



Outsourcing for EFFICIENCY

Taren Grom

For many sponsor companies in the life-sciences industry engaging with outsourcing partners — from the clinic to the market — is imperative if they want to drive efficiencies in time, money, and personnel as well as innovation.

Life-sciences companies can reap the many advantages and benefits of outsourcing, including cost-savings, increased market share, productivity, and access to top talent, if the partnership is constructed properly.

Outsourcing has become imperative in all aspects of business, be it R&D, operations, marketing, advertising, or selling, agree analysts at TechNavio. Optimal use of outsourcing partnerships can help sponsors lower costs, improve organizational focus, and develop innovative products. The R&D of pharmaceutical and biopharmaceutical products usually takes as long as 15 years. Hence, with a view to reducing R&D costs and the time-to-market and focus more on business operations, pharmaceutical vendors are outsourcing pre-clinical and other drug development processes to CROs. In this way, sponsors and partners can develop an equitable relationship by forging strategic outsourcing partnerships.

According to Cognizant analysts, many large pharmaceutical companies are moving toward significant externalization of their R&D function, partnering with academia, research institutions, and technology providers to understand and find new therapies, im-

“Novel partnerships and alliances hold significant promise to transform the nature, pace, and cost of new drug development — to the benefit of patients, as well as to drug sponsors, their development partners, and investors.”

prove productivity, and reduce overall cycle times.

They say obstacles to outsourcing are predominantly cultural, geographic, and language related especially in European countries. Issues such as data privacy and security that were concerns a few years back have mostly been addressed due to outsourcing maturity over time.

Job protection laws, such as Transfer of Undertakings regulations (TUPE) and the Acquired Rights Directive (ARD), and other immigration laws in Europe continue to play a key role when life-sciences companies consider outsourcing options and evaluate risk-benefit analysis.

In the coming years, pharmaceutical outsourcing will focus on creating fewer strategic partnerships to drive large scale transformation and take advantage of economies of scale, Cognizant experts say. Sponsors will expect partners to share a greater level of risk and invest more in thought leadership and innovation to yield significant business benefits. Success in outsourcing partnerships will be measured on delivering business outcomes, such as cycle time reduction, end user satisfaction, and market share increase.

Newer areas that traditionally have been managed in-house are likely to be outsourced such as regulatory submissions, statistical analysis and brand marketing. As the focus on emerging markets increases, the need for flexible, price competitive solutions, and technologies to enable these markets will become paramount.

In addition, the adoption of new technolo-



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Drug Discovery Services Market Expected to Grow

The world market for drug discovery outsourcing will reach \$16.6 billion in 2015, according to visiongain's Drug Discovery Outsourcing: World Market 2013-2023 report. The drug discovery outsourcing market will experience high revenue growth from 2013 to 2023.

Expansion of the market will be stimulated by the rising costs of pharma research and development, advancing technologies, and development of biologics. The complexity and technological advances in drug discovery will make it more challenging for many companies to conduct drug discovery in-house. Visiongain predicts that more companies will use contract service providers to gain access to technologies and skills not available in-company.

▼ For more information, visit visiongain.com.

Global CRO Market

The global contract research organization (CRO) market is expected grow at a CAGR of 10.7% over the 2011 to 2015 period from \$25.48 billion to \$38.27 billion, according to TechNavio. One of the key factors contributing to this market growth is the increase in outsourcing of R&D activities. The global CRO market has also been witnessing forward and backward integration by vendors. But the strict government regulations on drug development could pose a challenge to the growth of this market.

▼ For more information, visit technavio.com/content/global-contract-research-organization-market-2011-2015.



gies, such as cloud, big data, and mobile, will begin to have a profound effect in driving business transformation.

TechNavio analysts agree that a risk-sharing agreement is an integral part of the global CRO market. Vendors use service agreements

Commercial Partnerships

If done properly, the right commercial outsourcing partner offers a biopharmaceutical company a wide range of strategic advantages even as it gains access to commercialization power, including:

- » **Local expertise, geographic reach:** an established presence in multiple countries and insights into the realities “on the ground” can prove crucial to commercialization success.
- » **Operational efficiencies:** access to critical knowledge such as regulatory best practices, risk management programs, medical affairs functions, and performance management can help simplify processes, reduce costs and accelerate market outcomes.
- » **In-depth market access expertise:** across geographies and therapy areas to optimize pricing strategies.
- » **Real world data:** observational research capabilities continue to prove product value.
- » **Broad scope:** depth of experience in clinical, commercial, consulting, and communications can provide a more holistic perspective while offering innovative methods and nontraditional alliances to further brand success and ROI.
- » **Greater flexibility and lower fixed costs:** adding or subtracting resources depending on changing dynamics and the success of the product is valuable.
- » **Management involvement:** the role of senior management oversight can be as in-depth as is needed to ensure a focus on quality and performance, along with joint discussion and decision making.

