Perspective

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Nimble Partnerships in the Pharma Industry *Well-Designed CRO Relationships Enhance Focus and Flexibility*

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EXECUTIVE SUMMARY

Following an era of rapid expansion, the pharmaceutical industry has spent the last decade struggling to improve research and development productivity. In today's particularly difficult business environment, the world's leading pharmaceutical companies, including biotech firms, are scrutinizing their research and development capabilities, seeking ways to extract more value. Clinical research organizations (CROs) have become increasingly valuable partners as pharmaceutical companies fight to ensure their future success.

A pharmaceutical company's CRO relationships should reflect its corporate strategy and its views on which clinical development capabilities can be outsourced and which should remain in-house. Booz & Company has spent much of 2011 conducting qualitative research to gain insight into the ways pharmaceutical companies engage with their CRO partners. We have identified four types of CRO relationships, ranging from straightforward vendor arrangements to highly integrated alliances in which CROs become deeply embedded in the pharmaceutical company's critical research operations.

To choose the most effective partnership structure, pharmaceutical companies need to first assess their internal capabilities to identify those areas where they already excel or where they want to make additional investments. CROs will need to make similar decisions about where to focus their efforts in order to ensure that they are attractive partners. These capability choices will form the basis of a coherent partnership strategy. A "new nimble" approach based on developing differentiated internal capabilities and building on outside partnerships allows pharmaceutical companies to stay ahead of changing market dynamics and generate value at every point in their organizations. Properly designed CRO relationships are a valuable approach for pharmaceutical firms as they experiment with new strategies in a constantly evolving scientific and business environment.

KEY HIGHLIGHTS

- Managing partnerships with clinical research organizations (CROs) is an increasingly important capability in the pharmaceutical sector.
- CROs are moving beyond simply providing capacity when needed and are taking a greater role in clinical research functions.
- Pharmaceutical firms and CROs can choose from a variety of ways to ally, from a straightforward vendor relationship to a highly integrated, strategic partnership.
- Pharmaceutical companies and CROs must align the design and structure of their relationships, and associated capabilities, with their strategy.
- In an evolving pharmaceutical business environment, there is more than one model for success.
- Key capabilities grouped into coherent systems create a "new nimble" approach that generates value for both partners.

FROM EXPANSION TO FOCUS

Over the past 30 years, pharmaceutical companies grew into behemoths, continually extending the scope and scale of their operations through megamergers and global expansion. Strong revenues and profits allowed them to fund big, broad businesses. They did it all—from discovering new molecules to obtaining regulatory approvals to marketing and distribution—while carrying large fixed costs to support periods of peak demand and avoid development delays. During this period, the industry grew more concentrated. The top 20 pharmaceutical companies now account for 70 percent of global industry revenue—with just the top 10 accounting for half.

The days of rapid, broad-based expansion and "staffing to the peak" are over. Increasing business pressures around the globe are forcing pharmaceutical companies to acknowledge that it is impossible to be the best at everything in the wide-ranging and complex business of drug discovery and commercialization. For example, regulatory requirements and cost pressures compel companies to expand global clinical trials. Today 65 percent of trials originate outside the United States where different languages, cultural overlays, and oversight call for specialized management tools and skills. Even the largest pharmaceutical companies cannot excel in all aspects of trial design and execution in every country while also maintaining peak-load capacity globally.

Pharmaceutical companies must instead focus on capabilities in which they can be truly best in class. A capability is a distinctive strength—a combination of people, processes, and tools—that a pharmaceutical company relies on to successfully compete in the marketplace. To secure strong returns in today's low-growth environment, pharmaceutical firms must continue to achieve high capacity utilization and efficiencies from scale. At the same time, they have to remain flexible enough to respond to rapid changes in

