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New Survey Finds Fragmented Processes and System Silos Slowing Clinical Trials

Sponsors and CROs accelerate move to modernize and speed study execution

PLEASANTON, CA — June 19, 2019 — There is an industrywide drive to streamline trial processes and systems for better study visibility and collaboration, according to the *Veeva 2019 Unified Clinical Operations Survey*, one of the largest-ever surveys of clinical operations professionals.

New research from Veeva Systems (NYSE:VEEV) finds that all (100%) respondents surveyed report the need to improve information exchange among study partners. On average, they utilize at least three methods to share trial data and documents among sponsors, CROs, and sites, with email as the primary tool. Majorities say the move to streamline information exchange is driven by the need to reduce manual processes (71%), improve collaboration (66%), and increase visibility and oversight (64%) during trials.

Nearly all sponsors and CROs (99%) say they also need to unify clinical applications for greater visibility (70%) and easier collaboration (61%). Many of the challenges in managing trials stem from siloed processes and systems that prevent a complete view of study progress and slow trial execution. Integration (68%) and reporting (57%) are the top two issues cited – both are the direct result of clinical system silos.

Improving Study Start-up to Speed Trial Execution

Study start-up is one of the clinical areas with the most potential to improve trial efficiency and speed. All respondents report significant challenges with study start-up, likely due to the heavy reliance on manual processes since most (81%) use spreadsheets to manage this area.

Sponsors and CROs are increasingly adopting purpose-built study start-up applications to speed cycle times. Nearly one-quarter (23%) of respondents are now using newer, purpose-built study start-up applications.

Findings show that the majority cite faster study start-up times (71%) as the primary driver to improve study start-up processes. Half of respondents (50%) say easier collaboration during study start-up is also an area of improvement, highlighting the importance of collaboration in driving clinical trial efficiency and speed.

Steady Adoption of Advanced Clinical Applications

Over the past several years, sponsors and CROs have steadily adopted function-specific applications to improve study execution. The industry is modernizing its processes and systems in major clinical areas such as eTMF and are seeing positive impact. Sponsors and CROs, however, report challenges in other areas such as CTMS because of the prevalence of legacy systems.

Nearly all respondents (95%) say they need to improve the use of CTMS in clinical operations. For most, better analytics and reporting (68%) and increased visibility (60%) are among the primary reasons. Roughly half of sponsors and CROs (48%) also say easier collaboration is a top driver, underscoring the importance of streamlining communication and information sharing during execution.

The number of respondents using purpose-built eTMF applications has tripled since 2014. At the same time, the use of general-purpose methods to manage TMF processes has decreased, indicating the continued move from TMFs that act as static repositories to store and archive documents upon completion to modern purpose-built eTMF applications that enable more ‘active’ trial management. Those using purpose-built eTMF solutions report improved ability to maintain a constant state of inspection-readiness (60%) and visibility into TMF status (58%).

“There is a significant industrywide opportunity to improve study visibility and partner collaboration to speed trial execution,” said Jim Reilly, vice president of Vault Clinical. “As more sponsors, CROs, and sites focus on streamlining clinical processes and systems, drug development will become more efficient and stakeholders will be better aligned throughout the trial lifecycle.”

The *Veeva 2019 Unified Clinical Operations Survey* examines the life sciences industry’s progress toward a unified clinical environment by gathering the experiences and opinions of 461 clinical operations professionals from around the globe. The annual research examines the drivers, barriers, and benefits of a unified clinical operating model and tracks the industry’s progress in its move to unify clinical systems and processes and align stakeholders throughout study execution.

The full results of the *Veeva 2019 Unified Clinical Operations Survey* will be presented at the DIA 2019 Annual Meeting on June 24 at 1:00 p.m. in Innovation Theater 1 in the exhibit hall. The full report is available online at veeva.com/ClinicalSurvey.

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Forward-looking Statements
This release contains forward-looking statements, including the market demand for and acceptance of Veeva’s products and services, the results from use of Veeva’s products and services, and general business conditions, particularly in the life sciences industry. Any forward-looking statements contained in this press release are based upon Veeva’s historical performance and its current plans, estimates, and expectations, and are not a representation that such plans, estimates, or expectations will be achieved. These forward-looking statements represent Veeva’s expectations as of the date of this press announcement. Subsequent events may cause these expectations to change, and Veeva disclaims any obligation to update the forward-looking statements in the future. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially. Additional risks and uncertainties that could affect Veeva’s financial results are included under the captions, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in the company’s filing on Form 10-Q for the period ended April 30, 2019. This is available on the company’s website at veeva.com under the Investors section and on the SEC’s website at sec.gov. Further information on potential risks that could affect actual results will be included in other filings Veeva makes with the SEC from time to time.