▼ Source: Quintiles

(SAs) to partner with CROs. Traditionally, the risk-share outsourcing model dictates that the sponsor owns the intellectual property while the CROs have no claim on it. Risk-sharing will encourage the partners to participate more actively in outsourcing partnerships.

According to the Tufts Center for the Study of Drug Development, drug developers need to more fully identify and address root causes of R&D inefficiency.

“Many companies are taking steps to improve clinical success rates and reduce the cost of new product development, including using enhanced clinical trial designs, making greater use of biomarkers, and adopting sophisticated statistical analyses,” says Kenneth Kaitin, director, Tufts CSDD. “It’s a good start, but in a world shaped by increased patent expirations, diminished cash flow, and fewer promising breakthrough products, companies will need to hone their efforts to streamline development.”

One of the ways to streamline development is partnering with a trusted provider of clinical services. The trend toward outsourcing those services is on the upswing, and according to TechNavio, the global CRO market is expected grow at a CAGR of 10.7% reaching \$38.27 billion by 2015.

“The emergence of open innovation models, where scientists worldwide openly share knowledge, and novel partnerships and alliances hold significant promise to transform the nature, pace, and cost of new drug development — to the benefit of patients, as well as to drug sponsors, their development partners, and investors,” Mr. Kaitin says.

According to Tuft’s Outlook 2013 report, drug companies will accelerate their move from traditional trial-and-error approaches to exploratory drug development and adopt new R&D paradigms based on biomarkers, modeling and simulation, novel formulation techniques, and adaptive clinical trial designs.

Additionally, in an effort to simplify clinical trial operating complexity, sponsors and CROs will scale back the number of investigative sites they operate and the number of countries where they locate their trials.

An Outsourcing Case Study

AstraZeneca is embracing a new outsourcing strategy based on an ecosystem concept,

which involves a new way of working with partners as well as how services are delivered. The new model, which is the outcome of the revised IS Operating Model. Sam Covell, IS lead at AstraZeneca, confirmed that although its early days, the model is proving to be very successful and the concept is being evaluated both internally and externally.

The new model was developed based on a particular need as the company was moving from a large monolithic outsource arrangement that involved the termination of a contract before the terms were completed. Ms. Covell and her group had to multisource the various requirements and get the partners involved to work together. About 60% of AstraZeneca’s IT spend is on third-parties outsourced services.

“We worked very closely with our suppliers, who we call partners, that were going through the process to help refine our initial thoughts,” she says. “We wanted a process that worked not just from a customer perspective but from the supplier/partner perspective as well.”

While the individual partner contracts vary

Pros and Cons of Outsourcing

» Advantages

- Outsourcing can help sponsors achieve economies of scale
- Outsourcing can help sponsors alleviate their legal burdens
- Development costs and life-cycle margins can be reduced
- Sponsors can realize cost-benefit advantages by using the pull-model effectively

» Obstacles

- Any oversight from either of the companies can strain the partnership
- Financial constraints might adversely affect the relationship between the companies
- Outsourcing requires the partners to dynamically upgrade their technology and infrastructure, increasing the operational costs significantly

▼ Source: technavio.com



based on the services being provided, the overarching contract terms are identical.

“The contract focuses on the services to be delivered and the service level agreement or SLA,” she says. “Over the top of the SLAs we have a collaboration agreement, which isn’t

contractually binding, but rewards good behavior across the ecosystem. We call this the cooperation policy, which is signed by everybody, including AstraZeneca, so we are all equal partners in the ecosystem.”

Ms. Covell says rather than de-incentiviz-

ing partners through contracts that force suppliers to look for ways to cut costs in order to meet the terms of the contract if things go wrong, the cooperation policy rewards positive cooperative problem-solving.

“This process also identifies missed oppor-

VIEWPOINTS



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Relationship Management

Clearly identifying in advance the parameters of the relationship is the primary driver of success as well as identifying the expectations of each party and distinctly outlining the deliverables.

While often the contract addresses many of these concerns, it behooves everyone involved to go above and beyond that. Once a contract is signed, the first thing to do is set up a kick-off meeting that involves most, if not all, of the key individuals involved in the project from both sides. It is here that definition, in pain-staking detail, of the full scope and timeline of the project occurs.

Everyone gets to assess and agree at this point minimizing misinterpretations and misunderstandings later.

