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# EVIDENCE-BASED DEVELOPMENT AND SMARTER SOURCING

The pharmaceutical industry is at a transformational moment. The financial returns once realized will be tougher to realize; and for large pharma companies, there's a series of questions over what the future growth strategy should be. With fewer FDA approvals, diminishing pipelines and the decaying blockbuster business model, the imperative to adopt new growth strategies is paramount.

JAY NORMAN, president of Quintiles Consulting, discusses the changing landscape of drug development and suggests that better, evidence-based decisions, combined with smart sourcing strategies, will differentiate the future winners.

From an industry standpoint, it's important just to recognize the magnitude of the challenges. There's a new series of financial constraints that call into question the future viability of an integrated in-house resource model, and given the current state of research pipelines, companies need to transform the development life cycle to increase speed-to-market for a wider array of products. The United States is rapidly evolving into a more centralized health care system with drug purchasing buying power concentrated within CMS. As we see increased health care spending driven by Medicare Part D in the United States, commercial payors are using an expanded set of tools to control drug utilization including limiting coverage, imposing quantity limits, mandating generic conversion and even establishing new evidence requirements for formularies. These external pressures are affecting the viability of traditional product development and as such, the industry must change its long-held business model and do it quickly.

Companies that adapt to this changing landscape successfully will be the ones who adopt a more balanced specialty-based product portfolio that is less dependent on large blockbuster drugs and more focused on getting a broader array of more targeted products to market more quickly and cost efficiently. In doing so, they'll need a better understanding of how to use clinical, epidemiologic and pharmacogenetic data to better segment the market and position these products for maximizing commercial potential and reimbursement.

## THE DRUMBEAT OF DATA

In moving from a mass-marketer type of model that was able to produce products for very large segments of the population, to a more market-focused model requiring specific expertise and specific understanding of much smaller patient segments, pharmaceutical companies must better utilize data to drive decisions. Maximizing available data can not only increase understanding of product potential and market potential, it can also provide business intelligence that will lead to a better understanding of how to target specific health care provider and patient audiences and eventually sell to those specific audiences.

Part and parcel to using data wisely is to better integrate product development and commercialization teams—such that they are no longer two separate organizations with different goals and metrics. By integrating these two entities through the linkage of data, speed-to-market can be enhanced, costs saved and revenue increased. At the same time, a parallel "value track" to the conventional regulatory-driven clinical development needs to be established early on to focus on commercial requirements in order to ensure optimal market access if the product is indeed approved.

> Successful companies will adopt a more balanced specialty-based product portfolio focused on getting a broader array of more targeted products to market more quickly and cost efficiently.

## LESSONS FROM OTHER INDUSTRIES

At present, the pharmaceutical industry as a whole looks very similar to other industries that have faced a major transformation. The sector is awash with a series of large competitors, downward pressure on pricing, increasing regulation and a challenged business model. Based on what has happened in other industries in similar circumstances, the basis of competition is likely to change to favor those companies who can use data as a competitive weapon. For example, the major consumer-oriented businesses long ago learned how to compete better—using data to segment their customers, target their customers with tailored value propositions, provide more distinctive products and get to market quicker.

In the pharmaceutical industry, a successful new business model must also use evidence-based data as a competitive weapon, which will require tighter linkages between patient-reported outcomes, how products are developed and how they are subsequently priced. In a holistic view of the traditional discovery-development-commercialization value chain, companies will need to take an earlier look at likely questions, such as: "What are the value drivers in this therapeutic area from a commercial payor perspective?" "How do we position the product versus other competing products that are out there (i.e., comparative

effectiveness)?" And "What is the likely coverage and reimbursement for the product given the target product profile?" An early understanding of these issues and how the product will be measured in terms of value will in turn lead to better development decisions and more focused market segmentation.

Data sharing and analytics must become central to the process to integrate decisions across the discovery, development and commercialization value chain and create a virtuous circle of information that can inform better decisions throughout the entire development life cycle.

## SMARTER SOURCING STRATEGIES

In addition to making evidence-based development decisions, formulating an effective sourcing strategy is also critical for companies of any size or at any stage in their maturation. When an entire industry is in this type of transformational moment, leading players must understand what they need to own, what they need to source externally and what they need to source more effectively. Many companies are beginning to realize that they can still keep control of a development program without necessarily owning the entire value chain.

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What this implies is that large pharmaceutical companies need to decide what functions they do best and are core to their business model. If they've got a great pipeline and can move things through efficiently, that's great. But the answer to the question "What do we really want to own, partner or source externally" will challenge the industry. The historical fully integrated business model, with outsourcing of a few non-core functions, must give way to taking a hard look at where core development business functions are optimally sourced. In fact, we could envision one future state model to be a mega-brand company that in-licenses and out-licenses at specific points, rather than owning most of the discovery, development and the commercialization infrastructure. I believe we can expect to see more companies that will outsource major portions of their operations; they'll own the brand, but maybe not most of the resources. In today's market, it makes a much stronger financial proposition when a company can move to a more variable cost structure and remain nimble.

Outsourcing today is primarily geared around some parts of the clinical development processes, such as data management or patient recruitment. Going forward, many companies will have to ask, "Can the future economic potential of our development pipeline support today's development infrastructure?" And that further reinforces

why companies have to look at what's really core to their business. If you look at the banking industry's transformation, for example, the large branded players prevailed. However, banks chose to own the customer interface and outsourced much of the product infrastructure (e.g., the check processing, the credit card issuance and the loan processing to service providers). In that industry, a series of behind-the-scenes vendors grew that essentially have provided the infrastructure for much of the non-customer-facing capabilities. One could easily imagine seeing a similar scenario in pharma, with company leaders asking themselves: "What part of the customer, patient or market interface do I want to own?" The rest should be fair game to source externally to partners or other service organizations. As more and more companies make these tough decisions, it'll be very hard for those who keep a fully integrated, in-house model to be cost-competitive.

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## DEMONSTRABLE VALUE

A final piece of pharma's new business model is to show a greater linkage between measurement of anticipated value and actual commercial outcomes achieved. Today, there is a disconnect between clinical value (i.e., efficacy and safety) proven in a randomized controlled trial and actual comparative effectiveness and safety demonstrated in the "real-world." Outcomes, by definition, need to be measured more at the end of the value chain. As an industry, we need to agree on a demonstrable form of evidence, as well as some fact-based and value-based measures. Then we must find a way to build the drivers of value earlier on in the process. If the pharmaceutical industry doesn't adopt a clear way to measure value, it will continue to introduce products that the market will view as too expensive or not differentiated—which serves neither patients nor the industry.

Part of the issue is that there has historically been little incentive to develop a uniform understanding of what drives market access, level of coverage, adoption, utilization and brand loyalty. All these commercial drivers need to be evaluated and tested earlier in the development process. The end result might be fewer developed medicines, but those that are introduced will confer greater safety, greater effectiveness, and ultimately greater benefit to public health.

From smarter sourcing to doing a better job of demonstrating the value of its products, the industry has in its grasp the potential to seize this enormous market and economic opportunity. Future winners will embrace evidence-based decision-making to create the virtuous circle of information that links discovery, development and commercialization, while embracing smarter sourcing strategies in order to out-execute the competition.