

The Outsourcing BIG PICTURE

► *More companies are turning to outsourcing partners to tackle many noncore activities, but challenges remain.*

Outsourcing is now firmly entrenched in the pharma industry. While pharmaceutical companies have been outsourcing back-office activities for many years now, they are increasingly turning to external partners for research and development activities that traditionally were retained in-house.

Today, the pharmaceutical and biotech industry has the highest level of R&D outsourcing across all high-technology industries,

according to a recent PwC report. And demand for outsourcing services is increasing, allowing pharmaceutical companies to focus on core competencies.

Other reasons for outsourcing include gaining access to new technology capabilities, faster response time, and improving processes, according to Kalorama Information.

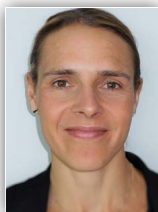
In the past cost reduction was the main driver, Gens and Associates have noted.

Tapping New Capabilities

Resource and cost pressures, combined with the need for specialized knowledge, are increasingly leading pharmaceutical companies to outsource drug discovery activities, such as biology services and lead optimization — the final stage in the discovery process before a compound moves into preclinical studies, according to experts at Kalorama Information.

In parallel, life-sciences companies have been partnering more frequently with academia and nonprofit organizations to bolster drug discovery.

EXECUTIVE VIEWPOINTS



ELAINA N. HAEUBER
Executive Director of
Strategic Operations,
Acurian

THE KEYS TO A SUCCESSFUL

STRATEGIC PARTNERSHIP

The goal should be to create a framework for identifying and collaborating on processes that result in the maximized performance of both organizations. The cornerstones of this framework should be transparency/ sharing of information, commitment of organization leadership to success, and openness in managing and resolving issues. This includes recurring mechanisms to provide information related to changes and trends in capabilities, regional and country experience, etc.; monitoring key performance and relationship indicators; and following a robust risk management and escalation process to ensure accountability.

COLLABORATIVE SUCCESS

Outsourcing partners can implement a robust governance framework with defined remits, to not only oversee the strategic relationship and assess key initiatives, but also match future capabilities with future organizational needs. The PRO should be allowed to evaluate the

pipeline, to facilitate resource planning and availability at the right time. Both parties should work together to ensure management of operational issues at the most appropriate level.



TERRY HERRING
President, Alamo
Pharma Services

UNDERSTANDING WHAT SUCCESS LOOKS LIKE

In my experience the most successful partnerships are those in which there is a clear understanding and consensus around what success looks and feels like. It is also important that there are reasonable expectations around the journey to success, for example, timing and possible hurdles and how to overcome them. Sometimes, even with the very best planning, unforeseen challenges arise. In those instances, it is most important that we've built a true partnership based on trust and mutual respect.

EXPERIENCE COUNTS

The best way we can help our partners is to help shape their thinking up front. Often clients come to us with an idea of how many reps they need. We bring our experience to help our partners to truly optimize their approach and modify quickly to yield the best possible ROI. Through this view of their strategy, we determine the best

promotional levers available through our organization.



PENNY BEMUS
Senior VP, Business
Development,
Dohmen Life
Science Services

CONSISTENCY ALONG

THE PATHWAY

Look for a partner that can work with your organization throughout the development pathway to commercialization cycle. For example, our life-sciences clients, from start-ups to established brands, recognize that building their own complex commercialization structure is a redundancy that adds cost to healthcare delivery and diffuses their attention. We've built a bench-to-bedside outsourcing model that doesn't require the traditional and disjointed use of multiple vendors that are not in direct alignment with the sponsor. It's a new model that aims to reduce risk, cost, and operational complexity.

DIRECT-TO-PATIENT MODEL

Business process outsourcers need to evolve. The traditional model of multiple service providers with disparate services is often rife with inherent conflicts of interest. In the rare disease industry specifically, that model often

EXECUTIVE VIEWPOINTS

allows patients to fall through the cracks from onboarding to ongoing adherence. We advise clients to consider a more holistic, direct-to-patient service model in which the outsource partner acts as an agent of the manufacturer focused on reducing the burden of the disease and increasing therapy adherence through coordinated care, patient education, and data-driven insights. This connects manufacturers more closely with patients and streamlines care delivery and support.



JUDY SWILLEY, PH.D.
Executive VP and
General Manager, Head
of Strategic Alliance
Management,
INC Research

PARTNERSHIP DNA

The partnership approach must truly be part of the corporate DNA of both parties. Fit-for-purpose operating models and a partnership culture designed to drive success of the relationship are key. There needs to be true alignment among both organizations — everyone involved needs to understand why the partnership exists, what the goals are, and the roadmap for attaining success. Transparency is critical, as is appropriate resource allocation for partnership oversight along with an effective governance structure.

COLLABORATIVE JOINT ACCOUNTABILITY

Recognize that a partnership isn't something you outsource. Sponsors need to manage and drive the partnership expectations internally to achieve objectives. Partnerships are collaborations with joint accountability. Ideally a sponsor will "mirror" the CRO's partnership oversight, appointing someone internally with alliance management experience to shepherd the relationship. It's also important to realize good partnerships evolve over time; models change as partners work together to build efficiencies that include shared insights into pipelines and long-term planning.



