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More Sites Seek 'Partner of Choice' Label

Tables Turn as Sites Strive to Match Sponsors and CRO Efforts

By Karyn Korieth

Investigative sites have stepped up efforts to become more attractive as "partners of choice" in clinical research, eager to move toward the top of highly competitive preferred provider lists, as they increasingly recognize the importance of meeting sponsor and CRO needs for greater efficiency and collaboration in order to win more business.

"We want to be a partner for anything sponsors or CROs need," said Kelly Toms, director of Business Development, Corporate Sites, Meridien Research, which operates six dedicated research sites throughout central Florida. "With higher visibility and recognition, we see opportunities on a regular basis and it shortens timelines between feasibility and study award because they are very familiar with our site."

For many years, it was the sponsors and CROs focusing on ways to become partners of choice for investigators as competition for high-performing sites has intensified. The industry has now begun to see the same discussion occur from the site perspective.

"It's important that everyone is starting to think that way and we are all making that effort (to be great partners) because, in my mind, it comes down to the flow of information, transparency and visibility so we can understand how we are going to work well together," said Jen Heckman, senior director, Clinical Trial Logistics at Incyte, a Delaware-based biopharmaceutical company that specializes in cancer discovery and development.

Selected Qualities for a Site Partner of Choice

- Consistency and predictability in patient enrollment and study execution
- Investment in document exchange portals
- Dedicated staff for data entry and study start-up processes
- Willingness to provide input into protocol feasibility
- Membership in site networks or site management organizations
- Innovative initiatives that reduce cycle times
- Access to high volume of patients
- Attends industry conferences

Shift to Strengthening Partnerships

Another factor of this shift is the unprecedented level of M&A activity in the clinical research site sector during the past 24 months, which included large CROs buying or obtaining ownership interest in investigative sites, encouraged many site owners to expand and position themselves for sale. Now that the consolidation has slowed, attention has shifted to how sites can strengthen infrastructure and improve performance in the hope of thereby becoming a site partner of choice.

"Being a site of choice is really important," said Clare Grace, Ph.D., vice president of site and patient access for Syneos Health, formerly INC Research/inVentiv Health. "The sites are readjusting back to the reality that it's not about being a certain size or legal framework for acquisition. It's about that age-old adage: Predictable delivery and consistent quality enrollment in studies is what CROs and sponsors have always looked for and continue to look for. That is the number one key."

Quintiles, which has since rebranded as IQVIA, laid the groundwork for establishing strategic alliances with high-performing clinical sites more than a decade ago through the creation of global preferred site alliances. Since then, most of the major CROs have established some sort of preferred provider or direct partnership program with proven investigators to streamline clinical research processes and drive greater predictability and consistency in study execution. Fewer sponsor companies have established similar preferred programs as many outsource site selection and study conduct management to their CRO partners. In one notable exception, Pfizer has established its INSPIRE program, a network of highly productive sites that are given early access to Pfizer portfolio data and clinical trial information.

Preferred site networks and partnerships have operated for many years, but many sites didn't understand the selection process. They

also weren't widely advertised. Sites would be invited to join the partnerships based on past performance metrics with an organization or their relationships with key personnel. More recently, as sites have learned about these programs and their potential value to their businesses — which could include higher study volume, master agreements, designated relationship managers and faster payment terms — sites have increased efforts to get noticed and become site partners of choice.

"We are all vying for the same opportunities," said Nancy Baker, site director at Clinical Research Consulting, which has two dedicated research sites in Connecticut and New Jersey. "Being a preferred site cuts down your costs of going out and finding new business to make sure that you've got a year-round pipeline of studies that keeps your team engaged, involved and intellectually stimulated. If you are a preferred site, then you know you are going to hear about them first. You at least get a chance to say, 'Yes, this a good one for us and we'd like to put our hat in the ring.'"

Increasing Visibility and Expanding Capabilities

Investigative sites are taking a variety of approaches to increase their visibility among sponsors and CROs and become involved as partners of choice or preferred providers.

