PRELIMINARY FINDINGS

Veeva 2018 Unified Clinical Operations Survey

The *Veeva 2018 Unified Clinical Operations Survey* examines the life sciences industry's progress toward a unified clinical environment by gathering the experiences and opinions of 331 clinical operations professionals from around the globe. This annual research details 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 show the industry is taking action to unify their clinical trial systems and drive end-to-end processes for better visibility and improved study execution.

- Nearly all (99%) respondents report the need to unify clinical applications, and 87% say their organizations have, or plan to have, an initiative in place to do so.
- All respondents say they want to improve the use of CTMS in study operations. Top drivers are greater visibility (70%), more proactive risk mitigation (65%), and better study analytics and reporting (61%).
- Organizations have made progress in modernizing trial processes with purpose-built applications like eTMF, ensuring a constant state of inspection-readiness (70%), increased visibility and oversight (61%), and improved collaboration (42%).
- Consistent with the aim to improve study execution, study start-up is a priority focus. Most (83%) organizations have programs to speed study start-up, (63%), streamline contract approval cycles (48%), and improve site selection (44%).
- Organizations that use metrics (77%) report fewer challenges with clinical operations and are four times more likely to have programs in place to unify their clinical applications than those not using metrics.
- Those that have programs in place to unify their clinical landscape are also more likely to use operational metrics to measure performance, manage risk, and implement process improvements.

The Move to Unified Clinical Trial Systems and Processes

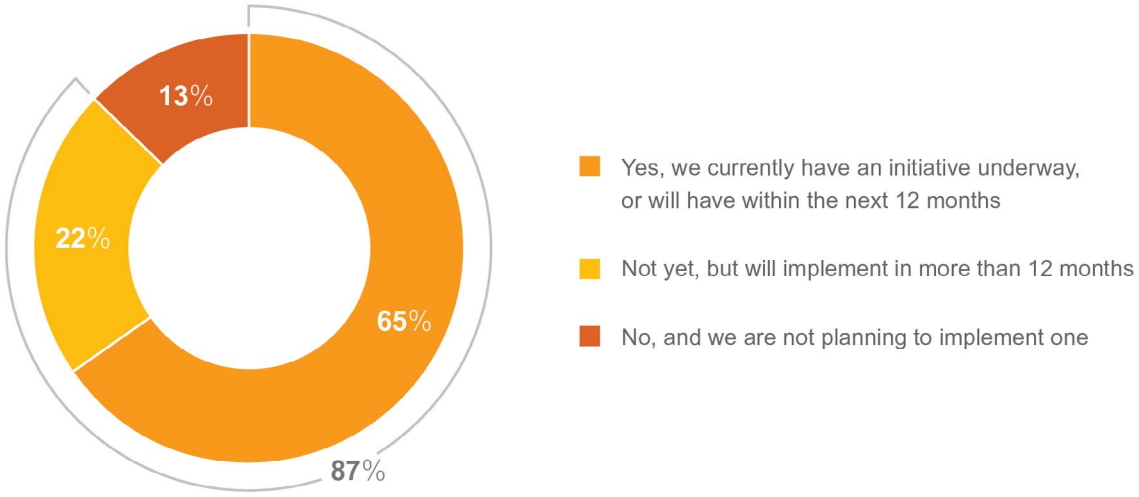
Over the past 15 years, sponsors and CROs have steadily adopted function-specific clinical technologies. Standalone eClinical applications, including EDC, CTMS, and eTMF, are now the norm, with newer purpose-built applications like study start-up gaining traction.[1]

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

Nearly all respondents (99%) report the need to unify their clinical trial systems and processes. Of these respondents, 87% have, or plan to have, an initiative to unify their clinical application landscape.

The Number of Organizations with Unification Initiatives Underway

Base: Total respondents, N=331



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 respondents. This may be, in part, due to the recent ICH E6 (R2) amendment requiring increased sponsor and CRO oversight during study execution.[2]

