

Pharma's Future in Virtual Health

With virtual health transforming the entire healthcare landscape, pharma is leveraging digital health tools to improve its processes.

As healthcare is swept up in the extensive development of health management apps, telemedicine platforms, AI diagnosis, and the use of video, mobile apps, text messaging, sensors and social media, the pharmaceutical industry is also getting in the game. Over the past several years, pharma companies have been partnering with tech and data companies to discover ways to best use virtual health and how it can improve processes all across the business continuum. On the pharma level, virtual health tools will enable the industry to have broader engagement with patients and physicians along multiple touchpoints. From digital tools to help solve

problems associated with clinical trials to enhancing R&D, the life-sciences industry is investing in virtual health tools, such as artificial intelligence, machine learning, virtual reality, and augmented reality.

Our experts agree that patient services and clinical trials are the first places where virtual health and digital technology are gaining traction in the industry, but the real exciting news is what lies ahead in a virtual future. They discuss these developments, as well as what they see coming in the next five to 10 years.

LEO Pharma is one company that has been innovating in the virtual space for several years, having established an innovation lab just

for that purpose in 2015 with hubs in Copenhagen, San Francisco, Tel Aviv, and Shanghai.

LEO Innovation Lab's focus on digital health has included the launch of a wide range of digital solutions targeting patients and healthcare practitioners. The Lab's developments include the ability to diagnose skin conditions through AI and augment the decision making of doctors. "There are three things that we're working on; the hybrid setting, the fully virtual setting, and the pharma setting," says John Zibert, Ph.D., chief medical officer at LEO Innovation Lab.

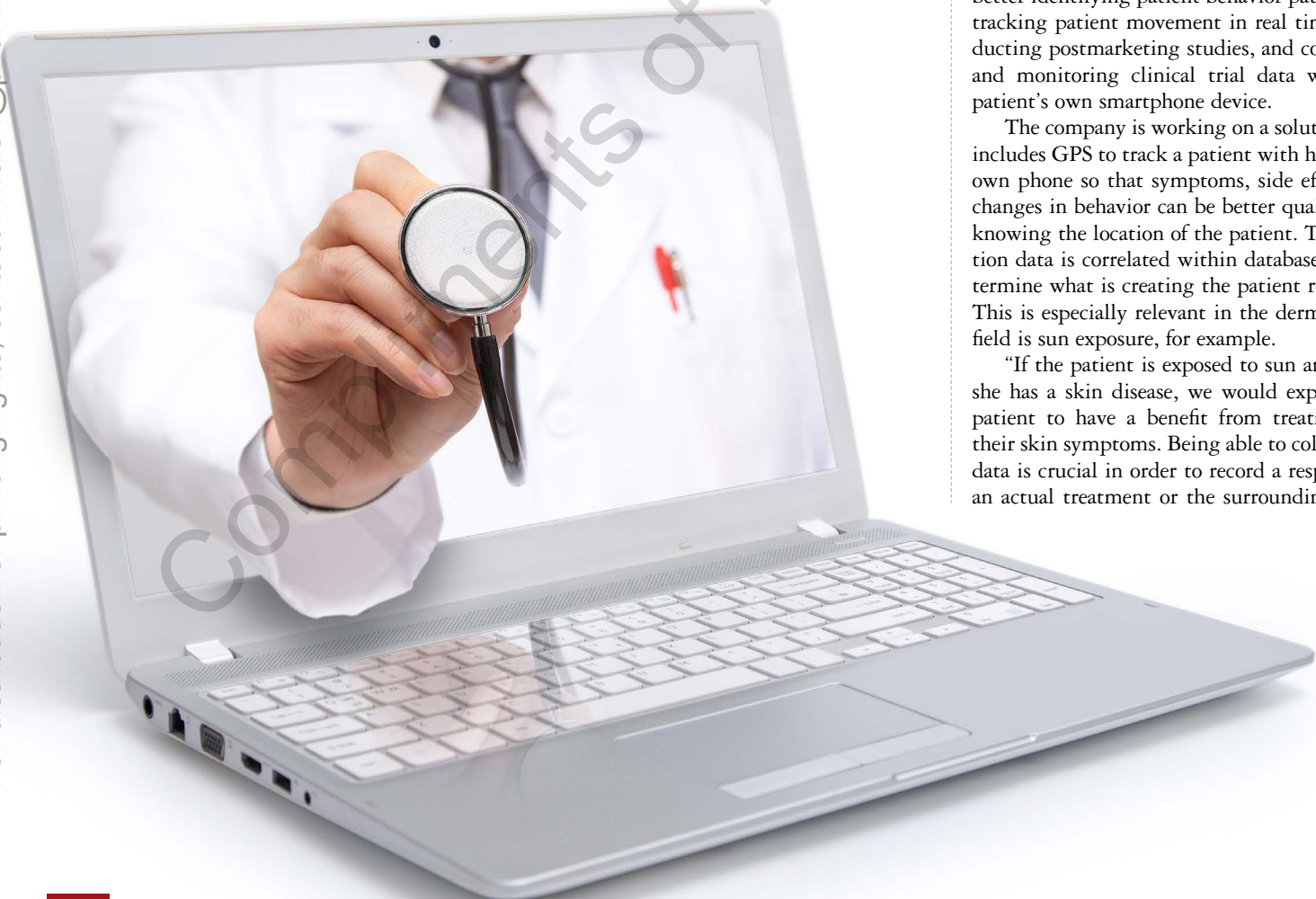
Interestingly, many employees at the Leo labs are nontraditional pharma professionals, such as data scientists and computer vision engineers, Dr. Zibert says.

