Industry Disruption

Disruptive technologies are transforming the industry and presenting companies with real opportunities to do business — from molecule to market — more efficiently, cost-effectively, and faster.

Most disruptive technology initiatives are taking place in smaller, more agile companies, and in the clinical trial phase of development, but even big companies such as Pfizer and GSK are testing the possibilities of artificial intelligence, blockchain, and especially mobile and other transformative clinical tools.

When speaking of this new environment, Bernard Munos doesn't like to use the word disruption, because it scares people. He prefers the word transformation in describing the changes taking place in the industry. Mr. Munos, senior fellow at FasterCures, Milken Institute, says disruption is happening because the industry's business model has aged to the point where resources — time and money — are being squandered in vast amounts.

"So, the industry is going to have to undergo a transformation," he says. "I prefer to use that term rather than disruption, because I find disruption spooks people."

Dr. Amir Kalali, head, neuroscience center of excellence, QuintilesIMS, also does not use the term disruption. He finds that in the risk-adverse pharma industry, it is not a useful term and can actually be a barrier to adoption of new technology. "Nobody wants to be 'disrupted,' " he says.

While disruption — or transformation — happens about every 30 years or so across all industries, companies still seem to get caught off guard. "I find this really fascinating because they have everything that they need in order to avoid the disruption," Mr. Munos says, speaking specifically about pharma. "Pharma companies have lots of money, lots of smart people, and they've got a lot of staying power — they know their market, they know their customers, and they have technological expertise. But they are so caught up in the traditional model's inefficiencies, making transformation very painful."

However, there are pharma companies that have begun to adapt to meet the pressures of developing drugs in today's market, and a couple of new business models are emerging as a result of the transformation.

The first is the traditional pharma model with the addition of "hyper-innovation."

"Companies such as J&J and GSK, for example, and Novartis to some extent, have stuck to the traditional big pharma model, but they have embraced innovation to increase their output, which I call hyper innovation, which is yielding close to two new drugs per year," Mr. Munos says. "If a company has that level of output, it generates enough cash to cover the significant structural costs that the big pharma model implies."

Blockchain is very intriguing in terms of engaging patients, capturing data, and the ability to manage permissions.

CRAIG LIPSET
Pfizer

The hallmark of this century will be the merging of biology and technology, with DNA becoming the new programming language.

DR. AMIR KALALI
QuintilesIMS

The second model is the specialty biopharma model, which is exemplified by companies such as Bristol-Myers Squibb, which used to be considered a big pharma company, but has redesigned itself into a specialty biopharma company, Mr. Munos says. BMS shed all the assets in which it was not world-class, selling them to other companies, and reinvesting the money in breakthrough science.

Companies that fall in between the two models may face extinction, Mr. Munos says, adding that if they want to survive they will have to decide which transformative model works best for them.

"If they want to stick with a big pharma model, that's fine, but they have to start adopting hyper innovation, and not all companies are capable of doing that," he says. "If they

Pfizer Embraces Transformation

We have an opportunity to potentially redefine how we think about patient outcomes and 24/7 monitoring by combining Pfizer's scientific, medical, and regulatory expertise with IBM's ability to integrate and interpret complex data in innovative ways.

DR. MIKAEL DOLSTEN
President, Pfizer Worldwide Research and Development

Pfizer and IBM launched a first-of-its-kind research collaboration to develop innovative remote monitoring solutions aimed at transforming how clinicians deliver care to patients suffering from Parkinson's disease. The experimental approach will rely on a system of sensors, mobile devices, and machine learning to provide real-time, around-the-clock disease symptom information to clinicians and researchers. The ultimate goal is to obtain a better understanding of a patient's disease progression and medication response to help inform treatment decisions and clinical trial design, while also speeding the development of new therapeutic options.

"We have an opportunity to potentially redefine how we think about patient outcomes and 24/7 monitoring by combining Pfizer's scientific, medical, and regulatory expertise with IBM's ability to integrate and interpret complex data in innovative ways," says Mikael Dolsten, M.D., Ph.D., president of Pfizer Worldwide Research and Development. "The key to our success will be to deliver a reliable, scalable system of measurement and analysis that would help inform our clinical programs across important areas of unmet medical need, potentially accelerating the drug development and regulatory approval processes and helping us to get better therapies to patients — faster."

"With the proliferation of digital health information, one area that remains elusive is the collection of real-time physiological data to support disease management," says Arvind Krishna, senior VP and director of IBM Research. "We are testing ways to create a system that passively collects data with little to no burden on the patient, and to provide doctors and researchers with objective, real-time insights that we believe could fundamentally change the way patients are monitored and treated."

Pfizer has been a leader in applying mobile health applications, social media, and health information technology to capture data and insights from patients, enhance the patient experience, and coordinate the clinical trials conducted in partnership with thousands of independent researchers. Its program, mClinical, provides research participants and investigators with advanced tools that streamline information access and maintain compliance using a flexible and modular approach.

According to Craig Lipset, head of clinical innovation, global product development, Pfizer, in pilots using these innovative tools, found the response was overwhelmingly positive. Perhaps because mobile technology is familiar and people are more comfortable with it. Pfizer also communicated results companywide and its success was very visible.

"Many of our study teams were very enthusiastic to be fast followers," he says. "They didn't want to wait. They saw other teams getting early access through the pilots and they believed that electronic informed consent or apps to support participation and better and smarter ways to capture patient self-reported data was the way to go."

According to Frost and Sullivan, by 2020, chronic conditions, such as cancer and diabetes, are expected to be diagnosed in minutes using cognitive systems that provide real-time 3D images by identifying typical physiological characteristics in the scans. By 2025, AI systems are expected to be implemented in 90% of the U.S. hospitals and 60% of the global hospitals and insurance companies. In turn, AI systems will deliver easily accessible, cheaper, and quality care to 70% of patients.