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

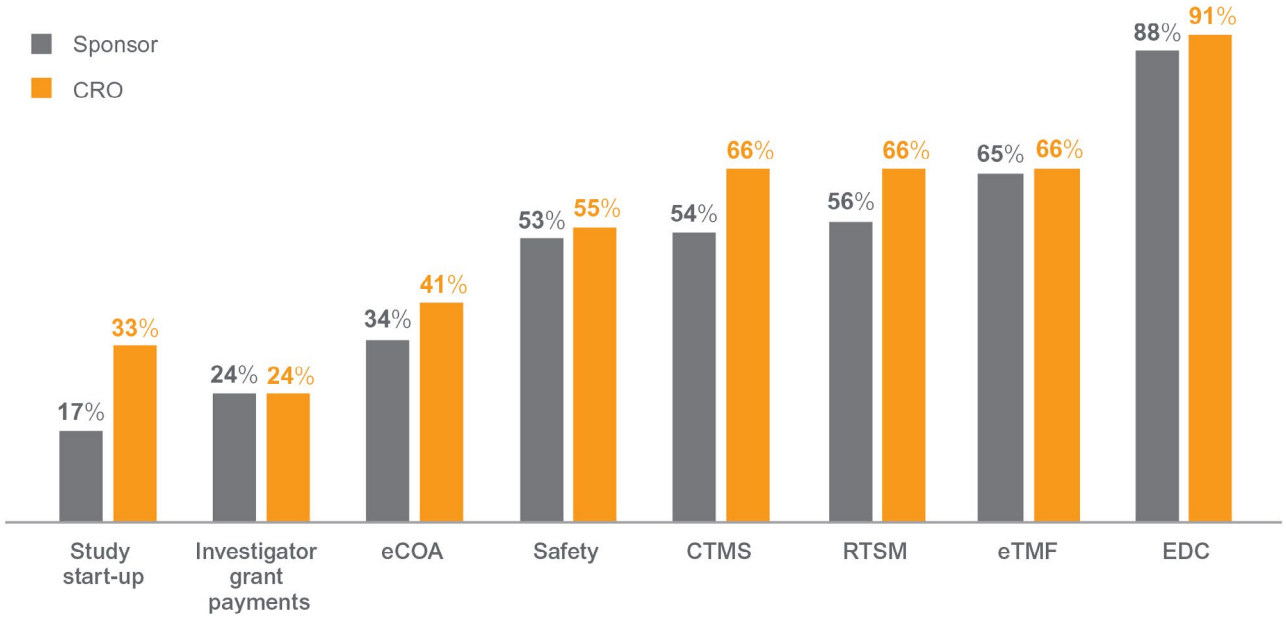
To the degree your organization needs to better integrate/unify the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.), what are the most important drivers? Select all that apply. (Q.5)

On average companies use four applications to manage clinical studies, and more than one-third (38%) use at least five applications. The most commonly used applications are EDC (90%), eTMF (66%), RTSM (61%), and CTMS (60%).

CROs lead 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



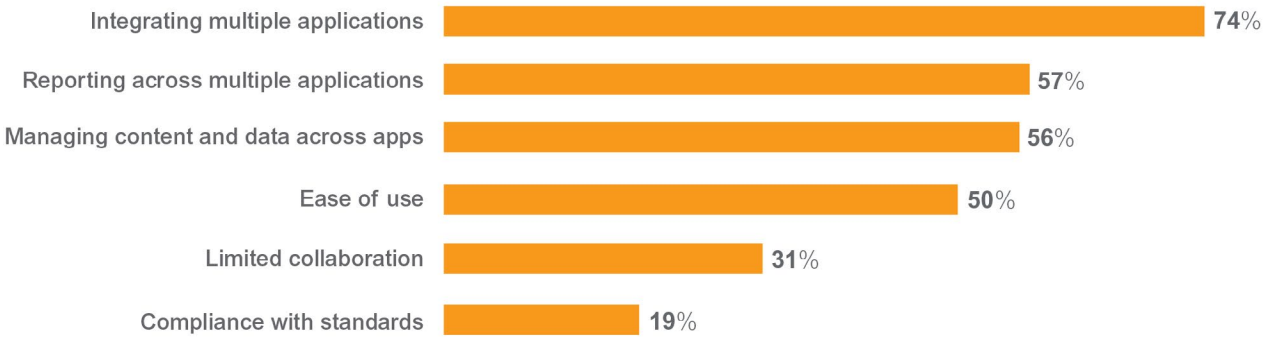
Does your organization utilize applications developed by third-party vendors in managing clinical studies? If yes, please indicate which are currently in use. (Q.3)

Nearly all respondents (99%) have at least one major challenge with their clinical applications, and more than three-quarters (88%) have two or more challenges.

The top system challenges are a direct result of clinical application silos and include integrating multiple applications (74%), reporting across multiple applications (57%), and managing content and data across applications (56%).

