PREFERRED RELATIONSHIPS BETWEEN CROs AND INVESTIGATORS:

A Proactive Approach to Speeding Patient Enrollment

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Increasingly over the past few years, pharmaceutical companies have engaged clinical research organizations (CROs) in preferred provider relationships to streamline and improve their outsourced services. The notion is that by working closely with vendors that have been awarded preferred status, companies can gain efficiencies and boost quality. This same practice is now being extended downstream in the clinical environment. Progressive CROs, eager to satisfy the needs of their sponsor partners for faster patient enrollment and higher data quality, are developing preferred provider relationships with investigator networks and site management organizations (SMOs).

This paper highlights how such relationships work, what benefits they offer, and how CROs should ensure that the advantages accrue to sponsors.

POISED AND READY

While preferred provider relationships between sponsor companies and CROs have become quite common, they are still a fairly new phenomenon between CROs and investigative sites. The principle, however, is essentially the same: The relationship between the parties is established through an umbrella contract and characterized by close working ties that strengthen over the long-term.

Rather than formalizing a working relationship to meet the needs of individual studies as they come along, CROs proactively seek out qualified site organizations and structure a broad agreement that is put in place in *anticipation* of future studies. Stephen Covey puts "Be Proactive" first in his list of *The 7 Habits of Highly Effective People*, and the concept is equally valid for corporations. CROs that strike such partnerships are poised and ready to go once they're approached by a sponsor. By anticipating what will be needed, they can get some of the preliminary steps out of the way before the sponsor's trial clock starts ticking.

Such relationships between CROs and site networks or SMOs generally entail:

- An assessment on the part of the CRO to ensure that the network will meet the CRO's quality standards. This is typically based on specific performance metrics that the site must meet, and can often be evaluated based on the CRO's past experience in working with the site.

What's the Advantage for Sites?

For the preferred provider relationship to be sustainable, it obviously must be a win-win proposition for both CROs and investigator organizations. Sites that enter into such agreements stand to benefit from:

- **Access to more studies.** The opportunity to participate in studies is, of course, important to investigator sites in their quest to improve their patients' health as well as to produce revenue. One network reported that in the first two years of operating under partnerships with CROs, its study opportunities increased from 478 to 1,387 between 2010 and 2012. The number of studies it was awarded increased from 85 to 203 during the same period.[2] Sites must still, of course, make good choices when it comes to signing on for studies.
- **Improved two-way communication.** The partners should regularly discuss upcoming opportunities and the status of ongoing programs, giving sites a preview of what's coming and a channel for raising issues and asking questions. CROs can make sure that investigators understand industry pipelines so they can be ready to meet future opportunities.
- **Operating efficiencies.** Their CRO partners can help sites improve startup processes and recruitment techniques, and simplify the paperwork required during site selection. This translates directly into administrative cost savings.
- **Assistance with expansion**. Global CROs can help networks expand globally into targeted regions, providing guidance on global regulations. Sites should be cautioned, however, that with an increase in study opportunities and the number of awarded studies comes an increase in overall workload, not all of which is revenue generating. Sites must be prepared for additional study load planning and more staffing and resource planning, for example.

- A Master Service Agreement (MSA) that lays out the terms of the relationship, including the quality expectations and financial arrangement.
- An understanding that when there is a match between a study's scientific area and the investigator organization's therapeutic specialty, it will be given "right of first refusal."
- No expectation of exclusivity in the arrangement; CROs may have similar agreements with other organizations, as may sites.
- No quotas in terms of the number of studies a CRO is expected to deliver to a site organization.

BENEFITS FOR SPONSORS: ACCELERATING DRUG DEVELOPMENT

When sponsors work with CROs that have established preferred provider relationships with investigator networks and SMOs, they benefit from both the CRO's foresight and established ties with sites. This materializes in the following:

More Precise Enrollment Forecasting

Estimating how many patients can be enrolled, how quickly, and from what sites has traditionally been challenging. It's well known that, for a variety of well-meaning reasons, sites tend to overcommit to trial proposals and are overly optimistic about their ability to supply patients. In fact, in any given trial, 11 percent of sites fail to enroll a single patient and 37 percent underenroll .[1]

When CROs work with site networks in preferred provider relationships, it alleviates some of this uncertainty in enrollment forecasting. Over time, the CRO gains an understanding of the network's patient population and of the organization's performance history (see "Improved Data Quality" below). And, as trust builds between the parties, the site network becomes more candid in discussing its realistic enrollment capabilities.

Faster Study Startup

Because the CRO has already established a relationship with preferred sites and because there is already an MSA in place, CROs can skip the contract negotiations with preferred sites, and studies can be jump-started. This alone can save an average of four weeks, since typically the contracting process can take up to three months or more.

And, because CROs may call upon their investigative partners to consult on the nature of a given protocol even before the study is awarded, CROs can bid on projects knowing in advance where there might be complications in the protocol. Potential issues can thus be dealt with before they pose a problem that causes a delay in study start.

