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eTMF: Yes, Virginia, Paper is Disappearing

By Lisa Henderson

This week before Christmas, my kids are bouncing off walls. Not even the threat of Santa watching is bringing them back to some semblance of normalcy. They are borderline believers; at an age where they've been told by well-meaning friends that Santa doesn't exist, but dealing with a mother who refuses to budge on the topic with a firm "I believe."

And just like the discussion around Santa and his reality becomes a noisy signal at certain ages, you can be sure that the noise around eTMF is a signal that change is imminent.

Last month, I attended CBI's Sponsor/CRO System & Business Process Integration forum and discovered a lot of people needing advice, and discussion about eTMF. One insider tidbit I learned was: Use the TMF Reference Model from DIA. Outside of that, I did understand that sponsors are struggling with eTMF, as are the CROs who need to either use the sponsor's eTMF or provide one for the sponsor to use.

This is not atypical as most CROs and sponsors struggle with many parts of their system and process integration, especially with the growth of outsourcing. Another feature of the noise is that the adoption of EDC—at 70% or more in this industry—has led to the implementation of the next phases of electronic efficiency. And eTMF is high on the list. A DIA subgroup analysis of eTMF adoption showed that 48% of sponsors currently use a combination of paper and electronic, which is up from a 27% combo rate in 2010.

With this background in mind, I spoke with executives at CRO Worldwide Clinical Trials (WCT), who recently chose TransPerfect's Trial Interactive platform as its eTMF solution.

Prior to choosing the eTMF, WCT was using a paper-based system, consisting of the usual scanning and storing of documentation, held in file folders. Laurie Myers, Global Director of Central Records and Documents for WCT, noted that when the decision was made to invest into an eTMF, a list of user requirements for their ultimate eTMF choice was developed and ranked and included features such as accessibility, global presence, helpdesk, audit trails, access speeds, among others. Ultimately, the company chose TransPerfect's Trial Interactive eTMF.

Jim Volpe, director of corporate administrative services for WCT, noted the company is taking a conservative, phased-in approach toward its eTMF implementation, with the first phase goal of increasing the visibility of paper documents globally. "There is still a lot of uncertainty in the industry around eTMF," he said. Examples included: Do you need wet signatures? What will regulatory authorities allow and not allow in an eTMF? And in the end, Volpe noted, the CRO is at the mercy of what the sponsors' auditors are asking for. "As we use it more, and we understand more of what sponsors want, we can move to a more paperless environment," said Volpe.

Volpe, Myers and Senior VP of Clinical Operations, Annie Clark, are behind that statement 100%. Ultimately, the paperless environment is what is desired. However, they are also in agreement that the phased approach will work best with its CRAs, sponsors, and in the future, investigative sites. Clark noted that the ability to offer sponsors operational transparency into quality control for trial is a major driver for the implementation, as well as the sponsors asking CROs for the eTMF capabilities.

Michael Smyth, general manager of TransPerfect's Life Sciences Division and Trial Interactive, has high hopes for eTMF, and eventually a paperless clinical trial. "Every study still has a level of paper," Smyth told me. "But more and more sponsors are realizing that the regulators aren't the bottleneck. It's their own internal processes. They realize there is technology now for the other things they could be refining in clinical operations."

For Trial Interactive, the WCT deal follows two others with CROs in the past year: INC Research and Premier Research. Trial Interactive offers other modules, including Study Start-Up, which was another selling point for WCT. "We want to phase this in before we go full on into the startup process. Culture change is always difficult, so we are slowly moving and evaluating what we can do. But study startup is a definite area that is a paper-intensive process," noted Volpe.

Smyth described the eTMF disconnect for sites: they already have experience with EDC and web-based study portals for document delivery and study management, but then they still have the paper trial binder. He says the sites don't want the paper, "But sponsors and CROs keep sending it."

Getting beyond the paper culture, says Smyth, can be addressed when the eTMF is determined the agent of record and the primary resource file. "If that's stated, then paper just becomes supportive," says Smyth. Then the next step, and in discussion as part of TMF Reference model subcommittee, is how or when to destroy paper documents. And he said it is a larger discussion around the TMF Reference Model and the industry in general. It also can involve a pharma's legal department, which may require the company to keep the paper. "It can be a company decision around keeping paper forever," said Smyth.

Clark said, "We are quite excited to get to the next step of quality oversight. I think it's really great, eTMF pulls the project together in a cohesive way. And we are 100% hoping down the line to save some trees."

Ten years ago, EDC in clinical trials was in the early adoption phase. Now, a paperless clinical trial is not such the glimmer it once was. Which brings us back to belief.

A close friend to belief is faith. So for those of you losing faith with the speed of progress, change or "innovation" in our conservative pharmaceutical industry and the even more tightly regulated and rigorously controlled clinical trials, I have one word, "believe."