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Survey: Electronic Processes Increasingly Replacing Paper In Clinical Trials

By [Ed Miseta](#), Chief Editor, Clinical Leader
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Veeva Systems has released the results of its latest survey on the use of electronic processes in clinical operations. The results of *Veeva 2015 Paperless TMF Survey: Annual Report*, released during the Drug Information Association's (DIA) annual meeting, show the industry continuing to move towards a more paperless clinical trial environment.

The global study of TMF (trial master file) owners found a striking drop-off in the use of paper. In its 2014 survey, 43 percent of TMF owners reported most or all their TMF documents were managed on paper. In the 2015 report, that figure fell to just 31 percent. The survey also found that both sponsor companies and CROs were relying less on paper shipments and faxes (down 10 percent and 12 percent, respectively). At the same time, the number of companies leveraging purpose-built eTMF applications to exchange TMF documents increased by 9 percent.

Jennifer Goldsmith, VP of Veeva Vault, states she has observed these trends in the industry anecdotally, but was happy to see that trend play out in the survey numbers as well.

"We were pleased to see more companies moving away from paper to manage their TMF files, but equally thrilled to learn they were also using less paper to exchange TMF documents," she says. "We felt these were really big trends, especially the results around the electronic component. The increased use of purpose-built eTMF applications shows companies are doing their research, and not just purchasing a generic document management or email management system. Twenty-four percent of respondents are now using this type of system, and we expect that trend to continue to grow and gain momentum in the coming years."

Jennifer Goldsmith, VP of Veeva Vault

When talking to users about eTMF systems, it does not take long to realize that not everyone defines it the same way. Some individuals believe that if they scan all of their TMF documents, and store them electronically, they have an eTMF system in place. Most users know an actual eTMF would allow you to do much more. The Veeva survey took the additional step of digging a little deeper to determine if a system is electronic in terms of its process. In other words, does it have the electronic workflow, and is the process being managed in electronic formats? The survey found many TMF processes remain heavily paper-based, with the electronic component coming in only with regard to the archiving function.

"Companies that do not have a complete eTMF system in place are reporting adoption of electronic components of some key processes," says Goldsmith. For example, 59 percent of respondents reported performing electronic archiving of documents. Another 21 percent reported using e-signatures, 25 percent are creating documentation electronically, and approximately 30 percent are collaborating electronically. Essentially, last year we saw a shift in the medium of the information, but this year we are beginning to see a shift in how information is managed."

True eTMF does not simply mean you end up with an electronic document on the back end. eTMF means the entire TMF process is somehow be managed electronically. This is a challenge that many eTMF vendors face when trying to educate users on the benefits of an electronic system. Goldsmith believes more users now understand the process needs to be electronic, and that they can end up with much more than an electronic archive at the end of the process.

"Managing the process electronically will lead to significant benefits that users can't get from an electronic archive system," says Goldsmith. "More and more we are finding that investigators require the ability to upload and access TMF documents from any location, as well as perform review and approval of documents. An electronic archive system simply does not provide you with that capability."

The survey also found that an eTMF system will provide users with better audit and inspection readiness. Sixty-one percent of companies using a purpose-built eTMF application reported improvements in both areas. An additional key benefit of that type of system is visibility into process metrics. Having the ability to electronically collect information is the first step in getting to that stage.

A final interesting trend to come out of the survey has to do with a shift in the compliance landscape. The rate of expected remote access for auditors and inspectors to the TMF is expected to double in the next two years. A majority of survey respondents reported they expect to be able to provide remote access to their TMF applications by the end of 2017.

For the non-adopters of eTMF, one has to wonder what reasons companies continue to give for not making the conversion. Although this question was not specifically asked in the survey, Goldsmith does believe it comes down to cost and resource availability. eTMF systems may save companies money in the long run, but getting one set up still requires an initial set-up cost. The company would also have to have resources, human and other, to devote to the effort.

"There are different stages of TMF maturity," adds Goldsmith. "There is a curve that companies move along in going from paper to fully electronic processes. At the early end of the spectrum, I think what is really holding people back is cost and the time allotted to do it. A big part of this conversion is reengineering the way in which you conduct your process. That takes time and effort, and it can be disruptive. For some companies that feel like they are running a million miles a minute, that can be a difficult thing to try and absorb. They will eventually do it, because the health authorities and the way they are viewing TMF compliance will move the industry there. As more companies do this, and as more people in the industry become experienced at doing it, the process will become easier. But some companies will find they just don't have the time and the bandwidth to do it right now."

In citing benefits to inspection readiness of an eTMF system, 66 percent noted benefits around missing documents, 60 percent mentioned benefits around duplicate documents, and 55 percent cited benefits around incomplete documents.

An online edition of the report is available at www.veeva.com.