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Industry Survey Shows 87% of Clinical Operations Leaders Taking Action to Unify Clinical Processes

Better visibility and improved study execution are top drivers;
organizations moving to next-generation clinical applications

BOSTON — DIA 2018 Annual Meeting — June 25, 2018 — Over the past year, there has been significant industrywide momentum toward streamlining clinical systems and processes, according to one of the largest annual life sciences surveys of clinical operations professionals from Veeva Systems (NYSE:VEEV).

The latest findings of the *Veeva 2018 Unified Clinical Operations Survey* reveal that nearly all (99%) clinical leaders surveyed cite the need to unify their clinical environment. Most (87%) report their organizations are taking action with initiatives planned or underway to unify their clinical operations for improved trial performance.

Consistent with the industry's focus to advance operational performance, many have also made progress modernizing their clinical processes with the adoption of purpose-built applications in key areas. Most notably, the number of organizations that have adopted eTMF applications has quadrupled since 2014, and a majority of respondents (83%) say they have, or plan to have, programs to improve study start-up processes.

End-to-End Visibility, Faster Trial Execution Among Top Needs

Standalone eClinical applications, including EDC, CTMS, and eTMF, are now the norm as sponsors and CROs have steadily adopted function-specific clinical technologies. Application silos are contributing to the industrywide move to unify the clinical operations landscape. Sponsors and CROs say integrating multiple applications (74%) and managing content and data (56%) across them are among the top challenges with their clinical applications.

Findings indicate that disconnected applications hinder the ability to get a full view of clinical trial processes and slow execution. Better visibility and oversight is the primary driver for unifying clinical applications for 77% of respondents, followed by faster study execution (67%) and improved study quality (62%). With a unified clinical environment, organizations can streamline collaboration across study partners and ensure all parties are working within complete end-to-end trial processes.

Consistent use of standardized metrics and KPIs to measure trial performance is one of the greatest areas of opportunity for improving clinical operations. Data shows that those extensively using standardized operational metrics and KPIs report fewer challenges across key trial processes, including study performance metrics and reporting (44% versus 66%, respectively) and visibility into TMF status (32% versus 45%, respectively).

Modernization of Trial Processes Underway

The industry is advancing its processes and systems in major clinical areas such as eTMF and study start-up to impact visibility, collaboration, and compliance, yet significant opportunities remain to further improve efficiency in other operational areas, including CTMS.

Adoption of eTMF has grown significantly and is now the second most commonly used clinical system at 66%. At the same time, the types of eTMFs used has also changed dramatically. Half of sponsors (50%) now have a purpose-built eTMF application versus 13% in 2014. This increase was matched by a sharp decline in the use of general purpose content management systems and file shares. This signals a shift away from passive TMF management toward a mature, active TMF operating model where TMF processes and information are managed in real-time. These active TMF solutions have a

positive impact on inspection-readiness and trial performance.

Organizations are also looking at upstream process improvements as an area of significant potential, focusing on study start-up processes and leveraging study start-up applications as major priorities. Top drivers for moving to purpose-built study start-up applications include faster study start-up times (63%), improved site feasibility and site selection outcomes (48%), and better visibility into site performance (44%).

Respondents also cite the need to improve their CTMS as 84% say it is a limiting factor in trial operations. Most have CTMS applications that cannot fully support a range of key functions, including governance and oversight (89%), resource management (88%), and issue and task management (86%). They see improving the CTMS as a way to gain greater visibility (70%), more proactive risk mitigation (65%), and improved study analytics and reporting (61%).

“The life sciences industry sees a significant opportunity to run far more efficient and effective trials,” said Jennifer Goldsmith, senior vice president of Veeva Vault. “As organizations continue down the path toward a unified operating model, trial processes will be transformed for greater visibility and improved trial execution across the clinical lifecycle.”

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 research examines 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.

The full results of the *Veeva 2018 Unified Clinical Operations Survey* will be presented at the DIA 2018 Annual Meeting on June 26 at 9:45 a.m. in innovation theater #2 in the exhibit hall. The report is also available online at veeva.com/ClinicalSurvey.

Additional Information
For more on *Veeva 2018 Unified Clinical Operations Survey*, visit: 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, 2018. 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 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. One of the largest annual life sciences surveys of its kind, this research examines 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.

Industrywide Momentum to Unify Clinical Processes

- Nearly all respondents (99%) report the need to unify their clinical trial operating environments, and 87% have or plan to have an initiative underway to unify their clinical operations for improved trial performance.
- The top drivers for unification are to improve visibility and oversight (77%), enable faster study execution (67%), and improve study quality (62%).
- An average of four applications are used to manage their clinical studies, and more than one-third (38%) use at least five applications.
- Integrating multiple applications (74%) is the top challenge resulting from application and process silos, followed by reporting across multiple applications (57%), and managing content and data across applications (56%).
- Clinical applications are now the norm, with EDC (90%), eTMF (66%), RTSM (61%), and CTMS (60%) as the most commonly used applications.
- Those extensively using standardized operational metrics and KPIs to measure clinical trial performance, manage risks, and implement process improvements report fewer challenges across key trial processes, including study performance metrics and reporting (44% versus 66%, respectively) and visibility into TMF status (32% versus 45%, respectively).
- Organizations using metrics are four times more likely to have programs underway to unify their clinical applications than those not using metrics (47% versus 12%, respectively).

Increased Industry Adoption of eTMF Applications

- Half of sponsors now use a purpose-built eTMF application, nearly four times the number since first measured in 2014 (13%).
- The increase in use of purpose-built eTMF applications is matched by a 57% decrease in the use of general-purpose content management systems. This signals a shift away from a passive TMF operating model toward active solutions characterized by the ability to manage TMF processes and information in real-time as the TMF is being generated.
- Organizations' primary drivers for using purpose-built eTMF applications are improved inspection readiness (70%), better visibility (61%), and improved collaboration across study partners (42%).

Opportunity to Improve Clinical Performance

- Nearly all respondents (99%) cite issues when asked about their most challenging clinical trial management processes, including study performance metrics and reporting (51%), study and site management (49%), and resource management (45%).
- All respondents say they want to improve use of CTMS in their trial operations, with the top drivers being greater visibility (70%), more proactive risk mitigation (65%), and improved study analytics and reporting (61%).
- A majority of respondents (84%) report significant deficiencies with their current CTMS

applications, with almost all highlighting the inability to fully support key functions like governance and oversight (89%), resource management (88%), and issue and task management (86%).

Streamlining Study Start-up a Top Priority

- A key finding reveals that streamlining study start-up processes is gaining traction, with 83% of respondents reporting their organizations have a study start-up improvement initiative underway.
- 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 and ethics committee planning and approval (45%), and site identification and selection (41%).
- More than half of respondents (63%) cite faster study start-up times as the primary driver 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%).

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Contact:
Roger Villareal
Veeva Systems
925-264-8885
roger.villareal@veeva.com

Lisa Barbadora
Veeva Systems
610-420-3413
pr@veeva.com