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Shared Expectations, Data Help Can Improve Site, Sponsor Collaborations

By Jane Anderson

Clinical trial sponsors and research sites—citing the need for better communication and realistic expectations—are seeking to turn their sometimes adversarial relationship into one more focused on collaboration, representatives from across the research community said.

To that end, researchers are urging trial sponsors to curtail unnecessary communications and consider streamlining data collection, the representatives said during a webinar sponsored by WIRB-Copernicus Group.[1] At the same time, trial sponsors are providing technical assistance to sites that may be struggling with some aspects of a trial's requirements, they said.

This shift in mindset means researchers and trial sponsors are working together more and no longer perceive themselves to be at odds with each other, explained MaryLou Watson, chief clinical research operations director, clinical trials office, the State University of New York (SUNY) Upstate Medical University.

"I think what we have seen at Upstate is a definite evolution of the relationship between sponsors and our site," Watson said. "I think we were much more siloed and we didn't communicate well with each other." This relationship has changed, she said: "We currently are seeing much more of a collaboration and a back-and-forth relationship."

This leads to more effective management of every aspect of the relationship, ranging from protocol input to having a master clinical trial agreement, Watson said. Also, she said, having a preferred site relationship with a trial sponsor "just expedites everything exponentially to get clinical trials up and running."

Manny Lazaro, senior vice president of clinical development operations, Jounce Therapeutics, said that establishing two-way communication is critical to a trial's success. He cited figures provided by WCG that showed a top site may have up to 214 trials underway at the same time. "So, setting realistic expectations and setting priorities [are] critical," he said.

Operational Calls Facilitate Partnership

Meghan Brennan, chief operating officer, University of California, Los Angeles (UCLA) and TRIO-US, said the relationship between research sites and trial sponsors is much more of a partnership now. For example, she said, "We have operational calls with our industry partners so we can exchange information, and they can know what's going on from our perspective at a site level, and we can understand what's going on from their perspective." In fact, this partnership is helping the organization reach patients who are underrepresented in clinical trials, Brennan said.

Brennan, who represents a site management organization that manages 14 independent oncology practices across the country, said she understands that sponsors expect site coordinators to be responsive to messages. However, she explained, "we get 50 to 60 messages a day, depending on how many studies we have going on, and

the expectation is to respond. A lot of times, there's 10 from the same organization about the same study, just from a different aspect. We have worked with our industry partners to consolidate that, and I think consolidating communication is very helpful because it is overwhelming for our sites."

Requirements for data can be similarly overwhelming, Brennan said. "The government is not looking for this deluge of data," she said. "So, I think it would be helpful for sponsors to listen to that and really pull the data that they need and ask for that to be what's entered for the patients because there's a lot of data that really doesn't meet the needs of the endpoints." Some sponsors have provided a temporary data manager or some other help at the site level, Brennan said, adding, "everyone is short on staff, so anything that we can do to either augment the staff with data management or reduce some of the burden would be very helpful."

Brennan said that TRIO-US has helped with training for several oncology sites interested in doing clinical research but which had minimal research experience. "Obviously, we use the web-based platforms related to study training, and then we actually have a hands-on person that will go to the site—she's the director of our network, and she's a clinical research nurse," she said. "She really does take the time to go through the processes with all the staff." If necessary, TRIO-US also will provide sites with a staff member trained in oncology research, Brennan said.

"We also offer them trials that are going to be a little bit easier for them to participate in, to start, and then we spend a lot of time working with the faculty, talking to them about what their expectations are, and meeting with them pretty regularly," Brennan said.

Site staff enthusiasm and dedication are important to success, she said. "We've had this one site that joined us about five years ago, and it was a relatively new practice, with physicians very eager to participate," Brennan said. "That site actually is one of my highest accruing sites now, but we started them out slow. We provided them with not only staff support, but also faculty…support." TRIO-US's partnership with UCLA provides access to academic faculty members who can be a resource for community practices, she said.

Oncology research can be burdensome for patients, Brennan said. "That makes it hard to accrue, and that makes it hard to complete studies. So, we've been exploring some different initiatives related to making some complex studies a little bit less complex, partnering with our industry partners and also working on some home health relationships," she said.

For example, Brennan said, her organization has partnered with a home health company to build a research task force with home health nurses who can help with some of the procedures within their scope of practice, including blood draws and EKGs. That way, she said, "patients don't have to come to the clinic for multiple days in a row for something where they're just doing a blood draw, and they don't have to spend long days there."