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Technology Solutions for Investigative Sites – are They Just a Burden?

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Digital technologies are revolutionizing the ways in which we communicate with each other, impacting all aspects of modern life, including the ways in which clinical research is being conducted. Increasingly under pressure to reduce study timelines and costs, the pharmaceutical industry has been deploying eClinical solutions to reduce the inefficiencies in trials resulting from complicated protocols, globalization, and paper-based methods—with improved communication and collaboration between teams an essential component of these technologies.

There is no doubt that technology solutions help both sponsors and contract research organizations (CROs) improve operational efficiencies and facilitate decision making. While one would expect to hear a similar story from all stakeholders involved in clinical trials, a recent survey by CenterWatch suggests that these technologies are having the opposite effect at investigative sites —adding to what is already a heavy workload burden.

Of the 252 global investigative sites surveyed by CenterWatch, only 9 percent reported that the technology solutions provided to them to conduct clinical trials met their operational needs “very well.” Investigative sites are being overwhelmed with numerous technology solutions mandated by sponsors and CROs that generally do not communicate with each other.

Investigative site issues with technology solutions

The survey revealed that developers of eClinical technologies were not considering site workflows and the needs of principle investigators when designing their technologies. As Michael Koren, M.D., CEO of the Florida-based Jacksonville Center for Clinical Research, and principle investigator put it, “In simple terms, the software wasn’t designed for us. Software that would actually look at our workflow and respond to our needs would be useful. But in virtually every product I’ve seen, the investigator is an afterthought and not central to the design. The software isn’t focused on the way that physicians, coordinators and clinicians work. There is nothing about it that is investigator-friendly.”

"An investigator sent us a photograph of her desk covered with the various electronic devices she was using," said Christine Pierre, president of the Society for Clinical Research Sites. "Each of the devices is useful and time-saving on its own, but a pile of them is not. This is the problem industry has to solve."

Given that sponsors and CROs choose the technology systems that will be used in a study, and many sites conduct numerous studies concurrently, managing all the software and hardware has become a full-time job. This has led to a situation where investigators at sites are being forced to accept and work with technologies that often make their jobs more difficult. The survey exposed several areas where technologies are increasing the complexity of protocols at investigative sites:

Too many separate eClinical technologies: Almost half of the investigators surveyed (46 percent) reported that they felt sponsors and CROs were mandating use of too many separate technologies, and complained that these different technologies usually did not communicate with each other. The survey revealed that sites used around 10 different software applications to manage clinical studies in 2015. And there is no sign this trend will reverse itself anytime soon. Market research conducted in 2012 showed sponsor companies reported using EDC in roughly two-thirds of their Phase 1-4 trials. By 2015, that number had risen to 90 percent.

Inventory challenges: Sites are required to maintain inventories and manage an increasing number of technologies used by study participants, such as electronic diaries, drug adherence sensors, and wearable devices. For a site running concurrent studies, keeping track of which technologies are utilized per trial, and when, where and how a particular technology is to be used, is extremely challenging.

Burdensome training requirements: According to the Clinical Trials Transformation Initiative (CTTI), streamlining GCP training can save resources and allow investigators to focus on patient safety and other critical factors. As detailed in the official CTTI Recommendations on GCP Training for Investigators, GCP training should 1) provide a framework for clinical research conduct, 2) occur at least every 3 years and be documented in a formal manner, and 3) be mutually accepted across organizations. Unfortunately, much of the training is not mutually accepted across organizations, even if the same technology platform is used. These concerns were reflected in the survey with 39 percent of respondents indicating that too much training for technologies was required, with 95 percent of respondents stating that training requirements were too repetitive, as sponsors and CROs typically don't accept prior training on a particular system.

Having to deal with incompetent vendors: With numerous platforms comes numerous vendors. In the EDC space alone (which has seen consolidation more than other areas), some investigative sites report to using up to 10 different EDC platforms. And too often these vendors have cumbersome interfaces, limited support resources, which in turn can result in data integrity issues.

Creating duplicative work: Given the limited interoperability of eClinical technologies, important study information from patient visits or laboratory test reports needed to be manually transcribed from either paper of electronic sources into study software. This increases not only workload, but also the chance for transcription errors.