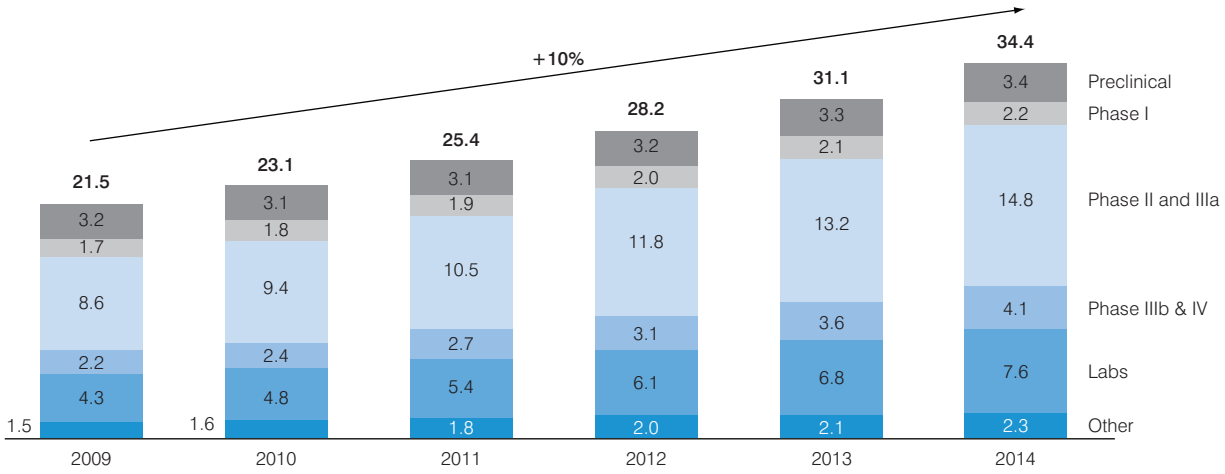
the market and new scientific developments (such as biosimilars and personalized medicine).

The current climate presents significant challenges for pharmaceutical leaders. In response, many are now rethinking their businesses and taking action to focus on developing their strongest capabilities, while finding other ways to fulfill business requirements where the company is clearly not advantaged. As pharmaceutical leaders assess their strengths, consider the trade-offs, and place their bets, clinical research organizations will play a critical role.

Today we see pharmaceutical companies increasing the amount of clinical work they outsource to CROs. Research and development outsourcing is expected to reach US$29 billion to $35 billion globally by 2015 (*see Exhibit 1*).

In addition to the growth in scale of clinical outsourcing, in the past three years pharmaceutical companies and CROs have begun to form more strategic business relationships. Pharmaceutical companies using this approach typically partner with two or three CROs for a majority of their outsourcing needs.

Exhibit 1
Pharmaceutical Research Outsourcing



Source: Business Insights; UBS; PhRMA; CMR R&D Factbook

PHARMACEUTICAL OUTSOURCING OPTIONS

Managing relationships with CROs is now a critical capability for large, research-based pharmaceutical companies. To better understand where pharmaceutical–CRO partnerships are headed, Booz & Company spent much of 2011 conducting qualitative research with business leaders in leading pharmaceutical companies, and at CROs, to explore several questions:

- What is the strategic rationale for clinical development outsourcing among large pharmaceutical companies?
- What clinical development capabilities do various companies consider core and noncore, and how is that changing?
- How are large pharmaceutical companies designing and operating their relationships with CROs?
- To what extent is the design of relationships, and associated capabilities, aligned with strategic intent and objectives?

Our findings suggest that most pharmaceutical companies have a broad strategic rationale for clinical outsourcing. It can be a flexible way to meet peak demand or to focus and simplify internal operations on a limited set of core capabilities. Despite expanding use of CROs, many pharmaceutical companies have not translated their clinical outsourcing plans into specific guidelines reflecting an overarching strategy. For example, several companies declared that clinical trial monitoring is not a core capability and would be outsourced. However, they have not always determined how to outsource in a way that enables them to maintain desired relationships with key clinicians at clinical trial sites.

