

Successful Strategic PARTNERING

Urgent and competing demands are challenging the clinical development efforts of today's biopharmaceutical companies. Pressures to enhance innovation, feed pipelines, and improve efficiency and quality, all while lowering costs in an evolving regulatory environment are more acute than ever before.

An immediate response to these challenges has been for biopharmaceutical companies to cut costs in order to improve profitability primarily through mergers and acquisitions, reductions in workforces, and strategic outsourcing.

Biopharmaceutical companies are turning to strategic outsourcing to address their business needs because these partnerships lower the cost of doing business, increase productivity and efficiency, and maintain or improve quality; all of which help a company gain a competitive advantage.

Laying the Foundation for Partnering Success

To ensure success of the strategic partnership these critical attributes are required:

Executive sponsorship. Without executive endorsement, involvement, and support from both partners' executive management, the alliance will fail. These partnerships demand a long-term, strategic commitment that is embraced and implemented from the top down.

Long-term focus. Durable, effective relationships have goals that are achieved over time. Both partners need to remain focused on achieving the long-term goals and avoid being sidetracked by short-term needs and issues. Success depends on the ability to identify sustainable and scalable ways to increase efficiencies and productivity.

Flexibility. Both partners need to be flexible and innovative. Functional areas in both organizations, for example data services, IT, human resources, and finance, will be challenged to develop and implement customized, innovative solutions meeting the unique needs of the partnership and enabling it to evolve over time.

Additional Sponsor Attributes

For a strategic alliance to thrive and be successful, sponsor associates must make the transition from the customer/supplier sponsor/vendor mindset to a partner/collaborator mindset. Transparent communication within the sponsor company is also required. Sponsor associates who will be affected by this relationship need to be told the reasons why this particular strategy is being implemented. A deep understanding of the key objectives and outcomes throughout the sponsor organization is critical in ensuring a successful partnership.

Required CRO Attributes

A CRO partner with a solid understanding and history of successful strategic partnering is critical to meet the challenges and objectives of such a partnership.

Financial Stability and Strength. Entering into and sustaining a strategic alliance may require investing in new technology, additional facilities, new geographies or organizational infrastructure. The CRO must be able and willing to support the necessary investments.

Innovative Culture. To attain the long-term goals of increased productivity and reduced costs, it is key that the CRO has a proven culture of innovation. The CRO needs to constantly work to identify better, more efficient ways to perform the work, and then successfully apply the new ideas, driving definition of new best practices and standardization.

Organizational Flexibility and Accountability. Partnering successfully with a sponsor requires a CRO that is willing and able to create a customized team structure composed of leadership and associates who are dedicated to developing and growing a mutually beneficial and highly effective partnership. Dedicated leadership for the partnership within the CRO is critical to ensure the CRO has clearly identified internal ownership and accountability for the relationship.

Execution. The ability of the CRO partner to execute is vital. Dedicated leadership and staff members who are able to move ideas and work forward, deal with ambiguity, and trans-

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form words in a contract into actions, are essential. Often the CRO finds it necessary to push the sponsor to move forward at the pace needed to ensure the expectations of the alliance are met.

Customer Service. The CRO needs to be committed to getting the work done efficiently, on time, and with consistent quality, and the sponsor organization must be able to see (measurable KPIs) and feel this commitment. The sponsor needs to have confidence and see evidence that its partner shares its level of interest and commitment to doing the work and supporting the business objectives. Customer service is something that each individual on the CRO team should understand and be committed to.

When both partners have the necessary attributes they will be able to work as a cohesive, highly performing, highly successful team able to deliver to the objectives of the alliance.

A Successful Partnership

A successful strategic partnership has a number of critical attributes:

- » It has a governance structure with engaged executives from each company. As they acknowledge the need for top-down implementation, these executives will set the goals and direction for the alliance.
- » Decision-making responsibility is clearly defined with open discussion of information and ideas.



A Case Study: Applying the Principles

A global biopharmaceutical company wanted to improve the way it managed clinical trial data and consolidate its data management activities. To effectively and efficiently enhance these processes and activities, the sponsor entered into a strategic partnership to address several key challenges.

Reduce fixed costs. Similar to other organizations in the biopharmaceutical industry, the sponsor needed to reduce costs — particularly fixed costs. The ability to significantly lower the cost of clinical data management was essential to achieving the sponsor's objective.

Move to a deliverables-based model. By utilizing a deliverables-based model, the sponsor would pay vendors only for the actual costs of deliverables and, as a result, help the sponsor keep its spending within its budget.

More efficiently manage data from clinical trials. The company believed that improving clinical data management process efficiencies would help expedite data delivery and, ultimately, its use for important trial results.

Avoid disruptions to the portfolio. To avoid any disruptions to the sponsor's portfolio, it needed a trusted partner with the right expertise and a well-thought out plan for a seamless transition.

Maintain high standards. Most of all, the sponsor wanted to protect its reputation and ensure its standards for clinical data management excellence.

Solution

The sponsor was able to overcome these challenges by engaging in a strategic partnership using a functional service provision (FSP) model to meet its objectives.

Effective Use of Resources

Experienced personnel, previously employed by the biopharmaceutical company, were hired to ensure that the company retained knowledge vitally relevant to the clinical trial and therapeutic area. This strategic decision enabled the sponsor to help place employees in new jobs and ensured well-informed and talented staff members were assigned to the project.

Seamless Transitions

Clinical managers moved quickly to ensure the efficient transition of data management activities to the FSP team. They opened a new office in close proximity to the client's study team. Additionally, the FSP team was provided with ongoing support and training to successfully accomplish its responsibilities, which included the management, coordination, and delivery of clinical trial and analysis datasets.

Client Service

The FSP team managed outside vendors on behalf of the sponsor, ensuring the high quality of the project's deliverables and freeing up the sponsor's internal study team was able to tackle more strategic work.

With the right people properly trained and in place on the FSP team, the biopharmaceutical company sponsor was guided through the process to transition from a data management-based transactional model to a deliverables-based model.

Outcome

Under an FSP partner model, both entities were able to take advantage of flexible, scalable staffing solutions. In turn, the sponsor was able to reduced its fixed costs, as well as the number of vendors contracted to support clinical data management activities. And with more efficient clinical data management processes in place, the sponsor company could gather results more quickly.


The company has already accrued substantial savings and productivity improvements, and expects to see a cumulative net benefit of up to \$98 million in savings projected over five years. The sponsor has already realized a:

- » 60% reduction in overall fixed costs
- » 50% decrease in effort for dataset creation
- » 54% reductions in study build cycle times
- » 60% increase in utilization

- » Business objectives and long-term strategies are shared, aligned as necessary, and of benefit to both partners.
- » Communication is constant, open, and honest, regardless of whether the message that needs to be delivered is good or bad; transparency is essential.
- » Successes and failures are attributed to the "team" and not to one partner or the other.
- » Key performance indicators are developed jointly and reviewed on a consistent basis
- » A successful alliance continues to innovate and evolve.

The partners work together to evolve the relationship and find innovative ways to add value, whether through new processes, new technologies, or new services, that can be incorporated into the alliance and increase the value being realized.

Conclusion

Establishing a highly productive relationship is key: it depends on working together to meet the goals of both partners, while continuing to seek ways to add value as a team. 

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