Trending 2017: Smart Technology

From electronic biomedical implants that dissolve within the body to ubiquitous smartphones, smart technology is improving everything from patient adherence to data collection.

The ability to capture health information in real time is changing the face of healthcare and clinical trials.

Take for example Novartis and Qualcomm's next-generation inhaler that enables patients to have access to their own data on the use of their inhaler in near real time. The small, disposable, and low-power module contained within the inhaler device can detect and report usage, the time that the inhaler is used, as well as additional relevant information for patients and physicians. The module then wirelessly transmits the data to the patients' smartphone and a Novartis COPD mobile application, which sends the data to the cloud, allowing patients and potentially their healthcare providers to monitor their COPD.

This is just one example of how smart technology and wearables have already been adopted in various ways across the industry and are showing enormous potential, particularly in the area of measuring patient adherence and outcomes.

"Smart technology and connected sensors provide healthcare providers with patient behavior data to offer real-time, information on drug usage and impact," says Jeremy Sohn, VP, global head of digital business development and licensing, Novartis.

"The proliferation of connected sensors is enabling pharma to improve how to measure clinical endpoints, and it's enabling us to measure these endpoints in a home setting, thereby reducing the burden on patients having to come into the clinic and giving us the ability to capture these endpoints in real-world settings," he says. "In many cases, we can now capture endpoints continuously, allowing us to understand better how these endpoints might vary over time, or from setting to setting."

Novartis is also collaborating with Proteus Digital Health to develop "smart" pills that use tiny sensors to alert patients when they fail to take a drug as prescribed. These pills also inform physicians about the medication habits of their patients. Physicians are often left guessing why a prescribed drug may not have resulted in the expected outcome, but this technology can help physicians better understand if medication adherence or non-adherence is correlated to their patient's most recent outcomes.

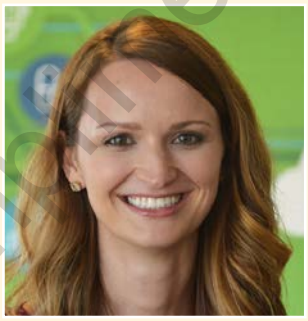
Another company working on smart pill technology is etectRx, which is developing medication adherence solutions for use in clinical research and healthcare. The company recently initiated a clinical trial using its ID-Cap System to better understand how pain medicine is used by patients. The ID-Cap System consists of an ingestible microsensor that is embedded in an oral dosage form that, when activated by stomach fluid, transmits digital messages to an external wearable reader to confirm ingestion.

"The near ubiquitous use of smartphones, the increasing prevalence of wearable sensors, and the development of ingestible microchip transmitters now give the pharmacy profession a powerful array of tools to finally improve medication adherence across all therapies," says Harry Travis, president and CEO, etectRx.

"Because of the increasing miniaturization of sensors and circuitry, we have reached an exciting inflexion point where we are seeing huge growth in inventive and innovative solutions packaged in very practical and affordable ways; much of this is targeted toward the growing health and wellness technology market," says Bill Byrom, senior director of product innovation at ICON. "This is an exciting opportunity for the pharmaceutical industry in two ways. First, in clinical trials we can collect richer data to better understand treatment effects and health status, we can enable more frequent measurement without significantly adding cost or burden, and we can better monitor patient safety and adherence between clinic visits. These all help to ensure trials have the best chance of success and enable accurate

It is time for pharma to fully acknowledge that we are at a crossing point of the analog/digital divide.

PAUL GILBERT
MedAvante



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JENNIFER PLUMER
Validic

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DR. ANDREAS KOESTER
Janssen Research & Development

go/no-go decision making. Second, we can leverage smart gadgets to develop engaging beyond-the-pill strategies that add value to patients and healthcare professionals and increase brand stickiness."

As companies continue to look for new and improved ways to better understand what patients are experiencing in trials, Aaron Fleishman, head of emerging markets and technologies, BBK Worldwide, believes that smart technologies offer great promise in terms of seeing how patients are doing through better, real-time, physiological data collection.

"Beyond that, smart technology can also help with patient adherence," he continues. "What's more, if access to better data through smart technology led to fewer study visits, participating in a study feels less overwhelming, which has the potential to eliminate a key barrier to participation too. I believe we need to get to a place where technology decisions are made on a franchise level rather than on a study-by-study basis. Once this infrastructure is established, it will be far more efficient and cost-effective for implementation in studies."

There are a number of areas where smart technology will open up a new set of additional opportunities as well as expand the reach of clinical researchers into areas that were until now not within their reach.

"At the epicenter of the smart technology shift is the ability to engage patients in their own real-world setting and provide information to both patients and investigators when they need it, in a manner they can easily interpret," says David Blackman, business innovation director of PPD. "In essence, we're on a path toward empowering patients as advocates in their own personalized care and potentially even becoming part of behavioral change programs for them."

