UPPING THEIR GAME:

CROs Must Develop a New Mindset to Partner with Sponsors

by Mark Scullion

Today, sponsor companies engage Clinical Research Organizations (CROs) on several different levels: to handle specific responsibilities on a trial-by-trial basis, to manage an entire program or trial, or to perform an entire function. In all cases, whether the relationship is transactional or strategic, sponsors are expecting more input from their CRO partners. CROs should be able to provide both operational and scientific recommendations that add value and ultimately advance outcomes. Especially in the highest-order relationships—aligned partnerships marked by long-term deals and shared goals—CROs must demonstrate an understanding of how to add value, what constitutes success, and what risks they may encounter. In short, they must approach their role with a new notion of what it is to be a partner.

GREATER EXPECTATIONS

It used to be that when biopharmaceutical companies contracted with a CRO on a transactional level, the CRO was given a specific scope of work with very prescriptive guidelines. Now, even in very task-oriented engagements, CROs are increasingly invited to offer suggested alternatives to the sponsor's planned approach. Sponsors expect CROs to be more than order takers, and to add value.

In recent years, many pharmacos and CROs have taken things to an even higher level of engagement by entering into strategic partnerships aimed at improving R&D productivity. In such partnerships, the focus is not on the provision of resources, but rather on the deliverables or outcomes desired, with both parties sharing a common definition of success. The goals are ambitious and cannot be reached in the short term or at the project or program level. The two parties approach the challenge as equals, and the lines between where one organization begins and ends become blurred. Through close collaboration with the sponsor, the CRO has the opportunity to understand its customer's needs completely and to find new ways to contribute value.

So, at all points along the partnership continuum, CROs must be willing to work under a different framework. They are tasked not merely with completing goals, but also with strategizing, and bringing ideas, innovations, and technology to bear in achieving those goals.

THE COMPONENTS OF ALIGNED PARTNERSHIPS

For the parties in a partnership to be successfully aligned, they must have:

- Clarity around shared goals. In this context, the goals are not simply Key Performance Indicators (KPIs), which typically measure lagging short-term performance. Instead, they are what Jim Collins and Jerry Porras referred to in Built to Last as "big, hairy, audacious goals"—those that are visionary, strategic, and a stretch. The timeline for achieving them is not measured in months, but in years. For the CRO to be able to accept such a mandate, the sponsor must share details of the current state with the CRO and fully describe the endpoint it has in mind. This will allow the vendor to assess what is realistic. For example, if a sponsor's goal is to reduce costs by 60 percent over three years, but the work it outsources to a CRO accounts for only 30 percent of its costs, the CRO cannot achieve the goal singlehandedly.

- A match of cultures and capabilities. Assessing whether the vendor has the necessary capabilities is fairly straightforward, as compared to determining if the two companies' cultures mesh. A determination of "cultural fit" cannot be made on the basis of pitch meetings or even empirical data and case studies; typically it requires the familiarity gained through an existing relationship. For this reason, aligned partnerships tend to emerge from some prior experience between the two companies or the principals involved. Even though the goals are business ones, they are, at some level, also personal and affect livelihoods and careers. Vendors should, therefore, be willing to commit to delivering on the goals on an equally personal level.

- A Pay-for-Performance structure. The CRO, to be in synch with the sponsor, must have "skin in the game" at a level that is more meaningful than financial penalties for not meeting the terms of a Service Level Agreement (SLA). After all, the consequences of not achieving a milestone are more than financial for the sponsor; they are strategic, scientific, and often public. If the sponsor suffers a clinical setback, a small Service Level Credit (SLC) payment—a portion of an invoice, for example—is scant consolation. In an aligned and collaborative partnership, the two parties' views of risks, rewards, and success must be compatible.

A sponsor's choice of CRO partners may, in fact, be driven more by a shared vision of the future and cultural compatibility than it is by cost.

DELIVERABLES-BASED CONTRACTS

Any contract between aligned partners must, of course, spell out what is to be provided by the CRO, for what remuneration, although settling upon these terms is a very complex business. In deliverables-based contracts, CROs can be compensated on the:

- completion of simple units of work or tasks that are time based (such as site visits);
- delivery of work products (such as the creation of site training materials); or
- achievement of specific milestones or clinical outcomes that materially affect a product's commercial success (such as a database close).