"AI is making use of existing data in a way that can be absolutely game changing," Mr. Lipset says. "In clinical development, instead of a scientist sitting and constructing his or her hypothesis, much of that data can be driven by AI all the way from the initial thought process to a final study report."

Pfizer is also looking at blockchain applications, which can impact everything from supply chain to regulatory compliance to informed consent and privacy implications. According to the BlockRx Project, a collaboration of pharma and blockchain experts is developing and implementing new solutions to innovate and improve the drug development lifecycle. The organization cites opportunities for blockchain to enhance the interaction between pharma, CROs, investigators, and patients during clinical trials. As a method to facilitate user validation, proof of work, and smart contracts, the blockchain will change how organizations manage and record data providing security and transparency across all stakeholders. An even stronger use case will be for the pharma supply chain to shore up the process of tracking data and metrics.

Mr. Lipset says Pfizer has a multidisciplinary team looking at blockchain opportunities from a number of different angles. He says the company has a few small blockchain experiments ongoing with clinical trials recognizing the importance of engaging with patients, capturing data in new ways, and the ability to manage permissions.

"Blockchain is very intriguing in terms of what it may bring in the future scene," Mr. Lipset says.

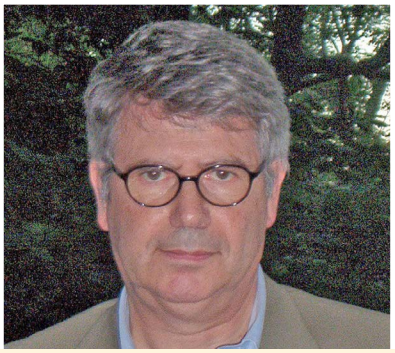
The FDA is putting value in blockchain as it partners with IBM's Watson Health AI unit to explore using blockchain technology to securely share patient data for medical research and other purposes.

IBM Watson Health and the FDA will explore the exchange of patient-level data from several sources, including EMRs, clinical trials, genomic data, and health data from mobile devices, wearables, and the Internet of Things. The initial focus will be on oncology-related information.

don't think they can adopt hyper innovation, then they have to transform into a specialty biopharma company if they want to survive."

Mr. Munos estimates that about half of the top 22 pharmaceutical companies are well on their way to a successful transformation, but the other half have not embraced the technology disruption occurring around them.

"Many of today's companies are still scratching their heads and wondering which way they're going to go, but they don't really have a lot more time to decide," he says.



Half of today's top companies are still scratching their heads on how to transform their business model, but they don't have a lot more time left.

BERNARD MUNOS
Milken Institute

Really cool things happen when pharma and technology companies partner to apply new technologies to impact disease.

DR. MICHAEL SIERRA
LEO Science & Tech Hub

"They're going to have to make a decision because billions of R&D dollars are being spent every year, and if they are not producing adequate returns, something is going to break, sooner or later."

According to Dr. Kalali, every aspect of the industry can be improved by new technology. "The ones I will call out are synthetic biology, artificial intelligence, ambient biosensors, robotics, 3D printing, and technologies enabling deeper engagement with patients," he says. "The hallmark of this century will be the merging of biology and technology with DNA becoming the new programming language."

One biotech company that is embracing such a merger is Capricor Therapeutics, which has been built around a cardiac cell-based therapy that is showing signs of promise in certain cardiovascular disease settings.

"As an industry for which relentless innovation has been a defining characteristic since its inception, biotechnology has not only provided society with therapeutic products that have improved and extended life for countless people, but has also fostered the evolution of platform technologies that continue to bear fruit as we continue to better understand the mechanisms and targets intrinsic to specific illnesses," says Linda Marbán, Ph.D., CEO, Capricor Therapeutics. "A relatively recent and exciting development is the realization that our cells exert their effects through nano-sized bubbles that they secrete, which get taken up into the cells of organs in the host. These exosomes, as they are termed, are chock full of bioactive molecules that have long-lasting effects on how their target cells express their own genes, which in turn can sustainably alter their functions. Not only are the exosomes able to reproduce the effects of our cells in cardiac disease models, but they are also able generate profound effects in other disease settings such as those of the eye and skin. And, in contrast to cell-based products, exosomes can be handled much like traditional biopharmaceuticals such as recombinant proteins and monoclonal antibodies."

Capricor is one of several companies that is investing heavily in the field of exosome science, powered by the growing belief that these tiny particles, which had once been thought to serve merely in the disposal of cellular waste, are a "disruptive" platform technology that have the potential to generate a new class of medicines in the not-too-distant future.

Tech Driving Transformation

Whether you call it disruption or transformation, there is evidence that the industry has certainly started adopting new processes in response to the new technology environment, including AI, blockchain, and especially mobile data capturing mechanisms that improve clinic response times. These tools can help cut costs by streamlining processes so more can be done efficiently and faster, including failing.

Failing faster is important these days in terms of moving science along — or not — and keeping costs down through the discovery and development phases.

"Most of what we do in research will fail," says Michael Sierra, Ph.D.,VP, LEO Science & Tech Hub. "The issue is most companies are built to push as hard as possible. As a scientist, you give me good data or bad data, and I can always provide a reason why we should go on. It may not be the right reason, but it is a reason. That's what we do."

Using new tools can improve predicting, diagnosing, and monitoring disease, as well as help the company make better go or no-go decisions.

LEO is hoping to harness the power of artificial intelligence and cloud computing to assist in its endeavors to help patients and doctors to diagnose, monitor, and treat skin diseases more effectively. For example, patients could use their iPhone to send a photo of their skin condition to a cloud data platform that quickly analyzes it using AI. Another goal for the company is to help patients avoid skin biopsies by using a picture of the skin and with the help of advanced data analysis, a physician

Looking for Disruption?

