# The Future of Health Begins With You: All of Us 4/17 Webinar

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A Section508–compliant PDF of the slides presented in this video is available at <https://allofus.nih.gov/sites/default/files/AoU_Patient_Advocacy_Webinar.pdf>. Refer to this PDF for further description of the slides referenced below.

## Title Slide

Logo of the All of Us Research Program

The Future of Health Begins With You

Logo of the National Institutes of Health

April 17, 2018

## Dr. Richardson-Heron:

Hello and welcome. My name is Dr. Dara Richardson-Heron, and I am the chief engagement officer for the *All of Us* Research Program. I first want to extend my heartfelt thanks and appreciation to everyone for taking the time today to join us here at the *All of Us* Research Program for this very important conversation. It’s truly an honor for us to have the opportunity to speak to you today. And we certainly hope that we have a critical mass of patient, disease, and research advocacy groups on the call as our target audience for this discussion. But I also want to extend a hearty welcome to all other individuals and groups who have joined us. I am confident that we have a great deal of very exciting information to share with everyone. So we’ll kick off the conversation with information about the basics of the *All of Us* Research Program and our current program status.

## PowerPoint Slide 2, Together, we will generate a conversation about, appears on the screen.

## Dr. Richardson-Heron:

And we’ll leave time at the end of the presentation to explore and begin the first of what we hope will be many important conversations with you about ways we can work together with patient, disease, and research advocacy organizations—that’s each of you—to support the program and your interests at our national launch and well beyond.

So let’s get started.

As many of you know, the *All of Us* Research Program is the cornerstone of the broader federal government Precision Medicine Initiative, *All of Us*. And we’re spearheaded by the National Institutes of Health, and it’s an ambitious and unprecedented effort designed to enroll 1 million or more diverse people living in the United States who will volunteer their health data over a decade. Now the program will be open to all communities, to all communities. Unlike a single research study focused on a specific disease or population, *All of Us* will serve as a national research resource to inform thousands of studies covering a wide variety of health conditions. Next slide.

## PowerPoint Slide 3, Today’s Speakers, appears on the screen.

## Dr. Richardson-Heron continues:

Now certainly, patient advocacy organizations, research advocacy organizations, and voluntary health agencies are some of the biggest champions for National Institutes of Health, and having personally served as the CEO of the Greater New York City affiliate of Susan G. Komen for the Cure and as the national chief medical officer of the United Cerebral Palsy associations, I fully understand the valuable resource voluntary health organizations are and the expertise and value that each of you can bring to *All of Us.*

We absolutely share your organizational mission and passion for accelerating research to get to better treatments and cures and for identifying risk factors and individual differences to better understand how to keep people healthy and, even more importantly, how to prevent diseases before they ever develop. And we want to ensure that you are a part of this journey with us to develop, build, and utilize the amazing tool and data platform that is *All of Us*.

So since we’re unfortunately not together in person, I want you to see who we are. You can see me here on the screen in the orange. But the real headliner today that I am pleased to introduce is Eric Dishman, our *All of Us* director. Eric is leading NIH’s efforts to build this national research program of 1 million or more United States participants to advance precision medicine.

Now, previously, Eric was the vice president of the Health and Life Sciences Group at Intel Corporation, where he was responsible for driving global strategy, research and development, product and platform development, and policy initiatives for health and life science solutions. Eric is a widely recognized global leader in health care innovation with specific expertise in home- and community-based technologies and services for chronic disease management and independent living. He’s trained as a social scientist, and he’s known for pioneering innovative techniques that incorporate anthropology, ethnography, and other social science methods into the development of new technologies. But perhaps most importantly, he’s an amazing and passionate leader who brings his own experience as a cancer patient for 23 years, finally cured thanks to precision medicine, to drive a person-centric view of health care and health care transformation.

Eric, it is my distinct pleasure to hand things over to you to get us started.

## PowerPoint Slide 4, A special update & conversation with advocacy groups: Advocating & Accelerating Precision Medicine for All of Us, appears on the screen.

## Mr. Dishman:

Thanks Dara. You know, I have—I’m so lucky to have—an amazing team helping out with this effort and not the least of which is Dara as our chief engagement officer, clearly bringing the expertise she did from the various roles that she just described is just instrumental to what we’re doing.

So I am thrilled to be with you. I’m joining in today from the West Coast in lovely Banks, Oregon, a farm town that I live in just west of Portland, Oregon. I go back and forth, so I have a long commute back and forth to Washington, D.C., from here, but happy to be here with my dog and my chickens and especially my wife, though she says I should put her first in that list, not last.

So, in some ways, for some of you, this is the continuation of a conversation that we’ve had for many times. I was involved with what was called the Precision Medicine Initiative Cohort Program initially as one of the people on the original working group, and we did listening sessions around the country and were involved with many advocacy organizations in its earliest of days that helped conceptualize and lay out at least a rough scaffolding of a plan of what we now call the *All of Us* Research Program.

## PowerPoint Slide 5, “My first week of chemo, Summer 1989, Chapel Hill, NC,” appears on the screen.

## Mr. Dishman continues:

And what I want to do today is start just a little bit—some of you have heard this before and some of you are completely new—but I’ll just give you a little bit, a sense of my own story.

