STRATEGIC PARTNERSHIPS 2014

Driving Biopharmaceutical Outsourcing Effectiveness
Dear Industry Leader,

As biopharmaceutical companies continue to seek opportunities to increase efficiencies, drive greater flexibility, extend expertise, reduce costs and leverage limited resources, they are increasingly turning to outsourcing services offered by biopharmaceutical service providers. In particular, growing numbers of Sponsors are adopting a Strategic Partnership model. These multi-year, highly integrated engagements are proving to accelerate development cycles, create cost efficiencies and ultimately enable important new treatments to reach patients more quickly.

PAREXEL, a pioneer of the Strategic Partnership model between biopharmaceutical companies and service providers, continues to invest in revealing insights on the value this model delivers. This report, Strategic Partnerships 2014: Driving Biopharmaceutical Outsourcing Effectiveness, specifically analyzes how Sponsors globally perceive clinical development outsourcing. In addition, this report reveals why the Strategic Partnership model is particularly effective and points to a growing adoption of this model. This report also outlines additional drug development challenges Strategic Partnerships may be capable of addressing in the future.

Insights regarding the growing importance of Strategic Partnerships within the industry reinforce findings from our 2013 report. That year, PAREXEL published the industry’s first research to explore the outsourcing landscape and the value of Strategic Partnerships. It revealed that 85 percent of biopharmaceutical executives surveyed believed Strategic Partnerships positively impacted CRO-Sponsor relationships. As a clinical research outsourcing leader, PAREXEL remains committed to investing in this evolving model and expanding our capabilities across the clinical research spectrum through our global expertise, our focus on reducing drug development complexity and our commitment to forging long-term relationships with Sponsors.

By simplifying the journey between science and new treatments, PAREXEL believes the world would be a healthier place. Biopharmaceutical service providers and drug developers that leverage Strategic Partnerships have a compelling opportunity to collaborate effectively to make this possible.

JOSEF VON RICKENBACH
CHAIRMAN AND CEO, PAREXEL INTERNATIONAL
As biopharmaceutical companies compete across a challenging global market, their road to success becomes increasingly difficult. The entire drug development process—a long, complex journey from molecule to market—puts developers under intense pressure to discover and adopt solutions that improve efficiency, optimize performance and deliver value at every step.

To gain a competitive advantage, clinical trial Sponsors are focused on generating greater productivity from their research and development investments. As a result, they are using outsourcing models offered by Clinical Research Organizations (CROs) in growing numbers.

Simultaneously, many Sponsors are transitioning from traditional Project-by-Project and Preferred Provider outsourcing methods to a more holistic approach based on Strategic Partnerships.

In recent years, this model has played a pivotal role in advancing the overall CRO-Sponsor relationship paradigm. These highly integrated engagements often span many years, driven by shared objectives, mutual investment in aligned processes and early involvement in protocol design and operational plan development.
KEY FINDINGS

Strategic Partnerships 2014: Driving Biopharmaceutical Outsourcing Effectiveness reveals compelling new insights that not only highlight this model’s value, but point to additional opportunities to drive future efficiencies and effectiveness. In particular, this report indicates how and why:

1. Positive perceptions of outsourcing effectiveness within the biopharmaceutical industry have significantly increased in the past three years.

2. The Strategic Partnership model is perceived to be the most effective biopharmaceutical outsourcing approach in meeting a number of key sponsor needs.

3. Among biopharmaceutical companies surveyed, more than half now use a Strategic Partnership model.

4. The Strategic Partnership model holds untapped potential to yield additional value and meet future biopharmaceutical industry needs.
KEY FINDING 1:
PERCEPTIONS OF BIOPHARMACEUTICAL OUTSOURCING EFFECTIVENESS GROW

Positive perceptions of outsourcing effectiveness within the biopharmaceutical industry have increased significantly in the past three years.

The percentage of total biopharmaceutical development spending allocated to outsourcing has increased substantially from 2010 to 2013, with additional future growth expected, according to survey respondents.

The perceived value of CRO-Sponsor relationship effectiveness has never been stronger. The last three years have seen elevated effectiveness-perception levels across all geographies, models and levels of spend. This trend adds to findings from a 2013 report\(^1\) that indicated 85 percent of executives believed Strategic Partnerships have positively impacted the CRO-Sponsor relationship.

