STRATEGIC PARTNERSHIPS 2013
Transforming and Unlocking Value in Biopharmaceutical Development
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Dear Industry Colleagues:

Biopharmaceutical companies are under enormous pressure. Current market and economic realities are compelling the industry to reduce fixed costs, improve efficiency, and concentrate limited resources on core competencies. The challenge of accelerating pharmaceutical product development while controlling costs creates a difficult balancing act for industry executives.

To make clinical development more effective, PAREXEL International formulated a multidisciplinary and systems-oriented approach to outsourced clinical development, bringing efficiencies, scalability, and standardization to the process. Today, many biopharmaceutical companies are engaging clinical research organizations (CROs) through this more integrated approach aimed at optimizing performance and improving efficiencies.

At PAREXEL, we recognize the value of providing biopharmaceutical companies with a strategic partner who can offer the deep expertise, flexibility and efficiencies of a worldwide infrastructure. The Strategic Partnerships 2013 report represents our investment in understanding the value of these long-term, substantial, and committed relationships among CROs and sponsors. This report highlights the growing importance to biopharmaceutical companies of engaging in Strategic Partnerships to drive greater value through seamless integration, aligned goals and mutual investment.

Importantly, our new research offers the industry greater clarity on the facets of Strategic Partnerships that are working today, and how these relationships should evolve tomorrow.

As a pioneer in clinical research outsourcing, PAREXEL is committed to evolving the Strategic Partnerships model. Along with this insightful research, we have made an investment with in-house expertise across the clinical research spectrum, technology that streamlines the clinical trial process, and an expansion into prominent and developing regions around the world.

We believe that Strategic Partnerships provide companies with the level of integration, alignment and collaboration that will support the future success of the biopharmaceutical industry.

Josef H. von Rickenbach
Chairman of the Board and CEO, PAREXEL International
The end of the blockbuster era, patent cliffs, rising development costs, increasing regulatory and reimbursement issues, and a sluggish global economy have put enormous pressure on the biopharmaceutical industry. To remain competitive, companies are increasingly focusing on generating more productivity from their research and development (R&D) investments.

To respond to these pressures, biopharmaceutical companies have been changing the way they approach virtually every aspect of their business, including R&D. Outsourcing allows organizations to use only the resources required at any given time and hire experts that they may not normally employ in-house. This has been a growing trend over the past decade. According to an industry survey from the Association of Clinical Research Organizations, the CRO workforce more than doubled from 2001 to 2010*.

Driven by the need to manage costs and utilize internal resources more efficiently, biopharmaceutical companies have traditionally engaged CROs on a project-by-project basis or for specific functions. This transactional model can reduce fixed costs and improve flexibility to a degree, but it cannot deliver the level of operational efficiencies needed to help the biopharmaceutical industry meet the challenges of the changing R&D landscape. That value can be unlocked through Strategic Partnerships, which are transforming the way new therapies are developed and commercialized.

For the past five years, a wave of Strategic Partnerships between biopharmaceutical companies and CROs has been implemented to drive more flexibility, reduce costs and extend expertise. Strategic Partnerships have evolved the CRO-sponsor relationship into multi-year, highly-integrated engagements focusing on shared objectives, mutual investment in aligned processes and systems, and early involvement in protocol design and operational plan development.

The Strategic Partnerships 2013 report is the first study to understand the current outsourcing model and the value Strategic Partnerships provide to biopharmaceutical companies of all sizes. It defines the next-generation of Strategic Partnerships that advance and optimize clinical development.

*Association of Clinical Research Organizations. The ACRO Member Demographics Survey, 2011.
Strategic Partnerships 2013 Key Findings

The Strategic Partnerships 2013 report included in-depth interviews with senior-level executives from global biopharmaceutical companies representing 39% of the industry’s total R&D spend. The interviews included both quantitative and qualitative questions to better understand the current state of clinical development outsourcing and future trends in Strategic Partnerships.

Key findings from the report include:

- Industry executives who have already implemented Strategic Partnerships recognize the value, believing these integrated relationships positively impact CRO-sponsor relationships as well as their operations.

- The operational efficiencies and impact seen by implementing Strategic Partnerships will continue to drive clinical development outsourcing.

- Biopharmaceutical executives most often equate Strategic Partnerships with oversight, governance and the level of mutual partnership investment, rather than the volume of work, an important consideration for smaller and mid-sized companies.

- Executives believe showcasing consistent value and measuring results is critical for the future success of this more integrated model.

- Strategic Partnerships will continue to evolve away from the traditional transactional model toward more integrated relationships that drive value through increased alignment and efficiencies. The next-generation of Strategic Partnerships must involve a greater alignment of commercial terms and a true collaboration of the best talent from the CRO and sponsor, according to biopharmaceutical executives.

- The hallmark of an optimized Strategic Partnerships model will be the measurable success of collaboratively bringing a compound to market faster.
Strategic Partnerships 2013

REPORT FINDINGS
“Definitely increase because part of our future strategy is that outsourcing will play a critical role in the success of our company.”

