



Help from THE OUTSIDE

As life-sciences companies look to improve operational efficiencies within their organizations, they are increasingly reducing the number of activities that they would categorize as core competencies and outsourcing them to third-party partners.



DR. FRANCOIS NADER NPS Pharmaceuticals

“Successful outsourcing depends upon well-defined objectives and deliverables, a clear understanding of respective roles and responsibilities of the parties involved, an alignment of the incentives, and a commitment to robust communication.”

IDC Health Insights notes that while historically outsourced activities were those efforts that would be considered commoditized and industry-independent, such as accounting or human resources, there has been a gradual shift to increasingly outsource industry-specific activities.

“Contract manufacturing and IT support were early industry-specific areas outsourced in the life sciences, followed by clinical trials,” says Alan Louie, Ph.D., research director, IDC Health Insights. “Drug safety and analytics have more recently grown as outsourced activities, and even discovery research is being

looked at as a noncore competency. To better position themselves to capture these expanding opportunities, outsourcing vendors have expanded their industry-specific knowledge, expertise, and capabilities.”

The industry outsourcing trend appears to be moving toward pharmaceutical companies consolidating their functions and focusing on basic or specialized functions, while outsourcing the rest of their functions to contract manufacturing companies. BCC Research data indicate that global pharmaceutical contract manufacturing and contract research organizations revenue grew to an estimated \$218 billion in 2011, up from \$196 billion in 2010,

Outlook Bright for Outsourcing Sector

In fall 2011, William Blair & Company partnered with Life Science Strategy Group to conduct a survey of pharma and biotech sponsors regarding their outsourcing experience and general trends in the CRO industry. Results of the survey found that sponsors remain optimistic on R&D spending growth, a key outsourcing indicator. The recent heightened level of macroeconomic uncertainty has not yet had a material impact on spending plans by pharma sponsors, with R&D spending growth projected at 2% in 2011 and 1% in 2012.

More than three-quarters of respondents expect the percentage of their respective company’s R&D budgets to increase or remain consistent with 2010 levels across the

development spectrum, with a particular focus on clinical. Although 63% of survey respondents expect their R&D budgets to commit an increased or similar level of focus on the discovery phase, spending on this phase of the pipeline seems to be getting the least amount of attention when compared with preclinical, in-licensing, and clinical.

Over the longer term, the survey data suggests growth rates should improve as the industry moves beyond the peak generic conversion year in 2012, although analysts continue to believe that it is not likely that the industry will return to prerecession levels of spending growth — at least not until overall new product approvals and revenue growth improve.

The survey also indicates that the ongoing restructuring initiatives of pharma sponsors will likely lead to more outsourcing, with announcements

from large pharma companies like Pfizer, Takeda, Sanofi, and Lilly over the past few years suggesting that a virtual pharma model could become a reality. Under a virtual model, analysts believe that outsourcing penetration could ultimately reach rates of 60% or more, compared with the estimated range of 25% to 35% that currently exists.

Most survey respondents expect the reorganizational efforts of their respective companies to result in headcount reductions and fewer internal resources, closely followed by increased functional outsourcing, narrower therapeutic scope, and increased strategic relationships with CROs. Based on those findings, William Blair says its industry model currently anticipates a roughly 10-percentage-point increase in outsourcing penetration from 2010 through 2015.



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“The trend toward outsourcing is partially being driven by established biotechnology companies and small startup companies, with promising drug candidates but limited staff expertise in drug development.”

and the market is projected to exceed \$361 billion by 2016, increasing at a compound annual growth rate (CAGR) of 11%.

Pharmaceutical companies are finding that outsourcing production brings them cost and time savings, among other benefits, but that it doesn't come without risks. According to the BCC Research report, Contract Pharmaceutical Manufacturing, Research and Packaging: Global Markets, an organization must identify the factors that make it competitive in the marketplace; it is only when a company can maintain its core competencies that outsourcing is effective.

The Kalorama report, *Outsourcing in Drug Development: The Contract Research (Clinical Trial) Market*, finds that more than one-third of clinical trials conducted by pharmaceutical companies are now outsourced outside of the organization. The report also notes that drug development expenditures dedicated to in-house core activities declined from 74% to 62% in the past year.

“The trend toward outsourcing is partially being driven by established biotechnology companies and small startup companies, with promising drug candidates but limited staff expertise in drug development,” says Bruce Carlson, publisher at Kalorama Information. “Senior management personnel at many biotechnology companies possess impressive scientific or entrepreneurial backgrounds, but have little or no experience in preparing regulatory submissions, interacting with regulatory agencies, designing and managing clinical trials, or producing investigational drug supplies for clinical trials under the FDA's good manufacturing practices (GMPs).”

