Robin Robinson

PHARMA 3.0: A Call for Collaboration and Experimentation

The industry needs to move beyond planning stages and take some 3.0 action.

Success or failure in Pharma 3.0 — an ecosystem comprised of established industry members, nontraditional companies, and an increasingly informed data-empowered consumer — will be based on life-sciences companies' ability to develop innovative, outcomes-focused offerings through structured, systematic, and scalable approaches to business model innovation. The two most prevalent elements that will separate the winners and losers in Pharma 3.0 in the coming year are radical business model experimentation and collaboration. Not only will companies have to jockey for a spot among the usual industry competitors, but nonindustry investors that are getting in the game also pose a threat, and that threat is real.

According to the Ernst & Young report Progressions: Building Pharma 3.0, nonpharmaceutical companies are investing substantially more in 3.0 business model innovation than pharmaceutical companies — at least $20 billion to date — and the inherent advantages the pharmaceutical industry has held in the healthcare marketplace are rapidly fading.

The experts in this forum have experience and knowledge of the evolution to a more patient outcomes-focused business model.

Say Hello to Nontraditional Partnerships

The industry faces many challenges in evolving to a 3.0 model, but the biggest one may be the need to collaborate with nontraditional partners, such as healthcare facilities, telecom companies, and large employers.

- An outcomes-focused environment will require nontraditional collaborations.
- Right now, the new business model is a moving target.
- Nonpharmaceutical companies will become more instrumental in health outcomes, pushing pharma from first place.

FAST FACT

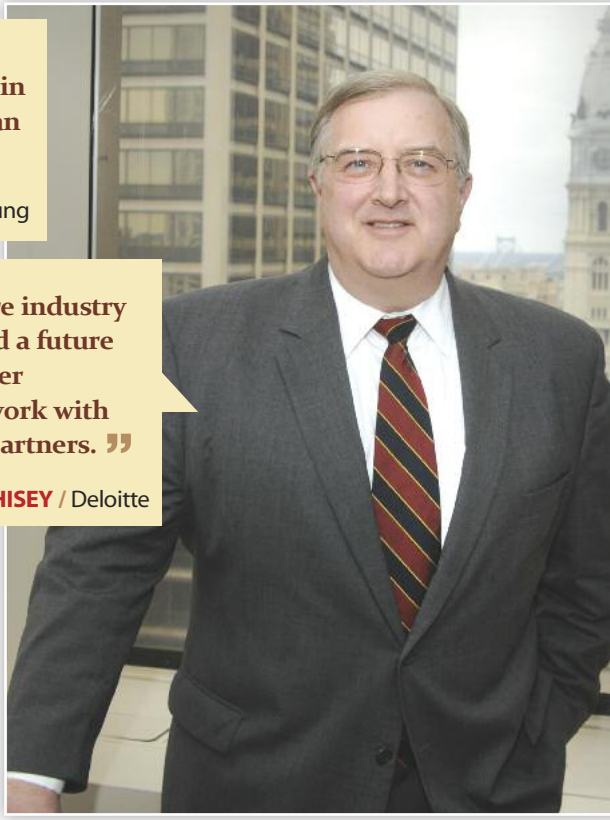
PHARMA COMPANIES LAUNCHED MORE THAN 220 PHARMA 3.0 INITIATIVES BETWEEN 2006 AND 2010; 44% OF THOSE INITIATIVES WERE LAUNCHED IN 2010 ALONE.

Source: Ernst & Young

CAROLYN BUCK LUCE. ERNST & YOUNG. The hallmark of the evolution to Pharma 3.0 is the need to shift from only producing new medicines to demonstrating improvements in health outcomes and creating innovative new business models. No one company has the litany of skills and assets needed to be successful in the outcomes-focused environment of tomorrow. Rather, companies will need to leverage the investments other companies have already made, such as the platforms of IT companies and the networks of mobile telephony players. An important implication of this new approach to collaboration is that companies will need to change their long-standing view for how intellectual property is treated in their interactions with nontraditional players. In the past, protecting IP had been a primary value driver, but pharma companies will increasingly have to learn how to contribute assets and knowledge into new models that they do not entirely control.