STRATEGIC PARTNERSHIPS 2013 PARTICIPANT

Delivering Value to the Biopharmaceutical Industry

For Strategic Partnerships 2013, industry executives were asked a series of questions exploring their perspectives on clinical development outsourcing. As part of the interview, industry executives were asked about the value of outsourcing to their business, the attributes they expect in CROs, and how they define Strategic Partnerships.

Among the biopharmaceutical executives interviewed, 65% expect their companies will increase their level of clinical trial outsourcing over the next five years. (Figure 1)

Q. Do you expect your company’s outsourcing to increase, decrease or remain the same over next five years?
There are a number of factors driving the executives’ decisions to increase their investment in outsourcing. Two of the leading factors include an ability to access capabilities not found internally, and to reduce fixed costs and minimize utilization of internal resources. (Figure 2) Executives felt that outsourcing provides sponsors with flexibility, helping to manage the volatility and unpredictability of the pipeline. Outsourcing allows for the sponsor to utilize internal resources more effectively while the CROs handle the peaks and troughs in activities.

Q. Please tell me the top drivers of outsourcing for your company

*Respondents were allowed to give multiple responses.*
Overall, the biopharmaceutical industry has acknowledged the beneficial aspects of Strategic Partnerships. The majority of the industry executives interviewed (85%) believe that the integrated and collaborative model used in Strategic Partnerships has had a positive effect on the CRO-sponsor relationship. They also said this more integrated approach to clinical development reduces their level of oversight, decreases fixed costs and provides them with access to capabilities not found internally. It also improves global reach and accelerates time to market. (Figure 3)
With respect to defining Strategic Partnerships with CROs today, the industry executives overwhelmingly identified the type of oversight and governance required by the sponsor (88%) and the level of mutual partnership investment (85%) as the two most important attributes. Fewer executives identified the volume of work being outsourced or the overall scope of work outsourced as important attributes of Strategic Partnerships. (Figure 4) That is an important consideration for smaller and mid-sized companies who may feel that Strategic Partnerships only benefit larger companies.

"Sponsor oversight. If you know how to work with each other as agreed... it requires less oversight... on any given deliverable."

STRATEGIC PARTNERSHIPS 2013 PARTICIPANT

Q. How would you define a Strategic Partnership with a CRO today? Please select your top three choices.

Some respondents provided less than or more than three choices.
When considering the conceptual meaning of Strategic Partnerships, the executives interviewed noted the importance of commitment, trust, and alignment between the companies. That may be why industry leaders often select their CRO partnerships based on meaningful traits such as a history of quality (88%) and whether the two companies have matching cultures (65%). (Figure 5)

Q. Please tell me the top three items that influence your selection of a Strategic Partner.

Some respondents provided less than or more than three items.
Evolving Strategic Partnerships for Success

The demands of a constantly changing development and regulatory environment continually require biopharmaceutical companies to discover more efficient ways of operating to retain their competitive position in the market. Strategic Partnerships must adapt to help companies effectively meet these challenges. But to evolve successfully, CROs must address some of the industry’s concerns with the present state of CRO-sponsor relationships.

When considering the relationship today, the executives noted these top five concerns, in order of importance:

• Limited alignment of goals and objectives
• Inadequate number of “A-Teams”
• CRO employee turnover, which can potentially erode team quality
• Change orders when the initial cost estimates were incorrect
• Lack of information sharing

As Strategic Partnerships evolve, the model will provide biopharmaceutical companies and CROs with a strong foundation to address these concerns. The hallmark of well-executed Strategic Partnerships is how efficiently these dynamics are managed through the partnership infrastructure. This is built on a team of experts from both parties who are seamlessly integrated from the beginning of the engagement and throughout the program lifecycle.

“You are putting some of the key programs out there with companies who may not have the same vested interest in seeing it succeed.”

STRATEGIC PARTNERSHIPS 2013 PARTICIPANT
In the future, changes in the Strategic Partnerships model will be driven by the need for greater collaboration and more operational efficiencies. Executives viewed this as:

1. **Dedication**, where the CRO team is committed to the client’s results and success, and aligned with the company’s specific needs.

2. **Risk-Sharing**, where the CRO is operationally or financially vested in shared success.

3. **Value**, in which the relationship is expected to yield cost and operational efficiencies without sacrificing quality.

4. **Transparency**, which the executives define as better communication between the two organizations, and greater sharing of information and expertise.

*Risk-Sharing as a concept covers a wide-range of activities including investment in operational efficiencies such as technology, processes, staffing, and time as well as financial incentives and penalties.*
Continued investment in Strategic Partnerships may hinge on CROs proving the economic success of the model such as increasing the pipeline’s Net Present Value (NPV) (50%) and improving average cycle times (50%). (Figure 6) To impact these metrics, CROs will be expected to validate their ability to deliver on-time, high quality results with lower, predictable costs. On-time delivery helps improve cycle times, allowing the biopharmaceutical company to bring compounds to the market faster.