Today, the overwhelming majority of contract terms between sponsors and CROs are based on units and tasks, but in strategic partnerships the focus is increasingly on deliverables and outcomes. One measure is not necessarily preferable to another, so long as:

1. Both parties understand what they are agreeing to in the process. Definitions of what is a unit, an output, or an outcome may differ, affecting perceptions of accountability; and
2. Every deliverable can ultimately be linked to an outcome. Life sciences companies deal in scientific achievements and health outcomes. So, a CRO ought to be able to show how the completion of even a unit of work ultimately supports the sponsor's desired outcome.

The scheme selected must be aligned with the stated scientific and financial outcomes, promote the right behaviors, and recognize incremental levels of complexity in the work.

PRICING DESIGN

Determining the reimbursement structure in a deliverables-based contract is not a straightforward process, even if the deliverables measured are simple units or tasks. The CRO's costs will necessarily be based on:

Scope of work. The particulars of who will be doing the work, where they are located, the number of units of work to be performed, and how long it will take to do each unit have to be calculated. These factors, however, while important to the CRO's cost structure, may not figure into the actual contract. When a deal is based on milestones or outcomes, the CRO is tasked with serving that result, without regard for the scope of work behind it. What is more, in aligned partnerships that extend over multiple years, there is an expectation that efficiency gains from continuous improvement will be set against increases in operating costs.

Quality. Quality of clinical data is the ultimate product, and of critical value. Everyone wants high quality, but understanding the cost of quality—balancing it against cost and risk—is critical. The vendor should be able to put a tangible value on that quality so that the sponsor can determine if it will be worth it. For instance, if an acceptable quality standard is 98 percent cases without error in a pharmacovigilance partnership, how much additional cost is it worth to achieve 99 percent?

Risk. Sponsors and CROs generally interpret risk differently, yet in an aligned partnership, the sponsor's worries should also be the CRO's worries. This includes scientific risk, geopolitical risk, resourcing risk, and financial risk.

Successful vendors understand, and proactively address, the full range of issues—offering solutions that advance the shared goal.

MANAGING RISK ON A HIGHER LEVEL

To support their sponsor partners, CROs need to consider the full spectrum of operational, scientific, and business risks at play. How might the issues with site compliance in a given study impact the protocol design of subsequent studies? Are we detecting signals that might affect the risk-benefit profile of the investigational drug? Do we have the right geographic footprint for our portfolio and budget?

Risk management and risk mitigation plans are not new features of clinical development outsourcing, but as partnerships have evolved, and as the level of accountability given to CROs has increased, the CRO's ability to manage risk has become more critical. In aligned partnerships that focus on deliverables or outcomes, the CRO is more fully integrated into the sponsor's general management model, and must, therefore, be prepared to take a 360-degree view of risk. Whether or not the deal involves risk sharing, the CRO should provide counsel on points of risk and serve as "another set of eyes on the road" for the sponsor.

There are two components to this. First is the quantification of risk—what is the baseline? Of course, completing this exercise on behalf of sponsors requires that CROs be privy to the daily challenges to success and are given the full business context within which the sponsor operates. It also requires that both parties be able to quantify the risk of making a change, understanding that the baseline level of risk is not zero and that a procedural change does not automatically increase risk.

The second component is risk-scenario planning. It is even advisable for CROs to practice "paranoid planning" by methodically asking a series of penetrating "what if" questions and then considering the potential impact. What will we do if several sites are unavailable due to a natural disaster? How might a regulatory change to monitoring frequency affect the protocol design? The questions, which are only the first part, should also come with scenarios to meet the identified needs, with risk-benefit analyses, and with recommendations tailored to the sponsor's circumstances and culture. These scenarios should go beyond operational risk—and even beyond the current contract scope—to take as full an account as possible of the entirety of the sponsor's circumstances.

CONCLUSION

Developing an aligned partnership is not easy, nor can it be done quickly. Even when there's an established match of cultures and capabilities between the parties, structuring the deal and designing the pricing is a complex process. As companies evaluate CRO partners, even for transactional work, they should be considering their potential fit for a more aligned relationship in the future. Forming an aligned partnership can lower costs, reduce oversight, and support the type of visionary goals that will deliver competitive advantage.

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