The new innovation imperative

Reshaping biopharma business models

January 2017
New technologies, customers and competition are forcing – and enabling – biopharmaceutical companies to find novel ways to create and capture value

Technological, economic, competitive and consumer-driven pressures are forcing fundamental changes in how pharmaceutical and biotechnology ("biopharma") firms do business. The buyers of their products are changing. The products themselves are changing. And the nature, and number, of their competitors is changing too (Exhibit 1). These external and internal pressures are shifting how value is defined in the pharmaceutical industry, as well as how it’s captured – and by whom.

Those buying pharmaceutical products are now highly price-sensitive and demand proof of value. Buyers now include not just traditional government or commercial payers, but also increasingly discerning providers (many at risk to deliver cost-effective outcomes) and more informed, connected and cost-conscious patients. These stakeholders have been empowered by ready access to advanced data and digital tools, raising expectations for a more engaging and efficient customer experience.

Scientific advances are making it harder for pharma firms to differentiate their products based on molecular design or mechanism of action alone. Same-class alternatives are getting to market faster, thereby dramatically shortening the exclusivity period for “first-in-class” breakthrough therapies. This demands differentiation based on proven outcomes, lower prices or both in order to secure positioning in increasingly competitive and complex treatment pathways.

Digital technology and data can enable some of that differentiation. Rapidly multiplying novel sources of data, including from wearables, plus improving analytical tools, offer huge promise in boosting treatment efficiency, in engaging patients and in turning products into more integrated solutions. But they also require new capabilities, partnerships, stakeholder relationships and organizational models.

**Exhibit 1.** Driven by the consumer and enabled by digital, the basis of competition is radically changing

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
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<tbody>
<tr>
<td>1. Uninformed patients, payers and providers</td>
<td>Super consumers: Patients, payers and providers in the driving seat</td>
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<td>2. Analog</td>
<td>Digital: Driving new customer experiences, process automation and efficiency</td>
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<td>3. Sick care</td>
<td>Health care: Focusing on prevention and addressing affordability</td>
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<td>4. Blockbuster drugs</td>
<td>Precision medicine: Mining data to deliver tailored medicine</td>
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<td>5. Discontinuous care</td>
<td>Connected care: Integrating health care data, “man and machine” delivering better interventions</td>
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Meanwhile, technology firms, wellness companies and other non-traditional players—many rich with consumer data—are venturing onto biopharma’s territory. These newcomers provide opportunities to collaborate, but they also present a competitive threat as digital tools’ potential to enhance outcomes becomes clearer. Consumer technology giants like Apple and Alphabet (the latter primarily through its Verily Life Sciences) are actively engaged across several key parts of the biopharmaceutical value chain, from research tools (for instance, Apple’s ResearchKit mobile platform) to R&D programs (Google’s aging-focused venture Calico) and innovative products (like sensor-embedded pills or glucose-sensing contact lenses). These competitors may be new to the timelines and risks of therapeutic R&D. But they are far ahead in understanding consumer behavior, brand building, big data analysis, IT and short-cycle innovation—precisely the areas that are shaping today’s health care landscape, and where most biopharma companies lack skills.

Exhibit 2. Market and technology forces differentially affect how value is captured and created across segments

<table>
<thead>
<tr>
<th>Traditional product-focused business models</th>
<th>Impact of market and technology forces</th>
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<td>Austerity and price pressures</td>
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<tr>
<td>Traditional pharma/biotech Developing advanced therapies with high value and high price</td>
<td>Acute/severe</td>
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<td>Established/generic products Lower all-in product costs and compete on pricing</td>
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Biopharma knows it must adapt – the question is, how?

The disruptive forces of rapidly evolving customer expectations, intensifying competition, digitally empowered consumers and data democratization collectively threaten to drive down pharma’s profitability and sustainability, at a time when payers’ pricing squeeze has already put margins under pressure.

We have moved beyond the point of asking whether pharmaceutical firms need to “invest in digital,” “embrace data analytics,” “focus on outcomes” or “be patient-centric.” The answer is, they do. The important question now is, how? How should these changes be implemented – with what kinds of expertise, tools, partners, investments and organizational structures?

The answer depends heavily on the businesses and therapy areas that a group operates in. The forces affecting health care are changing how value is created and captured across the board. But they’re not doing so in the same ways, or with the same intensity, across all business segments, disease areas and geographies (Exhibit 2).

For instance, those operating in chronic disease areas like diabetes or some respiratory conditions face a far more urgent need to expand into consumer technology-enabled solutions and services than those working in oncology. Instead, oncology players must leverage advanced data analytics and engage with providers to influence clinical decision algorithms. (See box.)