USAMA MALIK. PFIZER. It has become clear that the industry status quo is not sustainable and the traditional healthcare model, based on monopolized information, is antiquated. Neither the current supply nor the quality of care is sufficient to meet increasing demand and needs. Additionally, there are the increasing financial challenges for funders of healthcare. Faced with these challenges, it will be critical for pharmaceutical companies to forge innovative collaborations across the healthcare value chain — public, private, civil-society — as well as with new nontraditional entrants, such as technology entrepreneurs, nutrition companies, and consumer-lifestyle businesses, which are entering the sector in increasing numbers. Healthcare systems are reaching the tipping point of comprehensive transformation, and the pharma industry must find ways to respond to an emerging system of value and outcomes-

> "Nonpharmaceutical companies are investing more in business model innovation than pharmaceutical companies."
>
> **CAROLYN BUCK LUCE** / Ernst & Young



> "The healthcare industry is moving toward a future with much greater opportunity to work with nontraditional partners."
>
> **TERRY HISEY** / Deloitte

based payments stemming from national and global health reform efforts. We are witnessing unprecedented investments in HIT infrastructures designed to enable transparency through the electronic capture and exchange of real-world clinical data. Providers of healthcare products and services are facing distinct challenges in responding to this new environment because now no single entity has an advantage when it comes to available information. Pharma companies must respond effectively to the challenges brought about by information transparency and the dramatic changes in customer needs and societal expectations that are taking place in the marketplace. Payers, providers, and consumers are all demanding a value- and outcomes-based health environment, which will be fueled by the increased use of technology, real-world data and new clinical effectiveness research rules. Pharma companies will need to be able to overcome the commercial and market access risks that are certain to accompany this shift.

KIMBERLY PARK. JANSSEN HEALTHCARE INNOVATION. The biggest challenge the industry faces when working with nontraditional partners is getting comfortable in a space where market exclusivity is less definite and competitive barriers to entry are less certain. In the typical pharma model, companies invest in R&D and expect exclusivity in the market for a defined period of time. As an industry, we need to continually evolve and differentiate our offerings.

NAGARAJA SRIVATSAN. COGNIZANT. While organizations agree on the need to collaborate with nontraditional players, they lack the organizational structure that is required to do so. The responsibility for these interactions is spread across many different stakeholders in the organization, with no clear articulation of goals or measures of success for this strategic role.

ANN WALZ. MEDISYS. Aligning key internal stakeholders around assets at earlier development phases is a critical first step in making the move to Pharma 3.0. This will ensure there is unified agreement around the unmet market needs, product differentiation, and ultimately the clinical value that a new product will need to offer to assure uptake in the evolving healthcare model. Key stakeholders should have a seat at the same table as soon as there is a viable compound since they will collectively play pivotal roles in demonstrating what the Pharma 3.0 model will demand: data to support a product's ability to improve health outcomes. These stakeholders include traditional commercial representation, i.e. marketing, as well as representation from clinical R&D, medical affairs, market research, and managed care markets.

TERRY HISEY. DELOITTE. The healthcare industry is moving toward a future in which there is a greater opportunity to work with nontraditional partners. This is changing the paradigm for healthcare delivery and provides both challenges and opportunities. Life-sciences companies need to recognize the dynamics of the changing ecosystem and discover what their proposition is for new stakeholders. For example, large employers will play a bigger role in healthcare as

