A New and Better COMMERCIAL MODEL FOR ENHANCED VALUE

By combining the expertise of a CRO with that of a contract commercial organization, an outsourced provider can help clients bring business strategy to science and scientific expertise to business. Those companies able to take strategic advantage of this new model will be better positioned to focus on their strengths, bolster innovation, build value, and succeed against fierce competition in the year ahead.

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The biopharma industry entered 2015 with increased confidence in a future that promises a new era of growth. We saw 2014 end with the FDA approving more new therapies than at any time since 1996 and this year begin with the FDA poised to approve the first biosimilar drug. We saw the beginning of advances rooted in genomic science coming to fruition. We saw the Standard & Poor's pharma index rise 29% in the last year. And Deloitte's "Measuring the Return from Pharmaceutical Innovation 2014" publication reports a return on R&D investment last year of 5.5%, up from 5.1% in 2013, the first such rise since 2010. All very promising.

Worldwide, the industry sees massive opportunities that feed this optimism. The number of people over 65 is forecasted to triple to 1.5 billion globally over the next 35 years, creating increased demand for treatments to combat age-related diseases, among them diabetes, heart disease, and cancer. Meanwhile, expanding wealth and a growing middle class in China, Brazil, and other parts of the developing world continue to bring increased demand for more sophisticated medicines. And for the first time in the pharmaceutical industry's history, projected worldwide prescription drug sales are set to exceed $1 trillion.

But our industry also continues to face significant headwinds, obstacles that require companies to rethink how they do business and restructure operations. While the pharmaceutical sector may view the aging population as a market opportunity, governments see it as a potential tsunami that will hit health systems already overburdened and struggling to contain costs. We now routinely see European health systems challenging pharmaceutical companies on pricing and value, with reimbursement subject to downward pressure over time. Health systems in both China and the United States are becoming increasingly price-sensitive, as well. Companies have been under tremendous pressure for some time to contain costs while encouraging innovation — both in drug development and in commercialization. The Deloitte report "2014 Global Life Sciences Outlook" noted that 58% of pharmaceutical executives surveyed last year said they will be adapting their sales models to respond to legislative healthcare reforms.

As a result of all these factors, we are seeing the emergence of the next phase of biopharmaceutical outsourcing, the natural evolution of a trend that began nearly 40 years ago with pharmaceutical companies shifting drug development to outside experts. This was followed by moves to outsource sales and manufacturing. Now, companies are looking for ways to increase value through more strategically outsourcing commercialization.

The Year of Comprehensive Commercial Outsourcing

We believe that 2015 will be the year of comprehensive commercial outsourcing. Biopharmaceutical companies well know that to win in today's complex, global marketplace they need to rethink the commercialization of their assets. Across the industry, there is a need for a better model, one that is flexible, scalable, and innovative. Out of this need has emerged a new category of service, the contract commercial organization, or CCO.

A CCO delivers comprehensive commercial services to optimize performance, reduce risk, and expedite the global delivery of healthcare innovation to patients. It encompasses a vast range of services that include consulting, sales teams and training, market access services, non-personal promotion, branding, advertising, public relations, medication adherence, and full management of commercialization teams. Breadth of expertise is key to value creation, but equally important is the quality of those services. Each service must be top-tier to deliver the greatest value across the commercialization continuum, from pre-launch to the last product sold off a shelf. A CCO should give companies a critical competitive advantage by integrating strategic, creative, and operational expertise as never before.

By broadly outsourcing commercialization, both emerging and established biopharmaceutical companies can gain instant access to global reach, deep therapeutic expertise, and premium services. Multinational pharmaceutical companies find this approach provides complementary expertise, high-value strategic insights, and essential speed. For emerging innovator companies, outsourcing commercialization capabilities may allow them to maximize market share while retaining the value of their asset.

Large, small and mid-size companies can all find value in collaborating with a single, experienced partner rather than dozens of separate businesses. There are meaningful efficiencies gained in working across disciplines seamlessly, at the right intensity and at the right time.

