

Global pharmaceutical
industry report
2010

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Progressions

Pharma 3.0



Welcome

To our clients and friends:

Given the extraordinary challenges facing pharmaceutical companies, it is not surprising that recent issues of *Progressions*, our annual report on the pharmaceutical industry, have focused on the seismic changes taking place in the industry and the strategic decisions being made by executive leadership teams. To that end, our last two issues have put a spotlight on how companies are shifting from organizing for top-line growth to managing innovation for bottom-line returns.

Our report this year moves beyond a focus on how companies are changing internally and broadens the aperture to see how the entire industry is morphing into a new ecosystem, with new players, one that we have named Pharma 3.0. The shifts discussed in this year's report promise to dwarf anything the industry has seen so far. The convergence of new trends such as health care reform, demographics, personalized medicine, health information technology and the rise of the superconsumer will radically change the playing field as the value proposition moves from developing drugs to delivering "healthy outcomes."

In this new world of Pharma 3.0, we will see many nontraditional players. The core competency of business development will expand into business model development. Commercial model development will become a critical counterpart to drug development. Open innovation will be expanded on both ends of the value chain. Managing the "extraprise" and optimizing networks will be critical skills of leaders. Co-creating value for patients, payors and partners will be key capabilities. Learning how to combine your unique assets and attributes into someone else's business model will be the re-engineering goal of disruptive commercial innovations.

One common thread through all of this is innovation. While this has always been an innovation-driven industry, the winners in Pharma 3.0 will approach innovation in new ways. Innovation is no longer just about the product – it now encompasses how you do business, whom you do business with and how you mobilize your resources to contribute to healthy outcomes for patients.



It is our experience that the benefit of "scenario planning" is not to predict the future, but rather to better understand what one needs to do today to ready oneself for an uncertain future.

In this report, we explore the world of Pharma 3.0 and, through interviews and surveys, executive roundtables, lessons from other industries and perspectives

from Ernst & Young partners, suggest actions that you can take now to prepare for the exciting world of tomorrow.

Ernst & Young's worldwide organization stands ready to help you as you navigate your way forward.

Carolyn Buck Luce
Global Pharmaceutical Sector Leader

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Global Biotechnology Sector Leader



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Seeking healthy outcomes

Introduction

Pharma 3.0: the healthy outcomes ecosystem

Pharmaceutical companies have been moving to reinvent their business models in recent years, driven by trends such as the patent cliff, decreasing R&D productivity, pricing pressures, globalization and demographics. These trends have transformed the industry's long-standing vertically integrated blockbuster model (**Pharma 1.0**) into today's **Pharma 2.0** business model.

The transition to Pharma 2.0 has been characterized by several shifts. Companies have been moving from blockbusters to diversified portfolios of drugs, over-the-counter (OTC) medications, branded generics, consumer products, vaccines and/or animal health products. They have created R&D units that are more independent and flexible and have boosted partnering with biotech firms, universities and contract research/manufacturing organizations (CROs/CMOs). In product development, their focus has shifted toward specialized therapeutics (increasingly using biologics and focusing on novel targets for unmet medical needs in fields such as cancer and immunology). And in the financial sphere, they have moved from managing for revenue (Pharma 1.0) to managing for return, adopting aggressive cost-cutting measures, boosting cash flows, outsourcing non-core transactional activities and more actively managing their balance sheets to increase return on investment.

These have not been trivial changes. Pharma 2.0 is not so much a newer version of Pharma 1.0 as a movement from an *industry* of independent, vertically integrated firms into something else – a complex, dynamic and interdependent *ecosystem*.

While these have been sweeping changes, the industry is now on the cusp of its biggest transformation yet – **to Pharma 3.0, the healthy outcomes ecosystem** – spurred by the convergence of new trends such as health care reform, demographics, health information technology (IT) and consumerism. These transformative trends are driving the entry of large numbers of “nontraditional” companies – such as electronic/mobile health firms, large retailers, financial services companies and IT firms – that have historically not been in the health care business. At a more basic level, they promise to transform the very business of pharma itself, from developing drugs to the delivery of “healthy outcomes.” In Pharma 3.0, it will not be enough for companies to make progress in changing their own business models. Successful firms will build a core competency in learning how to attach their unique assets and attributes to the changing business models of nontraditional players in complex and dynamic collaborations. Growth will come not just from business development, but from business *model* development.

Pharma 3.0 will also see existing trends taken to entirely new levels. Comparative effectiveness, for instance, will get fundamentally reinvented as large volumes of information enable widespread data mining to demonstrate value in comparative-effectiveness decisions. Such **value mining** will be done far more cheaply and quickly than biomarker identification, which takes years of bench research. And power will shift out of the hands of pharmaceutical companies as knowledge of comparative effectiveness spreads outwards. Similarly, these trends should give consumerism a big boost, as technology changes the practice of health care from a paternalistic to a patient-centric

model and transforms the patients of today into the data-empowered **superconsumers** of tomorrow.

If history is any guide, change may come much faster than most people expect. Many of the trends propelling Pharma 3.0 are IT-related, and change occurs much more quickly in the Moore's Law-driven world of tech. And consumers – who soon overcame online privacy and security concerns regarding critical and intimate financial information – may just as quickly adopt new health technologies as they become available. To remain relevant in the new ecosystem, pharma companies will need to move quickly to redesign their business models, understand how they fit into others' business models and partner in creative new ways.

Collaborating to build healthy outcomes

Pharmaceutical companies will need new business models geared around delivering healthy outcomes in the new ecosystem. The term “healthy outcomes” refers to *positive* changes in the health status of individuals, groups or populations, attributable to human intervention. To deliver these health-status improvements, pharma companies will need to build models around some combination of three value propositions:

- Managing patient outcomes (e.g., boosting patient compliance, targeted health care delivery)
- Expanding access to health care (e.g., underserved/emerging markets, uninsured patients in industrialized nations)
- Meeting unmet medical needs (e.g., complex indications and underserved therapeutic areas)

Successfully executing on new business model development (as opposed to

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business development), will require a new approach to executing creative collaborations. Specifically, companies will proceed using a process of “**commercial trials**” (analogous to clinical trials). Many of these commercial trials will occur through innovative collaborations with traditional and nontraditional partners to transform the commercial model. The commercial trials process can be roughly segmented into four phases:

- Identifying areas of strategic focus
- Establishing proof of concept using “alpha” pilot projects
- Development, or testing the commercial feasibility of beta-version pilots
- Commercialization through scaling up projects and taking them global while managing risks

Unlike the long and expensive clinical-trial process, commercial trials will need to be much faster and more efficient – giving companies potentially quicker paybacks and high returns on investment. Given its importance and potential payback, business model innovation deserves more resources. At most pharma companies, the budget allocated to business model innovation is a tiny fraction of product R&D expenditures. Companies will also need to approach the various functions related to creative deals in a more unified manner, which may even require a new leader in the executive suite.

Preparing for success – and successful execution

As they enter creative alliances, often with nontraditional partners, to develop entirely new product or service offerings, pharmaceutical companies will confront a host of new execution-related questions. What creates the most value? Is it the medicine, the knowledge about efficacy,

the data, the risk analytics or the channel to the consumer? Who owns the intellectual property and can it be shared with parent companies?

Our survey of business development leaders sheds more light on these challenges and on how prepared companies are to deal with them:

- Across all deal-related functions, 50% of respondents say that deals will become more challenging in Pharma 3.0, while only 2% expect them to become less challenging.
- The issue areas most expected to become more challenging include: corporate and deal strategy; valuation and modeling; due diligence; offer and market positioning; intellectual property; data security and privacy; change management; and talent.
- The survey also reveals significant gaps in pharma companies’ level of preparedness to deal with these challenges, including in areas such as: valuation and modeling; talent; offer and market positioning; reputation; due diligence; change management; and data security and privacy.

To prepare for success, companies will need to focus on execution and address these gaps.

How this report was developed

This report represents the culmination of months of research and analysis. Since many of the trends described in this report are just starting to play out, it was critical for the research process to gather information from the companies and executives on the front lines of these changes.

The process started with a Rapid Innovation Session that Ernst & Young convened in New York last July. This day-long strategy and brainstorming

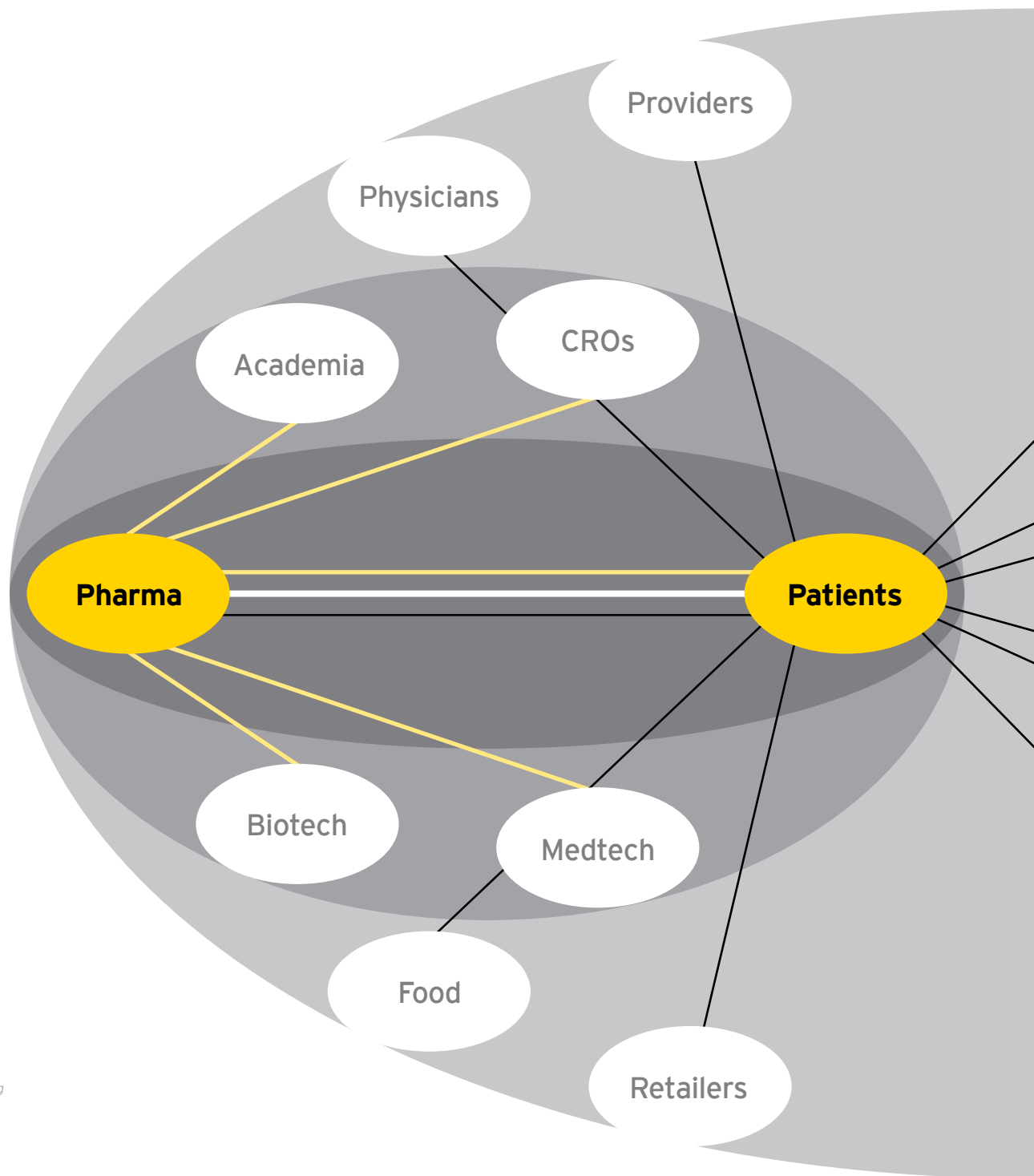
meeting brought together 30 business-development and innovation leaders from pharmaceutical companies and numerous nontraditional players to conduct scenario planning. The session supported many of our working hypotheses and identified key issues for further exploration.

The issues identified in the Rapid Innovation Session were further investigated through an extensive survey process. Given the specific focus of this report, our emphasis was on obtaining deep insights from the right executives at each company rather than simply maximizing the number of survey responses. We therefore conducted in-depth one-hour interviews with survey participants. In total, we surveyed 33 business development and innovation leaders at 24 companies, including 11 of the top 15 Fortune 500 biotechnology/ pharmaceutical companies.

Our sincerest thanks to the many executives whom we spoke to – pharmaceutical, biotechnology, medical device and technology, provider care, research, consumer products, distribution, social media, information technology, telecommunications, data management and retail – as we explored both the critical issues facing the pharmaceutical industry and what lies ahead in the world of Pharma 3.0. We appreciate the valuable time contributors set aside – whether for the Rapid Innovation Session, in-depth interviews, surveys or roundtable panels – to provide their perspectives. And a very special thank you to the members of the Ernst & Young Global Life Sciences Advisory Board who have generously provided their wisdom and guidance throughout this exciting journey. We look forward to the travels ahead. ►

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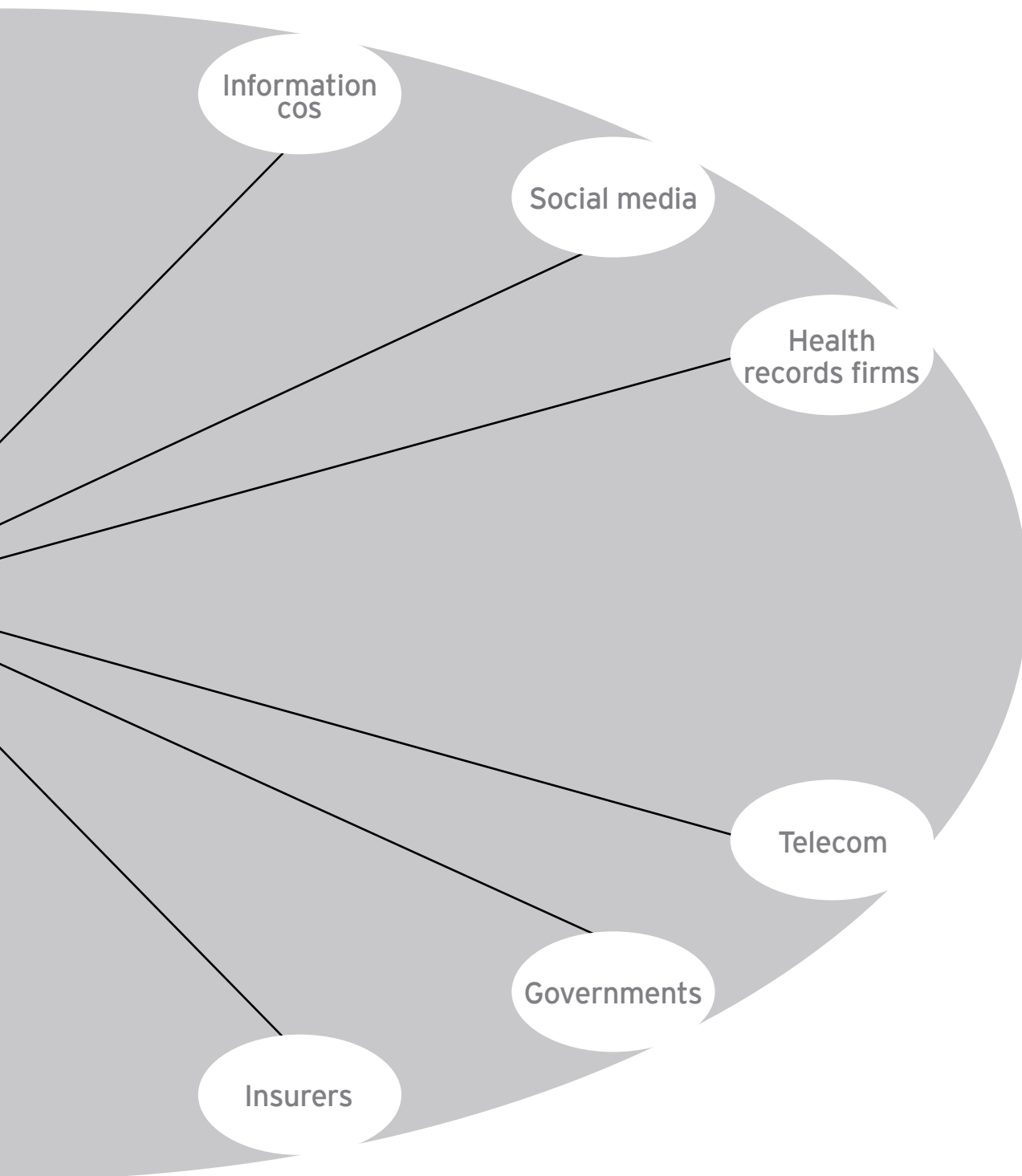
The healthy outcomes ecosystem



Source: Ernst & Young

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— Pharma 3.0 (outcomes)



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Pharma 3.0

A new ecosystem



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Chapter 1

Pharma 3.0

A new ecosystem

In brief

- ▶ Even as pharmaceutical companies move to reinvent their business models to respond to critical issues (the patent cliff and challenge of decreasing R&D productivity, pricing pressures, globalization, demographics and consumerism), they are being challenged further by the next wave of transformative trends, such as health care reform and health IT.
- ▶ These new trends, combined with changes already in play, will alter the rules of the game and transform the very business of pharma, from developing drugs to delivering health outcomes.
- ▶ These transformative trends will accelerate existing trends, such as consumerism and comparative effectiveness, and take them to an entirely new level.
- ▶ New entrants – including electronic/mobile health firms, large retailers, financial services firms, IT companies and information aggregators – are being attracted by these changes and health care's growing economic footprint. If the history of other industries (e.g., media, telecommunications) is any guide, change may come much faster than most people expect.
- ▶ To respond, pharma companies will need to redesign their business models, pay attention to how they fit into others' business models, and partner in creative new ways.

Introduction

It is evident, to even a casual observer, that pharmaceutical companies are living in an era of change. Their most successful products are losing patent protection, and their pipelines have been unable to fill the gap – eating away at the revenues, cash flows and margins that have funded increasingly high-risk research and provided returns for investors. Soaring health care costs and tightening payor budgets are increasing the pressure on drug prices and driving payors to consider comparative effectiveness or cost-containment approaches. Meanwhile, a host of other trends – consumerism, globalization, personalized medicine, demographic shifts – are creating new challenges and opportunities at every stage of the value chain.

These are not small changes, and pharma companies are not taking them lightly. Firms are responding in all sorts of ways, moving – it might sometimes appear – in several different directions at once. They are “rightsizing” to cut costs, outsourcing to tap efficiencies, diversifying to boost flagging revenues, acquiring to add new capabilities and divesting to focus on “core businesses.”

Yet, for all the focus on change – despite the soul-searching under way in boardrooms and transformation agendas being initiated in executive suites – the biggest change that the industry will face is just starting to play itself out: the pharmaceutical industry will soon find itself part of a fundamentally different health care ecosystem. Precipitated by new trends in health care reform, demographics and

health information technology (IT), this ecosystem will include many companies not traditionally involved in the health care business, and, more fundamentally, it will transform the business of pharma itself, from the delivery of drugs to the delivery of health outcomes.

Even as pharma companies scramble to transform themselves, they might find themselves faced with a more difficult question than how to modify their business models – namely, how to fit into *others'* business models.

This is a transformation that has the potential to rapidly overtake the reinvention efforts of companies and turn the questions underlying those efforts on their heads. Even as pharma companies scramble to transform themselves, they might find themselves faced with a more difficult question than how to modify their business models – namely, how to fit into *others'* business models. And an industry that has thrived by controlling its intellectual property may instead find itself questioning how it can sustain profit margins in a world where it has much less control over the new drivers of its success.

Of industries and ecosystems: Pharma 3.0

For much of their history, pharma companies have been famously independent organizations. Success in this business was driven by controlling the entire value chain, from

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the research labs where innovation takes place to the sales forces that sell products to the gatekeepers, the physicians. Not surprisingly, most pharmaceutical companies were vertically integrated organizations with “engineering” cultures that took tremendous pride in their independence and self-reliance, built on the back of a few patent-protected mega-brands powered by super-sized sales forces. This structure of the industry – one we call **Pharma 1.0**, the blockbuster model – flourished over the last 30 years.

Over the last decade or so, things started to change as the industry grappled with several extraordinary challenges and opportunities: the patent cliff and pharma’s inability to fill its pipeline gap; pricing pressures and the increasing focus on comparative effectiveness; globalization and robust growth in emerging markets; the progression toward personalized medicine; and consumerism. To adapt, companies

restructured themselves, giving rise to today’s **Pharma 2.0**, which has been defined by several significant movements:

- ▶ **Progressing beyond blockbusters.**

As their biggest products started to go off-patent, companies have had to wean themselves off the blockbuster model. They have instead developed strategies around diversified portfolios of drugs based on their therapeutic strengths. Some companies have moved into segments such as over-the-counter (OTC) medications, branded generics, consumer products and animal health.

- ▶ **From vertical to horizontal.** To adapt to a post-blockbuster world, companies started embracing decentralization. They have set up more autonomous and flexible R&D units and have increased partnering with biotech companies, academic institutions and contract research/manufacturing organizations (CROs/CMOs). As emerging markets started to come into their own, Western pharma companies

have also partnered with their eastern- and southern-hemisphere counterparts to increase efficiencies and tap new markets.

- ▶ **Targeting R&D.** The industry has shifted its R&D focus away from blockbuster drugs (often small molecules in me-too categories and chronic disease areas) and toward specialized therapeutics (increasingly using biologics and focusing on novel targets for unmet medical needs in fields such as cancer and immunology). Pressure from payors and scientific advances at the bench have driven firms to increasingly adopt personalized medicine approaches in drug development and delivery.
- ▶ **From revenue to returns.** With their biggest cash cows losing patent protection, pharmaceutical companies have focused on driving profits with aggressive cost-cutting measures, boosting cash flows and more actively managing their balance sheets to increase return on investment.



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► Spreading consumerism.

Accompanying these trends has been the growth of consumerism, a movement in which increasingly transparent information and changing economic incentives encourage patients to behave as consumers rather than beneficiaries. This has been driven by several factors – the democratization of information through the internet, an increased focus on containing costs, the impact of the global recession on families' financial health, direct-to-consumer advertising – and while it is in relatively early stages, consumerism's potential impact on pharma companies is huge.

► Changing demographics.

Around the world, aging populations, burgeoning middle classes and growing prosperity in emerging markets have begun to create new growth opportunities and challenges for pharmaceutical companies.

Pharma 2.0 is not a newer version of Pharma 1.0 as much as it is the movement from an *industry* of independent, vertically integrated firms into something else – a complex, dynamic and interdependent ecosystem.

The word “ecosystem” is used here in a very specific context. In a March 2004 *Harvard Business Review* article, Marco Iansiti and Roy Levien analyzed companies that operate in “ecosystems [that] extend beyond the boundaries of their own industries.” Unlike an industry, a business ecosystem has a relatively large number of diverse, loosely interconnected and highly interdependent participants. The survival of any one company is dependent on the health of the ecosystem itself. This is certainly evident in the drug development ecosystem that exists today: large pharmaceutical companies rely considerably on a thriving ecosystem for the innovative products and platforms that determine their ongoing success, while emerging firms depend on it for the capital and resources they need to survive. This highly complex ecosystem

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has included a thriving venture capital industry as well as R&D grants and other government support.

The Pharma 2.0 ecosystem is centered around a key objective: developing and marketing drugs at a profitable return on capital consistent with shareholder expectations. Pharma 2.0 is characterized by pharmaceutical companies grappling with important strategic decisions such as where to place their scientific bets, how to redefine their customers, how to price their products and how to organize for efficiencies. And instead of the industry moving in lock step, companies are making highly divergent decisions depending on their assessments of their own assets and attributes.

Although still knee-deep in the execution of their Pharma 2.0 strategic choices, we see the new set of trends changing the rules of the game. From a drug development ecosystem, the industry is being transformed into a “healthy outcomes” ecosystem, one that we call **Pharma 3.0**.

In the world of Pharma 3.0, drug companies will compete and collaborate with not just the denizens of the current ecosystem – biotech and medtech firms, CROs/CMOs, academic organizations, other pharma companies – but entirely new classes of nontraditional entrants, from IT companies to large retailers to nonprofit organizations. While pharmaceutical companies were at the center of the Pharma 2.0 ecosystem

(coordinating and aggregating the strengths of different partners to bring new products to market), the locus in Pharma 3.0 will be patients. And not the patients of yesteryear, but rather a new class of “superconsumers,” empowered as never before with new technologies and transparent information.

Driving the move to Pharma 3.0 are a number of new transformative trends, most notably health care reform, health IT, personalized medicine and the increasing importance of emerging markets. These macro trends will serve as catalysts, accelerating existing trends and taking them to an entirely new level. The consumerism revolution will go into overdrive as a new generation of superconsumers emerges, empowered by the internet and mobile devices. Similarly, payors' increasing demands for comparative effectiveness should get a significant boost as health IT, social media and increasingly ubiquitous data allow for creative new uses of data mining and patient feedback.

The locus in Pharma 3.0 will be patients. And not the patients of yesteryear, but rather a new class of “superconsumers,” empowered as never before with new technologies and transparent information.

Ecosystems are created through the interactions of discrete actors based on incentives that define their relationships with each other. When the incentives change, these relationships change, leading some actors to exit and others to enter the system. The confluence of waves of macro trends will create seismic changes in incentives for pill-makers, payors, providers, physicians, policy-makers and patients. These trends, and some of their implications for pharmaceutical companies, are discussed in the pages ahead.

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Health care reform

Significant health care reforms are now being considered in key pharmaceutical markets, chief among which are the US (the world's largest and most *laissez-faire* drug market) and China (the world's most populous nation and one of the fastest-growing drug markets in the world). While reforms in these two large countries have been garnering much attention, they are in fact emblematic of a larger global trend: the search for sustainable health care in the wake of escalating costs, aging populations and burgeoning middle classes. Indeed, health care reforms are being considered or enacted across a number of other major developing markets, from Brazil to Russia to India. (As this publication goes to press, there is some uncertainty about the passage of health care reform in the US. To a large extent, though, failing to enact substantive

reforms will only mean that the pressure keeps building in the pressure cooker. The issue of sustainability – with its implications for the industry – is greater than any single legislative effort and will still need to be addressed.)

Health care reform measures promise to redraw the competitive landscape, revise rules and regulations and reorder economic incentives. As with any significant change, the shifts will bring challenges as well as opportunities, and

Underlying many health care reform efforts is a common focus on achieving two somewhat contradictory goals: expanding equitable and affordable access while containing health care costs.

the net impact on individual companies will depend on their responses to the “price effect” and “volume effect” of health care reform. Another key variable will be how well companies innovate their “offers” to the marketplace and expand their channels to the customer.

To seize the opportunity presented by increased access, companies will work to optimize their product mixes to best serve the needs of finely segmented markets. For example, China's efforts to boost primary care and increase access in rural areas will boost the relative share of lower-priced generic and branded generic drugs and vaccines targeting basic diseases. In the US market, accessing the newly insured may require focus on new distribution channels, such as consumer networks and government agencies with influence over prescription-drug formularies.

One of the biggest challenges may come from the increased adoption of comparative effectiveness measures. Underlying many health care reform efforts is a common focus on achieving two somewhat contradictory goals: expanding equitable and affordable **access** while containing health care **costs**. To achieve these competing goals, governments are using a combination of policy measures, such as instituting health-insurance reforms, lowering drug prices (e.g., through rebates, tendering and price



Pharmaceutical companies will need strategic responses to adapt to an outcomes-driven world. This could span everything from patient compliance programs designed to boost health outcomes to risk-sharing pricing arrangements to entirely new business models and “offers” that reinvent the enterprise around outcomes.

A closer look

20/20? China's vision for health care reform

As health care reform initiatives gain momentum around the globe, some of the most ambitious reforms are those being undertaken in China as part of its Healthy China 2020 program. The plan is designed to provide care for 90% of China's 1.4 billion citizens by 2011 and for all citizens by 2020, including the vast numbers who currently lack health insurance. As in the US and other major markets, the program has two broad goals: (1) containing soaring medical costs through price controls, procurement and other measures and (2) improving access by addressing the cost and quality gap between urban and rural health care and inequities in funding and resource allocation.

Five pillars of change

Under the 850 billion yuan (US\$124 billion) plan, the government has promised five large-scale reforms:

- ▶ **Providing universal access to basic health insurance.** Cover more than 90% of Chinese citizens with three health-insurance programs, including the urban employee medical-insurance program, the urban resident medical-insurance program and a new rural cooperative program.
- ▶ **Creating a National Essential Drug List (NEDL).** Require that government-funded rural and community clinics use essential drugs, which could centralize drug procurement and distribution. These low-cost generic drugs will be completely covered by insurance and will be reimbursed by the government. The central government will set price caps for all drugs on the NEDL, and each provincial health authority will organize a transparent bidding process for procuring drugs within the province. The provinces will fix final purchase prices.
- ▶ **Improving health care providers from the grassroots level.** Renovate or rebuild over 3,700 community clinics and 11,000 community health centers. Also, construct 2,000 county hospitals and 5,000 township clinics, and train 1.37 million village doctors and 160,000 community doctors.
- ▶ **Enhancing public health outcomes.** Focus on preventing disease and promoting public health by providing immunizations, regular physical check-ups, and pre-natal and post-natal check-ups and by combating infectious and chronic diseases. Establish electronic medical records.
- ▶ **Reforming public hospitals.** Refocus government-funded hospitals to provide public service. Increase government subsidies for public hospitals so they don't rely on profits from the sale of drugs and expensive treatments and tests to cover operating expenses.

These decade-long reforms create substantial opportunities – and obstacles – for health care companies doing business in China. On the plus side, as health care becomes more affordable and accessible through expanded insurance coverage, the demand for drugs and devices should increase exponentially. Yet multinational corporations (MNCs) will need to restructure and reposition themselves to play in a radically reformed health care ecosystem, one that is focused on grassroots providers and governed by price caps and group purchasing.

Gearing for change

China's reform measures are designed to strengthen primary care, increasing the share of activity at rural and community health centers relative to urban hospitals. Demand is likely to grow for lower-priced medical equipment and drugs that treat and diagnose basic diseases. Targeting rural health care providers will require strategic responses, from adjusting product portfolios and pricing to retooling sales and distribution networks and partnering with local players.

