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From Vendor to Partner: Changing the Dynamic Between CROs and Drug Developers

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In the modern world of drug development, pharmaceutical companies are pioneering a new generation of partnerships.

They're teaming up with video game developers to stimulate the minds of cognitively challenged patients. They're acquiring developing-world generics players to deepen their distribution networks. They're working with software makers to create smart phone applications.

But despite all this partnering progress and innovation, the relationship between most drug developers and contract research organizations has remained stagnant. And that's something INC Research and its customer base is changing.

Expect More from Your CRO

Drug developers historically have viewed CROs as vendors – important vendors held to high standards of efficiently delivering reliable data – but vendors all the same.

While the CRO-sponsor relationship has worked at this operational level for years, it has never fulfilled its promise strategically—namely, that CROs act as stewards of our customers' assets and share in the same incentives for the success of those assets as our customers. Given continually rising drug development costs, the increasing complexity of trials, and ever-higher hurdles to regulatory approval, both sponsors and CROs are being forced to think differently about how to derive maximum value from their working relationship.

INC Research is at the forefront of a movement in which sponsors and CROs are working together to question the existing model, and consider the possibilities when sponsors and CROs act as true partners with shared goals.

This kind of change isn't applicable in all scenarios. In some cases, it may make sense for CROs to simply execute on a single clinical trial. But in other cases, there is value to be gained if the CRO can think strategically about the entire clinical continuum for a given product, for several products in a given indication, or even for a whole pipeline.

Current Alliance Partnership Models

The beauty of an alliance partnership is that both the CRO and the drug developer assume risk and realize rewards, creating value at the corporate level rather than just at the clinical trial level. Models will continue to emerge, but different types of alliances hold attraction to different types of customers.

For example, a pharmaceutical company might be interested in a risk-sharing model in which all projects are scoped on a fixed-fee basis and the CRO receives a bonus if study timelines are met or fee reductions if they are missed.



Alternatively, an emerging biotech company might be interested in a compound management program, in which the CRO is the exclusive partner for Phase II and Phase III development of its two lead compounds. The biotech gets not only efficiency-based cost-savings, but also continuity across its trials and improved visibility through regular reporting and analysis. Furthermore, since the CRO is contracted to support multiple programs, the project team becomes uniquely incentivized to help the biotech discover a successful compound or appropriately terminate a compound, as early in the process as possible, to avoid unnecessary effort and cost expenditures. This type of commitment is not inherently incentivized in a traditional sponsor-CRO relationship.

Similar benefits can be realized by larger biotechnology and pharmaceutical companies through a therapeutic area management program. In such an arrangement, a CRO would tap into its therapeutic area expertise to manage all of the company's trials in an indication, such as oncology or endocrinology.

Larger pharmaceutical companies may also derive benefit from a functional management partnership, in which a CRO assumes the management and execution of a specific function, like data management or site contracting, across a large portion if not all of the company. This may involve shifting certain pharma employees under the CRO company with management from a joint oversight committee.

Another option that might appeal to emerging biotech companies is business process outsourcing, in which a CRO manages all clinical trials for compounds in the company's pipeline, essentially serving as the biotech's clinical development department.

Shifting Incentives & Accountability Results in Significant Benefits

No matter how the alliance partnership is structured, the following benefits apply:

Shared Risk - Traditional CRO contracts are not conducive to a partnership mindset. For example, CROs are often paid per site visit and are thus incentivized to increase these visits, which can slow down the clinical trial process.

Shifting this traditional mindset, alliance partnership contracts take a performance-driven approach. The CRO gets paid when the customer gets value: when the trial is fully enrolled, when data monitoring is complete, and when the data are delivered, for example. An important component of this approach is putting performance metrics into place: the customer pays more if the CRO meets them, less if the CRO does not. In this model, everyone is incentivized to hit the same endpoint.

Cost Savings - There are obvious savings associated with building a partnership that spans several clinical trials for a compound or several compounds in an indication. Such a relationship eliminates the need to issue a request for proposal each time a new trial starts, and it avoids the time-consuming process of establishing a new CRO relationship. All of that saves time, and in the world of clinical trials, time is money.

Resource Commitment - Another benefit of alliance partnerships is that they help CROs to understand the drug developer's long-term needs and allocate resources accordingly. If an alliance includes both a compound for diabetes and one for cardiology, the CRO can have both endocrinology and cardiovascular teams queued up for quick trial starts.

Unlike a tactical outsourcing relationship, an alliance provides the CRO with visibility into a customer's pipeline, and enables the CRO to designate specific resources—at both study management and functional levels—to work with the alliance customer. This key element ensures that alliance customers work with dedicated CRO team resources that are knowledgeable about the compound and the customer's culture, and are not distracted by work on any other initiatives.

In addition to having dedicated operational resources, strong alliance partnerships benefit from management by a joint steering committee comprised of senior members from the CRO team and from the customer's team. The committee ensures not just operational but strategic excellence.

Creative Thinking - We understand that everyone from biotech start-ups to big pharma is facing bottom-line pressure. A CRO should be willing to think creatively to help its customers stretch each dollar further.

INC Research is uniquely positioned to build these kinds of alliance partnerships with our clients. We focus exclusively on Phase I through Phase IV clinical trials, and we have strategic expertise in pipeline management, registration strategies, compliance, due diligence, and other aspects of the drug development and commercialization continuum.

The concept of strategic alliances between sponsors and CROs is in its infancy. And, like any new idea, there will be models that work and models that don't. INC Research has created a team focused solely on structuring and managing successful alliance relationships, because we know that by working closely with our customers and applying best practices and first-hand experience of their unique program requirements, our team collaborates to develop "fit for purpose" solutions.

Based on our experience thus far, we are confident that through our exploratory process we can structure a working relationship that drives benefits in quality, consistency, efficiency, and the bottom line—far beyond what's possible in a tactical outsourcing relationship. Together, with our alliance partners, we can help advance the sponsor-CRO relationship to realize the true value of strategic outsourcing.

To explore alliance partnership opportunities with INC Research, please contact Tim Dietlin at tdietlin@incresearch.com or visit www.incresearch.com.

About the Author

In his role as Vice President, Alliance Development, Tim Dietlin is focused on identifying and developing strategic alliance relationships with INC Research customers. Alliances are defined as relationships in which INC Research owns a non-competitive status with a customer for a specific type or amount of work—whether functional outsourcing, co-development of a compound, management of a therapeutic area or entire pipeline, or sharing in the risk and reward of a compound's success.

Tim comes to INC Research after almost eight years at Campbell Alliance, a management consulting firm specialized in the pharmaceutical industry. While at Campbell, Tim founded and held leadership positions in consulting practices focused in both Clinical Development and Medical Affairs. Tim's clients at Campbell included Amgen, GSK, J&J, Genentech, Onyx, and Pfizer, as well as several CROs. In this capacity he worked directly with CMOs, VPs of Clinical Development, and heads of Clinical Operations and Clinical Data Management. Tim holds a BA from Loyola University Chicago and an MBA from DePaul University. He is based in Chicago.