Additionally, pharmaceutical companies expressed a surprising range of views about which capabilities they consider most strategic and would not consider outsourcing. While most are willing to outsource central laboratory functions, their attitudes about clinical trial monitoring and writing study reports vary widely. For example, some consider certain aspects of trial monitoring capability to be a source of competitive advantage by supporting the development of clinician relationships. These same companies tend to be skeptical about the notion that CROs can do a better job of monitoring trials at lower cost, given their own scale and expertise in target therapeutic areas. These companies will often source this type of capability externally only in certain circumstances, such as in a country where they lack critical mass. Meanwhile, other companies have concluded that trial monitoring is a "commodity" activity and have outsourced it entirely.

Outsourcing can be a flexible way to meet peak demand or focus internal operations on a limited set of core capabilities.

Our research finds a variety of evolving relationships between drug companies and their clinical research partners. These relationships tend to vary based on three key business considerations. The first is the work the CRO will perform. Will it add more flexible capacity to the firm's own organization, or will it provide capabilities that are not available internally? The second is the model used to deliver additional capacity or new capabilities—as a service, through individuals, or as a combination of the two. The third is the relationship structure: a standard contract, a sophisticated strategic alliance, or something in between.

When these business considerations are taken into account, four pharmaceutical–CRO relationship models emerge (*see Exhibit 2*).

Qualified talent supplier: CROs provide pharmaceutical companies with temporary employees with specific skills to expand capacity or enhance capabilities (including assistance with protocol design, monitoring of trial sites, analysis of findings, and production of study reports).

Preferred capacity partner: Flexible and responsive CROs offer services (which might include trial monitoring and study data management) that the pharmaceutical company also retains internally, in order to expand capacity as needed during periods of peak demand.

Preferred capability partner: CROs provide capabilities (such as clinical site monitoring) that the pharmaceutical company considers noncore and does not choose to build internally.

Strategic partner: The pharmaceutical company structures a long-term relationship with a CRO to jointly deliver overall development results (such as successful clinical trials in a particular therapeutic area), with the expectation that the partnership will result in improvements in quality, cost, and speed.

Exhibit 2
Overview of Pharmaceutical–CRO Relationship Models

CHARACTERISTIC	QUALIFIED TALENT SUPPLIER	PREFERRED CAPACITY PARTNER	PREFERRED CAPABILITY PARTNER	STRATEGIC PARTNER
What does the CRO relationship deliver?	People	Discrete services	Functional capability	Long-term results
Are any functions completely outsourced, globally?	No	No	Yes	Yes
What is the time frame of the agreement?	Short/medium	Medium	Medium	Long
Is there an expectation of innovation?	No	No	Limited	Yes

Source: Booz & Company analysis

Although the strategic partner model has not been widely adopted, certain pharmaceutical companies have embraced it. For example, a partnership between Pfizer and ICON initiated in May 2011 gives ICON responsibility for clinical trial program initiation and management, including evaluation of site and country feasibility, data management and reporting setup, program study drug logistics, scientific and medical communications, and quality assurance. Pfizer has signed a similar strategic partnership with Parexel International. Meanwhile, Takeda Pharmaceutical has announced strategic partnerships with Quintiles and Covance to execute global development programs supporting new therapeutic compounds.

The strategic partnerships Pfizer has established with ICON and Parexel illustrate how R&D strategy can align with the structure of CRO relationships. Pfizer's stated strategic intent is to sharpen its research focus and create a more flexible cost base by transferring responsibility for managing global clinical trials to CRO strategic partners. Pfizer will retain scientific leadership of the development process, including clinical trial design. ICON and Parexel will, on a long-term (five year) basis, manage clinical trials, including site selection, trial monitoring, data management, and other operational processes.

An important point is that the strategic partnership is not simply a reflection of the decision to outsource more extensively. To the contrary, the expectation is that the arrangement will not significantly change the proportion of clinical trial implementation services that Pfizer outsources. Rather, the partnership is expected to simplify outsourcing processes, improve clinical operations performance, and clarify accountability for risk and quality management.

Our last major finding about clinical outsourcing is that most pharmaceutical companies do not take a top-down, strategic approach to CRO partnerships. As a result, the design and structure of CRO relationships, and associated capabilities, do not clearly fit with the strategic rationale for outsourcing and sources of value within the organizations.