With caps on drug prices, and the provincial open-bidding process, manufacturers of NEDL-approved drugs will face lower margins. The Chinese government has also initiated group purchasing in some categories of medical devices. To gain market share in lower-tier hospitals, MNCs may need to partner with local companies that produce low-cost drugs and devices, and leverage their distribution channels. Local authorities have been encouraged to loosen regulations and add incentives for M&As.

New market opportunities may also emerge for China's commercial health-insurance plans – which currently cover only 5.6% of the urban population – and private hospitals, 90% of which are small, walk-in clinics serving consumers on a fee-for-service basis. Innovative MNCs are well positioned to satisfy demand for more lucrative products and services not covered by basic insurance programs. Demand for medium- to high-end drugs and medical devices will likely be restricted to major urban hospitals. Home health care, a market currently underpenetrated in China, also presents a promising segment, as do remote diagnosis technologies in areas where digital technology is present.

There's no questioning the potential of China's rapidly growing health care market. Western pharma companies have much ground to cover: 9 of the top 10 pharmaceutical manufacturers are Chinese companies, and generics account for 97% of the total market. Health care reform creates new opportunities to make inroads, but to seize these opportunities, companies will need to overcome pricing and purchasing obstacles and design their business models to align with the government's goals.

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negotiations) and reducing fraud and waste. Ultimately, however, reconciling the tension between increased access and lower costs will require increased **efficiency** – doing more with less – across the health care economy. This push for efficiency makes it increasingly likely that major markets that have not yet adopted comparative or

cost-effectiveness regimes will move in that direction.

Pharmaceutical companies will need strategic responses to adapt to an outcomes-driven world. This could span everything from patient compliance programs designed to boost health outcomes to risk-sharing pricing

arrangements to entirely new business models and “offers” that reinvent the enterprise around outcomes. Additionally, the convergence of health care reform and accelerating health IT adoption promises to take this challenge to an entirely new level – a shift that is discussed later in this chapter.

Seeking sustainability: health care reforms in major markets

Country	Pharmaceutical market size	Reforms
China	<ul style="list-style-type: none"> ▶ US\$25.5 billion ▶ Projected to reach US\$35.3 billion by 2014 	<ul style="list-style-type: none"> ▶ “Healthy China 2020” plan to realize universal access to essential health care services. ▶ Phase I to realize universal coverage of essential health care. Allocates US\$124 billion to curb medical costs, urban-rural gap. ▶ Phase II (2010-2015) to boost services beyond those of other developing countries. ▶ Phase III (2015-2020) to complete a robust essential health care system with universal coverage.
India	<ul style="list-style-type: none"> ▶ US\$8.4 billion ▶ Projected to reach US\$16.5 billion by 2014 	<ul style="list-style-type: none"> ▶ Recently established a system to track supply trends of drugs in the market, to allow the government to forecast drug supply shortages. ▶ The new drug tracking system may increase prices to incentivize pharmaceutical companies to relaunch their versions of drugs in local markets. ▶ Boosting regulatory regime to increase competitiveness of exports and outsourcing providers.
Brazil	<ul style="list-style-type: none"> ▶ US\$16.6 billion ▶ Projected to reach US\$24.9 billion by 2014 	<ul style="list-style-type: none"> ▶ Pharma is one of four pillars of new industrial policy. ▶ Federal government has created a special financing program to increase the local production of medicines, facilitate R&D developments and encourage M&A. ▶ Government plan to boost investment in biotechnology R&D through 2017.
Russia	<ul style="list-style-type: none"> ▶ US\$7.9 billion ▶ Projected to reach US\$13.6 billion by 2014 	<ul style="list-style-type: none"> ▶ Reforms to expand coverage for prescription drugs by 2010. ▶ Universal prescription drug coverage will expand demand for retail prescription drugs (mostly paid out-of-pocket at present).
Mexico	<ul style="list-style-type: none"> ▶ US\$13.2 billion ▶ Projected to reach US\$17.0 billion by 2014 	<ul style="list-style-type: none"> ▶ Plans to cover 85% of the country’s population under the public health care system by 2012. ▶ Pledged to invest US\$9.5 billion investment to improve infrastructure.

Source: The World Pharmaceutical Markets Fact Book 2009

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Health IT

Drug development has long been a technology-driven industry. Companies routinely collect and analyze vast volumes of data for clinical trials and regulatory submissions. And since the onset of the biotechnology revolution in the mid-seventies, they have embraced successive waves of new technologies in the search for more-efficient ways of developing drugs.

But while the process of taking a drug from research candidate to approved product has become data-rich and high-tech, the process of delivering those approved products to patients – health care itself – has remained remarkably low-tech in much of the world. That is now starting to change, with tremendous implications for pharmaceutical companies.

Going digital

Like health care reform, the concept of electronic health records (EHRs) has been around for decades. But while experts have long recognized the promise of EHRs to increase efficiencies, lower administrative costs and reduce medical errors, the adoption and meaningful use of electronic records has so far been mixed, at best.

In the industrialized world, some countries are far along in terms of EHR implementation: Denmark, Finland, Sweden and some areas of Spain, for instance, have fully implemented systems, while Australia and the UK are in the midst of major adoption initiatives. In 2004, the European Commission adopted an electronic-health (e-health) action plan – which covers everything from electronic prescriptions and health cards to new information systems that reduce waiting times and errors – to facilitate a more harmonious and complementary European approach to e-health. And while EHRs are far from common in the developing world, pockets of excellence such as India's Apollo Hospitals and



Thailand's Bumrungrad Hospital are years ahead of the US. In China, EHR implementation is part of the major overhaul of the health care system.

But while the process of taking a drug from research candidate to approved product has become data-rich and high-tech, the process of delivering those approved products to patients – health care itself – has remained remarkably low-tech in much of the world. That is now starting to change.

In the US, electronic records exist today largely as isolated solutions in health care institutions, hospitals and clinics. While some segments of the US system – notably the Veterans Administration and large, leading hospitals – have successfully deployed electronic records, the vast majority of providers continue to lag behind. A March 2009 survey in the *New England Journal of Medicine* found

that only 1.5% of US hospitals have a comprehensive electronic-records system (present in all clinical units), while 7.6% have a basic system.

Recent legislative changes have the potential to change that uneven record. While much of the focus in health policy circles in 2009 has been on the hotly debated efforts to reform the US health care system, the economic stimulus legislation passed early in the year could prove every bit as momentous. While the legislation's provision to encourage EHR adoption (also referred to as the HITECH Act) was small relative to the overall package – accounting for US\$19 billion of the bill's US\$787 billion price tag – it could produce real changes in the way medicine is practiced in the world's largest drug market.

Technological solutions to address privacy and security concerns have improved significantly over time, but physicians continue to resist adoption mainly because of the high cost of transitioning to EHRs. The stimulus package specifically addresses these concerns by providing financial incentives of more than US\$40,000 per physician over a number of years, as well as

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financial penalties that take effect after 2015 on noncompliant doctors. It should be noted, though, that despite the generosity of the incentives, many hospitals remain capital-constrained in today's capital-market environment and may still be challenged to fund implementation initiatives.

The EHR business, which had long been dominated by specialized niche players, has rapidly become more crowded, as big names have entered the arena.

Still, as incentives often do, these measures have already had a galvanizing effect. The EHR business, which had long been dominated by specialized niche players, has rapidly become more crowded, as big names have entered the arena. In March 2009, retail giant Wal-Mart and PC-maker Dell teamed up with software specialist eClinicalWorks to provide a user-friendly, low-cost

EHR solution specifically targeted at small doctors' offices, where EHR penetration has been low. In June, General Electric (GE) unveiled its new Stimulus Simplicity program as part of its "healthymagination" initiative, offering doctors and hospitals interest-free financing with deferred payments for its EHR products.

Even more significant is the rapid growth of two titans of tech that are developing data-centralization platforms to empower patients: Google Health and Microsoft's HealthVault. While most electronic records systems are designed for providers, these two platforms are aimed squarely at patients. They allow patients to upload health records from various sources into a centralized location. The data is owned by patients, who can choose to share it with physicians, friends or family. Both initiatives are still in the "beta" stage of development – Microsoft HealthVault was launched in October 2007, and Google Health was released later, in May 2008. Since then, both companies have actively been pursuing partners. Google Health's partners, for instance, include Allscripts,

Anvita Health, Blue Cross Blue Shield of Massachusetts, The Cleveland Clinic, CVS Caremark, HealthGrades, Longs Drugs, Medco Health Solutions, Quest Diagnostics, RxAmerica and Walgreens. By the time Google Health announced its alliance with CVS in April 2009, allowing CVS customers to upload their pharmacy data into Google Health, the company's deals in aggregate allowed more than 100 million Americans the ability to import at least a portion of their medical histories into Google Health. That's about one-third of the US population – impressive, indeed, for a beta-release offering that was less than a year old at the time.

This leads to the issue of standards and interoperability. Experts argue that to truly unleash the power of electronic records (e.g., by allowing them to be gathered across different platforms), they need to be interoperable and not confined within organizational silos. While the term we have been using so far – "electronic health record" – is often used interchangeably with "electronic medical record" (EMR) and "personal health record" (PHR), these have distinct meanings. EMRs, as defined by the National Alliance for Health Information Technology, refer to "information on a patient that can be created, gathered, managed and consulted by authorized clinicians and staff in *one health care organization*." EHRs, on the other hand, are records that conform to recognized interoperability standards and can therefore be created, managed and consulted by authorized clinicians and staff across *many organizations*. PHRs are interoperable like EHRs, but they can be drawn from a greater variety of sources and are *controlled by the patient*.

This distinction makes all the difference. With the rapidly growing PHR platforms of Google Health and Microsoft HealthVault, we are witnessing the start of a revolution. Over the next few years, we will see not only a vast expansion in the quantity of digitized patient data but also a transformation in the *nature* of that data – from EMRs that once resided



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in corporate silos to EHRs that can talk to each other and, most importantly, PHRs that are owned by patients.

While the digitization of patient records promises to lower health care costs and improve efficiencies for companies and the system at large, some of the biggest benefits could accrue to patients. Indeed, this is frequently what happens when industries go digital. The arrival of the worldwide web in the late 1990s, for instance, brought huge efficiency gains for companies, through everything from more-efficient supply chains to better integration with customers. But it was consumers who benefited the most, because the web made information transparent and instantly accessible. As a result, shoppers now routinely compare prices and offerings across hundreds of vendors in a matter of seconds, while retailers are forced to compete more aggressively on price than ever before. As Esther Dyson, CEO of EDventure Holdings, points out in “Embracing the new reality,” our roundtable on the changing ecosystem, patients are already starting to recognize the value of their health data and are demanding access and control over it.

Going mobile

Even as the digitization of patient records belatedly ushers some segments of the health care economy into the IT revolution of the 1980s and 1990s, other parts of the system are rapidly moving toward the cutting edge of the future. Health care is not just going digital; it is also going mobile.

Remarkably, the mobile revolution is happening simultaneously at both extremes of the economic-development spectrum. At one end, the arrival of “third-generation” (3G) smartphones is bringing powerful new applications that empower patients to monitor and manage their health care in real time and, at the extreme, are even starting to blur the line between mobile phone and medical device.

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The charge is being enabled by a third titan of tech, Apple, and its wildly popular iPhone. Apple’s “killer app,” its App Store, allows customers to choose from tens of thousands of applications (apps) developed by third parties using a common software-development kit. In March 2009, when Apple launched version 3.0 of its development kit, the company was markedly focused on health care apps. The launch included a demonstration by LifeScan (a Johnson & Johnson company) of

a prototype for an app that allows diabetics to interface their iPhones with the glucometers they use to track blood-sugar levels. The glucometer transmits blood-sugar readings to the iPhone app, which can then interpret the data to calculate sugar consumption during meals and allow the user to adjust medications and diet as needed. Meanwhile, Texas-based AirStrip Technologies has developed a suite of apps for the iPhone (and other smartphones such as Research In Motion Limited’s BlackBerry devices) that provide state-of-the-art remote health care surveillance at hospitals across the US. Its signature product, AirStrip OB, delivers patient waveform data – including fetal heartbeat and maternal contraction patterns – in virtual real time directly from the hospital labor and delivery unit to a doctor’s mobile wireless device. By some reports, medical apps are now the third-fastest-growing category on the App Store.



A closer look

Lynn O'Connor Vos
Grey Healthcare Group
CEO



Mobilizing a health care revolution

From simple short message service (SMS) devices to smartphones, mobile-driven health (m-health) is set to leapfrog the internet-enabled computer as a health care communications platform. Both in the industrialized world and developing nations, m-health is reshaping the health ecosystem by driving compliance, significantly improving health outcomes and expanding access for the underserved.

More ubiquitous than the internet

With more than 2.5 *trillion* SMS messages sent around the world last year, and more than 4 billion mobile phone subscriptions globally, health care companies must finally take SMS seriously as a communications medium – even more seriously than internet-based communications technologies. Mobile phone ownership easily outpaces internet access: the International Telecommunications Union, an agency of the UN, estimates that approximately 60% of people own mobile phones worldwide whereas just under 25% have internet access.

Over the last decade, the computer has upended the existing health information paradigm, empowering millions of patients to participate more fully in their own health care. But get ready, because another revolution is on its way. Sheer ubiquity makes even basic mobile phones a powerful alternative to the networked computer, and now smartphones such as the iPhone and Blackberry are, app by app, achieving true computer-grade power.

Connecting patients and providers

With m-health, the mobile phone becomes a surrogate health coach and advisor – one that is more accessible and responsive. Mobile phones enable a two-way communication cycle, connecting and sharing information between providers, patients and caregivers. Using simple SMS messages or high-resolution screens, phones deliver timely, tailored health messages and reminders. They can also channel information back from the patient to report symptoms and health status.

Developing solutions

M-health innovation and early success occurred in the third world, led by innovative companies like Voxiva. In Mexico, diabetics use text-enabled phones to track glucose levels and receive tips for healthy living. In Peru, health care workers report and track disease outbreaks. In Rwanda, health workers register patients, track supplies of HIV drugs and access lab results.

Now the m-health revolution is coming to the industrialized world, with applications to support everything from diabetes care to smoking cessation.

One of the most innovative new initiatives is tackling the challenge of infant mortality. The US has one of the highest rates of infant mortality in the developed world. To address this crisis, and to show how m-health can be leveraged to improve health outcomes in underserved populations, a unique public-private partnership has been formed. It's called Text4Baby.

Beyond baby steps

Text4Baby is an SMS-based maternal health information service. Women who sign up for the service receive free SMS text messages each week, timed to their due dates or babies' dates of birth. These messages provide information on maternal and child health topics – immunization, nutrition, seasonal flu and oral health – while also connecting women to resources and services.

Text4Baby is remarkable not only for the innovative approach it uses in engaging pregnant women and mothers, but also for the partners it has brought together: the federal government, CTIA Wireless Foundation, major mobile operators, specialized communication partners Grey Healthcare Group and Hill & Knowlton, health-industry giant Johnson & Johnson, and a new type of company altogether, an m-health company, Voxiva.

Next steps: the smartphone

While Text4Baby represents what is possible today using SMS, the smartphone is fast approaching critical mass, especially in advanced markets, and that could be another game changer in the evolving health ecosystem. Imagine the potential for remote diagnosis, using a built-in video camera to transmit images of rashes or other physical symptoms, teleconferencing to mediate physician interviews and support groups, or on-screen data entry for clinical trials.

Thanks to m-health, consumers enjoy convenient, real-time care and better health care outcomes. No surprise are predictions that by 2013, more than 21% of medicine will be practiced online, much of it via mobile phone.

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And this, by all indications, is just the beginning. "New generations of mobile phones will be able to link with medical devices," says Nokia's Jaakko Olkkonen. "They will use embedded sensors such as GPS systems or accelerometers to track and relay information to services, which can then use that data to help patients. And this is where we at Nokia want to play, by using mobile technologies to deliver value to the health ecosystem."

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– Jaakko Olkkonen,
Nokia

Even more exciting, though, are the changes taking place at the other end of the spectrum, through more basic mobile-phone technologies such as short message service (SMS, also known as text message) communications. Text messages are now being used to improve health care – for example, increasing health care access, disseminating information and improving treatment compliance among poorer segments of populations in developing and industrialized nations. The numbers make a compelling case – as Lynn O'Connor Vos points out in *A closer look* on page 10, mobile phones have far greater market penetration in poorer populations than personal computers do. As a result, the revolutionary impact of mobile-phone

technology extends far beyond the health arena: a recent study by the World Bank found that a 10 percentage point increase in developing-country mobile-phone adoption leads to an increase in per-capita GDP growth of 0.8 percentage points.

The process of taking health care mobile is not restricted to mobile telecommunications companies. Novartis, for instance, is currently working with consultancy Proteus Biomedical to improve patient compliance. Proteus manufactures a small chip that's placed in each pill and detected by a receiver. If patients do not take their medication, they receive a reminder by SMS.

Google and Microsoft are already working on ways to move data from mobile devices to their PHR platforms. In February 2009, for instance, Google and IBM announced a deal to develop new software that would allow data to move easily from remote personal monitoring devices, including those based on smartphones, into Google Health's PHRs. Microsoft's HealthVault can similarly accept data from mobile monitoring devices made by several manufacturers.

Social data

If mobile telecommunications are producing a revolution in economic development in developing nations, a new generation of communication channels is driving another revolution spearheaded in the advanced world. While these channels are referred to using a number of names – social media and web 2.0 are some of the more common labels – they all share some key features. From YouTube to Wikipedia to Twitter, the content in each of these channels is generated by tens of thousands of individuals working in real time.

And therein lies the revolution. In the first generation of websites (what is now referred to as web 1.0), content flowed primarily in one direction – from the companies that developed it to

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customers and other stakeholders, who consumed it. Now, information flows in multiple directions, it is constantly morphing, and no centralized authority controls the message. This is, of course, tremendously empowering for consumers – and is, in many ways, a logical extension of the consumer-empowerment revolution that the web first unleashed in the nineties – but it represents a corresponding loss of control for corporations everywhere. Media giants are scrambling to reinvent their business models to remain relevant in a world where anyone with a blog or YouTube channel has the potential to become a citizen-journalist. Wikipedia has put long-standing giants such as Encyclopedia Britannica on the defense, with articles that are continuously updated, cover a far broader array of topics and are about as accurate as those of their more established rivals.

The revolutionary impact of mobile-phone technology extends far beyond the health arena: a recent study by the World Bank found that a 10 percentage point increase in developing country mobile-phone adoption leads to an increase in per-capita GDP growth of 0.8 percentage points.

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In October 2008, financial-data giant Bloomberg announced it was partnering with Sermo to launch Healthcare Exchange, a forum that allows Bloomberg subscribers to see comments by Sermo members related to particular companies and products. Investors, in other words, are gaining an open window into leading indicators of trends that could directly impact pharma companies' stock prices – and the industry has no way to control the message.

Social media has the potential to be every bit as revolutionary in the health sector, though the pace of change has been slower than in some other industries. One reason for this is big pharma's hesitation to adopt social media in a large way, because the absence to date of guidance from regulatory agencies creates new sources of risk. (For more information, see "Tweet nothings" on the following page.)

When you bring together large numbers of users in online forums, their collective voices have the potential to become something much more meaningful. Once combined and analyzed, millions of individual conversations can collectively become valuable data.

More exciting than big pharma's cautious forays into established social-media networks such as YouTube and LinkedIn, though, are a handful of emerging health care-specific communities. PatientsLikeMe, for instance, was founded in 2004 and provides an online community where patients can share information with each other about subjects such as dosing regimens, adverse reactions, new treatments and clinical trials. In June 2009,

Belgium-based UCB became the first pharmaceutical company to partner with PatientsLikeMe when the two companies announced an agreement to build an online epilepsy community.

Other communities, such as Sermo and Medscape Physician Connect, provide places where physicians can confer with each other about diagnoses and treatments. Since its launch in late 2006, Sermo and its newer rival Medscape Physician Connect (a part of WebMD) have grown rapidly. About 15% of practicing US doctors have joined Sermo, and both communities sign up thousands of new members each month.

When you bring together large numbers of users in online forums, their collective voices have the potential to become something much more meaningful. Once combined and analyzed, millions of individual conversations can collectively become valuable data. Indeed, the business models of some of health care's social-media pioneers are predicated on such data mining. For instance, while Sermo and Medscape Physician Connect provide free access to their physician members, they make money by selling access to data on doctors' conversations to pharmaceutical companies. This data is rapidly becoming recognized for its value – echoing, in some ways, the role that the data aggregated by IMS Health has played in Pharma 1.0 and 2.0. The drug companies have signed up because it gives them a front seat to prescribing and other behaviors of leading physicians.

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There's no reason why the same principle could not apply to patient-based communities such as PatientsLikeMe. After all, the collected experiences of thousands of patients living with a disease and taking treatments for it are a treasure trove of data that is, at present, completely untapped. Similarly, for cancer and other serious diseases, there is important information to be gleaned from the experiences of caregivers (there are two caregivers on average for every cancer patient). Such data could help make drug development more efficient, by identifying trends and generating hypotheses. It could also lead to new insights that can dramatically improve compliance. And it could provide more comprehensive, real-world statistics on

In Pharma 3.0, companies will not be selling pills as much as managing entire patient experiences.

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the efficacy of different treatments for pharma companies – or indeed anyone else with access to the data (more on this in the “Value mining” section on the following page).

Using social media to track the experiences of patients will not just be about boosting compliance and increasing the efficiency of drug development. In Pharma 3.0, companies will not be selling pills as

much as managing entire patient experiences. Through tools such as these, companies will need to build the longer-term relationships with patients that will become increasingly integral to their brands.

A closer look

Tweet nothings

If life sciences companies are already struggling to fit their consumer messages in 30-second television spots, how could they possibly confine themselves to the 140 characters of text that Twitter requires or even the 1000-character limits found on Facebook? The disclosures required by the FDA on the risks and benefits of brand-name drugs can use up more than half, if not all, of the allotted space on these sites.

Drug companies are similarly challenged by how to effectively connect with consumers via blogs, videos on YouTube, and other formats where their original content can be repurposed (as “mashups”) or users can post their own comments as responses. Already many consumer-minded industries have embraced web 2.0 for its ability to quickly reach and engage with consumers, yet the life sciences industry seems to be caught in a quandary.

These issues came to a head on 26 March 2009, when the FDA’s Division of Drug Marketing, Advertising and Communications sent warning letters to 14 pharma companies. The letters cited 48 of their sponsored links – those messages that pop up with search results to lure searchers to other presumably related internet content – on Google as misleading. In response, life sciences companies quickly pulled up stakes. Both comScore and Advertising Age reported that paid search ads for pharmaceutical brands declined rapidly, measuring a 59% drop by the end of the month, and 84% by the end of June.

Noting in the Federal Register that “there are no regulations that specifically address Internet promotion separately from the other types of promotion” nor “regulations that prohibit the use of certain types of media to promote drugs and medical devices,” the FDA took long-overdue first steps at providing guidance. The agency held a two-day public hearing in November 2009 to provide a forum to “discuss issues related to the promotion of FDA-regulated medical products ... using the Internet and social media tools.”

Ken Burbary
Ernst & Young



At the hearing, speakers from 59 companies weighed in – global, midsize and emerging life science companies; communications firms; research and professional services organizations; online companies popular with advertisers, such as Google and Yahoo; trade organizations; and bloggers. For pharma participants, the themes were consistent and as expected. Pharma representatives emphasized their reluctance to venture onto web 2.0 because FDA guidelines were unclear. And they expressed an even greater concern over the lack of clarity on their responsibility for monitoring the internet for transgressions such as inaccurate or off-label commentary or discussions of adverse events.

Participants at the hearing proposed a compelling mix of solutions to better regulate internet content – from establishing working groups tasked with staying on top of e-developments, to establishing a sort of seal-of-approval to signify content that is FDA-approved, to developing new formats for sponsored pop-ups that would include links to risk or safety information. The bigger question, however, seemed to be whether regulators could establish and maintain timely guidelines that could keep pace with the speed with which the internet is evolving. And, as nontraditional industries – industries less regulated and already well entrenched in web 2.0 – enter the health care arena, it is clear that regulatory guidelines, and compliance with those guidelines, will be further tested. In the meantime, until the FDA makes its next move, pharma’s best bet is uncertain. Some companies may choose to wait on the sidelines – a decision not as safe as it may seem – while others may be willing to test the waters in small pilot programs that aim to minimize risk.

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Value mining

As cost pressures continue to mount, payors and policy-makers are increasingly gravitating toward measures that deliver more value relative to cost, such as comparative effectiveness. This is, in itself, a sea change for pharmaceutical companies, but the imminent expansion in health data could take comparative effectiveness to an entirely new level. Large volumes of information can fundamentally alter how evidence is gathered and demonstrated for comparative-effectiveness decisions – from value based on clinical research to value based on data mining (or value mining).

Instead of needing to identify genetic biomarkers for predicting efficacy in specific patient subpopulations, value mining allows one to identify “proxy variables” that are correlated with the underlying “true” variation. A large hospital system could mine its data and figure out that a certain drug is more likely to work with South Asian males over the age of 55 and a history of hypertension, even if it cannot identify the genetic basis for the correlation. What’s truly significant is that, unlike identifying biomarkers, value mining doesn’t involve years of bench research. It can be done far more cheaply and quickly. And since it could conceivably be done by any entity that has access

“The real potential [for electronic health records] is when consistent data is gathered and made accessible in ways that could help drive decision-making.”

Paul Nakagaki, Roche

to volumes of patient data, it doesn’t necessarily have to be done by pharma companies alone.

The monopoly that pharma companies have historically had over data on the efficacy of drugs has, to some extent, helped maintain prices, since this knowledge was implicitly bundled into the prices of drugs. But with value mining, knowledge about efficacy will move into the public domain and become unbundled from the pill – with significant implications for pharma companies and the prices of their products.

“Electronic health records as they exist today aren’t worth that much,” says Paul Nakagaki, Ph.D., from Group Research Strategy at Roche. “The real potential is when consistent data is gathered and made accessible in ways that could help drive decision-making in the pharma and diagnostics industries. And that is starting to happen.”

Consider, for instance, that many leading hospitals and payors have had EHRs for years and are actively mining that data to improve outcomes. Partners Healthcare in Boston is teaming with the FDA, the eHealth Initiative, Johnson & Johnson, Eli Lilly and Pfizer to mine its 4-million-strong EHR database for possible adverse drug reactions. US health insurer WellPoint announced a three-year alliance in April 2008 with the FDA and leading academic institutions to build the Safety Sentinel System, a tool that will mine and analyze claims, laboratory and pharmaceutical data from the company’s 35 million members. Meanwhile, Intermountain Healthcare, which runs a network of hospitals in Utah and Idaho, has been leading the charge on evidence-based medicine since the late 1980s, by developing best-practice protocols for its physicians using, among other things, its EHRs. Such programs may just be early indicators for what is to follow, because most providers have yet to adopt such measures.

Next, consider two recent head-to-head trials comparing the effectiveness of rival heart drugs. In their “Triton” study, Eli Lilly and Daiichi Sankyo conducted clinical trials to compare their newly introduced heart drug, Effient, to BMS’ long-standing product, Plavix, which will soon lose patent protection. In October 2009, however, large prescription-benefits manager Medco Health Solutions announced its own head-to-head study comparing the two drugs. Medco’s goal is to identify patient populations that will respond to Plavix versus those that need Effient. What’s truly noteworthy is how Medco plans to conduct the comparison – by simply enrolling patients from its existing customers and tracking outcomes using its existing data systems. Not only could Medco’s findings differ from those of the pharma companies, but its approach would be much faster and cheaper as well.

Last but not least, consider Steven Nissen. In 2007, Dr. Nissen of the Cleveland Clinic conducted analysis which claimed to find an increased risk



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of heart attacks for patients taking GSK's Avandia. The FDA reacted with a warning, and sales of the drug declined significantly. What was truly remarkable about the incident, though, was that Dr. Nissen did not conduct a clinical study to arrive at his conclusion. Instead, he relied on "meta analysis," a statistical technique which combines several existing studies to look for larger trends. This methodology and the conclusions it reached attracted much criticism, but the incident does offer a compelling example. If a single researcher can combine existing data in this manner and still have a marked impact on a drug company's product sales, imagine how much more could be done in a world where third parties have access to much larger volumes of data. For pharma companies, there is a lot at stake.

Superconsumers

Patients have always been relatively passive participants in health delivery. In most cultures, physicians have decided the diagnosis and chosen the optimal course of treatment (after all, they have had much more training and medical information than patients). And in markets where patients have had the benefit of health insurance, insurers have insulated patients not just from financial shocks but also from the "price signals" that are essential for producing optimal resource allocation in efficient markets. Patients have followed obligingly as experts made decisions that could, quite literally, have life-or-death ramifications for them.

The coming health IT revolution promises to give consumerism a major boost, as technology empowers patients and transforms the paternalistic practice of health care into a patient-centric model with the patients having more "on-demand" access to data.

And educated superconsumers, armed with new mobile phone technologies and apps, will take a more active role in managing their own health care.



Technology has a way of creating new markets and new demands as newly empowered consumers see what is possible.

Craig Barrett, the former CEO of Intel, used an interesting analogy at a Hong Kong-based industry conference in 2009, when he pointed out that health care is stuck in the equivalent of the computer industry's mainframe era. Before the advent of personal computers, the world's computing power resided in large mainframe computers that were controlled by technicians. Anyone with a problem that needed computing had to go to the technician with a request, let the technician, armed with punch cards, program the machine (a laborious and sometimes error-prone process) and often wait several days for the results. Today, technology allows individuals to compute, upgrade, download, troubleshoot and communicate with the world without stepping outdoors. In Dr. Barrett's analogy, doctors are mainframes in today's health care world, even though we already have the technology to revolutionize the system. With the coming m-health revolution, health care is poised to take not one but several

giant steps forward – moving from the labs to laptops, PDAs and smartphones all at once.

It's true that only a minority of patients use these tools today, but that is invariably the case with any new technology. It's important to keep in mind that what is initially a small band of passionate "early adopters" typically expands, and often does so quite quickly.

Technology has a way of creating new markets and new demands as newly empowered consumers see what is possible. Consider, for instance, online banking – a technology that emerged in the mid 1990s and involves data that can be every bit as sensitive as health information. In 1994, a survey by the Pew Research Center for the People & the Press found that only 9% of US households used electronic banking. A decade later, that number had increased more than fourfold, to 38%. In scores of other areas – from mobile phones to GPS devices – technologies once rare have quickly become so commonplace that users now wonder how they ever managed without them. Websites such as WebMD and PatientsLikeMe have already started to change some consumer behaviors. As patients become aware of new health IT applications, we can expect a similar expansion in usage – which in turn will take health consumerism to an entirely new level.