Biggest Challenges with Clinical Applications

Base: Total respondents, N=331



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

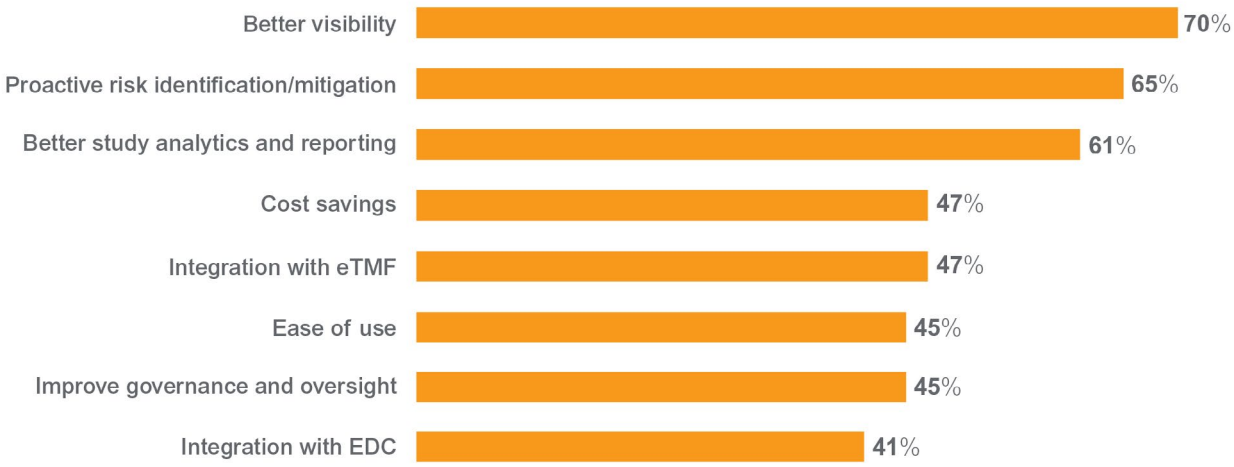
ICH E6 (R2) GCP guidelines were amended to keep pace with the scale and complexity of clinical trials and to ensure appropriate use of technology. Adherence requires improvements to clinical trial design, conduct, oversight, recording, and reporting. Companies are now required to document the rationale for their chosen strategy including the use of systems and processes.[3]

This heightened focus may contribute to respondents desire to enhance visibility (70%), enable proactive risk identification and mitigation (65%), and improve study analytics and reporting (61%).

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

Top Drivers to Improve Clinical Trial Performance

Base: Total respondents using a CTMS system, N=185

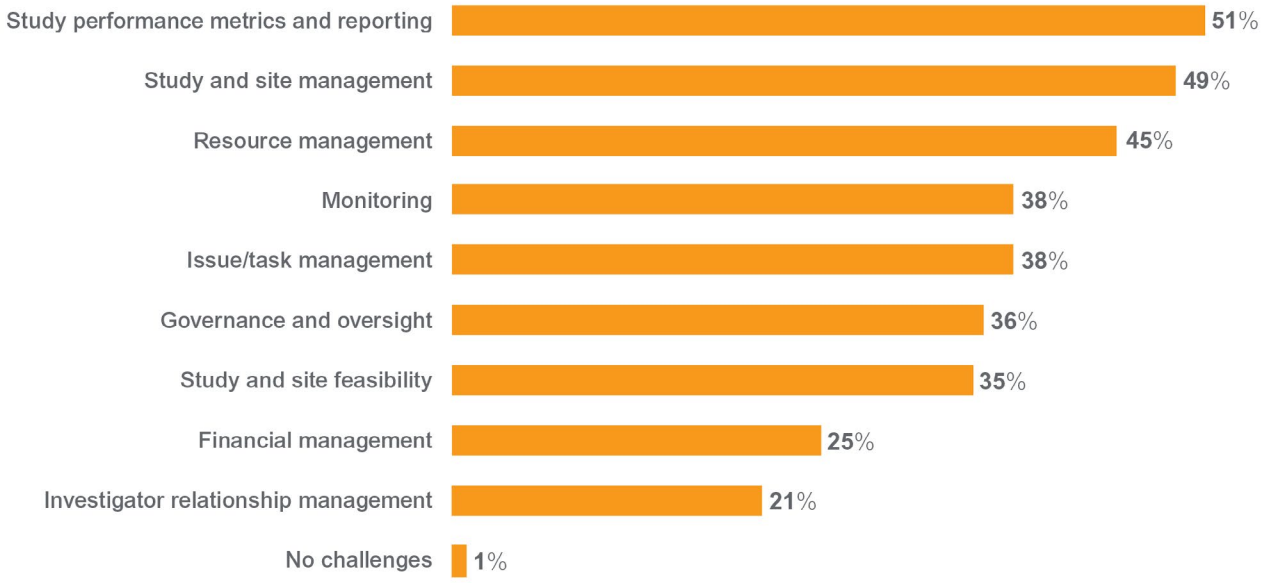


To the degree your organization needs to improve clinical trial management operations, what are the most important drivers? Select all that apply. (Q.9)

Nearly all (99%) have challenges with core trial management processes, such as study performance metrics and reporting (51%), study and site management (49%), and resource management (45%).