For example, several pharmaceutical leaders mentioned that they want CROs to move beyond time-based incentives for patient enrollment and demonstrate a commitment to business results, such as the rapid completion of well-designed trials. Within these same companies, however, we see CRO contracts featuring per-patient fee structures that provide little incentive for CROs to reduce overall trial lead times and patient requirements. Reducing protocol amendments by providing better information up front about patients who meet protocol inclusion and exclusion criteria would be a better way to speed the process.

In other cases, companies default to a new partnership approach rather than build capabilities to support a coherent strategy. One company reported that it had switched from a preferred partner to a strategic partnership to improve contracting results—specifically, to avoid having a CRO underbid work and then submit change requests later to increase project revenue. A more straightforward approach in line with strategic objectives would have been to improve contracting capabilities for specific services.

Another large company stated that it was pursuing a limited number of strategic partnerships in order to find and implement innovative approaches to clinical trials. However, performance measures for these arrangements were all designed to evaluate efficiency improvements, reduce transactional overhead costs, and streamline oversight, rather than focus on rewarding the stated strategic goal, which was to spur innovation.

CAPABILITY ANALYSIS INFORMS CRO STRATEGY

Clearly, companies can do much more to improve clinical development outsourcing by articulating a strategy and carrying it forward through the design and structure of pharmaceutical–CRO relationships. To realize the full value and potential of outsourcing, pharmaceutical companies must first take a step back and fundamentally consider their business needs in the context of the capabilities that will make them successful in the marketplace. To thrive in the low-growth future marketplace, pharmaceutical firms must identify and develop critical core R&D capabilities and build on them systematically. We have developed a distinct set of key R&D capabilities and describe them here in the context of the four relationship models (*see Exhibit 3*).

Exhibit 3
Aligning "Way to Play" with a Coherent Capabilities System

ALIGNMENT OF CRO "WAY TO PLAY" AND CAPABILITIES (SELECTED EXAMPLES)

KEY CHARACTERISTICS AND CAPABILITIES	QUALIFIED TALENT SUPPLIER	PREFERRED CAPACITY PARTNER	PREFERRED CAPABILITY PARTNER	STRATEGIC PARTNER
Provided by Relationship	People	Discrete services for programs/studies	Functional capability	Long-term results
Alliance Management & Governance	Contractual performance	Service-level agreements	Functional performance	Joint planning and management
Financial Management & Modeling	"Value for money" from alternative suppliers	Modeling of internal and partner economics	Modeling of internal and partner strategic intent and economics	Assessment of long-term financial impact
Operational Management & Performance Measurement	Individual contribution	Service-level commitments	Functional performance commitments	Development performance over time
Partner Assessment	Individual skill assessment	Service track record	Service track record	Management track record and culture

Source: Booz & Company analysis

Alliance management and governance capabilities support the strategic partner model to design and operate a joint "business." Selecting appropriate senior management for the alliance and agreeing on performance measures, operating processes, and procedures are critical. Tying performance measures to objectives is particularly important. If a primary goal of the alliance is to generate innovative approaches to clinical research, performance measures could be directed at new patient recruitment techniques, "siteless" approaches to patient access and data gathering (for example, using technology to allow study subjects to participate from home), and reduced complexity and scope of data requirements. At the other extreme, key capabilities of a preferred CRO supplier would include contract design and management that minimize modifications once contracts are signed.

Financial management and modeling capabilities allow firms to model different elements of alliance structures. For example, with a preferred capacity arrangement, the capability to model internal costs associated with modifying capacity and the economics of CROs is important. For strategic partnerships, pharmaceutical firms need financial modeling capability to assess the long-term benefit of knowledge provided by CROs with access to industry-wide data and experience.