All those titles and things that Dara just so kindly mentioned are not the things that really matter. I mean, that gives me experience in Silicon Valley at dealing with Big Data and all of that, so they matter to a certain degree. But at the end of the day, I am just Eric, and I’m the same guy that was right on that couch, though I am much wider. When Dara says that I am widely known, I am getting more widely known all of the time; I’m eating a lot of comfort food right now as we get close to our national launch.

But this was me during the first week in our apartment in Chapel Hill. My wife kindly said, “Let’s get him a puppy; he’s going to need a sense of purpose to help him get over this cancer diagnosis.” Especially when they said at that point that I would be dead within a year. And some of you have heard my story, and I’m not going to go tell the whole story here because I want to really get into the progress that was made in the program. But suffice it to say, at age 19, when you get a cancer diagnosis, instead you’re going to be dead within nine months, it’s not the happiest of times. And I started out as a very passive patient, just blindly accepting what was said to me. I kind of accepted without any questions or anything that I would be dead in nine months and sort of started preparing my life to die, quite frankly.

And it was another patient advocate, a woman named Berna, who I met in a waiting room that just woke me up. She woke me up in so many ways. First of all, that I should be proactive about my own health, that I should try to get my own data, and that I should try to fact-check my doctors and make sure that they knew the latest studies. So she went with me to a library at Duke University. She was much smarter than I am, and she helped me find the two studies that had ever been done at that point on me, or supposedly on me, on that particular rare disease that I had. And she said, “Eric, they don‘t know anything about you. You’re 19. Everybody in these studies were 65 and above, most of them in their 70s and 80s. So they’re giving you this nine-month death sentence based on the average of the people who happened to have been studied who are nothing like you.”

And that, I think, is the heart of the challenge and especially that motivates the *All of Us* Research Program. There are too many people who haven’t been studied, and we’re still mostly in health care being treated with the average of the people who happen to have been studied. So I got to say, people know that later on in my 23 years of cancer that it was a whole-genome sequence and the hell of pulling together my electronic health records that saved my life recently.

But what they don’t realize is that there were specific patient advocates and there were specific advocacy organizations in both cancer and in kidney disease who were absolutely key to helping me understand, like, there were alternatives and alternative treatments, and they were funding some of the pioneering research. So my life has been saved many more times over by advocacy, specific advocates and advocacy organizations, long before whole-genome sequence came to the rescue.

## PowerPoint Slide 6, In all my roles, advocacy has been a key part of my life…, appears on the screen.

## Mr. Dishman continues:

In all of the roles that I’ve had, these are some of the people that I’ve studied as a social science. I’ve focused particularly on those with chronic disease and lived with families in about 25 different countries who are dealing with chronic illness, especially those that are age-related. Lots of studies of Alzheimer’s. So, at the top here, literally some of the people I have both advocated for and studied. And many people that I studied were like, “Will you also be an advocate for me?” later on in their lives when they got cancer and were dealing with Alzheimer’s in their family.

So I really think of *All of Us* as needing to do both advocacy in the small and in the large. And in the small, it’s in that way of person by person, patient by patient, helping them through their own journey with whatever they need, whether it’s me helping somebody research their illness or driving them to chemotherapy or making doctors and nurses slow down when they’re undergoing through a painful procedure. And then there’s also advocacy in the large, which so many of you on the call represent today.

In my world, I’ve done advocacy work both for funding and policy issues with these organizations here and many more locally that you might not know the names of. So I appreciate and value what you do. I come from that world, and I’m eager to continue the conversation that we’ve had in some settings over the last year and a half or so as we’ve gotten off the ground.

## PowerPoint Slide 7, For today…,” appears on the screen.

## Mr. Dishman continues:

So what I want to do today is really just give you a reminder of—or for some of you, this may be first exposure to—the basics of *All of Us*. I’ll do that very quickly under the assumption that many of you know that well already. And then I’ll give you some updates on the accomplishments and status of the program. And then, most importantly, I want to share with you both a vision and some thoughts about and ask you some questions in ways to really start thinking about what’s next.

Now when we sent these invitations out, they were initially to patient and research advocacy organizations. Apparently the invitation has spread much more broadly than that. That’s terrific. Everybody is welcome. But we’re going to focus especially on those organizations today, and we’ve had to change to a different web platform since there’s many more people than we thought would initially join. So it’s harder to make it more interactive, but that’s partly why we want to record it, as well as capture the things that you might be typing in, both questions and feedback. And we’ll look for some more interactive kind of workshop-type things just to speed up.

## PowerPoint Slide 8, The basics: overview of the All of Us Research Program, appears on the screen.

## Mr. Dishman continues:

Now I’m going to admit that my team right now and the whole consortium are buried with the national launch, which I’m going to talk to you about, but I’m just starting to see the light at the end of the tunnel on the national launch and thinking about what’s next. Which is why I wanted to go ahead and let you know what the latest is about our program today, as well as plant some seeds for some conversations that—we get a month or so after our national launch—I want to start having with many of you individually and in collective ways to figure out some of these challenges.

So onto the basics of the *All of Us* Research Program.

