Advancing Drug Development with Digital Health: 4 Key Ways to Integrate Patient-Generated Data into Trials
Digital health is not only changing the way patient data is collected in healthcare, but it is also disrupting the way the pharmaceutical industry gathers data from clinical trial participants. By arming participants with wearable and FDA Class II medical devices, sensors and mobile applications, pharmaceutical companies can remotely collect activity data, along with key biometrics. This stands to significantly restructure the drug development process, allowing companies to bring a drug to market more efficiently and cost-effectively while also improving the clinical trial participants’ experience by decreasing the number of in-person visits and reducing the need for manual tracking of data.

Some companies have already begun the transition, while others are unsure how to start implementing a digital health strategy. In the 2016 Digital Health Trends webinar hosted by MobiHealthNews, Ryan Beckland, CEO and co-founder at Validic, issued a challenge to attendees: “Start small and scale. Identify an opportunity, a program, and partners—and implement. Work with your team, industry experts, and strategic and technology partners to launch an initiative this year to future-proof your business and help advance value-based care. If you don’t begin now, you run the risk of being left behind.”

Pharmaceutical companies looking to implement a digital health strategy can leverage patient-generated data from increasingly ubiquitous devices and apply it to these four areas:

1. **Subject recruitment**

Pharmaceutical companies face three significant, interrelated challenges in recruiting participants for clinical trials—time, money and ROI. Recruitment and enrollment consume about one-third of the time allocated to the average clinical trial, and most trials must substantially extend their timelines because of difficulties finding enough patients. That challenge is neither rare nor trivial: 90 percent of clinical trials do not enroll the target number of patients within the specified time\(^1\) and enrollment times typically take twice as long as projected.\(^2\) That drives up drug development...

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\(^1\) Source reference for enrollment rate

\(^2\) Source reference for enrollment time
costs—each extra day can cost a company $37,000 in operational costs and $1.1 million in lost revenue, according to a Tufts study.³

“In the past, recruitment has been difficult, with companies relying on posters, online advertisements and paper flyers in physicians’ offices,” said Drew Schiller, co-founder and chief technology officer of Validic. Using these traditional methods, 27 percent of U.S. clinical investigators fail to enroll any subjects and 75 percent do not enroll the target number.¹

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KARA DENNIS, MANAGING DIRECTOR, MOBILE HEALTH, MEDIDATA SOLUTIONS

Digital health devices offer new options that may turn these discouraging numbers around. In 2016, Biogen partnered with PatientsLikeMe to conduct a study to investigate whether patients with multiple sclerosis found it useful to track their activity using FitBits. Within 24 hours of launching the study, the companies had enrolled 248 patients, and 77% of them completed the study and follow-up survey, said Jane Rhodes, Ph.D., senior director of new initiatives, Innovation Hub at Biogen. “The process was remarkably seamless and showed us there was a significant population of patients who were willing to self-quantify and share their mobility data,” she said.

Others have found digital health devices useful for recruiting a large number of people who are willing to participate in future trials and exploratory studies to help identify new areas of research. A team at the Icahn School of Medicine at Mount Sinai in New York, for example, used Apple’s ResearchKit framework to develop their free Asthma Health app. The app enables individuals with asthma to participate in a large-scale medical research study entirely through their iPhones. Fifty thousand people downloaded the app and the study enrolled more than 8,600 participants within six months without any direct, in-person contact with researchers.⁴ The app also substantially extended the study’s geographic reach; only 13 percent of those who enrolled lived near the study site in New York. In trials that require patients to go to the test site, virtually all patients come from the local area, so ensuring geographic diversity requires more sites, investigators and money.

“We’re working with a number of sponsors who are excited to recruit patients using ResearchKit. These are patients who otherwise might not agree to participate in trials because of the burden that can be placed on participants. Typically, patients have to go to trial sites frequently, and these sites can be far from their homes. The tests to measure patients’ response to therapy, disease progression and health status can be invasive. Mobile health technologies – including wearables, sensors and apps – can help reduce the number of visits to sites and make the trial experience easier and more comfortable for patients,” said Kara Dennis, managing director of mobile health at Medidata Solutions.
Obtaining timely, accurate data from participants has been an ongoing challenge in clinical trials. Even in highly incentivized clinical trials, researchers struggle with getting participants to travel to clinical sites for testing and to report accurate data manually. As timing and accuracy of data are key components to the efficiency, speed, and therefore overall costs of operating a clinical trial, consumer wearables offer an unparalleled opportunity to remedy these issues.

