

Global Strategic Partnerships are Key Enablers for Transforming Clinical Operations

As the pharmaceuticals industry adapts to external market pressures, financial challenges and radical shifts in both process and technology, companies are pushing hard to reinvent the way they operate. The urgency to adapt is understandable considering such sobering facts -- the Top 9 pharma companies have lost a staggering \$600 billion in shareholder value between 2001 and 2009, and over the next three years, the industry stands to lose more than \$90 billion in revenue from patent expirations of the Top 10 drugs.¹

What's Driving Innovation Across the R&D Value Chain?

Unlocking innovation is of paramount significance across the entire pharmaceuticals industry spectrum, but nowhere is it more critical than in R&D.

To succeed, global clinical operations functions will need to rethink how they minimize their costs, maximize their efficiency, harmonize their processes and improve the overall quality of the clinical development process.

Supercharging the innovation engine is critical to the pharma industry's ability to conquer challenges such as expiring drug patents, rapid increases in competition from generic products, less robust pipelines, the introduction of "me-too" drugs, the need for more trials (smaller and highly specific, as well as global and more complex) and the reduction in qualified investigators to execute those studies.

In addition, there are several factors causing pharma companies to fundamentally change the way drugs are discovered, developed and commercialized. These include recent advances in new technologies (e.g., translational medicine, personalized medicine, in-silico modeling) and a smarter consumer looking for preventions and cures rather than merely managing symptoms.

While the industry has overcome a litany of business challenges over time, transformation of the end-to-end R&D process using innovative models is only being pursued in pockets by a few of the leading pharma companies. To succeed, global clinical operations functions will need to rethink how they minimize their costs, maximize their efficiency, harmonize their processes and improve the overall quality of the clinical development process.

Adapting Global Clinical Operations to Future Business Needs

Pharma companies are transforming their R&D models to succeed in the new market reality. Historically, R&D didn't have to worry about cost efficiency, but with changing market dynamics, R&D departments are adapting to corporate mandates for "working smarter" and "failing faster," while managing cost, quality and time. Likewise, global clinical operations functions are re-adjusting to fulfill expectations for greater

¹ Data from Tufts Center for the Study of Drug Development, 2010



levels of cost-efficiency, agility, flexibility and global competitiveness. Meeting these new expectations will require specialized sets of capabilities, such as:

- An infrastructure that is nimble, flexible and scalable, while still enabling secure collaboration among academics, CROs, investigators, regulators, etc.
- Globally scalable and flexible resources and skills to meet the demands of more discerning customers, patients and partners to address key business imperatives.
- Enabling capabilities -- including seamless data, process and technology integration, business and IT governance, as well as advanced business intelligence -- to deliver better business outcomes.

Companies that can rapidly deploy these capabilities to support their business needs will have a competitive edge.

Leveraging Strategic Partnerships to Transform Clinical Operations

So how is pharma going to accomplish all of this, given its severely limited resources and faster time-to-market objectives? The best way to accomplish this is through strategic partners, who can help with global operations; integrated process and technology expertise; and a willingness to invest in enabling better business outcomes.

All of the Top 5 -- and most of the Top 20 pharmas -- are in various stages of transforming their clinical operations, and some are more wide-ranging than others. We find that successful organizations adhere to the following transformation objectives:

- **Cost-optimization:** Leverage global resources and talent; harmonize processes and systems; utilize economies of scale.
- **Agility:** Develop and deploy an integrated information architecture; develop integrated portals/dashboards to enable real-time insights and ensure timely decision making.
- **Flexibility:** Design a flexible organizational and governance structure; create accountability to deliver tangible and predictable outcomes.
- **Global presence:** Establish a wide-ranging footprint to serve local and global markets;

build partnerships to access patients and investigators in "pharmemerging" markets.

- **Strong governance:** Develop governance and the "right" performance metrics aligned to business outcomes -- preferably, a balanced scorecard for clinical development that is aligned with corporate and R&D strategy.

We have found that organizations are able to achieve their transformation objectives much more rapidly; if they leverage their service providers more effectively. Global service providers have matured in their ability to operate globally, drive cost and productivity efficiencies, invest in continuous improvement and innovate, using domain, process and technology expertise. A strategic service provider partnership is most successful when it is based on complementary skills, capabilities and IP.

A global strategic partnership between service provider and client can deliver benefits across key areas of clinical operations, such as:

- Reduce overhead costs by sharing resources between client and provider in almost any geography.
- Decrease cycle times and improve quality, by optimizing workflow between upstream and downstream activities.
- Increase flexibility, to complement internal capabilities for a single process or an end-to-end function.
- Standardize processes and rationalize IT systems across geographies.
- Optimize study budgets, using transaction- and outcomes-based pricing and funding models.
- Enable transparent tracking and monitoring of the "right" metrics, which allows customers and providers to closely monitor realization of business outcomes.
- Inform proactive and strategic decision making with partnership-oriented governance models involving the right stakeholders.

Faced with the most significant challenges in industry history, pharma R&D is responding by fundamentally transforming the way drugs are discovered, developed and brought to market. Organizations that can adapt and accelerate their transformation efforts to meet the future needs of the business will have a competitive edge in the market. We believe this

transformation is rapidly enabled by leveraging strategic partners who are highly specialized in global operations, can integrate domain, process and technology to achieve measurable results, and are willing to invest in their clients' business success. Global strategic partnerships are most effective when built on complementary capabilities and mutual trust and are focused on achieving tangible business outcomes aligned with strategic imperatives.

Partners who provide integrated services across the clinical development spectrum, spanning consulting, IT and business process outsourcing, are best positioned to enable pharma to not only achieve near-term-cost and productivity savings through streamlined operations and improved process efficiencies across the R&D value chain, but also to lay the foundation for longer term innovation and R&D business transformation.

About the Author

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