Survey results reveal a trend toward better relationship management, increased savings for Sponsors and better overall results from outsourcing.

If this trend continues and outsourced relationship management becomes even more effective, Sponsors could realize greater value as their resources are released to support other important initiatives.

\(^1\)Strategic Partnerships 2013: Transforming and Unlocking Value in Biopharmaceutical Development

OUTSOURCING GROWTH IS EXPECTED TO CONTINUE

PROJECTED GROWTH OVER NEXT 3 YEARS

GROWTH OVER LAST 3 YEARS

<table>
<thead>
<tr>
<th>R&amp;D SPEND</th>
<th>$1B+</th>
<th>$500M-$999M</th>
<th>$250M-$499M</th>
<th>&lt;$250M</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROJECTED GROWTH</td>
<td>+10%</td>
<td>+5%</td>
<td>+3%</td>
<td>+7%</td>
</tr>
<tr>
<td>GROWTH OVER LAST</td>
<td>+13%</td>
<td>+7%</td>
<td>+11%</td>
<td></td>
</tr>
<tr>
<td>3 YEARS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
POSITIVE PERCEPTIONS OF OUTSOURCING EFFECTIVENESS INCREASE GLOBALLY

POSITIVE PERCEPTIONS OF OUTSOURCING EFFECTIVENESS INCREASE WITH SPONSORS OF ALL SIZES
KEY FINDING 2:
STRATEGIC PARTNERSHIPS CONSIDERED MOST EFFECTIVE OUTSOURCING MODEL

The Strategic Partnership model is perceived to be the most effective in meeting a number of key Sponsor needs.

Of all outsourcing models, Sponsors set the highest expectations when engaged in Strategic Partnerships. It best affirms critical Sponsor questions such as:

- Does this model enable my company to align our goals with those of the CRO?
- Does this model allow my company to share risk?
- Does this model allow my company to reduce total development costs?

In a number of key areas, Strategic Partnerships perform better than other models—and most closely meet Sponsor expectations.

STRATEGIC PARTNERSHIPS DELIVER GREATEST OUTSOURCING VALUE

- Management of capacity gaps
- Enabling strategic management of R&D portfolio
- Better cost predictability
- Reduction in fixed costs
- More efficient resolution of issues
- Consistency in quality of execution
- Reduced complexity

PERCEIVED EFFECTIVENESS (%)
STRATEGIC PARTNERSHIP MODEL DELIVERS
GREATER PERFORMANCE AND BETTER
MEETS SPONSOR EXPECTATIONS

% AGREEMENT AMONG PRIMARY USERS OF EACH OUTSOURCING MODEL

- DEVELOPS DEEP UNDERSTANDING OF SPONSOR’S CULTURE
- REDUCES TOTAL DEVELOPMENT COSTS
- SHARES RISK
- ENHANCES R&D PRODUCTIVITY

STRAIGHT PARTNERSHIP
PREFERRED PROVIDER
PROJECT-BY-PROJECT

PAREXEL® STRATEGIC PARTNERSHIPS 2014 / 9
KEY FINDING 3:
USE OF STRATEGIC PARTNERSHIPS REACHES 50% OR MORE IN ALL GEOGRAPHIES

Among biopharmaceutical companies surveyed, more than half now use a Strategic Partnership model. The Strategic Partnership model is now the dominant outsourcing approach for Sponsors with R&D spending of $500M+.

OPPORTUNITIES EXIST FOR SPONSORS TO FURTHER LEVERAGE STRATEGIC PARTNERSHIPS
KEY FINDING 4: OPPORTUNITIES EXIST TO EXTEND SCOPE AND VALUE OF STRATEGIC PARTNERSHIPS

The Strategic Partnership model holds untapped potential to yield additional value and meet future biopharmaceutical industry needs.

With continuous study optimization heading the list of desired outcomes for next-generation Strategic Partnerships, Sponsors may be increasingly willing to transfer additional activities to CROs under this model. Engaging their CRO’s scientific/medical, regulatory and commercialization experts could further positively address capacity and knowledge gaps. In particular, earlier participation by CROs in clinical protocol and study design may help Sponsors realize significant time and cost reductions in clearing hurdles for license approval and market access.

