



NEWS RELEASE

# Global Life Sciences Survey Reveals Significant Improvements in Inspection Readiness Among CROs

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CROs leading industrywide drive to improve the efficiency and speed of clinical trials

BOSTON--(BUSINESS WIRE)-- Outsourcing in Clinical Trials New England – **Veeva Systems** (NYSE:VEEV) today unveiled the results of the **Veeva 2016 Paperless TMF Survey: CRO Report**. The global industry survey of trial master file (TMF) owners shows growing use of electronic trial master file (eTMF) solutions among clinical research organizations (CROs) as a result of benefits in audit and inspection readiness. In addition, findings reveal that CROs are leading the drive toward active TMF management and making strides in the use of performance metrics and data to improve the efficiency and speed of clinical trials.

## eTMF Solutions Significantly Improve Inspection Readiness

eTMFs are helping CROs to maintain complete and accessible trial master files to reduce the number of inspection findings. CROs who use eTMF applications are achieving significant improvements across major inspection finding categories such as fewer duplicate documents (61%), misfiled documents (53%), and incomplete documents (51%).

Given these benefits, one of the top drivers of eTMF adoption among a majority of CROs (65%) is improved audit and inspection readiness. At the same time, CROs are now less reliant on document exchange methods that are more difficult to track and provide little to no audit trail. For example, the use of email for document exchange is down significantly from 80% in 2014 to 61% today, while almost a third (31%) are using an eTMF application to share TMF documents with sponsors (up from 24% in 2014).

## CROs Leading Transition to Active TMF Management

With a focus on improving inspection readiness, CROs are shifting to an active TMF management approach, a trend that has increased since the first Veeva Paperless TMF Survey in 2014. In active TMF management, purpose-built eTMF applications manage documents and processes in real-time as the TMF is being generated and provide global access for stakeholders. Conversely, in passive TMF management, TMF documents are simply stored and archived in file systems and other static repositories at the end of a trial rather than as part of the trial workflow.

Nearly one-third of CROs (30%) now use purpose-built eTMF applications that enable active TMF management, up from 21% in 2014. At the same time, there was a significant drop in the use of passive eTMF systems, including cloud file shares (9% in 2016 vs. 21% in 2014) and local file systems (16% in 2016 vs. 26% in 2014). In addition, CROs have significantly reduced the amount of TMF documents managed on paper, with less than a quarter (22%) reporting that most to all TMF documents are managed on paper (down from 47% in 2014).

## eTMFs Provide Better Visibility into TMF Performance

Another key driver of eTMF adoption among a majority of CROs (57%) is improved visibility into performance metrics. CROs are not only capturing metrics but also making large strides in putting the data to use, with a quarter of CROs (24%) now extensively using TMF data to improve trial processes (up from 16% in 2015) and another 46% leveraging data in some cases (up from 40% in 2015).

In terms of other key benefits of eTMF adoption, 44% of CROs find that they have better visibility into performance metrics. In addition, a majority of CROs have achieved significant improvements in central and remote auditing (56%) and automated tracking and reporting of documents (56%), both of which are key in providing timely and accurate status updates to sponsors.

“Over the past several years CROs have played a pivotal role in moving the life sciences industry toward more efficient clinical trial processes,” said Jill Johnston, vice president of Veeva Vault Clinical. “As clinical trials become increasingly outsourced, we’ll see that trend continue especially as demand grows for unifying systems, processes, and stakeholders across clinical operations.”

To hear the full results of the Veeva 2016 Paperless TMF Survey: CRO Report, see Veeva’s presentation at the Outsourcing in Clinical Trials New England conference on September 7 at 3:15 p.m. Conference attendees can also visit Veeva booth #7 for a copy or **download it here**.

## Survey Methods

The Veeva 2016 Paperless TMF Survey: CRO Report consisted of 13 questions, many of which included sub-questions with response matrices. Survey questions were designed for individuals with knowledge of TMF

document processes and with partial or full responsibility for a TMF within their organization. The survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and a \$5 donation was made to Doctors Without Borders for each valid completion of the full survey. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

## Additional Information

For more on Veeva Vault eTMF, please visit: [veeva.com/etmf](http://veeva.com/etmf)

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## About Veeva Systems

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 450 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit [veeva.com](http://veeva.com).

## 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, 2016. This is available on the company's website at [veeva.com](http://veeva.com) under the Investors section and on the SEC's website at [sec.gov](http://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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Veeva Systems

Roger Villareal, 925-264-8885

**roger.villareal@veeva.com**

or

Lisa Barbadora, 610-420-3413

**pr@veeva.com**