

Verily partners with Novartis, Otsuka, Pfizer, Sanofi to transform clinical trial data collection

By Stacy Lawrence, Staff Writer

The life sciences are terrible when it comes to information technology. Health care systems, devices and procedures often are oriented around a given patient's needs at a point in time. The clinical trials employed by pharma are a bit better, given their explicit need to track group data over time and draw conclusions. But clinical trials also are mired in the technology, systems and practices, or lack thereof, of the physicians and health care institutions that conduct them.

Now, the industry is turning to the preeminent tech giant to help solve its long-standing clinical trial technology and data collection issues. Pharma has been dabbling for some time in various partnerships with Google's med tech-oriented sister company, Verily Life Sciences LLC. Four major pharmaceutical companies – Novartis AG, Otsuka Pharmaceutical Co. Ltd., Pfizer Inc. and Sanofi SA – have committed en masse to collaborating with Verily to develop digital, patient-centered clinical research programs using its Baseline Platform.

A new baseline

“The clinical trial process for industry is still heavily burdened by paper and legacy technologies, and the adoption of eSolutions has been extremely slow; everyone wants progress, but no one wants change,” Deborah Profit, vice president of applied innovation and process improvement in Otsuka Pharmaceutical Development & Commercialization, told *BioWorld*.

“The Baseline Platform brings technical capabilities to the clinical trial process, and more importantly, to the patient [for example, electronic informed consent, trial information, study results] with the added benefit of delivering data in near or real time to study teams to allow for informed decision-making and analysis earlier in the clinical trial process,” she added.

That is all based on the evidence generation platform and tools that Verily and Google – before Verily became an independent subsidiary of Alphabet Inc. in August 2015 – have developed over the years to support Project Baseline, an ambitious, large-scale clinical research program.

Project Baseline was first reported in July 2014, although notably now Verily does not cite its start until 2017. It is a phenotypic health data study of about 10,000 people in the U.S. The participants will be followed for four years to collect and track health data in a bid to better understand what it means to be healthy – and what happens as the human body tips into disease.

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In order to manage Project Baseline, as well as its various related clinical efforts, Verily developed what is now known as the Baseline Platform. It is designed to enable the collection, organization and analysis of health information from electronic health records, sensors and other digital sources. Duke University School of Medicine, Stanford Medicine, Google and the American Heart Association have all contributed to Project Baseline and the development of that platform.

“This evidence generation platform is built to collect, organize and activate high volumes of disparate data from a variety of sources [e.g. molecular, clinical, imaging, self-reporting, sensor] that can be used at both the individual and population level. Through this platform that organizes the data into a single ‘operating system,’ we can give researchers faster access to higher quality data and advanced tools and analytics to generate insights,” said Scarlet Shore, who is the lead for Project Baseline at Verily.

Real-world realized?

Among them, the companies aim to launch various clinical trials using the Baseline Platform for clinical trials across a variety of indications, including cardiovascular disease, oncology, mental health, dermatology and diabetes, in the coming years.

However, the aim is not just to improve upon the use of data in clinical trials. Verily is planning to democratize clinical trials, making them accessible to a much larger part of the population. Only a very small part of the U.S. population, less than 10%, participates in clinical trials or observational studies. It expects to do so by changing how researchers interact with patients, collecting data in new patient-friendly ways such as

via Verily's recently FDA-cleared Study Watch, which is designed to integrate more seamlessly into an individual's life and gather more continuous, real-time data. The agency clearance was specifically for ECG data.

Mastering the management of various kinds of clinical trial data is also expected to lead into the real prize that pharma and regulators are hotly pursuing: real-world evidence. That would enable the systematic gathering of evidence regarding a specific product once it's in use by patients. The aim for pharma is to be able to use that sort of data to support line extensions for approved drugs that are prescribed off-label or in other regions to support indication expansion.

In addition, systematically amassed real-world data could enable the fundamental transformation of the standard randomized clinical trial, enabling researchers to do away with a control or sham arms and substitute them with matched patients from a monitored population.

"Leveraging real-world data in clinical trials has the potential to reduce the burden on clinical trial participants by reducing the number of trips to the clinical trial site because data is available from other data sources such as EHR, wearables, etc.," observed Otsuka's Profit. "However, real-world evidence is truly a work in progress for both industry and regulatory agencies

and the dialogue between the two needs to continue so that the maximum value for patients and regulators can be realized. Larger patient datasets can provide greater insights sooner, especially regarding the ongoing safety of a product."

With its immense reach and vast resources, if anyone can solve the data and IT conundrum that has plagued the health care industry for decades it seems likely to be Google. Verily has yet to demonstrate much heft on its own, having spent a lot with little to show for it yet across a huge array of med-tech endeavors via partnerships and joint ventures with leading players on all fronts, including robotic surgery, bioelectronics, diabetes care and ophthalmology.

But this data management, integration and analytics is right in the sweet spot for Google, which could make the Baseline Platform a good bet for how Verily will successfully make its mark on health care as it is practiced.

"A variety of barriers exist in the current system – from the lack of standardization in EHR data, to the limited understanding of a patient's health outside of a clinic," summed up Shore. "It's critical then for us to develop new tools and technology that enable real-time, continuous collection, organization and activation of diverse, holistic health data across a patient's life." ♦