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An expanding universe

Even as pharmaceutical companies are transitioning from the business of selling pills to the business of promoting and delivering health outcomes, large numbers of nontraditional players – companies that have historically not participated in this space – are being lured by the sector's financial potential. The numbers are compelling. Health care is a large (and largely recession-resistant) sector that is poised for rapid growth because of aging populations, growing incomes (and growing waistlines) in developing countries, growing emphasis on life-long wellness and prevention, and increased access to medical treatments by currently underserved patients.

The discussion so far has largely focused on entrants from technology-driven industries. Indeed, the convergence of escalating health care costs and the changes being accelerated by health care reform and the stimulus package create openings for firms that can harness technology to improve efficiency across the system. But the pool of companies looking to enter is by no means confined to the world of tech. Firms from a number of other industries are also making moves:

- **Creative access.** As pharmaceutical sales growth slows in the mature markets of the industrialized world, drug makers have increasingly been looking to emerging markets.

While the market potential is huge, so are the challenges. Intellectual property protections are often poorly enforced, as is adherence to regulatory agencies' good practice quality guidelines such as Good Manufacturing Practices and Good Clinical Practices, or "GXP's," and other standards. In addition, much of the focus has so far been on the major metropolitan areas. Increasing access in smaller towns and villages, where infrastructure is weak and many patients do not have the financial means to afford drugs, will bring even bigger challenges.

This, in turn, is creating opportunities for entirely different kinds of entities that can offer solutions to these problems. Many governmental agencies and nongovernmental organizations (NGOs) already have employees and facilities in remote areas, as well as charters to boost public health and economic development. Micro-lenders such as Bangladesh's renowned Grameen

"I'd expect to see more pharma companies partnering with food companies in emerging markets because of the distribution and infrastructure these companies have. They often have temperature-controlled trucks and FDA-compliant storage facilities because, like drug companies, they are storing products meant for human consumption."

– Richard Smith,
FedEx Express

Bank can offer finance to bridge the affordability gap and, more important, can bring strong rural networks and a high degree of trust. As already discussed, mobile telephone operators and manufacturers are using their increasingly ubiquitous devices for health education, data collection, monitoring and tracking disease outbreaks. And large retailers and



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food companies could leverage their existing distribution channels and expertise to bring drugs to underserved locations.

"I'd expect to see more pharma companies partnering with food companies in emerging markets because of the distribution and infrastructure these companies have," says Richard Smith, Managing Director, Life Sciences and Specialty Services at FedEx Express. "They often have temperature-controlled trucks and FDA-compliant storage facilities because, like drug companies, they are storing products meant for human consumption."

- **New business lines.** As big pharma's patent cliff exposes drugs that had been responsible for tens of billions of dollars to generic competition, the impetus grows for companies

to seek other sources of revenue. At the same time, companies in other industries that have been experiencing slowing growth are being attracted to the higher growth potential in the health-outcomes business.

For instance, food companies have been increasing their focus on health-related areas such as nutraceuticals and functional foods (foods that have been modified to provide health benefits). These segments are growing at a much faster clip than overall food sales. Borrowing a page from the biotech revolution, Swiss giant Nestlé is even looking at the field of "personalized nutrition." The company is conducting R&D in metabolomics and proteomics to develop foods, diets, devices and services that are targeted to specific subpopulations. Across the border,

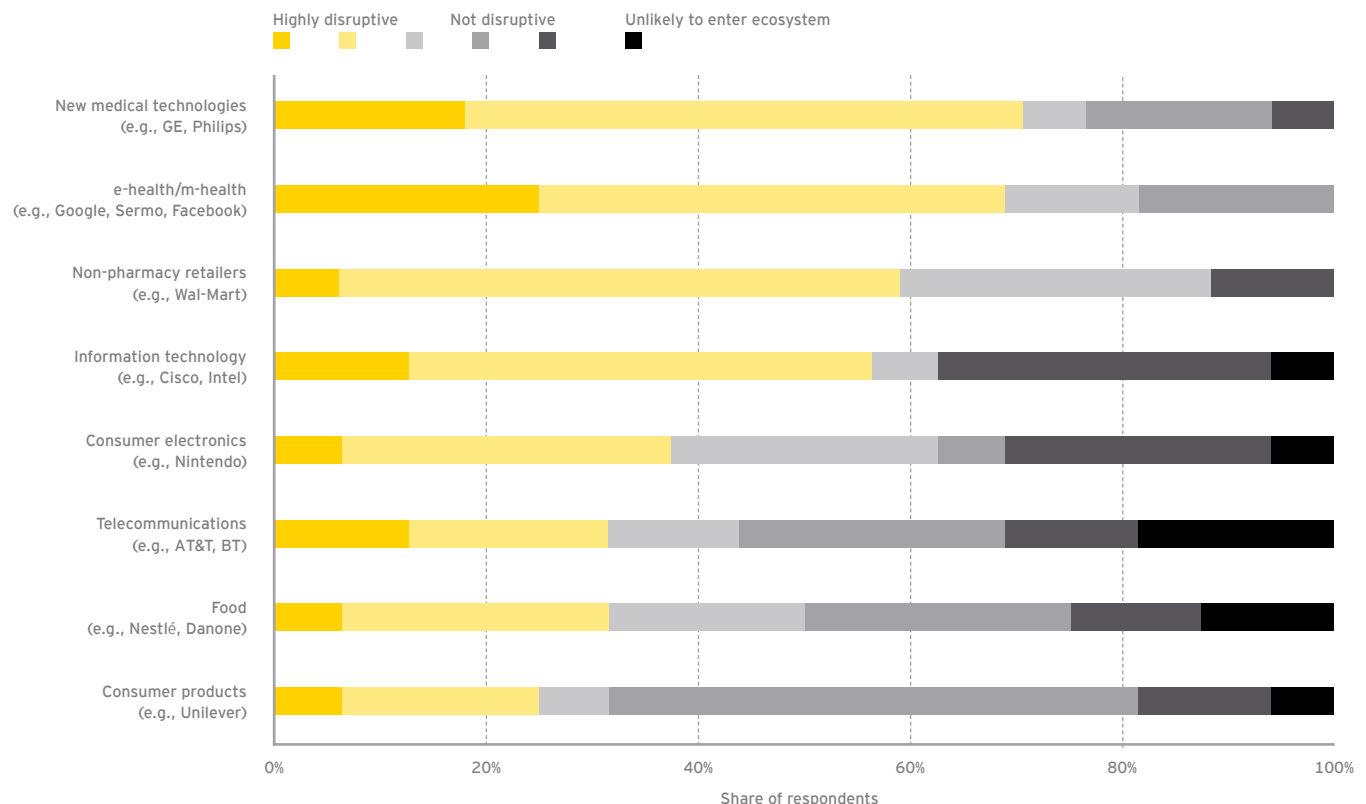
in France, Groupe Danone has made functional foods a linchpin of its market strategy. Over the last decade, the firm has sharpened its focus on functional foods while divesting other divisions.

Cosmetics companies have been moving into the health care space as well, eyeing the intersection between their traditional offerings and health and wellness. Avon's offerings in the wellness category, for instance, include its Curves range of products geared at weight loss and exercise.

Wal-Mart has recently entered the EHR market with a partnership to target smaller doctors' offices. But the health care ambitions of the world's largest retailer extend well beyond electronic records. Among other things, the company already offers in-store medical clinics and is positioning itself for the coming wave of generics with

Degrees of disruption: nontraditional entrants in the ecosystem

How disruptive do you think the potential entry of nontraditional players will be for the pharmaceutical industry?



Source: Ernst & Young Progressions survey, 2009

low-price prescription programs, such as its US\$4 program for generics in the US (launched in 2006 and since expanded to Puerto Rico, Mexico and Brazil). Wal-Mart now provides mail delivery of 90-day supplies for more than 350 generics for US\$10 and has discounted pricing for women's health medicines and more than 1,000 OTC items. Two other major retailers, Target and Krogers, have since launched their own discount programs.

If the world's largest retailer has bold ambitions with respect to health care, it's not surprising that America's leading conglomerate and one of the world's most respected firms – GE – recognizes the sector's tremendous potential as well. In 2005, the conglomerate launched its "ecomagination" initiative, aimed at reducing greenhouse gases and improving energy savings. Building on that success, it launched "healthymagination" in May 2009, a new initiative to invest US\$3 billion in R&D aimed at launching at least 100 innovations in the health care sector that reduce costs, increase access and improve quality. In the Pharma 3.0 ecosystem, it is the companies that can help move the needle on those measures that stand to gain market share and reap financial rewards.

- **Other people's money.** Pharma 2.0 was driven in part by the public and private capital poured into academic medical centers and biotech start-ups. To fuel the growing "healthy outcomes" ecosystem of Pharma 3.0, private equity (PE) firms have become increasingly active in recent years. The first wave of activity was not in traditional buyouts but rather in project-financing deals by specialized funds. Companies such as Symphony Capital and a number of royalty financing funds entered transactions that provided capital to biotech companies. In many cases, these new transactions were motivated by perceived valuation gaps, such as the valuation bump that

companies experience from positive proof-of-concept data, such as in the case of Symphony, or the premiums that pharma-company buyers are willing to pay for de-risked R&D assets.

*For this **Progressions** report, we polled business development and innovation leaders and found overwhelming agreement that these new entrants will play an increasingly important role in the healthy outcomes ecosystem.*

More recently, PE firms have been expanding into other segments of the ecosystem. There is, for instance, the opportunity created by pharmaceutical companies' need to boost R&D productivity at a time when resources are becoming increasingly scarce (as the cost of capital rises and revenue streams dry up). In July 2008, for instance, Eli Lilly announced a deal with TPG-Axon Capital (an affiliate of PE major Texas Pacific Group) and NovaQuest (a division of CRO giant Quintiles). Under the deal, TPG and NovaQuest provided financial capital and R&D advice to Lilly on two Alzheimer's compounds that were entering Phase III trials, in exchange for milestones and royalties.

The list of potential new entrants extends far beyond the sample listed here. In the US, the Obama administration is positioning health care reform as one of three investments in the future (energy and education are the others) that will lay the foundation for a more competitive 21st-century economy. That focus, if nothing else, sends a strong signal to the market. Across the global economy, firms looking for new growth opportunities are going to be attracted to the health-outcomes business. The ecosystem is about to become a lot more crowded and a lot more complex.

In our 2009 *Progressions* survey for this report, we polled business development and innovation leaders and found overwhelming agreement that these new entrants will play an increasingly important role in the healthy outcomes ecosystem. Looking at total responses across all categories of potential entrants, 92% of the respondents said that it is likely that new entrants will enter the ecosystem. Looking at responses by category, the most likely new entrants (as well as most potentially highly disruptive) are e-health/m-health and new-medical-technologies companies, where 100% of the respondents thought that these firms are likely to enter the ecosystem. (Read more on our survey in Chapters 2 and 3.)

On the opposite end, respondents were least confident about telecommunications operators entering the ecosystem, where a relatively low 81% of respondents thought that their entry was likely, followed by food companies at 87%. Food companies, as well as consumer product companies, were also considered to have the smallest disruptive potential on the ecosystem. Interestingly, non-pharmacy retailers ranked among the top four most potentially disruptive entrants, which might reflect the outsized impact that Wal-Mart has on any industry it touches, as well as the growing health-sector activity by retailers in Europe and Latin America.

Extraprise vs. enterprise

For pharmaceutical companies, Pharma 3.0 will bring a future in which they have much less "command and control" over the drivers of their profitability and enterprise value. This represents a radical departure from the world as they have known it, a world in which companies have taken huge R&D risks to develop new drugs but in exchange could count on largely unfettered access to relatively stable markets for at least a decade after launch.

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In the future, in the healthy outcomes ecosystem, life sciences companies will be rewarded not for how many units of a drug they sell, but for how individual patients respond to that drug – something that is inherently less predictable and less within their control. They will need to be able to manage and influence the growth and direction of the “extraprize” rather than the enterprise that resides within their corporate walls. Building business processes that allow them to stay up with and help modify the rules of the game and incentives in the ecosystem will be a necessary management skill of executives. The example of risk-sharing pricing models some companies have had to adopt to secure coverage by the UK’s National Institute for Health and Clinical Excellence (NICE) are likely just a precursor of what the future holds. The introduction of a risk evaluation and mitigation strategy (REMS) regime by the FDA could be a competitive advantage if a pharma company and its partners/customers can create a framework that defines a new standard of care. Another example is the implications of the expansion in the quantity and quality of electronic health data. In the past, successful drug development stemmed from having good *clinical trial data*, which companies owned and controlled. In the future, their success in the market will instead be determined by *post-marketing data*, of which they will no longer have sole possession.

Change may also come faster than the pharma industry is used to. As one pharma executive we interviewed pointed out, “five years from now, the pharmaceutical industry will not just be in the business of creating and developing pills or drugs. We will instead need to move to selling a health care concept based on information, health records, diagnostics and prediction.”

Five years is not a long time in an industry where it takes over a decade just to bring a new product to market, but it is several product lifetimes in the rapid-fire, Moore’s Law-governed



In the past, successful drug development stemmed from having good *clinical trial data*, which companies owned and controlled. In the future, their success in the market will instead be determined by *post-marketing data*, of which they will no longer have sole possession.

world of tech. Microsoft’s HealthVault and Google Health have grown rapidly in a dizzying flurry of partnerships – even though both are still officially beta releases. And 16 months after its launch, Apple’s App Store had gone from nothing to 100,000 applications and over 2 billion downloads – some of which will likely play their part in shaking up some existing paradigms. Five years from now, the pharma industry will finally be on the other side of the patent cliff, health care reforms will likely have been enacted in many major markets, comparative effectiveness should be more widespread, and digital health data may be vastly expanded and considerably improved.

To understand the pace of change and its implications, we convened a group of business development leaders from pharmaceutical companies and numerous nontraditional players in New York last July for a day-long strategy and brainstorming session. The session was kicked off by a roundtable discussion (which also forms the basis for the first of the roundtable articles in this year’s *Progressions*). As the discussion commenced, Pfizer’s Kristin Peck, Senior Vice President, Strategy and Innovation, set the tone with a bold recognition of where the industry is heading. “Health care as we know it is changing rapidly,” she pronounced. “The era of control over data is ending. Data will not be owned by one person but owned by many, with very different incentives.”

The question Kristin posed next is also right on point. “Once you accept that you don’t have control, how do you go about embracing the new reality?” And that’s what the rest of this report will focus on, because the shifts we are describing will have implications for everything from business models to business development, and companies will need to move quickly and creatively to adapt to the new ecosystem. ►

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Roundtable on the changing ecosystem

Embracing the new reality



Moderated by:
Dave DeMarco, Ph.D.
Ernst & Young LLP
Principal and Northeast US
Pharmaceutical Leader



Esther Dyson
EDventure Holdings Inc.
CEO



Wendy Everett, Sc.D.
New England
Healthcare Institute
President



David Norton
Johnson & Johnson, Inc.
Company Group Chairman,
Pharmaceutical Group



Kristin Peck
Pfizer Inc.
Company Senior Vice
President, Strategy and
Innovation

It's a whole new ecosystem out there. A host of nontraditional players are entering, from IT companies to large retailers to micro-lenders. The very business of pharma is being transformed from producing drugs to delivering outcomes.

Having examined these macro trends in Chapter 1, let's more fully examine what they mean for pharmaceutical companies. How do industry experts see the world of pharma changing? What are the biggest challenges confronting the executives on the front lines of these shifts? How are they responding, and what else might we see in the months and years ahead?

To answer these questions, we assembled four leading experts for a roundtable discussion on the changing ecosystem. The roundtable – conducted as part of our Rapid Innovation Session in New York City – benefited from the varied backgrounds and perspectives of the participants. As industry veterans, Pfizer's Kristin Peck and Johnson & Johnson's David Norton have seen a lot of change over their careers, and their candid assessments of the sweeping transformations now under way are thought-provoking and stimulating. As President of the New England Healthcare Institute, Wendy Everett is well suited to seeing the world through new eyes – she's been bringing together participants from across the health ecosystem for close to a decade. And Esther Dyson's multifaceted background – technologist, journalist, entrepreneur, investor – allowed her to provide valuable perspectives about the digital realms in which pharma will increasingly need to play. The roundtable was moderated by Ernst & Young's Pharmaceutical Leader in the Northeast US, Dave DeMarco.

DeMarco: How is the ecosystem that pharmaceutical companies inhabit changing?

Norton: To a great extent, we have lost control of the data and, in many ways, our traditional position as information providers. Patients and others (e.g., managed care providers and pharmacy benefit managers) now have much more information than we do. They can identify issues such as adverse side effects or inappropriate use of our products much earlier than we can. How will they use this control? Will pharma companies benefit from richer information so that we can deliver better outcomes?

Peck: Health care as we know it is changing rapidly. The era of control over data is ending. Data will not be owned by one person but owned by many, with very different incentives. Once you accept that you don't have control, how do you go about embracing the new reality? We need a paradigm shift in how we think about data, how we think about outcomes. To me, it's about delivering outcomes and healthier patients.

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Everett: The key change for me is the growing interest in personalized medicine. Personalized medicine is all about the individual. People are not averages. How do you create the right outcomes for individuals? We are at the point where we have both the power and the data to actually deliver improved outcomes – the challenge is how to make it happen.

DeMarco: What challenges will companies face in this transition?

Dyson: Data ownership will be a pivotal issue. For example, it has been commonplace that research subjects do not have access to their own clinical data. How do you go from that extreme to the growing movement where patients are saying: “It’s *my* data, and I should have access to it?”

Norton: A key hurdle will be accessing the data – at this time, there’s no single place to go for electronic records, and nobody has established a common format and guidelines for the “universal” record. Pharma could gain competitive advantage by moving early to forge collaborations with data vaults. We could then deliver better information and value to patients. And in the end, that’s what counts.

Dyson: Or maybe the centralized repository for this data is not some institution. Just as personal finance software such as Quicken enabled people to download data from all their financial institutions and integrate it themselves, there’s a new generation of patient-health databases to which consumers have access and from which they can integrate all their data themselves.

DeMarco: Let’s just play that out. Paint a scenario of how the world will change over the next five years.

Norton: You’ve heard of open-source code? Five to 10 years from now, there will be open-source medical research. Now, that horrifies medical researchers because it raises several issues, such as how to establish clinical validity, but the benefits are compelling. Five years from now, we’ll have millions and millions of genomes and associated phenotypic information. And people will routinely monitor their health-related behavior and outcomes – from weight fluctuations to blood pressure and more.

Peck: There’s more data out there than we are currently capturing in records. There’s a real-world need for real-world data. With it, we could be better informed, and in turn offer better choices for patients and physicians. But because many do not consider this pool of nontraditional data to have validity, it is often ignored. Yet five years from now, this data will probably prove to be just as significant as the traditional-source data that we use today.

“To a great extent, we have lost control of the data and, in many ways, our traditional position as information providers. ... Pharma could gain competitive advantage by moving early to forge collaborations with data vaults. We could then deliver better information and value to patients. And in the end, that’s what counts.”

Norton: I think we already have more data than we can manage and analyze. Certainly much more data than patients, who want to be empowered, can understand on their own. Who’s going to help set up systems that allow me to only focus on the data that is relevant in the short term or long term and ignore the data that is irrelevant? If somebody showed up in your office with seventeen volumes of data not organized or categorized in any way, you wouldn’t be able to use it. But if we can build this huge database – of self-reported patient data, physician observations, lab findings and other objective data – you could, over time, for example, determine common attributes for people who survived 10 years of pancreatic cancer. Data needs to become information so that we can use it to ask better questions. Right now, it’s just a million points of data.

DeMarco: How is technology empowering patients and enabling these shifts?

Peck: Consider what’s already happening. I have an inexpensive app for my iPod that prompts me to record my weight every morning. Compare this to the single, once-a-year data point on my weight that my doctor gets during my annual physical. With more data points, we can make real-time changes in

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behavior and draw much better conclusions, such as correlating weight with health. All of this translates to big steps forward in improving health outcomes.

"You can't manage what you can't measure, and there are now more and more tools that allow patients to start measuring themselves. ... Patients are becoming better informed about their health and they have more data than we do. The challenge for pharma is to take advantage of this."

Dyson: Absolutely. You can't manage what you can't measure, and there are now more and more tools that allow patients to start measuring themselves. Look at the wonderfully named Polka-dot-com in which you can record behavior data – such as food intake, exercise, sleep – and then view a chart that shows the impact of your behavior on your weight or well-being. [Disclosure: Esther Dyson subsequently invested in Polka.com.] Patients are becoming better informed about their health and they have more data than we do. The challenge for pharma is to take advantage of this.

As technology advances quickly, it is also very important to leverage the right technology for the right patient population. For example, for programs targeting teens and tweens, short message service (SMS) and social media are far more effective communication channels than email.

Peck: We're teaming with multiple partners to try to create "the Google of patient information from clinical trials." We have found that 90% of people who participate in a clinical trial have a positive experience. But convincing new patients to participate in trials is challenging. And once patients are interested, finding the right trials can also be challenging: some patients are not comfortable sharing personal information and medical history with researchers they don't know, yet this information is needed to match them with the trial that can help them most. Our goal is to increase patient interest in clinical trials as a potential treatment option, and then to broaden patient access to trials – trials that otherwise many would never know about – while enabling patients to control access to private information during the process.

DeMarco: How rapidly might this all take place? How will different constituents need to collaborate to make it happen?

Everett: Historically and regrettably, it has taken payors, providers, hospitals and physicians about 17 years to adopt a given innovation. We need to somehow whittle that down to

months, not years. The key is in collaborations – getting people who don't usually work together to partner and to use their combined intellect to solve cross-cutting issues. It has taken a while, but we are finally seeing a genuine and widespread acceptance of the need to collaborate to address our biggest health care challenges, to the point where we are seeing "unholy alliances" among constituents in the health economy that would traditionally not collaborate. In the US, payors, providers and pharma have come together with a widespread acceptance of the need to reform health care. In June 2009, representatives from these industries went together to Washington, DC, with an offer to decrease the cost of health care by 1.5% over the next 10 years. They will still compete, still have to negotiate contracts, but the fact that they realize they can work collaboratively to solve some of the problems of health care is critical. But it's going to be small incremental changes over time, and we have a long way to go.

Peck: The greatest collaborations will be those where everyone has the same goal, the goal of healthier patients. Right now, the goal is too often aimed only at lowering costs and increasing margins, not at improving outcomes.

Dyson: To enable the sorts of partnerships we will need, the issue of incentives for collaboration is critical. Right now, the incentives are misaligned. Across the health care system, we pay for care rather than paying for health.

DeMarco: Are there players that are not currently in the health care ecosystem but which will play an increasingly important role over time? How will pharma's business models need to change to work with these new entrants?

Dyson: We need to be talking to consumers before they get sick, for example, by working with health clubs – look at the joint venture between Virgin and Humana. The focus will shift to prevention and wellness, and the players who know how to talk to consumers and operate in that space will have a much larger voice and stake in the game.

Also, drug compliance is a real issue. Mobile health may be one way to chip away at it through partnerships with telecommunications companies and the ability to create mobile phone reminders or SMS text messages.

"It has taken a while, but we are finally seeing a genuine and widespread acceptance of the need to collaborate to address our biggest health care challenges, to the point where we are seeing 'unholy alliances' among constituents in the health economy that would traditionally not collaborate."

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New entrants will face challenges, too. For example, I know a beauty company with a strong global distribution network that is trying to transition to the health-and-beauty wellness business. The premise is that beauty, particularly in certain cultures, is about inner and outer beauty – an overall concept of wellness. So, the company feels it is part of this ecosystem, but it is not viewed that way – not yet, anyway.

Peck: Pharma faces a lot of skepticism from potential partners, too. I've had so many meetings with companies outside of the health care arena, companies that are attractive because of the data they own. Often times, the stigma of partnering with pharma or the difficulty in finding ways to share our data make this potential collaboration reach a dead end. Players across the health care and technology spectrums have to begin to realize they are in this together and collaborate more broadly.

Norton: The big struggle for us is going to be how to deal with forces pushing and pulling in opposite directions. Should there be a business model for wellness and a separate business model for sickness? Is there this break where I look after you when you're well and then, when you're sick, hand you over to someone else? Can we still have the traditional aspects of a business model?

DeMarco: What about the role of government in health care?

Everett: So far, the US has been an exception when it comes to the role of government in health care, because in most of the world, governments have a much bigger role. For better or for worse, we will have to deal much more with political decision-makers and government from now on. We need to consider how we move that part of the ecosystem in the right direction.

Dyson: The top 20% of any market often set the standards. It's interesting in the case of health care because the top 20% – the sickest people – are not necessarily the most upscale. But they are the ones with the time, the incentives and the passion to lead the charge and help shape government action.

DeMarco: If you could wave a magic wand and change one thing about today's health care system, what would you change?

Dyson: I think the real answer begins with health, as opposed to health care, which often really refers to sick care. Now individuals can monitor their own behavior and data with new sensors and software, including cell phone apps. They can also share the data with their friends, who may motivate them to good behavior when self-discipline flags. Providing these tools and services can be a profitable business. As for the wand – I guess I'd use it to accelerate this market, by getting payors to understand the value and to pay for such services.

Everett: One thing we haven't talked about today is the role of the food industry in the health ecosystem. Earlier this year, obesity passed smoking as the largest contributor to mortality in the US. Only the top 10% or so of the population is informed and actively engaged in managing their health care. Smoking and obesity are very much connected to socioeconomic patterns, and many of the people affected may not even be aware of the issues or of some of the innovations available to manage their health. So, I would use my magic wand to adopt incentives that really drive people toward actively managing their own health.

"The big struggle for us is going to be how to deal with forces pushing and pulling in opposite directions. Should there be a business model for wellness and a separate business model for sickness?"

Norton: I agree with that. I'd use my wand to completely realign the incentive system so that there are financial incentives that drive people toward managing their health. That would include aligning incentives to pay for outcomes rather than continuing to pay for services.

Peck: One great thing is that health care is becoming an individual right in many societies around the globe. But the danger of it becoming a right is that individuals, as a consequence, don't feel they should have to pay anything or do anything to contribute to their health. Personally, I think the personal incentives have to change so that people take personal responsibility for their health. Education plays an incredible role in making this happen. Japan has three indicators to predict whether you are at risk for heart disease. It's a really easy diagnostic; any person can do it in their house. Can you bring that kind of awareness to the masses? If we can give people both the right to health care as well as the incentives and control over information with which to take responsibility for their health, then we will have accomplished what we need: empowering patients for a patient-centric ecosystem. ►

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Other people's capital

New business models



Other people's capital

New business models

In brief

- ▶ To remain relevant in the changing ecosystem will require new Pharma 3.0 business models aimed at value propositions related to delivering healthy outcomes.
- ▶ To build new business models and access capabilities, pharma companies will need to partner in creative ways, including with nontraditional entrants – simply “buying it” will no longer be an option.
- ▶ Business model development (as distinct from business development) is as much about validating strategy and testing innovation as it is about “getting the deal done.” This will require a more strategic approach, longer-term involvement of multiple functions and adequate resources.
- ▶ A “commercial trials” process for new business model development involves experimenting in the market with multiple ideas, winnowing out the ones that don't work, active learning from failure, then commercializing and scaling up the successes.
- ▶ Given that commercial trials will be done in public as creative collaborations or business ventures with rapid market prototyping, a multifunctional commitment from the innovators is critical.

We use the expression “healthy outcomes” to refer to *positive* changes in the health status of individuals, groups or populations which are attributable to human interventions.

- ▶ **Meeting unmet medical needs**, for example in complex indications such as oncology or immunology as well as in underserved therapeutic fields such as malaria, dengue fever and orphan diseases

To deliver on these value propositions, pharma companies will need to change their business models in fundamental ways. While this will require pharma to undertake unprecedented reforms – and companies will need to overcome significant obstacles along the way – there are examples from firms in other industries that have successfully made similar transitions.

Managing patient outcomes. The first imperative for developing new business models in the Pharma 3.0 ecosystem – managing patient outcomes – will require companies to revisit the very foundation of their business model: their “offer,” or what they produce. While the industry's current business model is built around developing and delivering drugs, enabling health outcomes will require pharmaceutical companies to get involved in the cycle of care of the patient. This shift – from selling products to delivering services – will require pharma firms to develop resources, capabilities and customer relationships that are largely absent in today's pharmaceutical industry.

New business models for Pharma 3.0

We have seen in Chapter 1 how the pharmaceutical industry is changing from today's Pharma 2.0 drug development and delivery ecosystem to Pharma 3.0, the healthy outcomes ecosystem. To remain relevant, pharmaceutical companies will need new business models geared around the premise of the Pharma 3.0 ecosystem: delivering healthy outcomes to a more complex customer landscape that includes payors, patients and physicians.

To appreciate the challenges companies face in developing business models around healthy outcomes, we need to start by defining the term itself. We use the expression “healthy outcomes” to refer to *positive* changes in the health status of individuals, groups or populations which are attributable to human interventions. For a pharma company to deliver such health-status improvements, it basically needs to either reach *new* patients (by tackling underserved markets or unmet medical needs) or do a better job of serving *existing* patients (by managing patient outcomes). As such, companies looking to develop new business models for Pharma 3.0 will need to build their models around some combination of three core value propositions:

- ▶ **Managing patient outcomes**, for example by fostering patient compliance through patient engagement or enabling a more targeted health care delivery through patient population stratification
- ▶ **Expanding access to health care**, for example in underserved markets, including emerging markets and uninsured patient populations in industrialized nations

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This shift – from selling products to delivering services – will require pharma firms to develop resources, capabilities and customer relationships that are largely absent in today's pharmaceutical industry.

There are scores of examples of product companies in other industries that have made the transition to delivering services – and reaped benefits in customer loyalty, long-term relationships, critical feedback loops and stronger financial results. As margins declined in the increasingly commoditized personal computer (PC) business, for instance, IBM increased its focus on services and eventually spun off its PC operations in 2005. Nor is “Big Blue” the only PC manufacturer drawn to services – in 2009, industry giant Dell announced its intent to acquire Perot Systems, a transaction that would give the firm a much-expanded footprint in applications development, systems integration and strategic consulting. In the aircraft engine business, Rolls-Royce has moved beyond manufacturing to fully servicing the jet engines for its airline customers, basically charging a

Today, as pharma's margins face increasing pressure from payors and generic competitors, a move to service offerings could bring similar benefits: a way to differentiate oneself and build brand amid commoditization, with higher margins and more stable sources of revenue.

fee per hour of running engine. In other instances – such as GM's GMAC and OnStar divisions – firms have expanded into ancillary services partly as a way to drive growth in the core product business. Today, as pharma's margins face increasing pressure from payors and generic competitors, a move to service offerings could bring similar benefits: a way to differentiate oneself and build brand amid commoditization, with higher margins and more stable sources of revenue.

