Applied Clinical Trials Online

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Paperless Clinical Trial Optimization–Thinking Outside the Box

By Michael Smyth

The FDA realized the need to modernize clinical trials as part of its Critical Path Initiative, with the goal to better prepare investigators to safely and effectively perform clinical studies of investigational products. The European Medicines Agency is working on ways to streamline clinical development, for example, with a recently released draft, "Reflection Paper on GCP Compliance in Relation to Trial Master Files (Paper and/or Electronic) for Management, Audit, and Inspection of Clinical Trials." The paper hints at and paves the way to move towards a fully electronic trial master file process.

While sponsors, regulatory authorities, and CROs are collaborating, initiatives to streamline the interactions required during clinical trials for investigative sites are happening in a limited fashion at best. This is due to the sparse tools and high level of administrative activity.

Over the past 10 years, clinical trials have become more global, driven by changes in regulatory timelines to start up studies faster, provide better access to study subjects, and reduce costs.

More studies are seeing an increased number of investigative sites with fewer subjects per site, as compared to Phase II and Phase III studies conducted a decade ago. This impacts not only the sponsors and CROs, but global investigative sites as well in a number of ways.

Paper problem

One such result would be an increased administrative burden with paper. While more than 75% of 121 global investigative sites TransPerfect surveyed in October 2011 confirmed they use electronic data capture, 100% of the sites shared that regulatory binders and essential documents are still handled on paper. The majority of the sites indicated this was a sponsor/CRO requirement, even though the sites prefer to receive documents electronically.

There would also be a greater struggle to support multiple vendors. In a recent survey presented at the DIA 2013 Annual Meeting, data showed that sites typically work with between six and 10 different vendors when executing a study. Multiply this across studies and the number of vendors and contact points can be quite large, not to mention the number of passwords to be maintained.

Lastly, there would be a more cumbersome record archival and retrieval process. In order to comply with regulatory record retention requirements that differ by country, many sites keep investigative site files stored and archived in either their institution or in off-site storage. In the event of an audit, sites that share archival and retrieval would find it challenging to retrieve certain files—and some sites even indicated they would be unable to find documents.

Going paperless

There are a few best practices that stakeholders in the clinical trial process can be doing to evolve and adapt to these changes. One such change is to implement paperless regulator binder and essential document processes. From study startup through closeout, today's global e-clinical solutions provide opportunities for a completely paperless process.

Another option is to improve flow by using one study phone number. Regardless of the number of vendors involved, sites should use one phone number either globally or locally.

Today, call flow and routing in an IVR would allow for one number and based on the menu, support multiple languages and support for all vendors. This would triage calls to different vendors involved in study support as needed, eliminating the need for the site personnel to call different numbers.

Finally, it helps to establish one centralized portal. Currently, vendors retain their own portals, resulting in one study with many different portals. Giving sites one global portal with different security rights allows investigative sites and study teams to go to one place for any study or program information. This reduces it to one password per study and if the portal is used across studies, even further streamlines work for the sites.

Transforming clinical studies processes will require critical thinking outside of the 20-year-old box.

The good news is there is technology available to help. The implementation of best practices for clinical study and development conduct can streamline administrative burdens for investigator staff as well as study teams, and hopefully yield reduced costs in conducting global clinical development.

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