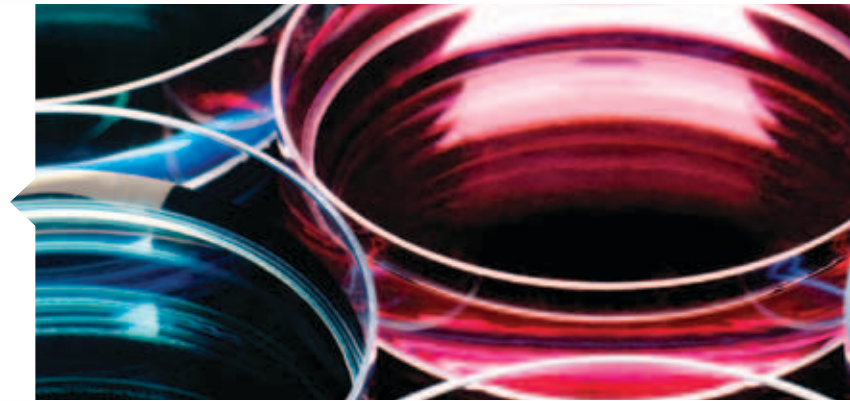


# *The New Health*

Navigating Risk and Seizing Opportunity  
in the Biopharmaceutical Industry's  
Changing Landscape



Quintiles examines the complex challenges and opportunities facing the biopharmaceutical industry and how companies must manage risk, demonstrate greater value and improve patient outcomes.

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## *The New Health*

There is plenty of discussion in the biopharma industry about declining R&D productivity, increasing development costs, diminishing returns on marketing and sales, and lower earnings. And the “patent cliff” that is quickly approaching will only increase pressure on biopharma players. From 2009 through 2014, an estimated \$128 billion of branded revenues will lose patent protection and face generic competition. At the same time, funding for the biotech sector remains heavily constricted in a capital-constrained economic environment.

These challenges are exacerbated by the increasing difficulties in commanding premium pricing for branded drugs and therapies in the absence of demonstrable value over cheaper alternative therapies. In the healthcare economic climate of today, government and private payers — along with managed care organizations — recognize that healthcare expenditures are increasing at an unsustainable pace (often significantly faster than local GDPs) and are seeking to rein in costs while providing greater value to patients.

Above all else, biopharma must cut the time it takes to get new drugs and therapies through regulatory approval and to peak sales to deliver to patients the most appropriate treatments at optimal value. And, as the industry grapples with these tough challenges, the balance of power continues to shift from biopharma to a new — and very powerful — group of stakeholders who are driving change. In this new environment where patients are exhibiting greater influence and wielding greater power, companies are under pressure to prove the safety of their medicines and at the same time demonstrate their value.

*The New Health* is Quintiles’ perspective on the fast-morphing world of biopharma, where the rules are changing on all fronts.

*The New Health* is both the movement toward an ideal state and the destination. It is defined by the challenges that biopharma executives are struggling to resolve, by the expanded stakeholder group, and by the promise of better health for humans through high-quality, accessible products and treatments that enable people to live healthier lives.

*The New Health* is not simply a landscape in which faster and cheaper ensures a competitive advantage. It marks a moment in which public health, multi-stakeholder collaboration and access to quality and affordable medicine must be factored into every decision — from how drugs are developed and delivered to assessing their value, and to how they are brought to market as safely and efficiently as possible.

*The New Health* presents unmistakable risks for biopharma, yet offers unmatched opportunities for those who can navigate those risks, usher in a new paradigm of drug development and put into operation a more innovative business model.

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Biopharma companies are under relentless pressure to increase speed and productivity, streamline development processes without sacrificing safety, ethics and stewardship, and create better value and greater accessibility for patients worldwide.

To do that, they must focus on four key platforms for change:

- > **Demonstrating value**
- > **Increasing productivity**
- > **Accelerating timelines**
- > **Overcoming complexity**

## Path to *the New Health*

Development costs are rising. Demand for quality, safety, value and accessibility are paramount. The high-risk, high-reward business model for drug development has been permanently altered. To address these challenges, innovative companies will need to take advantage of global expansion, enter into collaborative, risk-sharing relationships and adopt a more innovative and streamlined approach to drug development.

## Demonstrating Value

Consumers and payers have made it clear that if they are going to pay premium prices for new products, those products must be accompanied by solid proof that they are clinically and economically superior to currently available treatments. The gauntlet has been laid down, and it is biopharma's challenge to prove value or risk losing market share.