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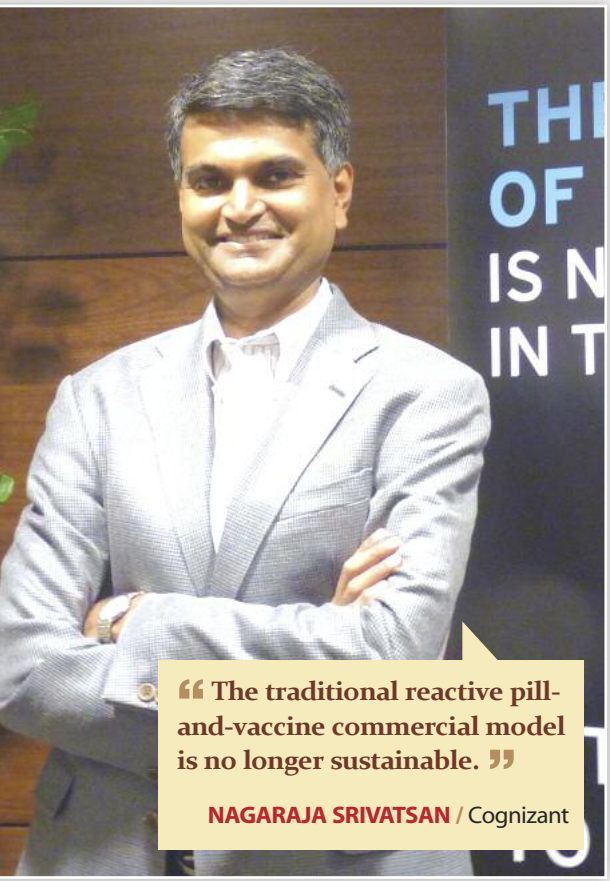


Nontraditional Partnerships Require Nontraditional Views

Beyond understanding the need to collaborate, pharma company executives also face the challenge of being able to move beyond the question of “how do these nontraditional companies fit into my business model?” To “how do I fit into theirs?” They will have to convince these new entrants that they are worth partnering with by:

- Articulating the unique knowledge they have about the drugs they develop as well as their deep understanding of disease states, regulatory pathways, and payer requirements.
- Addressing conflicts of interest that could preclude being seen as an unbiased partner, such as being perceived as favoring its own products or favoring treatment interventions instead of preventative measures.
- Taking action to build trust by engaging with all of the various stakeholders in ways that are transparent, unbiased, and demonstrative of their intent to improve outcomes.

Source: Carolyn Buck Luce. For more information, visit ey.com.

FAST FACT

J&J, PFIZER, NOVARTIS, MERCK, AND ROCHE HAVE LAUNCHED THE LARGER SHARE OF PHARMA 3.0 INITIATIVES.

Source: Ernst & Young

they seek greater influence in plan designs and as insurers take on less of the risk.

Mobile Apps One of the First Steps Into 3.0

As the shift from a product-focused model to a total solution-focused model inches forward, first steps by the industry include developing mobile apps and monitoring devices.

- Better outcomes stem from empowering patients.
- There are many apps currently being developed and implemented.
- Solutions need to include education, access, and adherence.

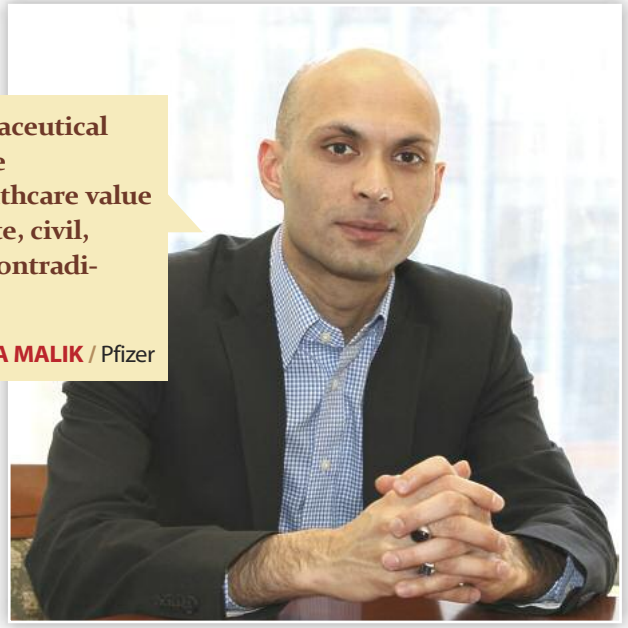
CAROLYN BUCK LUCE. ERNST & YOUNG. Companies are increasingly developing business models to improve patient outcomes that encompass a more holistic approach, including disease management, coordinated care, compliance, and expanded interventions across different stages of care. These approaches are driven by a goal of empowering patients to manage their wellness and health conditions more effectively and to more easily and safely share their personal data with healthcare professionals and communities of interest. Companies are still in the process of experimenting with new business models but the pace of such experimentation is accelerating with several clear trends emerging. Notably, Pharma 3.0-related initiatives continue to be driven by investments, by both consumers and businesses in mobile health technology, particularly smartphone apps. While these apps were until recently focused primarily on diabetes management, in the last year they have expanded into at least 14 disease areas. These apps include tools to help patients and consumers track vaccination schedules, manage infusions for treatment of hemophilia, and find cancer clinical trials within 150 miles.