PAUL HARNEY
VP Business Development
for Integrated,
Engagement Services
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FOUR KEYS TO SUCCESS

There are four keys to a successful partnership: proactive support, flexibility, communication, and innovation. Proactive support is different from just being responsive, which suggests a passive relationship, so we take initiative to drive success. Flexibility is crucial because the pharma landscape is always changing and only those partnerships that allow for change can prosper whereas rigidity leads to missed opportunities. Thirdly, there's nothing that can replace an open dialogue around the good, the bad, and everything in between. It allows both parties to quickly identify and resolve problems as well as capitalize on opportunities. Finally, innovation is imperative — and often missing — in outsourced relationships, characterized by defined contracts. We never rely on conventional methods. As a partner, the goal is to maximize our customers' success so that means offering innovative strategies and solutions.



STEVE DEVRIEZE
VP, Emerging Biopharma
and Technologies for
Integrated Engagement
Services North America,
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FOCUS ON BUSINESS GOALS

Seek and consider the input and strategic insights from a partner instead of just looking for bodies to fill a resource gap, this will enable a stronger and long-standing partnership. Overlooking the business goals often results in KPIs that are overly focused on the contract, which is a transactional relationship that delivers only what can be defined in the agreement. Creating a broader set of KPIs that cover things such as innovation objectives and even subjective measures will lead to better overall impact on the market and business alignment.



**EVAN DEMESTIHAS,
M.D., RPH**
CEO, The Medical Affairs
Company (TMAC)

PLAYING AN INTEGRAL ROLE

The most successful partnerships are those where an outsourced team is not viewed as "outsourced," but rather as an integral part of the sponsor company the same as the internal headcount. A leading pharma client of ours shared this view and outsourced a large MSL team to supplement its own expansive internal team, and never referenced nor treated the outsourced team any differently. It was always the collective MSL team; always an inclusive "we" and never an "us" and "them" when discussing mission and goals. This has very deep ramifications in that the outsourced team not only feels fully integrated, but truly valued, enhancing job satisfaction and ultimately yielding positive results. In addition, the most successful outsourced programs are when the sponsor also values the outsourced teams' management and takes advantage of their vast experience, including them in the decision making process that yields benefits for the entire team.



BRION BRANDES
Executive VP, Business
Development,
Spectra BioPharma
Selling Solutions

EXPERIENCE AND

EXPERTISE

Outsourced service partners have the ability to bring value to the partnership in multiple ways. First, the experience and expertise of being involved in similar partnerships over time should allow the service partner to provide a diversity of thought into the solution orientation. The service provider should also be able to think outside its individual service deliverables and bring in third-party solutions where necessary to drive success in the partnership.

The Clinical Trial Process

Partnership with CROs continues to expand amid growth in developing markets and an improving global economy. A 2016 Nice Insight CRO and CDMO (contract development and manufacturing organizations) outsourcing survey found that 77% of companies outsource services or operations to CROs, CDMOs, or CMOs organizations.

Typically, companies are outsourcing a high number of tactical activities. For example, a Cutting Edge Information survey found 83% of the top 10 and top 50 pharmaceutical companies outsource responsibility for clinical data management. Among activities these companies are outsourcing include traditional trial monitoring responsibilities and data management.

Companies are looking for more than to simply lift and shift activities with a majority of pharmaceutical companies (69%) seeking strategic partners, the Nice survey found. Other research indicates that there is an even split between a strategic and tactical approach to outsourcing.

Phase II projects are most commonly outsourced (63%), followed by Phase I activities (58%), preclinical work (53%), and Phase III (51%). Even postmarketing studies have a relatively high rate of outsourcing (39%).

According to a Gens and Associates 2016 survey, Pursuing World Class Regulatory Information Management (RIM), Strategy, Measures and Priorities, regulatory activities that companies most frequently outsource include investigational or new marketing application submission publishing, small maintenance submissions, local affiliate submission publishing, safety case processing, and safety reporting. The survey of 52 companies found that the biggest driver for regulatory outsourcing is deriving greater flexibility to manage spikes in submission volume (86%), followed by a push to improve operational efficiency (82%), with cost reduction being the third highest priority (78%).

Challenges in the Relationship

Despite more companies choosing to outsource, problems with the vendor relationships continue. In fact, a survey of pharmaceutical

R&D leaders found that managing outsourcing was the biggest day-to-day challenge they faced.

Loss of control, IP, and confidentiality remain among the main concerns for companies. Poor communication and cultural barriers are also cited as significant challenges in the outsourcing relationship.

Successful outsourcing relationships require careful planning and selection, continual vendor oversight and evaluation, and resource commitment to managing the relationship.

The Changing Face of Outsourcing

While outsourcing has grown across the industry, there has also been huge consolidation.

Perhaps the biggest CRO/vendor merger of the year was the \$18 billion deal between Quintiles and IMS Health that the two companies described as creating a “distinctive global real-world evidence solutions platform.”

It’s likely that during 2017 more alliances, mergers, and partnerships will form as the outsourcing industry seeks to meet the growing demands of life-sciences companies. 