Operational management and performance measurement capabilities keep alliances on track. The strategic partnership model relies heavily on the capability to define operational and performance targets in collaboration with the CRO against strategic research and development goals (financial or otherwise). Subsequently, effective measurements help refine the business approach in response to feedback or changes in strategic direction. For a pharmaceutical company seeking preferred capability partners or qualified talent suppliers, a different set of capabilities is required. These models rely on clearly defined performance measures in relation to a specific sub-function or therapeutic area, not at the strategic business level. Follow-up and the ability to change direction based on performance feedback are essential. Pharmaceutical companies that want preferred capacity partners require the capability to examine functional-level outcomes, such as timeliness and prior recruitment timelines, within the clinical development cycle. As with the capability partner and qualified supplier frameworks, assessing the CRO's ability to quickly respond to challenges and maintain timelines is critical.

Partner assessment capabilities are essential to shaping alliances. A strategic partnership requires a strong commitment from the leadership of both the pharmaceutical company and the CRO. The pharma's ability to assess the quality of management that the CRO will bring is crucial. The simpler preferred capability and preferred capacity models require different capabilities, such as the ability to assess customer service

metrics and to define and manage the relationship governance structure to mitigate problems. The capability to critically assess CRO claims and determine a potential partner's true aptitude and ability to deliver in particular areas is also important. So, too, are objective industry success stories or client references that substantiate prior projects and work that the CRO has undertaken. A successful qualified talent supplier model, on the other hand, depends on the capability to accurately weigh the quality of skills and the credentials of individuals the CRO assigns to the pharmaceutical company.

Of course, this capabilities-driven thinking is not just for pharmaceutical leaders. CROs must consider how to develop their own capabilities to become the partners that pharmaceutical companies seek. To remain viable, though, CROs have to approach their capabilities in a way that gives them an advantage relative to current and emerging CRO competitors (*see "CRO Capabilities Systems"*).

CRO Capabilities Systems

In order to achieve true business alignment throughout their partnerships, CROs also need to conduct a detailed analysis of their capabilities, taking into account the same issues as the pharmaceutical companies.

Alliance management and governance: A CRO that innovates in the way clinical research is conducted and in the design of relationships with pharmaceutical companies will be clearly differentiated in the marketplace. Additionally, almost all the companies surveyed would like CROs to demonstrate an "ownership mentality." One company is likely to stop working with one of its two current CROs because managers do not believe that the CRO is "putting skin in the game" to develop a sense of co-ownership of the business results.

Financial management: As pharmaceutical companies seek risk sharing or other ways to shift business risk to the CRO fixed-cost structure, CROs need to understand the implications of the pharmaceutical financial payment models on their long-term business goals, including their projections for revenues and profits, and shareholder value.

Operational management and performance measurement: Pharmaceutical companies have expressed a strong desire for CROs to assume more ownership and control of studies from start to finish. One major company mentioned the need for CROs to "train and retrain" investigators so that they "live and breathe" the oversight of studies. Additionally, companies have identified areas where they would like to see innovative approaches to performance improvement from CROs. One major company wants more innovative approaches to clinical trial monitoring to drive insight. Another firm that uses CROs for traditional trial monitoring said the most important job for a CRO is to get data immediately from sites and to capture outliers in the data that could indicate problems, or unexpected opportunity, in a trial. This company wants to know that a CRO has its "finger on the pulse of these developments." However, because CROs' incentives are often based on completion, they do not feel the pressure to spot surprising results quickly.

Partner assessment: Several pharmaceutical companies reported that they would like CROs to differentiate themselves with a talent model in addition to the current service model. They emphasized the need to invest in employees to diminish and prevent CRO turnover—a strategic partnership can be jeopardized by key staffers leaving in the middle of a project. One company surveyed noted that CROs "shoot themselves in the foot" if they bid up salaries to lure qualified people away from competitors, undermining trust at a time when pharmaceutical companies are seeking deeper partnership relationships. Another stated that CRO management teams are often more committed to business development than service and need to stay focused on accounts after the contract is signed. An ideal situation, according to this company, is when CRO managers spontaneously reach out to pharmaceutical clients and proactively manage issues.

