ePharma

THE FUTURE OF DIGITAL HEALTH:
Technological Advancements That Will Impact The Pharmaceutical Industry

The pharmaceutical industry is acutely aware that the future of health and care, particularly in the United States, are trending toward a digital revolution. The importance of successfully executing a digital health strategy, as well as creating new financial models and partnerships, cannot be understated. Nevertheless, this revolution is not often witnessed in current practice. While incorporation of digital practices has been slow, the future will move quickly. However, instead of fearing the future, the digital health transformation should have pharmaceutical leaders enthusiastic about the possibilities of the very near future. There are clear opportunities on the horizon, and those pharma organizations and leaders who are prepared for the potential, can soon capitalize on them.

It is well documented that health care systems, health providers and patients are using connected devices personally and professionally in almost all aspects of their lives. In fact, the convenience of technological advancements has become more and more integrated into the everyday activities of humans all around the globe.

Almost every aspect of demand and supply in the health ecosystem has been disrupted by the Internet of Things (IoT). And soon, this will include the way pharmaceuticals are designed, tested, administered, monitored and regulated. Therefore, digital health is quickly becoming a primary focus of industry leaders in pharma, as well as the companies, agencies and individuals that overlap with the pharmaceutical ecosystem.

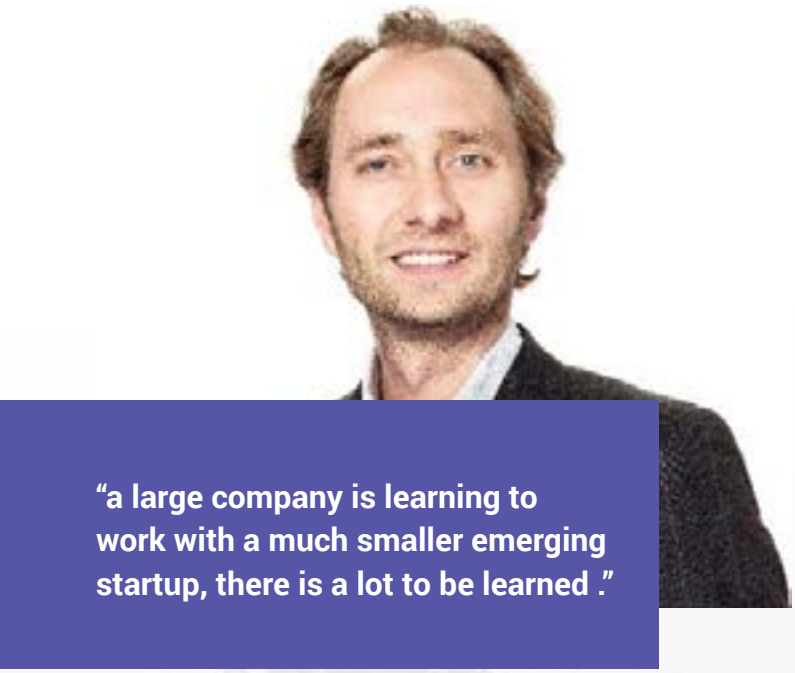
INCREASING THE VALUE PROPOSITION

Change and growth are the pillars of the pending digital revolution of the pharmaceutical industry, and industry leaders believe it is a key to success. In fact, as far back as 2012, 77% of pharmaceutical industry leaders claimed digital health will generate new business for them by 2020, and 94% said it would extend already existing value propositions . While these notions have proven to be correct thus far, the coming few years are posed to see exponential change with mergers and acquisitions (M&A) leading the way, while research and development (R&D) narrow their focus.

In pharma alone, there was a 94% increase in M&A deals between 2014 and 2015, with the major companies making deals for up to $160 billion **(Pfizer)** .1995 to 2015 proved that M&A was the future of pharma, with R&D taking a backseat. In

fact, 60 pharmaceutical companies condensed to 10 big pharma companies in just those two decades alone .