Many investigative sites have invested in business development and building infrastructure that demonstrates they take research seriously and are committed to addressing sponsor needs for high data quality and faster cycle times. Sites have hired dedicated staff to work on contracts, negotiate budgets and manage regulatory documents, which can expedite study start-up processes, or joined site networks or site management organizations that offer centralized processes. Others have designated personnel for data entry and query response to ensure contractual timelines for data collection are met. Some site networks also have implemented infrastructure, internal auditing and quality training programs that will make the implementation of new risk-based monitoring models more seamless.

"As a large site group that has the ability to centralize start-up and enrollment activities, we look at expedited start-up timelines, proactive patient screening goals, technologies that could improve the enrollment/quality assurance process, among many other items," said Christian Burns, president of ClinEdge, which supports a network of independently-owned sites across four continents, and vice president of ClinEdge's sister company BTC Network, a network of fully integrated and owned sites in the U.S.

Sites also have invested in technology systems to address new data requirements from sponsor companies and CROs. Some sites have established document exchange portals and central repositories of site information, which can streamline processes and expedite study start up. Others have invested in systems or signed on with technology providers to give sponsors access to de-identified electronic medical records, which can provide valuable information about patient populations available for clinical trials and create the ability for organizations to monitor and oversee sites remotely.

Additionally, many business development managers at sites have become more resourceful in using LinkedIn or networking with individuals at sponsors and CROs through other means to be noticed for new study opportunities and partnerships. Others have become more active in the conference space, presenting on case studies about the use of new technology or tools and showcasing their services in exhibition spaces. Some sites report sending brochures or flyers to site selection personnel about their capabilities.

"From a business development perspective, we try to keep in touch on a regular basis, keeping them up-to-date on our clinical and site capabilities without being overbearing," said Meridien Research's Toms. "We found that being persistent in asking to be added to preferred provider lists or asking about how we can be added, what are the requirements and what they are looking for is how we've been able to gain traction with some of our CRO and sponsor partners."

An increasing number of sites also register with databases operated by individual sponsor companies and CROs, in addition to the cross-industry collaborations, such as the Investigator Databank and TransCelerate BioPharma's Investigator Registry to increase their visibility among organizations. DrugDev, which manages the industry's largest network of investigators, encourages sites, investigators and study coordinators to each set up separate profiles in its database. Although there has been talk about standardizing investigator databases and creating a single sign-in for

Select Advantages for Site 'Partners of Choice'

- Access to higher volume of studies
- Greater visibility into upcoming pipeline of studies
- Improved communication and designated relationship managers
- Operating efficiencies
- More timely payment terms

sites, at the moment, sites need to approach each organization separately and join multiple registries, listing their abilities in several therapeutic areas, and keeping the information updated.

"The difficulty that some sites have is how to get into these preferred network programs in the first place," said Kirsty Kwiatkowski, vice president, FSP Solutions at DrugDev, an IQVIA company. "A lot of sponsors and CROs work with sites they have used before and have performed well on previous studies. Sites should make themselves as visible as they can. When creating a DrugDev profile, they should not just enter basic information, but also include the trials they've worked on so sponsors can see as much information as possible about their site and everything the site can offer."

Organizations Want Sites as Collaborative Partners

Winning status as partner of choice can be difficult and many times relies on an invitation from a sponsor or CRO. While the programs are all structured differently, organizations typically choose partners based on patient enrollment rates and data quality in previous studies. Additionally, many preferred provider networks have met their membership quota, making it nearly impossible for new sites to join unless the organization decides to expand the program or re-evaluate the network members.

"Sponsors and CROs are looking for shared commitment, consistency and predictability when selecting a partner of choice. We need sites and patients for our studies and we no longer have the luxury of "casting a wide net" in hopes that the majority of the sites will live up to their enrollment projections. As CROs, our reputation is dependent on knowing our sites and being able to confidently present a differentiated site and patient strategy. We want to work with high performing sites and we are willing to invest time and effort in cultivating and protecting those relationships," said Rhonda Henry, vice president, Site Collaborations and Patient Centricity at PPD, which has partnered with more than 800 sites/site networks globally. "Sites with little to no research experience are challenged to get the experience they need to demonstrate performance in order to become a partner of choice."