Many of the early examples of digital health data in clinical trials analyzed the exact output: number of steps taken or number of hours slept.

"Digital health data become much more interesting when activity and sleep data are correlated with other data being collected, inside and outside of office visits," says Jennifer Plumer, director of market development of Validic. This correlation can provide context as to why activity, sleep, or heart rate levels may have fluctuated. Sponsors can then uncover important patterns such as a participant being less active on days that a medication dose is missed or a participant sleeping more after taking the medication, indicating drowsiness as a possible side effect."

The Smart Future

Patrick Glinski, senior VP, head of IC/Health, Idea Couture, says in drug discovery, the market need is clear.

"The drive to identify new treatments is about reducing the burden of disease, meaning we always know what value proposition is being delivered," he says. "The industry is consistently replicating this mindset in conversations about medical technology, even though this is fundamentally at odds with how effective product development should work. Rather than starting with the biological, technology development that gets adopted needs to start with human needs. Has someone living with a chronic disease ever said, 'I'll swallow this technology because I really need an adherence solution?' The answer, of course, is no. This is a classic, technology-first example of the challenge to articulate a clear value proposition for the people most impacted by what is being developed. Yet, this is what the industry is consistently doing — developing solutions that work for an organization's business model, but not for the experiences of those impacted most by technology's introduction."

"At Janssen, we're excited about the potential of our eMeds platform, which applies smartphone technology, 'smart' medication packages, scanners, and apps to improve operational efficiency, patient adherence, and facilitate adaptive trial design," says Andreas Koester, M.D., Ph.D., VP, research & development operations innovation, Janssen Research & Development. "Through the use of these mobile tools and technologies, we see great future benefit to patients, study centers, and clinical development programs. Today, as pharmaceutical companies continue to innovate clinical trial approaches, mobile technology offers an ideal platform. By providing interactive applications through the convenience of a smartphone or similar device, clinical trial participants are more actively enabled and empowered, which creates many positive implications for the individual and the study center."

Google has put forward the idea of "micro-moments," which occur "when people reflexively turn to a device — increasingly a smartphone — to act on a need to learn something, do something, discover something, watch something, or buy something."

"These micro-moments are where pharma companies have huge opportunities — if they can get it right," Jason Levy, senior VP, experience strategy and innovation, Saatchi & Saatchi Wellness, says. "Tracking is nice, but there's a place for brands to enter the space through connected devices and sensors where they can participate, intervene, and persuade consumers — and influence behavior. Connected devices can fracture routines into micro-moments, which might not necessarily be the ideal place for brand marketing messages, but could be a place to deliver additional information that, by the way, is brought to you/sponsored by a pharma brand."

For example, Apple has an integrated breathing app, and instead of popping up randomly, sensors could trigger the app to

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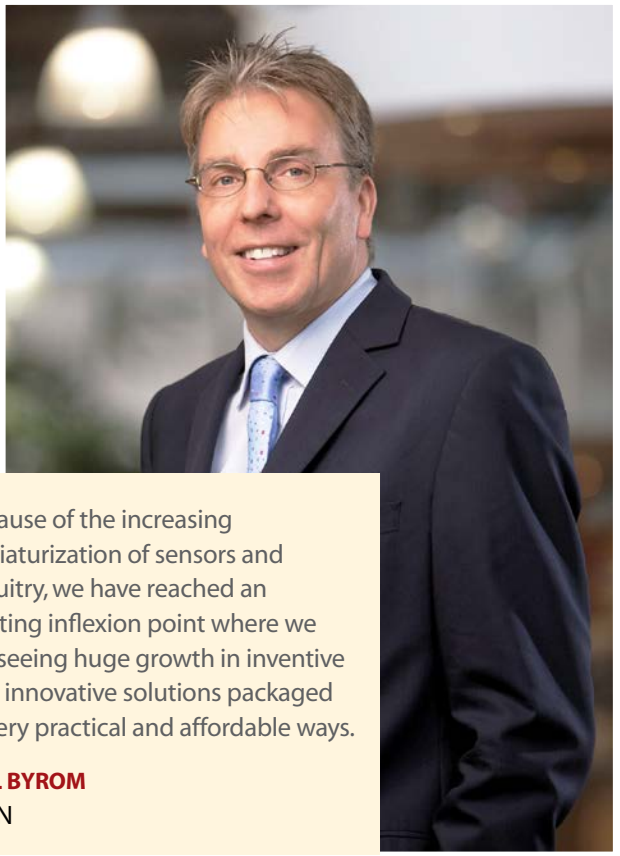

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HARRY TRAVIS
etectRx

run during moments of stress to remind users to breathe," Mr. Levy continues. "Ultimately, brands have an opportunity to be in the moment with the user via IoT and sensors."