USAMA MALIK. PFIZER. Companies are increasing their rate of experimentation in innovative, integrated health-solution collaborations. There are numerous examples of companies using real-world insights to drive patient compliance and demonstrate product efficacy. Examples of this shift would be the work done by Novo Nordisk linking Danish Diabetes and Cancer Registries to disprove the link between cancer and insulin; the partnership between AstraZeneca and Wellpoint to generate real-world evidence data/analytics; Novartis’ investment of $24 million in a chip developed by Proteus Biomedical that can be embedded in a pill to aid in patient monitoring; and our pilot program on patient-centered clinical trials and spontaneous adverse event reporting. Our partnership with Private Access, which leverages the Internet, focuses on patient privacy rights to connect patients, physicians, and researchers with tailored information, tools, and technology that will lead to more informed decisions about patient care, including clinical trial participation.

NAGARAJA SRIVATSAN. COGNIZANT. The traditional reactive pill-and-vaccine commercial model is not sustainable. A more pre-emptive, holistic approach that stresses patient wellness and prevention is the future. This wellness ecosystem is less expensive and less healthcare resource-intensive than the reactive model in the long term. Several life-sciences firms are exploring how medication can be a proactive wellness treatment — or in other words how Pill 2.0 can drive better health outcomes. Many are exploring remote patient monitoring solutions that can also help healthcare professionals intervene when necessary. Some life-sciences organizations are also exploring the potential of ingestible microchips embedded in medications to improve compliance.

TERRY HISEY. DELOITTE. We are moving toward a future where there will be much greater use of mobile technology. Older and more affluent consumers will have greater access to health information than ever before, ranging from continuous monitoring and diagnostics to apps that help them manage their conditions.

KIMBERLY PARK. JANSSEN HEALTHCARE INNOVATION. The initial focus has been on finding a solution that directly impacts the use of existing products. There are three main areas where I see progress being made today. The first is in the area of adherence where we can collaborate with external partners to better connect with the patient to improve compliance. The second area is around access; companies have been finding success in ensuring more patients have access to needed treatments. The third area is patient education; today patient education is available in physician offices, online, disease or product websites, patient communities, etc.



> **"It will be critical for pharmaceutical companies to forge innovative collaborations across the healthcare value chain, including public, private, civil, society, as well as with new, nontraditional entrants."**
>
> **USAMA MALIK** / Pfizer

Scalability is One of the Biggest Challenges of 3.0

Experiments and pilot programs are easily managed, but increasing the scope can be difficult.

- Start small, fail fast.
- Collaboration among all stakeholders is necessary.
- Expect lower profitability at first.

CAROLYN BUCK LUCE. ERNST & YOUNG. Experimentation is a critical part of Pharma 3.0. There will be no one right answer for how to succeed in this new ecosystem, but a rigorous process for business model exploration and development will be absolutely essential to finding the right path for a particular company. We believe in the approach of think small and fail fast when it comes to business model experimentation and liken it to the clinical trial process. Companies will need to make small initial investments in the form of pilots and prototypes — imagine a Phase I commercial trial — identifying the most successful models and scaling those up for market deployment while culling those that don't work. To truly take on the disruptive change that will be inherent in Pharma 3.0, companies will need to have the right capabilities and teams in place for change that will cut across the entire organization. This will entail building entirely new business functionalities or significantly enhancing existing ones to support activities, such as business model innovation and community engagement. It will also require disrupting the "value network" or incentives, metrics, and standards for all of the stakeholders that are truly aligned to health outcomes. While the pharma industry is behind other industries in this type of community engagement, in no small part due to a lack of clarity from the FDA on acceptable social media practices, such approaches are starting to appear in the health outcomes ecosystem.