Research Highlights
Veeva 2019 Unified Clinical Operations Survey

The *Veeva 2019 Unified Clinical Operations Survey* examines the life sciences industry's progress toward a unified clinical environment by gathering the experiences and opinions of 461 clinical operations professionals from around the globe. The annual research examines the drivers, barriers, and benefits of a unified clinical operating model and tracks the industry's progress in its move to unify clinical systems and processes and align stakeholders throughout study execution.

Unifying Clinical Processes for Better Visibility and Collaboration

- Standalone, eClinical applications, including EDC (88%), eTMF (69%), and CTMS (61%) are now utilized by most companies as sponsors and CROs steadily adopt function-specific technologies to run clinical trials.
- Nearly all (97%) respondents say they have at least one major challenge with their clinical applications, and more than three-quarters (83%) have two or more challenges.
- The top two issues – integrating multiple applications (68%) and reporting across multiple applications (57%) – are the direct result of clinical application silos.
- Nearly all respondents (99%) say they need to unify their clinical trial systems and processes. Main drivers include better visibility (70%), faster study execution (63%), easier collaboration (61%), and improved study quality (56%).

Improving Information Exchange Among Partners a Priority

- All respondents (100%) report the need to simplify information exchange in clinical trials between sponsors, CROs, and sites. The primary drivers are reducing manual processes (71%), improving collaboration (66%), and increasing visibility and oversight (64%).
- On average, sponsors and CROs use three methods for information exchange, and one-quarter (25%) use at least four methods. Email is the predominant way sponsors exchange information with CROs (78%), followed by portals (51%), file share (51%), and eTMF applications (38%).
- The majority (96%) of respondents say they have significant challenges with the methods used to exchange information during clinical trials. Tracking and reporting (71%), misfiled or missing documents (56%), and manual document exchange (47%) are the biggest challenges with information exchange.

Accelerating Study Start-up to Speed Execution

- All respondents (100%) report challenges with the study start-up process. Almost three-quarters (73%) say site contracting and budgeting is one of the most challenging study start-up processes, followed by site identification and selection (49%) and IRB/ethics committee approval and planning (42%).
- More than half of respondents cite faster study start-up times (71%), streamlined site contracting and budgeting (60%), and better site feasibility and selection outcomes (52%) as primary drivers to improve study start-up processes. Half of survey respondents (50%) say easier collaboration between sponsors, CROs, and sites is essential to improve study start-up.
- Most (81%) use spreadsheets to manage study start-up, followed by CTMS (38%), eTMF (35%), internally developed applications (29%), and online survey tools (25%). Nearly one-quarter (23%) now have adopted newer, purpose-built study start-up applications.

Streamlining TMF Processes and Trial Management to Improve Performance

- The number of sponsors and CROs using an eTMF application has tripled since 2014. More than half (56%) now use a purpose-built eTMF application, versus 17% in 2014.
- The increase in the use of eTMF applications is matched by a sharp decline in the use of content management systems, signaling a shift away from general-purpose methods where TMFs act as static repositories, to modern purpose eTMF application that enable more 'active' trial management. Today, only 8% use content management systems for TMF management, versus 31% in 2017.
- Those using active purpose-built 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).
- Nearly all sponsors and CROs surveyed (90%) say they have at least one major challenge with their CTMS applications, and three-quarters (74%) report two or more challenges. Integrating CTMS applications with other clinical systems (63%) and study performance metrics and reporting (53%) are the most frequently cited challenges.
- One-third say challenges with CTMS applications limit efficiency across key clinical trial management processes, including monitoring (38%), resource management (36%), and issue and task management (31%).
- Nearly all (95%) report the need to improve the use of CTMS in clinical operations. A majority cite better analytics and reporting (68%), increased visibility (60%), and proactive risk identification and mitigation (58%) among the primary reasons to improve CTMS. Almost half of sponsors and CROs (48%) say easier internal and external collaboration is a top driver to improve clinical operations.

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