NEWS RELEASE

New Research Shows Clinical Operations Moving to Electronic Processes, Industry on the Path to the Paperless Trial

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Industry-wide survey shows eTMF applications improve inspection readiness and seen as key to shortening development time

WASHINGTON--(BUSINESS WIRE)-- New research shows life sciences organizations are increasing their use of advanced electronic trial master file (eTMF) applications and clinical operations departments are moving away from paper processes in managing their trial master file (TMF). Some business processes have been slower to make the move from paper, but TMF owners say barriers to conversion are low and increased use of electronic processes could speed time to market.

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These are some of the findings of the **Veeva 2015 Paperless TMF Survey: Annual Report**, released today at the Drug Information Association's (DIA) Annual Meeting. The global study of TMF owners found a striking reduction in paper used by clinical operations since 2014. Today, 31% of respondents are managing "most or all" TMF documents on paper, down 12 percentage points from 43% last year.

One in four respondents now report using eTMF applications to exchange TMF documents between sponsors and CROs, up nine percentage points from 2014. With the use of more advanced technology, trial sponsors and contract research organizations (CROs) are now relying considerably less on paper shipments and fax to exchange documents with sponsors, both down 10 percentage points in just one year.

“ClinOps is responsible for more than half of all documents in the TMF; therefore, their move off of paper is vital,” said Jennifer Goldsmith, vice president of Veeva Vault at Veeva Systems. “After moving to an electronic format, the next phase is implementing electronic processes. Not surprisingly, the first advances are in sponsor-CRO collaboration, which has been a significant pain point for many companies. When we look at the transformation in sponsor-CRO document exchange, we see significant, measurable progress.”

However, there is considerable variation in the adoption of eTMF processes. Less than one third of respondents are “mostly or always” using electronic methods for e-signature of documents (21%), electronic creation of source documents (25%), and electronic collaboration with external partners (30%).

The majority of respondents see benefits to shifting additional activities to electronic processes. For instance, 63% of those surveyed said they believe managing TMF filing in an eTMF would shorten development time, while 57% believe managing study/site start-up in an eTMF would shorten development time.

Given the growing expectations from health authorities like the Medicines and Healthcare Products Regulatory Agency (MHRA) around inspection readiness and TMF accessibility, the survey provides some positive indicators. Half of all eTMF users (49%) and 61% of those using eTMF applications cited improvements in inspection readiness due to using an eTMF. Users of eTMF applications are also more than twice as likely (57%) to grant auditors and inspectors remote access to the TMF than respondents as a whole (26%). Two-thirds (65%) of all respondents expect to grant remote access within the next two years.

The survey found only a small number of organizations (14%) are extensively using TMF data to improve trial processes. But as an increasing number of clinical documents are managed electronically, the use of metrics to improve study processes is expected to rise. Organizations that use eTMF applications or content management systems are more than twice as likely to extensively use metrics than those using less advanced cloud file share and local file systems.

“Despite reports that eTMF metrics lead to critical study process improvements, Veeva’s 2015 study reveals that most companies are still not actively using metrics,” said Linda Sullivan, chief operating officer of Metrics Champion Consortium, an association dedicated to standardized performance metrics. “As more data is collected over time and across multiple trials, it will be possible to identify important trends about study performance. The eTMF can inform business decisions by capturing an array of quality, performance, and operational metrics, internally and externally, across multiple sites and studies.”

The full results of the Veeva 2015 Paperless TMF Survey: Annual Benchmark will be presented at the DIA Annual Meeting on Tuesday, June 16 at 1 p.m. EDT in the Innovation Theater. DIA attendees can also visit Veeva’s booth,

#1203, for a copy of the executive summary. The report is also available online at **veeva.com/2015tmfsurvey**.

Additional Information:

- Access the Veeva 2015 Paperless TMF Survey: Annual Report at: **veeva.com/2015tmfsurvey**.
- For more on Veeva Vault eTMF, please visit: **veeva.com/etmf**
- Stay updated on the latest Veeva news on LinkedIn: **www.linkedin.com/company/veeva-systems**
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About Veeva Vault

Veeva Vault is the first cloud-based regulated content management platform and suite of applications designed for life sciences. It spans clinical, quality, commercial, medical, and every major part of a global life sciences company to ensure one trusted source for content and data across the enterprise. Helping companies connect securely in the life sciences cloud, Vault provides complete control from start to finish, as well as the easy accessibility, visibility, and agility needed to speed time to market. All Vault applications offer real-time reporting and dashboards; an intuitive, consumer-web interface; and a true multitenant cloud architecture that continuously delivers rapid innovation. Today, more than 135 customers rely upon Vault to manage critical content and the number of Vaults has grown threefold in just one year.

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 275 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 **www.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, 2015. This is available on the company's website at **www.veeva.com** under the Investors section and on the SEC's website at **www.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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