The annual CNS Summit, Nov. 16-19, 2017, in Boca Raton, Fla., is a platform for change and a community passionate about shaping the future, with a focus on collaboration, innovation, and technology. The mission of the event — Collaborating for Novel Solutions, Shaping the Future — is to have a positive impact on the success of clinical development programs. The three-day conference is innovative in its approach to fostering collaborations through unique networking opportunities, innovator showcases, and solutions presentations. To register, please go to: http://www.cnssummit.org.

As an industry for which relentless innovation has been a defining characteristic since its inception, biotechnology has not only provided society with therapeutic products that have improved and extended life for countless people, but has also fostered the evolution of platform technologies that continue to bear fruit as we continue to better understand the mechanisms and targets intrinsic to specific illnesses.

DR. LINDA MARBÁN
Capricor Therapeutics

Defining and Fueling Innovation

Industry experts across the life-sciences spectrum provide their definition of disruptive innovation and their insights on how to fuel the disruption needed to move the industry forward.

MARCO ANELLI, M.D.
Head of Pharmacovigilance and Medical Affairs Advisory Services, ProductLife Group

DEFINING DISRUPTION

I would define disruptive innovation as a sudden change to the way things are done. The transition from traditional data to big data is one of these innovations. The very definition of pharmacovigilance and how a reportable case is investigated traditionally has required four pillars: a drug, a reporter, an event, and a patient. But social networks challenge those four pillars. Take a not-uncommon example from a social network: "don't take this drug, because my grandmother did and died." There is no identifiable patient or identifiable reporter, only a drug and suspicion of something that went wrong. But from a scientific point of view it needs to be investigated.

FUELING INNOVATION

Pharma companies should not react but be proactive. Take social listening for the purposes of pharmacovigilance. While companies might argue that they are not obliged to listen to social networks for adverse event reporting, this is the direction in which the regulatory authorities are heading. Pharmacovigilance is only one example. Today, vast amounts of data are generated every minute and we must find a way to handle this information and turn it into information knowledge. The first step is computing power, which continues to evolve. The second will be to develop and use AI techniques for specialized purposes — drug sentiment analysis, adverse event reporting, possibly even new indications. And the third will be for companies to become more actively involved with how regulations are put together. For example, if companies had been able to identify problems with statins from listening to social networks, they could have responded before the scandal broke.

MARK BOUCK
President and CEO, TrialCard

DEFINING DISRUPTION

Today's market demands engagement strategies that help patients take an active and ongoing role in their healthcare. Now more than ever manufacturers need to leverage multiple mediums, both emerging technologies as well as classic methods, to connect with patients on a continual basis as our social world has set the bar at a level where this is now the norm. Manufacturers are also expecting a much broader array of capabilities from their service providers without sacrificing depth of knowledge. Because of the increased need to interact with patients on a deeper level, finding a business partner that can craft integrated solutions that support multiple facets of the patient journey has gone from a nice-to-have to a must-have when designing any variety of patient support program. Overall, pharma appears poised to continue head-on into an era where forming a genuine connection with patients will become the primary expectation of all stakeholders and something that all service providers will make the focal point of their work.

FUELING INNOVATION

Technology has always played an important role in everything we do, but over the past year we have placed a heightened emphasis on it as the cornerstone of our business and the common thread that connects multiple services to form integrated solutions. We see this as a must in the technology-driven world in which we live; everywhere you turn technology plays a pivotal role in people's daily activities, and healthcare is certainly no exception. Patients are seeking information and expecting convenience, and we've leveraged technology on behalf of our clients to enable them to fulfill both of those needs. In an environment where engagement is the name of the game, providing multiple tools to interact with the patient such as customized text messaging, proactive refill reminders, behavior-based business rules, and real-time benefit research are all strategies that we have implemented to make our clients' programs easier for patients to use as well as more helpful. Another way in which we've harnessed the power of technology to deliver increased value for our manufacturer clients is through our data analytics capabilities. Innovations such as our mobile reporting app for field force representatives or our prescriber targeting analyses that identify a brand's most high-value targets help streamline commercial activities and deliver a greater return on program investment. Finally, developing our own internal technologies to enable ease of interfacing with other systems is technological advancement that has made us more nimble, flexible, and better able to support a wider range of client needs.

CHRIS CULLMANN
Senior VP, Engagement Strategy, Ogilvy CommonHealth Worldwide

DEFINING DISRUPTION

Disruption is a loaded term — one that carries with it a lot of cultural baggage. To truly call something disruptive requires that it cannot be "unseen." Such a change is significant and that turning back is not a practical consideration. And going forward all employees can use it as a reference point to build upon. The definition requires that it interrupt an existing behavior or activity. For healthcare, disruption can be a tall order since

can prescribe the right treatment without needing to perform surgery.

"We're looking at imaging, biomarkers, and noninvasive skin testing and tying it all together with AI/cognitive computer learning," Dr. Sierra says. "Usually, when we're looking at data, we're only looking at things that we can visually see. Having the computer to be able to learn, we can find correlations that would not have been seen with the human eye."

Dr. Sierra believes that collaboration is key in using technology to determine the viability of a new product or process. Transformation requires new skill sets that are not always available in-house, and it would be extremely

Defining and Fueling Innovation

by nature, we are tending to patients' health and few are brazen enough to dramatically change proven solutions in scale. For the context of this article, I think all readers should take the term and its role in our cultural vernacular as a rally cry to push toward change, evolution, and greatness. I think for all of us, to disrupt means to leave our mark and help move forward an industry that holds a charter to help people.

FUELING INNOVATION

The pharmaceutical industry needs to make an investment: It must attract and inspire new talent in every category. This is a tremendous industry to work within and one that should be attracting the best every generation can offer. The last few years has shown that the pharmaceutical industry can draw solutions from outside of industry. There is so much more room to grow and find innovation, reach, and dramatic evolutions from within. I would love to see more from the pharmaceutical companies that are funding incubation projects, to recruit from technology schools, art schools, and outside of the science categories. I think there is a tremendous amount to learn from industries that are well outside of healthcare. A modern sense of independence, and from leveraging the speed at which we can capture insights using connections from all over the globe, and these need to be mandates to attract innovators and light fires.