While R&D still has a very important role in the future of pharma, recent history has shown that purchasing, integrating and commercializing technologies from smaller companies can be more lucrative than owning the entire R&D process from start to finish. This is not without complication though, as **Unity Stoakes** from **Startup Health** asserts, as **"a large company is learning to work with a much smaller emerging startup, there is a lot to be learned ."**



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Investment trends and transparency in R&D have also entered the ecosystem in new ways due to digital advancements and data needs. For example, although the money being pumped into M&A has drastically increased, the number of transactions are decreasing – meaning less deals, but much bigger deals. With **Apple**, **Google**, **Qualcomm** and **IBM** entering the health ecosystem, the demand for data-driven results is motivating investment trends towards those who can produce real-world improvements in patient outcomes. This has, however, not necessarily changed behaviors of the smaller investors who remain risk averse when it comes to the health ecosystem. With so many unknowns, large number of competitors and regulatory hurdles, smaller investors still find the risks too great for early-stage investing.

Transparency has also become a must-have for those big investors - and the public - who want to better understand the clinical trial process, technological intellectual property and financial relationships with health providers. By better understanding those, the inefficiencies and ineffective components can be weeded out to decrease costs overall.

These changes have further pushed the need for innovative external partnerships and models. Digital analytics have introduced ways for data to be harnessed before, during and after drug development, as well as in commercialization and in the patient's home. Organizations can be combined to utilize digital tools for improvements in investment, research, development, dissemination, marketing and sales. Because of these opportunities, **EBD Group** saw a 33% increase in the number of pharma delegates attending their annual conference partnering sessions from 2010-2015 . Additionally, by targeting specific user groups along a drugs path, having real-

time validation by users and new payers entering the fray, entirely new "customers" can be created.

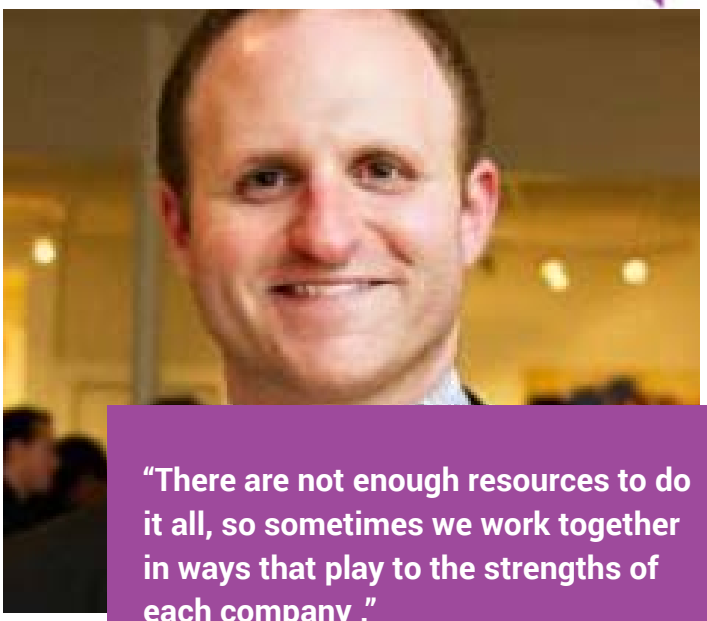
A NEW WAY OF DOING OLD THINGS

While payers will likely be the most important stakeholders in the pharma and technological industries, the payer of old is evolving, and so too must pharma's long-term strategies. Despite research indicating that almost everyone in pharmaceutical leadership believes in the digital health revolution, not everyone is preparing the same. But those commanding the field are targeting old players in new ways.

IBM Watson and **Wellpoint,** for example, have their cloud data being utilized by hospital systems and insurance agencies for reauthorizing medications and treatment plans, making pharma more accessible to patients. Walgreens is also allowing third-party apps to now scan bar codes for faster prescription refill.

Partnerships and shared data are also an integral part of interacting with consumers – from trial recruitment to testing to marketing. In some ways, these partnerships can be considered co-opetition, or cooperation in certain areas by those who would otherwise be competitors. For example, **Greg Cohen**, **UCB Pharma's** Manager of Social Media and Customer Influence contends that, **"There are not enough resources to do it all, so sometimes we work together in ways that play to the strengths of each company ."** UCB Pharma understands that connecting to customers takes old and new ways of using data and products for engagement.