Change affects each market differently – companies must adapt accordingly

Players in disease areas facing complex, personalized care decisions, such as oncology, must understand and influence development of increasingly complex clinical treatment algorithms that determine a treatment’s value and thus its uptake and profitability. This means accessing clinical data and advanced analytics skills, for instance, by partnering with integrated delivery networks and academic centers at the cutting edge of clinical care.

For example in late 2016, Celgene, working in cancer and inflammatory disease, licensed data firm GNS Healthcare’s machine learning platform to enhance its drug R&D, commercialization and access, bringing several of GNS’ causal modeling experts in-house. Meanwhile, leading clinics, including MD Anderson, Memorial Sloan Kettering and Mayo Clinic, have each partnered with IBM Watson to develop cancer clinical decision algorithms. Pharma companies already work with these centers to conduct trials; they must expand those collaborations to secure a position in the emerging data ecosystem. One example of this is the Lung Cancer Master Protocol (Lung-MAP) study for which multiple pharma companies have partnered with the NIH and Foundation Medicine to more effectively triage patients to optimal treatments.

Those operating in chronic disease areas like diabetes or some respiratory conditions face a far more urgent need to expand into consumer-focused technology-enabled solutions and services. In several of these therapeutic categories, the number of truly novel treatment options is dwindling, and the most stubborn challenges are now adherence and disease management. Thus pharma’s investments and partnerships in these markets look very different, aiming to capture value through capabilities and technologies that extend well beyond a drug. Differentiation in many chronic, lifestyle-related conditions depends on patient-centric use of artificial intelligence and other data-driven tools and tracking devices to drive more appropriate, targeted medication use and to encourage related behavioral change.

Examples of the new generation of chronic disease-focused partnerships include Sanofi and Verily Life Sciences’ (formerly Google Life Sciences) diabetes joint venture Onduo. Set up in September 2016, Onduo aims to develop an entire platform of care management solutions, spanning devices, software, medicine and professional care. In late 2015, Novo Nordisk in late 2015 teamed up with IBM Watson Health to create a “virtual doctor” that can provide treatment advice to patients, using real-time data generated from sources such as continuous blood sugar monitors.

Similarly, in respiratory disease, the main players have scrambled to access “smart” inhaler devices that help track adherence patterns, for use both in trials and to inform new drug development. Examples include Teva’s acquisition of Gecko Health Innovations, and Propeller Health’s deals with GSK and Boehringer Ingelheim.
Yet companies marketing patented drugs in any therapy area face similar pricing constraints and pressure to prove that their products deliver better outcomes. Innovators can no longer count on creating entirely new treatment classes that allow long periods of patent-protected pricing. Maximizing product revenues is now more likely to involve deeper integration into evolving treatment pathways, via an expanding network of partnering relationships with payers, care providers and/or data analytics firms. This explains the growing number of data-enabled outcomes-based reimbursement deals between payers and pharma across high-cost disease areas. However, outcomes-based payment deals are notoriously tricky to implement. (See box.)

**Pharma-payer outcomes deals appear inevitable, despite their complexity**

Pharma companies are increasingly engaging in outcomes-based contracts as price-sensitive payers demand evidence of value delivered by new therapies. Such contracts are complex to design and administer. They demand agreement on the particular outcomes to be measured (reflecting, as closely as possible, the effects of the treatment) and appropriate data collection infrastructure. Yet the compelling logic of paying for outcomes, rather than for drugs, has prompted several recent, high-profile deals across chronic, expensive conditions such as heart disease and diabetes. In early 2016, Cigna and Aetna both signed pay-for-performance deals with Novartis around heart drug Entresto, agreeing on a rebate linked to hospitalization rates among those taking the drug. In May 2016, Cigna sealed similar deals with Amgen and Sanofi/Regeneron around their respective cholesterol-lowering drugs Repatha and Praluent. The pharma companies must grant greater discounts if the drugs don’t deliver the same cholesterol-lowering effects seen in trials. In June 2016, Harvard Pilgrim added Eli Lilly and Co.’s diabetes drug Trulicity to its lengthening list of results-based deals, which also includes Entresto and Repatha.
New tools and technologies enhance customer knowledge and competitive position

The new landscape isn’t only about challenges; it presents opportunities, too. Businesses that rely on novel delivery methods and reformulations in competitive disease areas, for instance, can now create new digital tools and communication channels to further enhance outcomes and drive patient engagement. Whether monitoring and modifying patient behaviors, educating and intervening to support healthier habits or creating more connected online communities, such tools create additional product extension opportunities and increase understanding of customers’ current and future needs.

