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The Clinical Trials *Technology Ecosystem*

Technology improvements are enhancing R&D efficiency, accelerating time to market, improving safety, and boosting data accuracy — all of which are increasing the success rates for pharmaceutical sponsors and their clinical trial partners.

Companies need to have the right clinical experts as part of the process because it is a marriage between the people, process, and technology that makes for a successful solution.

SUZANNE CARUSO
WIRB-Copernicus Group (WCG)

Site Selection Technologies

Use of reliable data analytics, timely site start up and patient recruitment, and managing the supply chain for trials in ever-evolving innovative therapeutic areas are just a few of the many challenges involved with drug research and development.

Site selection is one of the more critical decisions sponsors make in preparing for a clinical trial. The selection of sites establishes the framework for whether sponsors will be able to meet their trial goals. Automating the process of selecting and validating sites can build consistency into the process, helping sponsors to enroll sites and patients faster and with less bias than more manual processes that do not have the transparency aspects that technology enables.

Merck is one of the companies that has taken steps to automate more of the site selection process using WCG's Site Feasibility Solution to help assess clinical sites. The solution helps Merck narrow the field of investigators for a specific trial based on therapeutic and enrollment trends. The solution also assists in determining the sites' and investigators' feasibility for the trial.

Merck used the feasibility solution for a non-small cell lung cancer trial in 2015 at a time when it was difficult to get teams out to sites to do on-site visits for site assessments. The feasibility tool helped to increase the investigator response rate to the feasibility questionnaire and allowed Merck to make better-informed site-selection decisions within a shorter time.

"Typically response rates to feasibility questionnaires average as low as 20% or 30%," says Suzanne Caruso, VP, clinical solutions at WIRB-Copernicus Group. "In leveraging our tool, Merck has more than doubled the response. This program is now used for all of Merck's studies."

Dawn Furey, executive director, head of global operations within global clinical trial operations at Merck, says the solution gave the global team the opportunity to use face time with sites in a more meaningful and more focused way.

"When manually conducting site feasibility, there's no transparency to the various stakeholders throughout the organization as to how the sites have actually responded," Ms. Furey says. "We found there were times when the site would provide an estimated number of patients they could contribute but by the time the decisions were made as to whether that site should participate or not, the numbers were pretty far off from the original estimate. We wanted to see if we were including more sites than we needed in order to execute our research and how we could tie those data points together."

In many cases, using the WCG system, Merck has been able to identify sites for participation within three days. Previously, this process sometimes took eight to 10 weeks. Merck has since rolled this solution out to all trials with more than 20 sites to be enrolled.

Ms. Furey says one of the important learnings from the process was the need for the field team to communicate with sites prior to electronic questionnaires being sent to them.

"We very quickly ascertained that if the sites received an email with no prior notification from our field team, they either ignored it or the communication went to their junk mail and they deleted it," she says. "Once we let the sites know the electronic site validation questionnaire was coming and that we were personally interested in their participation there was a higher likelihood of response. Our response rates have gone up from 63% when we first rolled out the technology to about 73% today."

Ms. Caruso adds that companies need to have the right clinical experts brought into the transformation because a successful solution is a marriage between people, process, and technology.

"It doesn't matter how good the technology is if you only have one piece of the equation — the experts, the process, and the buy in of the organization all have to be in place," she says.