Expanding access. In some geographies, and particularly in emerging markets, the pharma industry's current business model cannot offer a value proposition for low-income patients and remote rural areas. To expand access to new patients, companies will need creative solutions to make the numbers work – new revenue models, pricing mechanisms and distribution networks. Additionally, expanding access will require companies to better understand the attitudes and social context of micro-cultures in the developed and developing worlds.

Here, too, there are examples of creative models from other industries. Consumer goods giant Unilever, for instance, has introduced Project Shakti to expand access in rural Indian markets. The venture combines innovative packaging in the form of sachets for low-income consumers with a distribution channel built around entrepreneurial rural women with whom Unilever partners, offering them the opportunity to create a micro-enterprise eligible for micro-credit funding from sponsoring agencies such as nongovernmental organizations (NGOs), government bodies or public-sector banks. Similarly, the astounding success that mobile telecommunications firms have achieved in penetrating developing-country markets is attributable to creative business models tailored for local conditions – offering affordable pay-as-you-go plans with per-second (rather than per-minute) billing, among other things.

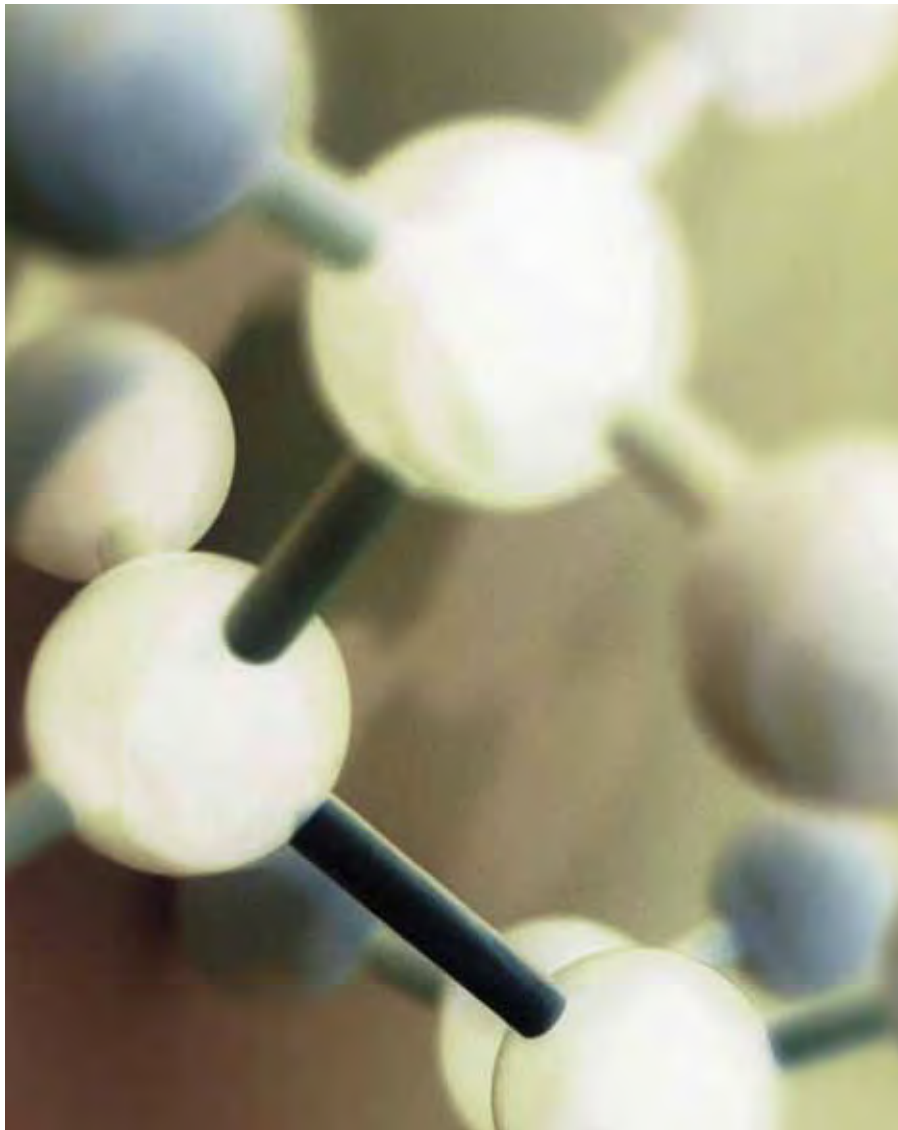
Meeting unmet medical needs. Lastly, companies will need to develop business models that focus on serving unmet medical needs. This is a two-part issue. The first component – involving the need to move beyond chronic diseases and develop breakthrough treatments for more complex challenges such as cancer – is a Pharma 2.0 challenge that companies have been grappling with for some time now. So far, in Pharma 2.0, companies have been reinventing their structures and incentives to boost R&D productivity. Now, in Pharma 3.0, companies may move beyond these measures to embrace more creative, outside-in approaches such as “open innovation.”

So far, in Pharma 2.0, companies have been reinventing their structures and incentives to boost R&D productivity. Now, in Pharma 3.0, companies may move beyond these measures to embrace more creative, outside-in approaches such as “open innovation.”

The second part of the unmet medical needs challenge is in the field of neglected diseases. This is not just a scientific challenge but, more fundamentally, a commercial one. Despite new funding schemes and partnerships for development, progress in addressing these unmet medical needs on the ground is slow, and companies will need to develop creative approaches – frequently by partnering with nontraditional players – to make the numbers work.

In the IT sector, many companies – including some long-standing ones – have become comfortable working in innovation models based on open code or involving true open innovation networks,

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In these collaborations, the relationship with the partner adds to the core capabilities of the pharmaceutical player or expands its resources to allow it to better deliver on the Pharma 1.0 or 2.0 value proposition. In the Pharma 3.0 ecosystem, stakeholders will combine key elements of their business models, i.e., capabilities, resources, channels and customer relationships, to deliver on the new value proposition around healthy outcomes. Designing these business models will require companies to learn how to fit into the changing business models of other key players in the ecosystem. Pharmaceutical companies and new entrants will have to step outside their comfort zones and areas of expertise.

The winners will need to understand not “what is invented here” but “what is being done elsewhere,” including in other sectors, so that the result is a much more “outside-in” way of innovating. It’s about learning how to become a critical component of another firm’s business model in order to leverage its assets and attributes.

both on the product development and commercial model fronts. Prominent examples include Red Hat (which uses open-source software development for a distribution of the Linux operating system) and Mozilla Corporation (whose Firefox web browser is also based on open-source code).

Everyone else’s business model

Delivering healthy outcomes will require the pharmaceutical industry to engage with nontraditional players, bundling business models in symbiotic,

co-creative interaction. It will be about co-creating value for the customer – patients, payors and governments – as well as for the partners.

Today’s Pharma 2.0 “contractual” collaborative approach – where the industry is in the driver’s seat, managing collaborations with biotechnology companies, CROs and academia, and where most of the value creation is controlled and commercialized by the pharmaceutical company – is not a sustainable proposition in the new ecosystem.

Innovation here is not just about the pipeline, but about how to do business. The winners will need to understand not “what is invented here” but “what is being done elsewhere,” including in other sectors, so that the result is a much more “outside-in” way of innovating. It’s about learning how to become a critical component of another firm’s business model in order to leverage each other’s assets and attributes.

Media copy

Making it real: scenario planning

To explore what lies ahead, we gathered 30 executives in a one-day Rapid Innovation Session to conduct scenario planning. The scenario planning was not intended for making predictions about the future, but rather for improving understanding of what companies need to do today to prepare for an uncertain future. In an atmosphere that resembled a cross between a Montessori school for adults and a state-of-the-art “idea lab,” we created a safe environment for executives to step outside their comfort zones and daily experiences in order to imagine the future of the healthy outcomes ecosystem.

Our guests represented a broad spectrum of business development and innovation executives from industries holding stakes in the current and future ecosystem. We immersed them in three deal-simulation exercises involving hypothetical Pharma 3.0 collaborations. Working in cross-industry teams, they articulated the value propositions underlying new business models for

these alliances, as well as their strategic rationales and visions.

The deals

Deal simulation A

The first hypothetical deal brought together a Pharma 2.0 company, a global insurance company and an internet services leader. The executives working on this simulation articulated value propositions based on delivering wellness and facilitating healthy lives for customers.

In this deal, the internet services partner contributes its PHR platform as well as access to patient data and insights. It also serves as a point-of-contact for patient engagement, allowing the alliance to get directly involved in the patient’s cycle of care. In turn, the alliance benefits by gaining a new revenue model.

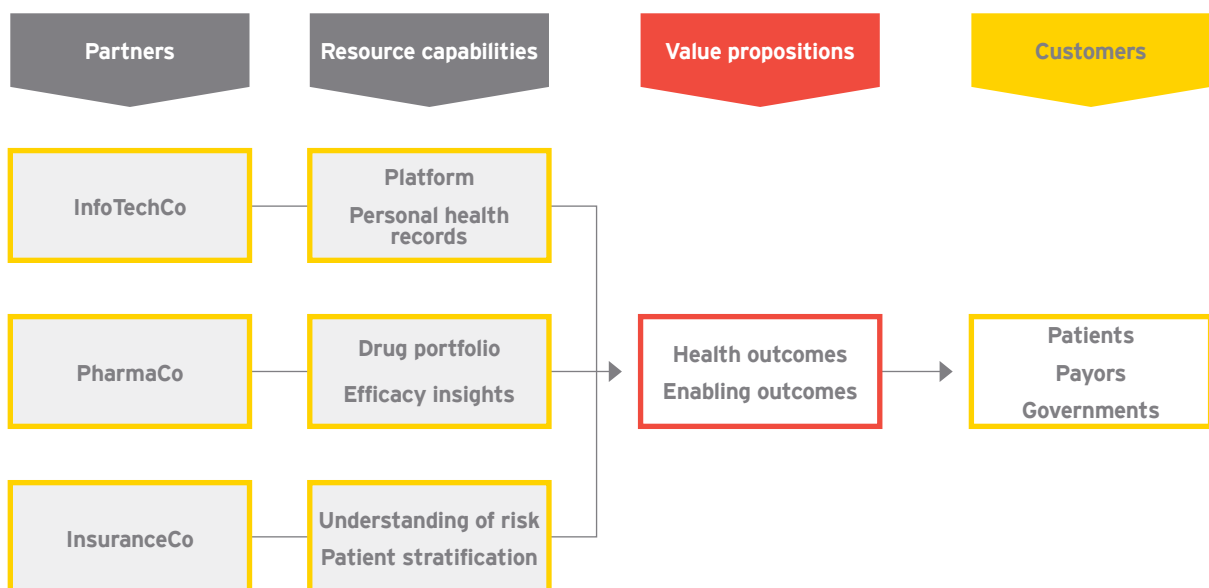
The global insurance company brings its data analytics and risk-management capabilities to the deal. These capabilities were seen as key to

translating and leveraging the data flow from the PHR platform into actionable information, for example through patient population stratification. In addition, these analytical strengths could also allow for more aggressive and dynamic pricing strategies and offers. In turn, the insurance firm gains better risk data and a new line of business.

The pharmaceutical company contributes its portfolio of drugs and insights about their efficacy. The alliance allows optimal use of its drug portfolio, driving compliance and providing a feedback loop on drug usage. It also allows targeted and improved R&D by directly accessing patient data for drug discovery and clinical trials. On the revenue side, the deal brings increased sales together with the potential of directly proving the value of the drug portfolio on the health outcomes of the patient population.

From a business model perspective, the new value proposition revolves around enabling health outcomes and bundles together the elements of the very different business models of the players involved. The combined

Deal simulation A



Source: Ernst & Young 2010

Media copy

model also allows the partners to leverage each other's assets, such as an internet platform, a drug portfolio and risk analytics. On the capabilities side, it combines strengths centered on patient health data, patient population stratification and the efficacy insights of the drugs. The new business model also aligns patient incentives, such as financial security, access to information and proven efficacy to drive patient empowerment and compliance.

With its holistic approach to enabling health outcomes, this deal brings the potential for strategic value-based collaborations with governments, both in developed and in emerging markets.

Deal simulation B

The second deal simulation brought together a Pharma 2.0 company, a direct-sales organization and a global food and beverage company – a transaction based on the value proposition of delivering global health.

The direct sales company brings its unique sales model to the collaboration.

This facilitates unprecedented customer intimacy for a health care enterprise, with promoters being in regular and direct contact with their rural and urban customers. The model involves the customer in a direct-feedback loop on health and drug usage. The deal extends the product portfolio of the direct-sales company.

The food company brings a portfolio of nutritional products that allows the newly created enterprise to expand its role in the patient's cycle of care to prevention and long-term care. The deal brings the potential for a new positioning of the food company in the health care sector, together with a new channel to the market.

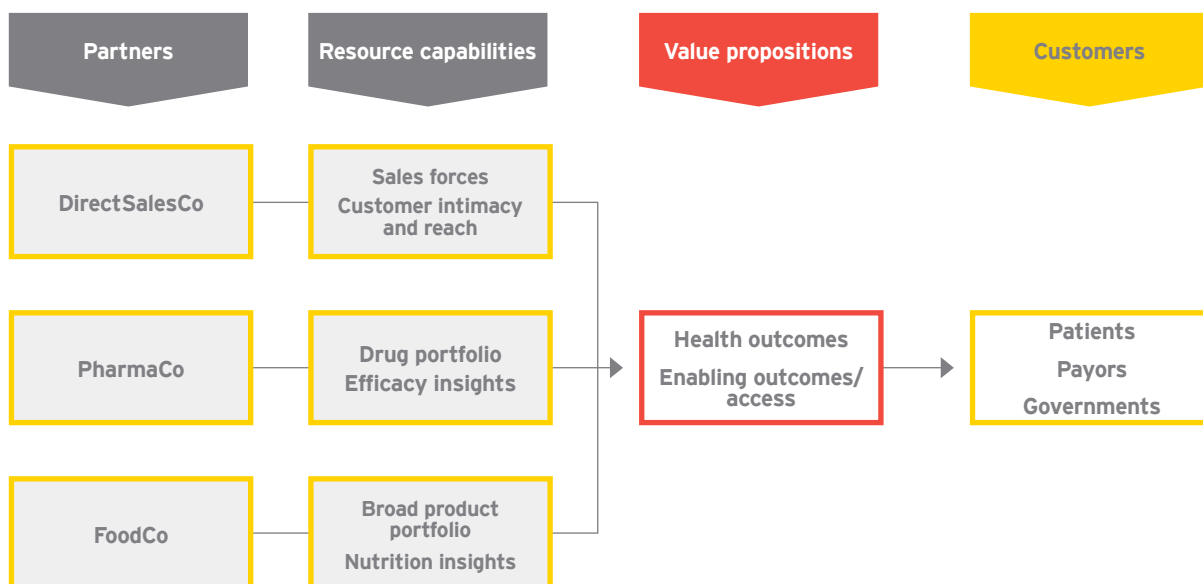
The pharmaceutical company contributes its portfolio of drugs and insights about their efficacy. The customer intimacy of the direct-sales model creates a dynamic mechanism for connecting with the customer, helping drive the optimal use of the drug portfolio as well as drug compliance. The deal brings increased sales volume for the pharmaceutical player, creating

a cost-effective way to expand its sales reach and customer base outside the traditional avenues in both urban and rural locations in emerging markets.

From a business model perspective, the new value proposition revolves around enabling outcomes with a focus on prevention as well as improved access. On the resources side, the model combines a strong "on the ground" sales force with a broad portfolio of nutritional products and drugs. It offers a unique combination of capabilities such as customer intimacy and reach together with nutritional and drug efficacy insights. Additionally, this innovative alliance allows a high-touch relationship with the customer to deliver a portfolio of products for every age group aligned to the cycle of care from prevention and treatment to long-term care.

With its customer-centric approach encompassing food and drugs, a partnership such as this could become a category leader in life-style-associated chronic diseases. Meanwhile, the direct-sales infrastructure could facilitate tremendous reach in emerging markets.

Deal simulation B



Source: Ernst & Young 2010

Media copy

Deal simulation C (wildcard)

To try to surpass the potential health outcomes achieved and value created by Deals A and B, the participants on the Deal C team were allowed to build an innovative alliance using any combination of traditional and nontraditional players. The team created an alliance involving a global financial services enterprise, a health care provider (leading not-for-profit hospital/ medical practice), and an internet services company.

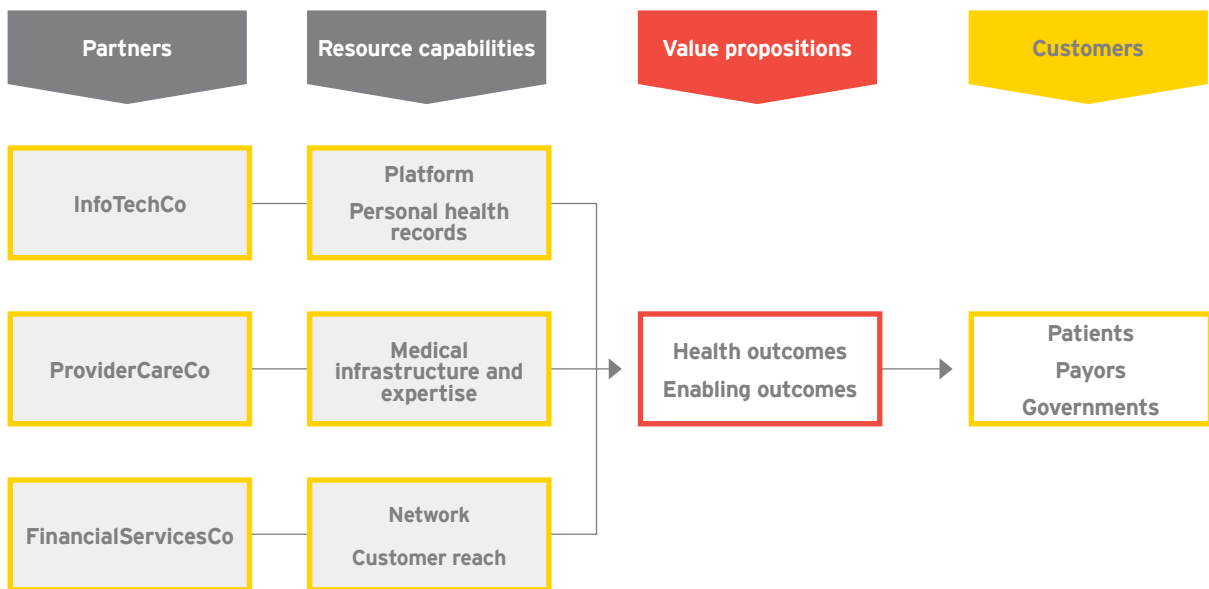
As in Deal A, the internet services company brings access to patient health data and allows direct patient engagement through its EHR platform. The financial services player enters the partnership as a trusted beneficiary of personal health records and provides a unique access to potential customers through its sales and marketing channel.

Remarkably, the alliance did not include a pharmaceutical firm – the parties felt that partnering with a single pharma company would limit their ability to provide health outcomes that leverage

the most appropriate combination of products for a given patient. They also believed that the “pill” would become more of a “sourcing strategy” that could be managed for quality at a highly competitive cost.

The business model, aimed at enabling outcomes, brings together the three players’ key resources and capabilities: medical infrastructure and expertise, an IT platform for the management of PHRs, and the financial services company’s network, which allows for unique access to customers.

Deal simulation C (wildcard)



Source: Ernst & Young 2010

Media copy

Pharma has often approached assets with an acquirer's mindset. ... But succeeding in the future will instead require companies to develop new products entirely from scratch. You can't buy it if it doesn't exist.

Early examples: Pharma 3.0 today

Pharma 3.0 is already happening today, albeit in smaller scale as pharmaceutical companies launch initiatives to test the waters. Some examples are listed in the accompanying table on pages 32 and 33.

It's all about execution

The three deals showcased how Pharma 3.0 business models could be structured to deliver health outcomes and build competitive advantage and brand around the customer experience. They also clearly highlighted that pharma companies do not have the necessary assets and attributes to move to Pharma 3.0 on their own – a world that is patient-insightful, customer-centric and measured on healthy outcomes.

While high-level business models, strategic rationales or visions were easily articulated, the discussion around the execution of these deals revealed a high degree of complexity. A recurrent discussion topic was valuation of the relative contributions of different partners. What creates the most value? Is it the medicine, the knowledge about efficacy, the data, the risk analytics or the channel to the consumer? And what provides more value over time? Who owns the intellectual property? Can it be shared with the parent companies? As they move forward, companies will have to address questions such as these. Other execution challenges that were identified include: deal structuring and governance;

management of cultural differences; new talent pipeline; and the emergence of new risks in the fields of data privacy, security and regulatory compliance.

These challenges are discussed more fully in Chapter 3 of this publication.

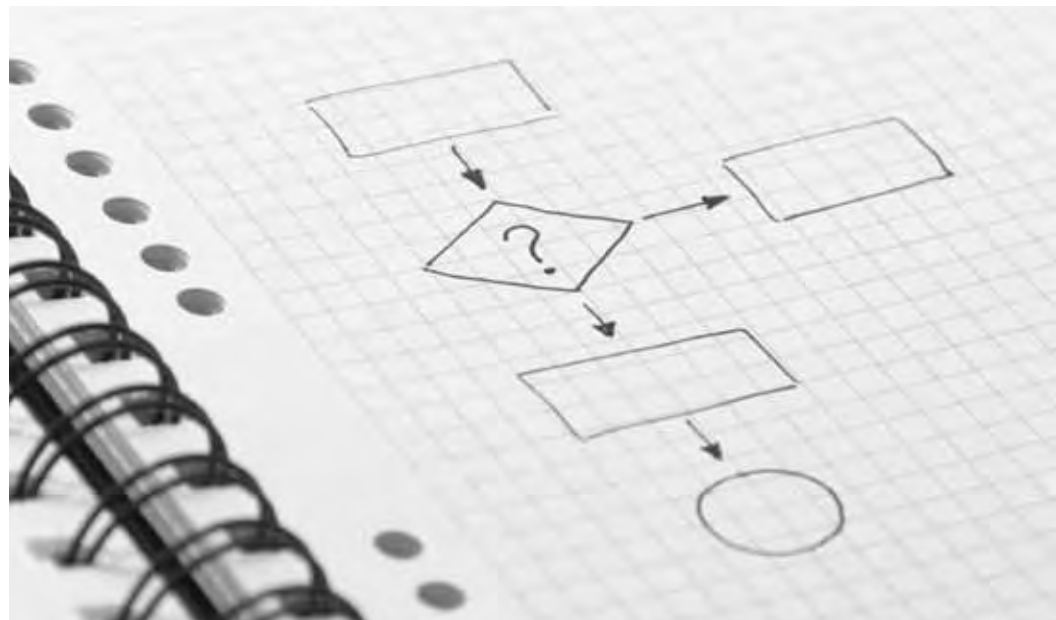
From business development to business *model* development

To successfully execute on new business model development, pharmaceutical companies will need to partner in new ways. Pharma has often approached assets with an acquirer's mindset – buying a company outright or in-licensing its intellectual property to take over late-stage development and commercialization. But succeeding in the future will instead require companies to develop entirely new product and service segments from scratch. You can't buy it if it doesn't exist. (More to the point, you can't buy it if you don't yet know what it is you need to buy.) And so, pharma companies will have to team up in more open and collaborative ways in order to build new business models that will become key components of the future healthy outcomes marketplace.

Since so much of this will involve unproven approaches in nascent market segments, pharma companies will also need to partner early and move quickly – not just to seize opportunities but also to terminate failing experiments and leverage lessons through rapid prototyping. This will require new cultural mindsets and a different tone at the top – one that provides incentives for speed, flexibility and experimentation. Critically, corporate cultures will need to truly celebrate failure as a necessary part of the innovation process – something that is considered a natural part of the drug development process but anathema to the existing commercial model.

To do all of this, companies will need to move beyond business development as they have known it, to business model development, which is something quite different, involving a merger of skills from corporate development, strategy, innovation and commercialization. Among other things, business model development in Pharma 3.0 will require companies to co-create value with partners and patients, which will require a new business process to leverage the assets and attributes of all the parties.

continued on page 34



Early examples of Pharma 3.0 initiatives

Companies involved	Objectives
Managing patient outcomes	
Building communities	
<ul style="list-style-type: none"> ▶ Bayer HealthCare ▶ Microsoft ▶ National Multiple Sclerosis Society 	Launching MyBrainGames, a free suite of online games with cognitive challenges for multiple sclerosis patients
<ul style="list-style-type: none"> ▶ UCB ▶ PatientsLikeMe 	Creating an open and online epilepsy community that captures patients' real-world experiences
<ul style="list-style-type: none"> ▶ Pfizer ▶ Sermo 	Developing open discussion with Sermo physicians and providing access to information on Pfizer's products to facilitate informed decisions
Developing technologies	
<ul style="list-style-type: none"> ▶ Bayer ▶ Nintendo 	Connecting DIDGET (Bayer's glucometer for diabetic children) to Nintendo's video gaming devices to promote consistent blood sugar testing
<ul style="list-style-type: none"> ▶ Johnson & Johnson ▶ Apple 	Creating an app (Lifescan) to allow uploading and sharing glucometer data using an iPhone
<ul style="list-style-type: none"> ▶ Novartis ▶ Proteus 	Creating sensor-embedded pills that transmit data to a receiver in order to monitor patients' vital signs and boost drug compliance
<ul style="list-style-type: none"> ▶ UCB ▶ OXO 	Empowering rheumatoid arthritis patients to self-inject through new syringe and components designed in patient-centric manner
Measuring outcomes	
<ul style="list-style-type: none"> ▶ Fresenius Medical Care ▶ Anadial (dialysis centers association) ▶ Portugal Ministry of Health 	Creating integrated and quality-driven reimbursement model for providing ambulatory care to hemodialysis patients
Expanding access	
Expanding products	
<ul style="list-style-type: none"> ▶ Greenstone (Pfizer subsidiary) ▶ Aurobindo 	Seeking new growth drivers (Pfizer is licensing generic drugs from India's Aurobindo Pharma)
<ul style="list-style-type: none"> ▶ Pfizer ▶ Strides Arcolab 	Delivering off-patent products by combining Pfizer's commercial infrastructure with Strides' manufacturing capabilities
Developing technologies	
<ul style="list-style-type: none"> ▶ Novartis ▶ Vodafone ▶ IBM 	Managing malaria through "SMS for Life" initiative that uses mobile phones, SMS and web sites to manage supply of drugs and injectables
Innovating distribution	
<ul style="list-style-type: none"> ▶ Novartis India ▶ Indian post office 	Boosting access through proposed concept to sell OTC medicines from rural post offices
Meeting unmet medical needs	
Leveraging data	
<ul style="list-style-type: none"> ▶ mondoBIOTECH ▶ 23andMe 	Understanding genetic basis of rare diseases through mondoBIOTECH's enrollment of patients in 23andMe's Personal Genome Service
Optimizing R&D	
<ul style="list-style-type: none"> ▶ GSK ▶ Pfizer 	Creating new HIV-focused company that is more sustainable and broader in scope than either party's individual HIV business
Orphan drugs	
<ul style="list-style-type: none"> ▶ Pfizer ▶ Protalix 	Expanding into treatments for orphan conditions (Gaucher's disease)

Companies involved	Objectives
Meeting unmet medical needs (continued)	
Public-private partnerships	
<ul style="list-style-type: none"> ▸ AstraZeneca ▸ Mental Health Research Institute (Australia) 	Research collaboration to develop new ways of identifying Alzheimer's disease patients at early stages
<ul style="list-style-type: none"> ▸ AstraZeneca ▸ Cancer Research ▸ Cancer Research Technology 	Teaming with Cancer Research UK and Cancer Research Technology (the charity's development and commercialization arm) to move a potential anti-cancer compound from AZ into clinical development
<ul style="list-style-type: none"> ▸ GSK ▸ TB Alliance 	Developing new medicines to combat <i>Mycobacterium tuberculosis</i>
<ul style="list-style-type: none"> ▸ Medicines for Malaria Venture ▸ Genzyme, GSK, Novartis, Sanofi-Aventis and others 	Discovering, developing and delivering new affordable anti-malarial drugs through public-private partnerships
<ul style="list-style-type: none"> ▸ EFPIA (European Federation of Pharmaceutical Industries and Associations) ▸ European Commission 	Accelerating drug discovery and development in cancer, inflammatory and infectious disease through Innovative Medicines Initiative
R&D risk-sharing	
<ul style="list-style-type: none"> ▸ Eisai ▸ Quintiles 	Risk-sharing alliance allowing Quintiles to develop six oncology products in Eisai's pipeline. Quintiles partially funds clinical studies in exchange for success milestone payments
<ul style="list-style-type: none"> ▸ Pharmaceutical Product Development (PPD) ▸ Celtic Therapeutics 	PPD invests US\$100 million in Celtic Therapeutics Holdings, a partnership that invests in/acquires mid-stage drug candidates. Sets the stage for a strategic alliance between Celtic and PPD
<ul style="list-style-type: none"> ▸ Symphony ▸ Several biotech companies 	Project-based financing to enable funding of clinical trials through proof of concept of the lead candidate
Pre-competitive R&D	
<ul style="list-style-type: none"> ▸ Enlight Biosciences ▸ PureTech Ventures ▸ Abbott, Johnson & Johnson, Eli Lilly, Merck, Novartis, Pfizer 	Developing pre-competitive technologies on behalf of six pharma companies through Enlight and PureTech
<ul style="list-style-type: none"> ▸ BG Medicine ▸ Abbott, AstraZeneca, Merck, Philips, Takeda 	Focused on discovering and developing novel blood tests and imaging methods to find individuals with high-risk plaque disease before the occurrence of the first cardiovascular event
<ul style="list-style-type: none"> ▸ The Predictive Safety Testing Consortium (PSTC) ▸ Critical Path Institute (C-Path) 	Public-private partnership of pharma firms led by C-Path to share and validate each other's safety-testing methods under FDA and EMEA advisement
<ul style="list-style-type: none"> ▸ Eli Lilly 	Encouraging sharing of pre-competitive content and software through Eli Lilly's decision to make its LSG Discovery IT platform open source
Partnerships with payors	
<ul style="list-style-type: none"> ▸ Novartis ▸ National Institute for Health and Clinical Excellence (NICE) 	Designing late-stage clinical trial to boost chances of reimbursement. NICE earns a fee for advising Novartis on criteria it will use in determining whether the drug should be paid for
Creative financing	
<ul style="list-style-type: none"> ▸ Eli Lilly ▸ TPG-Axon Capital ▸ Quintiles Transnational Corporation's NovaQuest 	Phase III development of Eli Lilly's two lead molecules for Alzheimer's
<ul style="list-style-type: none"> ▸ Paul Capital ▸ Several drug companies 	Providing financing for drug companies by monetizing revenue streams from royalties

Source: compiled from public information by Ernst & Young

Among other things, business model development in Pharma 3.0 will require companies to co-create value with partners and patients, which will require a new business process to leverage the assets and attributes of all the parties.

