# Pharma 3.0 NEXT STEPS

The industry ushers in the next phase of Pharma 3.0.

T

he role of the life-sciences industry is going beyond developing and manufacturing products to improving the lives of patients. Pharmaceuti-

cal companies will need to broaden their focus from producing new medicines to delivering healthy outcomes — a shift that will be driven through creative partnerships and business model innovation, reports Ernst & Young (EY).

In the past two years, pharmaceutical companies got in the game and started increasing their investments to meet the demands of patient-empowered, data-driven, outcomes-focused healthcare.

In 2010 alone, pharmaceutical company investment in smartphone apps, educational websites, social media platforms, wireless devices, and other programs increased 78%. At last count, industry outsiders — IT companies, large retailers, insurance providers, telecommunication firms — were still investing more than pharma, but the industry is working on narrowing the gap.

According to analysts at EY, the pharmaceutical industry is climbing on board with the idea of partnering with these nontraditional companies to help shape the future of healthcare, but many still feel unprepared to address the challenges these new creative alliances will bring.

The thought leaders who contributed to this forum are intimately involved in Pharma 3.0 — EY wrote the book on it and several pharma-ceutical companies are walking the walk with innovative collaborations and programs. They address some of the challenges and opportunities related to Pharma 3.0.

Our experts agree that for Pharma 3.0 to be successful and for innovation to thrive, it will take visionary leaders and passionate collaborators who are courageous enough to support the full journey of innovation, including learning, discovery, trial, failure, iterating, and reapplying.

With courage and commitment, Pharma 3.0 will help the healthcare industry move forward in bold ways that will benefit patients and consumers worldwide.

#### **FAST FACT**

PHARMA EXPANDS DISEASE CATEGORIES OF 3.0 EFFORTS BETWEEN 2006 AND 2009, 24% OF PHARMA 3.0 INITIATIVES FOCUSED FIRST ON DIABETES AND METABOLICS. IN 2010, ONCOLOGY MOVED TO THE TOP WITH 15% OF THE YEAR'S INITIATIVES, AND DIABETES AND METABOLICS TIED FOR SECOND WITH IMMUNOSCIENCE/INFLAMMATORY DISEASES, AT 12% EACH.

Source: EY

#### Setting the Stage for New Relationships

- Be clear about partnership capabilities
  Get comfortable with change
- **3.** Secure support from the top
- **5.** Secure support nom the to

**DR. DIEGO MIRALLES.** JANSSEN HEALTHCARE INNOVATION (JHI). It is very important that a healthcare company has clarity about what it brings to the partnership by way of specific capabilities. Beyond potentially having the desired financial resources, a company must focus on what it can uniquely offer to drive programs forward. In addition, it's important to be humble. The pharma company needs to recognize the skills and capabilities that the prospective partner brings and appreciate that these are often skills it doesn't have in-house. Finally, it is critical to accept that the partnership model will likely not resemble a traditional drug development partnership. To be successful, we must approach each potential business arrangement/collaboration with an open mind and remain flexible as we cocreate or architect a new business model. There has to be senior-level commitment to keep innovation alive in an established organization. Without support from the top of the organization, newer risk-taking projects can be easily squashed and deprioritized by the tendency to play it safe and support the more established, revenue-generating projects.

DR. KEN KRAMER. ALPHA & OMEGA. In the beginning, the goal of the pharmaceutical company was focused on the drug: developing it, testing it, getting it approved, and getting it to market. The PBM has the mandate of making drugs accessible to patients within their networks. Companies such as IBM and Telus are concentrating on developing health information algorithms that will interpret decades of treatment data. In the past, everyone was doing his or her part in isolation. The Pharma 3.0 business model is going to be a significant departure from business as usual. Groups will have to work in parallel — not in series — so transparency will be key, as will trust. Partnerships will need to function as a true collaboration, one where everyone's voice is heard. The major stakeholders at all stages of treatment should always be represented at the table, including scientists, clinicians, marketers, payers, patients, and their advocates, to name just a few. Each of these groups should have an active voice, or we risk missing serving the needs of one or more key audiences. We need to start thinking of these groups not in isolation, but as a living ecosystem. An ecosystem flourishes because segments with different responsibilities work together toward a common good, while still enjoying some individual benefits. There is no shame in reaping the rewards of hard work as long as no single group profits at the expense of another. This is a lesson that needs to be relearned, because a successful treatment benefits everyone.