Too many different logins to manage and keep track of: Numerous technology platforms can mean that users are stuck with tracking multiple login credentials. Nearly three-fourths (74 percent) of site staff surveyed said that having to keep track of multiple usernames and passwords was very challenging. Sites that conduct a lot of studies can be forced to keep track of login information for dozens of systems.

Executive director Jeremy Rigby of Advanced Clinical Research, summed up the difficulties being experienced by sites when he said, "I am a proponent of these technologies. But the difficulty is the need to use so many different systems, which are hard to keep track of and don't talk to each other. All of these systems work differently, have different login credentials and require training."

What can be done?

eClinical solution providers need to rethink point-based solutions that are designed without proper focus on workflows of investigative sites. The top-down design approach needs to be replaced with a more site-centric model that takes the needs of all stakeholders, including sites and principle investigators, into account. A significant number of investigative site workers desire the industry to move in the direction of adopting a common technology platform. There have, in fact, been several industry initiatives that have moved the needle in this direction:

Single sign-on (SSO): Almac Clinical Technologies, the world's largest privately-held contract pharmaceutical development and manufacturing organization, announced a collaboration in December of 2016 with Exostar, a cloud-based solutions company that helps highly-regulated industries mitigate risk and solve their identity and access challenges. The companies are collaborating to produce Single Sign-On (SSO) and Federated-Authentication access to eClinical applications used to support clinical trials. The initial efforts of this collaboration have resulted in the successful integration of Almac's Interactive Response Technology (IXRS 3IRT) with Exostar's identity and access management platform for life sciences. Using the SSO functionality of this platform, site personnel and patients are relieved of the need to maintain multiple login credentials. The platform has also served to enhance the controls and security around trial-sponsor intellectual property. Other federated partners of Exostar —TransCelerate, Merck and AstraZeneca —also have access to this platform with its enhanced functionality.

Site study dashboard: Another promising industry initiative involves efforts by the Society for Clinical Research Sites (SCRS) to improve communication and collaboration between sites and sponsors/CROs. In collaboration with sponsors, CROs and professional service providers, SCRS is working to create a Site Study Dashboard that will share study performance metrics with sites, allowing them to compare their performance with other sites conducting the same study. The intention is to strengthen the relationship between sites and sponsors/CROs by sharing information in a collaborative setting that will enhance and support investigator oversight, with the goal of helping sites improve their processes and performance. As Richard Litov, Ph.D., director of Pedia Research, puts it, "A big problem is that CROs and the sponsors do not talk to the sites and get input from them about how to create a system or communicate better. They are one-sided about how do it and then require everybody to do it their way. That is not very efficient."

Shared investigator platform (SIP): A third industry initiative of interest resulted in the development of single sign-on Shared Investigator Platform (SIP) that streamlines how investigators interact with biopharma companies. Resulting from a partnership between solutions provider Cognizant and a nonprofit industry group comprised of leading biopharmaceutical companies (TransCelerate BioPharma Inc.), the SIP provides a common platform that enables sponsors to collaborate and share data more effectively with sites. By improving the efficiency and effectiveness of interactions between sponsors and investigators, the platform is designed to facilitate a faster and more cost-effective means to manage clinical trials.

Site-centric development: Finally, some solution providers who recognize the technology burden problem for sites are developing technology solutions specifically designed to meet site needs. These solutions simplify the study startup process for investigator sites by providing access to training materials, clinical trial systems, and electronic document capabilities through Web portal technologies. Through simplifying the site activation process in ways that can significantly impact trial timelines, and these solutions provide benefits to both investigators and sponsors/CROs.

Conclusion

Utilization of new technology solutions to conduct clinical trials will continue to increase as both sponsors and CROs seek greater efficiencies in the drug development process. From their perspective, the solutions now in use offer huge benefits, as they get to access data as soon as it is entered and can thereby apply analytics to identify trends and highlight issues more quickly than in the past. Investigative sites, however, are being forced to adjust to these complex and often burdensome technology requirements at a time when site workload is already excessive. The technologies used by clinical researchers need to recognize the workflows at the site with the patient in the room, if the desired study efficiencies are going to manifest. In the end, helping sites reduce burdensome technology requirements and allowing them to focus on optimizing interactions with patients will help improve the quality of clinical trials overall, ultimately resulting in a faster and more effective delivery of life-saving medicines to those in need.

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