REALHEALTH™

New Program Aims to Increase Diversity in Research

Can data from more than 1 million Americans accelerate research and medical breakthroughs that benefit everyone?

December 21, 2018 By Alicia Green

After battling and surviving breast cancer, Michelle McNeely knew she wanted to give back somehow. So when she learned of a new initiative intended to improve the health of millions of Americans, she decided to participate.

“After going through treatment and this type of experience, you always are trying to find a way to give back,” says McNeely, age 41, an African-American woman who lives in Dallas. “This came along, and I thought it would be a perfect opportunity to help people.”

The All of Us Research Program, which launched nationally on May 6, is an initiative created by the National Institutes of Health (NIH) that aims to accelerate research and medical breakthroughs by gathering health data from more than 1 million Americans.

“It would be the largest cohort in the United States, in which we would actually have the availability of DNA samples and electronic health records to be better able to build a platform to do innovative research,” says Robert Winn, MD, a principal investigator for All of Us and director of the University of Illinois Cancer Center in Chicago.

The program would also help advance precision medicine, an emerging approach to disease prevention and treatment that considers differences in people’s biology, environment and lifestyle, according to the NIH.

“When I think of precision medicine, I really think of person-based medicine,” says Winn, who is Black. This would allow researchers to identify specific biomarkers in individuals and develop drugs to improve their health.

The data amassed could help researchers identify risk factors for certain diseases, identify the cause of individual differences in response to commonly used drugs, discover indicators that signal increased or decreased risk of developing common diseases and empower study participants with information to better their health, among many other potential benefits.

“We know now that there are certainly differences in the way individuals respond to medicines,” Winn says, noting, for example, that the standard of care for cholesterol, the prescription of Lipitor, does not work equally well for everyone. In addition, dosing for the sleep drug Ambien is different for men compared with women.

“Having different people involved in clinical trials and the All of Us Program becomes incredibly important to develop better therapies for multiple different groups in the future,” Winn explains.

Regardless of race, ethnicity, sex, gender or sexual orientation, enrollment for All of Us is open to adults age 18 or older who live in the United States. No health insurance is required, and participants can be healthy or living with a long-term health condition.

“You sign up online,” McNeely explains. “They ask you to complete different surveys about your health and general questions about yourself. Then, you set up an appointment to go in wherever you’re located.”

Participants, such as McNeely, are sometimes asked to visit one of All of Us’s partner centers across the country in order to be measured and to provide biosamples, such as blood and urine.

All participants in the program must provide health updates, can volunteer for other research and have access to their health information. Additionally, participants can opt to leave the program at any time.

“If you feel uncomfortable, you have the ability to say, ‘I don’t want to be in this study. I don’t want my information to be used anymore,’” Winn says.

A key feature of the program is its active recruitment of individuals who belong to population groups typically underrepresented in biological research, such as African Americans. Research has shown that Black folks are largely excluded from clinical trials and disproportionately enrolled in studies that don’t require scientists to secure the informed consent of individuals participating in certain experiments. (Examples of these are tests for emergency medical procedures during which patients are often unable to respond, such as a method of CPR.)

But African Americans could eventually reap many benefits from All of Us, especially because health disparities affect this racial group more than any other. For instance, according to the Centers for Disease Control and Prevention, Black people are twice as likely to die from heart disease than their white counterparts and are 50 percent more likely to have hypertension.

Typically, African Americans suffer from more illnesses than other groups. “Even if you were to believe that race is a social construct and it’s not genetic, those social constructs have environmental impacts,” Winn says.

Nevertheless, getting Black folks to volunteer for such a program can be challenging given African Americans’ deep-rooted distrust of the medical establishment and the government, an attitude that dates back to the infamous Tuskegee experiment.

Winn believes that in order to boost participation by Black people in such research scientists must regain their trust in specific ways.

“The first thing is not to do the colonial thing and tell them what’s good for them, show up in their communities and when the grant runs out, you’re out,” Winn stresses. “I believe that this program has been one of the first programs that I’ve been affiliated with that has gotten the voices from real community people right from its inception.”

What’s more, adds Winn, “Part of winning the trust back is to actually recognize and embrace that we have not always done things right and to actually have their voices at the table while we’re starting to even think about this and work through some of the issues.”

McNeely says she didn’t have any reservations about All of Us. She embraced the program as a participant partner, individuals who serve on committees and help support the design, implementation and governance of the initiative.

“Basically, we are advocates for participants,” McNeely explains. “If we have any questions, concerns or ideas, we get to bring them up from the participants’ point of view.”

This approach motivated Winn to become involved in the program. “I would never have participated in this program if the participants weren’t partners,” he says. “At the end of the day, the data doesn’t belong to the NIH and to the individual researchers. It belongs to the million-plus people who decided to participate.”

Winn believes treating participants as partners is important because it encourages scientists to interact with community members, who as advisers keep the program on the right path.

“This program to me is brilliant because it says to people for the first time, ‘You are not a data point. You are not some scientific experiment. We see you as an individual and we need you as a participant and as a partner to help us build what really would be the first million-person cohort in the country,’” Winn says. “On every single level, there is something good to say about that.”

The goal of All of Us is to reach 1 million participants in five years. By the end of August, more than 100,000 people had registered for the initiative.

“Sign up for it because you do want to be represented and want to have the chance not only to affect your health but also affect the health of future generations,” McNeely says. “It’s a wonderful opportunity to give back to your community.”