**Constant data stream**

Wearable devices enable consumers to passively track their health data 24/7, including when they are sleeping, which ensures the accuracy and timeliness of the information. And with growing consumer adoption and the level of engagement wearable devices deliver, they are the focal point of a paradigm shift in clinical trials.

Wearable health devices could be used in almost any clinical trial to passively grab more accurate data from patients at any time of day while they are doing any type of activity. This could not only benefit researchers during every phase of the clinical trial, but also the participants, as it would allow for passive trial adherence and more consistent, higher-resolution data for researchers. As well, this data can be analyzed to produce more valuable insights into individual and population trends over time. Most notably for trial participants, they would not have to travel to healthcare facilities as often to allow clinicians to assess their progress, nor would it be as intrusive to capture regular readings throughout the participant’s day. Instead, the information would seamlessly flow from the wearable device directly to the clinical-research team.

Wearable devices can also be used to provide contextual information around prescription therapies, enabling researchers to better evaluate how well a drug is working. In the near future, wearable devices from companies like Proteus will also be able determine a participant’s adherence to the medication.

**Expanding the depth of clinical data**

Wearable devices coming to market over the next year promise to expand the type of data researchers can ultimately collect and analyze. For example, a sensor could be used to receive pulse transit time information, which can be used to measure blood pressure. Because pulse transit time can be measured continuously, such data is incredibly meaningful for both researchers and patients in various trials, including those for hypertension or chronic heart failure. Data from these devices can also be used in sleep studies to detect sleep apnea or hypopnea, among other conditions.

Digital health has the potential to revolutionize how pharmaceutical and contract research organizations operate clinical trials for researchers and participants. The value of using wearable technologies in clinical trials is being realized as these devices continue to prove to be cost-saving and efficiency-maximizing solutions.
The ease of enrolling and participating in trials with digital health devices makes the process far more appealing to individuals with chronic diseases who may be elderly, have mobility issues or transportation challenges or live in remote areas. For some research trials, such as those involving Alzheimer’s disease, reaching these individuals is critical to success.

Together, digital health devices and ResearchKit have significantly transformed patient recruitment in a matter of months. “It’s totally revolutionary,” said Schiller. “It allows studies to get in front of more prospective participants and quickly identify those that are highly qualified for the specific trial. Where it used to cost $10,000 to recruit hundreds of patients, now it’s just $1,000 to recruit thousands of patients.”

### 2. Remote patient monitoring during studies

Once clinical trials begin, researchers must regularly capture measurements from participants to determine effects of the drug and monitor for potential adverse events. Digital health devices provide real-time feedback from the patient’s home or work, reducing the need for in-person visits to the site and manual tracking while expanding the number of data endpoints available. At the same time, researchers can collect data required by the trial protocol more efficiently and cost-effectively.

“We are increasingly using connected devices to explore early signals of efficacy and safety, as we make our own decisions about our early research portfolio.”

*CRAIG LIPSET, HEAD OF CLINICAL INNOVATION, PFIZER*

With real-time access to data collected by digital health technologies, early signals can be detected to help researchers quickly identify whether the drug in development works better for some subsets of the study population than others and whether certain behaviors affect efficacy. Studies can be restructured early on to recruit participants most likely to benefit from the treatment, according to Dennis.

“The data gathered from patients in clinical trials using traditional methods can be subjective. It may rely on patients to accurately remember how they feel or depend on consistency in symptom evaluation across many investigators. This calibration can be problematic in indications such as depression or stroke, among many others,” Dennis said. “In addition, traditional methods don’t provide researchers with insight into patients’ day-to-day response to therapy and disease progression.”
Trial sponsors often express concern about the validity of patient recall. In arthritis research, for example, a key measure of effectiveness is knowing how much a patient is moving in the first 90 to 120 minutes in their day, as joint stiffness can build up overnight. A patient’s report could be affected by how they’re feeling and whether they remember to record their movements early in the day.

“If they use a wearable tracker with sleep monitoring capability, we know when they woke up, how well they slept and how much they moved in those first two hours. We can see an improvement in just one or two weeks,” Schiller said.

