Rethink Reshape Restructure... for better patient outcomes

Steering Pharma R&D to Profitability through Integrated Outsourcing

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Pharmaceutical companies are actively exploring new sourcing strategies to stem the continuing decline in R&D productivity. Fragmented outsourcing has not sufficiently addressed this, and leaders are moving toward an integrated sourcing model that blends control of the development pipeline with the economies of scalable outsourcing. While many pharma companies recognize the potential value of this different outsourcing approach, few are prepared to fully exploit it. Accenture has identified four key considerations to help pharma companies increase R&D productivity through integrated outsourcing.

This point of view is one in a series on pharma's overhaul of development activities.
The need for smarter sourcing

It’s an understatement to say that pharma R&D organizations are under pressure to deliver differentiated products while holding spending flat. Over the last 15 years (1997-2012), R&D spend has grown five percent annually while output in terms of new molecular entities approved has dropped by approximately 22 percent1. Significant change is required.

During this same 15 years of declining R&D productivity, pharma companies have increasingly outsourced certain elements, including using specialty niche providers or contract research organizations (CROs) that focus on study-based programs (see Figure 1). For the foreseeable future, outsourcing is expected to increase as a proportion of R&D spending.

Figure 1: The shift to outsourcing development

While external sourcing has become an increasingly common way to try to manage cost and boost efficiency, results typically vary across different outsourcing models. Fragmented outsourcing with multiple specialty niche providers or study-based CRO programs can be challenging:

- Complexity is likely to increase from managing multiple external providers with different approaches.
- Project visibility may decrease.
- Standards achievement may be more difficult.
- Fixed costs are likely to remain high.
- Performance may be unpredictable.
- Staff/internal functions are likely to be retained, despite redundancies.
- Process improvements may not be prioritized and/or sufficiently incented.

Integrating outsourcing allows companies to realize the benefits of outsourcing while maintaining control of the science.

Smarter sourcing includes pursuing long-term relationships with a highly selective group of partners while retaining control of key dimensions that confer competitive advantage.
The new model of integrated outsourcing

Given the current need for step-change, rather than incremental productivity improvements, leading pharmas are seeking relationships with trusted providers to address larger portions of the development lifecycle. They are looking for a sourcing model that captures the core benefits of outsourcing without relinquishing control of the most strategic aspects.

This will be anything but business as usual: The new model will involve marked shifts in mindset and in operation (see Figure 2).

Figure 2: Comparing development today with development of tomorrow

<table>
<thead>
<tr>
<th>Today’s Model</th>
<th>Next Generation Model</th>
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<tbody>
<tr>
<td>Phase I-III</td>
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<tr>
<td>Regulatory</td>
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<td>Phase IV</td>
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**External Service Providers**
- Study based Outsourcing
- Functional Outsourcing (e.g., Site Monitoring)
- Contractors

**Sponsor**
- Internal Oversight | QA & Compliance | Vendor Management | IT
- Sponsor
- Strategic Partner
- Next Generation Managed Service for Development

**The current industry model is characterized by:**
- Multiple external service providers
- Lack of visibility and standardization
- Redundant internal functions
- Unpredictable performance
- Limited incentive to improve the process
- Significant fixed costs

**The future industry model is characterized by:**
- End-to-end global service delivery by few strategic partners
- Long-term relationships
- Staff/asset transfer with minimal disruption to organization
- Consultant-enriched process optimization
- State-of-the-art IT capabilities
- Access to cross-industry data analytics
- Top tier performance-based contracts
- Greater control of variable costs

Source: Accenture
How to proceed with integrated outsourcing

Pharmaceutical companies are unlikely to capture the desired value by only making small adjustments to their current operating models. For most, the change will need to be significant (see Figure 3).

Figure 3: Transition to integrated sourcing model

To help companies start the process, Accenture has identified four key considerations:

1. **Focus, with an end-to-end view:** Pharmas should focus their development activities on a single critical outcome: a target label that can be approved by regulators and is sufficiently data-supported to achieve reimbursement in target markets. This end-to-end focus necessitates a new, cross-functional operating model (i.e., regulatory, market access, clinical and pharmacovigilance) in contrast to typically-siloed and independent functions. A collaborative, value-based focus across the global organization allows for the proactive shaping of trials that generate data related to total value and enables functions such as Sales and IT to best support the value profile.\(^2\)

Regulatory labels should be the main factor in the clinical development program design, i.e., companies can execute their trials based on and targeted to labels for which they know they can receive reimbursement. This criterion can also help determine which clinical trials and related procedures are completed. Over time, this disciplined focus has the potential to help eliminate extraneous data that accounts for at least $4 billion every year.\(^3\)

Additional factors affect registration and reimbursement for compounds in each target market. For example, we anticipate the market access activities typical of late-stage Phase II–IV trials will accelerate. In fact, it’s our expectation they’ll see the “light of day” during the proof-of-concept stage of development, when R&D leaders start to influence how a clinically relevant molecule can lower the cost of care for a particular disease.