**ROB REBAK.** QUALITYHEALTH. With a greater reliance on external partners comes the need to be able to understand how to translate nonpharma services into the health model and to more systematically and accurately predict partner value. To be successful in the Pharma 3.0 partnership model, we will see value-mining emerging as a new discipline across various functions. Are these partnerships effective? Are they delivering the right kind of value? Are partners being held accountable for delivering performance? Will partners enter risk-sharing agreements? What do these look like?

#### New 3.0 Model Brings New Challenges

Understandng intellectual property issues
 Coordinating timelines
 Identifying the right partner

DR. DIEGO MIRALLES. JHI. The issue of intellectual property can be tricky in nontraditional partnerships. The pharmaceutical industry normally operates with relatively concrete patent allowances, as well as exclusivity in licensing IP. Patents for technologies, including software, hardware, and devices, differ dramatically from those for molecules and drug compounds. This challenge underscores the need to involve colleagues who have diverse experiences in multiple industries. When we partner with high-tech companies, we are cognizant of the fact that our product development timelines are vastly different. It can take 13 years to develop a drug, compared with a tech company that generates several revisions of one product in 12 to 18 months. We have to proceed at a very different pace, with different types of milestones and outcomes expectations, to increase the speed at which we drive our projects. This requires a totally different mindset than typical drug development.

**CAROLYN BUCK LUCE.** EY. One of the biggest challenges is synchronizing the purpose for the partnership. In the early manifestations, the partnership is about both results and

#### EXPERTS



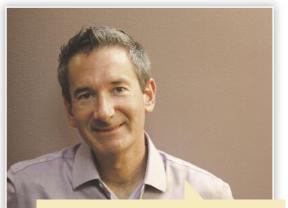
**CAROLYN BUCK LUCE.** Global Pharmaceutical Sector Leader, Ernst & Young, which helps companies identify and

capitalize on business opportunities. For more information, visit ey.com.



KEN KRAMER, PH.D. Senior VP and Medical Director, Alpha & Omega Worldwide, part of the Core Nation, a family of

healthcare marketing and medical communications companies (Core-Create, Brandkarma, and Alpha & Omega) that offers strategic branding and consulting. For more information, visit thecorenation.com or email ken.k@aandomedcomms.com.



**11** The Pharma 3.0 business model is going to be a significant departure from business as usual. **11** 

DR. KEN KRAMER / Alpha & Omega



**11** Partnerships with nontraditional players require creating something that currently doesn't exist. **33** 

**CAROLYN BUCK LUCE / EY** 



DIEGO MIRALLES, M.D. Head, Janssen Healthcare Innovation (JHI), a team within the Janssen Pharmaceutical Companies of Johnson & Johnson,

focused on developing partnerships and collaborations with both large and small organizations to expand the company's offering of healthcare services and solutions, empower healthcare consumers, and transform healthcare delivery. For more information, visit janssenhealthcareinnovation.com.



**ROB REBAK.** Chairman and CEO, QualityHealth, which offers performancebased customer acquisition solutions for healthcare marketers. For more

information, visit qhperform.com.

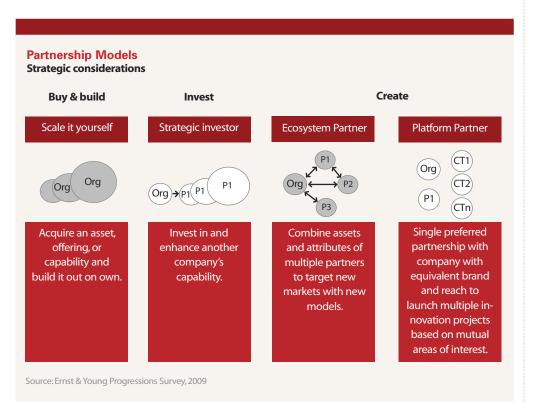
#### Pharma 3.0

learnings. There are many questions regarding how to align around the measures for success; how to deal with the IP exhaust that can be used by both parties for different purposes; how to deal with the issues of exclusivity and confidentiality, when in many cases this innovative partnership is leveraging assets and knowledge from both parties. The identification of the right partner is also challenging because innovative partnerships with nontraditional players are about creating something that currently doesn't exist and experimenting with creating a new business model.