SPONSORS SEEK EXTENDED VALUE IN NEXT-GENERATION STRATEGIC PARTNERSHIPS

1. Continuous Study Optimization
2. Shared Knowledge
3. Greater Integration
CONCLUSIONS

STRATEGIC PARTNERSHIPS ARE SIMPLIFYING THE DRUG DEVELOPMENT JOURNEY

Research findings in this report reveal that Strategic Partnerships are shaping future drug development, as Sponsors and CROs find more effective, efficient and productive ways to collaborate using this model. By committing to long-term relationships and sharing knowledge, risks and rewards, Sponsors and CROs are making strategic resourcing decisions that leverage existing expertise and bring new efficiencies. This close-knit collaboration is extending across investigator recruitment, feasibility, clinical monitoring, data management, biostatistical analysis, medical writing, and clinical logistics, among other areas.

However, untapped opportunities exist to further extend this Strategic Partnership collaboration. Sponsors surveyed clearly believe the next generation of Strategic Partnerships have the potential to deliver additional value through:

- Continuous Study Optimization
- Shared Knowledge
- Greater Integration

Enhancements in these areas will likely further accelerate the industry’s ongoing shift from in-house approaches and transactional outsourcing models to Strategic Partnerships.
PAREXEL ANALYSIS: REASONS FOR SELECTING A STRATEGIC PARTNERSHIP

Sponsors switch from Project-by-Project and Preferred Provider outsourcing to a Strategic Partnership model for a number of reasons:

1. **EXPERTISE AT EVERY STEP**
   Partners learn from each other – and expertise is more freely shared – when long-term commitments are established and maintained. This becomes particularly apparent when Partner CROs augment a Sponsor’s scientific, medical, technical, operational and commercialization expertise, creating a source of considerable additional value.

2. **SEAMLESS PROCESSES**
   Stop-and-go doesn’t work in this go-faster industry. Working within a Strategic Partnership model creates a seamless process to start new projects efficiently. Dedication of resources allows teams to transition from one project to the next, minimizing downtime between phases.

3. **STRATEGY FOR THE LONG TERM**
   With Strategic Partnerships, objectives are aligned and resource utilization is optimized. Rather than treating projects as standalone initiatives, Sponsors can take a broader, all-encompassing view of their clinical strategies and drive continuous improvement and innovation for greater long-term results.

4. **GLOBAL CONSISTENCY**
   In an increasingly global industry, biopharmaceutical companies require consistent world-class quality in every region and locality. Engaging in a Strategic Partnership helps Sponsors transition from the complexity and high internal oversight costs often associated with having multiple vendors. Use of a shared eClinical technology platform also encourages standardization and consistency.

5. **COST PREDICTABILITY**
   Because Strategic Partnerships are long term, the opportunity to engage the CRO early in the planning process becomes a reality. Sponsors share pipeline information, and on their side the CRO can plan more effectively. Together with increased pricing transparency, this delivers greater predictability of costs for the Sponsor.

A GROWTH STRATEGY FOR THE INDUSTRY

Strategic Partnerships are poised to make a significant impact to biopharmaceutical development in the coming years as more Sponsors embrace this model and those with existing partnerships find additional opportunities to drive value through collaboration.
About Strategic Partnerships 2014:

Driving Biopharmaceutical Outsourcing Effectiveness

For this report, independent research firm Blue Pyramid Consulting, a subsidiary of The Avoca Group, conducted an online survey of 148 senior-level executives representing a diverse range of large, mid-sized and small biopharmaceutical companies. It included both quantitative and qualitative questions to better understand the current state of clinical development outsourcing and Strategic Partnerships. The survey also included single- and multiple-choice response questions.
ABOUT PAREXEL INTERNATIONAL
PAREXEL International Corporation is a leading global biopharmaceutical services organization, providing a broad range of knowledge-based contract research, consulting, medical communications, and technology solutions and 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. PAREXEL 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 76 locations in 50 countries around the world, and has more than 15,000 employees.

For more information about PAREXEL International, visit www.PAREXEL.com.