Challenges with Clinical Trial Management Processes

Base: Total respondents using a CTMS system, N=185

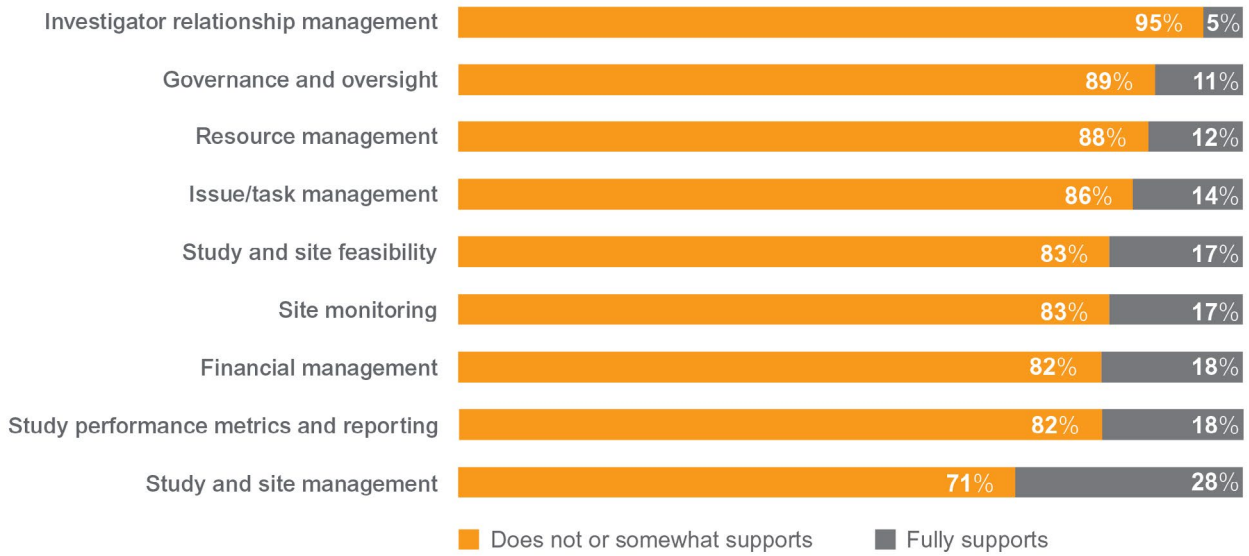


What are the most challenging, if any, clinical trial management processes for your organization? Check all that apply. (Q.7)

CTMS system issues are also a limiting factor for 84% of respondents. The vast majority have CTMS applications that can't fully support a range of key functions including governance and oversight (89%), resource management (88%), and issue and task management (86%).

Processes Supported by CTMS Applications

Base: Total respondents using a CTMS system, N=185



To what degree does your organization's CTMS application support the clinical trial management processes identified in question 7? Check only one box per row. (Q8)

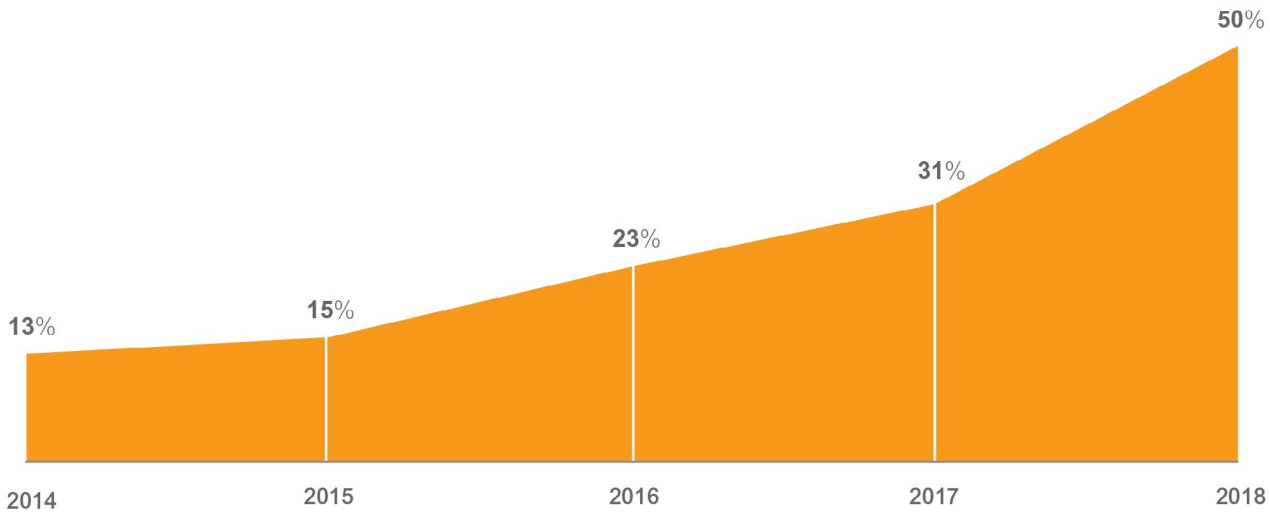
Industrywide Move to More Active TMF Management

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

The number of organizations now using an eTMF application has quadrupled since 2014. Half of sponsors (50%) now use a purpose-built eTMF application versus 13% in 2014, and 31% in 2017.

eTMF Application Use 2014-2018

Base: Sponsor respondents, 2018 N=233, 2017 N=203, 2016 N=137, 2015 N=124, 2014 N=135