USAMA MALIK. PFIZER. To achieve a company-wide scale of a Pharma 3.0 model, healthcare companies and stakeholders will need to develop value- and outcomes-based reimbursement models that can drive viable and sustainable economics. Such models will need collaborative innovation at their foundation as well as a process for value co-creation and risk-sharing between partners. Governments, the private sector, and society have to agree on and advance incentives on the supply and demand side to sustainably generate medical and business model innovation that delivers step-wise value to public health.

TERRY HISEY. DELOITTE. Healthcare will continue to evolve, not just in the United States, but in the global market. It's less a matter of pilot and scale and more a matter of learning to innovate and adapt. Companies that will succeed in this environment need to adjust to and make the most of a constantly fluctuating marketplace.

NAGARAJA SRIVATSAN. COGNIZANT. For companies to scale up, they need to create an organization that will have both the resources and capital to make it happen. The success of scale will have to be therapeutic area (TA)-based. So for every TA, one will have to consider a holistic approach on how one can implement the new 3.0 model. Pharma 3.0 requires a greater degree of collaboration among the different organizational silos. The new governance organization will need representatives from all the key groups to work together to deliver this model.

KIMBERLY PARK. JANSSEN HEALTHCARE INNOVATION. It's important to have reasonable expectations — both in terms of the time it takes to execute the pilot and scale up as well as the expected impact — for revenue, number of patients involved, etc. Unfortunately, what often kills a pilot is either not giving it enough time to succeed or when there are unrealistic expectations of the revenue. Another significant challenge for a total solution in the 3.0 model is profitability. Most solutions will have lower margins or not generate any profitability in the early years. Successful companies will have to have a well-defined business model. For example, they need to understand how the value is going to be created and how the partners are going to split or share in the value created. PV

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>
> **KIMBERLY PARK** / Janssen

Four Keys to Success in the Pharma 3.0 Era

To be successful within a Pharma 3.0 model, companies must:

1. Encourage experimentation and "outside-in" learning.
2. Accept failure as an inevitable byproduct.
3. Invest in business model innovation versus product innovation.
4. Maintain a rigorous and intentional pipeline of commercial trials for business model innovation.

Source: Carolyn Buck Luce, Ernst & Young.
For more information, visit ey.com.

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Robin Robinson

Research and Marketing Models Set to Change with 3.0

The focus on health outcomes transforms all phases of the pharma business.

Whether it's 3.0 or another model, it is going to be important for companies to recognize the major changes in the healthcare ecosystem, especially in light of the ever-increasing power and influence of government healthcare reform.

"The game has permanently changed," says Terry Hisey, vice chairman and U.S. industry leader, life sciences practice, Deloitte. "Companies need to have deliberate plans in place to understand the value vs. volume healthcare system and they need to pay particular attention to market demands as well."

According to Mr. Hisey, the most significant tipping point for the life-sciences industry is going to be the broad scale adoption of comparative effectiveness.

"We have seen that there is a ceiling for price, forcing companies to seek other solutions," he says. "The new paradigm is forcing companies to be intellectually honest with themselves about the value of the science. So more products in development will be terminated because they won't yield an effective ROI, which requires companies to select what they should do, rather than what they could do."

"To be successful in Pharma 3.0, pharma companies will need to develop new capabilities, either on their own or in collaboration with others, to extract meaningful insights from these ever increasing pools of disparate data," says Carolyn Buck Luce, global pharmaceutical sector leader, Ernst & Young.

However, the industry needs to focus on a larger picture than just Pharma 3.0, and realize this is not the end, but the beginning of an ever-evolving progression.

"Pharma 3.0 is not a destination," Mr. Hisey says. "Rather, companies need to understand the endpoints and look at it in total as an ongoing progression to X.0, as technology, markets, and patient needs continue to evolve."