The Kalorama report indicates that there has been a change in the types of trials companies are outsourcing. While Phases II-III clinical trials were the first clinical research operations to be outsourced, growth in R&D spending in Phase I trials began to outpace Phases II-III in 2003, and was the fastest-growing area of drug development until about 2006. Currently, growth in Phase I and Phases II-III is about equal; however, Mr. Carlson says the postapproval, or Phase IIIb/IV, testing phase is “quickly evolving into a hot opportunity for contract research competitors.”

The major objectives of Phase IIIb/IV programs are to satisfy regulatory commitments and extend knowledge about efficacy, safety, and effectiveness within actual use settings. In

addition, postapproval studies have emerged as a powerful tool for companies to distribute their drug more broadly and for longer periods.

Smart Sourcing

Knowledge of an organization's capabilities, as well as what it cannot realistically do, is a key component of a successful outsourcing partnership, Mr. Carlson observes.

“Successful outsourcing depends upon well-defined objectives and deliverables, a clear understanding of respective roles and responsibilities of the parties involved, an alignment of the incentives, and a commitment to robust communication,” says Francois Nader, M.D., president and CEO of NPS Pharmaceuticals. “These attributes have to flow from the top of each organization and be practiced throughout the course of the relationship.”

Shyard Wong, M.D., Asia regional head, clinical study unit, Sanofi, stresses the need for clear articulation of strategy and directions by both sponsor and CRO, with a view toward developing a common mission and vision in the partnership.

“A governance structure between sponsor and CRO that enables true partnership instead of a transactional relationship is key,” Dr. Wong says. “Both organizations also need an agreed set of key performance lead indicators reflective of the partnership's mission and vision that can be easily accessed and reviewed regularly by both partners.”

Dr. Nader says roles and responsibilities in the outsourcing partnership should be defined as early as possible, with a conflict resolution process for every stage of activity. Clarity of purpose and accountability are essential — and management by consensus does not necessarily yield the best outcome for the project.

Outsourcing in the World

Drug development has become increasingly global as sponsors seek to accelerate patient recruitment by gaining access to large treatment-naive patient populations, as well as broaden access to trained investigators and reduce clinical trial costs. Although the United States remains the world's largest clinical research market, Kalorama notes that

“Outsourcing vendors have expanded their industry-specific knowledge, expertise, and capabilities.”



BRUCE CARLSON Kalorama Information

clinical research is increasingly being conducted in Eastern Europe, Asia, and Latin America, as well as other geographic regions.

When considering outsourcing to global partners, Mr. Carlson recommends sponsors assess a potential CRO partner for financial stability and backlog of projects.

“The client wants a CRO to complete the project for the best price, but the client also needs to factor in that the CRO must actually complete the project, or any time savings and cost savings to development the drug product is lost,” he says. “The lack of financial stability associated with the smaller CROs may weigh heavily on the sponsor company's decision on whether to use them, with the risk of interruption or cancellation of a development project due to a CRO experiencing difficulties.”

Dr. Wong says pharma companies also need to consider the geographical footprint of a potential partner and how well it complements the company's global strategy. “Other key factors include core in-house capabilities versus dependency on third-party vendors, as well as the systems architecture and procedures used by the potential partner,” he adds.

Dr. Nader describes global strategic outsourcing as “a mindset that requires a unique set of management skills, a team committed to the success of each project, and a high degree of self-confidence” as execution is delegated to third parties.

“The key success factor of this business model, though, is to determine with absolute clarity and consistency what activities are core to the mission of the company versus non-core activities that can be outsourced,” he says. “Maintaining ‘institutional memory’ is important to the suc-



DR. ALAN LOUIE
IDC



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VIEWPOINTS



DR. RICHARD MALCOLM
CEO
Acurian

Making a Good Impression

A CRO or specialty recruitment partner needs to be able to answer several questions, including: the number of people in the organization devoted to patient recruitment; its analytics and tracking capabilities; how it defines success metrics; the services are available to support sites from beginning to end of the trial to make sure patients are successfully recruited, randomized, and retained; the proposed price-per-patient to recruit and the analysis used to support this figure; and the amount of risk it is willing to assume.

Best-in-Class Expertise

There are many niche players in the industry. The advantage to outsourcing in patient recruitment is that clients can access best-in-class talents and expertise. Obstacles include using a company that has limited skills and abilities in niche services. For example, CROs are experts at study conduct, but not patient recruitment. For patient enrollment and retention, separate specialized companies can provide the patients needed for the clinical trial to finish at or ahead of schedule.



