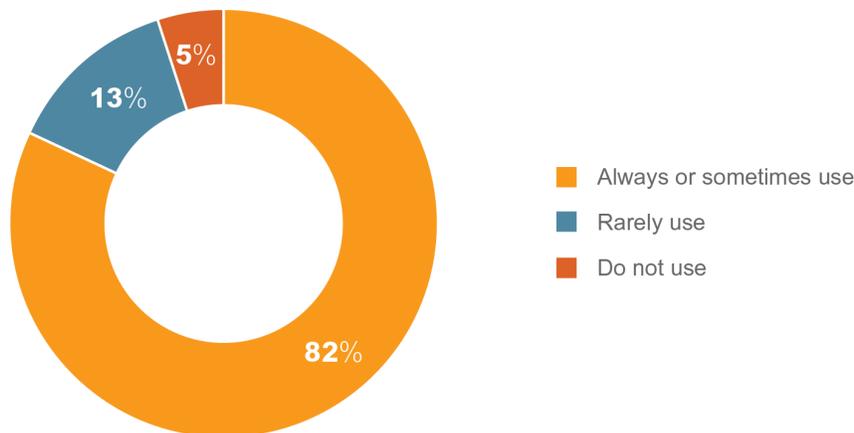
What are the most challenging, if any, study start-up processes that limit your organization's ability to speed clinical trials? Select all that apply. (Q.14)

The Use of Metrics in Driving Performance Improvements

More than three quarters (82%) of CROs use standardized operational metrics and key performance indicators to measure clinical trial performance, manage risks, and implement process improvements.

Use of Operational Metrics to Improve Study Processes

Base: N=58

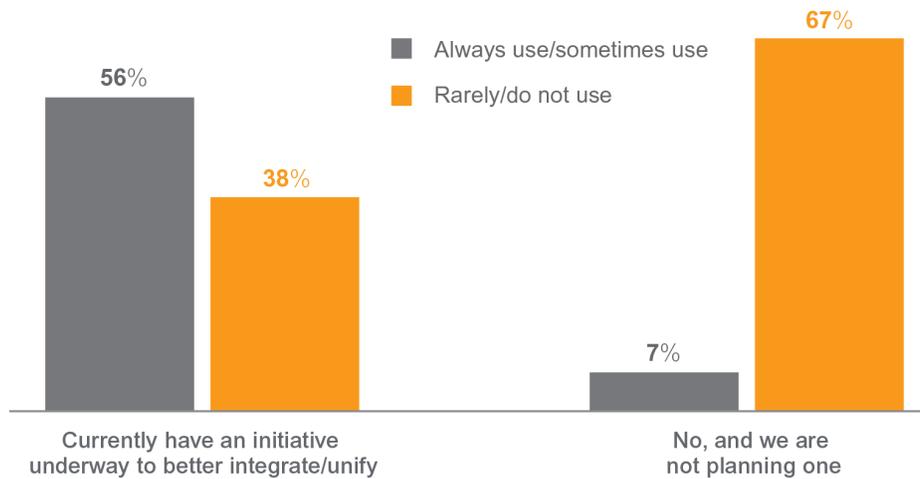


To what degree does your organization use standardized operational metrics and KPIs to measure clinical trial performance, manage risks, and implement process improvements? (Q.10)

Those using metrics are eight times more likely than their peers (56% versus 7%, respectively) to have an initiative underway to unify their clinical applications.

Organizations Using Metrics Lead the Move to Unify Clinical Operations

Base: CRO respondents, N=58



To what degree does your organization use standardized operational metrics and KPIs to measure clinical trial performance, manage risks, and implement process improvements? (Q.10)

Does your organization have an initiative underway to better integrate/unify the clinical applications in Q3? (Q.6)

Organizations that extensively use metrics also have fewer challenges across key trial processes, most notably study performance metrics and reporting (44% versus 66%, respectively) and visibility into TMF status (32% versus 45%, respectively).