DR. KEN KRAMER. ALPHA & OMEGA. Too often, pharmaceutical companies - and other companies — have been cloaked in secrecy and too resistant to share important information. This is completely understandable given that proprietary information equals life-sustaining revenue. In order for real progress to be made, however, information between partners must be shared willingly. Pharmaceutical companies will have to share key data, both positive and negative, so that a complete picture of who the key target patients are can emerge. Electronic data capturing companies have real-time, patient-level data that demonstrate how patients, their healthcare providers, and their pharmacies work together in an often difficult journey. Sharing data is important to understand why a patient switches medication, the steps they must take to receive a new prescription, and whether it will be covered partially or fully. Ultimately, outside forces will be concerned about two simple concepts: outcomes and privacy. Patient privacy must be maintained at all times or the entire process will fall apart. Without a reasonable expectation of privacy, we could see good data sources dry up before our eyes. We are pursuing outcomes because they are the ultimate gauge of a treatment's efficacy and the bar that all followers will be measured by in the future.

**ROB REBAK.** QUALITYHEALTH. I believe partner governance is the biggest challenge in this new operating model. With external partners handling patient data, patient communications, and patient nurturing, pharma companies have the challenge of ensuring that patient data are secure and handled in accordance with all relevant regulations, and that patient data are being used appropriately to drive real health outcomes and patient satisfaction, without doing it themselves. To help manage the governance issue, we will see chief privacy officers or chief data officers gain prominence, mutual investment in long-term partnerships, and risk-sharing as the norm.

**DR. DIEGO MIRALLES.** JHI. Identifying the best partner among many seemingly talented, passionate entrepreneurs is a challenge. There are a lot of interesting ideas out there for new healthcare solutions, but very few actual viable business models. For example, there's a wide array of applications and digitally enabled tools designed to drive be-



havior modification. But without the evidence our industry is accustomed to, such as clinical data or documented revenue streams, it's a challenge to evaluate and select partners under far less-structured go-to-market approaches. At Janssen Healthcare Innovation, we review opportunities against specific evaluation criteria such as strategic and cultural fit, viability of the business, alignment on an unmet need and shared passion for improving the healthcare experience for consumers and patients.

#### **New Relationships**

This isn't your father's business model
 New questions, new solutions
 3.0 summed up in a word: different

DR. DIEGO MIRALLES. JHI. The relationships we've established are different in every way. We have found that working with nontraditional partners can present new unchartered challenges in business modeling, value propositions, and asset ownership. Once we decide to explore a particular product or service, we're immediately faced with new questions. Which company is the best partner? What models are feasible for both parties? How do we establish a term sheet that makes sense for both of us? Not only do the questions differ dramatically from the traditional pharmaceutical partnership model, but they're different whether we're engaging with a small start-up company or a peer Fortune 500 company.

**CAROLYN BUCK LUCE.** EY. Unlike traditional development or copromotion partnerships between like players, health 3.0 partnerships are new business model innovations that are attempting to bring new solutions to market that combine the respective assets and attributes in different ways that will be delivered through a new operating model. As an example, think of a pharma company, an insurance company, and a telecommunications company combining to deliver telemedicine disease management services, or a pharma company and a bank combining forces to see "deductible" financing options for expensive procedures through their salesforces. These are totally different businesses for life-sciences companies that leverage their knowledge and infrastructure but need to be built and operated totally differently.

**DR.KEN KRAMER.** ALPHA & OMEGA. In the traditional sense, licensing agreements between two pharmaceutical companies functioned as a way to overcome their individual deficiencies. For example, Company A could engineer a molecule, but needed a partner to run clinical trials and then market it once it was ap-

Pharma 3.0

In Nontraditional partners present new, unchartered challenges in business modeling, value propositions, and asset ownership.