LOU SHAPIRO
Senior VP, Business Development
PhoneScreen, an AMAC company

A Global View

Global partnerships require local cultural competence to build and maintain relationships with healthcare providers and patients. It's also important to have local language fluency, because it's nearly impossible to build a relationship if there is a language barrier. It's vital to have knowledge of local government regulations and guidelines. Nothing will stop a program faster than violating governing regulations. Finally,

technology is critical to delivering effective and efficient services, therefore make sure solutions are compatible and can be integrated into both parties' processes.

Targeted Staffing

There are several benefits of outsourcing call center activities, including the ability to hire professionals with the background and expertise the program needs. The ability to hire professionals who align with the cultural and language requirements of the program is a distinct advantage. Additionally, the flexibility to increase and decrease staffing levels as required maximizes efficiency and cost-savings.



JOSEPH BEDFORD, PH.D.
Director of Marketing
Almac

Trust and Confidence

Developing high levels of trust and confidence are two of the key components to building successful outsourcing partnerships. Trust is developed on both sides when individuals commit to joint goals and objectives and work closely together to ensure that they are reached. Along the way, both partners need to be honest and responsive in their communications to cement a trusting relationship. Similarly, confidence on both sides of the relationship grows when both teams work together in a seamless manner to maximize productivity of the clinical trial or study.

Multinational Experience

Of central importance to successfully outsourcing on a global basis is to select partners with global reach and capacity, as well as expertise and experience in managing multi-national trials. Global studies require in-depth expertise relating to regulatory requirements, customs' policies and procedures, and managing personnel at sites, laboratories, clinical supplies depots, and other facilities abroad during the active phase of the study. Once data collection is completed, other factors such as multilingual capabilities, global data management experience, and statistical expertise prove essential to the successful analysis of the data and completion of the study.



JEANMARIE MARKHAM
CEO and Founder
Clinlogix
Trust, and Verify

Successful outsourcing begins with building trust and strong relationships with the right outsourced provider. Setting clear requirements and expectations are foremost and frame the groundwork. Success is dependent on not only how well-defined the requirements are but how well they can be measured — trust, but verify.



TOM AVERY
VP, Business Development
ERT Inc.

Mutually Beneficial

Outsourcing success starts with mutual understanding of the collaborative benefit each organization will bring to its common customer base. For instance, the core competency and expertise of one partner complements the other partner's primary services. When this understanding translates to executive commitment from each company, success will follow. Communication, planning, and implementation of integrated resources develop at all relevant touchpoints. The final ingredient that ensures success is a quantifiable business incentive based on incremental revenue growth directly derived from the relationship. With this recipe, over time, a simple partnership will become a strategic alliance enabling both organizations to springboard growth while minimizing fixed costs in a volatile and competitive marketplace.



DR. EVAN DEMESTHIAS
CEO
The Medical Affairs Company

The Customization Advantage

It is clear that one of the most important attributes of outsourcing is flexibility, particularly the flexibility to customize programs to meet individual company and product needs, providing clients exactly what they need. And ongoing flexibility is just as important — what a client needs may change over time. The ability to

quickly and efficiently adapt to new needs and requirements is of paramount importance in evaluating a potential outsourcing partner.

Company politics and corporate culture play a central role in how smoothly outsourcing is integrated in how a company does business. The ability of executives, both from within and outside the company, to navigate these challenges is key to successful outsourcing. Well thought-out planning, transition, and integration are critical. It is executives at both organizations who ensure outsourcing is successful and becomes a strategic component of how a business functions in today's ultra-competitive environment.



MONIQUE GARRETT

VP, Global Strategy,
Octagon Research Solutions Inc.

Sharing the Vision

The key word here is

partnership. Make sure your vendor partner's vision aligns with your organization's. Since the function being outsourced is critical to your company's success, your vendor needs to have the proven expertise and industry reputation you can trust. In addition, if their operating model, pricing strategies or methodologies don't align with your outsourcing objectives, you need to keep looking. Many outsourcing providers are becoming increasingly innovative and flexible in their approaches, ultimately creating new markets for outsourcing that didn't exist a few years ago. All of this means that there are plenty of options and choices to be made, so you need to take time to find the partner with the best fit. This upfront investment will provide a recurring pay off throughout the relationship.