"In our innovation lab, 80% of the staff are from other industries and have no experience in pharma," he says. "This is relevant because they do have experience in user-centric solutions and come with the skills to figure out what's in it for the patient. These are the people who we are learning from."

It is the same with many of the start-up companies LEO works with; they are not in the field of healthcare, but in the field of consumer-focused solutions. LEO is collaborating with these companies to develop methods for better identifying patient behavior patterns by tracking patient movement in real time, conducting postmarketing studies, and collecting and monitoring clinical trial data with the patient's own smartphone device.

The company is working on a solution that includes GPS to track a patient with his or her own phone so that symptoms, side effects, or changes in behavior can be better qualified by knowing the location of the patient. The location data is correlated within databases to determine what is creating the patient response. This is especially relevant in the dermatology field is sun exposure, for example.

"If the patient is exposed to sun and he or she has a skin disease, we would expect that patient to have a benefit from treatment of their skin symptoms. Being able to collect this data is crucial in order to record a response to an actual treatment or the surroundings they



are in which we're not able to in traditional clinical studies," Dr. Zibert says.

With correlated data, it could be determined if the patient is having an effect of a treatment in a clinical trial or the effect is caused by environmental factors, by tracking the GPS location, such as exposure to high levels of UV or even high degrees of humidity.

"With this information, we could determine if a reaction was a symptom of our vehicle, or if it was a symptom of the patient's behavior," Dr. Zibert says. "This type of data is the future. We are now working to understand what the effects of patient behavior are with respect to effectiveness of treatments and moving into the area of personalized medicine."

"This is where it gets interesting," says Ed Ikeguchi, M.D., chief medical officer at Ai-Cure. "Now that the industry has begun using technology to engage patients, what else can pharma do with it?"

Dr. Ikeguchi believes there are opportunities in diagnostics, therapeutics, clinical trials, and more. Technology brings a level of real-time, reliable data not previously available.

"Pharma companies are really interested to see how a drug is going to perform both in efficacy and safety in the real world, and with this technology they can accurately ascertain this information," he says. "Without adoption of technology, companies will be forced to continue to rely on paper diaries that are rife with various subjective measures, in essence leaving the determination of how a drug is going to perform in the hands of patients in the real world. The exciting exploratory work is happening with sensors to gather real-world evidence and develop new biomarkers."

Hannah Bayer, Ph.D., chief scientific officer at Datacubed Health, predicts exciting technology advances will enable better insights into disease processes to inform treatment.