## PowerPoint Slide 9, All of Us Research Program Mission and Objectives, appears on the screen.

## Mr. Dishman continues:

Our mission is fundamentally about acceleration, speeding up health research and medical breakthroughs that are going to enable the kind of precision medicine that saved my life, to really individualize treatment and prevention and care for all of us, and we’re going to do that in three ways.

The first strategic objective of our organization is we need to nurture relationships with a million or more people from all walks of life, all conditions, in the country for decades. This is—we’re planning for the first 10 years, but this is a multi-decade study in its intention and in its design. If we do that well, we nurture those relationships well, then we’ll deliver one of the largest, richest biomedical benefits ever, and, to all the degrees possible, we want to make it easy, safe, and free for people to access, for researchers of broad stripes. Well, if we build that, then that leads to the bottom left. We’ve got to catalyze a robust ecosystem of researchers and funders who are hungry to use this resource. If we build it, will they come? And I think this is all of these areas are ones that we need help.

## PowerPoint Slide 10, All of Us Research Program Mission and Objectives Are Larger Than Us!, appears on the screen.

## Mr. Dishman continues:

So I’ve thought about our objectives and I said, “They’re all larger than us. They’re larger than you, larger than this startup program at the NIH that’s aiming for these audacious goals and swinging from the fences.” And as I think about my own questions for you: How do we all promote that nurturing of relationships? How do we all promote the understanding of precision medicine, its promise, its limitations, today? How do we all continue to promote research participation? That’s a much broader issue than just *All of Us*. Many of you have experience that you’ve already lended to us to help us know how to do that.

What are the evidence-based methods for reaching and building trust with diverse and especially vulnerable populations? We are doubling down, tripling down, focused on those who are underrepresented in biomedical research. We were really depressed to find out there was very little literature that could help guide us on how do you reach those populations who have been left behind or just have no trust because in the past, quite frankly, we in the name of the federal government harmed people through research and things like Tuskegee. And then how can *All of Us* build relationships in recruitment with your community of patients and family members as key participants, hopefully, in the *All of Us* Research Program?

If I think about the second—deliver one of the largest, richest biomedical data sets—there are a lot of problems that we’re trying to tackle, the scale that most people have never done. And there are problems that, again, we as a research community need to continue to work on together. I do not believe in “not invented here.” So if there are things that you’ve already got that solve some of these problems and some of the things we’re inventing help you solve yours, that’s the right thing to do things.

So we are all still dealing with the challenge that getting individuals access to their EHR, especially their specialty EHR, is really difficult. We’re all starting to struggle with how do you do responsible return of genetic information to people. Are these mobile devices and wearables and Fitbits and things out there, are they really useful for research and, if so, what are the lessons that you need to learn about how to use that data appropriately?

What can we do to improve security and privacy practices? Every day, there’s a headline about, you know, another major security breach of some institution. So how do we make sure the research community is on the cutting edge and trying to stay up with all these things industry is doing to protect the privacy of those who have been so kind to volunteer.

Now how do we help researchers? We’re seeing this time and time again where researchers, you know, they’ve got some money to do a study or some science, but they have no money in the grant or the award to get access to storage of all that data or the computing of all of that data. And they may as well not have even done the study. And then, lastly, in terms of, okay, if we build it, will they come, will funders and researchers come to it?

How do we join in advocacy efforts in general for more support for research, both at the federal level as well as through philanthropy? How do we build common roadmaps of some of the key focus areas? Like, what are the methods and the data types needed for your domain across funders? Many of you represent very different conditions in disease domains, but I suspect you have some data types and some capabilities and some methods that are common across all of those and with what *All of Us* is trying to do.

And then, lastly, how do we make sure that your ecosystem of researchers for the area that you represent will come and leverage this resource? That means influencing the requirements up front about what we put into it, but also making sure that if we built it, there are funders that are ready to go leverage the resource and make accelerations and advances in your particular area.

## PowerPoint Slide 11, All of Us Research Program core values, appears on the screen.

## Mr. Dishman continues:

So many of you have seen our core values. You know making this program open to interested individuals around the United States is a big challenge that we’re up for. I’ll talk a little bit about our national launch in a moment. Participants as partners is fundamental to what we’re doing. We have had participants and participant advocates be involved from the beginning.

I’m happy to say now we have a lot of participants. Dara’s team has been working to infuse more actual participants who have been through our whole protocol into the governance and into the planning procedures that we have going forward, as well as making the data accessible to all researchers. We are not building a silo here. And how do we both balance the need to protect the privacy of those who donate it, but make this data open so thousands of flowers of study can actually bloom on top of it.

## PowerPoint Slide 12, Summary of our approach & protocol, appears on the screen.

## Mr. Dishman continues:

These values inform everything that we’re doing. The basic summary of what *All of Us* is about, for those of you who may be new to this call, it’s a longitudinal national resource. So this is a longitudinal study. I hope it goes 50, 60, 70 years, like the Framingham Heart Study. God bless the people in Framingham to this very day. They and their families are continuing to donate that study that started in 1948. I’m hoping we’re looking back 50, 60 years from now and saying those families are still doing this with the *All of Us* program.