> DR. DIEGO MIRALLES Janssen Healthcare Innovation

proved. Company B may have decided that developing medications in-house was not in their best financial interests and made a conscious decision to in-license promising products. We have seen this trend explode in recent years, with companies like Pfizer, Bristol-Myers Squibb, and Sanofi acquiring smaller companies with rich R&D histories. These conventional partnerships are designed to develop and get drugs to market. Patient outcomes, while important, were reserved for Phase IV trials or future reimbursement discussions. Nonconventional partnerships are going to be looking far downstream from what has been familiar in the past and will include a variety of companies. For example, Bayer's Didget, an FDA-approved device, al-

#### Getting to 3.0

#### **Change models:**

#### putting your money where your future is

- » Build goals, objectives, incentives, and scorecards to motivate and measure performance across the enterprise
- » Build an outcomes-focused scorecard
- » Monitor progress of pilots to build value proposition for systemwide change over time
- » Create targets
- » Drive new innovations
- » Deliver results
- » Communicate success
- » Build outcomes-based business models
- » Influence and guide business units to develop initiatives
- » Encourage and monitor pilot projects

Source: Ernst & Young Progressions Survey, 2009

lows players to transmit diabetes test data to a Nintendo DS as a way to earn new minigames. With so many children being diagnosed with type 2 diabetes, teaching them to be mindful of blood glucose levels is paramount to positive long-term outcomes. This is

not about selling a drug, but developing good habits that will improve all types of health-related outcomes, primarily in young adults. In this case, the benefits of the collaboration are not limited to one or two parties, but to the entire population.

**ROB REBAK.** QUALITYHEALTH. Contracts between life-sciences or pharma companies are still about the same thing: commercializing drugs. The new Pharma 3.0 partnerships will focus on patient outcomes. How that translates to driving value for drug commercialization is going to vary based on the perspective of the participating partner. Companies will need to be much more rigorous about scenario planning up front to ensure goal and strategy alignment, individual partner accountability, contingency plans, and out clauses.

#### Best Practices Still in the Making

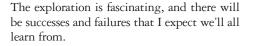
- **1.** Too early in the game for best practices **2.** A call for radical innovation
- **3.** A nod to pay for performance

**DR. DIEGO MIRALLES.** JHI. The concept of best practices assumes a level of maturity in this space that doesn't exist yet. We are in a nascent phase of collaborating beyond the pill. Every pharmaceutical company is taking a different approach, which is one reason why common best practices have yet to emerge.



**44** Value mining will emerge as a new discipline across various functions in pharma as a result of the Pharma 3.0 partnership model. **99** 

**ROB REBAK** / QualityHealth



CAROLYN BUCK LUCE, EY. Radical collaboration in Pharma 3.0 is really about innovation of the commercial model, which should be structured as rigorously and intentionally as innovation of new compounds, for example, proof of concept and structured commercial development trials - Phase I to Phase III as partnerships scale up. A best practice is to set up a dedicated Pharma 3.0 unit that has access and authority to choose the strategic areas for investment and identify, fund, structure, and launch the innovative partnerships and mobilize the right resources and assets of the company to do so. This unit is also responsible for knowing how to disseminate the learnings and results to maximize benefits to the company and to customers.

**ROB REBAK.** QUALITYHEALTH. A best practice to consider is the pay-for-performance business model where pharma clients only pay for the value they receive. This ensures that the pharma company and its partner are perfectly aligned and that both parties are bearing an element of risk.



## **3.0 Partnerships in Action**

Industry thought leaders contribute examples of successful alliances and discuss what their own companies are doing in terms of creating new partnerships.

o date, several large pharmaceutical companies have collaborated with technology and e-health firms to create tools that empower patients to manage their conditions more effectively and to more easily and safely share their personal data with healthcare professionals, thus moving into the Pharma 3.0 business model of partnering with companies outside of pharma.

The new business model is not about a single manufacturer producing a drug, but about across-the-board collaboration to create patient-centric services that accompany a treatment.

According to Rob Rebak at Quality-Health, several midtier and specialty pharmaceutical companies are taking big steps toward the adoption of this new partnership model, because they can.

With financial pressures across the industry and the need to do things differently, Mr.

#### FAST FACT

PHARMA 3.0 MOBILE APP INITIATIVES ON THE RISE

THE PERCENTAGE OF PHARMA 3.0 INITIATIVES INVOLVING SMARTPHONE APPS TOOK A GIANT LEAP IN ONE SHORT YEAR, ILLUSTRATING THAT THE INDUSTRY IS GETTING IN THE GAME

OF PHARMA 3.0. » 11% IN THE 2006 TO 2009 TIMEFRAME

» 41% IN 2010

Source: EY

Rebak expects big pharma to soon follow suit, and he says in fact some nontraditional alliances are already beginning to emerge from the top 10 companies.