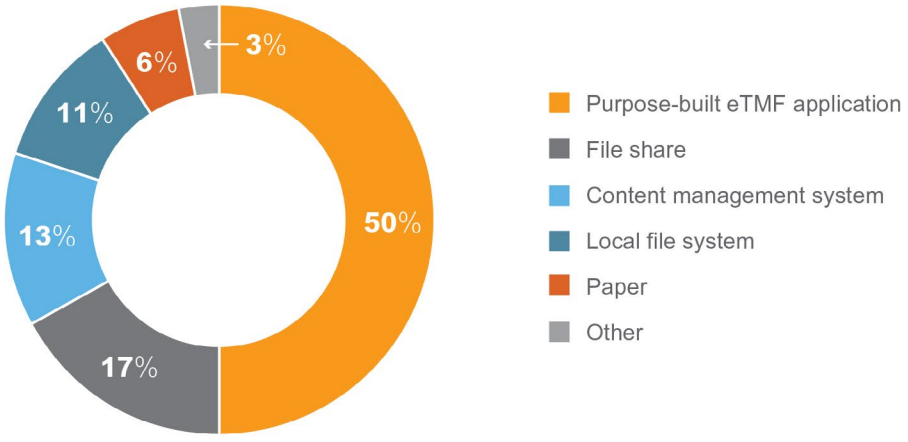


What type of eTMF solution do you currently use? Select only one. (Q.11)

The increase in the use of eTMF applications is matched by a sharp decline (57%) in the use of content management systems, signaling a shift away from general-purpose methods - typically used in 'passive' TMFs.

TMF System Used

Base: Percent of sponsor respondents, N=233



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

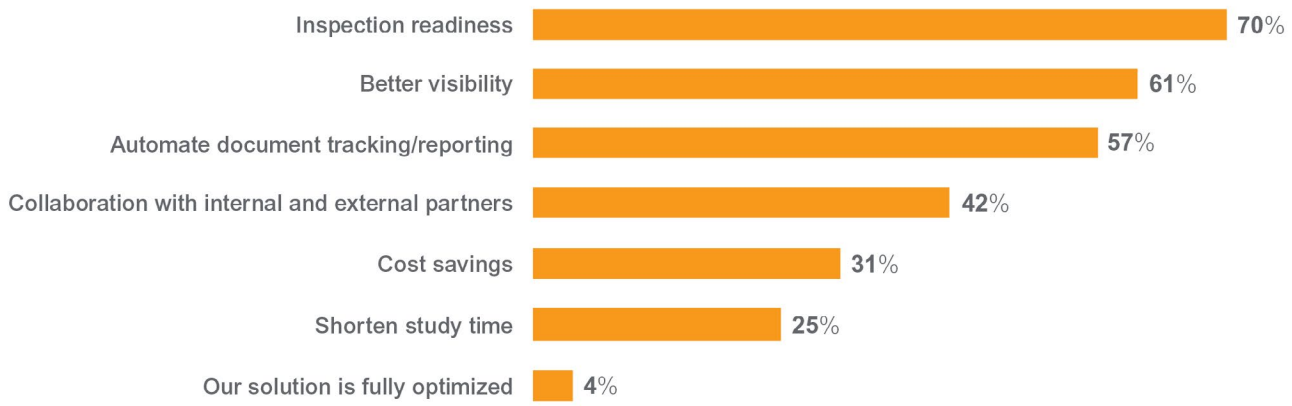
In a 'passive' TMF operating model, documents are uploaded and archived at the end of a trial, rather than in real-time as the process is executed. As a result, the underlying processes associated with documentation are mostly managed outside of the TMF system.

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.[4]

This new model and the emergence of modern systems to support it are helping to drive change in the industry. Sponsors and CROs are now looking to optimize the TMF processes in order to improve inspection readiness (70%), visibility (61%), and automated tracking and reporting (57%).

Top Drivers of eTMF Optimization

Base: Total respondents, N=154



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

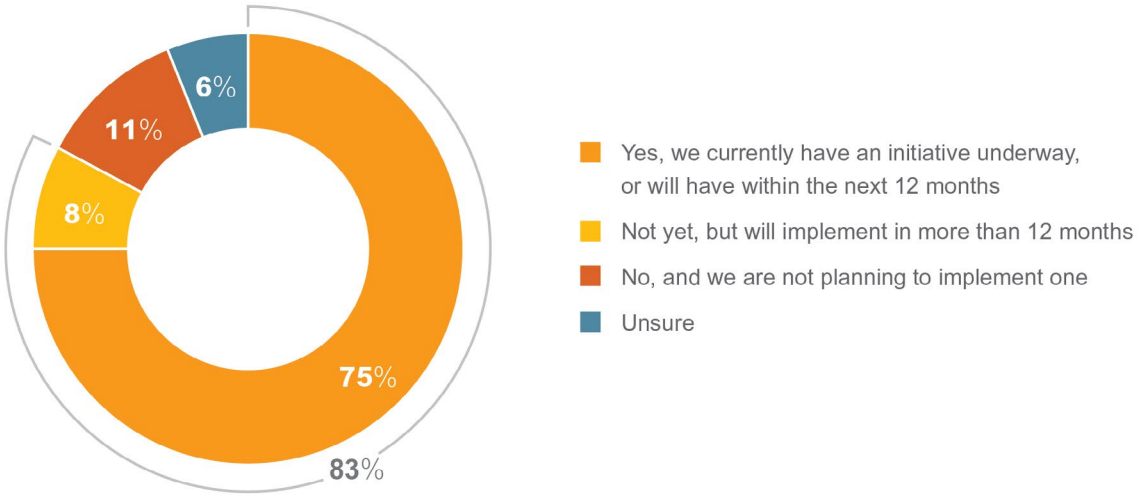
[4] Veeva 2017 Clinical Operations Survey. Benefits of an eTMF by Type of eTMF. (Q.13).