Critical Success Factors

Just as in preferred provider relationships between sponsors and CROs, those between CROs and site networks require joint governance and strong communication to ensure ongoing alignment and continuous improvement. CROs that have paved the way have established best practices for managing preferred site provider relationships. To be successful in partnering with preferred networks of sites, CROs must:

- **Establish a joint steering committee.** Senior executives from both organizations should convene at least biannually to ensure that the relationship is working as intended. The committee should be charged with setting direction, determining policies, reviewing performance, resolving issues, and evaluating advances that will strengthen the collaboration.
- **Set up a special team dedicated to assisting sites.** The preferred provider relationship requires focused attention and continuity in developing and managing the partnership. This responsibility should not fall on project managers, but rather on dedicated relationship managers. Then, during the feasibility and site identification stage of a trial, CROs should create a single point of contact for networks, with a coordinator assigned to work exclusively with the network. Minimizing the number of contacts in this way streamlines interactions and improves cohesion.
- **Coordinate and systematize communications.** Channels of communication between CROs and their site partners must be open and routine. This can be as simple as regularly scheduled calls to discuss upcoming opportunities and ongoing programs. It can also include electronic communication systems that allow sites to file questionnaires and documents (such as medical licenses and institutional review board approvals) efficiently.
- **Strive for continuous improvement.** To realize the primary benefit of the partnership — faster drug development with greater data integrity — both parties need to search continually for ways to engineer out cost, streamline procedures, and minimize errors. This will require a mutual investment in technology and an openness to new ways of working.

Additionally, because CROs can keep their network partners apprised of potential studies in the pipeline, sites can use this foreknowledge to begin identifying patients even before the study begins.

Improved Data Quality

As CROs and their preferred networks collaborate over time, they gain a better understanding of one another's expectations and capabilities. By working together on multiple studies and by establishing regular communication channels, networks become familiar with the CRO's standards, work processes, and systems, contributing to greater consistency in what they deliver.

There is the potential for the relationship to lead to technological collaborations that support remote-based monitoring as well as real-time reporting and document transfer through portals. And, selected sites can serve as key opinion leaders (KOLs), offering CROs their expertise in specific therapeutic areas.

Also, the ongoing nature of the relationship should give CROs visibility into sites' performance. CROs can track metrics on the network's performance, which can be monitored over time and be compared to benchmarks by country, therapy area, or protocol design. Metrics can include startup timelines, enrollment rates and timelines, retention rates, data quality, and number of data queries. These metrics should be shared with sites and may also be presented to sponsors.

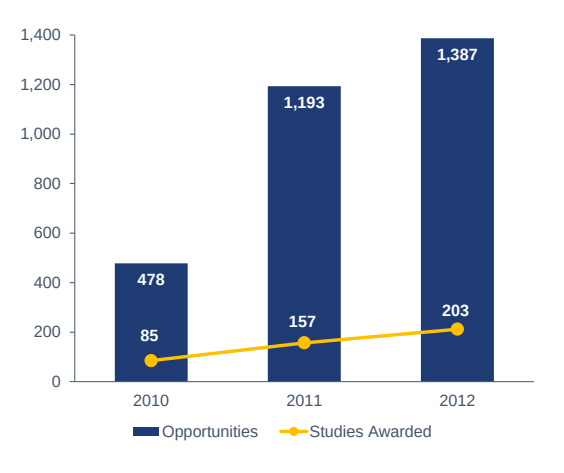
Another long-term benefit is the prospect of networks expanding to encompass more sites, often in more countries. Many networks are interested in expanding their footprint, and to the extent that they are successful, CROs have ready access to sites in more locations. Also, networks can gradually develop less experienced sites, tapping into CROs' training resources to expand their pool of available sites.

CONCLUSION

Preferred provider relationships between CROs and site networks is the next logical step for the life sciences industry in its quest to improve drug development productivity. By working proactively to have qualified sites under contract in advance of recruiting for a particular study, CROs can speed the selection and startup process. And, by establishing a close working relationship with sites that promotes continuous innovation and improvement, CROs can aim to realize process efficiencies and quality enhancements. When handled properly with management oversight, strong communications, and ongoing transparency, these relationships can benefit both parties — and ultimately sponsors.

Preferred provider relationships, although relatively new, can profit from everything that the industry has learned in maintaining similar relationships between sponsors and CROs. They only flourish when given the proper attention — not just during inception, but consistently and over time. This requires a commitment from both parties to nurture the relationship and continue to find ways to derive mutual value from it.

Figure 1: Volume of Study Opportunities and Studies Awarded Changed Through Preferred Partnership With CROs



Source: Benchmark Research, 2010-2012

Connecting With Sites via a Social Network Platform

inVentiv Clinical Trial Recruitment Solutions (iCTRS) has partnered with ViS Research to build a social network of sites interested in conducting clinical trials with inVentiv Health. The platform allows sites to share detailed information on their infrastructure, therapeutic expertise, and other information typically captured on feasibility questionnaires. This information is shared ahead of time through the built-in social networking tools. Therefore, when a specific study is awarded, iCTRS can focus on asking only the protocol-specific questions. This game-changing innovation in feasibility assessments has the potential to eliminate the traditional feasibility questionnaire (paper or online versions), significantly reduce feasibility assessment work effort, and give sponsors greater visibility into the progress of active feasibility projects. For further information visit: www.inventivhealthclinical.com/media-center-press-releases-2013.htm

REFERENCES

1. Tufts Center for the Study of Drug Development. *Impact Report*, Jan/Feb 2013, Vol. 15, No.1.
2. Benchmark Research, 2010-2012.

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