



APPLIED CLINICAL TRIALS — Online —

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Emerging Pharmas and CROs Need Each Other

By David Levin

How changing times require a new approach to partnerships.

(Getty Images) Strategic relationships with CROs have typically been the exclusive domain of large biotechnology and pharmaceutical firms with multi-millions to spend on clinical trials. But, as the face of the biopharma world is being altered by smaller firms, these strategic relationships have taken a new form. Now, growing biopharma companies are working with more synergistic and more specialized CROs for new gains in efficiency and cost-effectiveness.

Rather than being the small fish in a big pond, emerging firms are actively elevating their status by testing the waters of strategic partnerships with their CRO. Many of the benefits of working with a CRO that accrue to larger organizations are even more important for the smaller research sponsor that likely has limited resources, such as:

- Capitalizing on the capabilities of a CRO allows sponsors to focus on their own core strengths rather than organize, create, and administer a complete clinical trial themselves.
- Optimally designed trials that are conducted correctly the first time are crucial for success. CROs have the breadth of expertise to design trials that achieve stated clinical, regulatory, and commercial objectives in a focused and efficient manner.

However, it may be difficult for an emerging firm to elicit the level of attention needed from a large CRO to achieve these benefits.

At Clinipace, we have been successfully exploring the full range of a strategic relationship with Inspire Pharmaceuticals, a biopharmaceutical company focused on developing and commercializing prescription products for ophthalmic and pulmonary diseases.

With one or two drugs, Inspire was able to work directly with investigative sites to manage clinical trials. Generally, the company had been reluctant to outsource the management of studies. Inspire felt that it was good at developing relationships with investigators and had worked hard to build and maintain those

relationships. They felt that inserting a big CRO into the mix would dilute the relationship with those sites.

But as Inspire's portfolio grew, the company began to realize that time spent managing trials was time taken from development and other core competencies. While the company had worked with larger CROs in the past, Inspire felt the time was right to be more strategically engaged with its CRO partners.

Forging a new paradigm

Inspire had previously deployed another of our technology-based research software solutions and thus had established a good working relationship with our executive team. Chad Ice, senior director of Clinical Research at Inspire, has significant experience working with large CROs, and he knew the particular aspects and dynamics of those relationships that worked, and those that didn't.

As Chad and I recently discussed lessons learned from our strategic working relationship, several important themes emerged.

- Market-driven CROs can provide more focused and customized service. Many larger CROs offer line item services that get added to every contract, even when they might not be the best fit for a smaller customer or project. As a result, a smaller research sponsor may be paying for services that they don't need, or bearing a disproportionate overhead burden. A smaller CRO has the ability to tailor its services to the specific needs of the sponsor. This has the added benefit of building trust since the sponsor doesn't feel nickel-and-dimed with line items.
- Clinical operations-oriented CROs emphasize the need for building strong working relationships with research sites. One crucial element in driving a successful study is focusing on the importance of building and maintaining strong working relationships between experienced site monitors and the sponsor team. Clinical staff should serve as technology advocates, acting as extensions of the sponsor's staff, actively participating in team meetings and decisions.
- Fixed-price CROs can make rapid course corrections. Usually, a project with a larger CRO is based on strict adherence to an agreed-upon scope of work. Anything outside that scope must be negotiated and submitted in a contract addendum. Smaller CROs have the flexibility and agility to make changes without calling in the contract professionals and lawyers. Small tweaks to deliverables and deadlines can be made by mutual agreement among team members based on real-time information.
- Digital CROs provide more visibility and keep two-way communication going. Successful business relationships often hinge on transparent information exchange and successful personal relationships—the kind that come from trust, honesty, and open communication. Trial visibility and two-way communications at the highest level aren't always possible with a larger CRO where there are too many layers of managers to navigate. Responsiveness at the top also goes a long way toward avoiding problems and mitigating risk.
- Creative CROs are more open to solutions that maximize efficiencies and cut costs. Rather than depend on volume for efficiency gains, smaller CROs seek innovative new technologies and processes that often can't be introduced into larger CROs with entrenched procedures. For example, our technology platform brought together multiple sources of data that would have otherwise needed manual intervention. And, because smaller CROs tend to be privately held organizations they don't have to focus on quarterly results, but can instead offer price reductions.

According to Chad, "We especially like having the ability to communicate directly with senior members of the Clinipace team. It is important to us that we are important to them. As much as we value open communication, trial visibility is equally important as many program decisions must be made internally."

Much as this sounds like it all benefits the sponsor, the smaller CRO has a lot to gain from forging strategic partnerships as well. Some key benefits to the CRO include:

- Increased learning opportunities. For all CROs, every engagement may be a learning experience rather than just a repetition of established tests and trials, but larger CROs are less likely to operationalize these experiences in their standard operating procedures (SOPs). Discovering new efficiencies, methodologies, and capabilities leads to an interesting and challenging work environment that may also promote staff retention.
- Shared appreciation of the entrepreneurial point of view. CROs and their research sponsors enjoy a shared entrepreneurial spirit. Both companies understand the need to tightly manage cost and risk without constraining innovation and creativity. This allows the CRO to push some limits and jointly engage the sponsor in ways that a larger CRO or sponsor couldn't.
- Stability in tough economic times. Strategic alliances are likely to be longer term than contract engagements. A longer term commitment from a sponsor provides the smaller CRO with some stability and the ability to make investments in expertise or equipment that will enhance their overall service offerings.

Transparency strengthens the relationship

As relationships among sponsors and CROs of all sizes change from contract to collaboration, smaller CROs can distinguish themselves by becoming market leaders. The combination of visibility, personalization, and lower overhead will make the CROs more attractive as emerging company sponsors place higher value on skills and operational expertise, not just capacity.

At Clinipace, we've experienced firsthand how an open partnership with an emerging biopharma firm can benefit both companies. For any biopharma firms considering this kind of relationship, here are some parting words of advice:

- Don't be afraid to ask for exactly what you want—your CRO should be willing and able to accommodate your requests.
- Be open to exploring new ideas that may enhance efficiencies and improve your business processes.
- Be willing to negotiate on schedule and deliverables as new or unexpected situations arise.
- Participate in team building activities, social gatherings or other opportunities to engage staff from both companies.
- And finally, keep the channels of communication open, flowing, and respectful. You'll be glad you did.

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