Getting a diversity of participants, especially those underrepresented in biomedical research, is key, and I’ll show you how we’ve been doing in our beta phase so far. And then also a diversity of researchers. If the only people that get to use the *All of Us* research are the top-tier researchers who are well funded and already on the cutting edge of biomedical research, then we will have failed. How do we make it so that citizen scientists and community colleges and others who don’t have a computer science department to help them with all the technologies? How do they get to work with that as well?

The basic challenge here is a million or more people with a diversity of demographics, geographic and sort of exposure locations, if you will, different environments, as well as different health status when they come into the program through these networks that we’ve built.

So we have a network of direct volunteer partners—and you’ll see some of those in a moment—and they’re there just to help the person who comes in or calls in or clicks online and say, “Okay, how do we get a convenient nearby location for them to go do their blood or urine sample if they’re invited to do that?”

The health provider organizations range from small Federally Qualified Health Centers to large places like the VA, and they have sites that they’re opening up to recruit their patients and reach out to their members and eventually reach more broadly into their community than those who may be members with them.

And then key, Dara put together a set of national and local community partners who are really helping to get that education out about what is precision medicine and its promise and why is it important to be involved in research and then help people understand the *All of Us* program specifically.

The basic protocol as we start out is enrolling and consenting to share your electronic health record data; a series of three initial surveys with more in the works and many more imagined for the future; some baseline simple physical measurements like height, weight, blood pressure, and so forth; and then, for those who are invited, a blood and urine sample. And then we are increasingly working on some apps and phones and other kinds of wearables as other ways to collect social, behavioral, and health information from those who currently have them and then trying to figure out how do we expand that out to those who are not digitally savvy today.

## PowerPoint Slide 13, Major building blocks of the All of Us Research Program consortium, appears on the screen.

## Mr. Dishman continues:

These are the basic building blocks of the program. So a Data and Research Center—it’s all about making that data secure but also cleaning and curating that data and building the researcher portal that all researchers will eventually use to access the data. Biobank—clearly to store samples. Planning for more than 35 million vials. Those of you that have biobanks of your own know what an endeavor that is. The participant technology systems, they’re doing all of the web- and phone-based platforms so people can join online, they can join via an iOS app, they can join via an Apple app, to come into the program that way or be involved in a particular community site or community event.

I’ve mentioned these three networks down below—so the direct volunteer network and the participant center, the health provider organizations that I’ve described before, and then this mix of communications and community networks. Some of these are not-for-profits that focus on speaking out to physicians’ groups and nurses and others. These are community, National Hispanic Alliance and others. In fact, I’ll just show you; here’s some of the direct volunteer network partners.

## PowerPoint Slide 14, Current Consortium Members: DV & HPO networks, Comms & Engagement, appears on the screen.

## Mr. Dishman continues:

So you see like Quest and Walgreens and Blue Cross Blue Shield; these folks play different roles. This does not mean—and this is one of the messages we’ll need you to help manage expectations—that every Walgreens in the country will be set up to enroll *All of Us* participants. We’re reaching different areas and different geographies and different communities, and, over time, as we see where people cluster, where we perhaps don’t have the mechanism to do a blood draw or parts of the protocol, we’ll come to town and open that up for three or four months.

So this network will both increase, but we’re never going to have 24-by-7, every-person-in-the-country coverage. I will tell you, with those direct volunteer partners that we have, we have the capability of reaching to where 95 percent of everybody in the country lives within a 25- to 30-minute drive or bus. But, again, we don’t have the funding to turn on all of that capacity at once. So we’re choosing areas based on strategic areas we’re trying to get to reach the diversity, but then, as we see where people sign up, we’ll come up and sort of pop up an additional capacity in those places.

And then on the next slide, we see some of the consortium community members.

## PowerPoint Slide 15, Current Consortium Members: Community Partners Network, appears on the screen.

## Mr. Dishman continues:

Some of them may be on the call today, with a wide range of focus areas with who they’re focused on and really helping to localize messages to specific communities and address head on both the injustices done in the past and the issues of immigration and privacy protection and all of those kinds of things that we have to speak very directly with people about.

## PowerPoint Slide 16, Summary: Version 1 of Protocol Currently Underway, appears on the screen.

## Mr. Dishman continues:

So I talk a little bit about the protocol. We’ll send you this slide deck, but the whole protocol is at allofus.nih.gov. This is kind of 1.0, the basic protocol that many researchers, many participants, many advocacy groups helped us figure out, “Okay, you’ve got to get started with the basic protocol, and then you’ll add different protocols every two to five years to expand the areas of science or into different diseases that the basic protocol doesn’t cover.”

So you see enroll and consent surveys, and, then, depending on both whether we have capacity near you and as we’re trying to achieve the different kinds of diversity, you may be invited to do physical measurements and virus samples as well.

## PowerPoint Slide 17, Updates on accomplishments & current status, appears on the screen.

## Mr. Dishman continues:

So that’s the basics of *All of Us*. Apologies for those that—some of you know it better than I do, and you’re so tired of hearing me speak that you’re like, “Eric, come up with some new jokes and stories.” But, for others, this is probably a first exposure. So let me tell you where we are right now.