Consumer-focused companies that create value by building widely trusted brands are, similarly, well-positioned to expand their offerings to include information and wellness solutions to help prevent disease across their customer base. Johnson & Johnson has invested heavily to develop a suite of Health and Wellness Solutions, leveraging digital devices and patient engagement tools. This has the potential to strengthen their core market position while enabling new sources of revenue.

This emerging world of more numerous, digitally and data-enabled therapeutic solutions, new revenue models and new market participants is complex. Yet the fundamental needs of biopharma’s customers – payers, providers and patients – remain the same: improved efficacy, safety, convenience, compliance and outcomes at a lower overall cost of care (Exhibit 3). Pharma can now meet those needs in new and unique ways that extend beyond the drug, thereby gaining a competitive edge, and delivering more value at the same time.

Yet it must move fast to do so. Many of health care’s new players are accustomed to product life cycles many times shorter than biopharma’s. Those new entrants are rapidly investing in new capabilities of their own and partnering with biopharma’s traditional rivals. So biopharma must quickly determine exactly how technological, economic and competitive forces are affecting each of its particular disease franchises and markets, then prioritize investment in the most innovative solutions for those segments.

### Exhibit 3. Data and digital solutions provide new ways to address evolving stakeholder needs

<table>
<thead>
<tr>
<th>Primary path to value creation</th>
<th>Traditional product-focused business models</th>
<th>Analogous data and digital solutions models</th>
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</thead>
<tbody>
<tr>
<td>Premium breakthroughs</td>
<td>Traditional pharma/biotech: Developing advanced therapies with high value and high price</td>
<td>Advanced care solutions Advanced care delivery and decision algorithms for complex conditions to transform outcomes</td>
</tr>
<tr>
<td>Disruptive innovation</td>
<td>Specialty pharma/drug delivery Reformulation or novel delivery of existing products</td>
<td>Patient and caregiver engagement Engagement tools to modify behavior and enhance outcomes</td>
</tr>
<tr>
<td>Disruptive targeting prescribers</td>
<td>OTC/consumer products Build trustworthy brands for wellness and minor ailments</td>
<td>Health and wellness management Trusted solutions provider to maintain health, prevent disease</td>
</tr>
<tr>
<td>Incremental innovation</td>
<td>Established/generic products Lower all-in product costs and compete on pricing</td>
<td>Care and cost management Economical care protocols for high cost chronic, episodic or acute conditions</td>
</tr>
<tr>
<td>Addressing unmet customer needs for existing compounds</td>
<td>Patient relationships Understanding and building trust with patients</td>
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How can biopharma companies employ new digital and data-driven capabilities to strengthen ties to stakeholders? Which digital solutions are most aligned with their current business models?
Focus matters more than ever...

This differential change across sectors and therapy areas has two broader consequences. First, companies need to be more flexible than ever, capable of adapting their operating models and investment decisions to the markets they compete in. This flexibility requires developing a repertoire of capabilities, either internally or through collaborations. It also impacts all business functions, from innovation through commercialization, across capital allocation decisions, partnership strategy, portfolio mix and many operational processes.

Second, therapeutic businesses must rethink how they balance focus with diversification. “Companies will have to focus their capital more narrowly,” warns Pamela Spence, EY Global Life Sciences Industry Leader, “to ensure they maximize both value creation and capture” in their chosen business areas. The new skills, partnerships, stakeholder relationships and payment models required to effectively compete in each therapeutic area may make it more difficult and expensive to sustain a broad, diverse portfolio. It may no longer be possible to effectively compete in both chronic diseases and specialist, acute care conditions, for instance. So companies must carefully consider, in the digitizing, price-pressured and consumer-driven new health care world, the most appropriate mix of therapy areas and businesses where they are best positioned to compete effectively. The portfolios that succeeded in the pre-digital, free-pricing, physician-centric era are likely to differ from the ones that can compete effectively in the data-swamped, value-focused, patient-centric era.

The arguments for and against diversification across business areas are also evolving. Can a single organization leverage the efficiencies of better data across both innovative R&D and generic supply chains? Does a consumer care business enable the kind of brand-recognition that can support prescription drug uptake? These questions aren’t new. But the answers to what kind of businesses it makes sense to have under the same roof are changing.

Over the last decade, most pharmaceutical firms have been rationalizing and optimizing their portfolios through targeted dealmaking. This increasing focus on core pharma franchises has rewarded “divestors,” who have outperformed “non-divestors” by 11% in cumulative total shareholder returns over the last three years. (EY Firepower Index and Growth Gap Report 2016, Exhibit 10.) As market forces and technology convergence demand more investment in data, digital, device and diagnostic technologies — driving a greater range of products and technologies within a particular field — therapeutic focus is likely to become even more critical for effective capital deployment.