Digital health devices may also provide greater accuracy and broader “real world” application. Patients who use blood pressure monitors at home significantly reduce, or even eliminate, their trips to the clinic and are less likely to have artificially elevated numbers that are often seen when readings are taken at a clinic.

Conversely, a lack of data from digital health devices is also telling, alerting researchers to potential non-adherence or previously unreported side effects or challenges. Null reports from a connected glucose meter may trigger reminders for the patient to take a reading or a phone call from the investigator to identify other issues. This type of follow-up can get participants who miss a few readings back on track and help keep them engaged in the study, resulting in higher completion rates and more accurate study results. More frequent, objective data also allow investigators to distinguish between true non-responders and those who are actually non-adherent.

Integrating data from digital health devices can also increase the validity of data by eliminating errors caused by manual input on the patient’s or investigator’s part.

So far, consumer-oriented connected devices such as wearables and apps have proved most useful in Phase I studies. For later stage studies, clinical validation of the devices must be addressed or 510(k) cleared devices need to be used. “Doing the work necessary to expand the options may require collaboration across companies and with regulators to clarify how we evaluate new sensor-based endpoints and demonstrate their validity in a public and open way,” Lipset said.
Connecting to digital health devices has never been so easy.

Digital health – the use of in-home clinical devices, wearables, sensors and applications to remotely collect valuable patient data – is impacting the pharma industry and revolutionizing clinical trial processes and medication adherence.

As the industry’s leading digital health platform, Validic is helping companies like Medidata, Quintiles and Amgen easily integrate the actionable, patient-generated data from digital health devices and apps.

“Working with Validic is a big step toward realizing the potential of mobile health in clinical research because it offers life sciences organizations the flexibility to select the mHealth tools that provide the most clinically meaningful information for specific patient populations. We’re excited to be working alongside a like-minded company that is using technology to transform the way stakeholders across the healthcare industry collaborate and innovate.”

– Glen de Vries, President, Medidata

Are you ready to get up to speed on digital health and explore the impact it can have on your trials and initiatives? To learn more, contact us at hello@validic.com.
In addition, moving from a standard where all patients receive the same device for recording clinical outcomes assessments to one where patients employ the devices they already own raises other issues of comparability and validation. “If you read how the regulations and standards are written today, you would have to validate every survey or app on every device to use a BYOD [bring your own device] approach,” Lipset said. By the time all the validations were complete, updates and new devices would make them irrelevant.

“The landscape is shifting towards a model where companies will have to continue to demonstrate the benefit of treatments in the marketplace, generating evidence beyond traditional Phase III trials.”

JANE RHODES, PH.D., SENIOR DIRECTOR, NEW INITIATIVES, INNOVATION HUB, BIOGEN

New technology leveraging optical character recognition (OCR), such as Validic’s VitalSnap™, can help overcome this challenge. It enables users to capture health data from non-connected medical devices via their smartphone’s camera, and the data is automatically transferred to the clinician. This technology gives researchers the ability to integrate digital health data from the non-connected devices that are already clinically validated and being used in the trial.

“The phone is already an incredibly personal item that people feel comfortable with,” Schiller said. “Using OCR technology and a person’s smartphone, we can just allow them to use what they already know to participate in their own healthcare. With VitalSnap, we are going to be able to engage patients in a way that has not been possible before.”

3. Post-marketing research
In today’s regulatory environment, gaining FDA approval is just one step on the path to medical acceptance and profitability. “The landscape is shifting towards a model where companies will have to continue to demonstrate the benefit of treatments in the marketplace, generating evidence beyond traditional Phase III trials. They will need to deliver evidence that the therapies are working in the real world. We are exploring innovative ways to do this without requiring expensive Phase IV studies,” Rhodes noted.

Continued clinical demonstration of benefit requires ongoing patient contact to allow pharmaceutical companies to gather information about each participant’s quality of life and self-reported outcomes.
Digital health devices facilitate long-term monitoring without inconveniencing patients or driving up study costs.

Rhodes notes that multiple sclerosis patients see their neurologist for 30 minutes a year, on average. “Technologies today have the potential to effectively monitor MS symptoms in the patient’s own environment, which could be extremely helpful in chronic disease management and monitoring the effectiveness of therapies,” Rhodes said. During the annual exam, patients must have a full physical and psychological evaluation, and discuss their concerns about symptoms, tolerability and treatment changes.

