CLINICAL INFORMATICS NEWS

It's Site Selection, Not a Toss of the Dice

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By Craig Morgan

Conducting clinical trials is a high stakes game, but disturbingly, the risk of selecting non-performing or underperforming investigative sites is greater than losing at the gambling table. When shooting craps, for example, odds are 17% that the player will role a 7 to start the action, and the odds of actually winning may be even lower. But, the odds of selecting sites that perform well in clinical trials are worse, far worse.

More than 80% of clinical trials fail to meet original timelines, with enrollment problems largely to blame, branding the site selection process a perpetual bottleneck. According to research from the Tufts Center for the Study of Drug Development (CSDD), 37% of sites under-enroll and 11% never enroll a single subject. And while 89% of studies do eventually meet enrollment targets, sponsors often get there by doubling their original timelines or engaging in the costly practice of adding rescue studies, due to poor site selection and under-enrollment. In a typical Phase III study, this can translate into $2.25 million in expenses for non-active and under-enrolling sites. Overall, choosing the wrong sites can boost the cost of trials by 20% or more.

New Technologies, Better Intelligence

Site selection should not be an exercise in rolling the dice. Instead, this crucial activity should leave little to chance, and with new technologies, this is possible. Fortunately, adoption of new technologies is gaining traction, but there is a continual clinging to legacy methods that are paper-based or spreadsheet-based, providing little transparency to stakeholders looking to improve site selection and track performance in real-time. Older manual methods were never designed to leverage the massive volumes of operations data that are siloed in the electronic data capture (EDC) system, clinical trial management system, and other electronic solutions that can and should be used to build databases specific to site selection. The intense pressure facing clinical teams to comply with timelines, budgets, and quality metrics, topped by growing regulatory input for better risk management are driving major process change, especially as clinical trials become more global and complex

New processes start with purpose-built solutions that embrace big data analytics and offer workflow tools with real-time visualization, making site selection more precise, and ultimately, impacting study performance. This approach provides sponsors and contract research organizations (CROs) with intelligence based on data documenting sites' past performance, size of patient database, staff expertise in certain therapeutic areas, and ability to produce quality data and manage a clinical trial..

Christine Pierre is President of the Society for Clinical Research Sites, a global trade organization focused on greater site sustainability. In an email, she shared the sites' point of view. "To confront the ongoing challenge of choosing the right sites for the right studies, sites are encouraged that data are now available to sponsors and CROs to assist with this process. Sites are truly looking forward to working with these organizations to determine which data should be viewed as reliable in predicting future behavior, versus which merely reflect the specifics of a particular study. Last, sites are dynamic environments, and the new technology is an important complement to the critical need for relationship building and maintenance."

The necessary process changes around new technologies involve eliminating the manual steps associated with consolidating data from various spreadsheets and multiple electronic solutions. Collectively, these systems house rich data documenting past performance, but they are of little value until they can be quickly accessed for site selection. Solutions that combine internal and external data sources into a single meta-database, allow algorithms to assign weights to data based on details of the protocol. The algorithms enable the building of a target site profile that addresses three factors: study fit, site performance, and experience of the site and investigator. Study fit measures feasibility, such as facility information, protocol inclusion/exclusion criteria, and patient demographics. Site performance looks at numerous metrics, such as those for enrollment and data queries. Experience of the site and investigator defines clinical trial experience in various therapeutic areas.

By querying the database using parameters from the protocol and filtering options, a list of targeted sites is produced. Workflows built into site selection solutions help study teams collaborate in reviewing site profiles and picking sites from that list, shortening the time of activation. The goal is smart use of data to mitigate or reduce risk factors for recruitment and retention by finding the optimum alignment of the best sites with high patient availability.

"Top-performing sites are key to quality study execution, and using transparent data analytics to present the studies to the right sites with enough information to make an educated determination about likelihood of success is essential to this effort. This pro-active method should limit the selection of those sites with sufficient knowledge to know they never would be successful on certain studies. It will also help stakeholders execute clinical trials with greater efficiency, an essential goal of our industry," Pierre told me.

The use of data analytics, along with workflows and visualization tools will go a long way toward re-defining the site selection process, removing it from the realm of a frustrating gamble.

Craig Morgan *is a technology and life sciences management professional with more than 15 years experience in the application of informatics and bioinformatics to drug discovery. He currently heads up the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times and improve collaboration and oversight in clinical trials.*

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