Challenging the Clinical Status Quo

Targeting already has become so advanced that Internet of Things and sensor technology could rapidly transform the smart technology landscape for pharma.

"That said, there are two significant challenges that need to be addressed," Mr. Levy says. "First, few cutting-edge technologies are currently ubiquitous, although their increasing penetration and adoption will resolve that barrier over time. Second, and perhaps the greater challenge, is to ensure that smart technologies do no evil, give patients what they want, and provide utility while also protecting individuals' privacy."

According to Mr. Fleishman, one of the most predominant concerns he hears from his company's clients is about the data and whether or not the information is being captured accurately.

"The technology must be sophisticated enough to accurately capture all quantitative data necessary for clinical trial success," he says. "It's one thing to measure heart rate, exercise, calorie counts, etc., but if the care providers are seeing patients less, they could be losing the types of clinical observations necessary for best treatment and care. And participants in trials are most assuredly choosing a study as a viable treatment option for them. So while sensor technology is important, and will continue to play a bigger role as it develops, I believe it should be used to enhance not replace the human element of treatment."

As we look toward 2017, Paul Gilbert, co-founder and CEO, MedAvante, believes it is time to fully acknowledge that we are at a crossing point of the analog/digital divide.

"This transformation will permanently alter — for the better — how we develop drugs and assess their value," he says. "The FDA's two recent guidances formally encouraging the adoption of digital or eSource trials to replace paper, and risk-based monitoring to replace 100% source data verification, are catalyzing regulatory events and are game changers. And they are long overdue, with $4 billion a year spent on monitoring paper at sites. These FDA endorsements are properly upending the economics of trials and the existing industry power structure. The agency has paved the way for the industry to achieve less costly and more efficient drug development and set the stage for the use of smart technology in clinical trials. The result will be faster trials that detect better signal and are more frequently conclusive — pushing up historically low success rates. It will also mean a new class of technology companies will emerge to enable this turn to eSource."

Mr. Blackman agrees that one of the main challenges for our industry is the cultural change needed in the way we run clinical studies using new technologies.

"The use of digital health is still relatively new in our industry, and the reliance that comes with using technology as the method of endpoint collection to prove the effectiveness and safety of a new drug has not yet been widely adopted," he says. PV

The Blockchain

MARK STEVENS
Chief Commercial Officer, Publicis Health

No outcomes are revolutionary until the cost, quality, and outcomes of care are realized by the individual patient. Based on this premise, there are a number of ways blockchain can affect healthcare delivery in the United States. The technical definition of blockchain is that it is a record or ledger of digital events — one that is distributed or shared among different parties.

According to a recent study by Cutting Edge, patient recruitment accounts for about 32% of total trial costs. Vendor fees are an additional 25%. With blockchain's promise of portability and security, the patient can now hold the "key" to make his/her health records available, so that the industry can tackle this 57% cost by bringing in new cures faster and cheaper. Access by permission will revolutionize the time and costs of the future of clinical trials.

To some extent, we can envision the future of "organized customers" such as integrated delivery networks (IDNs) and accountable care organizations making the patient the owner of his/her health records. In the world of blockchain, the patient will hold the key for making referrals, emergency admissions, cross-geography treatments, etc. to be activated in a matter of minutes instead of days, weeks, and months.

If individual health records are made available anonymously by universal permission to key stakeholders in the blockchain, someday every one of us can have a "health score" (HS) like many of us have credit scores. This score will determine individual risk metrics and provide a huge encouragement to live healthy and thereby reduce the overall healthcare burden to employers and the government.

With this massive longitudinal data and with the individual patient holding the key, he or she can grant permission via blockchain to make his/her anonymous health information available for meta analyses. Treatment protocols will potentially be far better than they are today and this might even trigger more companion diagnostics (CDx) to increase the practice of precision medicine resulting in a massive increase in life expectancy.

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Getting Smart About Drug Development and Engagement

Advances in the sensing technologies that are embedded in digital health devices, including wearables, in-home clinical devices and sensors, have enabled a growing array of available data endpoints, making these devices an increasingly valuable tool in drug development.