## PowerPoint Slide 18, We are wrapping up a beta phase right now—about to launch nationally, appears on the screen.

## Mr. Dishman continues:

We’re wrapping up what’s been a controlled beta phase. We’re treating this like any other major launch of everything from a new car to a website that people use for banking, right? You’ve got to build it, test it, build it, test it. You do an alpha phase. And then you do a beta phase with a lot more people to prepare you for the national launch, which is happening very, very shortly.

The initial goal that we had for this beta phase was to enroll about the first 10 to 15,000 participants across our sites with the diversity to get feedback on all aspects before national launch. And that entails ramping over a hundred locations around the country slowly and carefully, week by week, so they start small. Then do a few more people, and then, once they got approved, they would expand their pieces. And I’m happy to say that we have exceeded significantly the beta goal. As of today, it was more than 40,600 participants who have started somewhere in that process—so they’ve at least consented, perhaps started their surveys or consented to share their EHR data—and already greater than 24,000 of them have completed that whole first protocol. So they’ve done, come in and done, blood samples and biospecimen measures and so forth.

And if some of you may be on the call who were participants who did this, you had to put up with, you know, some pretty primitive tools. And thank you for your patience, and thank you for the enormous feedback that you’ve given to have a very successful beta phase that has made things more ready for launch. And, as with all products, we’ve started with these sort of minimum viable products, and, as we get more feedback and as we get ideas from people, we’ll add lots more features and update those things as we go in time.

## PowerPoint Slide 19, Consortium accomplishments since May 2016 kickoff…, appears on the screen.

## Mr. Dishman continues:

So if I had to summarize it in one slide so you should understand the consortium is not quite two years old. We all met for the first time on July 6th in 2016; I should have said May 17 was the kickoff. The consortium was July 2016 kickoff. The beta phase began in May of 2017. So we all came together in July 2016, met each other for the first time. We had this great government report, but it was like, “Now how do we actually do this?” And to go from that to May of 2017 to start the beta phase—with real people, real protocol, real infrastructure, real partners set up around the country—I think is a pretty amazing accomplishment. I certainly couldn’t have done it any faster coming from industry, that’s for sure.

So, at this point, we have more than 115 health provider organization and direct volunteer sites enrolling around 18 states, expanding soon to about 25 states. That does not mean we have coverage in every aspect of that state. But you know we continue to sort of build and sort of see where people are who sign up and then can bring up that sort of burst capacity over time.

I mentioned the number of participants already, and then 73 percent of those are underrepresented in biomedical research. So this means especially focused on racial and ethnic minorities who have been left behind, socioeconomic status, as well as folks in rural areas, sexual and gender minorities. We are committed, and we are doing really well out of the gate. We all thought, “Okay, as we’re getting started, we might be 50 percent or less underrepresented in biomedical research,” but we’re kind of aiming for this, where it is now, and keep that stable as we scale up nationally, which is an enormous challenge.

In terms of participant-facing tools, all of those are well honed. So we’ve done the usability, the security, the bug bashing, the search testing, all of that still going on while we’re in this beta phase right now. You know, the support center is ready to help people. And then, you know, for those of you who’ve done studies like this, 1,800 pieces of collateral from videos to help it, help manuals for people who are digitally savvy, all of that in both English and Spanish, and getting the IRB group to approve all of that, that’s quite an accomplishment in and of itself.

The staff-facing infrastructure for all those sites around the country being tested and improved during this beta phase. The databank—so that’s a secure cloud repository that is already receiving electronic health record and survey data. The biobank at the Mayo Clinic—so I think, you know, we’re building the capacity for 35 million tubes, so it seems small to say that 710,000 tubes are already processed and frozen and stored. But I want you all to understand that this is real.

There are some people who have been very confused that our beta phase wasn’t with real people using real infrastructure and not getting real data. It’s all real. We’ve tried the launch before we’ve actually launched by making sure that these systems are working and data is flowing through and all the security tests that you would do. And then I mentioned that list of more than 25 community partners out there.

One thing I should say is, we are already working. We have working prototypes of the researcher portal infrastructure. So this will be what researchers from the general public to, you know, the researcher at a university or researcher at a company has. But like most of these studies, we’re not going to launch all of that until we have enough data cleaned and curated to be interesting. So think about that launch of the researcher portal in the first half of 2019. But we’ll already start doing some alpha and beta tests of that. So even that is real—it’s just not complete—and it’s going through all of that testing and infrastructure in that building.

So I’m happy to say we are on track for a launch that is coming Sunday, May 6. My team are not sleeping. The consortium is not sleeping between now and May 6. We’re going to do a press telebriefing for the details of the launch on May 1. If you’re press that are on the call today and you want to be part of that telebriefing, you can contact Alyssa Kotler. Her email is there as the head of our communications for the consortium and NIH on this program. You know, I was asked that, I mean, we’re trying to not make too much a big deal out of the date yet, but, you know, it’s out. We’re planning. All these sites around the country are going.

## PowerPoint Slide 20, Major parts of national launch to create “grass roots” awareness of PM & AOU, appears on the screen.

## Mr. Dishman continues:

And, in fact, I’ll just give you a little bit of a sense of what the national launch day on that Sunday is going to be like. We did it intentionally on a weekend with feedback from community groups around the country that “you need to wait until after church on a Sunday or a Saturday, which tends to be busier, so that people who cannot get off work can actually participate in these.” That’s why we’re also building the capacity for research participants to come in on Saturdays and eventually Sundays, for those who were never going to be able to get off during the week to go participate in a research study.