TIM DAVIS
CEO, Exco InTouch

DEFINING DISRUPTION

To me, disruptive innovation is an umbrella term for the devices, methods, and policies that change the way pharma thinks and acts. At the moment pharma is still engrained in processes that were developed before the technological revolution and this needs to change. Instead of introducing technology that makes existing processes simpler, or more efficient, true innovation will be achieved by those who can rethink those processes altogether, to consider the health journey of the patient as a whole. Pharma needs to displace siloed thinking and consider the entire healthcare continuum, targeting the pinch-points where technology can have the most impact. That's how technology and innovation can add true value, by adding a level of value above the cost and processes of bringing it on board.

FUELING INNOVATION

To be successful the industry needs to think about what data they need to collect and why. To achieve innovation and true change in the way we collect data, we must stop thinking about the individual goal or program in isolation, but think much more broadly about where the data they collect could be used. Rather than thinking about how information will be used today think about how needs might change in the future. Pharma needs to be adaptable to, and acceptable of, change so that companies can modify programs as required over time. Patients are happy to provide general health information when it is seen as being used for the benefit of others. We are already seeing this in many of our clinical studies where complementary data is being collected through sensors and wearables that provide broader information on patient well-being. This information is considered as supporting information to help pharma understand the effectiveness of treatment on patient lives beyond traditional measures.

BRETT KLEGER
Chief Commercial Officer, DrugDev

DEFINING DISRUPTION

Disruptive innovation isn't just about improving the current process. It's about breaking down barriers to think differently. Sometimes it is creating an entirely new process or business model that completely changes an industry by exponentially improving results. Other times it is simply taking a known business process or technology from one industry and applying it to another. And other times it might require an integration of multiple processes into one to find efficiencies. The key to disruptive innovation is to do something different to achieve a better result, but there are many ways to get there.

FUELING INNOVATION

The industry needs to think big. Our goal is to disrupt clinical trials via collaborations and technologies so the industry can do 10 times more trials for the same amount of money, and thus bring 10 times more products to those in need. If we all focus on the end result of patients and their loved ones, we will find solutions instead of combating change. Collaborative organizations such as TransCelerate and Investigator Databank are fostering teamwork to drive industry standards such as the Investigator Registry. But it should not stop there. All stakeholders need to continue to push for standardization, which in turn will drive down costs and allow us to do more trials. We also need to support smaller drug developers and solution providers as they drive innovation. As an industry, we cannot be afraid to change.

CHRISTINE HURLEY
Chief Operating Officer, 4G Clinical

DEFINING DISRUPTION

To be truly disruptive, the innovation must not just support a shift or an incremental improvement over the current way trials are conducted today but rather offer a real, measurable impact in time, quality, cost, and/or operations. A disruptive innovation is a game-changer and dramatically simplifies and accelerates the process for which it enables.

FUELING INNOVATION

The industry is at risk of becoming weary of technology and innovation. Almost everyone has been involved in a major project where they invested resources and time for the promise of innovation, to improve their workflow and streamline their trials. If at the end of that road, they don't feel a material impact for the better, it is disruptive in a negative way and they become resistant to innovation. To continue to fuel innovation in a positive way, there needs to be a material change — something people can see/feel. They also need to fully understand the unintended consequences of an innovation and view it holistically. If it makes one group's process easier, but completely derails the productivity of another stakeholder, there will be barriers to adoption. It

Defining and Fueling Innovation

is critical to make sure the innovation moves the needle enough in the right direction to make a disruption in process worth the investment.

ELVIS PACELAT
VP of Compliance Solutions, Amplexor

DEFINING DISRUPTION

In the context of the life-sciences industry, we define disruptive innovation as taking a quite different approach, methodology, process, or solution that enables a company to move more nimbly, enabled by increased simplicity, convenience, accessibility, and affordability so it can move more swiftly and make finite resources go further.

FUELING INNOVATION

As someone once famously said, if you keep doing things the same way, you shouldn't be surprised if you get the same results. We believe that by applying the more-of-same approach — ie., the same ways of doing things, the same solutions, and working with the same technology vendors for example, big names who are typically less innovative than emerging agile vendors — life-sciences firms will continue to suffer the same restrictions they always have. As the pressure mounts to reinvent what companies do and the way they operate, firms need to be willing to place their trust in newcomer/challenger suppliers that can bring fresh ideas and more agile approaches to bear. Just as big pharma companies may find it harder to move as swiftly as CROs and small biotech companies, so large established technology vendors and service organizations are often slower to adapt and provide the new approaches and solutions required to meet today's and tomorrow's needs.

WILL REESE
President, Cadient, a Cognizant Company
Chief Innovation Officer, Cognizant Life Sciences

DEFINING DISRUPTION

A true disruptive innovation should entail a rethinking of the value proposition and a reimagining of the supporting commercial model. In the traditional sense, it's something that starts within the market at the lowest common denominator and works its way to the top and ultimately creates a new market of its own. To be disruptive, we have to build products and services grounded in human science and design thinking. The comfort has to be with changing your market perspective and simplifying the value proposition. True disruptive innovations are almost always built on a much simpler fundamental idea or truth that is highly relevant to the customer.

FUELING INNOVATION

There are three keys to fueling innovation in our industry: collaboration, culture, and commitment. New approaches to productive partnerships and collaboration are going to be necessary to speed innovation. Now more than ever the path to innovation is driven by an organization's ability to connect and align their customer value with healthcare, technology, and service partners who can add exponentially to that value. The second key is culture; in almost all cases the most innovative high-performing companies have internal experiences that mirror their external value proposition. If companies don't commit to internal innovation it is difficult to innovate externally within their products and services. Finally, they need commitment. Often what is considered innovative by the industry is short term, a pilot, or a novelty, not sustaining innovations. Commitment requires change management, new talent, and new approaches to measuring value.