Fifty years ago, the only relationship that mattered was between doctor and patient. Today, a range of organizations have a stake in treatment decisions, including government and private payers, pharmacy benefit managers, employers and government regulators. Additionally, each stakeholder group has its own set of priorities and wields bargaining power to drive the selection of drugs and therapies for patients. The new stakeholders have made their demands clear: they want better value, safer and more reliable healthcare solutions faster, and they will withhold their loyalty, influence, approval and purchasing power for anything less. To successfully commercialize a drug in *the New Health*, biopharma must demonstrate value to every stakeholder, often adjusting the criteria for success to meet the diverse evaluation expectations of multiple decision makers.

Patients are emerging as ever-stronger stakeholders. They are knowledgeable and vocal. They want clear information about treatment options and greater assurances from the health care professionals regarding the risks associated with those decisions. But meeting the needs of patients is a complicated process as access to funding dwindles, development cycles extend and regulatory issues and treatment paths become increasingly complex. To maintain patient loyalty and competitive market share, biopharma companies will increasingly need to consider patient needs in every decision making process. That means addressing the quality, accessibility and cost concerns of the global population through the delivery of products that safely and reliably address critical healthcare issues.

Biopharma firms also must respond to the specific needs and enhanced bargaining power of payers. The larger and more sophisticated biopharma firms, for example, are designing clinical trials to deliver results which resonate with payers. As a result, executives from payer organizations are increasingly involved in R&D advisory boards. Meeting these high expectations and demands for accountability has been exacerbated by obstacles that limit market access and reimbursement, which increases the challenge of building a business case for premium pricing on branded drugs and therapies.

Tools and applications such as comparative effectiveness research and health technology assessments need to not only be understood, but embraced and incorporated into the development plan for every potential therapeutic product. Ultimately, every manufacturer must communicate the value of its products to multiple stakeholders in a manner that allows for comparison to competing agents. Indeed, *the New Health* is the development of *better* medicines, not just *newer* ones. Furthermore, these medicines must be developed more quickly and safely, with fewer resources than previously available. And to accomplish that, biopharma must undergo an intense sea change of streamlining its operational and development models to increase its overall productivity.

## Increasing Productivity

In today's biopharma economy, declining R&D productivity combined with increased development costs have made investment portfolio managers skittish. The risks associated with investments are high, and the lack of output is making everyone nervous.

To manage this new high-risk environment, and continue to deliver valuable and accessible therapies, biopharma companies must find ways to increase output, decrease costs and eliminate unnecessary layers of bureaucracy that hinder productivity.

As new drug applications arising from discovery efforts have dried up, investors and executives have relied on merger and acquisition activity to fill their pipelines, enhance their portfolios and gain access to new products. Biopharma will continue to pursue these opportunities as a means to shore up business and reduce costs, but they are short-term solutions that do not position companies to sustain their business. Quite simply, companies cannot cut their way to either success or long-term profitability.

The availability of acquisition and in-licensing opportunities cannot — and should not — impede the drive for innovation. Forward-thinking biopharma companies are expanding into complementary markets — including biosimilars, diagnostics and over-the-counter medicines — to create a more diverse portfolio that will better address global healthcare needs. They are specifically directing research effort and funds toward identifying and addressing unmet medical needs, particularly in critical therapeutic areas such as oncology, CNS and anti-infectives.

### Rethink, Resize, Restructure

But it is not enough to pursue new projects or markets. For biopharma companies to achieve ramped-up productivity goals, they must completely *rethink*, *resize*, and *restructure* their approach to discovery. That means reducing infrastructure costs across the board and converting fixed costs into variable costs through more aggressive, strategic outsourcing strategies. Outsourcing creates a more streamlined business model by matching critical infrastructure investment to the lifecycle of the product. It makes the most of diminished budgets and schedules, while adding value to the process through collaborative co-development and co-commercialization relationships with a select group of industry allies.

### Strategic Outsourcing

Smarter, more effective outsourcing strategies are just one component of *the New Health*; biopharma companies, both established and emerging, must look to rebalance the risk inherent in the capricious arena of drug development. Service providers and capital institutions are taking a larger role in sharing financial risk to allow biopharma firms to be more effective, more efficient and more agile. In *the New Health*, a transactional relationship with a provider becomes a trusted relationship with a strategic partner — a partner who can provide development expertise and share in the development risk to allow resources to be better spent on delivering additional therapies to patients more efficiently.

### Outsourcing Options

*By outsourcing functions such as data management, biostatistics, sales, medical education and safety monitoring, biopharma companies can minimize their own permanent infrastructure needs and focus on their core strengths, with the confidence that well-chosen partners can aptly manage non-core activities.*

## Accelerating Outcomes

Despite industry and regulatory efforts to speed the approval process for new medicines, it still takes eight years to bring a new drug to market, according to an *Outlook 2009* report on pharmaceutical and biopharmaceutical trends from the Tufts Center for the Study of Drug Development.

