Engage With Patients, Not Paper

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Technology has come a long way, and continues to evolve in ways that many of us could not have imagined 20 years ago. Consider the iPhone 5. This device has a user friendly interface, PassPort (an app that keeps all your gift cards, coupons, boarding passes, and tickets organized, and which are ready for you when you need them), enables cloud computing, and of course has Siri, which remembers where you are, reminds you of appointments, and gives you directions. Just 10 years ago, I could not have imagined doing all of that from the palm of my hand.

Michael Smyth, general manager of TransPerfect Life Sciences Solutions, thinks of this technology every time he walks into a clinical investigative site and sees row after row of shelves piled high with binders full of paper. "When a new technology comes out, like the iPhone 5, most people can't wait to embrace it," he says. "It makes our lives better and easier in so many ways, it is almost counter-productive to NOT embrace it. I know many people in the life science industry who have this device. Yet when it comes to documentation in clinical trials, many sites continue to use the same methods that were used 100 years ago, even though far more efficient and time-saving technologies are now available. I believe it is time for the life sciences industry to embrace these technologies as well."

The Move To Electronic Documents

The evolution of eClinical technologies only goes back about 20 years. In 1994 we had the initial appearance of an electronic alternative to paper-based records. Nine years later, in 2004, electronic solutions gained industrywide approval via the FDA's Guidance for Providing Regulatory Submissions in Electronic Format. "This was a clear shift in guidance from the FDA," says Smyth. "The FDA was telling life sciences companies that it was OK to implement electronic document management and to use it to streamline clinical development."

In 2006 the ICH (International Conference on Harmonisation) validated web-based solutions as the best implementation platform for an electronic common technical document (eCTD) delivery system. In 2008 and 2009 eCTD was established as the mandatory method of electronic submissions within the United States and the European Union. "Today, EDM (electronic document management) solutions continue to provide improved features and functionality to the life sciences industry," says Smyth. "We have new technologies still emerging, such as eTMF (electronic trial master files), CTMS (clinical trial management system), cloud-based platforms, and other forms of online, collaborative workspaces. And yet, at many clinical sites, we still see the binders full of paper. It's like they have the iPhone 5 available to them, but instead choose to continue using that old, bulky, desktop rotary telephone. This is likely due, in large part, to outdated sponsor or CRO processes and procedures."

This entire situation frustrates Smyth. “I feel the industry has been developing products faster and more cost effectively, while keeping a strong focus on quality data and patient safety,” he adds. “But if companies refuse to adopt the technologies, we all lose out on those benefits. While other industries have rather quickly evolved into fully paperless environments, the conduct of clinical trials continues to be a laborious process that relies heavily on paper-based processes and procedures. What we need in the clinical space is a new mindset.”

Clinical Challenges Involve Paper

A recent investigator global site survey showed that when it comes to data capture, 75% of sites used electronic tools, while the remaining 25% still used paper. When it comes to study binders, 100% of the 121 investigative sites surveyed still used paper. The survey concluded that this was the greatest pain point with electronic document management. This duplication (having both paper and electronic files) resulted in the wasting of labor, since monitors still had to come to the site to verify information. Although investigators complained that they didn’t want paper, sponsors and CROs continued to ship it to them.

Another survey, this one by Harold and Jesse Glass that focused on global challenges and opportunities for improvement in clinical trials, showed that SAE (serious adverse effect) reporting was a concern for 26% of firms in the U.S. (tied for 3rd on the list) and for 10% of respondents from Asia/Pacific sites. SAE follow-up and study-monitor time at sites were also concerns cited by respondents. Smyth notes a paperless solution would resolve these issues as well. “Right now site personnel have too many distractions, most of them related to paper” he says. “SAE collection and reporting methods are inefficient, due mainly to the handling of paper. For example, many sites still use fax forms for the completion of SAE reports. This use of paper in regulatory binders can result in missing and misplaced documents and pages. And since the clinical-study documents cannot be accessed remotely, all monitoring activity needs to be done at the site. That means more time spent hosting CRAs (clinical research associates). The end result is a terrible waste of time, which keeps site personnel from completing their more important tasks.”

A Much-Needed Global Focus

When speaking to Smyth, you quickly discover he is a huge advocate of having firms look at their clinical development from a more global perspective. Thinking about clinical trials from a global point-of-view will require firms to accept newer, more commonly accepted technologies, rather than many of the homegrown or outdated technologies currently in use. Some of these outdated technologies include faxes, express mail, palm pilots for patient diaries, regulatory binders, and document control rooms. He does not believe many of these technologies are useful in today’s domestic clinical market, much less in a global environment.

When looking at the global landscape, Smyth sees several trends that he believes will impact firms performing clinical research. The first is the adoption of a single-technology provider. Going forward, he believes sponsors will select a limited number of functional technology providers to supply tools across several functional areas. This will enable site personnel and study teams to deal with fewer vendors and passwords, and less time-consuming training.

Electronic documents will also grow in popularity, for many of the aforementioned reasons. This will result in the elimination of paper, allow for remote access, cut down on missing study documentation, and make SAE collection and reporting more efficient. Having all of the documentation in one location will also make it easier for site personnel, study teams, and regulatory authorities to review any of these documents, when required.

“The end goal is allowing site personnel to have more time to spend with patients,” he says. “We need to allow these folks to focus on their tasks of finding, consenting, enrolling, and completing subjects, all while overseeing the safety of each study subject. More time spent with patients will mean a better patient experience, an increased focus on patient safety, higher quality data, and additional time to evaluate more patients. We need to get to the point where site personnel have more time freed up, and can spend less time engaging with paper and more time engaging with patients.”