"I've seen organizations become much more interested in providing apps for messaging and ancillary services such as transportation and reimbursement — essentially tapping into the kinds of apps that patients already use for similar kinds of services in other aspects of their lives," she says. "Virtual visits are rapidly becoming more common in study design as well."

At LEO, there are visionary plans to increase the use of virtual health tech in clinical studies to the point of enabling physicians and investigators to handle a huge patient base. Dr. Zibert says LEO has been experimenting with different ways to make these types of large studies a reality, particularly in the dermatological space.

"Our line of thinking is to move toward a complete guideless clinical trial and empower the patient 100%," Dr. Zibert says.

He suggests that medication can be



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DR. HANNAH BAYER
Datacubed Health

shipped to each participant by using a similar infrastructure to Amazon shipping, and blood sampling can be done at home or a nearby facility, making the process much more patient-focused. If a participant wants to speak with a doctor, study coordinator, or the sponsor, this can be done through a mobile app. This way, one doctor can be responsible for up to 200 to 400 patients.

"Right now we are planning to do a virtual clinical study that will have one investigator who is responsible for 2,400 participants," he says. "It's being reviewed by the National Ethics Committee in Denmark right now. This is a paradigm shift and this is where we want to go. We want to ensure that everything is done in such an engaging way that patients feel that the trial is personally designed for them."

In the mental health space, another technology advancement, virtual reality (VR), has proven its effectiveness in helping treat patients living with mental health conditions. According to Georgia Mitsi, Ph.D., senior director, Frontier Business Office Sumitomo Dainippon Pharma, parent company of Sunovion Pharmaceuticals, "Scientific evidence has already indicated that VR has therapeutic benefits in many conditions such as depression, anxiety, PTSD, pain management, etc. It has tremendous power to be engaging, empowering, and therapeutic. The portability and accessibility of VR in combination with the af-



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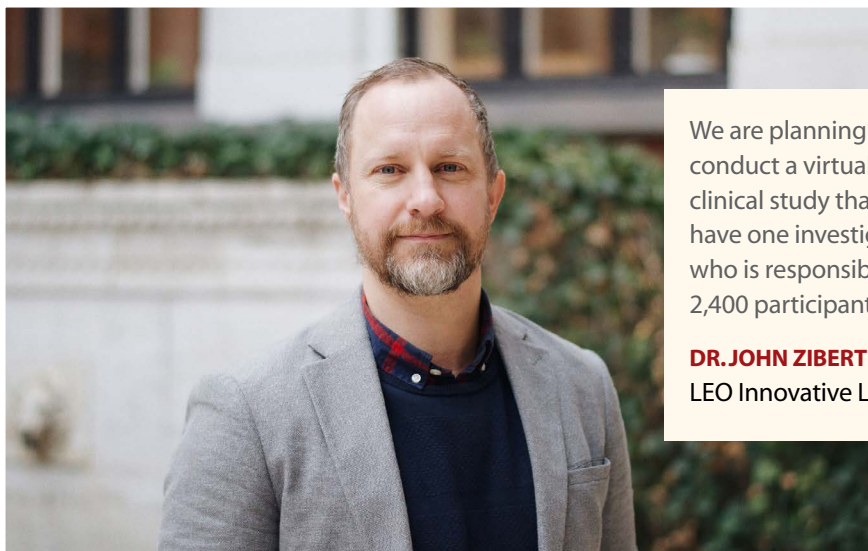
DR. GEORGIA MITSI
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fordability of these systems and the ease of use in a home environment, will enable adoption across a wide range of patient populations."

For example, with the familiarity of VR systems especially in younger populations, there is tremendous potential for VR to help support a proactive approach to address mental health issues and could be considered as a powerful tool to integrate into approaches used by schools and other youth organizations.

A new opportunity for pharma lies in providing connected patches and wearables as part of a patient's overall therapy. Biometric, real-time remote data, and digital therapeutics can provide critical feedback as part of the overall therapy, says Kent Dicks, CEO, at Life365, a digital health platform provider.

