GSK collaborates with Apple on ResearchKit

In July, London-based GlaxoSmithKline (GSK) announced they would be exploring Apple's ResearchKit, a software toolbox to turn iPhones and Apple Watches into data-harvesting tools for clinical trials. GSK has not yet specified which programs are under consideration, but vice president of clinical pharmacology sciences and study operations Rob DiCicco anticipates some degree of deployment within the next 12 months. He hopes that ResearchKit will allow clinical trial participants to get involved in studies in a way that's "more aligned with their daily life and less disruptive than it might otherwise be."

Apple launched ResearchKit in March, and within months drug developers had begun to explore its possibilities. Purdue Pharma in Cranbury, New Jersey, known for producing analgesics, created a prototype Apple Watch and iPhone application that could be used to track pain levels and drug efficacy in patients, says Chief Information Officer Larry Pickett. In addition, he notes, vibrating feedback from the watch could boost patient compliance in taking medications in a timely fashion. Indeed, on September 10, the US Food and Drug Administration cleared the first ingestible sensor for tracking patient compliance. The tablet, produced by Proteus Digital Health of Redwood City, California, combines Otsuka's Abilify (aripiprazole) schizophrenia drug with Proteus' sensors that can digitally record ingestion and send information to caregivers and healthcare professionals' smart devices.

But Apple built its ResearchKit as a medical research tool. The idea behind this open source software is for scientists and drug developers to shape it to their own particular needs, whether for collecting clinical research data, or patient recruitment or gathering informed consent. ResearchKit can gather activity data, for instance, from individuals asked to perform app-based tests on an iPhone or Apple Watch. Or the wearable mobile devices can gather data as passive monitors, tracking heart rate or temperature, for example.

A handful of academic and clinical partners were first out of the gate and have already started monitoring chronic conditions like asthma and diabetes with ResearchKit (*Nat. Biotechnol.* **33**, 322, 2015). An iPhone app for tracking Parkinson's disease symptoms has already been rolled out. Sage Bionetworks, based in Seattle, and the University of Rochester, in Rochester, New York, built mPower to collect passively acquired data from individuals with Parkinson's disease. The mPower app asks users to complete daily tasks that measure disease activity—for example, using the iPhone's gyroscope sensor to monitor gait and balance, or the phone's

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With one of these and ResearchKit, people can get involved in clinical trials.

First US biosimilar launch

Sandoz in September announced the US launch for Zarxio (filgrastim-sndz), the first biosimilar to be approved by the US Food and Drug Administration (FDA) (*Nat. Biotechnol.* **33**, 222–223, 2015). Sandoz, a Novartis company, is headquartered in Holzkirchen, Germany. The biosimilar Zarxio is a biosimilar to Thousand Oaks, California–based Amgen's Neupogen. Both originator and biosimilar products are approved for the same set of medical indications, principally several kinds of cancer involving myelosuppresive therapies. When FDA approved Zarxio in March, agency officials said that they considered 'filgrastim-sndz' a placeholder name, as the agency had yet to define a policy for naming biosimilars (*Nat. Biotechnol.* **31**, 264, 2013). In August, not coincidentally, FDA issued its much-awaited draft guidance, proposing that biosimilars share nonproprietary names with their reference products. To set such products apart, FDA proposes designating unique four-letter suffixes for each biological product, with those suffixes otherwise carrying no particular meaning. Using suffixes would help prevent inadvertent substitutions of biological products that are not considered medically interchangeable, and they might also help with safety monitoring, FDA says. But possibly complicating matters is an approach proposed by agency officials—one evident in Zarxio's provisional name—of using suffixes that reflect the name of the company that manufactures each drug. FDA also says it may apply one or another of these approaches to renaming products that are already licensed, suggesting these extended names could help with recordkeeping and also might avoid "inaccurate perceptions" of the safety and effectiveness of biological products based on their regulatory paths to approval.

"**It's a game changer, and we expect investment to keep pouring in to Japan. After years of struggling with slow returns on investment, regenerative medicine companies across the world see a faster path in Japan, and they're watching closely.**" Sanjeev Kumar, a consultant at market research firm Frost & Sullivan on a change in the Japanese regulatory pathway that took effect last fall. It enables therapies to get conditional marketing approval for seven years based on phase 2 clinical trials. (*Japan Times*, 3 September 2015)

"**Eventually, this will hurt us on the research side in the UK. This is just a bad decision, not only for patients but also for society as a whole.**" Roche CEO Severin Schwan, commenting on Britain's Cancer Drugs Fund's decision to drop two Roche drugs from its list, Avastin and Kadcyla. The fund provides patients access to drugs not provided by the National Health Service. (Reuters, 8 September 2015)