Combining the Expertise of a CCO with a CRO

Perhaps the greatest value, however, comes

from combining the expertise of a contract commercial organization with the capabilities of a clinical research organization (CRO). A CCO linked with a CRO can provide biopharmaceutical companies with valuable insights that can only be found in viewing opportunities and challenges through a strategic lens that sees across the entire life of a product.

Time and again, CROs have proven their worth in offering biopharmaceutical companies therapeutic expertise, world-class scientific know-how, experience in navigating global regulations, and state-of-the-art systems scaled to need. Today, the need for outsourced drug development is greater than ever.

The Deloitte "Innovation" report noted that almost 60% of revenues from late-stage R&D pipelines as forecasted by nine of the biggest drug makers come from acquired assets or partnerships. A record $250 billion in deals were struck in 2014, according to the Financial Times, with most industry observers predicting continued strong M&A activity in the year ahead. With so much innovation in drug development coming from outside, companies understand they need to further reduce the cost of fixed infrastructure to reflect the changing nature of pipelines. Meanwhile, development costs are rising.

The Tufts Center for the Study of Drug Development reported last year that the average development cost for bringing a drug to approval is now $2.6 billion, three times the cost that Tufts reported in 2003. This skyrocketing investment is driven at least in part by the greater cost of developing biologics, which are replacing small, chemically manufactured molecules, the basis for most medicines today. The Deloitte 2014 Outlook survey found 65% of life-science executives saying they have had to, or will have to, change their innovation processes within the next three years. CROs, particularly those with expertise in biologics, are more valuable than ever in helping companies control costs while making research more nimble and collaborative.

Innovative biopharmaceutical companies are now seeing ways to increase value by outsourcing to a single provider of both clinical and commercial services. And the broader the services offered, the greater the potential value to be found.

A comprehensive provider of CRO and CCO services can help break down silos and bridge the traditional gap between development and commercialization. For example, understanding from managed market experts the precise questions that regulators will ask at approval and reimbursement can help inform the questions asked in the clinical trial process. Better use of digital communications techniques in patient recruitment, drawn from the expertise of public relations, advertising and behavioral science, can expedite enrollment and increase retention. And gathering feedback from the right patients at the end of a trial can expedite and enhance launch.

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WHAT TO LOOK FOR IN AN OUTSOURCED SERVICE PROVIDER

Companies looking to improve their outsourcing in 2015 should look for companies with the broadest range of top-tier services. Even if choosing not to use all services, it is advantageous to have a provider that understands the spectrum of drug development and commercialization. Here are some attributes to look for in a provider:

Clinical

- Size and Scale: A top-tier, global Clinical Research Organization
- Medical, Scientific, and Regulatory Expertise
- Phase I-IIa Clinical Trial Services
- Proof-of-Concept Experience
- Bioanalytical, Bioavailability, and Bioequivalence Services, Phase IIb-III Clinical Trial Services
- Feasibility and Clinical Trial Recruitment Services
- Phase IV/Late Stage Services
- Global Clinical Staffing Solutions and Functional Service Provider options flexible enough to provide a single source or an entire team for core clinical trial services, including Data Management, Biostatistics, Statistical Programming, Medical Writing, and Study Monitoring
- Therapeutically Aligned Project Teams
- Systematic Risk Assessment for Risk Based Monitoring, Risk Management, RMPs, and REMS

Commercial

- Outsourced Sales Teams, MSLs, Clinical Nurse Educators, Sales Support and Recruiting
- Marketing and Medical Communications, Advertising, and PR
- Public Affairs and Advocacy
- Digital Innovation and Social Media
- Product Launch Consulting
- Managed Markets Services
- Patient Engagement through Adherence Programs, REMS, and Rx Access
- Market Research and Sales Analytics
- Medical: Medical Affairs, Clinical Development, and Program/Risk Management
- Corporate Development: Corporate Strategy, Acquisitions, Integration, and Optimization
- Commercial Strategy: New Product Planning, Launch Expertise, Lifecycle Management, and Capability Development
- Market Access: Payer Insights, Access Strategy, and Access Capability Development
- Commercial Excellence: Commercial Model Design, Local Market Strategy, and Learning Solutions