DEB SCHNELL
VP, Managing Director, Taylor Strategy Partners

DEFINING DISRUPTION

How would you define an apple, a dog, a chromosome? The Merriam-Webster dictionary definition is specific. It is what it is. The same is true for disruptive innovation. We do not get to define disruptive innovation. In fact, "a disruptive innovation is an innovation that creates a new market and value network, displacing established market leading firms, products and alliances." The term was defined and phenomenon analyzed by Clayton Christensen, professor of business administration at Harvard, an educator, author, and business consultant. The pharma/biotech commercialization process could most definitely benefit from disruptive innovation. The healthcare landscape is rapidly changing and is ripe for disruptive innovation, creating a new market, and new value network. Big industry changes require big innovation, which requires an entirely new way of thinking and new approaches. No longer can we simply refine the industry standards and call it innovation.

LANCE SCOTT
President and CEO, Zephyr Health

DEFINING DISRUPTION

I actually think we overuse the term "disruptive." To me it means doing something that is fundamentally different from what we do today, how we do it, and who we do it with. People, process, and technology are essential components of bringing about innovation and must work in concert with one another. Our industry is at an exciting turning point where we need the kind of innovation that is not merely incremental, but radical — with the meaning of radical being based on thorough or complete change. By taking this kind of approach we can adopt the emerging technologies available to us, align our processes with these, and ensure our people have the right skill sets to support the adoption and execution of the kind of innovation that will separate the leaders from the pack.

FUELING INNOVATION

As an industry, we need to look toward other industries that have used data to transform their business, from financial services to travel, and we need to be more committed to making the patient — ultimately a consumer — a part of that innovation. Those two industries, for instance, have been able to improve the consumer experience while simultaneously making that experience increasingly digital. I'm not suggesting substituting the patient-physician relationship with a digital

Defining and Fueling Innovation

alternative, but thinking about the complete lifecycle of a product coming to market, using data to drive the strategic plan and successful adoption of that product, and integrating consumer/patient data every step of the way will help us continue to fuel innovation from a commercial perspective. Having a common vision spanning multiple functions, from analytics and technology to marketing and medical affairs, will be an integral part of this innovation.

PAUL SHAWAH
VP, Commercial Cloud Strategy, Veeva Systems

DEFINING DISRUPTION

Disruptive innovation is a fundamental change to a business model that makes things easier and more efficient. In the life-sciences industry, the commercial business model is still pre-Internet and hasn't been disrupted. It's like taxi cabs before Uber, hotels before Airbnb, retail before Amazon. Digital initiatives have started, but there is so much more opportunity. For example, it's not easy for physicians today to get information about drugs and treatments because each manufacturer provides the information digitally in a different way. This causes friction, which inevitably lowers information consumption. Digital disruption has been slow to reach our industry because regulations and legitimate safety concerns have caused companies to be more resistant. But disruption is coming. Eventually, companies will be shown an easier path, and they'll take it. Travelers take public transportation more now that Uber makes it so easy. People take more vacations with Airbnb. We shop more online because of Amazon. The same will happen in life sciences.

FUELING INNOVATION

Across many industries, up to 90% of IT spending focuses solely on operational issues — leaving little time and money for strategic priorities. The life-sciences industry is not immune to this challenge. But, our industry is shifting its focus onto transformational initiatives rather than keeping the lights on. These advances simplify core tasks to give people time back so they can refocus on business goals. Arguably, this is more critical in the life sciences than other industries, considering the importance of getting the right information to doctors and speeding the right treatments to patients. To focus more on innovation, companies need to revamp internal operations to be more efficient and they need to start with areas that are most strategic to your business and that have the most opportunity to provide a competitive advantage, such as customer-facing applications.

STEVE STEIN
Lead Research Specialist, 3M

DEFINING DISRUPTION

In the corporate world, we might define disruptive innovations regarding changing market dynamics or displacing market leading companies or products. The customer probably thinks of disruptive innovations with questions such as "What would I do without my …" or "Why didn't someone think of this before?" The iPhone certainly fits into that category. Think how differently people think about and use their phone than they did before the iPhone.

FUELING INNOVATION

Innovation is the lifeblood of who we are at 3M, and we continue to invest heavily in research and development. We aren't interested in innovation for the sake of innovation. Rather, we always try to make sure that our innovation is connecting to real needs of our customers. For example, we want to understand the challenges patients may have using existing inhaler products. We ask questions, such as what would make an inhaler fit into the life of an asthmatic or COPD patient? What would make a good inhaler in the eyes of a caregiver? What insights do physicians or payers have that we need to understand to develop a better inhaler? These are the types of questions we asked as we developed the 3M Intelligent Control Inhaler, a new connected inhaler that addresses patient adherence and patient competence. The more we, as an industry, can understand our customers, the better we can innovate in ways that fit patients' circumstances and make a difference in their lives.

SCOTT WEISS
VP, Product Strategy, IDBS

DEFINING DISRUPTION

Disruptive innovation is about fundamentally transforming a market or industry, and displacing existing processes, products or services. While novel technologies can be transformative to a market, we believe disruptive innovation is about changing the underlying business model to achieve significant gains in efficiency, productivity or cost savings, or establishing entirely new markets.

difficult to build all that was required from within a company, especially in the fast-paced technology revolution.

"It is difficult to build all the competencies in-house as quickly as the world is evolving, especially if we start thinking about all the digital technologies and innovations that are emerging," he says. "It's just impossible to build all the competencies necessary internally and execute on them."

However, when pharma companies partner with cutting-edge technology companies, Dr. Sierra says, this is where really cool things happen.