With the help of our thought leaders, PharmaVOICE has compiled a list of 3.0 partnerships that have recently been implemented. More partnerships are being developed every day. (Editor's note: to alert us of similar partnerships not listed, please contact rrobinson@pharmavoice.com.)

#### **QualityHealth Partnership**

According to Mr. Rebak, a specific example of a Pharma 3.0 collaboration is between his company and a specialty pharma brand. The partnership involved QualityHealth



**44** Midtier and specialty pharma are taking big steps toward the adoption of this new partnership model. **99** 

**ROB REBAK** / QualityHealth



#### Pharma 3.0

being responsible for finding appropriate patients, qualifying them for brand messaging, and delivering the messaging in the right cadence and for the right duration to drive action.

"The business arrangement was a riskshare performance-based agreement, where QualityHealth did not charge for patient access, recruitment, or engagement ---- there was neither a media nor a marketing charge; rather, we were paid only when a brand conversation occurred between patient and doctor," Mr. Rebak says. "The program was successful because qualified patients were able to learn about treatement options and take action. All parties were aligned and incentivized to drive performance. Tactical management and metrics were important, but only as early indicator and optimization levers and not as ends in and of themselves."

#### J&J and 23andMe

Diego Miralles, M.D., explains JHI's course of action regarding its own partnership with 23andMe. According to Dr. Miralles, JHI leadership saw an opportunity to better understand the potential power of personalized genomics and recognized an opportunity to actively engage in this space by partnering with the personalized genomics company 23andMe.

Johnson & Johnson Development Corporation led 23andMe's Series C financing, and the Janssen Healthcare Innovation team engaged with 23andMe on specific projects.

"We were passionate about collaborating with 23andMe based on our strong belief in consumer empowerment," Dr. Miralles says. "We believe that by allowing consumers to have direct access to their own genomic data, we start to help create a new kind of informed empowered consumer that can better make decisions around their own health."

Dr. Miralles believes these types of partnerships will be an important force of change in the new world of healthcare.

Through this alliance, the company anticipates tremendous benefits for patients in the future, where they will be able to access more effective medicines that are reimbursed by payers that appreciate the benefits of getting the right drug to the right patient.

"The partnership has also given us the opportunity to do more in less time than we could have on our own," Dr. Miralles says. "More critically, this agreement helps us modernize our core business by leveraging Webbased genomic tools to inform future personalized drug development by our therapeutic area teams."

**66** Partnerships such as Medco and UCB provide a commitment to personalized medicine and the end of the one-sizefits-all approach to treating illnesses. **JJ** 

DR. KEN KRAMER / Alpha & Omega



#### Approved product Therapeutic focus Discovery and early Late development Commercialization Proof of concept Disease areas development Number of leads New business model Market segments Number of ideas Proof of concept Pilots and Scale up and larger Strategic/risk assessment Market assessment **Partnerships** partnerships **Business model development**

**I.Strategic focus:** Areas and business models that are a strategic fit for the organization

**Drug Development** 

II. Proof of concept: Ideas that work in concept."Does it work and is it safe?"

**III. Development:** Most promising pilots. "Is it commercially feasible?"

**IV. Commercialization:** 

Service or product offerings "Can it be scaled and replicated across markets?"

#### EXPERTS



**CAROLYN BUCK LUCE.** Global Pharmaceutical Sector Leader, Ernst & Young, which helps companies across the globe to identify and capitalize on business oppor-

tunities. For more information, visit ey.com.



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**ROB REBAK.** Chairman and CEO. QualityHealth, which offers performancebased customer acquisition solutions for healthcare marketers. For more

information, visit ghperform.com.