Focus on Streamlining Study Start-up

The data show that 83% of organizations have an initiative underway, or will within the next year or more, to improve study start-up processes.

Study Start-up Improvement Initiatives

Base: Total respondents using a study start-up system, N=71



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

It is estimated that 70% of studies run more than one month behind schedule, costing sponsors between $600,000 and $8 million per day of delay.[5]

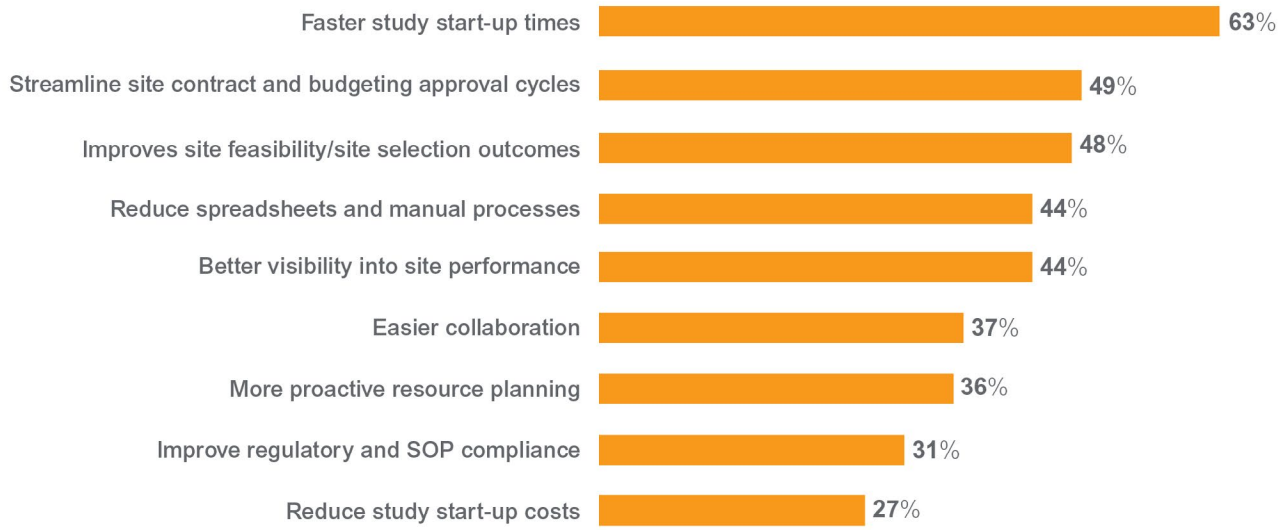
With as many as 11% of sites failing to enroll a single patient, and another 37% failing to meet enrollment targets, poor site selection can increase the cost of trials by at least 20%.[6]

Consistent with these findings, 63% of survey respondents cite faster study start-up times as a primary focus for improving study start-up processes, followed by streamlining site contract and budgeting approval cycles (49%) and improving site feasibility and site selection outcomes (48%).

[5, 6] Temkar P. Accelerating Study Start-up: The Key to Avoiding Trial Delays. *Clinical Researcher*. February 2017.

Top Drivers to Improve Study Start-up Processes

Base: Total respondents, N=71



To the extent your organization has a study start-up improvement initiative underway, what are the most important drivers? (Q16)

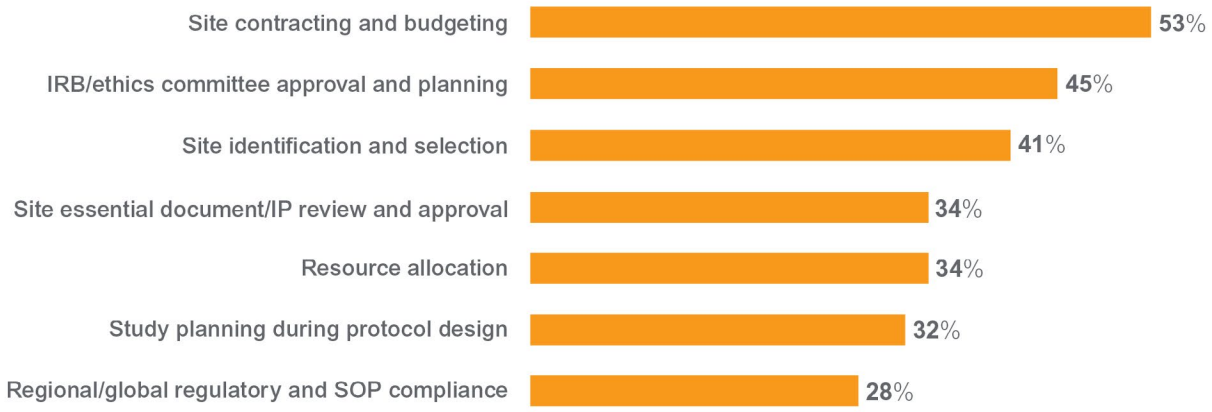
Tufts CSDD research shows that the early stages of the site initiation process, like site contracting and budgeting, account for most of the cycle times. As more global trials are conducted, challenges with country selection, initiation, and regulatory compliance add to these cycle times.[7]

Correspondingly, more than half of respondents (53%) 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 IRB/ethics committee planning and approval (45%), and site identification and selection (45%).