"New technologies when applied in the clinic setting or with devices can really impact predictability of disease, facilitate the diagnosis of disease, and help patients better understand and monitor their disease," he says.

In large companies such as Pfizer, there may be many skill sets available in-house, but in some cases even they may need to bring new hires on board who have different and new expertise.

Craig Lipset, head of clinical innovation, global product development, Pfizer, says his company has invested significantly in making sure that it has the right clinicians, technologists, and engineers to execute around its innovative platforms, such as Blue Sky, its AI cognitive computing-driven program in Parkinson's. He says bringing the right talent together creates more diverse teams in terms of new skills, roles, and thinking.

"Our digital and AI projects required us to create some new roles, including unique

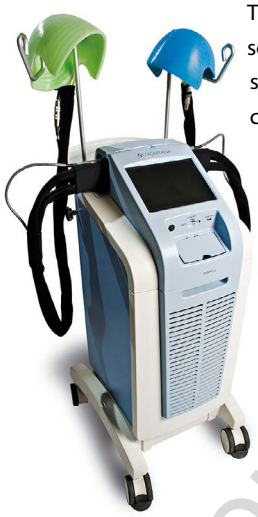
Cool Tech

New technologies are at the forefront of transformation in healthcare. This is just a small sample of cool, new technologies that are helping to improve patients' lives.

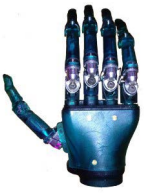
CYRCADIA HEALTH'S BIOSENSOR BRA PATCH MONITORS CELLULAR CHANGES

Cyrcadia Health, a cancer therapy startup, has developed a sensor-filled patch that can be inserted comfortably under a bra for daily wear. The biosensor company uses predictive analytics to accomplish early breast cancer detection through personalized wearable devices. The technology collects two to 12 hours of normal and abnormal cellular activity associated with breast cancer. Circadian rhythm-based temperature variances of cell cycles are measured to identify abnormalities at the earliest stages of abnormal cellular growth and proliferation.

THE DIGNICAP HELPS REDUCE HAIR LOSS DUE TO CHEMO



The DigniCap scalp cooling system reduces chemotherapy-induced hair loss in women with breast cancer, and replaces uncomfortable manual cold caps that are kept in special freezers. When a patient's scalp is hypothermically cooled, blood vessels in the localized scalp area constrict and limit the amount of chemotherapy agents delivered to scalp area. Cooling also slows the metabolic processes: a reduced scalp temperature causes normal cellular activity in the localized scalp area to slow dramatically. This means that fewer chemotherapy agents are absorbed by the hair cells and damage is reduced.



A HAND WHEN YOU CAN'T AFFORD ONE

GE engineer Lyman Connor has launched his own non-profit company, Handsmith, to make customized, affordable prosthetics through the process of 3D printing. Handsmith is able to make bionic prosthetics for children at a fraction of the cost.

YEAR-LONG GLUSENSE CGM SENSOR

GluSense is developing a miniature injectable continuous glucose sensor for under the skin to transmit continuous glucose values to an external wearable device for up to a full year, outlasting current CGM implants that last only a week.

MEDTRONIC'S CARDIAC-MAPPING VEST

Medtronic's cardiac-mapping vest is the first commercially released, noninvasive, cardiac electrical mapping system in the world, eliminating the invasive steps of inserting a catheter into the heart via an artery or vein. The system provides electroanatomic 3D maps of the heart via the 252-electrode sensor vest.

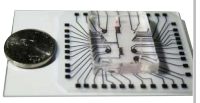
PATHWAY GENOMICS OFFERS EARLY DETECTION OF CANCER FROM BLOOD SAMPLE

Pathway Genomics offers digital healthcare and genetic testing and is developing a simple blood test to determine if early detection or prediction of certain cancers is possible. Its physician-ordered tests include assays for diet and weight loss, circulating tumor DNA (liquid biopsy), hereditary cancer, pharmacogenomics and carrier screening. The company's program with IBM Watson is a smartphone app, called OME, which merges cognitive computing and deep learning with precision medicine and genetics to enable Pathway Genomics to provide consumers with personalized wellness information.

ROTEX'S ULTRA-THIN ELECTRONIC TATTOOS MONITOR VITAL SIGNS

Rotex Inc. is developing credit card-sized ultra-thin electronic tattoos that can last up to a week on the body. ECG, respiration, temperature, hydration, movement, and other biometrics can be monitored in synchronization by one tattoo. E-tattoos will be used for fitness tracking and human-computer interface, but it will more likely be used by people who need to monitor their vitals for health reasons.

STANFORD DEVELOPS LAB-ON-CHIP DEVICES TO LOWER COSTS



Scientists at Stanford University have developed a new method of manufacturing lab-on-chip devices that cost only pennies to make, which can be used for research and point-of-care diagnostics, particularly in poorer places around the world.

By sending currents through the device, cells separate by type based on their polarizability, and costs are lowered considerably, but the viability of the chip is not. In about 20 minutes, an inkjet printer can lay a reusable electronic strip onto a polyester sheet using a conductive ink.

crossovers of engineers and clinicians," he says. "We are making sure we have places where engineers and clinicians can work side by side in collaborative ways. We have young, digitally savvy clinicians, as well as more senior clinicians who are very savvy around the drug development process. We have an interesting opportunity to bring that diversity together as we're looking at these new tools. I'm not sure that any one phenotype of an individual has all the right skills and competencies today to manage everything we want to achieve." PV

Transforming for the Future

To be successful in the future, the industry will need to find transformative solutions to address a number of market factors.

Disrupting the Status Quo

Experts agree that disruptions are needed to fuel the industry's goals regarding big data, commercialization, connected care, enterprisewide solutions, patient-centricity, and talent.

