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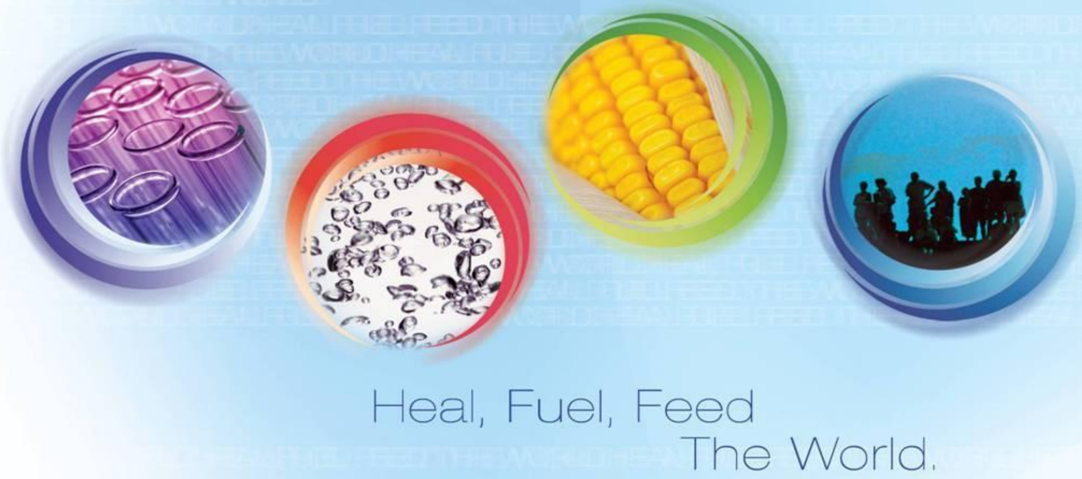

Partnering for Volatile Times

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The BIO International Convention

Never before has deciding to invest in joining a global event with 60 countries, 300 public officials, 20,000 life science thought leaders and dealmakers been so important. With 14,000 partnering meetings in four days and 2,200 companies within the BIO Exhibition, the BIO International Convention, May 18 – 21, 2009 in Atlanta, GA provides you efficiency and effectiveness - all together. http://convention.bio.org

Partnering for Volatile Times

It's a certainty that pharmaceutical and biotech companies will experience rough times for quite some time in the future, requiring us to work smarter and more efficiently if we're to survive and even prosper.

One important success strategy will be our ability to build and maintain strong strategic partnerships. Companies of all sizes are facing intense cost pressures and are continually reviewing and reducing expenses. While outsourcing can be a very effective strategy during these volatile times, companies must shift toward developing more strategic partnerships vs. numerous "one off" relationships to ensure the most successful clinical research. Why? This article will discuss key reasons.

"One off" relationships require significant money and manpower to maintain, and funding for even large biotech companies is becoming scarce in today's economic climate. Managing multiple vendors isn't linear, rather exponential, in terms of management effort. Strategic partnerships require clients to take a long-term view of their outsourcing goals. Working with one partner provides companies with more seamless, efficient carry-through from planning to execution, which is more difficult with multiple vendors. In addition, there are time and money savings, and companies can ensure increased quality throughout the development process. Current market conditions do not allow for missteps or mistakes, especially when trying to launch a product before a competitor. Companies only get one chance to ensure their products' success.

The word "partnership" is used a lot these days, but few companies have invested in building true strategic partnerships. These partnerships require trust; honesty; a commitment from both organizations to ensure success; and common, compatible objectives. They also require shared decision making; agreed upon long-term objectives; and open, candid communications.

Let's look at how a small to mid-sized biotech company and a CRO would benefit from a strategic partnership and how that will then translate into product success.

<u>Biotech Company</u>
A small to mid-sized company (Company A) can reduce costs and time by maximizing its research spend through one or possibly two strategic partners who can create increased efficiencies. In contrast, Company A will need more resources to manage multiple vendors. Company A receives additional benefits by delegating responsibility to a partner whose culture, priorities and organizational structure they are familiar with and who they know have the resources and expertise to complete the work. By reducing day-to-day management of each project, Company A can further reduce its overhead costs. These savings won't happen overnight as it takes time to establish a level of trust. Yet, by working closely with its partner, Company A can more accurately forecast its costs and maximize its return on its R&D investment.

<u>CRO</u>
By evaluating and selecting a CRO (Company B) with the therapeutic expertise, global reach and experience needed to meet a program's goals through the product's lifecycle, biotech companies can establish a long-term partnership that helps decrease Company B's business risk. This is demonstrated in several ways:

1. Not having to continually respond to RFP requests and/or bid defense meetings, Company B can reduce its overhead and pass those savings on to its partner.

2. Advance planning for future work allows Company B to predict more accurately its revenue and resources, which benefits both companies. Understanding its workflow creates an opportunity for Company B to reserve and utilize resources when needed.

3. Upfront planning can reduce Company B's employee turnover by ensuring employees have a reliable stream of work and they are recognized as a critical resource to Company A's program goals versus jumping from one client company activity to another and/or study to study.

4. Employees' learning curves are greatly lessened, translating into increased speed and higher quality services. This core group of employees provides Company A with a powerful "brain trust" and valuable program input to further increase speed and quality. CRO employees will also feel a greater sense of team spirit and take more ownership of each project. As discussed previously, this level of experience will negate the need for day-to-day involvement by Company A, which lessens the workload on both companies', allowing their respective employees to devote their resources and expertise to their core strengths.

It is vital to invest time and energy selecting the right strategic partner and to ensure adequate communication, risk management, issue resolution, strategic planning, etc., are in place after the selection process.

What should a biotech company consider when selecting a strategic partner? In today's turbulent economic times, financial stability is key. Companies do not want to enter into a long-term partnership with a company that may not be around in a year or two. Starting over with another company during the critical development of a product(s) can be devastating to the product and company. It's also important to consider a CRO's therapeutic expertise and global footprint. Does the CRO have an established presence in the regions important to the company's product? Selecting a partner with strong therapeutic expertise and clinical experience brings many benefits, including ongoing site relationships, an understanding of regulatory challenges in various regions and knowledge of the challenges other compounds in development are facing. In addition, a partner with a global footprint can be a strong asset to find and recruit the right patients for each trial and to ensure key developmental timelines are met.

Companies should partner for the developmental lifecycle of the product for the partnership to be the most beneficial for both parties. As a result, companies should select a full-service provider who can assist with all aspects of a product's development, including preclinical, regulatory, laboratory services, clinical and even through product approval and maturity. Recent changes by the U.S. Food and Drug Administration, related to REMS, PMCs, post approval safety, etc., mean it's critical to select a partner who understands and has the capabilities to address the hurdles of later development stages. Early planning creates a foundation for a successful launch and early product acceptance and helps ensure costs are managed more effectively. It helps companies looking to commercialize their product as well as those looking to out-license a product that can then be easily assimilated into another company's pipeline.

Lastly, a strategic partner should have a broad range of technology capabilities as clinical research is becoming more and more technologically focused. Technology brings many benefits (e.g., reduced cost, "real time" access to data, reduced timelines due to quicker database lock, etc.) that can not only reduce development timelines, but also make the whole research process more efficient for both companies and participating sites.

To summarize, effective strategic partnerships can result in increased efficiencies for both parties and ultimately lead to reduced timelines and costs coupled with higher throughputs for both companies.

In today's volatile times, getting products to market as quickly and efficiently as possible and partnering with qualified, motivated companies is critical to success.

Coming together is a beginning.
Keeping together is progress.
Working together is success.
-Henry Ford