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Industry Survey Reveals 99% of Clinical Operations Leaders Report the Need to Unify Their Clinical Applications

Majority cite faster study execution and improved study quality as key drivers

CHICAGO — DIA 2017 Annual Meeting — June 19, 2017 — There is an industrywide drive toward a unified clinical operating model, according to the Veeva 2017 Unified Clinical Operations Survey, one of the industry’s largest annual surveys of clinical operations professionals. The new research from Veeva Systems (NYSE: VEEV) reveals that nearly all respondents cite the need to unify their clinical applications, including EDC, CTMS, and eTMF. More than 60% say faster study execution and improved study quality are the top drivers toward a unified clinical model, which is characterized by end-to-end processes and systems, visibility across the clinical lifecycle, and modern information systems.

Streamlining Clinical Systems and Processes

Many of the challenges sponsors face today in managing clinical trials stem from the disparate nature of their processes and systems. Respondents use an average of four applications to manage their clinical studies and more than one-third use at least five applications. The most commonly used applications are EDC and CTMS (81% and 59% respectively).

Nearly all survey respondents have at least one major challenge with their clinical applications and the top two challenges – integrating multiple applications (69%) and reporting across applications (61%) – are a direct result of system silos. Half of sponsors say issues integrating their EDC or eTMF applications with CTMS limits their organization’s ability to improve clinical operations.

Companies also say their current clinical systems are hard to use (46%) and lack the ability to support collaboration (33%). Usability and accessibility issues likely contribute to the difficulties one-third say they face with data being tracked outside of their clinical systems.

Half of respondents also cite better study visibility as one of the most important drivers for unifying the clinical landscape, especially given the challenges most have with reporting across multiple applications. The ability for companies to collect and leverage operational data throughout the clinical lifecycle has a direct impact on improving efficiency and execution in clinical operations.

Transitioning to Modern Information Systems

Companies have started on a path to unified clinical enabled, in part, by the introduction of newer, more advanced applications and platforms. Trial master file (TMF) management is one of the first areas to experience rapid transformation. Over the past four years there has been a major shift as one in three (31%) sponsors now use an advanced eTMF application, more than double the number in 2014.

The transition toward modern, purpose-built eTMF applications and ‘active’ TMF management – the ability to manage information and processes in real-time as the TMF is being generated – is delivering greater benefits than ‘passive’ first-generation local file systems and cloud file shares. More than three-quarters (79%) of sponsors report improvements in inspection readiness after implementing an active eTMF application. Modern eTMF applications also significantly improve activities key to unifying clinical operations and better managing the growing volume and complexity of clinical trials, including visibility into key study performance metrics.

There is also a significant shift underway in clinical trial management as life sciences companies expect to increase their CTMS investments by almost 15% each year through 2020. This is being driven by rising demand for data and site collection solutions and the availability of next-generation
CTMS applications. This is not surprising, given that nearly all sponsors (98%) say challenges with their current CTMS applications are limiting their ability to improve clinical operations. Among their biggest issues are their inability to fully support resource management (77%), study and site feasibility (76%), financial management (75%), and issue/task management (73%).

“The industry’s transition toward a unified clinical environment is being driven by its need to address the silos legacy systems have created,” said Jennifer Goldsmith, senior vice president of Veeva Vault. “Life sciences companies are taking steps to streamline their end-to-end processes and systems with modern applications so they can execute faster and improve visibility across their study portfolios.”

The Veeva 2017 Unified Clinical Operations Survey examines the life sciences industry’s progress toward a unified clinical environment by gathering the experiences and opinions of 300 clinical operations professionals from around the globe. Evolved from the annual Veeva Paperless TMF Survey, this research examines the drivers, barriers, and benefits of a unified clinical operating model and tracks the move to streamline clinical systems and processes.

The full results of the Veeva 2017 Unified Clinical Operations Survey will be presented at the DIA 2017 Annual Meeting on June 20 at 9:45 a.m. in innovation theater #1 in the Exhibit Hall. The report is also available online at veeva.com/ClinicalSurvey.

In related news today, Veeva announced that Veeva Vault CTMS is gaining momentum as customers drive toward a unified clinical operating model. Within just two months of the product’s release, five customers, including a top 50 global pharmaceutical company, are implementing Veeva Vault CTMS. In more news, Regeneron Pharmaceuticals (NASDAQ: REGN), is standardizing on Veeva Vault Submissions and Veeva Vault eTMF to further streamline clinical and regulatory operations.

Additional Information
For more on Veeva 2017 Unified Clinical Operations Survey, visit: veeva.com/ClinicalSurvey
For more on Veeva Vault Clinical Suite, visit: veeva.com/Clinical
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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, 2017. 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.

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