Pharma continues to refine and tweak its product development process grounded in clinical trials, a process which is replete with rigorous sub-business processes, metrics and best practices. For *business model* development in Pharma 3.0, a similar yet quite different business process is needed – one that will require “commercial trials” to ultimately achieve success. The key aspects of this process are discussed below.

Integrated approach

First and foremost, creating new business models will necessitate a more holistic approach to business development functions that have typically been housed in different organizational silos, for a number of reasons:

Business models affect the entire organization. The creation of new business models is, by its very nature, more likely to cut across the entire organization. The value created from an in-licensed drug may be confined to a single therapeutic segment or business unit, but a new offer around increasing rural access in emerging markets or expanding into different business lines could very well affect the entire enterprise. For success, companies will need to tear down their internal walls and approach the task of developing new business models in a cross-functional manner.

Co-creating value with partners. Traditionally, corporate development got involved in the front end of deals and then moved on to the next

transaction once the deal closed and the business became responsible for value creation. These new kinds of innovative partnerships will compel companies to adopt a different approach. Consider, for instance, the interplay between corporate strategy and business development. Pharma companies have usually developed corporate strategies (typically led by the CEO and head of strategy) and then identified deals (managed by business development executives) to help implement those strategies. In Pharma 3.0, however, the distinction will no longer be so straightforward. While companies will still need to identify strategic priorities up front, there is so much genuinely uncharted territory here – unfamiliar market segments, novel offerings, entirely new lines of business, customer centricity – that firms will need to figure out much of it as they go along. The business model development process for Pharma 3.0 will use early-stage partnerships and pilots to develop business models in dynamic “commercial trials” and flesh out strategies through rapid prototyping.

This may even require a new leader in the executive suite, such as a chief development officer, or perhaps a leader with a job title that doesn't yet exist (chief partnering officer?).

Portfolio management. In recent years, there has been much discussion of the need for a pharma company to assess its entire portfolio of alliances using a common set of metrics in order to extract more value from its partnering strategies. The process of building new business models through partnerships will only heighten that need. To address the multiple unknowns in these new market segments, companies will inevitably

need to experiment simultaneously with several different partnerships. (See “Commercial trials” on page 38.) Creating a new business model around expanding emerging market access in rural areas of developing countries, for instance, may require answering questions regarding distribution networks, safety and counterfeiting, pricing mechanisms, packaging and consumer financing. On each of these issues, a pharma company may decide to experiment with several different partners and/or partnering structures in different geographies. But it is only by viewing the information gathered from all these partnerships in totality that a company can unleash their full value. Companies will need mechanisms to look across their alliance portfolios so that partners can learn from each other, identify synergies and increase the overall value produced. In optimizing network value, the bigger the “node” the pharma company builds through its network connections, the more valuable it becomes and the greater its options.

The next star in the executive suite.

Our *Progressions* survey reveals that the key functions related to deal-making are currently led and supported by a number of different executive offices. (See “A house divided” on the following page.) While this may not be very surprising, these disparate functions will need to be conducted in a more unified manner for the purposes of business model innovation. This may even require a new leader in the executive suite, such as a chief development officer, or perhaps a leader with a job title that doesn't yet exist (chief partnering officer?). More important than the title, though, is what this new leader will need to do – wear multiple hats (part strategist, part business developer, part innovator, part scientist, part technologist) and conduct business model innovation more effectively than is the norm at pharma companies today.

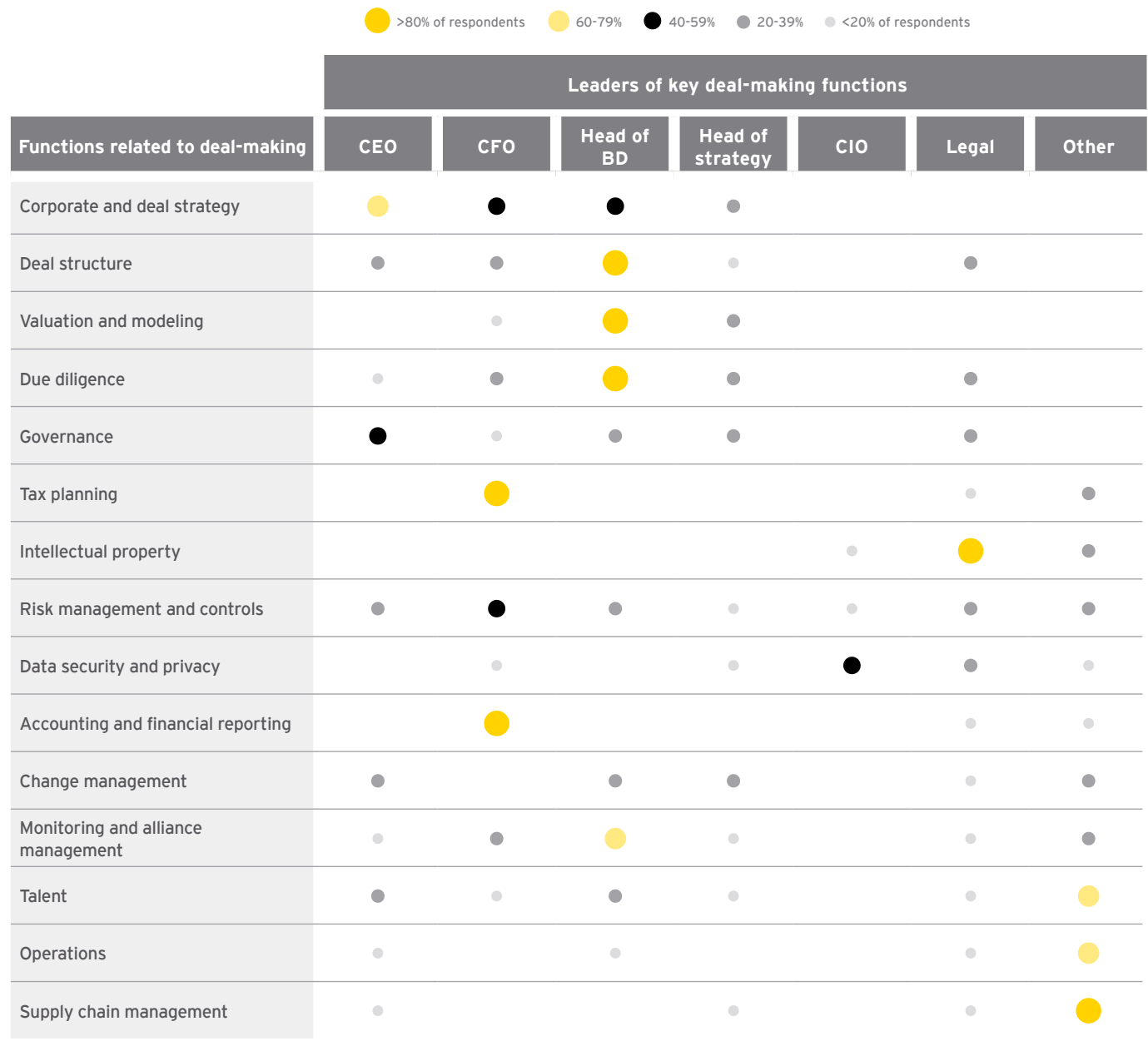
Media copy

Putting your money where your future is. Last but not least, this holistic approach will require adequate resources. While pharma companies are starting to look at these challenges, they have yet to allocate the sorts of resources that will be required for building new business models. If you are reading this at a big pharma company,

follow the money. How much did your company spend on R&D (i.e., product innovation) last year, and how much did it spend on business model innovation? Is business model innovation a core part of your firm's strategy and resource allocation, or is it being conducted by a small team with limited resources? In our survey of business development

executives, 57% of big pharma respondents reported that the amount their companies were devoting to business model innovation amounted to less than 1% of their R&D budgets, while the remainder said that it was 1%-5% of R&D spending. None devoted more than 5%.

A house divided: structuring pharma companies for business model innovation



Source: Ernst & Young Progressions survey, 2009

Media copy

Commercial trials

Given that pharma companies will need to fundamentally reinvent their business models to thrive, and doing so will require more innovative partnerships with traditional and nontraditional players that leverage their respective business model innovations, the industry winners need to build new business model processes that are as rigorous as their product development processes. How do you actually go about the business of building a new business model from the ground up? How do you pick the right strategies and experiments for your company when the very ecosystem in which you operate is changing in unprecedented, and unpredictable, ways?

"To figure out how to transform medical communities, with all their diversity and complexity, is going to involve trial and error. And this will require pilot programs – a lot of them."

*– Dr. Atul Gawande,
The New Yorker*

In a December 2009 article in *The New Yorker* about health care reform, Dr. Atul Gawande, associate professor at Harvard School of Public Health and Harvard Medical School, discusses the thorny challenges associated with containing health costs. The problem, as he points out, is that with complex challenges such as comprehensive reform of health care costs, there is often no obvious path forward. In such cases, the answer lies in experimentation – hence the inclusion of large numbers of pilot programs in the health care reform legislation. As Gawande puts it: "To figure out how to transform medical communities, with all their diversity and complexity, is going to involve trial and error. And this will require pilot programs – a lot of them."

Transforming the business of pharma is no less complex, and it's not surprising that a number of pharma companies are already using a similar approach. As they look to diversify into new businesses or expand access in underserved markets, for instance, firms are typically starting with pilot programs. Of course, these programs are – almost by definition – in early stages, which means that there are many unanswered questions. What happens down the road? How will companies optimally pick between different projects? What criteria will they use, and what challenges and risks will they need to focus on at each stage? To truly succeed at the complex challenge of developing new business models and efficiently allocating scarce resources in an environment of tremendous uncertainty, companies need a comprehensive and structured process.

We outline below a four-step process to business model innovation that strongly resembles the way in which companies approach drug development. We refer to the process as a series of **"commercial trials."**

The commercial trials process consists of four phases:

- ▶ **Strategic focus.** A pharma company looking to develop new business models will start by identifying the new areas in which it wants to play. Which areas and business models are a strategic fit for your organization? Companies will need to make these determinations based on factors such as overall corporate strategy, existing and planned product/service offerings, resources and geographic presence.
- ▶ **Proof of concept.** Once a company has identified a strategic area in which it wants to focus, the next step is to identify different ways in which it can play in that space and to test those concepts or hypotheses in early pilot projects (akin to "alpha" versions in software parlance). For instance, a company that has decided to focus on outcomes may come up with several
- ▶ **Development.** Companies will then take the ideas that have been established and piloted and test these as beta versions. The objective of this phase is to hone in on the most promising pilots and partners by experimenting with several different ideas simultaneously and developing a solid business case. The guiding principle is therefore **commercial feasibility**.
- ▶ **Commercialization.** Once the company has identified the most successful projects from the development phase, companies will need to bring these new product or service offerings to the global market. In this phase, the guiding principle for companies should be **scalability and replicability across markets** – to take new offerings to market in a broad way, while also

A four-step process to business model innovation that strongly resembles the way in which companies approach drug development. We refer to the process as a series of **"commercial trials."**

pilots for developing new business models in this area. Examples could include: partnering with a video game company to increase drug-regimen compliance; partnering with a smartphone manufacturer, mobile telephone operator and medical device manufacturer for monitoring blood pressure or blood sugar levels; or partnering with an insurance company and health care provider to offer an outcome-improvement service.

The objective of this phase, as in its drug development analog, is to reach proof of concept by identifying which ideas work in concept and terminating quickly those that don't. The guiding question for both you and your partners is therefore, **"does it work and is it safe?"**



ensuring that partnerships are structured with appropriate controls to manage risks.

Unlike the clinical trial process, which is famously long and expensive (in large part due to the regulatory hurdles companies must cross), commercial trials will need to be much faster and more efficient. What we are describing is a process of *rapid prototyping*, which allows companies to test large numbers of hypotheses and pilot programs on their way to isolating viable market solutions. As such, alliance structures will need to be sufficiently well defined to maintain the focus of the collaboration but flexible enough to allow for quick response to new challenges and opportunities.

Business model innovation has the potential to bring considerable upside. Unlike developing a new NME, which on average costs US\$1 billion and takes 10-15 years, developing new business models should be much less expensive with a potentially higher relative return on investment. Consider the field of compliance. It has been estimated that the revenue lost due to patients' failure to take their medications as prescribed increases annual US health care costs by US\$70 billion. In a recent interview in the *Financial Times* on the launch of the venture between Novartis and Proteus Biomedical, Joe Jimenez, now Novartis' Chief Executive Officer, said "tests using the system – which broadcasts from the 'chip in the pill' to a receiver on the shoulder – on 20 patients using Diovan, a drug to lower blood pressure, had boosted "compliance" with prescriptions from 30% to 80% after six months."

Funding and control during the commercial trials will depend on the strategic importance a company attaches to a new venture. Firms will

need to decide whether to project manage the process with internal capabilities for critical initiatives or let investors and markets take over the development burden by spinning it out at an early stage. In an example of the latter highlighted by Henry W. Chesborough and Andrew R. Gaman in their latest paper on open innovation, Unilever spun out MLife, a business that delivers personalized wellness and weight-loss coaching to consumers via wearable devices that are linked to the internet. Unilever plans to enter market collaborations with MLife as soon as the basic model is proven.

Companies that have been actively engaged in business model innovation for some time have often used a sustainable commercial trial business process. Fresenius Medical Care, for instance, a German firm that has developed some innovative outcomes-based models, has used a process that includes experimentation with multiple innovative projects that are then funneled down over time. (In our survey, Fresenius also reported that its spending on business model innovation amounted to 10%-25% of R&D. As such, the company – whose business model is not typical of pharma – provides an interesting counterpoint to big pharma enterprises, all of which reported spending 5% or less of R&D on business model innovation. For more information on Fresenius, refer to "The most innovative survive," our interview with Emanuele Gatti, on page 40.)

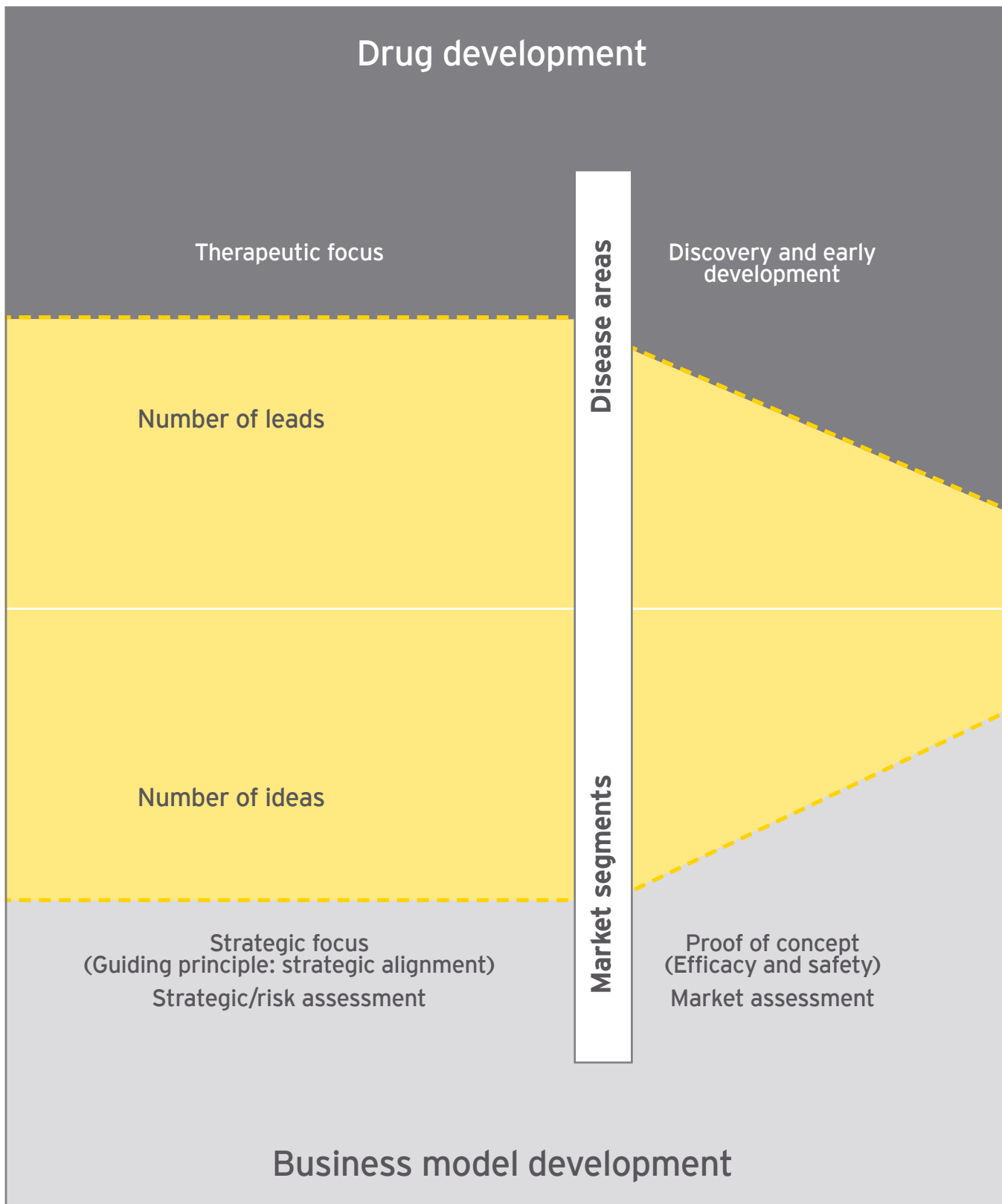
The analogy between product innovation and business model innovation applies at multiple levels. Indeed, some of the same dynamics are at play in both areas, since pharma companies need to make their R&D engines more productive at the same time that they need to make their business models more relevant.

Firms have taken several steps to boost R&D productivity in recent years (see Chapter 1 for more information), and some of the new measures being deployed – greater use of external networks, allowing internal and external R&D projects to compete for survival – are broadly applicable to business model innovation as well.

One idea that has been attracting much attention in recent years is "open innovation." Dr. Paul Stoffels at Johnson & Johnson, a leading pharma industry proponent of the concept, argues that an approach that extensively uses innovation from outside the enterprise is sorely needed at a time when addressing increasingly complex unmet medical needs will require strengths that no individual company can claim to possess. (For more of Dr. Stoffels' insights, refer to "The world is our laboratory," our interview with him on page 41.)

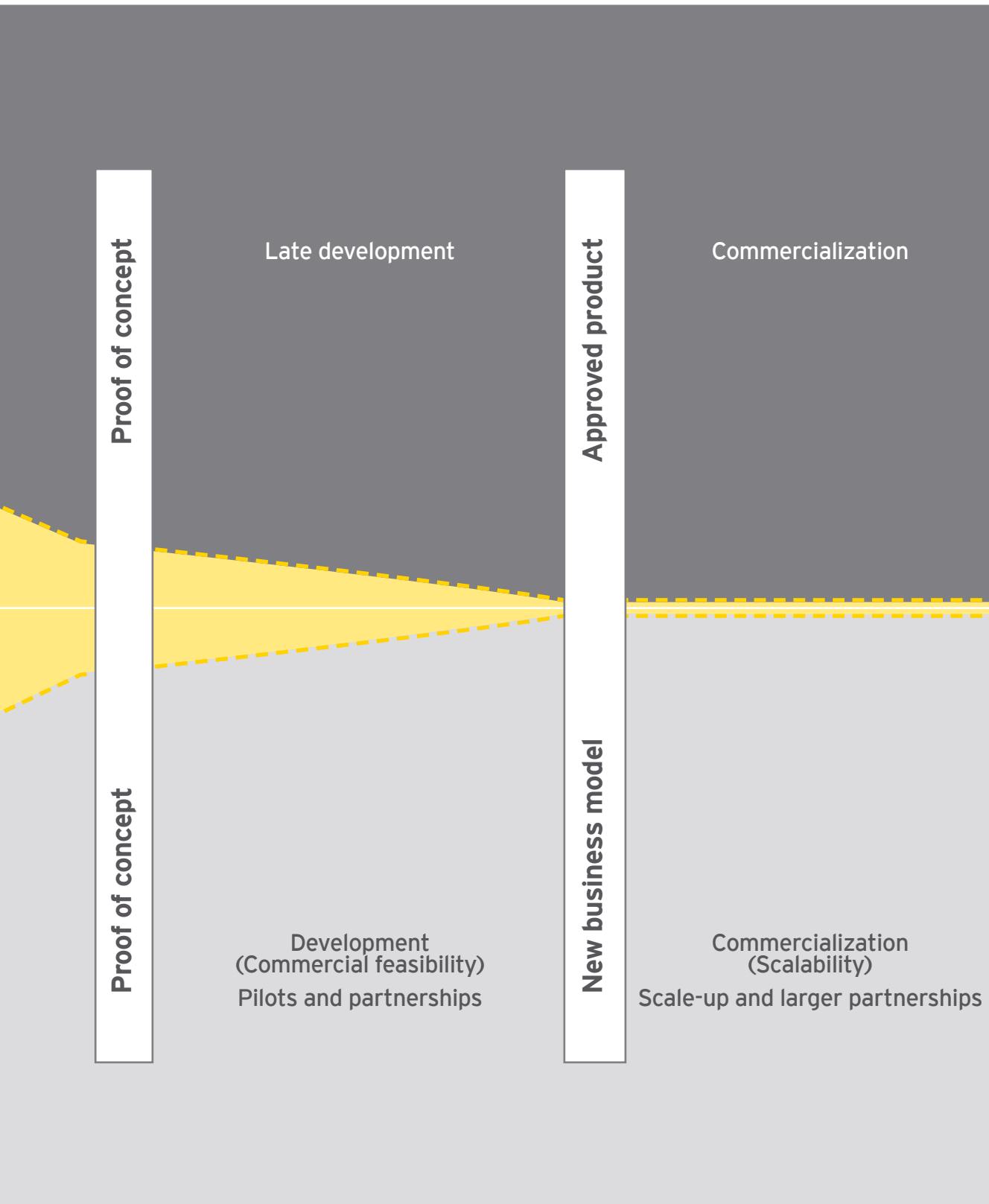
The same constraints, of course, apply to business model innovation. Delivering new outcome-based products and services in the Pharma 3.0 ecosystem will require combinations of competencies that no individual firm possesses, and companies will need to bring an outside-in, open approach to developing new business models. ►

Commercial trials: from product innovation to business model innovation



Source: Ernst & Young

Media copy





Emanuele Gatti, M.D.
Fresenius Medical Care
CEO for Europe, Latin America,
Middle East and Africa

Business model innovation: a conversation with Emanuele Gatti

The most innovative survive

Ernst & Young: As the health ecosystem changes and companies move from selling drugs to outcomes, how is Fresenius Medical Care responding to these changes?

Gatti: Fresenius is doing more than responding – we have been leading the charge! Since the foundation of this company in 1996, we have focused our business model on delivering quality health outcomes to patients undergoing dialysis because of chronic kidney failure (Fresenius is the world's leading dialysis company). In order to do this, it has been crucial for us to establish hard facts on what constitutes quality outcomes. We've gathered that information by cooperating with associations of professionals and universities. Most importantly, we collect and analyze data related to each treatment in our daily interactions with patients.

Ernst & Young: Could you provide some examples of innovative business models you have developed?

Gatti: Our outcomes-based approach is the basis for our business model around disease-stage management. We've been experimenting with these approaches in a number of markets. For example, in the US (with Medicare) and in Portugal, we have set up a case management model where we effectively get a per-participant fee to take care of patients in a holistic manner, including their drug regimens and hospitalization. Such business models have the potential to revolutionize health care systems. Of

course, dialysis is a very specific field with a high level of urgency, but such models should still be applicable in several different medical fields.

Ernst & Young: How does Fresenius go about business model innovation?

Gatti: First and foremost, we have been investing for years in hiring entrepreneurial people. We then infuse our organization with a sense of urgency to spur innovation. Today, we have a number of entrepreneurs within the company, and entrepreneurs will inevitably find new ways to improve their businesses. As a result, we have many ongoing experiments in business model innovation, management innovation and operational innovation.

At the top, we are regularly reviewing our business model and new innovations. Basically, projects go through a funnel – experimental projects compete with each other and the most innovative survive.

Ernst & Young: What advice would you give big pharma companies that are looking to innovate new business models – and perhaps even move toward services?

Gatti: As the health ecosystem increasingly focuses on outcomes and new companies enter the fray, pharmaceutical companies risk being left out in the cold. At the extreme, they face the prospect of becoming little more than suppliers to players with expertise in analyzing patient

data. To really change, they will need the right skill sets and management expertise. Pharma companies need to integrate people into their teams who bring diverse backgrounds – for instance, experience in insurance, hospitals or health care providers. It is also crucial for them to understand that changing business models requires experimentation. A one-size-fits-all global approach will not always work, because you don't necessarily need the same business model in every market

"As the health ecosystem increasingly focuses on outcomes and new companies enter the fray, pharmaceutical companies risk being left out in the cold."

segment. Another major hurdle may be that few people in pharma truly believe that viable alternatives to the current business model could exist. This has to do with margins. It's true that no service business will provide the sorts of margins that the pharmaceutical industry has historically earned, but lower-margin business models could also bring lower-risk and quicker paths to commercialization. The bottom line: you need the right talent, you need to experiment and you need to believe in and embrace the concept of change. ►

Paul Stoffels, M.D.
Johnson & Johnson
Company Group Chairman,
Global Research and
Development, Pharmaceuticals



Open innovation: a conversation with Paul Stoffels

The world is our laboratory

Ernst & Young: The concept of “open innovation” seems to be attracting increasing attention. What does the concept mean, and why is it gaining popularity at this point in time?

Stoffels: Open innovation can mean different things in different contexts, but in the pharma industry it essentially means external innovation. This involves extensive collaboration with many partners across the ecosystem – academic centers, public and academic research laboratories, biotech companies – to codevelop new science and new products. The concept is particularly relevant today because the paradigm of finding drugs has changed significantly. Many diseases are now routinely treated with generic drugs, and the true unmet medical needs are in challenging areas such as Alzheimer’s, oncology, schizophrenia, depression and multi-drug resistance. To address such complex challenges, companies need to access clinical information, biomarkers, new targets, safety information – all of which are generated not within their organizational walls but across the clinical and research communities. To sum it up, open innovation is about harnessing external innovation with the attitude that “the world is our laboratory.”

Ernst & Young: You refer to open innovation as “external innovation,” but pharma companies have been looking externally for much of their innovation for some time now. What makes open innovation different?

Stoffels: You’re absolutely right – pharma has been doing some form of external innovation for a long time. Part of what differentiates open innovation is that companies are learning to collaborate in fields where they might earlier have competed. In “pre-competitive” research on biomarkers, for example, companies can gain more by sharing information and collaborating to solve tricky problems. Firms in other industries have figured out where to compete to advance the interests of the company and where to collaborate to advance the interests of their field. We need to do the same thing in the health care ecosystem to advance medical science more quickly.

Ernst & Young: Is big pharma embracing open innovation?

Stoffels: Absolutely! Look at product introductions in today’s pharmaceutical industry – only a limited number originate from internal research. Most products come from collaborations with academia or biotech. Now more than ever, we have to become better at picking scientific advancements from the ecosystem rather than trying to do it all ourselves.

Ernst & Young: What challenges do pharma companies face in implementing open innovation? What can companies do to address these issues?

Stoffels: The biggest challenge is intellectual property (IP) protection. In the technology industry, open innovation is sometimes used to refer

“Now more than ever, we have to become better at picking scientific advancements from the ecosystem rather than trying to do it all ourselves.”

to things such as open-source software development. That is not what we are talking about in the pharma industry. In our business, we will always need IP protection to finance the cost of bringing new products to market. Opening IP to the world will simply not work. So, the biggest challenge for open innovation in pharma is making sure that the right IP protection is there on the core product. And how do you make that happen? Well, you have to be very careful that all your collaborations (and open innovation in our industry will inevitably be very collaborative) carefully address IP issues.

The second big challenge is change of mindset. Other members of the health ecosystem sometimes view pharma companies as the enemy. Well, we are also part of the scientific community and the health care community. We work hard to provide solutions for patients. Yes, we happen to work in the private sector and as such we have to generate profits to pay for our work, but we are not fundamentally different. We need to foster trust between pharma and the academic and scientific communities so that we can work together to create the innovative breakthroughs that will fulfill unmet medical needs and benefit patients everywhere. ►

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Roundtable on deals

Shaping healthy collaborations



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Ernst & Young Ltd.
EMEIA Life Sciences Leader



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Novartis Pharma AG
Head of Business Development and Patent Franchise, and Molecular Diagnostic Liaison



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Michael Schwartz
Bayer Healthcare LLC
Vice President, Global Business Planning and Administration

The changing health care ecosystem is making for strange bedfellows. To develop new business models for the world of Pharma 3.0, pharmaceutical companies will need to team with nontraditional partners that run the gamut from IT firms to nonprofit organizations and retail giants. They will be coming together not to do the things that pharma companies have always done – licensing and acquisitions around drug targets and technologies – but to enter uncharted waters by developing unproven business models, innovative market offerings and new customer segments.

To say that this will be challenging is an understatement. To succeed, companies will need to span radically different work cultures, attitudes toward intellectual property (IP) and regulatory regimes. They will need to figure out how to value IP in the face of tremendous uncertainty. They will need to control through brand and customer loyalty, not just through patents and regulatory approvals. And they will need to move quickly just to keep pace with the rapid transformation of the health care business.