BIG DATA

MARCO ANELLI, M.D.
Head of Pharmacovigilance and Medical Affairs Advisory Services, ProductLife Group

If there is a common denominator with what has been changing across the pharmaceutical industry in the past few years, it's that there are the means to originate a lot of "untidy" data. This data can be gathered from social networks, from multiple websites, and from published articles on the web. And there are now a lot of devices that can record data thanks to the Internet of Things. However, for that data to become information and, ultimately, knowledge companies will need to adopt new means for processing it. Companies therefore need to adopt appropriate hardware and software tools, and make use of artificial intelligence. Because either you teach your system how to analyze data, how to recognize patterns, how to make sense of what is reported in the different social networks, or become overwhelmed by the sheer volume.

CHRIS CULLMANN
Senior VP, Engagement Strategy, Ogilvy CommonHealth Worldwide

The disruption that is most critically needed within our industry is to respond to market needs faster and with an awareness for market response: Access to information and the empowerment of the patient have greatly increased the "noise" in all the areas of medical practice. For healthcare manufacturers to find and maintain an authoritative position in the minds of healthcare professionals and patients, information needs to be served with the patient's needs first and foremost. To truly deliver on this idea (and it is often talked about as a mantra and rarely delivered) manufacturers, and brands need to make information in every category — clinical, access, support, research, and pricing — transparent. Too few patients understand the role their medicines and treatment play in their lives and the processes that are required to get them their care. Clarity and openness are going to be critical to finding a place of trust and relevance with our audiences.

WILL REESE
President, Cadient, a Cognizant Company
Chief Innovation Officer, Cognizant Life Sciences

One of the easiest ways to fuel disruption is to look at constraining a resource or amplifying a resource and imagining a future state based on that shift. Applied to commercial, if particular markets didn't have any physical presence, how would all the non-physical channels need to shift and what would the new model become? If you take the opposite view, physical channels are highly abundant, could you maximize or extend their physical presence in novel ways and how does that change the commercial presence? For patients there have to be better ways to start a therapy. Getting diagnosed today is a health literacy and financial literacy challenge. Disruption is to re-imagine start. For discovery and R&D, quite often knowledge, data, and information are still siloed, disparate, and often disconnected. Imagining a future where data and research is hyper-connected, real-time, and collaborative creates new models of discovery.

SCOTT WEISS
VP, Product Strategy, IDBS

The advances across the many sub-disciplines of molecular medicine over the past 20 years have brought us to the cusp of a radical new approach to the treatment of disease: one designed to tailor medicines for the individual, rather than treat heterogeneous patient populations. The technology is here today to monitor the discrete biochemical cascades that characterize a disease state, and to listen at a molecular level to an individual patient's biomolecular pulse. While the technology is quickly maturing in terms of scalability and cost- effectiveness, enormous challenges lie ahead before these promises become mainstream enough to provide benefit to the wider public and displace traditional medicine. We need to fundamentally rethink how we organize and manage, secure, share, derive insight, and take decisions from such large data sets with complex relationships. The big data challenge in pharma is not managing the quantities of zeros and ones we will soon be generating. The challenge will be connecting the dots to enable us to derive value from it.

Disrupting the Status Quo

COMMERCIALIZATION

CHRISTINE HURLEY
Chief Operating Officer, 4G Clinical

When I think about needed disruptions in R&D, I immediately focus on meaningful impacts to the speed at which we can commercialize a drug. We've automated so many manual processes over the last 20 years — we have more technology than we've ever had in clinical trials. So why haven't we been able to reduce development time? We aren't optimally using the technology. Our systems don't talk to each other. We are duplicating work. Vendors are not being challenged to problem solve, to put aside their competitiveness, and collaborate for the betterment of the industry. In essence, technology has evolved, but our processes have not — and in some cases our processes have become even more complex and convoluted. The process should drive the technology, not the other way around.

LANCE SCOTT
President and CEO, Zephyr Health

I believe that data and supporting technology solutions that give more stakeholders across commercial teams access to an integrated view of the entire data landscape are a leading "disruptive need" in pharma today. The commercial side of pharma — marketing, brand, sales teams — can no longer afford to work in silos, with different views of the market based on outdated insights regarding key customers and trends affecting change in the marketplace, such as formulary status, purchasing decision changes, or physician participation in IDNs or ACOs. We've been saying this for some time, but now we have the greatest opportunity to connect the myriad of data sources available with the right technology that bring those together for us in a single, transparent and refreshed vision of the market.

CONNECTED CARE

STEVE STEIN
Lead Research Specialist, 3M

Issues of cost are increasingly important in the pharmaceutical industry with developed nations seeking to control rising healthcare costs and developing nations seeking to ensure that their people have access to affordable medicines. In the field of respiratory medicines, we see two very different forms of disruption looming on the horizon. The first looming disruption is the entry of lower cost generic inhalers into the market. The regulations required to receive market authorization for new generic inhalers are extremely complex, and we are just now seeing the entrance of new generic inhalers, such as Sirdupla in the UK, that have the potential to impact market dynamics significantly. The development of connected digital inhalers is a very different approach to bringing down healthcare costs. There have been several studies recently showing that overall patient outcomes are significantly influenced by patient adherence to their prescribed therapy and that connected inhalers can greatly improve patient adherence. If a connected inhaler could reduce even a few expensive hospitalizations by helping patients adhere to their treatment better, there are significant potential cost savings to be realized. These two very different approaches to reducing healthcare costs have the ability to change the inhaler market dramatically.

ENTERPRISEWIDE SOLUTIONS

BRETT KLEGER
Chief Commercial Officer, DrugDev

The disruption required to improve the efficiencies for clinical trials is simply the adoption of known and proven technologies and bundles that have driven efficiencies in practically every other industry. In consumer and business life it is becoming the norm to have one provider offer bundled technologies to simplify every day processes. It makes tremendous economic and cultural sense to apply those same principles to clinical programs. Our customers are doing just that — adopting an enterprisewide, unified clinical solutions suite that operates on a common platform and gives study teams and sites the tools they need to manage clinical trials all in one place.

