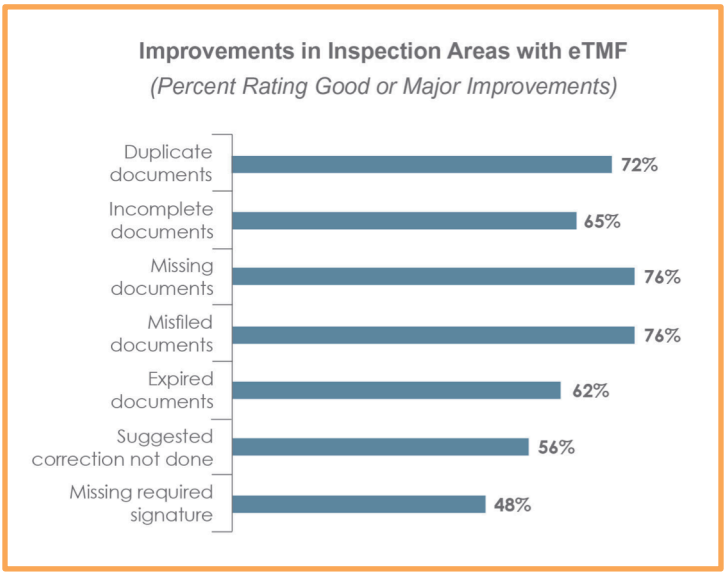
FOR IMMEDIATE RELEASE

Majority of CROs Exchange Regulated Clinical Trial Documents via Outdated, Hard-to-track Methods

New survey signals big opportunity for CROs to create competitive advantage in rapidly growing market

PLEASANTON, CA – Oct. 7, 2014 – The vast majority of contract research organizations (CROs) surveyed lag clinical trial sponsors in how they exchange trial master file (TMF) documents, according to the *Veeva 2014 Paperless TMF Survey: The State of CRO TMFs*. Eight in 10 (80%) CRO respondents report using email and 65% still rely upon paper-based methods to share TMF documentation, whereas a smaller number of sponsors exchange TMF documents via email (64%) and paper (52%). This new research details CROs' progress in moving toward paperless trials and reveals opportunities for managing and maintaining inspection-ready TMFs on behalf of sponsors. The data show those CROs leveraging eTMFs have higher quality and more complete trial master files, noteworthy in a market where CROs contributed to the development of all of the top 20 selling drugs in 2013.[1]

The *Veeva 2014 Paperless TMF Survey: The State of CRO TMFs* also reveals that CROs achieve important strategic advantages when utilizing an eTMF. For example, many CROs report improvements in real-time tracking and viewing of documents (61%), and increased document quality (43%). CROs also see improvements in multiple inspection areas, including reduction of missing (76%), misfiled (76%), duplicate (72%), incomplete (65%), and expired (62%) documents.



R&D outsourcing continues to rise sharply to meet the demands of life sciences organizations' growing pipelines. CROs that operate more efficiently and collaboratively will be better able to partner with sponsors in delivering new and innovative drugs and therapies. "Life sciences companies today are increasingly looking to their research partners to streamline the clinical trial process and facilitate faster time to market," said Jennifer Goldsmith, vice president of Veeva Vault. "CROs today have a tremendous opportunity to distinguish themselves as trusted partners by enabling closer collaboration and strategic process improvements."

Collaboration with external partners is another area where CROs are effectively leveraging eTMFs. CROs surveyed report easier collaboration with sites (45%), other CROs (49%), and institutional review boards and ethics committees (28%). Given the importance of collaboration, 67% of CROs cite secure access for external parties as a key eTMF requirement.

"Veeva's survey results are eye-opening, yet point toward a clear-cut way for all CROs to step up their level of support to sponsors," said Jessica Vicari, director of regulatory support services and document management at Advanced Clinical, a fast growing CRO. "We invested in a cloud eTMF 12 months ago and almost immediately began collaborating more efficiently with sponsors. Our customers also benefit from increased visibility for greater control throughout the trial process, which helps us build trust and foster ongoing relationships."

The full *Veeva 2014 Paperless TMF Survey* showed advanced eTMF solutions, in particular, deliver greater visibility, inspection readiness, SOP compliance, and cost savings over local or cloud file systems. Process-driven functionality and easy, secure cloud access to the eTMF, enables CROs, sponsors, investigator sites, and other partners to more effectively and efficiently work together. All parties benefit from greater visibility throughout the trial, plus sponsors are better prepared for remote or on-site inspection. And health authority inspectors are easily granted access to an eTMF in the cloud without elaborate training or complicated provisioning.

"Increasing demand from U.S. and European health authorities for direct access to TMF documents indicates a growing trend – a move toward in-process inspections by regulatory bodies globally," explained Goldsmith. "The highly accessible nature of the cloud supports this need by allowing all collaborators to upload and access documents in real-time rather than having to go back and reconcile the entire TMF at study close-out."

The top drivers of eTMF adoption among CROs surveyed are cost savings (63%) and speeding study start-up (59%). Some CROs perceive regulatory requirements for wet ink signatures (40%) and institutional review boards and ethics committees' demands (34%) as major/insurmountable barriers to eTMF adoption. These perceptions, however, are likely based on dated notions since all major health authorities now accept electronic signatures. These perceived barriers are out of step with sponsors as well, who are less likely to see regulatory or IRB/IEC requirements as barriers. Only 19% of sponsors report regulatory requirements as a major/insurmountable barrier and only 9% cite IRB/IEC requirements.

About Veeva 2014 Paperless TMF Survey: The State of CROs

The *Veeva 2014 Paperless TMF Survey: The State of CRO TMFs* examines the current state of eTMF adoption among sponsors and CROs, as well as the benefits, drivers, and barriers to implementing electronic processes. This research builds upon respected surveys conducted by the TMF Reference Model group by providing additional insight into the remaining sources of paper and the types of eTMFs utilized.

Additional Information

- For a copy of *Veeva 2014 Paperless TMF Survey: The State of CRO TMFs* report, visit http://www.veeva.com/cro-report.
- To learn about the Veeva Vault family of content management applications including Veeva Vault eTMF and the Veeva Vault Platform, visit veeva.com/vault.
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Forward-looking Statements

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1. Association of Clinical Research Organizations, *Survey Shows Strong CRO Growth,* September 16, 2014. http://www.acrohealth.org/acro-survey-shows-strong-growth-cro-industry/