The critical data that is collected can be transmitted and stored in the clinical backend system and run through AI systems to analyze user patterns and change the function of the wearable or patch based on a user's own data in a continuous feedback loop that can improve the therapy and patient experience.



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DR. JOHN ZIBERT
LEO Innovative Lab

“By adding the pharmacist into this equation, you have a cost-effective solution to help drive maximum adherence, someone who sees the patients much more frequently than any other healthcare team member, a way to lower ER visits and hospital stays and thus lower overall costs,” Mr. Dicks says.

Mr. Dicks believes the product and pharma companies are becoming data companies. The

future lies in disposable wearables that are located around the body, using “lite” sensor data designed to detect a patient’s everyday patterns, driven through artificial intelligence, to personalize a patient’s engagement in their own therapy.

This personalized user data would be at a lower cost and provide critical data to analytic and AI systems that allow for a greater

population of patients to be monitored in a cost-effective manner.

“Many times companies develop state-of-the-art-sensors that have great accuracy, but come with increased cost,” Mr. Dicks says. “I believe there is an opportunity to look at data points and trends — not reported to the patient or provider — generated through analytics and AI systems to look for normal trends to make sure the patient is doing okay.” In a given situation, if more accurate data is required, then FDA-regulated and approved devices can be used to collect the data and report it to the clinical backend system in near real-time for the clinician to review and take the appropriate action.

Another future game changer is the transition of rapid diagnostic tests moving away from the point of care to the pharmacy in the retail drug chains. Rapid diagnostic tests are being produced smaller in size with more tests per strip making them much more cost-effective, which allows them to be available to consumers on the shelf at the retail drug chain and used for at-home patient testing, Mr. Dicks predicts. At-home tests can be integrated with RFID or near-field technology working in conjunction with a healthcare wearable, sending the data directly to the clinical backend.

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Once patients get used to using mobile devices to participate in clinical trials, Dr. Ikeguchi expects they will want to extend that type of support throughout the rest of their healthcare journey. He has witnessed this happening already and says there are benefits for both patients and pharma in this practice.

Dr. Ikeguchi says “medical assistants” will become the way of the future; they will be used to collect pertinent patient data but also lead and modify patient behavior change. “We’ve had many patients over different clinical studies at the end of the study who hoped that they could hold on to the technology, so we know they are interested in these solutions,” he says.

The medical assistants allow an opportunity for pharma to collect measures at the many patient interactions. For example, pharma can ask a simple set of questions around how the patient is feeling or what his or her mood is at time of each dosing without seeming intrusive. This leads to more objective measures around how that patient is performing from day to day, over time.

“Patients would be able to leverage the technology as an assisted device to generate reminders or help them give feedback to the physician on how well they’re doing,” Dr. Ikeguchi says. “This also gets into an interesting area

around what else the technology can actually begin to measure in terms of not just patient behavior but also in actual real digital biomarkers, which is pretty cutting edge.”

Five or 10 years ago, the clinic and the pharmaceutical company would never know how accurate patient-reported data was. Through technology, it would be possible to detect dose by dose when an ingestion occurs, whether it was on time or not, and then data are fed back to the clinic. When there’s a problem, the nurse can reach out to the patient and actually say, “Look we noticed that you haven’t taken your medicines for the last day or two.” This is the perfect time to ask if the patient is experiencing a problem or if he or she just forgot, or the medication pill bottle was lost, for example.

“This allows companies to enact intervening behavioral changes, something that wasn’t possible five years ago, and the impact this can have is pretty dramatic,” Dr. Ikeguchi says.

All of these changes and more are on the horizon, and have been established in other parts of the world. For example, Dr. Zibert



The real exciting exploratory work in virtual health is the development of sensors for gathering real-world evidence and developing new biomarkers.

DR. ED IKEGUCHI
AiCure

has been carefully following the evolution of China’s Ping An Good Doctor, a one-stop healthcare ecosystem platform that uses unstaffed AI clinics. The system includes a smart medicine cabinet where patients can get their medication after receiving a diagnosis.