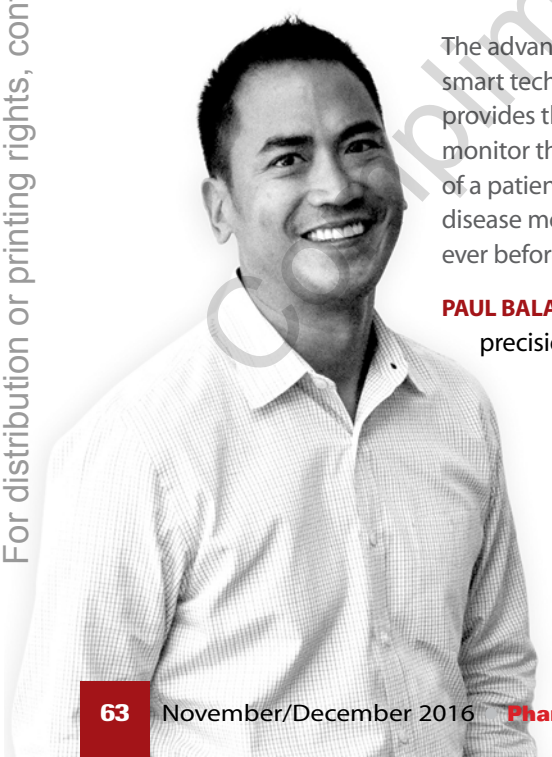
There is a tremendous amount of collaboration between healthcare and technology companies.

"Whether it's Apple and GSK partnering on research, Google and DexCom partnering on diabetes, or IBM and J&J partnering on healthcare delivery, the health and tech industries are already finding ways to work together to advance and improve patient care and I only see these types of collaborations/partnerships continuing to grow," Paul Balagot, chief experience officer, precisioneffect says.

Smart devices have become a central point of everyday life, whether paying bills, consuming media, or communication. Now this technology is playing a more significant role in medication delivery and may help improve adherence, says Eric Resnick, VP and chief technology officer, West Pharmaceutical Services.

"Medication non-adherence is a leading cause of poor clinical outcomes and increased healthcare costs," he says. "Motivation is often lacking when it comes to sticking with a chronic disease medication. Many patients may not see short-term benefits and find self-administering their injectable therapy to be a chore. With many chronic conditions on the rise, there is a need for pharmaceutical companies to tackle the adherence problem in a new way. Smart health-related devices and applications can engage patients in their treatment regimen to take a more active role in their self-care and allow them to communicate adherence to prescribed therapies with their provider."

For example, Mr. Resnick says electronically connected drug delivery devices can now track in real time when patients take their medication, while educating and engaging them to help increase adherence and medical literacy. Some programs also reward patients for compliance with their prescribed treatment regimen. Additionally, this information can also be transmitted to physicians to provide them with accurate data regarding their patients' adherence. This level of interactivity and engagement — together with user-friendly drug delivery systems — creates a powerful next-generation digital health ecosystem that can help tackle the medication adherence challenge.



The advancement of smart technology gadgets provides the ability to monitor the progression of a patient's health and disease more closely than ever before.

PAUL BALAGOT
precisioneffect

Earlier intervention/prevention is one of the key opportunities smart technology has opened up for our industry, Mr. Balagot says.

"The advancement of smart technology gadgets provides the ability to monitor the progression of a patient's health and disease more closely than ever before," he says. When it comes to issues around health and disease, we often find ourselves wishing we were able to catch something sooner. As smart technology continues to advance and gets further integrated into our everyday lives, this will become more and more of a reality.

Improving Adherence

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ERIC RESNICK
West Pharmaceutical Services

Jennifer Plumer, director of market development, Validic, says in trials that rely on patients to take drugs according to a set schedule at home, poor adherence on the part of participants can greatly impact the results. In fact, research from the New England Journal of Medicine shows that only 34% of trial participants take medications as prescribed.

"The good and exciting news is digital health technologies are changing this, and drug developers see the benefits," Ms. Plumer says.

According to survey results Validic published in September 2016, medication adherence was flagged by pharma and CROs as the most important outcome and data point for drug developers by over two-thirds of respondents; while 100% of respondents concluded digital health technology improves medication adherence.

"With adherence to dosing and intervals being key in demonstrating efficacy, sponsors can now have more visibility into a drug's true outcome," Ms. Plumer says. "These new digital health tools are enabling sponsors to collect real-time adherence data to track not just that a participant took a medication, but also the time at which it was taken and the dose taken. This data can even be used to uncover patterns in medication-taking behaviors and to remove non-adherent participants from a trial. By knowing which participants did not take their medication or adhere to the dosing interval, sponsors can choose to intervene and encourage positive medication-taking behaviors."

Real-time visibility into adherence also allows sponsors to design data-driven, adaptive trials. Armed with this data, sponsors can feel confident making adjustments to protocols based on actual indicators, while eliminating outliers that are due to poor adherence.

While sensor technology offers the value of collecting continuous patient data in real time, it's also important to select the right "fit for purpose sensor."

"Digital sensors can collect biometric data in so many different ways," says David Blackman, business innovation director of PPD. "While it's important to identify whether your goal of using a sensor is for medication adherence, tracking a patient's activity and sleep level, or something that is more critical to a patient's quality of life — such as blood glucometers or blood pressure cuffs — in the end, someone has to wear this device so the aesthetics, simplicity of setup, lifestyle compatibility and the value to a patient should not be overlooked." PV