CLINICAL INFORMATICS NEWS

The Struggle To Speed Study Start-up

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By Caroline de Lacvivier

Recent research conducted by Tufts Center for the Study of Drug Development (CSDD) has found that clinical research organizations (CROs) face an increasingly complex and competitive environment in which to administer clinical trials. Study start-up, in particular, can be a drawn-out process that, depending on the protocol, budget negotiations, and availability of patients, can last anywhere from a few months to a full year. CROs are therefore looking for strategies, whether in the form of tools or processes — often a combination of both — to streamline this complicated phase.

As CROs make their way from feasibility studies to site identification, selection, and activation, they must draft regulatory and startup documents, determine the proper budget, negotiate a contract, and navigate the legal requirements of the Institutional Review Board (IRB). Indeed, the Tufts CSDD research study found that site selection alone took an average of 3.2 months (ranging widely from two weeks to six months). With the site activation process, the full cycle can take about a year.

The site selection process has also become increasingly competitive. Carol Aliyar, Senior Vice President and Global Head of Study Start-Up at INC Research, a global CRO, explained, “There’s many sponsors out there and we’re all competing for the same sites.” Meanwhile, as CROs accumulate performance data on different sites, many end up targeting the same ones. Tufts CSDD research indicated that, on average, 70% of the sites CROs select are familiar, with only 30% new. “Everybody’s fishing from the same lake if you will,” said Jae Chung, president and founder of GoBalto, a study start-up platform.

While the supply and demand side of the equation is largely outside the CROs’ control, there are certain inefficiencies that could be avoided. Many CROs have not graduated beyond manual data entry and Excel spread sheets. This is a time consuming, error-prone approach that makes it, according to Chung, “very hard to get global visibility in terms of where you are in the process.” This issue is compounded by the fact that processes are disjointed and siloed between departments. For example, some organizations have attempted to streamline this phase by creating dedicated start-up teams or roles. “There are many companies and many sponsors with versions of a start-up team,” Aliyar explained. “They tend to be small teams that focus on an aspect of [study start-up] and therefore operate in isolation in multiple departments, so what they end up doing is handing off and handing off and handing off.” In other words, these teams have not been properly integrated into the rest of the organization.

Some CROs have turned to online tools to streamline the process, others have developed strategies in-house to try and speed their workflow. At Boston MedTech Advisors, a consulting company that specializes in clinical trials, they have generated documentation based on the data they've accumulated internally. "We have our own questionnaire that we run by the potential clinical investigators that covers both the experience and the standing of the investigator, as well as the infrastructure that exists at their site for enrolling patients," said Zvi Ladin, PhD, Principal at Boston MedTech Advisors. He went on to explain that their tailored questionnaires helped determine the involvement rate of future patients, allowing them to make educated predications during their discussions with a potential investigator.

INC Research has leveraged a technological platform to improve their data analysis and help create a consistent global experience. According to Aliyar, this has helped them anticipate bottlenecks: "Having an integrated study start-up technology system that maps a critical path and lets you view the end to end deliverables such as GoBalto allows us to navigate the site successfully through the start up phase to the point where patients can be enrolled. In addition, this allows us to use the robust data we generate to build a future predictability model." Data mining electronic medical records (EMRs) has also been a key part of CROs' attempt to leverage technology to speed the start-up process as well as to identify and recruit potential patients. "EMR mining is a very promising area," Chung said. "If you think of the number of health records that are out there, there are ways you can actually mine to identify potential patients that are much more relevant to a particular protocol."

When it came to articulating the key to speeding study start-up, the overall advice was a variation on a theme: prepare, prepare, prepare. "Early identification of some of the key elements and key potential bottlenecks in the process is a key to streamline and plan appropriately," Ladin said. Chung also commented on the preparation process, or lack thereof, saying, "People just go about recreating the wheel. They don't have a standard process."

Ultimately, study start-up will always be a complicated process fraught with inefficiencies. "There's no panacea; there's no silver bullet," Aliyar explained. It is therefore an organization's responsibility to focus on optimizing their process in order to get patients the treatment they need faster than the current process allows.