Pharma MNC	Partner company	Therapy Area	Details	
Pfizer	Humana	NA	Pfizer has formed a partnership with health insurer Humana to research ways to im- prove healthcare for the elderly. The companies are seeking "to develop an important body of knowledge" to advance their work and to study prescription drug use and how it affects areas such as cost and quality of care and patient outcomes.	
WellPoint	IBM	NA	WellPoint has announced an agreement to use IBM's Watson supercomputer system to create a commercial application that could help diagnose medical conditions and authorize treatments for WellPoint's members.	
Hewlett Packard	SingTel, HealthSTATS and Frontier Healthcare GroupTherapy area	Cardiovascular	HP, SingTel, HealthSTATS, and Frontier Healthcare Group launched an eight-week clinical trial of a mobile health monitoring solution. To improve patient monitoring, the four companies are collaborating on a trial of the HP Mobile Health Monitoring Solution to wirelessly link clinics, doctors, and patients via SingTel's 3G/GRPS mobile network.	
Humana	Discovery Holdings	NA	In February 2011, Humana entered into a joint venture with Discovery Holdings to offer the Vitality wellness and loyalty program and the program's wide range of well- being tools and reward partners to its health plan members. As part of the joint ven- ture, a new entity has been established — the U.Sbased HumanaVitality LLC — that will offer the Vitality program.	
ВІ	Press Relations	NA	Boehringer Ingleheim has developed a social media-monitoring tool in collaboration with German agency Press Relations. The tool aggregates information found in various social media websites and evaluates it to gather key insights for the company.	
Pfizer SOURCE: EY. For more in	Medco Health	Virology	Medco Health Solutions and Pfizer have collaborated on an HIV/AIDS personalized medicine program that advises physicians on patient adherence to all antiretroviral medications, delivers information on applicable genomic testing, and provides pharmacist-based counseling for patients less than 90% adherent to their Highly Active Antiretroviral Therapy (HAART) regimens.	

#### Partnerships Taking Shape in 3.0 Model

#### **Humana and Pfizer**

Humana and Pfizer have formed a five-year research partnership to explore new ideas and ways to improve the quality, outcomes, and costs of the healthcare delivery system for senior citizens and other populations.

The companies will bring together researchers and healthcare experts from both organizations to study key issues and deliver interventions to reduce inefficiencies in the management of chronic conditions such as pain, cardiovascular disease, and Alzheimer's disease. This collaboration will leverage Humana's experience with making healthcare more affordable for seniors and Pfizer's expertise in researching and developing medicines to treat chronic conditions, while bringing together data and scientific information to better understand patient needs and the effectiveness of treatments. The two giants envision building on clinical evidence using real-world data and comparative effectiveness research to better understand patient needs and improve access to appropriate care so that the right services are delivered to the right patients at the right time.

#### Medco and Sanofi

Medco Health Solutions and its wholly owned subsidiary United BioSource joined with Sanofi in a global, multi-year agreement to improve patient care in real-world settings. The partnership will leverage several capabilities, including personalized medicine and pharmacogenomics, health economics, and safety research, as well as clinical/adherence support. The goal of the collaboration is to enable drug manufacturer Sanofi to precisely identify patient populations with the greatest unmet medical needs. Sanofi also will attempt to determine those populations in which drugs are most effective; generate real-world comparative effectiveness data to support product value that meets stakeholder evidence requirements; and facilitate the development and implementation of novel care models to improve practice of care, adherence, and patient outcomes, Medco reports in a prepared statement. New drugs from Sanofi resulting from the deal are expected to have companion diagnostics, and pharmacogenomics will be part of comparative effective research.

#### Bayer HealthCare Diabetes Care and Nintendo

In 2010, Bayer brought its Nintendo-based blood glucose meter for kids with diabetes to the United

Pharma 3.0 Initiative	Sub-classification of Pharma 3.0 initiative	Initiative Type	Geographies Covered
Managing patient outcomes	Disease management	NA	United States
Managing patient outcomes	Data management	Technological tool	United States
Managing patient outcomes	Disease management	mHealth (excluding smartphone apps)	Singapore
Managing patient outcomes	Disease management	Rewards program	United States
Managing patient outcomes	Data management	Monitoring tool	Germany
Managing patient outcomes	Disease management	Patient support program	United States

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DR. DIEGO MIRALLES Janssen Healthcare Innovation

#### **Medco and Sanofi**

The pharmaceutical industry has been struggling to overcome the discrepancy between the outcomes from clinical trials and the outcomes in the real world — as they often differ.