ELVIS PACELAT
VP of Compliance Solutions, Amplexor

The life-sciences industry cannot hope to achieve the agility and innovation seen in other markets as long as it is mired in system and process complexity and held back by a lack of information flow and process visibility, so disruption must start here: the

Disrupting the Status Quo

status quo must be challenged. Obviously, this is a highly regulated industry, and there is no getting around all of the necessary rigor and vigilance. So organizations need to find a way to work this to their advantage. As long as knowledge is locked in dedicated systems, used for a single purpose, this will limit its value and stifle the ability of teams to collaborate in new ways, to foster new thinking and deliver scientific and competitive breakthroughs. System integration; information usability; process simplification; reduced IT cost of ownership; operational efficiency; improved productivity through easier collaboration; and the ability to adapt in an ever-changing regulatory and business environment – all are vital components in driving real progress.

PAUL SHAWAH
VP, Commercial Cloud Strategy, Veeva Systems

There is a significant opportunity to make the traditional model for customer engagement easier and more efficient with new digital communications channels. Each life-sciences company engages with healthcare professionals digitally in many different ways, which — from a customer perspective — creates frustration and hinders access to important information they need to treat patients. Challenges in two particular areas, identity and consent management, are driving doctors to rely on third-party sources, such as Wikipedia and Google searches. The good news is that the industry is now coming together to address this challenge through a new standards group called Align Biopharma. Top life-sciences companies are defining common standards that are open and global to streamline how physicians get the information they need. Seven of the world's largest pharmaceutical companies have already joined Align Biopharma, including Allergan, AstraZeneca, Biogen, Eli Lilly & Co., GlaxoSmithKline, Novartis, and Pfizer.

PATIENT-CENTRICITY

MARK BOUCK
President and CEO, TrialCard

The pharmaceutical industry is undergoing a paradigm shift where value creation through helping patients achieve positive health outcomes is now the barometer of success. Simply garnering a large volume of script writing won't suffice in a changing landscape where all stakeholders from patients to healthcare professionals to payers are seeking real-world proof of a drug's positive impact. Specific to patients, expectations with regard to engagement and establishing a true healthcare relationship are also changing as a result of the world in which we live. Gone are the days when patients saw drug manufacturers as faceless, "in the background" entities.

TIM DAVIS
CEO, Exco InTouch

To achieve a truly patient-centric approach pharma will need to incorporate patient support as a fundamental requirement across all their programs. Within clinical research patient-support mechanisms will need to be defined much earlier in their planning stages to enable inclusion in ethics submissions, incorporating a content strategy that provides meaningful support and motivation alongside service design and user interfaces. I think we will see this evolve even further as well, seeking opportunities to truly integrate research into patient's everyday lives by reducing the need for site visits. This will be achieved by the inclusion of home monitoring through medical devices, sensors, and wearables that enable continuous data to be collected from patients. As an industry, we still need to work out the regulatory aspect but that will be a real driver, and a real innovation, for the industry as a whole.

TALENT

DEB SCHNELL
VP, Managing Director, Taylor Strategy Partners

No one will dispute that the healthcare market place is changing. The days when a sales rep with strong relationships could "close the script" and deliver increase in NRx, TRx, and market share are gone. The disruption that is so needed starts with the people/talent. Minor tweaks won't solve the problem because the market has seen dramatic shifts in the way business is conducted; 60% of docs are part of an IDN, 25% of physician interactions are digital, 90% of Medicare docs are compensated on outcomes, and the list goes on. The talent of the future requires strong B2B skills, agile selling, working with intermediaries, channel partners and customers. Legacy recruiting assessment and hiring strategies, even if refined, will yield legacy sales talent - not the talent of the future. It is time for an entirely new, disruptive approach; one that is based on facts, science, and data.

Clinical Trial Supply Southeast 2017

Organised by ARENA INTERNATIONAL EVENTS GROUP

FREE PLACES reserved for VP/Director/ C-Level executive of Pharma/Biotech/Medical Device companies.

Cary is part of the Southeast's Research Triangle Park, a growing and thriving community of over 80 biotech and life science companies. With such a booming community, **Clinical Trial Supply Southeast** gives local trial sponsors and vendors the opportunity to come together and discuss the latest trials and tribulations for the local industry.

Key 2017 Speakers:

- Leslie Holme, Supervisory Import Specialist, Pharmaceuticals – **U.S. Customs and Border Protection**
- Greg Hottell, Director, Supply Chain Group Lead – **GSK**
- Tim Holmes, Manager, Performance Operational Capabilities – **Biogen**
- Margaret Schubert, Sr. Investigational Product Specialist – **Cato Research**
- Mark Mann, Associate Director of clinical Outsourcing and Contracts – **Upsher-Smith**
- Lynne McKerlie, PhD, Lead Clinical Trial Materials Project Manager – **Grifols Inc.**
- Stephen Porter, CEO, President – **VDDI Pharmaceuticals**

Key 2017 topics:

- **Exploring** import/export methods to ensure clinical supplies get through border control
- **Analysing** approaches towards forecasting and impacts on supply chain efficiency
- **Insight** into effective vendor management for clinical trial supplies
- **Improving** clinical study start up and lifetime operation by enhancing clinical supply team communication with clinical operations team
- **Investigating** best practices for obtaining patients to ensure you meet patient recruitment goals and avoid loss in revenue
- **Overcoming** challenges in managing overseas trials – steps for success in China

Join your peers at this year's CTS Southeast conference to discuss the most pressing topics and explore opportunities in clinical supply, secure your place by quoting reference code: MK-ACAD

For more information on the event, please visit:

www.arena-international.com/ctssoutheast