



WHITE PAPER

Successful Strategic Partnering

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INTRODUCTION

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 companies to cut costs to improve profitability, primarily through mergers and acquisitions, reductions in workforce, and strategic outsourcing.

Biopharmaceutical companies are turning to strategic outsourcing to address their business needs. Such partnerships lower the cost of doing business, increase productivity and efficiency, and maintain or improve quality, all of which contribute to a company's competitive advantage.

LAYING THE FOUNDATION FOR PARTNERING SUCCESS

To ensure the success of a strategic partnership, the following 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, 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 mandatory. Sponsor associates affected by the relationship need to understand the reasons for a particular strategy. In addition, a deep understanding of the key objectives and desired outcomes throughout the sponsor organization is critical in ensuring success in partnering.

REQUIRED CRO ATTRIBUTES

A CRO partner with a solid understanding and history of successful strategic partnering is essential in meeting the challenges and objectives of 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, the CRO must have a culture and proven track record of innovation. The CRO needs to work constantly to identify better, more efficient ways to perform the work, and then successfully apply the new ideas, creating 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 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. An indispensable element of success is dedicated leadership and staff members able to move ideas and work forward, deal with ambiguity, and transform words in a contract into actions. Often, a CRO finds it necessary to urge the sponsor to move forward at a pace needed to meet the expectations and goals of the alliance.

Customer Service

The CRO needs to be committed to efficiency, meeting deadlines, and delivering consistent quality while the sponsor organization must be able to see (measurable KPIs) and feel this commitment. The sponsor needs to feel confident, based on evidence provided by the CRO, that its partner shares the same level of interest and commitment to supporting the business objectives. Customer service is something to which each individual on the CRO team should feel committed.

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A SUCCESSFUL PARTNERSHIP

Successful strategic partnerships share a number of critical attributes:

- They have 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.
- 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 is good or bad. Transparency is essential.
- Successes and failures are shared by the team and not attributed to a single partner.
- Key performance indicators are developed jointly and reviewed on a consistent basis.
- A successful partnership continues to innovate and evolve.

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

CASE STUDY: APPLYING THE PRINCIPLES

Challenge

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	<i>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.</i>
Move to a deliverables-based model	<i>By employing 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.</i>
More efficiently manage data from clinical trials	<i>The company believed that improving clinical data management process efficiencies would help expedite data delivery and, ultimately, its use for important trial results.</i>
Avoid disruptions to the portfolio	<i>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.</i>
Maintain high standards	<i>Most of all, the sponsor wanted to protect its reputation and ensure its standards for clinical data management excellence.</i>

Solution

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

Effective Utilization of Resources

Experienced personnel from the biopharmaceutical company were transitioned to inVentiv Health employment 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 close 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 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 organizations were able to take advantage of flexible, scalable staffing solutions. The sponsor was able to reduce its fixed costs, as well as the number of vendor contracts to be managed in support of clinical data management activities. And with more efficient clinical data management processes in place, the sponsor company could gather results more quickly.

The company 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