2. **Enable through integrated technology:** With the gradual introduction of new, integrated sourcing models will come complex workflows, massive amounts of data, and a pressing need for nimble execution of tasks. All of this demands a sturdy infrastructure and the adept use of new technology capabilities. However, that doesn’t automatically translate into larger IT budgets. Most pharmaceutical companies can no longer afford deep, long-term investments in proprietary, enterprise-wide technology implementations. Nor can development organizations afford to commit extensive time and resources to identifying, building and maintaining large systems and infrastructure. Increasingly, they will need to turn to service providers and strategic partners that can provide alternative services and associated technologies.
There will likely be growing reliance on cloud services to reduce infrastructure costs and to provide "burst capacity" when needed. According to Accenture’s Tech Vision 2013, "Cloud is no longer an emerging trend, nor is it a single concept. It can and does have a transformational impact across the business... Companies will create hybrid capabilities that combine the best of all cloud’s elements, mixing on-premise and off-premise IT and integrating cloud with legacy systems and traditional software."  

In addition to the new technology platform, pharma will need to keep looking for ways to integrate technologies that support development. Building custom interfaces has generally become too costly, so pharma companies will look to deploy software tools that seamlessly communicate and pass data to each other. Lastly, technologies that enable collaboration as well as data/document exchange will be key enablers. For example, life sciences companies can leverage cloud-based platforms to better collaborate with other stakeholders, such as payers, and create services that can help promote new treatments. The goal of these initiatives will be to help identify less expensive and more sustainable ways to treat an illness.  

Driving effective communication between sponsors and their strategic partners, as well as maintaining the audit trail for regulatory inspections, will be important.

3. **Standardize processes and data:** One very encouraging example of collaboration and partnership is the creation of standardized processes and data formats that span R&D, including clinical, market access, regulatory, and pharmacovigilance activities. Leading companies recognize the value in sharing platforms, using the same standard processes and tools for trial sites, and embedding standards in data collection tools.  

The launch of TransCelerate Biopharma, a nonprofit joint venture signed in the fall of 2012, brings together 10 big pharma companies to find ways to make the clinical trials process more efficient.  

This signals the industry’s increasing maturity when it comes to standards, and the TransCelerate venture itself may be a powerful catalyst for the widespread adoption of industry-standard utilities capable of driving large cost reductions. The Clinical Data Interchange Standards Consortium (CDISC) is another indicator of this trend. Its mission is to “develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.”  

Pfizer, with Accenture’s help, pioneered an innovative approach to align to CDISC standards with its alliance partners, Parexel and ICON. This approach was designed to use the companies’ internal systems and processes to capture operational and clinical data for clinical trials. Working closely with Accenture, Pfizer conceived a scalable clinical aggregation layer, based on industry-standard technology that would give it easy access and control over all of its data. Business users benefit from rapid and easy access to high-quality, relevant and analysis-ready clinical data. They get an aggregated view, or “single version of the truth,” across internal and external data that conforms to CDISC standards.  

4. **Transform internally:** New integrated outsourcing models will require that pharmaceutical companies and service providers commit to major internal transformation. The scope of this undertaking includes breaking down organizational conventions, behaviors and processes that have been entrenched for decades.  

The pharmaceutical industry has, over the past 20 years, generally built large, fully integrated development factories with siloed functions. These include clinical research that “competes” with clinical operations as well as the regulatory and pharmacovigilance strategy and operations. All of these functions will need to be transformed—some radically—and their interactions "rewired" to get the greatest value out of the next-generation drug development model. In essence, the current functions must collectively become more strategic at the same time as they become more agile.  

Additionally, there should be clarity about roles and responsibilities and about accountability and processes. Any new operating model should have a defined governance structure, clearly delineated roles and responsibilities for all those involved, and possibly a different organization structure.
A future vision of R&D

The current challenges facing R&D will hopefully be the catalyst needed for significant change. There are exciting new opportunities for pharma companies that want to seize competitive advantage.

In the future, Accenture anticipates that most companies will consolidate and fully outsource the clinical, regulatory and pharmacovigilance functions, including all of their associated processes and technology. Companies will select either one or a few strategic vendors for this purpose rather than patching together services from dozens of specialty niche providers, including CROs.

Eventually, pharma companies will meld all three separate functions into a single, consolidated entity for a seamless flow. Silos will be broken down across R&D, making end-to-end operational excellence possible for the first time. The companies that achieve this consolidation quickly and effectively will likely see enormous competitive advantage: they will be free to focus on strategic, value-adding activities once their operational, non-value-add activities have been externalized and industrialized.

In subsequent points of view, Accenture will address aspects of change introduced in this paper to help pharma companies capitalize on these opportunities.

Conclusion

As pharmaceutical companies look to resolve the continuing decline in R&D productivity, many are recognizing that fragmented outsourcing through multiple niche providers is not the answer. Rather, leaders are moving toward an integrated outsourcing model. This approach balances control of strategic factors that contribute to competitive advantage, while also realizing the economies of scalable outsourcing for undifferentiating activities. The change will not be easy, and the pace is likely to be evolutionary rather than revolutionary.

To help pharma companies begin this journey, Accenture has identified four key considerations for integrated outsourcing to help drive R&D productivity and, ultimately, help achieve better patient outcomes.

Sources


About Accenture

Accenture is a global management consulting, technology services and outsourcing company, with approximately 266,000 people serving clients in more than 120 countries. Combining unparalleled experience, comprehensive capabilities across all industries and business functions, and extensive research on the world’s most successful companies, Accenture collaborates with clients to help them become high-performance businesses and governments. The company generated net revenues of US$27.9 billion for the fiscal year ended Aug. 31, 2012. Its home page is www.accenture.com.

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