Sponsors and CROs are more likely select partners that have access to higher volumes of patients or with site networks that offer multiple sites under a single contract or centralized process. Yet smaller investigative sites have opportunities to partner with industry if they have the necessary patient populations or have proven themselves in prior studies. For example, although Clinical Research Consulting has only two locations, it has become a preferred site with a sponsor company for seasonal flu studies based on its strong and reliable past performance.

"We are always at the top of their list, even though we are small," said Baker. "The key thing that actually matters, at the end of the day, is how well you do your job in terms of recruiting, enrolling patients and being consistent with that and how well you do your job in terms of ensuring that you are getting good quality data, you are getting it back to the sponsors on a timely basis, that you are responding to queries. It's the basics, quite frankly, that make you stand out."

Select Advantages of Preferred Site Networks for Sponsors

- More accurate enrollment forecasting
- Improved data quality
- Faster study start up
- Site input on protocol feasibility and executability
- Framework for greater collaboration

Just as importantly, sponsors and CROs want site partners that share a commitment to reducing cycle times, providing greater certainty around patient enrollment and improving processes.

For its therapeutically focused Catalyst Site Network, an invitation-only network that is part of its Catalyst program, Syneos Health scours both internal and external data to identify the best sites that can deliver predictable enrollment and quality. In addition, the CRO looks for sites with the ability and desire to partner not only with the CRO, but also with other sites and vendors in its network. Partners also must show a willingness to collaborate on building new methodologies, designing studies, reviewing protocols and adopting new technologies.

"That is what is going to take our Catalyst sites to the next steps of efficiency and quality and speed, so it's really important that they are able to do that," said Grace. "By working together proactively, we can save the site time and effort, reduce their administrative burden and enable them to be more efficient, as well as us being more efficient. Everybody wins."

Additionally, Mark Lacy, president and CEO of Benchmark Research, an integrated site network with six locations that specializes in vaccine studies, said CROs also have begun asking site partners to serve on their bid defense teams to win new projects from sponsor companies.

"Five years ago, we were never asked to provide feedback on protocols or to par-

ticipate in bid defenses for the CRO to get work. They are now recognizing that it provides great value for them in improving protocols and giving them a better chance of winning the award. That is dramatically different and is showing an increase year over year," Lacy said.

At Incyte, which works in some rare oncology diseases, the company frequently uses adaptive clinical trial designs, which may begin with a trial in one targeted population and expand based on the results of an interim analysis, so it wants to work with sites that can be flexible when conducting research. The organization also looks for sites willing to provide input into designing the least burdensome clinical trials for patients.

"It's really important for sites and sponsors to be looking at being the trial of choice for our patients. That requires a partnership between the sites and us," said Heckman.

When looking to get on preferred provider lists, sites should avoid accepting a study they won't be able to enroll or inflating anticipated enrollment projections in hopes of establishing a long-term strategic relationship with the sponsor or CRO. Organizations look at historical performance and compare responses from feasibility questionnaires to their performance on the trial. If sites overcommit and under deliver, that will affect whether a company would want to work with them in the future.

"Sites need to understand that a lot of the decisions that are made come down to data that people have accessed about past performance. So rather than just accepting any study to have a study, sites should accept studies they know they will be successful at," said Melissa Easy, founder and head of strategic partnerships at DrugDev, an IQVIA company. "For many sites, it comes down to you are as good as your last recruitment on a previous study compared to what you said you would recruit."

Looking Ahead

One of the biggest complaints from sites about preferred provider networks is that they don't always result in higher study volume. In some CROs, the site team and therapeutic team for a program may have two lists for preferred partners that don't necessarily match. The preferred partner designation also may become irrelevant as the industry moves toward development of therapies for personalized medicines and rare diseases that might require CROs and sponsors to look beyond their preferred partnership lists and engage referring physicians who may not be involved in clinical research in order to reach smaller patient populations.

Yet preferred provider relationships between sponsors/CROs and sites or site networks has become an established strategy in the industry for improving drug development productivity and both sponsor/CRO organizations and sites will continue to invest time and resources in becoming "partners of choice" going forward.

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