According to Ken Kramer, Ph.D., senior

#### WellPoint and IBM

WellPoint and IBM have teamed up to develop and launch Watson-based solutions to help improve patient care through the delivery of upto-date, evidence-based healthcare. IBM developed the base Watson healthcare technology on which WellPoint's solution runs. Watson, named after IBM founder Thomas J. Watson, is a computing system built by a team of IBM scientists that rivals a human's ability to answer questions posed in natural language with speed, accuracy, and confidence. Watson's ability to analyze the meaning and context of human language, and quickly process vast amounts of information to suggest options targeted to a patient's circumstances, can assist decision-makers, such as physicians and nurses, in identifying the most likely diagnosis and treatment options.

States, after first launching it in the United Kingdom. The Didget meter connects directly to Nintendo DS and DS Lite gaming systems and adds an element of fun to the routine of checking blood glucose and is designed specifically for kids to motivate them to maintain consistent blood glucose checking habits and meet customized glucose targets, as instructed by their healthcare provider. By tapping into their existing passion for handheld gaming, the meter reinforces consistent testing habits by awarding points that kids can use to unlock new game levels and customize their gaming experience.

#### Intel and GE

In a partnership that began in 2009, Intel and GE joined forces to develop Care Innovations to address issues faced by and because of the growing number of elderly people in the United States. Launched in January 2011, Care Innovations combines teams and assets from Intel's Digital Health Group and GE Healthcare's Home Health division to develop technologies that support healthy, independent living at home and in senior housing communities. The companies' main focus includes disease management as well as independent living and assistive technologies. In July 2011, the collaboration launched Care Innovations Connect, a tablet-based digital platform that aims to combat social isolation among seniors. The Connect software acts as an in-home digital device for seniors and a customized portal that can be used by professional caregivers. The platform includes wellness surveys, wellness data, a community calendar and other tools, such as a webcam and social network, making it like a Facebook for seniors, in tablet form.

VP and medical director, Alpha & Omega, the answer lies in a few variables, including patient selection, motivation, accessibility, and adherence. These variables are more easily controlled in the clinical trial setting than they ever can be in the real world of jobs, kids, and mortgages.

"If we are to serve the public to the best of our abilities, however, we need to understand why things go astray," Dr. Kramer says, and that's where Pharma 3.0 comes in.

For example, the partnership between Medco and Sanofi to support real-world evidence assessments during product development and pre-/post-approval processes allows Sanofi to identify patient populations with the greatest unmet medical need and help determine which drugs may be the most effective.

They will also generate real-world comparative effectiveness data to support product value and facilitate the development and implementation of novel care models to improve practice of care, adherence, and patient out-comes.

"This framework provides Sanofi with an ecosystem of payers, manufacturers, and researchers to study throughout a product's lifecycle and will support improved health outcomes and deliver meaningful benefits to all," Dr. Kramer says. "Overall, it shows a commitment to personalized medicine and the end of the onesize-fits-all approach to treating illnesses."

#### **EY Partnerships**

As EY continues to actively work with targeted life-sciences companies to help them organize a Pharma 3.0 strategy and initiatives, it also focuses on building a portfolio of commercial trials that entail innovative partnerships with nontraditional entrants to test business models in the areas that include adherence, compliance, self management, education, monitoring, group support, data management, and disease management. In this work, EY is able to identify many successful partnerships. EY designates the companies listed in the accompanying chart as leaders in 3.0.

Further, Dr. Miralles identifies Care Innovations — the company that was formed by Intel and GE — as a role model agreement for Pharma 3.0 partnerships.

"Establishing the new entity by combining assets and expertise from GE Healthcare's Home Health Division and Intel's Digital Health Group was an important milestone," Dr. Miralles says.

JHI has learned much by studying partnership models outside of the healthcare industry, as well.

"We've also learned a lot from talking to other companies in the banking, airline, and automotive industries as they have faced similar challenges to driving innovation," he says. "We've listened to their experiences and internalized key learnings that we think are relevant to our initiatives."

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It's not getting any easier to understand or be in compliance with all the various regulatory and legal requirements that apply to Rx and OTC drug and device promotional materials. The Food and Drug Administration and Office of Inspector General/Department of Justice continue to take enforcement actions. In addition, there are many voluntary codes and other standards that companies must adapt to their own products. The penalties for noncompliance go beyond an FDA warning letter. The substantial fines. criminal and civil legal actions and corporate integrity agreements affect how every company and vendor does business.

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