In an effort to speed delivery of results ethically without compromising patient safety or quality of data, the biopharma industry increasingly is relying on the globalization of clinical trials. Globalization has enabled drug developers to cut years from trial times by utilizing global patient pools, often in emerging regions where costs are lower. In cancer research alone, the time saved from globalization is extraordinary. If the 2,296 cancer agents currently in clinical research relied on U.S. patients alone as volunteers, it would take five years to complete Phase III trials. If the same clinical research is conducted using a global population, the trials could be completed in two years, potentially enabling the introduction of a new generation of cancer medicines in a fraction of the time.

But on its own, globalization is only part of the answer. The industry also must capitalize on other opportunities to accelerate outcomes, such as triggered monitoring, adaptive trial design, biomarker technology, digital pathology and data-driven patient recruitment, among others, to shorten the time from development to peak commercial value. In biopharma — perhaps more than in any other industry — time is indeed money. A single day's delay in a candidate drug's development costs the sponsoring company up to \$8 million. This not only affects shareholder value, but also delays patients' access to new therapies.

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It is only when the industry takes a broad approach — implementing every strategy available to streamline the drug development process — that we can hope to see the time-to-market for new drugs shrink.

## Reducing Complexity

A major driver of longer development times and increased costs is the growing complexity of the environment in which biopharma companies operate. In addition to accommodating the growing numbers and demands of key stakeholders, biopharma companies must also address increased regulatory constraints, complexity of the diseases targeted and the strategies and technologies required to investigate solutions.

*Molecules:* One of the biggest challenges for biopharma today, is that in terms of drug development, the low-hanging fruit have all been harvested. The new biochemical targets and the molecules to address them currently in development are more complex, as are the medical conditions they are designed to treat. The complexity of these targets and drugs must be factored into the projected development cycle, in addition to measuring the costs of development against the long-term market value.

*Technologies:* Emerging technologies and their applications, such as biologics, add layers of complexity that must be acknowledged, understood and properly managed. Recombinant derived-products, for example, have been heavily researched and more than 200 candidates are currently in development, yet only a limited number of biologics have been approved in this decade. Looking forward, stem cells offer a great deal of promise for new therapies, but at present, the technology to fulfill that promise is more costly than the expected return, creating a deeply unbalanced value proposition that impedes progress.

*Geographies:* While globalization has added vast numbers of trial participants and contractors to the biopharma network, it also has added management challenges. The logistics of global trials can be extremely difficult to manage, particularly when factoring in time zone differences, adjusting to regional regulatory requirements and accessibility and reliability of remote treatment populations. Cultural influences and political uncertainties add further challenges.

*Biopharma's definition of quality:* Each firm has its own process for drug development, often differing from other firms' approaches in small but significant ways. Those small differences greatly increase costs in drug trials because they add variability to the process.

Recognizing the counter-productivity that results from a lack of standardized practices and procedures, biopharma is beginning to explore new and more uniform ways to define quality. Core to this exploration process is the drive to move away from focusing on the quality of the process and toward defining the quality of the *deliverable*, such as how many patients must complete the trial, or the timing of regulatory submission.

Conceiving and implementing effective strategies for reducing complexity in all of these categories requires a global approach to market dynamics. Market research tools in the past have focused on single audiences (e.g., physicians, payers, regulators, patients, etc.), but success in *the New Health* demands innovative processes to measure, understand and guide *integrated* strategies that simultaneously address the needs of multiple audiences.

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## Seizing the Opportunity

*The New Health* is not an easy environment to navigate. It is complicated and crowded, full of obstacles that hinder progress towards the ultimate goal of delivering quality accessible products and treatments that enable patients to lead healthier lives. Biopharma companies seeking to sustain their future viability must completely redefine their business model for drug development and commercialization. To do that, they must utilize every opportunity available, including globalization, a streamlined infrastructure model, standardized development methodologies, and collaborative relationships with industry, government, payers and patients.

By navigating the risks of *the New Health* effectively, biopharma will be able to reshape the drug development process to meet the demands of all stakeholders, and ultimately deliver on a promise and opportunity to enable people to live healthier lives.

## EMR

*From a healthcare delivery standpoint, payers now use electronic medical records (EMR) technology, in part to monitor doctors' prescriptions and in part to intervene to recommend substitute generics. But EMR needs considerable upgrading to capture even basic information regarding a patient's primary diagnosis. Even more upgrading and multi-stakeholder collaboration are needed to enable EMR to be used as a drug development tool to identify clinical trial candidates.*

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