MICHAEL ACKERMANN

Senior VP, Commercialization
Quintiles

Expert Experience

Before thinking about outsourcing, it is important to have clarity around the outsourcing needs. Key

considerations include: are the needs local, regional, or global? This lends itself to the question of whether a company should look for a partner with global capabilities that assures consistent execution or a series of local partners, which could present significant management and administrative challenges. It is also important to determine if the need is for a simple outsourcing activity or if a partner is needed to provide strategic/design expertise to challenge/confirm assumptions.

Many companies forget that an outsourcing partner can provide significant insights and expertise given the multitude of experiences they have gained across the industry. That experience is the added value of an effective outsourcing relationship. Many companies define outsourcing needs too narrowly, literally prohibiting the potential outsourcing provider the opportunity to demonstrate their true potential. Successful partnerships are achieved by aligning goals, followed by executional pathways that allow both partners to bring their best ideas to the table, leading to a greater feeling of ownership and a much more robust implementation plan.

In addition to clarity around the needs, a company should look at a potential partner from a medium- to longer-term perspective. This can serve as a tremendous "carrot" for potential partners who are looking for longer-term relationships, especially if the relationship is built on head-count needs.

Finally, it is important to perform thorough due diligence on the outsourcing partners' capabilities and ensure the right team and team leadership is assigned to the project. The project owner needs to make sure to take into consideration the potential for a project to shift course, so due diligence should include the breadth of services and experiences of the provider so the project owner does not have to go through another search should the program take an alternate course.

Outsourcing Advantages

Advantages of outsourcing include flexibility of resources, expansion, or supplementing internal expertise or experiences; gaining an independent/objective opinion; potential for risk-sharing and true partnering while maintaining strategic control and ownership of the asset

value. Obstacles include selecting the wrong partner, being unclear about the partnership needs leading to multiple changes midstream, strictly focusing on cost rather than a combination of quality, peace of mind and value, focusing on paralyzing oversight, rather than teamwork.



ERIN NEARY

VP Training and Development
The Remedy Group

Forward Momentum

The only way to truly grow your business is to put a business plan in motion, and then surround yourself with competent forward-thinking people who will take ideas you've developed and initiatives you've put in place and manage, refine, and grow them for you, while you move on to the next growth opportunity. This is exactly what outsourcing does for the pharmaceutical manufacturer. Your team has a goal, but is lacking the resources to implement that goal. There is an alternative to bogging your team down or stretching your current resources thin, leading to a failed initiative. Take advantage of the option to outsource your project to a company that, for example, specializes in the niche market you want to enter or covers the white space you do not have the resources to cover.

If you can match up your organization's needs with the value proposition offered by an outsourcing company, you have found utopia. The win-win situation is when you have a partnership where there is 100% understanding of where each party is coming from and expected to go; an agreement on risk-share, timelines, resources, communication and goals. This allows the company to put the project in the hands of the experts, while still ensuring their vision is being upheld, freeing up their time to focus on their own value proposition.

The key component to a successful outsourcing partnership is acceptance of the concept that success itself is based on partnerships. If you're doing all the work, who's doing all the innovating?

cess of certain projects and can be supported by hiring former employees as consultants.

“Of utmost importance is ensuring compliance, since it can be your Achilles’ heel and requires constant focus by company executives and outsourcing partners,” Dr. Nader continues. “Not all employees adapt easily to outsourcing, since this business model requires delegation and oversight rather than execution only.”

Advantage Realized

Chief among the advantages provided by outsourcing are lower costs and increased capacity, Mr. Carlson says.


“Without the outsourcing option for clinical trials, the only choice companies would have is to reduce their R&D operations, damaging future offerings and increasing the danger that generic competition will level

company revenue,” he says. “Outsourcing allows companies to maintain robust pipelines while keeping a check on expenses. Also, the CROs often have knowledge of regulatory trends and technology that the client isn’t focused on.”

Dr. Nader notes that outsourcing has enabled NPS to access specific expertise, technologies, and facilities with great efficiency.

“Outsourcing allows us to operate a leaner organization, allocate internal resources more effectively, and limit the potential for bottlenecks, which in turn contribute to lower infrastructure and overhead costs and more rapid integration and execution of new programs,” he says. “In addition, it has in many instances increased the quality of the deliverables, since these activities were conducted by companies for whom these functions are their core business, versus a one-off by NPS.”

Dr. Nader adds successful outsourcing requires managers with both strategic acumen and tactical skills who can strike the ideal balance of “thinking” and “doing” required to thrive in an outsourcing environment.

“This combination of talents can be hard to find,” he says. “Outsourcing also requires more careful succession planning, since many functions may involve only a few in-house people whose retention is critical.” 

EXPERTS



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