"Big data needs clever, thoughtful analysis."
— Benedict C. S. Cross

know that using drugs targeting specific molecular dependencies of the cancer cell leads to significant increase in response. We expect that the future of medicine is going to be even more predictive, rather than being based on trial and error."

The next big game-changer was the Precision Medicine Initiative, launched by President Obama in 2015, with USD 215 million in the 2016 federal budget. The allocation included USD 70 million for the National Cancer Institute (NCI) at the U.S. National Institutes of Health (NIH) in Bethesda, Maryland, to accelerate programs to single-out genomic drivers of cancer and to use that knowledge to create more effective treatments. Also part of the package was USD 130 million for NIH to collect the health profiles of 1 million Americans and establish a database that can be shared and used for research.

Called *All of Us*, the database project aims to gather information from as many different segments of the population as possible, says **Kelly Gebo,** M.D., M.P.H., chief medical and scientific officer of the *All of Us* Research Program. "We know different people respond to different types of medicines," says Gebo. "We're trying to do research on a diverse group of people that traditionally have not been included in biomedical research."

While researchers often look at factors such as gender, *All of Us* is recording other information including age, income, and education. "We want to try to look at [these other] differences in populations and how they affect clinical outcomes in the field," Gebo says.

Since the program launched on May 6, 2018, 150,000 volunteers have registered, 90,000 of whom have supplied data about their health and family history. The goal is to have people stay with the program for several years, updating their health information. NIH has gone to great lengths to ensure participants' privacy and intends to create a data platform that can be used by all scientists, as well as other companies and individuals.

"This is going to be a tremendous data resource that allows us to look at information we never could before," continues Gebo. "I look forward to researchers getting their hands dirty as they look into the data."

Companies get into the act

One of the fastest-growing precision medicine approaches, thanks to the availability of more genetic information, is the development of cancer drugs that target specific types of cancer and are effective in individuals with a particular genetic makeup or biomarker.

"Now we understand the genetic architecture of each cancer. Sometimes it is better to know the genetic basis of cancer rather than its location. Drugs are being developed based on cancer's genetic vulnerability rather than [on] tissue of origin," says **Chris Boshoff,** chief development officer at Pfizer Oncology in New York City, citing as an example the fact that lung cancer has at least 10 different subtypes. Currently, Pfizer has 14 cancer drugs approved, and out of those, seven are based on precision medicine and target a specific subtype of lung cancer, he says.

Some companies are even more specialized, such as Loxo Oncology in Stamford, Connecticut, (recently acquired by Eli Lilly), which focuses on treatments for cancers caused by a single DNA abnormality. A single drug could have a dramatic effect on that type of cancer.

"I'm excited about the work—you take a biopsy of a tumor and use next-generation sequencing to identify alterations in the DNA or RNA that indicate why it became cancer in the first place and help you identify vulnerabilities against which we can use drugs," says Loxo's CEO **Josh Bilenker.**

One new trend in precision medicine is noninvasive testing, according to a statement from Novartis. While cancer is traditionally diagnosed with solid tumor biopsies, some scientists are using blood tests known as liquid biopsies, followed by genomic analysis of fragments of tumor DNA found in the bloodstream. These DNA remnants reveal the kinds of mutations that may be driving a patient's cancer and could provide clues about how to treat it. Novartis researchers have been developing liquid biopsy technologies for several years and are now working to make them a reality in clinical practice.

Novartis has also launched several targeted medications, such as Gleevec, which was the first in a new class of drugs for precision medicine known as tyrosine kinase inhibitors. Gleevec treats forms of leukemia—chronic myelogenous leukemia and acute lymphocytic leukemia—that were often deadly in the past, but are now treatable, chronic diseases.

Overcoming obstacles

Developing precision medicine treatments is not without challenges. These include the cost of testing and implementation, the fickle and resilient nature of cancer, and the volumes of data and regulations that researchers must deal with. Lack of uniformity in testing also hinders the field.

The complexity of drug discovery and development can also slow progress. Enter Harvard Business School's Kraft Precision Medicine Accelerator, whose mission is to streamline processes so patients get treatments sooner. "We're trying to apply business thinking to blockages in the system," says **Richard Hamermesh,** faculty cochairman of the accelerator.

The initiative was funded by a USD 20 million endowment from Robert Kraft, owner of the New England Patriots. Kraft's wife, Myra, died from ovarian cancer, and received targeted therapy late in her treatment, but her disease had progressed too far. "The experience made him realize there is a lot of friction in the system. If it could be eliminated, treatments could come to market faster," says Hamermesh. cont.>

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