... but what does focus mean?

At the same time, digital disruption is redefining “therapeutic focus” to be about not only biology and chemistry, but also the patient journey and related data. As a result, businesses that offer multiple products and deep expertise in particular disease areas are well positioned to further strengthen their competitive position by creating integrative digital-enabled solutions across that therapy area. This in turn drives both disease understanding and new product development. Biogen, for instance, with a portfolio of related products to treat multiple sclerosis, has partnered with Verily to combine wearable sensors, traditional clinical tests and new lab-based tests with machine learning to better characterize and monitor multiple sclerosis progression.

Meanwhile, the same technology-, data- and customer-centric forces compelling greater focus are also driving convergence across the health care spectrum. Medical device player Medtronic, for instance, recently partnered with wearable maker FitBit to provide diabetes patients with an integrated app tracking both glucose levels and physical activity. This convergence may allow diversified businesses to reap greater rewards from broad portfolios spanning patented drugs, generics, consumer products and devices — portfolios which, until now, most players have struggled to cross-fertilize.
Steve Wooding, head of Janssen’s Global Commercial and Market Access Strategy Organization, defended his company’s diversified model at the FT Global Pharmaceutical and Biotechnology conference in London in November by highlighting patient data: “When we’re looking for trial patients in immunotherapy, for instance, we tap into the huge amount of data we have from the consumer side [of the business], for example on mother and baby. It’s about the power of the data behind the relationship.” Wooding pointed out that in theory, having a consumer products business should help an adjacent pharmaceuticals division become more consumer-centric. And having a medical technology division should allow businesses to more rapidly capitalize on the emergence of more integrated, technology-enabled solutions.

Going forward, focus matters more than ever. But to achieve market leadership even within their focus areas, companies need to build new capabilities across a wider range of technologies and forge a broader set of cross-sector partnerships. Increasingly, being “best in class” will not only mean having the best drug, but also the best data-enabled holistic solution.

What do companies need to consider to implement these models?

Exhibit 4. New business models will require different strategic, operational, and financial approaches

- Shaping corporate structure and governance to enable and evolve new business models
- Drive and manage cultural change
- Pursuing new commercial models to deliver value “beyond the pill”
- Aligning operating model, supply chain and cost structure with basis of competition
- Rethink balance between focus and diversification – not just biochemistry but patient journey-oriented
- Appropriate mix of therapy areas, geographies and customers
- Best data-enabled holistic solution
- Redefining capital agenda and transaction strategy to accelerate transformation
- Add new skills, partnerships, collaborations and alliances to maximize value creation and capture
- Leveraging big data and digital tools critical for success going forward
- Create centers of technology excellence to work within or across divisions
Creating operating models to allow business model adaptation

No matter how focused or diversified, any strategy is only as good as its execution (Exhibit 4). Operational considerations are paramount as biopharma companies adjust and adapt their business models to remain winners in an increasingly complex, fast-changing marketplace.

For example, deploying data analytics and digital technologies smartly across the entire enterprise – including all franchises, geographies and functions – may require creating centers of technology excellence to work within or across divisions. Therapeutic franchises, regional affiliates and R&D units can then liaise with these centers to develop specific products, applications and solutions.

Driving and managing the cultural changes required for (traditionally conservative) pharmaceutical firms to take full advantage of the scientific, technological, data- and consumer-driven revolutions is as important as identifying the new kinds of required expertise – data scientists, behavioral experts, sociologists or psychologists. “The biggest challenge we have is a cultural shift,” affirmed Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer (CMO) at Novartis, in a recent interview about how data is changing the R&D process. “It’s trying to convince people that decisions are still human decisions, but informed by a powerful data set.”

In some cases, for example where a group seeks to invest in a business with an entirely novel product and revenue model, attempting to integrate it into the existing organization may present too much of a culture shock – even if both groups share the same goal of improving patient outcomes. Setting up a separate venture, at least initially, is one solution. This is what Sanofi and Google did with their Onduo joint venture. This limits the risks to the legacy business, but also prevents it from stifling creativity and innovation while reducing potential conflicts of interest.

Senior management needs to provide the leadership, and establish the resources and processes necessary, to understand changing stakeholder needs and competitive imperatives, and adapt the company’s portfolio and organization to the new landscape. Leaders need to bring their people along too. The challenges are difficult. But every biopharma player faces them, in one form or another. They present tremendous opportunities for the most agile and forward-thinking to establish new kinds of relationships with payers and patients, targeted application of rich data sources and tools, and a lasting advantage over the competition.
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Our Global Life Sciences Sector brings together a worldwide network of 11,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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