In late 2009, we talked with four senior executives representing leading big and midsize pharmaceutical companies – Markus Christen (Novartis), Rene Hansen (UCB), Beverley Jordan (AstraZeneca) and Michael Schwartz (Bayer Healthcare) – to get their insights on the industry challenges ahead. Here are excerpts from those conversations, featuring Patrick Flochel, Ernst & Young EMEIA Life Sciences Leader, in the role of moderator. The insightful discussion describes an environment characterized by significant challenges – issues that are further explored in Chapter 3 (“Challenges every step of the way”).

Flochel: To what extent are you seeing the pharmaceutical industry working with “nontraditional” players – companies in industries such as telecommunications, consumer products, social media and IT – that have not had a significant presence in the pharmaceutical business environment?

Schwartz: I am seeing interest from a number of different industries but no real traction yet from any one industry. I think the real turning point for our industry will be when we start to see a real commitment to what I call “digitized data,” capturing extensive health care information – X-rays, test results, diet regimens, lifestyle, prescription information, family history and so on – in digital format. How will pharma stay ahead of this transformation? The industry will need to quickly move up the learning curve to become proficient in data collection and analytics to determine trends that can lead to new business models. But should pharma companies try to build their own competencies around sophisticated

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data management, or is it best to develop partnerships with companies that already have that expertise?

At Bayer, we recently launched a blood glucose monitoring device, DIDGET, which works on the Nintendo gaming system to encourage diabetic children to monitor blood glucose levels. We were aware that gaming technology changes quickly, and we had to decide whether we would develop our own competency in gaming programming or develop partnerships with companies that specialize in this area. As we continue to explore innovative business models, the question becomes: when should pharma companies go beyond their own boundaries, and when do collaborations with the nontraditional industries bring better, faster, cheaper solutions to new business models?

Christen: I'm seeing an increase in nontraditional companies entering the health care marketplace. However, I may have more insight into this than most because my role at Novartis is to explore collaborations with nontraditional partners. Innovation is the true value driver for our industry and these nontraditional entrants can potentially provide valuable new avenues to innovation for us. One area where we see a lot of potential is collaborations with companies that have access to health care data that we can use to better understand and ultimately improve health outcomes.

Jordan: I am also seeing nontraditional players in the market. They are not engaging as much with big pharma as I would have expected but taking the initiative on their own and putting propositions forward – whether it is in diagnostics,

"At Bayer, we recently launched a blood glucose monitoring device, DIDGET, which works on the Nintendo gaming system to encourage diabetic children to monitor blood glucose levels. We were aware that gaming technology changes quickly, and we had to decide whether we would develop our own competency in gaming programming or develop partnerships with companies that specialize in this area."

patient-data management or clinical-trial management – to carve out opportunities in health care.

One industry I see increasingly involved in collaborations with pharma is the mobile telecommunications and cell phone industry. Because mobile phone ownership is so extensive in populations around the world, these phones may be useful for a variety of health care applications, such as compliance – e.g., with daily short message service (SMS) messages reminding patients to take their medicine – health care monitoring and record keeping, and even diagnostics.

Christen: At Novartis, we also have discussed working with telecommunications companies on compliance, such as, if a patient is adherent and can demonstrate that she has taken her medication on time, she gets rewarded with bonus points



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“One of the biggest challenges in executing nontraditional partnerships is valuation. In traditional alliances among life sciences companies, you can usually agree on value. For example, when licensing a Phase II molecule, one can estimate the size of the consumer market, predict with a certain probability the future value of the product in that market, and then appropriately divide that value between contributing partners. With innovative collaborations, there is little familiar ground to stand on.”

on her telephone for free talk time. Wireless transmission and wireless monitoring will also be very important in areas like India and China where you have numerous remote areas without access to health care services. But it's not yet clear how telecommunications companies will partner with pharma. Where and how will they play?

Hansen: Pharma companies know the health care arena is changing, and they have lots of good ideas, but they don't seem ready for the big leaps yet. This leaves plenty of room for nontraditional companies to make their moves, and in many cases, they may decide to forge ahead on their own without pharma. But either way, it is still too early to tell where the real opportunities will be for new business models.

Flochel: What challenges are you seeing in these innovative partnerships?

Hansen: I think every pharma company at this moment has people looking into innovation – whether through new commercial models or new partnerships. But that has been the case for a long time. Now, though, there is a convergence of forces – financial, consumer, demographic, governmental – creating new urgency and new activity around innovative partnerships. Yet for pharma, there are still two key hurdles: How truly progressive can you be with your thinking and your vision for innovative partnerships? And, more importantly, can you actually execute them?

Christen: One of the biggest challenges in executing nontraditional partnerships is valuation. In traditional alliances among life sciences companies, you can usually agree on value. For example, when licensing a Phase II molecule, one can

estimate the size of the consumer market, predict with a certain probability the future value of the product in that market, and then appropriately divide that value between contributing partners. With innovative collaborations, there is little familiar ground to stand on. We are moving away from a culture of precision – the precision of scientists giving us an assessment on a molecule in a clinical program. Often it is very difficult to assess what the future value of these innovative solutions is, so it is hard to assess if a collaboration is worth US\$1 million, US\$10 million or US\$1 billion.

How to value what different players bring to the table – especially when everyone believes their company's contribution is the most important – increases the complexity of negotiations and discussions. If a smaller company comes to us proposing an alliance, the assets we put into such collaboration, by comparison, can be huge – multibillion-dollar drugs which have huge investments behind them but also very big risk aspects if something goes wrong. Also, from pharma's viewpoint, the most important component contributing to patient outcome is still the drug – that is, there can't be a successful patient outcome without prescribing a drug. Therefore, the natural tendency for pharma in such collaborations is to want both control and a significant proportion of the value from such collaborations.

Jordan: Another key challenge has been around the regulatory hurdles. AstraZeneca looked at partnering with a telecommunications company to deliver reminder messages on prescriptions. But the dilemma was whether we could make pharma part of that direct relationship with patients and still meet regulatory guidelines. There is also the challenge of getting the right level of information back to the pharma company without breaching patient confidentiality. In the end, we couldn't make it work.

E-related initiatives also pose their own unique regulatory challenges. How can you innovate in a very stringent regulatory environment yet comply with regulations that can often be interpreted in different ways?

Hansen: Intellectual property is another complex area for these innovative collaborations. How do you figure out who owns data,

“Change in companies – particularly cultural changes – can be difficult to manage. It may be that many of the bigger pharma companies are just too complex to change as quickly and easily as may be necessary to thrive in the new health ecosystem.”

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IP or rights of use? There is also the issue of governance and how to agree on a model that can effectively govern innovative collaborations. Change in companies – particularly cultural changes – can be difficult to manage. It may be that many of the bigger pharma companies are just too complex to change as quickly and easily as may be necessary to thrive in the new health ecosystem.

Flochel: How do you see your interaction with nontraditional industries changing in the next five years?

Schwartz: I expect a significant increase in our interaction with technology companies. The internet has enabled consumers to empower themselves with all kinds of information and has also accelerated the speed of change. It is hard to believe that only 12 months or so ago, now widely popular social media tools such as Facebook and Twitter had modest recognition. Personal information is becoming less personal and we'll soon see leaps forward in the digitization of personal health data – from blood pressure readings to X-rays to test results – as demand increases for better information and management

“The digitization of personal health data will have an enormous impact on the industry, creating exciting new sources of information that could dramatically change how pharma approaches health care solutions. So we will increasingly need skills in technology, predictive modeling and data mining and management – capabilities that are best achieved through partnerships rather than internally developed.”

tools. This is something pharma has to get ahead of through collaborations with companies that understand technology and data management. Otherwise, personalized health care and health care management are going to happen outside the pharmaceutical industry.

Jordan: The question is whether pharma can even stay in the game. We need an almost total reinvention of the pharmaceutical business. Pharma must adopt a more consumer-focused mindset and move away from the long-standing tradition of “selling the science,” because selling the science will no longer be enough.

“We have to be willing to think the unthinkable, which is not about the next new pill. Kodak, for example, realized that consumers were going to stop putting film in cameras. So they reinvented themselves, moving into the digital world and developing new print capabilities.”

Schwartz: The catch, though, is that I don't think the pharmaceutical industry can get there fast enough on its own. Pharma needs to develop the culture and skills required to transform the business model fast enough to even keep pace with the changes that are happening – at the same time – across the health care ecosystem.

Flochel: What skills and capabilities will pharma need to address these increasingly complex deals?

Schwartz: The digitization of personal health data will have an enormous impact on the industry, creating exciting new sources of information that could dramatically change how pharma approaches health care solutions. So we will increasingly need skills in technology, predictive modeling and data mining and management – capabilities that are best achieved through partnerships rather than internally developed.

But the big challenge may be in changing the culture and mindset on digitization of health data. There seems to be a generation gap – between those currently in management positions in pharma and those likely to be the next generation of management – in how far digitization can go and on when we are pushing the boundaries of data privacy. Members of the younger generation – who love Facebook and social media – publish personal information on the internet without any misgivings. This generation is already market-ready and will have fewer concerns about sharing health data. As these technologies come of age, so will consumer and patient attitudes. But we may not see much progress from pharma in e-health, m-health and health IT solutions until the next generation of management is in place.

Jordan: I also think it will take a very different management philosophy, and if that means it is the next generation, then the next generation it is. I think we have got to get better at out-of-the-box thinking and not be restricted by the here and now. Pharma is still very much wedded to what is working now. We have to be willing to think the unthinkable, which is not

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"With new collaborations, we will also, by necessity, see more knowledge sharing in areas such as costing and even IP ... that in the past were not negotiable. This is a big change for pharma, but the benefits will be in faster delivery of better health outcomes."

about the next new pill. Kodak, for example, realized that consumers were going to stop putting film in cameras. So they reinvented themselves, moving into the digital world and developing new print capabilities.

Flochel: How will the risk environment change?

Jordan: I am seeing pharma companies beginning to go beyond traditional risk management to new models based on risk sharing. With new collaborations, we will also, by necessity, see more knowledge sharing in areas such as costing and even IP – the “secrets of the trade,” in some minds – that in the past were not negotiable. This is a big change for pharma, but the benefits will be in faster delivery of better health outcomes.

I think we'll also see risk becoming better aligned by being more transparent. It's understanding up front where there is risk and why, rather than just allowing it to happen and reacting. We're not there right now, and that is a challenge.

Hansen: For companies on both sides of new collaborations, the key risk is simply their lack of familiarity with each other's business. Nontraditional companies are not familiar with the intense scrutiny and regulatory challenges in pharma, while pharma companies are not familiar with the culture and pace of less regulated, demand-driven industries. The big question is whether the pharma industry can move outside its comfort zone – away from tightly controlled, long-term alliances with companies within the industry – to more innovative collaborations with unfamiliar, quick-moving industries that may bring new opportunities along with less control and more risk.

Schwartz: Teaming with telecoms for m-health, with IT firms for e-health or with nutrition companies for health management services are ideas that pharma has been discussing for a while. But it may be that the combined risk of moving outside their knowledge sphere and new regulatory hurdles has held pharma back and made them slow adopters.

Jordan: I think it is simply that pharma doesn't like to be a first mover. We believe in the solidity of our traditional model of “science will sell.” We also depend on data – clinical outcomes, statistical history, empirical data – to determine what science will sell. So we see big pharmas exploring a number of pilot projects, collecting data and – using the same portfolio approach that is used in R&D – eliminating scenarios as they get a feel for where they think the market's going. This is still where we are most comfortable. By contrast, technology companies have a business model and philosophy that is much more aggressive in making decisions. These businesses are used to moving fast and trying things out. And if a new product fails, it fails, and if it wins, then great. But whether a product wins or fails, these companies are always thinking: “What's the next thing?”

Flochel: What challenges are you finding in making connections with nontraditional players?

Hansen: UCB is pretty well positioned for alliances with nontraditional partnerships. In fact, it is part of our culture. As a midsize company, we are small and nimble enough to move quickly on partnership opportunities. We have already established quite a few innovative partnerships, such as the recent alliance with OXO, the consumer goods company, to design an innovative, consumer-friendly syringe and packaging for our injectable, Cimzia. And there is our strategic partnership with social networking website PatientsLikeMe in the field of epilepsy. Currently, we are looking at reinvigorating our research organization by adopting “open innovation,” an approach that advocates teaming and open access to research theories and discoveries. [Editor's note: for more on open innovation, refer to “The world is our laboratory,” our interview with Dr. Paul Stoffels on page 41.]

Jordan: I think we are getting a clearer idea about the directions in which we want to move, but we are not there yet. Part of the challenge is that we don't have a methodology to compare investments, nor do we really have a clear view yet of what it is we are looking for in any of the diversification avenues. It's also back to understanding how to link those interventions with prescribing. Because that's still our end game no matter how we've approached it: usage, prescribing and, therefore, sales. We do see the new opportunity with creative alliances, but it needs to fit with business priorities, especially when there are resource constraints. Isolating speculative money has been a bit of a Catch-22. So far, it seems pharma has only been able to dip a toe in the water with some small initiatives. Nobody has gone for the big bang, venturing with major players such as GE or Siemens.

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This is because the opportunities from alliances with nontraditional players are still unproven. The business model we have today – albeit with what the market feels is a limited future existence – is still the most successful thing we’ve known. So knowing when to jump across will be the biggest challenge for pharma.

Christen: The current model may be enticing, but the next big business model for our industry may be one where we don’t sell drugs anymore. It could be that a pharma company collaborates with a big insurance company and says, if you allow us to treat all your heart failure patients, we will guarantee their hospital stays will be no more than a certain number of days per patient. In return for saving you the expense of excessive days in the hospital, you pay us a fixed amount with incentives depending on whether outcomes are reached or not. How we do it is our choice – we could treat the patients with our drugs, maybe with

“The big question is whether the pharma industry can move outside its comfort zone – away from tightly controlled, long-term alliances with companies within the industry – to more innovative collaborations with unfamiliar, quick-moving industries that may bring new opportunities along with less control and more risk.”

generic drugs, maybe with a system we put in place to measure the heart condition, it doesn’t matter. What matters is that we have created big savings for the insurance company by reducing costly hospital stays. I don’t know whether Novartis will actually go in this direction. [Editor’s note: for another example of such a model, refer to “The most innovative survive,” our interview with Emanuele Gatti on page 40.]

But what if we were to go one step further and move to a scenario where we just sell the data? What would be the implications for our business model? Would our business model have morphed to make us essentially an insurance company or health care provider, or are we still a pharmaceutical company? And do we really want that? I don’t know. Only time will tell. ►



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Challenges every step of the way

New ways of partnering



Challenges every step of the way

New ways of partnering

In brief

- ▶ As pharma companies look to develop new business models for Pharma 3.0, creative partnering will be critical.
- ▶ As they team with very dissimilar companies to build entirely new product or service offerings, companies will face challenges every step of the way.
- ▶ There are significant gaps in pharma companies' level of preparedness to deal with these challenges, with large gaps in areas such as: valuation and modeling; talent; offer and market positioning; reputation; due diligence; change management; and data security and privacy.
- ▶ To successfully transition to Pharma 3.0, companies will need to focus on execution and will need to address these preparedness gaps. These issues are discussed in detail in this chapter.

It is far from clear which players will thrive and which will fail to capitalize on the new healthy outcomes ecosystem, but much of the answer will lie in the ability to execute and manage creative collaborations and transactions.

widespread capability gaps in areas that will become increasingly important for the Pharma 3.0 ecosystem.

Expanding the transaction toolkit for creative collaborations

Chapters 1 and 2 described how the ecosystem is changing and how pharmaceutical companies will need to reinvent their business models – trends that present both threats and opportunities for today's pharmaceutical companies. It is far from clear which players will thrive and which will fail to capitalize on the new healthy outcomes ecosystem, but much of the answer will lie in the ability to execute and manage creative collaborations and transactions. To succeed, companies will need to assemble capabilities they don't currently have to build products and services that don't yet exist. In some cases, this may be done through acquisitions of companies or assets, but in most situations, we expect firms to enter alliances in which they will join assets and capabilities to co-develop new offerings. (The relatively recent emergence of a third path – acquisitions that, like alliances, are structured with contingent payments – could play an increasingly important role given the inherent uncertainty around partnering in Pharma 3.0. For a more detailed discussion, see "The rise of structured M&A" on page 50.)

The life sciences industry has become quite proficient at executing traditional R&D collaborations. While negotiations may often bog down over risk and value allocation, at least all parties speak the same language and understand each other's goals. When big pharma talks with biotech, there may not always be overwhelming mutual trust, but they do have several decades of industry experience from which to draw. Partnering with nontraditional players from other industries – including technology, insurance, internet services, food and retailing – holds the potential for deal-breaking clashes over different goals, operating principles and cultures.

Inter-industry collaborations will face challenges at every stage of the process. Our survey of business development leaders at major pharmaceutical companies and nontraditional entrants canvassed the opinions of the key executives most likely to be at the forefront of these changes. Their self-assessments reveal surprisingly

More challenging, less prepared

The scatter plot on page 51 summarizes the responses to two questions. Along the left axis we graph the portion of respondents who believe each execution element will be more challenging for nontraditional collaborations. For all but one of the 18 execution activities, respondents indicated that these tasks would become relatively more challenging. Across all deal-related functions, an average of 50% of respondents expect deals to become more challenging, while only 2% expect them to become less challenging.

The tasks expected to be especially challenging reflect the unique nature of the journey ahead. Since this is fundamentally about developing new business models, it is not surprising that *corporate and deal strategy* as well as *offer and market positioning* are near the top of the list (with 75% and 64%, respectively, of respondents saying these functions will become more challenging). The vast majority expect the same of *due diligence* and *valuation and modeling* (75% each), for reasons that are discussed later in this chapter. Reflecting the critical roles that *data security* and

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intellectual property will play, 62% of respondents, for each category, expect challenges to increase. Likewise for both *change management* and *talent*.

The bottom axis in the scatter plot provides the responses to the second question, which asked executives to rate how prepared they were to address each challenge. The percentage graphed represents those who felt they weren't highly prepared, that is, they answered "Medium" or "Low." The chart suggests that the further up and to the right an execution activity lays, the more attention it requires, either because it will tax traditional partnering skills or require new capabilities, or both.

Two bar charts, on pages 52 and 53, provide more detail on whether companies think that different execution elements will become

For all but one of the 18 execution activities, respondents indicated that these tasks would become relatively more challenging.

more or less challenging, and on how prepared companies are to deal with these challenges.

The greatest gap between the level of challenge and the degree of preparedness is in *valuation and modeling*, where 75% of respondents think the issue will become more challenging, while a remarkably high percentage (67%) think that pharma companies are *not* highly prepared to deal with the issue. Other issues with

large preparedness gaps have a high degree of overlap with the list of "more challenging" issues. These include *talent*, *offer and market positioning*, *reputation*, *due diligence*, *change management*, and *data security and privacy*.

One notable exception is *intellectual property*, where a handsome majority (62%) think the issue will become more challenging, but an even larger percentage (71%) consider pharma companies to be highly prepared to deal with the challenge. This may be an area of misplaced confidence. As we discuss below, while pharma companies have lots of expertise dealing with IP issues, their entire approach to IP may need to be revisited in many creative partnerships, particularly those involving IT companies.

A closer look

The rise of structured M&A

Savvy deal-makers know that acquisitions are becoming much more creative in response to the growing forces of uncertainty. In recent months and years, we have seen several options-based M&A transactions, in which the would-be acquirer purchased only the option to buy its target at some point in time. The subsequent option exercise decision is usually triggered by the conclusion of a clinical trial, the results of which are expected to have a large effect on the target's value. In January 2009, Cephalon announced a deal to pay Ception US\$100 million up front for the option to acquire Ception for US\$250 million within a specified period once results are announced for the final study report for Ception's lead product. In 2008, Boehringer Ingelheim (BI) announced a deal where it would pay US\$515 million to acquire shares of Actimis as the company reaches milestones in the development of its lead compound. If the compound reaches Phase III, BI will purchase all of Actimis' shares. In addition to options-based structures like Cephalon's and BI's, we also see growing use

of various contingent-consideration mechanisms such as contingent value rights (both traded and non-traded) as well as puts and calls.

While clinical-trial uncertainty has been the primary driver for structured M&A, we expect that commercial-trial uncertainty will increasingly influence M&A terms. We could see the emergence of contingent structures, for instance, that parse the reimbursement risk accompanying comparative effectiveness. It should be noted, however, that the rise in option use has also been driven by shifts in bargaining power in an environment where target companies have grappled with dwindling sources of funding. It is not clear that pharma companies will have the same bargaining-power advantages when partnering with nontraditional companies. One thing is clear, though. Whether they proceed through alliances or structured M&As, executives will face the same execution challenges when they undertake these creative deals in Pharma 3.0.

Jeffrey Greene
Ernst & Young



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For our survey, we outlined the 18 key components of successful partnerships and deals – from planning to execution to monitoring and reporting. For each of these 18 critical areas (defined briefly below), we asked our survey participants two questions: whether the business function will become more or less challenging as companies pursue more innovative partnerships in building new business models, and how prepared they perceived their own companies to be in these areas:

Strategy, structuring and governance:

1. **Corporate and deal strategy**
Strategic vision for enterprise and nontraditional deals
2. **Deal structure**
Terms, contributions of nontraditional partners
3. **Offer and market positioning**
What nontraditional alliances will deliver
4. **Increased capital requirements**
Continued funding for deals and implementation
5. **Governance**
Control, decision-making and relative contributions
6. **Tax planning**
Structuring nontraditional deals to minimize taxes
7. **Monitoring and alliance management**
Appropriate metrics for new kinds of alliances

Due diligence:

8. **Due diligence**
Verifying information and assumptions

Valuation and modeling:

9. **Valuation and modeling**
Ability to adequately model new kinds of deals
10. **Accounting and financial reporting**
Analyzing and communicating financial information

Talent and change management:

11. **Talent**
Appropriate skill mix for new products/services
12. **Change management**
Accommodating very different cultures, building trust

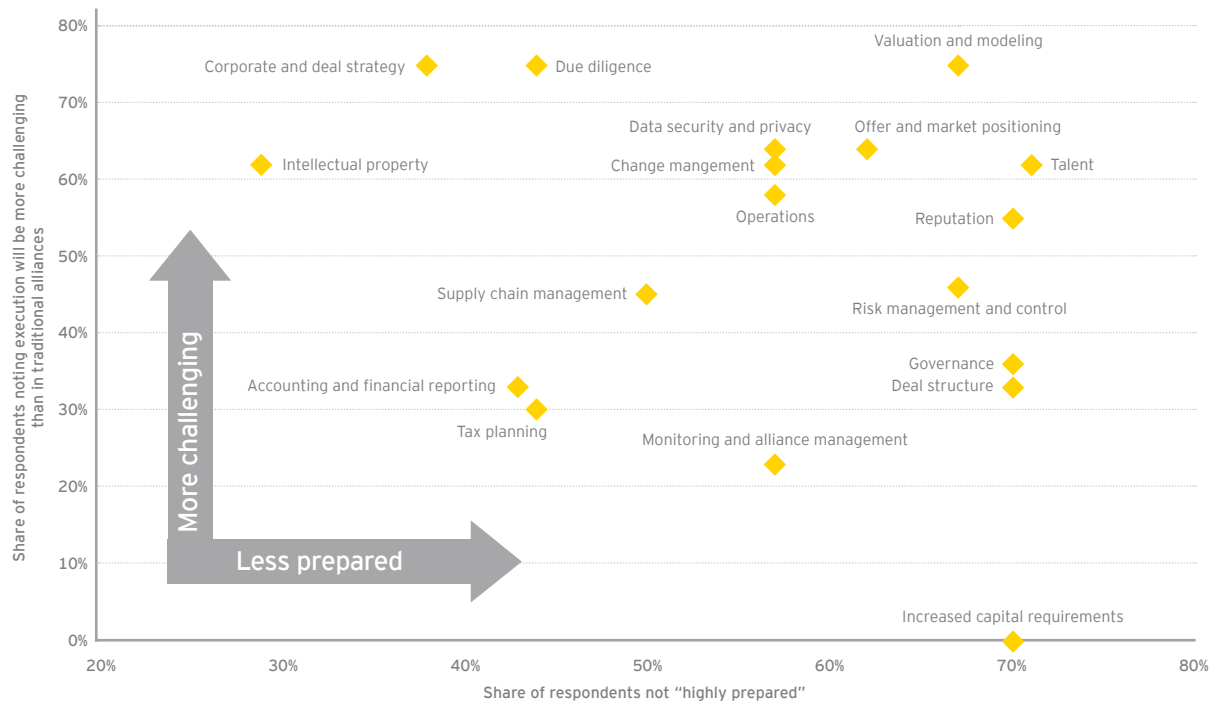
Risk management:

13. **Risk management and controls**
Reputation, compliance and other risks
14. **Data security and privacy**
Protecting data that may be increasingly central
15. **Intellectual property**
Protecting, managing and ownership of IP
16. **Reputation**
Safeguards for partnering with newcomers to health

Operations and supply chain management:

17. **Operations**
Systems integration, manufacturing, etc.
18. **Supply chain management**
Global supply of new products and market segment

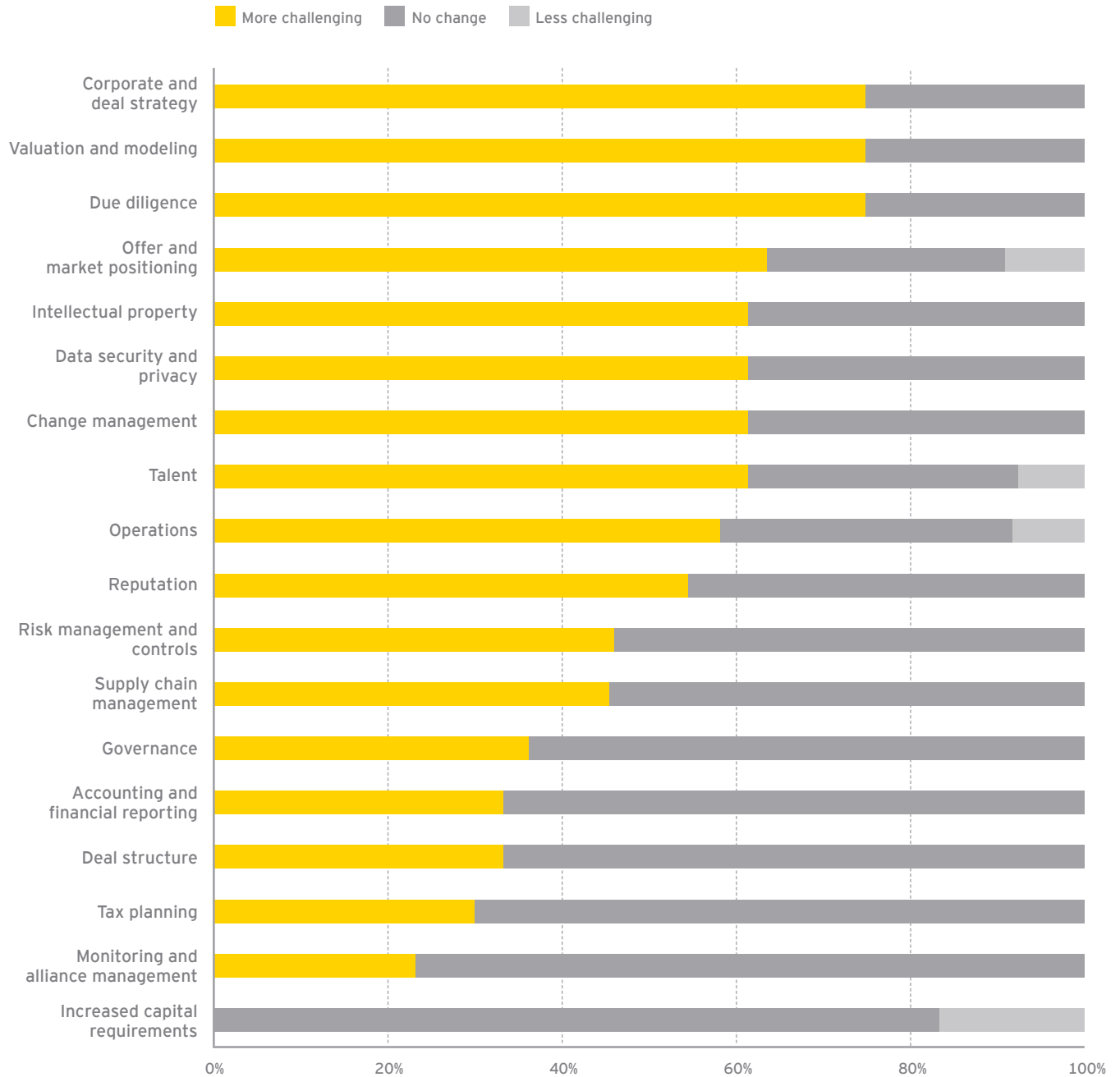
Challenges and readiness for executing nontraditional alliances