There will be seven key sites in different parts of the country with very different grassroots communities. They will be simulcast, and there’ll be an hour speaking that’s common across all of these online, so if you’re in a particular part of the country and you want to go participate in that event, that’s great. And there’s all kinds of speakers set up locally there, as well as a simulcast of some speakers who are going to be speaking across multiple sites. Community education fairs, health fairs going on, as well as our activation at those local seven sites around the country. At the same time those will be simulcast, at the same time there’s a Facebook Live program, but many more sites from around the country and both prepackaged as well as live footage coming in from researchers, from experts in different areas, from community members talking about why this is important there. And we’ll also be doing national and local print broadcast and social media strategies around that. So if it’s something that you want to try to help amplify this message up or get involved in, Dara’s team has been working with those, but you can contact alyssa\_kotler@nih.gov, and we can help coordinate some of those with you.

## PowerPoint Slide 21, Good progress on principles, policies, infra for Research Portal launch in ’19, appears on the screen.

## Mr. Dishman continues:

So there’s good progress on the principles and policies and infrastructure for research portal. One of the first questions I get from folks is, “When can researchers get the data?” I just talked about that. It will be the first half in 2019. You know the commitment and policies here that, again, that broad access that ties to that core value that we’ve had. So researchers from all sectors, from all conditions. It’s opening up to community colleges, to citizen scientists, and so forth so that we have a national resource that’s incredibly thorough, incredibly diverse, incredibly diverse data types, and is truly open to everybody.

There’s no first dibs for anybody; have at it all at the same time.

Researchers will get a data passport. While they need to describe each research project that they want to do in an open and transparent way for all of us to see, they don’t need to go through the pain of applying each time. So getting a passport allows them to get to the science faster, and a lot of that process will be very automated so, hey, we can do some credentialing, make sure that you’ve passed your visit, various quizzes, or not quizzes, but taking the commitment to the pledge of how you will and won’t use the data, some human subjects training depending on the level of controlled access.

There are three tiers of access that we’re working on: a general tier that you don’t even have to have a log-in for. The public can go to it, ask questions of, and there’ll be a bunch of questions already sort of prepackaged for them to sort of characterize the cohort: “How many people with this condition who live in the Pacific Northwest,” right, or, “How many women dealing with this particular condition?” So things that are at low to no risk, free of identification of somebody, will be in that public category.

The next layer up just has simply more risk, and then the next layer up beyond that has the most risk of re-identification—so things like your whole genome sequence data—and in all these cases, we remove, to the best of our ability, all of the identifying contact information to protect the privacy of the folks. I don’t think any of us who do research can claim that there is a 100 percent chance that nobody will be re-identified—so that’s why we try not to make that promise—but we are working with all the experts on algorithms and both human labor that go through to make sure that we could protect the identity of those participants to the best of anybody’s ability to actually do that.

In terms of the data, it is stored and used in a secure enclave in a public cloud. It can’t be downloaded; the researchers go to the data. People really get worried about that because they’re like, “I won’t be able to bring in my own data sets, or you won’t have enough computing power.” There will be enough computing power, and we really need to do this to adhere to our promise of protecting the privacy of our individuals. But it also creates a lot of other possibilities where we can make it very easy to put the common tools that all researchers use into this environment, optimize them for it, and they’re just going to be there, but also make it easy for them to pull in their own data set because they want to do analysis going forward. There’ll be a whole lot more about that later.

The main message I want to get across to you is the approximate timing and to understand that that’s not just PowerPoint, there’s real prototypes of this happening now. But, as often many of you have your either your own cohort or your own patient registry, it takes time to collect the data, validate that data, and clean it and curate it so that researchers can get right to the research and not spend a bunch of time trying to figure out whether or not the way that this site refers to this disease and the way that this site refers to this disease aren’t the same thing. That’s part of the cleaning and curation that our Data and Research Center at Vanderbilt, Google Verily, and the Grove Institute take care of.

## PowerPoint Slide 22, Vision: Towards the end of cohorts as we know them?, appears on the screen.

## Mr. Dishman continues:

So let me switch now—I mean, this is a lot to sort of take in, but I want to make sure that we’ve got the time for some interaction and some questions. Some of you may have seen this before and some of you have not, but I ultimately hope that we get to the point where we are at the end of cohorts as we know them. And I mean no offense to anybody by this as I sort of go through this, this is an Eric’s way of thinking about things. It’s not an official NIH position, but it’s like my vision is to, like, let’s end cohorts as we know them.

## PowerPoint Slide 23, Stage 1: Era of Individual Study Silos, appears on the screen.

## Mr. Dishman continues:

And what I mean by that is, you know, if you’ve been looking at the past of research, we have had a lot of little era, the sort of what I call Stage 1, the era of individual study silos, right? Small studies of a hundred people or thousands of people often done in isolation and, you know, somebody over here in this part of the country doesn’t even know that this part of the country was doing the same kind of study or collecting the same data. For the most part, I think we’ve moved beyond that, but there are parts of us that are still in this era of individual study silos. They may have sample sizes a lot larger than those numbers.