“NPV tells you about the total value to any investor... and I think cost per patient is becoming important.”

STRATEGIC PARTNERSHIPS 2013 PARTICIPANT

Q. How do you measure the economic success of your company’s investment in development activities?

Respondents were allowed to give multiple responses.
Ultimately, CROs involved in Strategic Partnerships will need to showcase how the partnership is meeting specific metrics like quality and timeliness. These and other factors will influence the level of clinical development that a biopharmaceutical company will complete internally or outsource through its Strategic Partnerships. (Figure 7)

Q. In what ways do you measure success of outsourcing versus internal development?

*Respondents were allowed to give multiple responses.*
Defining the Future of Strategic Partnerships

What is the future vision of Strategic Partnerships? How will the model differ from Strategic Partnerships today? The industry executives interviewed for this report believe Strategic Partnerships are transforming the way new therapies are developed and commercialized. However, they also noted that the model must evolve to adequately and effectively meet the challenges of a constantly changing regulatory environment. When asked about the vision for the next generation of Strategic Partnerships, the respondents identified increased alignment in commercial incentives, deeper team collaboration (strategic and targeted expertise), and faster time-to-market through improved cycle times as the top three areas. (Figure 8)

**Key Attributes of Future Strategic Partnerships**

- More risk-sharing* on development timelines: 54%
- Greater alignment between the sponsor & CRO, a true collaboration of the best talent: 50%
- Faster time-to-market through improved cycle times: 35%
- Support emerging geographies: 27%
- Ability to take compounds from FIM - NDA/MAA**: 19%
- More risk-sharing* (in general): 19%

Q. What would strategic partnering 2.0 look like to you? In which of the following ways will it differ from strategic partnerships today? Please tell me your top three choices?

* Risk-Sharing as a concept covers a wide-range of activities including investment in operational efficiencies such as technology, processes, staffing, and time as well as financial incentives and penalties.

** First in Man (FIM), New Drug Application (NDA), Marketing Authorization Application (MAA)
When considering a more long-term vision for the CRO value proposition – over the next three to five years – the industry executives said that it will be defined by cycle time improvements and further reduction in sponsor oversight. (Figure 9) For the executives interviewed, value is about the drive for economics and efficiencies with their CRO partners.

Q. Please tell me which two of the following will define the value of Strategic Partnerships with CROs in the next three to five years?
Today's promise of Strategic Partnerships – founded on such ideals as sharing, aligning, and collaborating – must be optimized to demonstrate results and efficiencies to ensure shared future success. Tomorrow, clinical development outsourcing will depend greatly on CROs delivering on the promise of Strategic Partnerships. For the executives interviewed, this means greater alignment and collaboration, improved cycle times, less sponsor oversight and supporting expansion into emerging markets. (Figure 10)

“I want CROs saying…  ‘How do I enable a pharma company to get medicines to market faster, more cost effectively, with high quality?’”

STRATEGIC PARTNERSHIPS 2013 PARTICIPANT

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* Risk-Sharing as a concept covers a wide-range of activities including investment in operational efficiencies such as technology, processes, staffing, and time as well as financial incentives and penalties.
About Strategic Partnerships 2013

For the report, Booms Research & Consulting, Inc. – an independent research firm conducted in-depth interviews among senior-level executives such as C-suite leaders as well as heads of clinical operations, R&D, and strategic outsourcing, representing global biopharmaceutical companies (n=26). The sample size included: 71% large pharmaceutical companies, 12% mid-sized pharmaceutical companies, and 17% small biopharmaceutical companies. The interviews were conducted in English in the fall 2012. Participants represent companies with 39% of industry R&D spend. The report included both quantitative and qualitative questions to better understand the current state of clinical development outsourcing and strategic partnerships. The survey includes both single and multiple response questions. As such, some percentages will exceed 100%.

About PAREXEL International

PAREXEL International Corporation is a leading global biopharmaceutical services organization, providing a broad range of knowledge-based contract research, consulting, and medical communications services to the worldwide pharmaceutical, biotechnology and medical device industries. Committed to providing solutions that expedite time-to-market and peak-market penetration, PAREXEL has developed significant expertise across the development and commercialization continuum, from drug development and regulatory consulting to clinical pharmacology, clinical trials management, medical education and reimbursement. Perceptive Informatics, Inc., a subsidiary of PAREXEL, provides advanced technology solutions, including medical imaging, to facilitate the clinical development process. Headquartered near Boston, Massachusetts, PAREXEL operates in 73 locations throughout 51 countries around the world, and has approximately 14,000 employees. For more information about PAREXEL International, visit www.PAREXEL.com.
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The PAREXEL Strategic Partnerships Office is dedicated to helping companies like yours achieve their development goals.