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Apple launches ResearchKit platform to tap millions of iPhone users to enroll in observational studies using apps

Apple has taken a key step this month toward helping to improve patient recruitment for medical studies with ResearchKit, a new iPhone-based medical software platform researchers can use to design and administer app-based observational studies. ResearchKit will help both doctors and researchers gather patient data frequently and more accurately track disease signs using sensors that are on the iPhone.

With an estimated 700 million iPhone users globally, Apple has seen more than a flurry of activity from some of its five initial apps, all being used in medical observational studies.

Currently, iPhone users must already be aware of ResearchKit and search the Apple app store for available observational studies. It is unclear how Apple will tap into the gigantic pool of iPhone customers not yet aware of these apps.

Of the five apps currently in use, a large-scale observational study of Parkinson's disease, Parkinson mPower, broke some previous enrollment records, recruiting 7,406 participants in six hours. The app for this study, co-developed by **Sage Bionetworks** and the **University of Rochester**, allows patients to track their signs and symptoms of the disease, continuously monitoring the same symptoms a physician would during an office visit but on an ongoing basis.

A diabetes study created by **Massachusetts General Hospital** enrolled more than 4,000 diabetic iPhone users in just five days. This app, called GlucoSuccess, allows people with diabetes to enter information about their diet and exercise and their daily blood glucose reading—capabilities that allow patients to examine their own data on their phones and derive some insights.

A third study is examining the long-term after effects of cancer treatments and seeking ways to provide a better understanding of the breast cancer patient experience, including why some patients recover faster than others. Share the Journey was developed by **Dana-Farber Cancer Institute**, **Penn Medicine**, Sage Bionetworks and **UCLA**'s Jonsson Comprehensive Cancer Center.

Another is MyHeart Counts, a cardiovascular disease study from **Stanford University** that uses risk factor and survey information to help researchers more accurately evaluate how participants' lifestyles and activity levels relate to heart health.

The fifth study, from the **Icahn School of Medicine at Mount Sinai** and **LifeMap Solutions**, is called Asthma Health. It is designed to track symptom patterns and potential triggers of asthma attacks, enabling researchers to learn new ways to personalize asthma treatment. The app also makes self-monitoring easier, promotes positive behavioral changes and reinforces adherence to treatment plans according to current asthma guidelines.

"In terms of opening up research to a broader group of people, what Apple has done is a potential game changer," said Stanley Shaw, M.D., a researcher at the Massachusetts General Hospital Center for Systems Biology, who helped developed the GlucoSuccess app to study diabetes. "We hope it changes the culture of participating in a research study, as people can share data. All five observational apps foster a more engaged relationship with trial participants."

Apple says with this new kind of patient data in research, drug companies and patient advocacy groups can use these apps to engage and keep in touch with patients and get clearer answers.

"iOS apps already help millions of customers track and improve their health. With hundreds of millions of iPhones in use around the world, we saw an opportunity for Apple to have an even greater impact by empowering people to participate in and contribute to medical research," Jeff Williams, Apple's senior vice president of operations, said in a statement. "ResearchKit gives the scientific community access to a diverse, global population and more ways to collect data than ever before."

ResearchKit, an open-sourced set of tools and services used to assemble a study, is designed to turn an iPhone into a tool for medical research that also can tap into the information being collected by wearable and other portable medical devices. Apple's HealthKit activity logger enables users to track their personal habits—data can include blood pressure, weight and blood glucose levels, as well as exercise habits from data captured on wearable devices and uploaded to the iPhone.

"What Apple has done with medical observational studies is applicable to tradi-

tional clinical studies, which have complex enrollment criteria and scientific evaluations by physicians," said Matthew Kibby, principal, technology and innovation, at **BBK Worldwide**. "It is a convergence that can provide researchers and patients with new kinds of data between visits that will change our interaction with clinical research studies. This will enable clinicians to harness and use the data with patients."

To maintain privacy, each app allows patients to customize which data they want to be shared. So a participant can have some information added to a study database while keeping some data only on his or her phone. The apps also enable study participants to respond to surveys on a regular basis. None of the data shared on the ResearchKit platform are shared with Apple, which provides a layer of privacy to protect the identities of patients.

Future plans call for expanding the platform into recruitment for clinical trials. However, some say there are obstacles on the approval pathway.

"The challenges I see would be regulatory acceptance of the data and collection methods, potentials authentication challenges and the need for a user interface that organizes all of the research projects similar to our existing trial directories," said Scott Ballenger, founder and CEO of **Trial Acceleration Institute**, a consulting firm that helps clients improve study cycle times.

The key difference, he said, is that the Apple approach creates each study as a standalone app that needs to be discovered and downloaded.

Still, Ballenger sees tremendous value in the approach. "Apple's decision for ResearchKit to be open source will lead to more rapid evolution of best practices and data capture techniques."

-By Ronald Rosenberg