## PowerPoint Slide 24, Stage 2: Era of Competitive Consortia (larger silos?), appears on the screen.

## Mr. Dishman continues:

If you think about it, people started finding each other, right? And we had this sort of era of competitive consortia. So these five academic centers and these two hospitals and this one insurance company came together and formed a consortia, and this helped them boost their sample sizes. Wow! We have tens of thousands of people with data that we can look at, maybe into 100,000 people’s worth of data. And that was great that they came together, but they often, not always, created another silo. It was a larger solo, but it was only for the people that were in their sandbox, and they still weren’t sharing that data necessarily with other consortia outside of that.

## PowerPoint Slide 25, Stage 3: Era of Large Cohorts? (some as silos, some as national resource?), appears on the screen.

## Mr. Dishman continues:

Now I think we’re kind of entering into this era of where you add to that last era, this era of large cohorts, and some of these large cohort studies are also silos only available to select researchers or people who were, you know, involved in it, and others, like ours, are going to be a national resource open to everybody, and many of these have gone before us. We are learning from lots of the other large cohorts that are out there, especially MVP, the Million Veterans Program. They are partners of ours. They’re going to be recruiting people from that particular cohort; they already are—they want to come and see if they want to join the *All of Us* program as well.

And when you get these large cohorts—I mean, there’s not a ton of them out there that are going for a million people like we are, but there’s many of them out there, and there’s some like the Million Veterans Program that started 5 to 10 years earlier than we have. And, of course, they’re well ahead of us in terms of the total number of people that they’ve reached and being able to start to do science on that because they started a long time ago. Very few of them are focusing, if any of them are focusing, on the diversity of people and the diversity of conditions that we’re trying to do, and certainly very few of them are making this open as a national resource as soon as the data is ready to actually do that.

But I worry that some of those are still too many silos and, quite frankly, particularly for those of you who may be on the call focused on particularly rare diseases. A million people for the *All of Us* is great for a lot of research questions, but there are going to be lots and lots of scientific questions that a million people is not even close enough to actually answer.

## PowerPoint Slide 26, Stage 4: Era of “America as a Cohort?,” appears on the screen.

## Mr. Dishman continues:

And that leads us into the era of what I think we’re all trying to get to. What if the sample size is the entire population of the United States or, at least, the entire population of the United States who is willing—and we’ve made it easier to decide if they want to choose—to share their data with research purposes, right? It’s America as a cohort, as opposed to all these individual cohorts, or, even better, get the universal cohort representing the entire world.

## PowerPoint Slide 27, Stage 5: Era of a “Universal Cohort” (no silos? no cohorts?), appears on the screen.

## Mr. Dishman continues:

Now this is a long vision off, but if we don’t start working on the policies and the procedures and the technologies to facilitate this, I think we’re going to get larger and larger silos, but never be able to get a sample size of a billion people to go study and understand how do we deliver better care, better prevention, better quality of treatment, to people. So to me, in many ways, the *All of Us* Research Program is starting to try to pilot some of these issues that scale up so that we can more quickly move to this era of a universal cohort or, in some sense, there’s no cohort, because we’re all part of it.

## PowerPoint Slide 28, End State: what many people call a “learning healthcare system,” appears on the screen.

## Mr. Dishman continues:

And for many people, that’s what we often call “a learning healthcare system,” right? We’re doing scientific discovery on a huge number of people because we’ve got so much data we can start to make faster progress. We’re putting that into translation very, very quickly and in studying the effects of that and tweaking that and going through that whole lifecycle of research and discovery and translation much more quickly. So we’re part of that. We’re by far not the first nor the last of those large cohorts to do that, but that’s the vision that I think we’re at least trying to contribute to, and that’s part of the conversation. I plant this vision with you because I think many of us are like, “We still don’t have enough people even with these larger sample sizes.”

## PowerPoint Slide 29, How do we begin to achieve that kind of vision?, appears on the screen.

## Mr. Dishman continues:

How do we get bigger, and how do we get more robust statistics and statistical power?

So I want to close in this section and then we’ll open it up for questions that Mary, the operator, will help us moderate here.

How do we begin to achieve that kind of vision? And again, like, I’m probably being a little bit premature. I probably should be sitting down right now making sure that everything is perfect for our launch, but I’m like, hey, we’re getting close enough to this that I want to give you an update and start planting some seeds, because I need your help to think about where are groups of disease organizations coming together to already solve the EHR problem or who, you know, collectively are working on some of these things. And how do we lend our voice to those and our resources to those, but join things that are already there as opposed to go create the wheel?

## PowerPoint Slide 30, First, Build an Evolving Public Resource that Grows / Generates Lots of Studies, appears on the screen.

## Mr. Dishman continues:

So as I think very specifically about folks on this particular call, I think there are several ways in which we can start to build that. So first thing I want you to know is—and, you know, we just held a research questions workshop and I’ll talk more about that in a moment—and, you know, no matter how many people we invite, there’s people that are left behind. I want people to understand that the *All of Us* Research Program, we’re in the first tiny steps at this national launch on May 6 of what’s going to be a 50-, 60-, or 70-year journey.