The Transformation of Marketing

Credibility will be an essential currency within community engagement and will require companies to provide true personalized value to consumers and a willingness to share unbiased information, even if it shows a company's offering in an unfavorable light.

"In an ecosystem where market share will be built through word-of mouth and personal experiences rather than sales messages, trust will be a paramount asset," Ms. Buck Luce says.

According to Kimberly Park, partner, Janssen Healthcare Innovation, marketers will be looking more broadly at the entire spectrum of patient care.

"They will be thinking about the entire continuum of care and all the aspects of treatment," Ms. Park says. "The focus of pharmaceutical companies today is primarily on what role the drug treatment plays. I would expect that marketing will evolve from a focus on the role of the product to understanding care from a more holistic approach — the way patients and physicians approach the disease."

With the prospect of key patent expirations looming, the loss in revenue will cause many of the major industry players to transform how they do business, resulting in more partnerships, more outsourcing, and more consolidation, says Nagaraja Srivatsan, senior

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CAROLYN BUCK LUCE / Ernst & Young

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> **NAGARAJA SRIVATSAN** / Cognizant

VP and head of life sciences, North America, Cognizant.

"Cost pressures will also lead life-sciences companies to significantly provide variability to their businesses to move from fixed capital costs to variable costs," he says.

The ongoing healthcare reform and the tremendous cost of bringing a new drug to market, which is now estimated to cost $1.6 billion from molecule to market, will drive shifts in innovation strategies in two fundamental ways, Mr. Srivatsan adds. First, a relentless focus on innovation productivity, such as getting the same or better clinical outcomes at lower cost; and second, increasing the role of comparative effectiveness research, personalized medicine, and outcomes information in setting research priorities.

"We will also experience a huge emphasis on financial innovation, especially in emerging markets where there will be a lot of financial innovation to fund the cost of healthcare that will be different from the payer model of mature markets," he says. "From a marketing perspective, Pharma 3.0 will require pharma companies to go beyond traditional sales and marketing and establish more comprehensive approaches to community engagement with consumers. In this environment, listening will become infinitely more important than pitching, and the guiding principle will be it's not about you."

Creating a collaborative environment with strong governance with internal and external partners will help ensure consistent business outcomes, Mr. Srivatsan adds. Sales and marketing organizations must become valued partners for prescribers, providing them with the products as well as tools and information they require to manage the health of their specific patient populations. Sales representatives will not disappear, but will become service-oriented, tailoring information and offerings to bring greater value to specific physicians and practices.

"Successful organizations will build comprehensive views of regional, local, and even individual physician influencers, needs, and activities," Mr. Srivatsan says. "Smart mobile devices and dashboard apps will enable faster two-way communication with prescribers, as well as increase the throughput of the sales organization so sales approaches can be adjusted based on real-time information."

The Changing R&D Model: Streamlining Data

Currently the focus in R&D is to address productivity.

"For example, if we conduct 10 trials and get two approved; the yield is 20%," he says. "R&D organizations are looking to improve yield by getting better decision support, information, and simulation infrastructure so that they can proactively look at information and determine how successful their trials will be."

Post analysis, it would be better to conduct only four trials, but get two approved, thus improving the yield to 50%, he adds.

The externalization of R&D models that is already afoot in the industry will be taken to an entirely new level in Pharma 3.0, driven by the continued explosion of health data that remains largely untapped by pharma, Ms. Buck Luce says.

"Such data could help make drug development more efficient by identifying trends, driving new insights for improving compliance, and providing new evidence of the efficacy of approved therapies to aid reimbursement," she says.

Companies are addressing these challenges by developing better decision infrastructures, such as data repositories and dashboards to access past and present clinical trial information; integrating safety data proactively and up front in the clinical process; and integrating discovery, preclinical and postmarketing information, including claims and outcomes data. Another key driver is clearly differentiating core and noncore activities and outsourcing those that are noncore to the business.

According to Ms. Park at Janssen Healthcare Innovation, Phase II and Phase III clinical trials will need to include outcomes endpoints with the renewed focus on health outcomes.

"We will need to further expand our understanding of the value to patients and payers when we are designing clinical trials," she says. PV

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