[7] 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

Biggest Challenges with Study Start-up Processes

Base: Total respondents, N=71



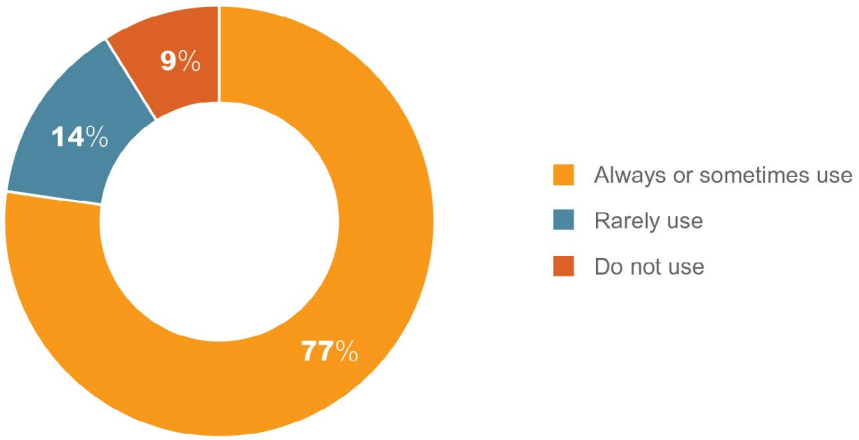
What are the most challenging, if any, study start-up processes, if any, that limit your organization's ability to speed clinical trials? Select all that apply. (Q.14)

The Use of Metrics in Driving Performance Improvements

Three quarters (77%) of respondents use standardized operational metrics and key performance indicators (KPIs) to measure clinical trial performance, manage risks, and implement process improvements.

Use of Operational Metrics to Improve Study Processes

Base: Respondents N=331

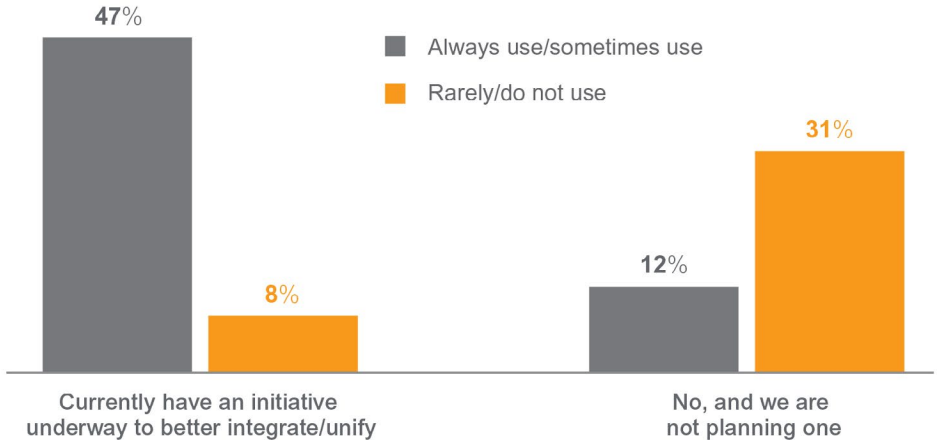


To what degree does your organization use standardized operational metrics and KPIs to measure clinical trial performance, manage risks, and implement process improvements? (Q.10)

Those using metrics are also four times more likely than their peers (47% versus 12%, respectively) to have an initiative underway to unify their clinical applications.