Source: Ernst & Young Progressions survey, 2009

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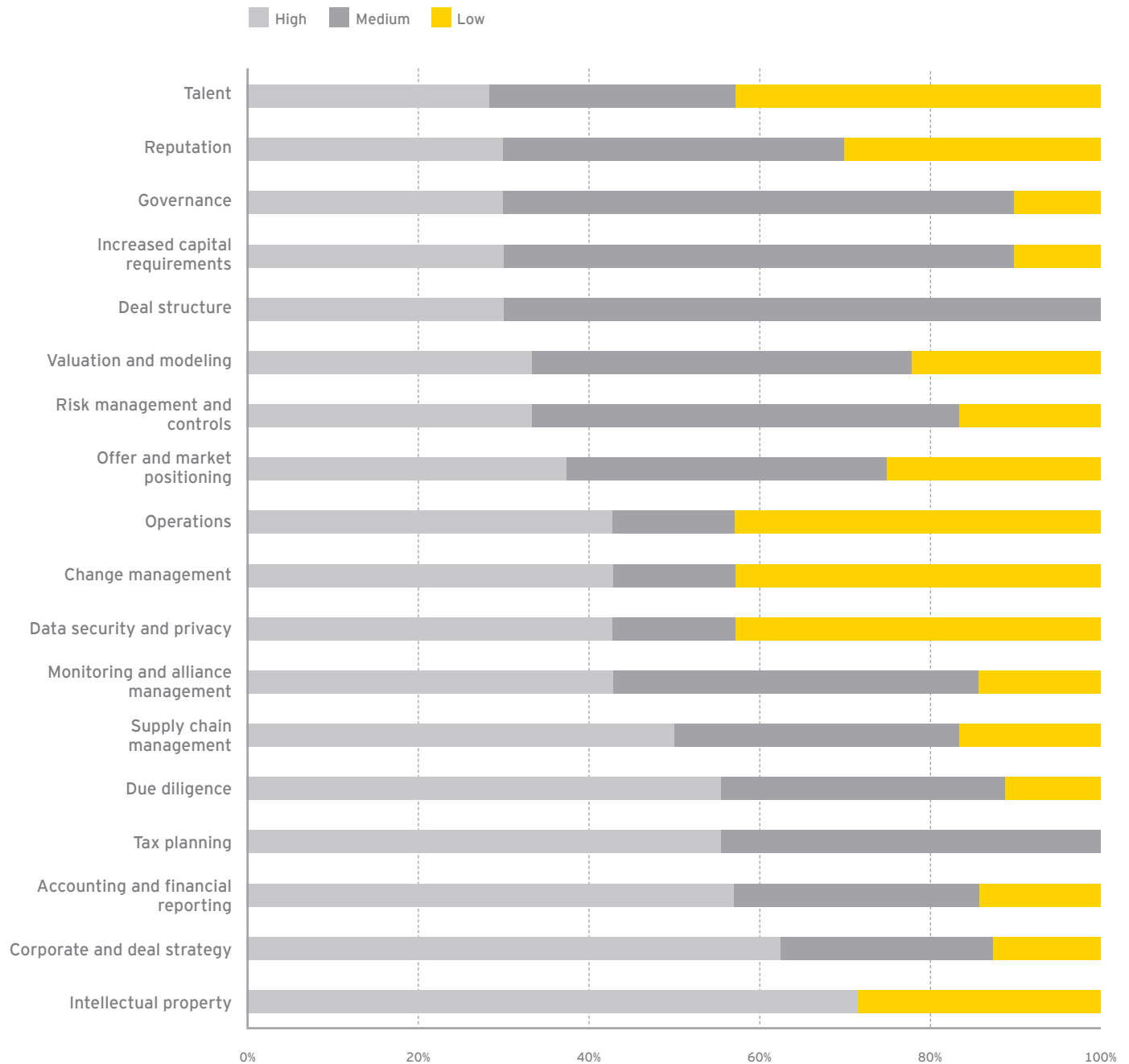
Challenges of creative partnering



Source: Ernst & Young Progressions survey, 2009

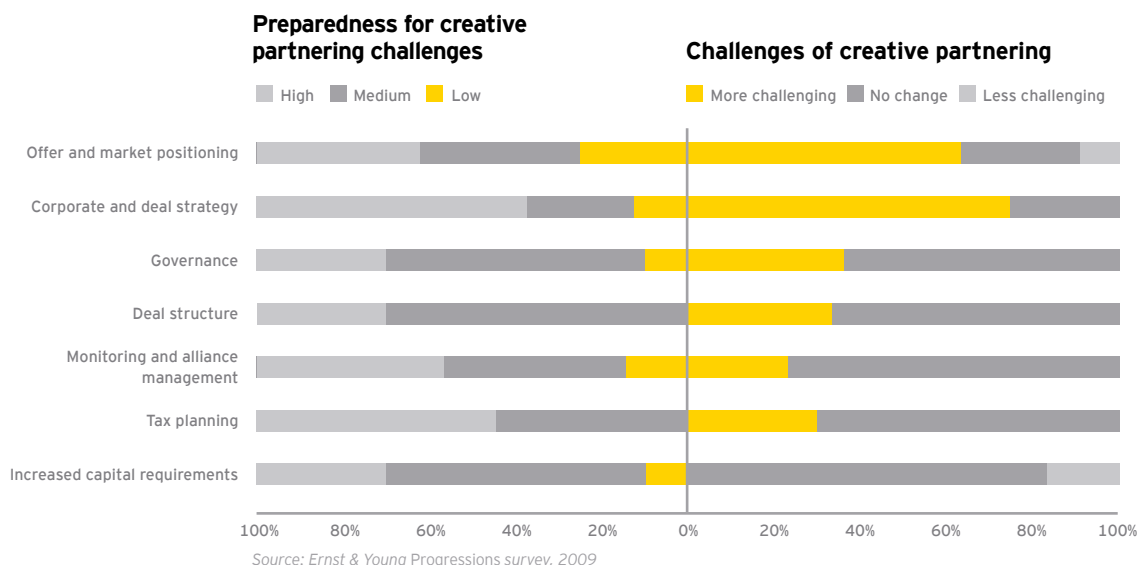
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Preparedness for creative partnering challenges



Source: Ernst & Young Progressions survey, 2009

Partnering challenges snapshot: strategy, structuring and governance



Challenges every step of the way

What follows are the key skill sets pharma companies will need to address as they delve into creative collaborations and business model innovation.

Strategy, structure and governance

Executives are clearly concerned about making the right strategic and market-positioning choices as they wade into nontraditional collaborations. They told us they are likely to experiment with different business models through limited and informal arrangements prior to making large-scale investments. For instance, they might structure the relationship as a service or a limited collaboration with the functions of the alliance taking place within each partner's existing structure. As discussed in Chapter 2, many small pilots are under way, because of the tremendous uncertainty inherent in the nascent phases of Pharma 3.0. For example, in social media, not only is the revenue model unclear, but regulatory policy on pharma companies' roles has yet to be resolved satisfactorily.

Partner selection

Finding the right partners for nontraditional collaborations requires a selection process every bit as rigorous as for M&A target evaluation. On the next page is a matrix we used recently to successfully help a large pharma company identify partners as it explored approaches to expand access in several emerging markets. The criteria included a weighted mix of financial and nonfinancial

Many small pilots are under way, because of the tremendous uncertainty inherent in the nascent phases of Pharma 3.0.

metrics, some with necessarily subjective quantification. A facilitated process within the pharma partner determined the criteria and their weightings. As might be expected, this process is more fraught with uncertainty when dealing with nontraditional partnerships with new offerings than it is for traditional

alliances. The list of criteria may need to be widened beyond companies' familiar checklists, and determining appropriate weights for these criteria is far more difficult when firms are playing in entirely new spaces, where it is hard to know which capabilities will turn out to be true value drivers. Still, the exercise is valuable. It compels companies to explicitly identify criteria for success and allows all the participating functions and departments to align their expectations for the collaboration.

Defining success

Unlike traditional R&D alliances and outsourcing arrangements, where the collaboration's goals are well understood, what each partner wants to achieve in a nontraditional alliance will likely vary from opportunity to opportunity. Goals could range from gaining insight into new technologies in a certain area, to establishing a market, enhancing reputation, improving process efficiencies or building a brand. Especially when the goals are not purely financial or readily quantifiable – or when the real value will

Partner selection matrix

Relative priority of criteria	Organization	Weighted criteria on a scale of 1-5						
		Partner A	Partner B	Partner C	Partner D	Partner E	Partner F	Partner G
50%	Strategic alignment	2.6	3.3	3	3	3.2	3	3.3
10%	Financial strength	2	4.3	2.8	3.6	4.3	3.3	3.5
10%	Corporate governance	1	4	4.3	2.5	5	3	3.3
10%	Experience on the ground	2	4.4	3.3	3.7	3.5	3	3.8
10%	Partnering history and experience	2	4	4.5	5	4.5	1	3.3
10%	Reputation and global credibility	2	3	4.7	4	3.6	2.6	3
	Average score	2.2	3.6	3.5	3.4	3.7	2.8	3.3

Source: Ernst & Young, 2010

be generated outside the collaboration – partners need to get comfortable with qualitative metrics and a process for verifying them. In one robust example cited in the January/February 2010 *Harvard Business Review*, a successful clinical-trials alliance between Solvay Pharmaceuticals and the contract research organization Quintiles used the balanced-scorecard framework to focus on delivering three important stakeholder outcomes:

- ▶ **Dramatically improved clinical development efficiency**
- ▶ **A significant number of commercially viable compounds brought to market**
- ▶ **Increased value from innovative approaches to clinical development**

The Solvay/Quintiles teams also explicitly addressed the value proposition for each “customer”: patients, payers, regulators, investigators and prescribers. This group would expand for Pharma 3.0 ventures to include providers and nontraditional parties.

Unlike traditional R&D alliances and outsourcing arrangements, where the collaboration's goals are well understood, what each partner wants to achieve in a nontraditional alliance will likely vary from opportunity to opportunity.

Any approach to goal-setting must also allow for mid-course corrections when the environment changes. Particularly in the new collaborations that form the backbone of business model innovation, partners need to have a well-defined process for adjusting goals and priorities as market uncertainties are resolved in the new ecosystem and new challenges emerge.

Tax structuring considerations

Historically, the pharma industry has not conducted alliances through the formation of formal legal entities but rather spelled out the rights and responsibilities of the parties in detailed contracts. In the toe-in-the-water early stages of “commercial trials,” we expect this to continue. However, as some of the survey respondents indicated, the parties may establish more formal legal structures – such as corporate joint ventures – as an alliance progresses to later phases of commercial trials. This would be driven by considerations such as the need for protection from legal liability in higher risk, unproven markets and the need to create a vehicle for increased investment in infrastructure. In selecting the appropriate structure, companies will also need to consider tax considerations and accounting implications such as consolidation requirements. (For a discussion of tax considerations related to joint ventures, refer to *A closer look* on page 56.)

A closer look

Tax considerations in joint ventures

While operational and legal needs may be the primary drivers in creating a legal entity for a joint venture, companies often fail to consider tax implications. The result can be unexpected tax consequences and inefficient tax structures. Pharmaceutical companies are very experienced in structuring collaborations relating to drug development and commercialization, and they typically employ complex tax structures because of the high intellectual-property content of their products and the global scope of their operations. But creative alliances with nontraditional partners can sometimes result in more structural complexity and therefore increase the tax challenges.

The first questions are what type of legal entity the joint venture should use (e.g., corporation, limited liability corporation (LLC) or equivalent, or partnership) and whether it should be a domestic or foreign entity. The answers typically depend on the goals and geographic scope of the joint venture, the domiciles of the parties and their motivations. While a corporation provides certain legal protections, the entity will generally be treated as a separate taxpayer. Any losses accumulated during the development stage may not be used by the partners to reduce their taxable income but rather will carry forward as net operating losses that might diminish the joint venture's tax liability in the future. A partnership, on the other hand, may not provide the same legal protections as a corporation, but will generally allow for the current "pass-through" of income and losses for recognition at the partner level. Lastly, an LLC (or perhaps a non-US equivalent) is often a popular choice, as it offers certain legal protections and provides for the current pass-through of income and losses to the partners.

Choosing the domicile of the joint venture is another important consideration. If foreign partners are involved in the venture, a flow-through entity may expose them to taxation in the country in which the joint venture operates. There may also be withholding-tax considerations relating to future distributions as well as interest and royalty payments. While a corporation may insulate the partners from taxation in the foreign jurisdiction, withholding taxes would still be a consideration. A flow-through entity could also subject the

Bruce Bouchard
Ernst & Young



partners to taxation in the states or provinces in which the venture has taxable activities. Corporate joint ventures would generally file separate returns but may need to file unitary and combined returns with a partner, depending upon elements of ownership and control over the venture.

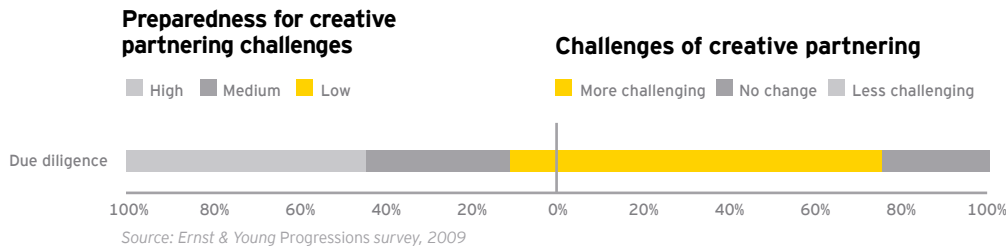
Companies will need to consider a number of questions related to the contribution of tangible or intangible property to a joint venture, how the venture will be funded, and how each party might exit the venture. These issues can become especially complex in the context of a creative alliance *vis-à-vis* a traditional collaboration arrangement. Such issues include:

- ▶ Will property be licensed or contributed to the joint venture?
- ▶ Can the licenses and property be transferred to the joint venture on a tax-deferred basis?
- ▶ What should the debt and equity mix consist of, will there be various classes of equity, and are there any special arrangements such as reciprocal option agreements?

The answers to these questions will influence the choice of legal entity. In addition, if a pass-through entity is used, the parties may have greater flexibility to allocate tax attributes of the venture differently from the allocation of ownership interest, to meet their specific needs.

Revenue recognition and tax accounting matters may also be significant to the joint venture. It is important to consider the tax treatment of license payments and milestones, since the timing of income recognition for tax purposes may vary significantly from that used for financial statements. Depending on the jurisdiction, the joint venture may also qualify for various tax and business incentives, including R&D tax credits, investment tax credits, and employment-related grants and credits. The structure of the joint venture may allow the credits to be passed directly through to the partners or reserved for use against the venture's own tax liabilities. And finally, it is important to identify tax-efficient exit strategies for the partners or alternatives for a tax-advantaged termination of the venture.

Partnering challenges snapshot: due diligence



Due diligence

In a recent study conducted by Ernst & Young (*Why capital matters*), 79% of the life sciences senior executives surveyed expect increased or significantly increased scrutiny by stakeholders. Thorough due diligence is an important tool to identify potential deal issues and reduce the probability of difficult conversations with stakeholders. In Pharma 2.0, deals have typically involved alliances and acquisitions of molecules, technology platforms or entire companies. In such instances, firms are essentially buying familiar assets with which they have considerable experience, and due diligence is consequently a well-defined process. In Pharma 3.0, as pharmaceutical companies increasingly experiment with developing nontraditional products and services using alliances, it is not surprising that 75% of executives surveyed believe that due diligence will become more challenging.

In the early phases of commercial trials, where companies are investing less capital and resources and have less reputation at risk, we expect diligence activities to be more limited. At this stage, companies may often have more limited objectives and will place more emphasis on moving quickly and conducting pilots – forgoing excessive amounts of diligence, especially related to information that can be ascertained through the pilot process. The art will be determining what needs to be understood and assessed in the

In a recent study conducted by Ernst & Young (*Why capital matters*), 79% of the life sciences senior executives surveyed expect increased or significantly increased scrutiny by stakeholders.

proof-of-concept phase and what can wait until the later commercialization phase. Pre-commercialization, companies will want to assess the following factors.

Commercial diligence on new products and services

Many of the new deals we anticipate may not be about accessing a technology as much as they are about co-creating entirely new products, services and business models from scratch. Consider “Deal A” discussed in Chapter 2, which brought together a pharmaceutical company, a global insurance company and an IT company into an alliance that focused on developing technology to enable outcomes. This scenario presents multiple diligence challenges for the pharma partner – in particular, understanding the assets and capabilities of the potential partners.

These concerns are especially acute when partnering to access cutting-edge technologies – an area where pharma companies are likely to lack internal

capabilities. A number of pharmaceutical executives commented on these challenges during our interviews. For instance, Beverley Jordan, Vice President, Special Projects and Business Development at AstraZeneca, observed that when pharma firms seek to enter nontraditional partnerships with IT companies, “this is a move away from due diligence conducted through scientists giving us a scientific assessment on a molecule in a clinical program. Our scientists couldn’t perform such assessments in an IT environment or a diagnostic environment.” Similarly, an executive from a major global pharmaceutical company observed that “when we talk to companies in the [IT] space, there’s no manufacturing line to see. Their ‘manufacturers’ are programmers and developers. How can we truly understand what’s there at the company? How do we assess what their assets are and how much they are worth?”

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For alliances in the IT space – such as personal health record offerings, social media networks and mobile health devices – pharma companies will probably be unable to conduct detailed technical reviews and will rely on the partners' expertise. Still, they will want to assess higher-level considerations such as scalability of the platform, interoperability of data, ease of use and security/privacy.

Companies will need to conduct diligence on partners from non-IT industries as well, to understand, for example, their brands, reputations and abilities to serve particular market segments or geographies.

Cultural due diligence

Even when a target technology or operating model is thoroughly understood, many deals in the life sciences industry fail to achieve their full

It is incumbent upon the pharma company to educate the partner on the industry, regulatory risks, and pharma company's code of conduct, and to ensure that its contract with the partner includes appropriate compliance provisions. Likewise, pharma companies will need to get up to speed and understand the risks resident in the regulatory regimes of other industries, such as insurance and provider care.

potential because of cultural differences. If cultural gaps are an issue between big pharma companies and emerging

biotech firms, think how much greater the chasms could be when dealing with firms from entirely different industries. Potential partners from the IT industry, for instance, may be accustomed to very different IP regimes and may have very different expectations around product development cycles and regulatory compliance, including in the commercial arena. In these new creative partnerships, companies may therefore need to make sure that the evaluation process includes cultural due diligence. Companies, and even entire industries, have very different cultural norms in areas such as decision-making processes, work processes, communication protocols, confidentiality expectations, risk management and regulatory guidelines. Developing a checklist around such indicators can help identify potential cultural gaps that need to be addressed.

Regulatory compliance

Due diligence must go beyond the basics of understanding the financial stability of the potential partner, its ownership structure and reputation. It must also include an evaluation of the company's organizational capability for working in a highly regulated commercial environment. General health care credentials, such as those of a health care provider, are helpful but may not provide sufficient knowledge of the regulatory-compliance requirements that lurk in the background of every pharma company interaction with patients. Lack of this knowledge might result in development of tools that result in violations with respect to off-label information and direct-to-consumer marketing, or create improper incentives. It is incumbent upon the pharma company to educate the partner on the industry, regulatory risks, and pharma company's code of conduct, and to ensure that its contract with the partner includes appropriate compliance provisions. Likewise, pharma companies will need to get up to speed and understand the risks resident in the regulatory regimes of other industries, such as insurance and provider care.



A closer look

Ted Acosta
Ernst & Young



Navigating the changing compliance landscape

Given the high levels of regulation they face, pharma companies must make significant investments in practices that aim to ensure that employees – regardless of their locations or business settings – abide by all applicable regulatory standards. As even the most rigorous of pharmaceutical companies still face compliance challenges, collaborations with industries unfamiliar with the complexity of pharma's regulatory landscape can only further the strain.

FCPA compliance

Compliance with the US Foreign Corrupt Practices Act (FCPA) is one area where the industry will face more scrutiny, and thus, challenges. In fact, in the last few years, there has been a notable increase in investigations of life sciences companies for FCPA allegations and matters. To be fair, this increase is not unique to life sciences companies, as overall FCPA enforcement actions have reached record numbers. From 2005 to 2008, the US Department of Justice (DOJ) brought 57 new prosecutions – more than the number of prosecutions between the FCPA's enactment in 1977 and 2005 – and has conducted more than 130 FCPA investigations since 2009.

However, with an estimated third of pharmaceutical sales coming from outside the US and the deep level of involvement of governments in many foreign health care systems, life sciences companies are particularly at risk for illegal or corruptive activity and have become the focus of even greater DOJ and SEC scrutiny. As pharmaceutical companies establish alliances with industries unaccustomed to such regulatory scrutiny and also unfamiliar with the seemingly ubiquitous presence of government officials in health care systems outside the US, it is likely the US government will keep a careful eye on these relationships and, especially, on how companies are managing the risk of corruption and bribery.

Sales and marketing compliance

Another area that continues to present compliance hurdles for pharmaceutical companies is sales and marketing guidelines. These guidelines are very specific to the life sciences industry, preventing illegal inducements and restricting purchase incentives, direct-to-consumer marketing and sharing of off-label information. Yet as communications media continue to evolve – thanks largely to advancements in mobile phone technology and the internet – lapses in compliance continue. (For more on the regulatory challenges of social media and Web 2.0, see "Tweet nothings" on page 13). In-house and contract sales forces also are a risk factor as companies strive to provide enough training, cost effectively, to ward off human

error and intentional misconduct. As pharma companies create innovative partnerships outside their industry, extra training and diligence will be essential for these new partners that, in many cases, have had minimal restrictions on how they promote products.

Physician Payments Sunshine Act of 2009

Transparency continues as an important theme in new government laws and regulations, and with that, the US Congress has introduced the Physician Payments Sunshine Act of 2009 as part of the country's broader health care reform proposal. The latest version of the act – which was originally introduced in 2007 – proposes that pharmaceutical companies, as well as manufacturers of medical devices, supplies and biologics, disclose payments with a cumulative value over US\$100 made to health care professionals and health care institutions and organizations. Ownership interests in manufacturers or group health organizations must also be disclosed. Because financial relationships can clearly influence support of new products and prescribing behavior, some speculate this act could eventually be adopted globally.

In the interim, some states in the US have put in place their own reporting regulations. Pharmaceutical companies, though, are already finding that existing processes and systems are challenged in tracking payment activity in full, making compliance onerous. As pharma companies form new collaborations with nontraditional partners, the challenges in tracking these investments will only become more complex, as processes and systems will need to be modified to enable tracking in aggregate across both entities.

The integrity of medical judgment, patient benefits and health benefit programs is a major focus of governments around the world, and compliance oversight and enforcement efforts continue to increase. As pharmaceutical companies explore collaborations with industries new to health care, compliance risks become exacerbated because new partners may simply be unaware of certain industry regulations that are contrary to the way these new partners have always done business. The emphasis on adequate and specific due diligence before a relationship is forged, as well as after, is imperative to ensure that the additional challenges to regulatory compliance are understood and can be met. As pharmaceutical companies branch out with new collaborations, success can depend simply on how well these new entrants to the industry can play by the rules.

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Given the forecasted growth opportunities in emerging markets, pharma firms may increasingly enter nontraditional alliances with foreign partners as a point of entry. Understanding cultural, regulatory and operational differences will be critical. Foreign-owned companies are often treated differently from their domestic competitors, including through ownership restrictions that require them to partner with local companies. US corporations are subject to the Foreign Corrupt Practices Act, and companies everywhere face increasing focus on foreign-generated revenues. Regulatory violations, or even allegations of impropriety, can be expensive to resolve and devastating to corporations' and executives' reputations. (For more detail, see "Navigating the changing compliance landscape" on page 59.)

Financial

The financial elements of a transaction have always been a significant part of the due diligence process. In their deals so far, pharma companies have typically dealt with for-profit entities. In some cases (e.g., when partnering to develop new solutions to expand access in rural areas in the developing world), companies may now find themselves partnering with nonprofits, NGOs or government agencies. These entities may not have the same levels of financial reporting, controls and safeguards as private-sector firms – making due diligence on the financial viability of the partner all the more

challenging. In addition, pharma firms will want to confirm that these other parties have sufficient internal systems and controls to report quality financial data about their contributions to the alliance on a timely basis.

Financial due diligence considerations would also include accounting and financial reporting as well as valuation and modeling. These topics are discussed in greater detail later in this chapter.

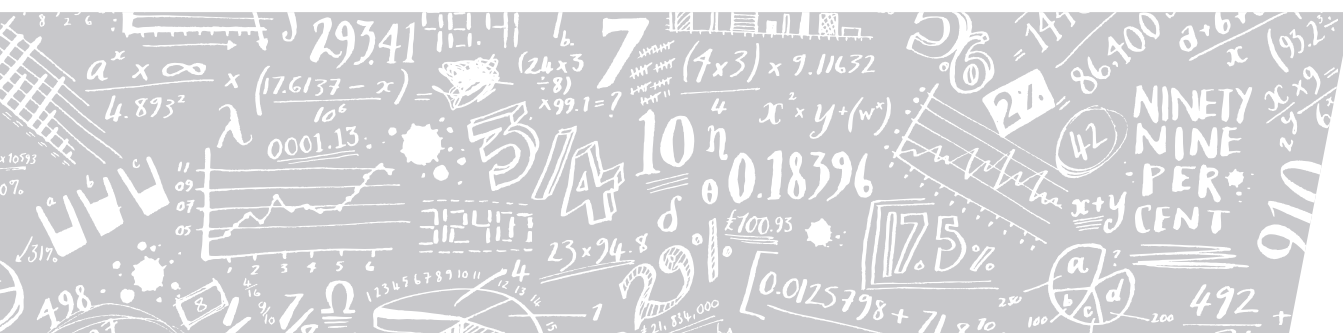
Information technology

The issues around IT diligence go beyond understanding the infrastructure and applications. In Pharma 3.0, when pharma companies partner with firms from other industries, they may find that both parties have IT systems suited to the needs of their specific industries, while neither system is quite perfect for the new product or service being developed. Understanding the capabilities of each system and determining where incremental investments will be needed therefore becomes a key part of the diligence process. In addition, interoperability, security and standards play a vital role in fulfilling the extraordinary communication requirements of joint ventures and nontraditional alliances. In adapting the existing IT systems of the partners – or when creating a new system from scratch – firms will need to consider industry-specific regulatory requirements and whether the IT team and business-line staffs have the requisite knowledge and experience.

In addition to the risks, due diligence can also identify opportunities to utilize new technologies that can potentially increase efficiencies and reduce forecasted operating costs. Developments in technology and standards have enabled simplification and time reductions that many IT departments are not

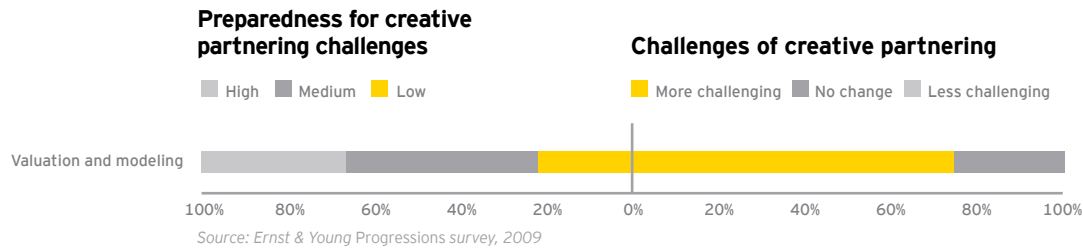
In Pharma 3.0, when pharma companies partner with firms from other industries, they may find that both parties have IT systems suited to the needs of their specific industries, while neither system is quite perfect for the new product or service being developed.

familiar with, or have not implemented. Advancements in software as a service (SaaS), data standards, transmission technology, application design and data handling may allow work to be completed for far less than the participants presume. Thorough diligence will identify alternative approaches and identify and quantify potential risks and benefits.



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Partnering challenges snapshot: valuation and modeling



Valuation and modeling

Valuation and business modeling has always been a core competency in the pharmaceutical industry. Given the extended product development life cycle, companies must make long-term investment decisions based on assumptions such as a product's future market opportunity, the probability of success and the ability to meet internal "hurdle" rates of return. In the case of alliances with nontraditional partners, we expect that this will continue to be the case, especially for those alliances that move beyond the proof-of-concept stage and require additional investment in infrastructure to fully exploit the commercial opportunity.

As companies enter creative transactions to develop new business models for the Pharma 3.0 ecosystem, the complexity of the valuation and business modeling challenges will also increase. To appreciate why, consider that any

valuation exercise essentially requires information about three variables: the probability of a project's success, the anticipated time frame to success or failure, and the size and timing of future revenue streams from a successful outcome. Estimating these variables for an entirely new service offering (which may essentially have to create its own market and therefore lack "comparables" on which to base assumptions) will be more difficult than estimating the potential market for a new drug.

Not surprisingly, the gap analysis conducted on the Ernst & Young survey results found that companies consider "valuation and modeling" to be the number one future challenge as they seek to structure creative deals for the Pharma 3.0 ecosystem. While 75% of business development executives expect that valuation and modeling will become more challenging, only 33% said that they were highly prepared to deal with the challenge – a 42 percentage point spread, and the biggest gap of any deal-related challenge considered in the survey.

So how can companies address these valuation challenges? One answer may lie in the use of different kinds of valuation models. For all the talk of alternative modeling techniques, the mainstay of valuation and modeling in the pharma industry has remained discounted cash flow (DCF) analysis, primarily because of familiarity. This may need to change as companies enter deals with much higher

For all the talk of alternative modeling techniques, the mainstay of valuation and modeling in the pharma industry has remained discounted cash flow (DCF) analysis, primarily because of familiarity. This may need to change as companies enter deals with much higher degrees of uncertainty.

degrees of uncertainty. Monte-Carlo simulation, for instance, allows companies to incorporate this increased uncertainty into their modeling. Instead of requiring a specific "point estimate" for each input, Monte-Carlo models use randomly generated ranges of input values based on specified probability distributions. Using these ranges of randomly generated values for different inputs, companies can then simulate a distribution of outputs and make decisions based on the range of likely outcomes.

In traditional licensing transactions or acquisitions, easily measured cash or other consideration is being exchanged in one direction. In a joint venture, on the other hand, each party is trying to understand the information provided by the other side in order to value its own and its partner's contributions. Inevitably there is some disagreement between the parties' analyses, which

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must be reconciled. In a new business model created by nontraditional partners, there is more inherent uncertainty about where value will be created. As such, companies may gravitate from relatively simple structures toward more strategic commercial relationships where equity interests and returns are adjusted based on the relative contributions of each party's contributed assets to the overall performance of the venture.

A particularly innovative partnership structure that illustrates this point is the recent HIV deal between GlaxoSmithKline (GSK) and Pfizer, named "ViiV." This new joint venture was built from GSK's existing marketed product strengths and Pfizer's early-stage and emerging R&D portfolio to form a new entity with greater combined sustainability and growth potential. The parties aim to share value, risk and reward based on their relative contributions and the commercial outcomes that may eventually be created. This was handled through the use of the scalable equity construct (which uses contingent future equity and preference dividends based on pre-agreed milestones for specific products – and makes valuation quite a bit more complex). Initial ownership was based on contributed assets, while upside (and potential downside) was based on the success of the pipeline products.

A particularly innovative partnership structure is the recent HIV deal between GlaxoSmithKline (GSK) and Pfizer, named "ViiV." This new joint venture was built from GSK's existing marketed product strengths and Pfizer's early-stage and emerging R&D portfolio to form a new entity with greater combined sustainability and growth potential.

