Streamline Trial Operations with Cloud Opportunities

eTMF applications provide a strategic asset in the drive for greater efficiency in clinical trials.

Jennifer Goldsmith, Vice President, Veeva Vault for Veeva Systems, spoke to *Applied Clinical Trials* about the changes in life sciences technology that are improving increased collaboration. Specifically, companies are taking information out of silos to share documents and data in cloud-based systems. For clinical trials in particular, Goldsmith says rapid adoption of cloud-based solutions provides benefits such as speeding study start-up, improving monitoring, improving inspection readiness and easing collaboration with external global partners.

Jennifer Goldsmith, Vice President, Veeva Vault for Veeva Systems

A recent survey of clinical trials professionals showed mixed opinions on cloud technology and a significant percent admitted being confused by cloud. Can you comment on the results?

The survey shows that people continue to find the cloud and the term cloud confusing. When Veeva says cloud, we are really talking about multi-tenant Software as a Service (SaaS). But there is confusion because some use the term cloud when in actuality they are simply systems hosted in a different location.

Multi-tenant SaaS has many benefits over hosted systems, including software that is always up-to-date, with the most current capabilities. It also is possible to avoid massive upgrade processes that are seen with on-premise systems.

The leading response from 34% of the respondents was that they viewed cloud as cost-effective. This is important because cloud is the ultimate democratization. Cloud allows small- and medium-sized businesses to adopt enterprise quality technology that they could not afford in the past. So it brings the best capabilities to companies of all sizes within the life sciences industry.

How can cloud improve trial operations?

One of the greatest challenges facing the clinical trials area is the ability for sponsors, investigators, and CROs to work together in a collaborative environment—without needing to exchange information via overnight documents to multiple locations, or waiting for information to come at the end of the study. Cloud can really improve collaborative business processes.

Collaboration breaks down when there are separate systems for exchanging and managing TMF documents. Some companies have a portal that allows them to exchange information with investigators and CROs and then they have a separate and distinct content management system to manage that information as it comes into the electronic Trial Master File (eTMF). We created an investigator portal that extends the eTMF itself, so when investigators at the site upload a 1572 or CV in the portal that information is being routed directly into the eTMF without an interim step.

How can organizations begin to turn their eTMF into a strategic asset?

There are important steps to take to leverage the eTMF as a strategic asset. First and foremost is to get the information and the processes electronic. Some organizations are still working with paper-based processes and scan-to-digital for filing. Electronic information opens a new world of capabilities–whether searching for information or automating manual steps, electronic is critical. If your information is not electronic throughout the collection, QC and monitoring processes, then your eTMF isn't generating the data it needs to deliver strategic insights.

Step two involves collaborative pro-

cesses. Since work spans sponsors, CROs, and investigators, the electronic processes or workflows should span all three parties as well. Traditionally, documents are managed in one or more repositories, exchanged via email or FedEx, and tracked in spreadsheets. It is impossible to have efficient operations when collaboration is splintered across separate systems. When the eTMF provides all three functions—document management, exchange, and tracking—across all three parties, you see a huge leap in productivity.

The third step in the process is creating a repeatable framework. Companies should establish a common understanding of what's needed, what's it called, who provides it, and when. This blueprint gets built into the eTMF and keeps everyone working to a common goal.

Also, a repeatable framework supports repeatable processes. This means that companies can operationalize their SOPs, not just follow written SOPs. Many of us have had to read and understand SOPs throughout the course of our career, and many of us can say that those SOPs, once read and understood, went into a drawer that nobody looks at until the next time you have to verify that you have read and understood those SOPs. By operationalizing that process in the form of a workflow or automated business process, it helps people work seamlessly with one another, and ensures that they are following a common process.

The final piece in leveraging the eTMF as a strategic asset is around metrics. Measuring performance is absolutely critical when driving process improvements. This requires defining the right metrics and ensuring they are reflected in the eTMF system workflows and reports. This allows companies to garner new information specific to how a process runs, and how efficiently it runs. The information can also be strategic, for example, to identify which sites are better for which therapeutic areas, which sites have faster study start-up and why, and which service providers can the sponsor work with most effectively.

How can organizations make the most of their eTMFs?

An eTMF represents an opportunity for clinical organizations to gain three things: better access, better visibility, and better control of their information. These high-level concepts have a wide-ranging impact on the clinical trials process overall, such as speeding site and study start-up. Visibility, access, and control also impacts and improves inspection readiness. Inspection readiness has been a hot topic because in paper-based environments, it's incredibly difficult to determine what is or isn't inspection ready. It takes a lot of time and manual effort to track what's complete, what's missing, and to correct mistakes. TMF applications on the other hand provide real-time visibility into overall inspection readiness. Also, in terms of auditing, eTMFs can support remote auditing of information. We are seeing this as a growing trend for regulatory agencies globally. The MHRA, for example, has stated a preference for remotely auditing the trial master file.

Can you describe Veeva Vault?

Veeva Vault is the first cloud-based content management system for regulated content. Built from the ground up for the life sciences industry, it supports 21CFR Part 11 compliance, Annex 11 compliance, and GxP-related requirements. We also built a suite of applications serving the most content-intensive areas of the business—everything from eTMFs in the clinical space, to regulatory submissions in the R&D space, to SOPs and batch records in the quality and manufacturing space; and even to medical affairs and promotional materials on the commercial side of the house. This is the first time that a software company has built both the platform and applications for life sciences content, and there is unprecedented control when you can manage documents from end-to-end across the enterprise.

VEEVA SYSTEMS

Veeva Vault eTMF improves trial efficiency by giving both sponsors and CROs secure access to documents and status reports throughout the study duration. With Vault eTMF, you create, exchange, and update all documents in one location: the cloud.

Vault Investigator Portal speeds collection of all trial-related content through a single interface that is a part of Vault eTMF. Veeva's multi-study model brings sponsors, sites, and CROs together for more efficient collaboration and population of the eTMF.

Veeva is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence and customer success, Veeva has over 170 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Founded in 2007, Veeva is headquartered in the San Francisco Bay Area, with offices in Philadelphia, Barcelona, Budapest, London, Paris, Beijing, Shanghai, Osaka, Tokyo, Sydney, and Singapore.

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