Organizations Using Metrics Lead the Move to Unify Clinical Operations

Base: Respondents N=331



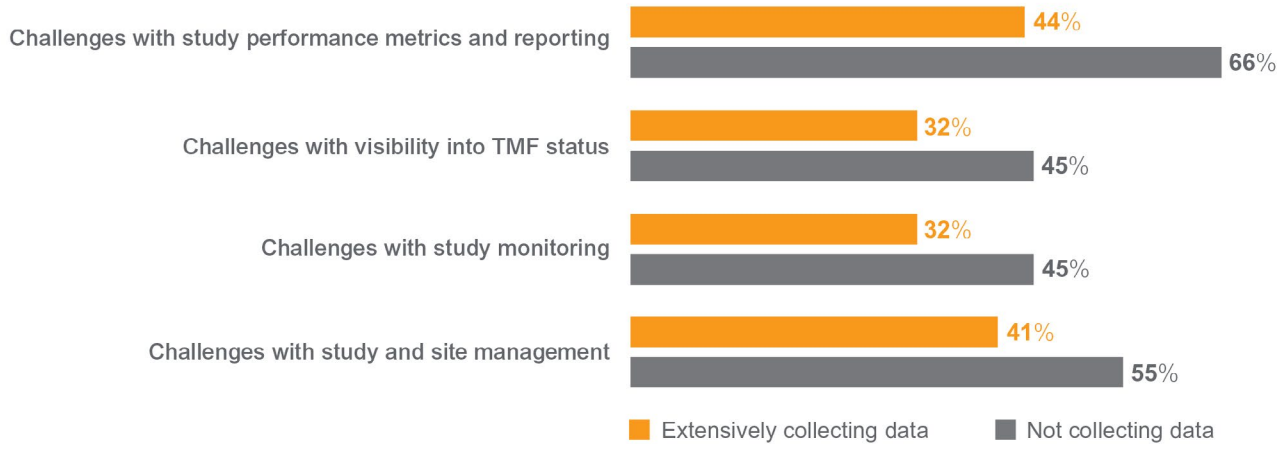
To what degree does your organization use standardized operational metrics and KPIs to measure clinical trial performance, manage risks, and implement process improvements? (Q.10)

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).

Trial Management Challenges by Level of Metrics Used

Base: Respondents N=331



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)

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

What challenges, if any, does your organization have with your current TMF solution? (Q.12)

Conclusion

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

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

- **End-to-end visibility and the use of standard metrics:** Consistent use of standardized metrics and KPIs to measure trial performance is one of the greatest areas of opportunity for improving clinical operations. A unified clinical environment provides the visibility across end-to-end trial lifecycle needed to effectively manage and optimize trials.
- **Seamless collaboration across study partners:** Unified processes and systems streamline stakeholder communications and collaboration. All parties work from a single source of truth and within a well understood (and where possible automated) end-to-end process. Full role-based visibility into status KPIs ensures alignment and drives performance.
- **Modern technologies and a unified clinical platform:** Adoption of newer, more advanced cloud applications is on the rise and having a measurable impact on visibility, collaboration, and compliance. Rationalizing systems, eliminating silos and manual processes, and having best-in-class applications on a single clinical platform is critical to unifying clinical operations.

The industry sees tremendous opportunity to transform their operations by unifying their clinical environments. The change underway will enable the industry to better manage the growing complexity of trials, improve compliance, and leverage insights across the full trial lifecycle to accelerate time to market.

Survey Methods

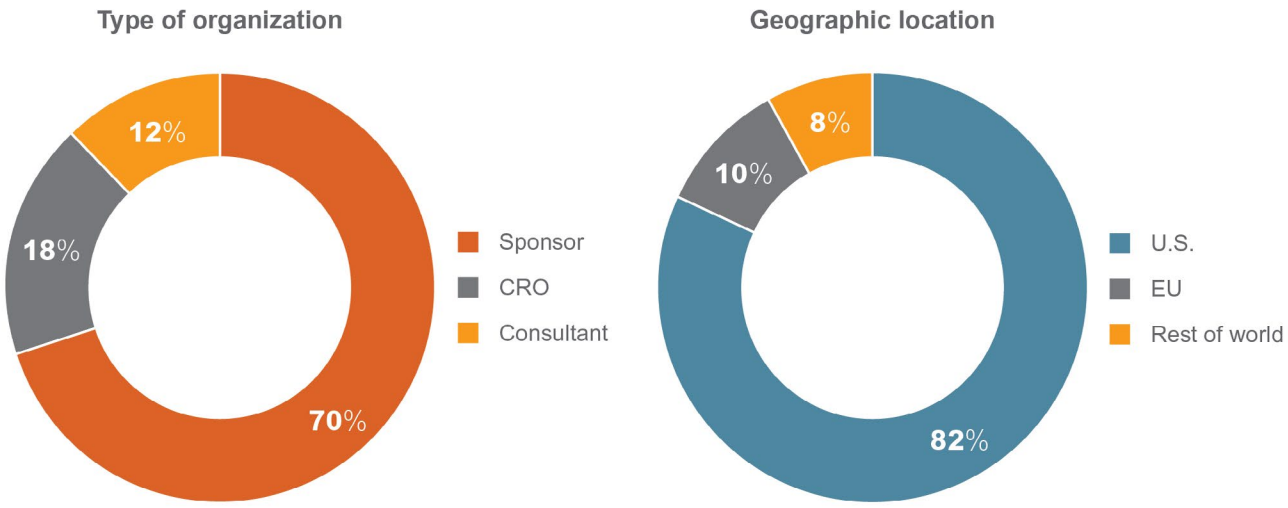
This survey consisted of 17 questions, many of which consisted of sub-questions with response matrices. Survey questions were designed for individuals with knowledge of clinical operations processes and with partial or full responsibility for clinical operations within their organization. This survey 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.

Survey Respondent Demographics

Base: Respondents N=331



Contact

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