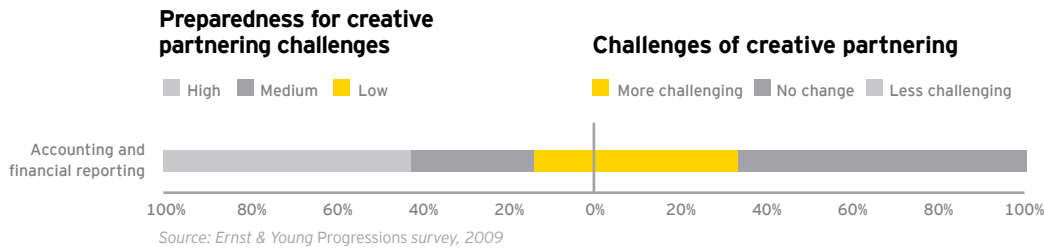
Even what should be straightforward gets complex. Although GSK and Pfizer are both English-speaking companies, they found themselves speaking two different accounting languages – International Financial Reporting Standards (IFRS) and US GAAP – which influenced valuation treatments.

Companies should also keep in mind that current valuation methods for financial reporting include the concept of the "market participant acquirer" – which seeks to apply the assumptions of a typical market participant rather than

those of the actual participants. While this is a difficult concept to apply in any transaction, the level of difficulty is much higher for joint ventures. In a joint venture, two specific companies come together for very definite commercial and strategic reasons. When valuing the new joint venture company, it is harder to put aside the specifics of the real transaction because of the obvious and important interplay between the business of the parent companies and the joint venture. This can relate to assumed tax rates, synergies and contractual agreements with the parent companies – each of which must be considered in a market participant framework.

While the above discussion focuses on valuation and modeling challenges related to alliance (including joint venture) transactions, it is possible that pharma companies will seek to access certain capabilities through M&A transactions as well. Because of recent changes to accounting rules and increased use of deal terms such as contingent consideration, more companies are realizing the benefits of simultaneously working toward determining the price and modeling the allocation of that price for financial reporting purposes. Doing so allows firms to better align the post-deal accounting with the overall rationale for the transaction.

Partnering challenges snapshot: accounting and financial reporting



Accounting and financial reporting

While accounting for alliances and collaboration arrangements can be complex for both parties, the majority of survey respondents did not believe that transactions with nontraditional partners would present more challenges than historical deals, and a similar cohort felt they were highly prepared to deal with the accounting challenges that did arise. The facts and circumstances for any particular arrangement are unique and will ultimately determine the specific matters requiring consideration. The discussion below examines common accounting considerations which require evaluation.

Formation and subsequent accounting for the alliance

The formation documents and legal structure of an arrangement will determine the related accounting by the partners, in particular the accounting for the assets contributed upon formation and whether a partner is required to consolidate the joint venture entity – or even, in an extreme case, the joint venture partner – into its financial statements. Determining the initial accounting, including the valuation of contributed assets and the determination of whether a collaborator should consolidate the venture or account for its interest using another method, requires a careful analysis of the specific facts and circumstances. This initial determination, as well as the ongoing accounting for the arrangement, can be even more complicated for unique or innovative

structures. Consider, for example, a case where a pharma company is partnering with a nontraditional player to develop a new product or service offering. In such a situation, where the parties don't know in advance exactly which assets or capabilities will drive more value, they may structure an arrangement to provide variable returns to the partners based on the outcome of the uncertainty – for example, through adjustable profit splits or changes in ownership interests. Such a structure could affect the ongoing accounting for the partners' ownership interests in the venture, including whether a party must begin consolidating. Additional complications may arise if the partners utilize different financial reporting conventions.

Recognition of revenue

The timing and amount of revenues recognized by the partners from product sales are impacted by the structure of the alliance and related sales terms. Examples include determining whether products developed will be sold by the alliance or by a partner and if they will be sold under pay-for-performance arrangements. In addition, the partners should consider who will be considered the "principal" in the arrangement. The determination of the principal – the party able to record the full, or gross, amount of revenue related to a particular transaction – is dependent on the individual facts and circumstances, but it is generally the primary obligor in an arrangement or the party with general inventory risk. The other parties typically only record the net amount retained in a transaction.

As such, determining the principal is critical, particularly to a collaborator's growth in reported revenues. An example is in the sidebar below.

Revenue recognition: matters of principal

Consider an arrangement where **Company A** agrees to sell its products to **Company B**, which then bundles those products with its own products before selling them to the end user. The arrangement also provides **Company A** with a contractual right to share in the profits generated by **Company B**. While such a structure can eliminate some of the complexities associated with the creation of a formal joint venture entity, the arrangement has revenue recognition considerations for both parties. **Company B** would need to consider whether it was the principal in the arrangement in order to determine if it should report the gross revenue from sales of the bundled products. If **Company B** were not deemed the principal in the arrangement (as may be the case if **Company B** never took delivery of **Company A**'s products), then it would reduce reported revenues by the amount paid to obtain product from **Company A**. From the perspective of **Company A**, the primary revenue recognition question is the ability to estimate the amounts to be received from its interest in **Company B**'s profits. Depending on the information available, **Company A** may not be able to reasonably estimate the amount due from **Company B** prior to receipt of payment, which could delay revenue recognition beyond the date of the customer transaction.

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Recently, life sciences companies have responded to an increased emphasis on cost-effectiveness and economic value by developing innovative pricing structures as a way to share risk with payors. Some arrangements go so far as to link reimbursement to achieving a desired clinical outcome – in essence providing a “money-back guarantee” on a product. While providing a means to secure market entry, pay-for-performance arrangements introduce multiple questions related to the timing of revenue recognition and, in certain circumstances, may result in the deferral of revenue until the performance criteria are met. Companies should carefully consider the design of such arrangements in order to minimize any unintended financial reporting impacts or operational challenges in administering the plans. For example, performance guarantees based on less objective outcome measures or long treatment periods may lead to prolonged revenue deferral and the requirement to track large volumes of data.

Financial reporting

The inability to obtain reliable financial information or financial statements that are prepared on a comparable basis can negatively impact the partners’ ability to monitor alliance performance against metrics and comply with their respective financial reporting requirements. In circumstances where the parties to an arrangement utilize different financial reporting conventions – as would be the case in a partnership between a US company reporting under US

“To succeed in partnering with nontraditional companies, a pharma company has to put someone in charge who is credible. That person needs to clearly view this as a way of enhancing his or her career and needs to be given the credibility and resources to succeed.”

– Peter Garrambone,
Torreya Partners

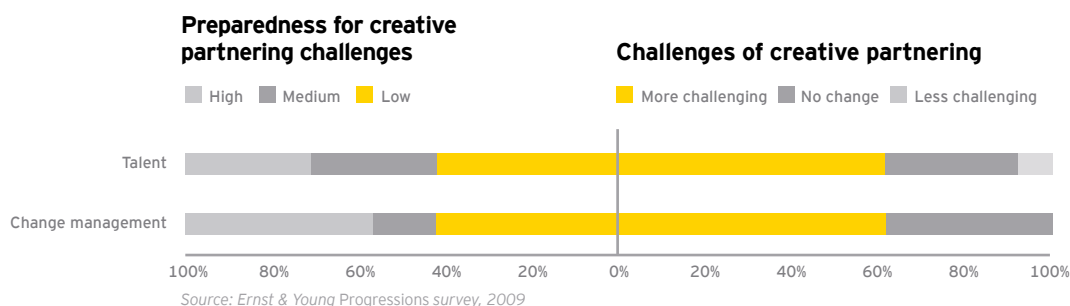
generally accepted accounting principles (US GAAP) and an entity reporting under International Financial Reporting Standards (IFRS) – the challenges may increase as the different financial reporting requirements of each company could complicate the design of a mutually beneficial structure. Furthermore, alliances with nontraditional partners may result in a partner using financial reporting requirements applicable to another industry. Agreements should clarify the financial statement requirements of the partners and related controls should be designed and implemented to ensure the information is both accurate and complete. In a formal joint venture arrangement, collaborators will likely need to develop a controls infrastructure specific to the joint venture to facilitate the venture’s financial reporting requirements and produce accurate information for accounting by the partners.

Talent and change management

What happens *after* the deal is signed? Managing change, and getting organizations aligned with the transaction’s objectives, has always been an area of focus, and change management for nontraditional alliances will be even more challenging. Not surprisingly, “talent” and “change management” had the second- and sixth-largest gaps, respectively, in terms of preparedness. The two are linked – to succeed at managing change, companies will need to manage talent well. “The major challenges are not technological – they are human,” says a pharmaceutical executive we interviewed. “Change is tough on people, and changing an organization’s culture and value system takes time.” Indeed, effective change requires strong executive sponsorship, focused talent and expertise, a shared vision and culture, effective measurement and time:

► **Strong executive sponsorship.** In our interview with him, Peter Garrambone, Principal at Torreya Partners (and someone who has 25 years of experience as a pharmaceutical industry executive and has been involved in over US\$200 billion worth of M&A transactions), emphasized the need for strong executive support. “To succeed in partnering with nontraditional companies,” he said, “a pharma company has to put someone in charge who is credible. That person needs to clearly view this as a way of enhancing his or her career and

Partnering challenges snapshot: talent and change management



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"The major challenges are not technological – they are human. Change is tough on people, and changing an organization's culture and value system takes time."

needs to be given the credibility and resources to succeed."

- **Invest in expertise.** In addition to strong sponsorship, companies will need to engage subject-matter experts who understand the drivers of the alliance. "If pharma firms don't have people who understand technology – and are part of operational units and core teams – it will be very, very hard for these firms to successfully partner with technology companies," states Paul Smit, formerly SVP of Philips Healthcare. Managers should engage subject-matter experts and listen intently to what they believe will make the alliance successful. It is not only important to identify current experts within their organizations but also to develop new talent by shadowing

more-experienced colleagues and by creating and rewarding a knowledge-sharing mind-set.

- **Consider the culture.** In nontraditional alliances, cultures can clash. To avoid this pitfall, companies should identify each party's cultural norms and look for common ground. Then the partners should create a shared vision by focusing on necessary behaviors rather than on which culture is better. Leaders will need to communicate this vision frequently and should "walk the talk" by displaying optimal behaviors, coaching others, and swiftly removing "blockers" – those who are actively working to derail the alliance.
- **Invest time for, and measure, success.** Even with a strong sponsor, the right talent and a synchronized culture, it is important to focus on the execution process. Firms will need to put a governance model in place and determine a shared escalation path for conflict and decision-making. They should identify the objectives of the alliance and the tangible benefits for each party and then measure and monitor outcomes. They should also incorporate lessons learned into the process. Finally, firms need to

recognize that change takes time and to give people the opportunity to adopt change and to also celebrate successes often and openly. This will gain trust and reinforce the alliance vision.

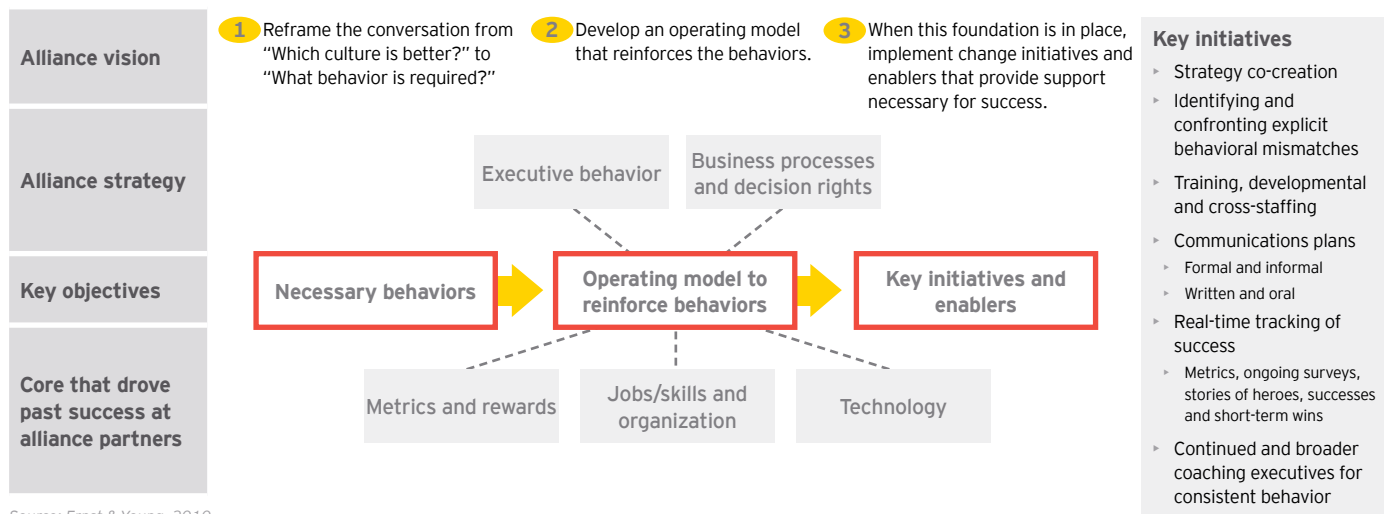
- **Develop a change management road map.** A formal change management plan helps ensure that the issues discussed above and other critical tasks are effectively addressed in a timely manner. Such a plan converts the key objectives of the alliance into the initiatives and corresponding enablers needed to succeed (see chart below).

"If pharma firms don't have people who understand technology – and are part of operational units and core teams – it will be very, very hard for these firms to successfully partner with technology companies."

– Paul Smit,
Philips Healthcare

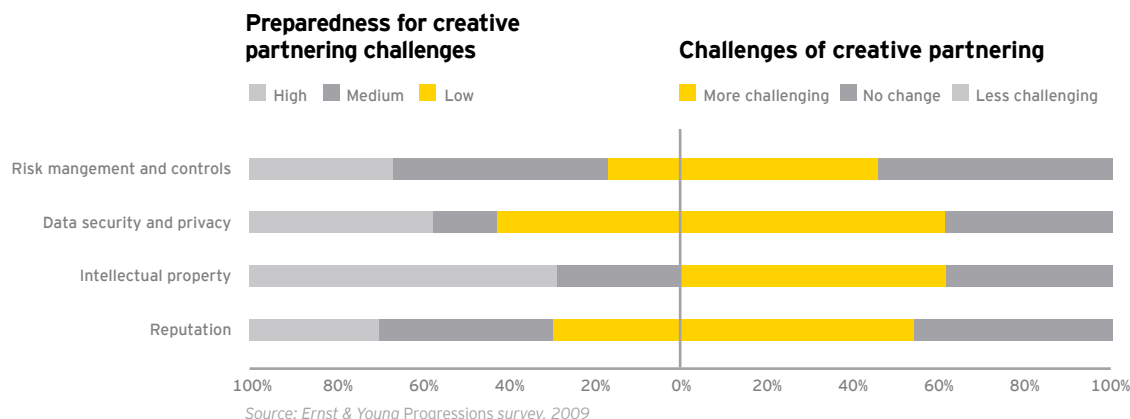
A change management plan

Establishing clear organizational leadership and reinforcing required behaviors are key to achieving the alliance objectives



Source: Ernst & Young, 2010

Partnering challenges snapshot: risk management



Risk management

Risk management and controls

Life sciences companies have always been in the business of risk. Developing drugs is an activity fraught with considerable uncertainty, where companies spend large sums on R&D and only a small minority of drug candidates becomes commercialized products. As they adapt to Pharma 3.0 and develop new business offerings, companies are taking on new risks and in many cases they will enter completely uncharted territory, where firms may not even fully know *what* they are developing, let alone how likely it is to succeed.

When the core business of companies involves undertaking large amounts of product development risk, it becomes

As they adapt to Pharma 3.0 and develop new business offerings, companies are taking on new risks and in many cases they will enter completely uncharted territory, where firms may not even fully know *what* they are developing, let alone how likely it is to succeed.

all the more imperative for them to minimize *secondary risks* from other sources. (For a deeper discussion on this perspective, see 2009 Ernst & Young *business risk report: life sciences*.) This approach is every bit as applicable in the development of new business models as it is in the development of new products.

Consequently, risk management becomes even more important in nontraditional and creative alliances. Companies will need to consider the broad spectrum of risk – strategic, financial, operational and compliance – and identify the potential risks in each category:

- **Strategic risks** could include threats to a company's brand and reputation, since firms may ally with partners that are unfamiliar with the industry's regulatory environment. This challenge is compounded in partnerships that seek to expand access in emerging markets, where the regulatory environment is often in flux and where pharma companies may themselves have less familiarity with the regulatory landscape.
- **Financial risks** are also likely to be more tricky in nontraditional alliances. The challenge of making sure that financial terms are followed by partners becomes harder when there is increased ambiguity in defining and measuring partnership goals. It is

Companies will need to consider the broad spectrum of risk – strategic, financial, operational and compliance – and identify the potential risks in each category.

quite straightforward to identify when a drug-related milestone, such as the endpoint of a clinical trial, has been reached. But it may be considerably more difficult to define what constitutes an acceptable beta version of a groundbreaking new service offering, particularly when neither party knows up front exactly what the final offering will look like. Tracking financial items such as expenditures and transfer prices may be more difficult when other parties, such as NGOs or nonprofits, do not have the sorts of financial reporting to which pharma companies are accustomed.

- **Operational risks** will be a critical area of focus as the day-to-day operations of new business offerings likely give rise to a host of risks and challenges. Maintaining the integrity of the supply chain, already demanding in the era of globalization, is likely to become even harder as companies enter new

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alliances to expand into remote rural areas. (For more details, see *A closer look* below.)

► Last but not least, **compliance risks** are inescapable in a highly regulated industry such as pharma. The range of legal/regulatory risks facing pharma

companies is incredibly broad and difficult to manage even within the organization. The introduction of third parties or alliance partners

A closer look

Managing supply chains

The inevitable loss of control that comes as pharma companies extend the reach of the “extraprise” to involve outside partners is probably most apparent in supply chain operations. From a procurement standpoint alone, a whole variety of sources are being used today to supply raw materials, many of which are being manufactured in far-flung regions of the world.

While many companies expected to gain flexibility in capacity and lead times through the use of contract manufacturing organizations and other third parties, the reverse has often been the case. Outsourcing has produced efficiency gains, but has also reduced pharma companies’ nimbleness in responding to changes in market demand. Lead times for orders that can span six months – or up to two years in the case of biologics – have increased pressure on forecasting models to accurately gauge what demand will look like months or even years down the road.

As the pharma industry moves to new business models, alliances and joint ventures, it will need significant shifts in its approach to supply chain and manufacturing operations. Companies will need to foster more collaboration, both internally between departments as well as across an extraprise. Identifying and transferring assets into a collaborative environment is challenging – there are many significant questions to consider, including:

- Who contributes and who owns intellectual property and the derivatives that may come about from the collaboration?
- What personnel are being pledged by the parties? Who is responsible for their training, development and continuing education?
- What manufacturing, operational and packaging assets are part of the collaborative operation? Does the ownership and intended use of these facilities align with the tax structure of each of the parties? If each organization in the collaboration is trying to minimize its asset footprint and ownership, can this be achieved?

Mark Hassenplug
Ernst & Young



- How will service-level, quality, compliance, risk and liability sharing agreements be handled?
- What are the water, power, waste and cleantech approaches? Who gets carbon offset credits if they exist?
- Who contributes the methods and tools that power the collaboration’s success? What ownership rights do each of the parties have in these work methods?
- How will the information systems work in a collaborative, open environment, and whose system is it? If the partnership is dissolved, who will retain responsibility for maintaining and providing access to the data? Who is responsible for litigation discovery?

Pharma companies are in the beginning stages of exploring nontraditional business models to unlock value in their supplier relationships and increase the flexibility of the network. They’re partnering with overnight shipping companies to create customized distribution capabilities. They’re joining up with supply-logistics companies in China to improve their access to rural markets. And they’re in the beginning stages of applying IT solutions to improve the transparency of the manufacturing process by considering process analytical technologies and serialization solutions.

As a result of these evolving collaborations, the supply chain of the future won’t be an ad hoc collection of acquired businesses and partners working in isolation from each other, but a streamlined network of suppliers and distributors working in coordination to incorporate market input, increase speed to market, and identify and resolve bottlenecks.

On top of all this, historically, the industry’s supply chain was structured to function as more of a “push” than a “pull,” meaning companies focused on the front end of production and less on responding to the market’s needs. But now health care reform and other trends are driving life sciences companies to improve their upstream and downstream communications with health care providers, physicians and patients.

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“Companies will have to pay close attention to how data is managed. If your stakeholders – patients, consumers, doctors – believe that their data is compromised in any way, you can expect an immediate loss of value and reputation.”

only exacerbates these challenges, particularly when these entities are not as familiar with pharma compliance issues. These issues run the gamut from product-liability risks to anti-corruption/fraud matters and sales and marketing practices associated with interactions with health care professionals.

Compounding the reductions in pharma sales forces because of expiring patents on blockbuster drugs, sales forces will likely continue to shrink in Pharma 3.0 as technology more efficiently disseminates scientific and therapeutic information. Without effective compliance monitoring programs

and training, this environment could result in new kinds of noncompliant behavior (e.g., sharing off-label or other information inappropriately through social media).

Establishing a strong control environment is critical to managing these risks. Alliances should define clear formal policies and controls that are regularly validated by internal audit departments. Each partner needs to have defined responsibilities and be armed with sufficient resources and testing to help mitigate risk.

Data security and privacy

In the patient-centric world of Pharma 3.0, it will be critical for pharma companies and their new partners to make sure their innovative product and service offerings are customer-centric. And since much of the action will involve data-enabled offerings (such as electronic record platforms, social media networks, health IT solutions, new mobile apps), ensuring the privacy and security of patient data will be vital to building trust. (For a more detailed discussion, see “Whose data is it anyway?” on the next page.) As several firms in financial services and

IT have learned the hard way, even a single slip-up can bring a barrage of negative scrutiny and hurt a company’s reputation. “Companies will have to pay close attention to how data is managed,” says an executive from a global EU-based pharma company. “If your stakeholders – patients, consumers, doctors – believe that their data is compromised in any way, you can expect an immediate loss of value and reputation.”

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IP management and protection

As discussed in the valuation section above, pharma has always been an IP-driven industry. For pharma companies, therefore, retaining control and extracting returns from IP are high priorities. As companies develop new offerings in partnership with other firms, it will be important to continue to define who owns the IP that will be created. This will be all the more challenging since the offerings may often be poorly defined at the outset and since the alliances themselves might be loosely structured initially.

The challenge is further compounded by the fact that a good number of the new partnerships will likely be with companies from the IT universe – software developers, database providers, mobile device companies, video game creators, etc. Drug and IT companies innovate in very different ways and have dissimilar approaches to IP. The IT industry is engineering-driven and characterized by short innovation cycles. As a result, patents aren’t nearly as valuable as



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they are in the drug development universe – it's relatively routine for a tech company to engineer its way around a patent or to engineer a next-generation, slightly improved innovation that quickly renders the existing patent obsolete. Indeed, the different approaches to IP were starkly illustrated a few years back, when the US Congress' attempt to reform the existing patent system, the Patent Reform Act of 2007, elicited diametrically different responses from two camps of

innovation-driven firms: pharmaceutical and biotech companies (which opposed the changes) and IT companies (which supported the legislation).

In our discussion of new business models in Chapter 2, we pointed out that the challenge for pharma companies will be not just about creating new business models, but also about figuring out how they can fit into *other companies'* business models. IP is one area where

pharma companies may need to do just that. As long as drug development remains the extensively regulated, long and expensive affair that it is, we don't expect radical shifts in how companies approach their drug-related IP (hence Paul Stoffel's insistence, in our interview with him, that open innovation in the drug development space should not be construed to be the equivalent of open-source software development). But when companies are

A closer look

Whose data is it anyway? Privacy and security in the era of Pharma 3.0

When financial data went digital in a big way about a decade ago, consumers gained speed and convenience through electronic transactions – but they paid a price as well, as identity thieves added new weapons to their arsenal. With the life sciences sector now heading down the digital path, similar concerns arise about the ability of health care providers, drug companies, doctors and patients to adequately protect EHRs and EMRs from misuse.

But in some ways, the privacy and data protection risks facing life sciences companies are more pronounced than those confronting banks and other financial intermediaries. For one, the damage wrought by failing to protect patient data is often irrevocable. Unlike episodes of identity and monetary theft, there is no recompense available to the individual whose history of diseases, surgeries and prescriptions is made public.

In addition, there are key differences in the transmission of data. Financial transactions are conducted over common global communications platforms such as the one managed by the Society for Worldwide Interbank Financial Telecommunications (SWIFT). In the health care sphere, there is so far little in the way of interoperability protocols or standards for sharing information. Rather, individual networks carry sensitive patient data, making it more difficult to secure. Data is also more adequately structured in finance than in life sciences, considering the intricacies of medical histories involving treatment regimes, procedures and outcomes.

The increasing involvement of nontraditional players in the life sciences industry is compounding these privacy risks and challenges as larger amounts of data float in the networks of new players. These actors typically keep a tight rein on

such information through defined and documented policies, procedures, controls and security mechanisms to prevent, detect and correct misuse of data.

When nontraditional players enter the equation – consider the example of a mobile phone application that stores and distributes personal health records – sensitive data leaves the life sciences domain. Its protection then relies on the security protocols of the technology provider, the user and any communications networks that distribute the information. As recent history has shown, these protocols are often compromised when they aren't maintained – or aren't used at all.

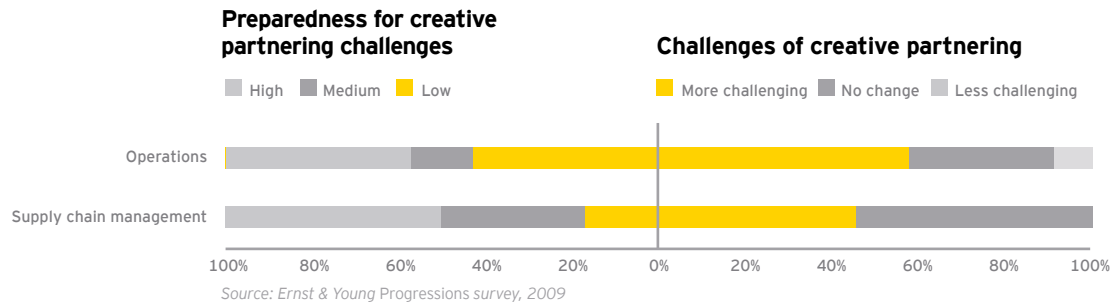
The question that life sciences companies are now grappling with is: who is responsible for safeguarding data once it leaves the boundaries of traditional privacy protection? Nontraditional partners aren't used to adhering to the same onerous data privacy regulations that govern life sciences companies, many of which levy significant penalties for noncompliance. In Germany, companies deemed liable for losing sensitive customer data are forced to notify the public in newspaper advertisements. Questions such as these need not prevent life sciences organizations from reaching out to nontraditional partners as they explore digital platforms and other new frontiers; however, these risks should be addressed as part of due diligence procedures.

Technology is evolving rapidly, sometimes at the expense of adequate data protection. Companies that lay the groundwork now to protect and secure the information shared through new and innovative collaborations will help assure they stay on the leading crest of change – and don't fall by the wayside.

Michael Dalla Torre
Ernst & Young



Partnering challenges snapshot: operations and supply chain management



partnering to develop a new software or technology-based solution, it is perfectly reasonable that the norms of tech will apply. In such alliances, pharma companies will need to develop more open and flexible approaches to IP protection. The best defense may not be IP protection as much as rapid innovation.

Reputation and other risks

Companies will also need to focus on reputation risk. This is, of course, a sensitive topic for any firm, and all the more so in the pharma industry, which has seen its standing plummet in recent opinion polls. There's much to be careful about in a highly regulated, closely scrutinized industry where missteps can have disastrous – even fatal – consequences for patients.

For example, a pharma company might partner with a nontraditional entrant – a retail giant, a global shipping company, a micro-lender – to expand access in developing-country rural markets. These partners could contribute real strengths, such as infrastructure, distribution networks and trust, but they likely will be sorely lacking in real-world experience on pharma sales and marketing regulations, much less the restrictions placed by laws such as the US Foreign Corrupt Practices Act (see “Navigating the changing compliance landscape” on page 59).

The challenges are significant, but so is the potential reward: the ability to serve larger populations of patients in more efficient and effective ways by delivering real improvements in health outcomes.

Operations and supply chain management

In an environment of globalized operations, increasing cost pressures and heightened scrutiny on safety, pharma companies are very focused on operational and supply chain management issues. This is reflected in the survey results, which did not find significant preparedness gaps and found that 50% of respondents considered themselves highly prepared to deal with supply chain issues, while 43% were highly prepared to deal with operational challenges.

Despite their focus on these issues, companies can expect to face new challenges as they enter Pharma 3.0. Partnering with very dissimilar companies and developing entirely new products and services are bound to have implications for the operations and supply of these offerings. These implications are discussed more fully in “Managing supply chains” on page 67.

Conclusion

Pharmaceutical companies and their talented business development teams have been growing through transactions for decades and have tremendous experience in executing deals. Pharma 3.0 puts a whole new spin on many of the traditional transaction-related challenges and competencies. Building complex collaborations with nontraditional partners to create new products and markets is difficult enough on its own. However, Pharma 3.0 requires companies to merge business development acumen with strategy and innovation in a commercial development process of rapid prototyping out in the open. Not for the faint of heart or casual dabbler. The challenges are significant, but so is the potential reward: the ability to serve larger populations of patients in more efficient and effective ways by delivering real improvements in health outcomes. ►

What's next? Guiding principles for Pharma 3.0

Define your Pharma 3.0 brand.

The ecosystem is becoming more complex. Incentives are changing. New, nontraditional players are entering.

- ▶ Are your front-line executives focused on these trends?
- ▶ How will these changes impact your business?
- ▶ What's your strategic focus, and what will be your competitive advantage in this more complex reality?

Co-create value with partners and patients.

More than ever, firms will need to combine unique assets and attributes to build relevant offerings for the healthy outcomes ecosystem.

- ▶ How open is your (business model) innovation?
- ▶ Are you focused on being a partner of choice for *nontraditional* players?
- ▶ What is your network strategy to become a critical player by intentionally co-creating value for partners and patients?

Experiment. Think small. Fail fast.

There is no one right answer. Companies will develop solutions by experimenting with large numbers of "commercial trials" – and culling those that don't work.

- ▶ How well does your organization encourage experimentation and "outside-in" learning (and accept failure as an inevitable by-product?)
- ▶ How much are you investing in business model innovation (versus product innovation?)
- ▶ How rigorous is your pipeline of commercial trials for business model innovation?

Prepare for success.

Our survey and interviews indicate that pharma companies aren't fully prepared for the challenges that these creative new alliances will bring.

- ▶ What gaps do you have in your skill sets and capabilities, and what are you doing to fill them?
- ▶ How are you monitoring and addressing the new and heightened risks in Pharma 3.0 deals?
- ▶ Have you identified and empowered a leader for business model innovation?

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