Expert Partners

A key advantage to outsourcing is tapping into the well-earned expertise of the outsourced partner. Many individuals with many years of experience are available to the sponsor company and should be taken advantage of. Sponsors should also enhance the flexibility outsourcing provides and thus maximize the use of this type of resource. A key obstacle is trust. Sponsors need to feel that the partners they have selected understand them and their needs and are capable of delivering without micromanagement. Trust comes with reputation and also with time.

PAUL FADDEN

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Partnership Benefits

Today's leading e-clinical solutions support easy configuration and deployment by nontechnical sponsor personnel.

However, in some instances, outsourcing system setup responsibilities to the e-clinical vendor or a CRO partner can provide an excellent alternative. The benefits include: time and cost savings gained by leveraging the vendor/CRO's specialized knowledge and expertise; peak work load overflow support, reducing sponsor headcount fluctuations; and sponsor staff training, which is accomplished by working alongside the vendor/CRO's e-clinical experts.



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Clinical to Commercial Goals

Successful commercial launches are complex, resource-intensive processes, so effectively seizing market opportunities requires understanding the landscape and making the right strategic decisions. Commercialization is quite different from clinical development; the challenge is to find a way to harmonize a wide range of disciplines, e.g., clinical, regulatory, sales, marketing, etc., within a strategy that aligns clinical development with commercialization goals while maximizing returns and reducing risk. Increasingly, partnering with a commercial outsourcing provider is becoming a viable option for companies looking to commercialize innovative products. Outsourcing partners with sufficient scope, commercial expertise, and geographic reach can help address the complex sales and marketing challenges developers face. At the same time, the right partner can mitigate

barriers to entry such as capital constraints, lack of familiarity with foreign markets, and management and resource flexibility.

Mitigating Risk

For firms that have weathered great risks to get their asset past previous development hurdles, the path to commercialization represents another significant period of risk and these risks can be substantial. Whether it's signing away future revenue streams, misunderstanding the regulatory landscape or choosing a partner organization with hidden or changing priorities, it's easy to see how even the most well-intentioned commercialization strategy involves risks that smaller and more entrepreneurial developers may find untenable.



BHASKAR SAMBASIVAN

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Innovative Transformation

Outsourcing relationships have matured significantly in the pharmaceutical industry and so have expectations of sponsors. Today, outsourcing partnerships are not just about driving cost-savings and efficiency, but have a big focus on innovation and transformation. There are some significant forces, such as pricing, patent cliff, emerging markets, and new technology, in the pharmaceutical industry driving a business model change and hence partners who want to develop an equitable outsourcing relationship with the sponsors, need to be able to adapt their services and solutions to accommodate these changes.

On the other hand, pharmaceutical company sponsors need to evaluate their outsourcing strategy and focus on creating fewer strategic partnerships that creates a win-win leveraging large volumes of work, efficiencies, and innovation.

tunities and areas for improvement so the team can take the best practices and learnings to the rest of the ecosystem,” she says. “Ecosystem champions who are in place internally and at all of our partner companies preserve the integrity of the cooperation policy and act as the point person in their own organizations.

“We also have an independent arbiter who works across the ecosystem,” Ms. Covell continues. “He’s our go-to person if there is anything that we can’t resolve. He also provides coaching not just to our partner suppliers but but internally to AstraZeneca folks on any missed opportunities. This is a completely different construct from how people would normally manage a partner contract. We don’t have any operational level agreements or agreements between each of the suppliers. It’s all managed through the cooperation policy.”

Ms. Covell says it’s important to treat providers as an extension of one’s own company.

“We want to provide a construct that allows us to deal with any difficulties so we can have a direct conversation, which allows us to be very focused on performance,” she says. “This is how we manage processes internally, so it made sense to provide the same types of incentives for people to do the right thing at the partner companies as well.

“In the past, outsourced contracts focused on what happens when things go bad or provide some type of incentive for profit share or benefit share if money is saved,” she continues. “But these triggers can be really hard to measure and manage and they don’t feel very real for the people who are involved in the process and therefore they don’t necessarily incentivize the behaviors that are needed. We want to think through the process in terms of what is actually going to move the dial.”

To make the process work, it’s important, and should go without saying to find partners that have the capability to deliver what is needed.

“If we take that as a given, the second most important factor of a successful partnership is cultural alignment,” she says.

Under a typical agreement once the contract is awarded, the customer believes it is going to get everything that’s been promised, whereas the suppliers and partners tend to focus on how they can make the most money out of the contract.

“The two sides come look at the contract from completely different perspectives,” she says.

This is where a lot of contracts go wrong, Ms. Covell says.

“Everyone’s doing the right thing for their organization but no one’s focused on how to improve and transform the service,” she says. **PV**



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