The healthcare and medical mobile app Good Doctor backed by Ping An Insurance Group, which was launched in 2015, provides free diagnosis, treatment, and online appointment booking. It also enables users to communicate with healthcare professionals through text, photos, and video.

“The magnitude of what is already happening is so much bigger in the Eastern world

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than in the Western world,” Dr. Zibert says. “Suddenly one doctor can see many more patients because AI is augmenting the doctor to make faster decisions.”

Ping An is seeing 200 million patients per year. In comparison, the largest hospital in the Western world is the Texas Medical Center in Houston, which sees 10.5 million patients per year. Ping An is proof that the transformation is happening around the world faster than in the United States, Dr. Zibert says.

“In the next five years we will see a paradigm shift in the way that healthcare is being provided,” he says. “I think it may happen even faster.”

The Tipping Point

The industry has reached a point where there is a consensus about providing value for patients through tools that help them become more involved and empowered. Research has shown, and recent market trends have reinforced, that such technologies that respond to unmet needs could play a strong role in the new collaborative care model. By leveraging these technologies, not only would patients become more satisfied with and in control of their care, but also they would realize an improvement in their health.

“We are at a tipping point; pharma should embrace this new patient-empowered technology model wholeheartedly and offer these services and solutions as a value-add along with treatment options,” Dr. Mitsi says.

At LEO Innovative Lab, while it took a few tries, the teams hit on two apps that resonate with patients.

“We started by focusing on mapping out the patient journey and identifying the gaps; it took several different attempts to succeed,” Mr. Zibert says.

The digital solution, the Imagine app for skin disease tracking, initially engaged quite a few patients, but utility fell off. Several iterations later, the app became a success.

“We apply machine learning and AI technologies where we can support the patient in obtaining high-quality images of their skin disease, and track progression over time. Patients can then at the next visit at the doctor’s office show the progression over time to support the doctor in making a more firm diagnosis, which allows the doctor to determine an even better treatment plan.”

According to Mr. Dicks, it is difficult to hit on a technology that fits all consumers, and in his case, he believes just because the

company can build something, doesn’t mean that it should. “If we don’t take into consideration how users will engage in taking their drugs or stick to their therapy, then we are going to lose the battle in driving maximum adherence and benefit in the long run,” he says.

Even as a digital health thought leader for the past 13 years, and with many patents and inventions under his belt in digital health, Mr. Dicks doesn’t use an app to track his medication.

“I use a Saturday to Sunday pill case and refill it every two weeks,” he says. “I take my pills in the morning and in the evening and I am not willing to use an app to record that I took the pills, so why would we expect that seniors might? I use an Amazon IoT button on my kitchen countertop, which I press when I take my pills in the morning and evening. It’s simple and it engages me in the way I live. I don’t have to adapt to technology or change how I live. The bottom line is that we have to design technology and solutions the way that people really live, not because it is the cheapest way to collect data.”

According to Dr. Mitsi, companies that are building solutions and those that are looking for the right ones to apply need to determine the intended use of the solution or identify the problem they are hoping to solve with a virtual health application. With regard to developing the right virtual health solution for the right application, this is driven by the company and its priorities.

“Companies that are building these solutions as part of their business strategy, which is combined with their core expertise, will best define the solution and its intended use,” Dr. Mitsi says. “From the user’s perspective, the same principle applies. Some users — for example pharma companies, hospitals, payers, individuals, etc. — may be simply looking for an engaging and empowering solution.”

The future lies in wearable technology with sensors designed to detect patient’s everyday patterns, as opposed to high-tech, ultra-accurate sensors that are developed for medical data.

KENT DICKS
Life365



Virtual Health and Patient Services

Creating a better experience for the patient should be a well-coordinated effort among all of the stakeholders involved, including pharma companies, payers, healthcare providers, patients, and their caregivers.

“This may seem like a challenging balancing act but as patients remain our true north star, the industry has a responsibility to determine how to best leverage these technologies, sometimes within new collaborative approaches,” Dr. Mitsi says. “There are already many ongoing efforts from pharma companies to improve the patient experience.”

