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Largest-ever TMF Survey Reveals Lagging Technology Adoption and Manual Processes Significantly Impacting Clinical Trial Operations

Research shows advanced eTMF technologies improve inspection readiness and compliance while reducing costs

SAN DIEGO, CA – June 16, 2014 – Today, at the Drug Information Association's (DIA) 50th Annual Meeting, Veeva Systems released the results of the *Veeva 2014 Paperless TMF Survey: An Industry Benchmark*, the largest TMF survey to date. This in-depth study of more than 250 trial master file (TMF) owners found that many (57%) still use paper or simple electronic file systems to manage their TMF. The data also show that those using advanced eTMF technologies experience greater inspection readiness, visibility, SOP compliance, and cost savings from their eTMF than those using local or cloud file systems.

Respondents utilizing more mature technologies, specifically process-driven eTMF applications and content management systems, derive greater benefit from their eTMF. For example, 47% of those with an eTMF application realize cost savings, as compared to only 29% of those using a local file system. TMF quality is also higher, as 81% of those with eTMF applications report good or major improvement in misfiled documents, compared to 62% of local file system users. Yet, today only about one in ten respondents (13%) use an eTMF application to manage their TMF.

The use of paper and electronic file systems to manage the TMF contributes to the industry's continued reliance on manual processes. The survey reveals that email (69%) and paper (57%) remain the predominant means of exchanging trial documents with sponsors/CROs.

"This research confirms not all eTMFs are created equal. Many eTMFs are simple file shares that perpetuate manual processes," said Eldin Rammell, a renowned clinical records management expert and managing director at Rammell Consulting. "In the face of MHRA's updated definition for critical findings, it is encouraging that organizations utilizing eTMF applications are experiencing significant benefits in inspection readiness and business efficiency gains."

Metrics usage is also connected to greater TMF quality and benefits. Nearly half (47%) of those with an eTMF application gain greater visibility into trial performance metrics, versus only a quarter (25%) of cloud file system users. Those extensively leveraging metrics to improve the execution and/or design of trial processes are more than twice as likely to report business improvements from their eTMF than those not using metrics. These advantages include better TMF document quality (63% and 29% respectively), audit readiness (56% and 25% respectively), and increased SOP compliance (49% and 16% respectively).

"Historically, the industry has focused on the rate of eTMF adoption in broad, general terms," said Jennifer Goldsmith, vice president of Veeva Vault. "With this more in-depth look at which specific eTMF technologies, processes, and metrics are used, we gain a comprehensive understanding of what is really driving improvements. Technology is a key aspect, but we now know the use of metrics to optimize trial operations is also having an impact."

There are a number of drivers prompting the move to eTMFs, chief among them are cost savings (56%), faster study start-up (55%), improving remote and central monitoring (49%), and inspection readiness (45%). By contrast, respondents are far less likely to report barriers to going paperless. The most frequently cited barriers (major or insurmountable) are technology costs (38%), implementation costs (33%), and regulatory requirements (28%). While 38% of respondents see cost as a significant barrier to going paperless, an equal number (38%) report cost savings as a benefit of their eTMF.

The top capabilities required to go paperless are digital/e-signatures (66%), e-forms (65%), and secure access for external parties (62%). "It is interesting to note that most of the perceived barriers to eTMF adoption can be resolved using tested and proven technologies companies can implement in a very cost-effective manner," added Rammell.

The largest eTMF study to date, the *Veeva 2014 Paperless TMF Survey: An Industry Benchmark,* examines the current state of eTMF adoption, as well as the benefits, drivers, and barriers to implementing electronic processes. This research builds upon respected surveys conducted by the DIA TMF Reference Model group by providing additional insight into the remaining sources of paper and the types of eTMF utilized—with each question providing a different lens to understanding the industry's journey to a paperless TMF.

The findings from the *Veeva 2014 Paperless TMF Survey* will be presented at the DIA 50th Annual Meeting on Tuesday, June 17 during the 12:45 p.m. PT Innovation Theater session and the "Transforming Culture and Mindsets to Deliver a Higher Quality eTMF" session at 3:30 p.m. PT. Attendees of DIA Annual 2014 can visit Veeva's booth #2240 for a copy of the executive summary. An online edition of the executive summary is available at veeva.com/tmf-survey-2014.

To learn more about the Veeva Vault eTMF application or the Veeva Vault family of content management applications, visit veeva.com/vault.

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 200 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.

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Veeva 2014 Paperless TMF Survey Highlights

The *Veeva 2014 Paperless TMF Survey* explores the life sciences industry's progress toward paperless clinical trials by gathering the experiences and opinions of 252 Trial Master File (TMF) owners. The goal of the research is to understand the impact of growing eTMF adoption as well as the drivers, benefits, and barriers to going paperless. The survey examines the success factors for fully electronic trials and gives an industry-wide view of where organizations fall on the spectrum of paper-based to paperless TMFs. Highlights from the survey include:

Usage of Paper and Types of Electronic Trial Master Files (eTMFs)

- A majority of TMF owners rely on manual processes—paper (57%) or email (69%)—to exchange TMF documents between sponsors and CROs
- Many (57%) use paper or simple file shares to manage their TMF
    - 13% paper
    - 18% cloud file share
    - 26% local file share
- eTMF applications are used by 13% of respondents

Benefits Attributed to eTMF Solutions

- Those using an eTMF application or a content management system achieved a significantly greater number of benefits than those using a local or cloud file system, including:
    - Improved audit and inspection readiness (51% vs. 28%)
    - Cost savings (45% vs. 31%)
    - Better visibility into key trial performance metrics (44% vs. 28%)
    - SOP compliance (40% vs. 21%)

Top Drivers and Barriers to Going Paperless

- Top drivers motivating eTMF owners to go paperless are:
    - 56% cost savings
    - 55% speed study start-up
    - 49% remote and central monitoring
    - 45% audit and inspection readiness

- Few see impediments to going paperless with roughly a third or fewer citing major barriers or barriers that can't be overcome. These included:
    - 38% cost of new technology, yet an equal number (38%) report cost savings as a benefit of their eTMF
    - 33% implementation time and services cost
    - 28% regulatory requirements

Use of Metrics

- Those using metrics extensively to improve trial execution and/or design realize greater benefits from their eTMF than those that do not collect data or utilize metrics, including:
    - Improved document quality/reduced QC findings (63% vs. 29%)
    - Improved audit and inspection readiness (56% vs. 25%)
    - Easier collaboration with sites (54% vs. 32%)
    - Increased TMF SOP compliance (49% vs. 16%)

- Nearly half (47%) of those with an eTMF application gain greater visibility into trial performance metrics compared to a quarter (25%) of those with a cloud file system

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