Biogen uses an iPad-based neurological assessment tool to remove some of the burden from the office visit and enable better tracking of a disease that changes daily. The tool is clinically validated and provides quantifiable information that the physician can trust is actionable. Having the results of the assessment allows the physician to better identify changes in mobility, cognition and other factors quickly, and then personalize the treatment plan to the patient.

Post-market research enables companies to gain a deeper understanding of the patients who benefit most from the drug—and those in whom it has no impact or adverse effects. “Connected devices can show if a particular patient is not responding as well as others. That can start to get into personalized medicine with more opportunities for genomics input,” Schiller said.

On a simpler level, data from digital health devices can help pharmaceutical companies see whether alternate dosages or dosing schedules may work better for some patients, based on age, sex, co-morbidities and drug interactions.

Continuous post-marketing monitoring may also alert companies to potentially serious but rare adverse events that did not appear during clinical trials. “So many patients only come in once a year, so there’s no real way of knowing what’s going on during that time unless a subject calls in an adverse event,” Dennis said.

Digital health devices can provide earlier notice of emerging issues that may enable companies to respond quickly to unexpected outcomes and head off severe, or potentially fatal, events. The information from real world usage may also help them avoid expensive and reputation-damaging recalls by rapidly identifying the subset of individuals most likely to experience a specific adverse event.
4. Patient communities

Patients are more than the sum of their prescriptions, and pharmaceutical companies need to know the other factors that affect the ability of a specific drug to improve lives and outcomes. Patients often want to know the same information and, increasingly, individuals who have a disease in common gather in online communities to help each other and informally exchange data.

Patients often freely share the factors that may affect their response to specific drugs, such as co-morbidities and other medications, in these online communities. “In very active communities, patients develop a strong bond and like to help each other. Patients respond very positively to being in trials and being able to share their data,” Schiller said.

“Sites such as Genomera enable communities of patients to self-track and to answer research questions together,” he added. There is great potential for these patient communities to impact drug development.

Those that use digital health devices can provide additional information and insight on the importance of factors such as physical activity, sleep, blood pressure, diet, blood glucose levels and weight. The information benefits patients, too. Connected scales can alert clinicians or investigators if a patient with congestive heart failure suddenly gains weight. Connected inhalers can deliver asthma medication and simultaneously measure lung capacity. Patients can share the information with each other, their physicians and researchers. And they want to.

According to Lipset, “when patients are empowered with access to their electronic health data and confidence in their privacy preferences, 90 percent are willing to share their information to support research. If just one out of 10 were willing to share that data and participate in a clinical trial, that would be transformational.”

Conclusion

Pharmaceutical companies are leveraging digital health data more than ever before to improve clinical trials and the drug discovery process, ultimately allowing the efficient creation of game-changing drugs that could have a significant impact on patient lives. To get started, pharmaceutical companies can integrate digital health data to streamline four key areas of drug development: subject recruitment, remote patient monitoring during study conduct, post-marketing research and patient communities.

Lipset calls PatientsLikeMe “the granddaddy” of websites and apps that allow patients to improve their health and wellness through data sharing. That information can help pharmaceutical companies gain a deeper understanding about their patient population and how their drug fits into the overall patient environment.

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Conclusion

Validic provides the industry’s leading digital health platform connecting providers, pharmaceutical companies, payers, wellness companies and healthcare IT vendors to health data gathered from hundreds of in-home clinical devices, wearables and consumer healthcare applications. Reaching more than 223 million lives in 47 countries, its scalable, cloud-based solution offers one connection to a continuously-expanding ecosystem of consumer and clinical health data, delivering the standardized and actionable insight needed to drive better health outcomes and power improved population health, care coordination and patient engagement initiatives. Validic was named to Gartner’s “Cool Vendors” list and received Frost & Sullivan’s “Best Practices and Best Value in Healthcare Information Interoperability” and “Top 10 Healthcare Disruptor” awards. To learn more about Validic, follow Validic on Twitter at @validic or visit www.validic.com.

Communities. Fortunately, pharmaceutical companies don’t have to face this alone. Digital health platforms, such as Validic, are enabling the easy integration of data from hundreds of digital health devices.

Are you ready to integrate digital health data and advance your trials? Contact Validic at hello@validic.com or visit validic.com to get started.