Conclusion

There is universal recognition of the importance of a unified clinical landscape in improving trial performance, and most CROs are now working toward this goal. The industry sees it as essential to simplifying collaboration, increasing visibility, and accelerating study execution.

As the industry moves toward a unified clinical environment, this research underscores the importance of:

- **Modernizing clinical systems and processes:** CRO adoption of newer, more advanced cloud applications is on the rise and having a measurable impact on operational efficiency, compliance, and improved study execution. Eliminating system silos, streamlining trial management, and having best-in-class applications on a single cloud platform enables CROs to deliver high quality outsourced services with greater efficiency, visibility, and speed.
- **Seamless collaboration across study partners:** Unified processes and modern cloud-based systems provide full transparency into trial activities from study start-up to close, making it easier for CROs to work with sponsors and sites throughout the trial processes. All parties work from a single source of truth and process, streamlining stakeholder communications and collaboration.
- **End-to-end visibility and proactive trial management:** A unified clinical operating environment provides CROs with complete visibility across the end-to-end trial lifecycle and enables proactive, closed-loop issue management necessary to manage and optimize trial performance. Organizations can manage the entire clinical trial process and gain a global view into trial status, improving efficiencies and streamlining operations.

CROs see tremendous opportunity to improve operational efficiency and deliver high quality outsourced services by unifying their clinical environments. The change underway will enable the industry to better manage the growing complexity of trials, and ultimately, accelerate time to market.

Survey Methods

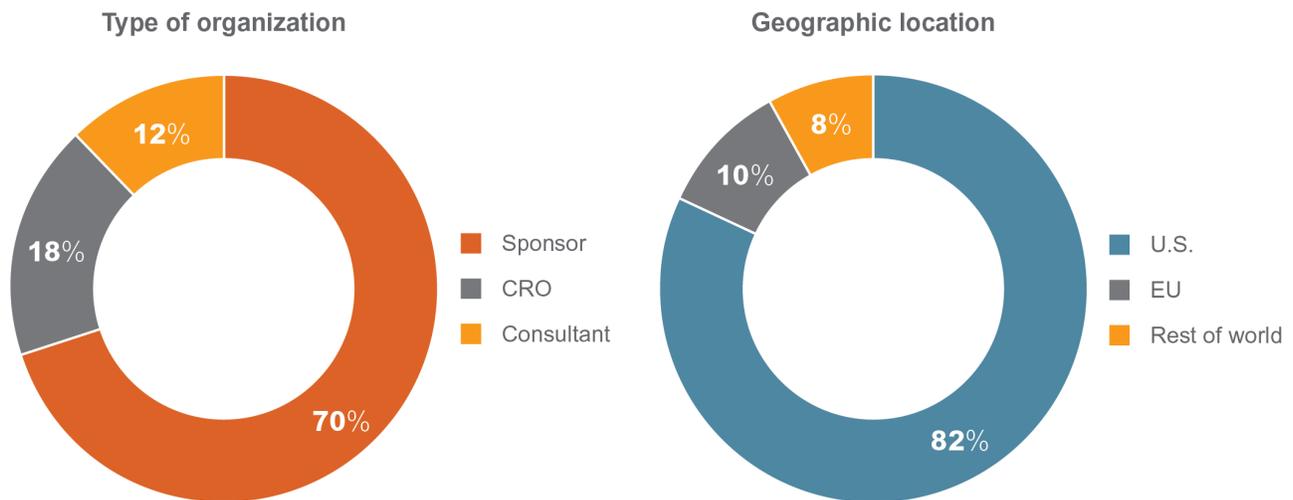
This survey consisted of 17 questions, many of which consisted of sub-questions with response matrices. Survey questions were designed for individuals with knowledge of clinical operations processes and with partial or full responsibility for clinical operations within their organization. This survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and the first 25 respondents received a \$5 Amazon gift card. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

Survey Respondents

Of the approximately 280,000 individuals invited to take the survey, a total of 2,702 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 280 unverified responses were eliminated, yielding 331 qualified responses, 58 of which were from CROs.

Survey Respondent Demographics

Base: Respondents N=331



Contact

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