Electronic diaries are enhancing the way the industry collects, monitors, and tracks patient behavior and are a definite improvement over the old paper diaries patients would fill out — sometimes retrospectively so there was a large margin of error.

“In the past, there was the ‘parking lot syndrome’ where patients would fill out a week’s worth of questionnaires all at once, possibly fabricating much of it,” Dr. Ikeguchi says. “Now, the electronic diary device is built to maintain an audit trail and provides a timestamp when each of those diary items are completed. Likewise, the technology can be used to timestamp when a patient takes medication, which is helpful in determining adherence.”

Providing easy-to-use and accessible mobile tools that help patients keep track of their many medication interactions can give patients a sense of empowerment.

By designing those tools based on the best behavioral science research, we can also make it easier for patients to stay motivated and meet adherence goals over the course of a study or as advised by a clinician, Dr. Bayer says.

Many companies are now moving quickly from just selling products to now selling services based on critical data coming from patients taking their drug or pill.

“Pharmaceutical companies should now consider themselves data companies, because of all the data coming from taking their drugs combined with the analytic and AI systems being used to better target drugs and therapies to patients,” Mr. Dicks says. “The patient has to be connected in some fashion to provide critical feedback.”

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Virtual Health in Clinical Trials

Experts say the next logical place in the life-sciences industry to employ virtual health is within the clinical trial space.

“Clinical trials are the obvious first place to begin, but there’s also real interest to see where companies can take technology into commercialization to determine how a medication does in the real world after the clinical setting is finished or the regulatory process has been completed,” Mr. Ikeguchi says. “There is a lot of promise for virtual technologies, such as wearables, in the clinical trial setting. I can imagine pharma companies are very interested to see how tools, such as the iWatch, which is already pretty widely accepted by the general public, could help them to essentially see how their drugs are tracking.”

“Virtual technologies, such as telemedicine options, could be incorporated relatively easily into clinical trial design and would allow for a more patient- and caregiver-friendly approach, especially for patients whose conditions may limit their ability to travel to sites,” Dr. Mitsi says.

Yet, Dr. Bayer believes the healthcare and pharmaceutical industries have a ways to go in fully taking advantage of these advances, and that this is a missed opportunity to improve the effectiveness of care and the recruitment, retention, and engagement of patients in clinical trials and still lower costs.

“Virtual technologies offer a wide range of possibilities for improving the experience of patients participating in clinical trials,” she says. “Virtual clinic visits reduce time and travel burdens, making participation far more convenient.”


Mobile applications make it possible to deliver personalized messaging, validate questionnaires, and share educational material in an engaging package. Messaging provides an easily accessible way to facilitate communication between patients and clinicians. Sensors provide a new method for easily gathering the type of objective real-world evidence needed to support the development of new and more reliable biomarkers without requiring additional input from participants. (For example, deploying an in-bed sensor to track sleep, eases the burden of data collection for patients.)

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“Practically speaking, ensuring that new applications provide useful solutions requires that we clearly define and measure the right endpoints. Then we can test these applications in the field and objectively measure those outcomes to determine effectiveness of these solutions. However, in the long run, if we are successful, we will see real changes in the rates of patient retention in clinical studies, and even more critically for sponsors, we will see drugs come to market sooner,” Dr. Bayer says.

According to Dr. Zibert, this paradigm shift is already happening. “We’re simply conducting clinical studies faster with much lower drop-out rates, and patients are much more engaged,” he says. “They feel that they are contributing to something, so they stay engaged with studies and that is the key.”

The real test, of course, is whether or not patients in the two-, four-, or six-week interim period are actually doing the right thing in terms of taking their medications, filling out their diaries, or following the protocol accurately to get accurate information. This is where technology can come into play and potentially help because the company is able to use the technology to maintain contact with that patient on a daily basis if not more.

“We can change patient behavior so that ultimately patients don’t drop out of the study or they maintain their follow-up visits on time or they keep their drugs, their medications, or injections on track,” Dr. Zibert says. “These are the types engagements that are I think pretty groundbreaking in terms of how technology can help pharma.” 

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