FDA trails and gold standard randomized control trials are also being revisited thanks to digital health technologies. Digital tools have proven that subject



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recruitment for trial participation is much better using devices, and participation much better with observational data than conventional test data . Further, the introduction of real-time data analytics creates interactive trails, unlike passive trails of the past, leading to richer data. As Thompson Reuters found, the number of observation research studies tripled from 1990-2011 .

Moreover, the creation of biosimilars and other biologics has severed the traditional pathway for FDA approval. Over the last five years the European Union and the United States have generated all new rules for the gaining market approval that argues "fingerprint-like" biologics do not need to go through the rigorous process of the original drug . As many pharma patents expire in the coming years, these alternatives could mean billions of dollars in revenue shifts. They could also mean billions of dollars that are regulated like never before.

POLICY AND POLITICS

In the post-reform healthcare environment, pharmaceutical companies have a clear opportunity to play a greater role in delivering a better experience for patients, improving clinical outcomes, and reducing the total cost of care. The key is digital health technology. That said, the government is playing an ever-increasing role in the technology and pharma arenas. Not only in development and consumer engagement, but also in all aspects of payment.

The Patient Protection and Affordable Care Act (ACA) aimed at moving our health structure from a fee-for-service to a value-based system, which includes the outcomes of using pharmaceuticals. However, with Washington, DC facing a 2017 – and beyond - that looks very different from the last eight years, the ACA, health insurance access and payment reform could change drastically.

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There are also calls for transformation in the global pharma industry from around the world. For example, a 2016 United Nations panel issued a major report, "calling on world governments to negotiate a binding treaty 'de-linking' R&D costs from the final price of drugs in areas where market incentives have been insufficient, such as for new antibiotics or for tropical diseases ." The world's health organizations and some world leaders praised the initiative suggesting that advancements in technology will enable things to move forward cheaper and faster, while pharma groups criticized the report, contending that the recommendations would be "detrimental" to R&D .

Therefore, the greatest impact on pharma will be coming from the U.S. federal government – at all stages of the process from research grants to commercialization regulation to reimbursement challenges. Given that, and pressure mounting internationally for cheaper drugs, policies that promote and enable better, faster, cheaper trails will be necessary. As will policies like the Biologics Price Competition and Innovation Act (BPCI) of 2009 that promote shorter pathways for approval and promote competition .

The government will also have to grow its public-private partnerships, so investment dollars can drive

this kind of innovation. Those on Capitol Hill will also have to ensure that as technological advancements beget technological advancements, that regulation and red tape do not stand in the way.

One example of a partnership that has proven very useful is the joining of **Abbott** and the **Department of Defense** to develop a portable blood test that evaluates traumatic brain injuries (TBI), including concussions . With brain injuries taking a lead role in 2016 Congressional hearings, the $20 million deal was ahead of its time. And the output could be several years ahead of competitors – not to mention have a first mover advantage of already being integrated into the government health system.

Yet, as new players emerge in the pharma space and new payers begin to engage, the agencies that determine the day-to-day operations of the pharma industry also evolve. For instance, when thinking about the ways patient drug data can be mined, repackaged and shared, the Federal Communications Commission (FCC) could enter the picture. And, in cases of marketing, advertising and potential false claims by a pharma company, the Federal Trade Commission (FTC) becomes involved. Not to mention the role of Centers for Medicare & Medicaid Services (CMS) who manage issues such as off-market labeling.

With pharma companies spending twice as much on marketing as R&D, these new organizations regulating the space could have huge implications for revenue . With so many agencies inserting themselves into the pharma and technology spaces, regulatory interference will be inescapable. However, with the right health policy advisors, leaders in the industry can be ahead of the curve.

By working with knowledgeable stakeholders from the public and private sectors, as well as government, throughout the ecosystem, pharmaceutical industry leaders are poised to see their digital health dreams come true. Although the industry has been slow to adopt digitization and the IoT, ongoing changes by investors, consumers, technology and payers will mean there is no going back. And, like other industries that have had a technological revolution, those who are the most adaptable, will be the most successful. Therefore, 2017 is going to be a groundbreaking year for many in the pharmaceutical industry, and those with the right partnerships have the most to gain.

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