A SHIFT TO NIMBLE PARTNERSHIPS

By developing coherent approaches to outsourcing, underpinned by the capabilities needed to manage their relationships as well as possible with outside clinical research teams, pharmaceutical companies can drive a new, mutually beneficial approach to their outsourcing relationships. This sort of nimble, capability-centered partnership is characterized by deep alignment and clarity between a pharmaceutical company and a CRO based on complementary capabilities.

As the industry confronts challenges including cost pressures, low growth, and rapid scientific advances, closely aligned and nimble relationships are essential. Pharmaceutical companies need to have the capabilities in place to innovate and to stretch in new ways that place a stronger focus on molecular innovation. And they need flexible CRO relationship models allowing them to expand and contract capabilities to suit changing business needs. In a nimble partnership, both the CRO and the pharmaceutical company undergo continual evaluation to make effective pairings that define success.

A "one size fits all" approach will not lead to sustainable partnerships between CROs and pharmaceutical firms. Rather, capability analysis will determine the best partnerships. For pharmaceutical teams that want to get started, we suggest consideration of 10 questions (*see "Getting Started: 10 Questions to Consider for a Successful Pharmaceutical–CRO Relationship"*).

Getting Started: 10 Questions to Consider for a Successful Pharmaceutical–CRO Relationship

1. What are our core capabilities in clinical development?

2. What are the ongoing, regulatory, and therapeutic-area business requirements?

3. What core capabilities need to remain in-house? Which capabilities can be outsourced?

4. What are the sources of value in an outsourcing relationship?

5. Is the relationship designed to deliver against sources of value?

6. Are my capabilities, including business processes and personnel, linked to the sources of value and design of the relationship?

7. Is the necessary infrastructure in place from both the pharmaceutical and CRO perspectives?

8. Who is a capable CRO business partner today? And who is emerging that we should watch carefully?

9. Of the feasible CRO partner set, which potential partners have already entered analogous partnerships, and which are able to demonstrate advantaged capabilities of the type we are seeking?

10. Across my company, who is already working with potential CRO partners? Can I discuss with them the CRO capabilities for my particular needs?

METHODOLOGY

The findings, conclusions, and perspectives in this article are based on proprietary Booz & Company primary and secondary research. We conducted 20 structured interviews with senior executives at the vice president or senior director level in 11 of the top 20 pharmaceutical companies. Of those interviewed, 13 were in clinical functions, three in safety, two in sourcing, and two in medical positions.

The interviews covered a number of questions designed to provide a perspective on how to make pharmaceutical–CRO relationships as productive as possible. The questions focused on the following:

- Strategic rationale for clinical development outsourcing
  - Flexibility in peak-load demand/capacity management
  - Access to capabilities (and the specific types of capabilities in demand)
  - Cost management
  - Acceleration of innovative approaches to development
  - Consistency of strategic rationale across the company
- Core and noncore clinical development capabilities
  - Functions that differentiate products and create value
  - Functions that are operational and less critical to maintain internally
  - Covering a specific list of functions from clinical protocol design through finalization of study reports and database analysis
- Design and performance of current CRO relationships
  - Number of CRO relationships
  - Structure of relationships
  - Measures of performance
  - Opportunities to improve services and performance
- Alignment between pharmaceutical company strategic objectives and the design of the CRO relationship
  - Clarity of strategic objectives
  - Link between strategic objectives and measures of CRO performance

CONCLUSION

In lockstep with significant shifts taking place in the pharmaceutical industry, we expect to see major changes in pharmaceutical–CRO alliances in the future. Currently, the industry seems to be taking a piecemeal approach to these arrangements, with many diverse reasons for forming partnerships. As a result, companies are experimenting with different CRO relationships, often trying out several that do not fit their core value proposition or provide the strategic insights they hope to realize.

Companies will move beyond this experimentation stage as they realize the critical need for business and strategic alignment—grounded in a realization of what each partner does best—to guide future clinical development outsourcing decisions. In the future, pharmaceutical companies and CROs will establish coherent partnerships by determining their approach to new research relationships and the capabilities systems that underpin them. Ultimately, companies that achieve the new nimble will be more focused, make better use of their distinct capabilities, and differentiate themselves in the marketplace.

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