We’re focused on the first 10-year plan because anything beyond that is pretty science fiction except for some of the scientific design. But, you know, think of it as this is our version 1 platform and protocol, and we’ll be working with people to develop the version 2 in a few years and version 3 in a few years, depending on the scientific questions and the funding available to do each of those releases.

And we’re doing some pilots already to sort of figure out, like, we’re going to be doing a very large pilot with 20,000 people later in 2018. So on the responsible return of genetic information of the first 20,000 people with both whole-genome sequencing and genotyping data—some will have one and some will have both—and compare those. That’s to help us and we’ll share that data with anybody else, learning on how you actually scale up the responsible return of information, how we are going to deal with the shortage of genetic counselors that are the reality in the country right now.

So some of these are pilots that we will do. But the whole purpose of our program is for people to come to us and say, “We want to fund a pilot on this leveraging your resource” or “We want to do an ancillary study on this.” And before we get to big ancillary studies like everybody that, like, somebody may want to come and say, “We want to do an ancillary study on everybody with, you know, a background with depression and reach and have you reach out to see if they’re willing to participate in an ancillary study.”

Well, we’re probably going to want to do much smaller piloting studies of some of those kinds of things that people may come to us and say, “Hey, we want to fund a pilot study on this on our way towards a larger ancillary stuff.” So some of you, when we open the researcher portal resource, will be working and say, “Hey, we just want to run secondary analysis on all the data that you’ve got.” That’s great. And others, when this is a mechanism that we are working on, they might come and say, “Hey, I want to do an ancillary sub-study. You know, we’ve got the funding from this particular foundation.” And we’re inventing that process of how we’re going to go through all of those and figure out how to handle those and that will all be part of the researcher portal launch.

But my point here is we have a long way to go together, and, if your particular needs and requirements aren’t in there yet—and there’s never a guarantee we’ll get them all—it’s not too late, because you’ve got to start with a basic minimum viable product and a minimum viable protocol and then add to it when the user needs and scientific needs are better understood.

## PowerPoint Slide 31, Second, Develop an Iterative Process with Others to Work on Shared Roadmaps, appears on the screen.

## Mr. Dishman continues:

So similar to that I think the second thing that folks can do is really start to develop—that we can develop an iterative process with others to start to work on shared roadmaps. I want the people who are in cardiovascular conditions, like we’re right here in V1 about to launch right now and we’re in production. We need the ability to start working on version 2 that may not come out for 3 more years and version 3 that may not come out for 5 to 7 years.

So let’s say that several of you on the call need—I’m going to make it up, you know. Wow. If you had robust capture of blood pressure information much more frequently and it’s not done with a cuff, well, how long is it going to be before the technology is there for that? And we jointly plan and say, “Look, this is a game-changing data type we’ve never had access before.” How can we jointly work on getting some of these things that are further out in time not only available for the *All of Us* Research Program, but across multiple studies, because we’re going to be accelerating and advancing the science as we go through that.

So I don’t want to create the *All of Us* roadmap in isolation. You know we haven’t been, but it needs to be invented and developed with the rest of the NIH institutes who have been intimately involved, but also the research partners, many of you who are on the phone. So let’s get started thinking about these releases and when are you going to release something, and maybe you’ll be the first one that tries out this new method or this new data type and the rest of us learn from you. Oh good. *All of Us* is going to go try that first, and you can actually learn from us as we go forward.

## PowerPoint Slide 32, Third, Be Requirements Driven (e.g., recent Research Priorities Workshop), appears on the screen.

## Mr. Dishman continues:

The third thing is to be requirements-driven. So these are pictures from the *All of Us* Research Priorities Workshop we held a few weeks ago. Many of you on the call were there. And part of this was an experiment for us to figure out how do you take requirements-gathering activities that industry uses all the time and apply it in NIH, *All of Us*, in a research environment. So it was really a big experiment to say, “How do we actually do this?” And I’m thrilled that both before and after there were over 13 hundred use cases.

So a use case is basically a story of a kind of research question somebody would like to answer, drill down into the specifics: Here’s the kind of research questions we would want to answer, but here’s the kind of data that we would need to do that, and here’s the specific ways we would need to capture that data. And we’re synthesizing all of those needs and we’ll share that back out.

Some of you I think will find it really helpful if you’re focused on cardiovascular disease, and we will, you know, you’ll be able to look at all the use cases that were submitted by individuals and organizations and institutions, as well as the analysis of that, and say, “Wow, there’s some really new kinds of research questions around cardiovascular disease that people are really eager and interested in answering.”

## PowerPoint Slide 33, (Thank you to the many advocacy organizations who provided requirements!), appears on the screen.

## Mr. Dishman continues:

So thank you. This is just a short list of some of you who were in attendance—of those, so many advocates of the advocacy organizers were there in person. Many more provided use cases beforehand and, once we get through national launch, not only will we be sharing all of that analysis out, we’ll be doing more workshops on specific topics. We’ll be doing more over the years, general workshops, of let’s just collect a whole ‘nother round of use cases from people. So it’s just the beginning. It’s not the end of all of these as we go forward in time. And you can see the variety of conditions and organizations that are already feeding into the scientific use cases.

## PowerPoint Slide 34, Fourth, figure out how to drive “franchising” and cross-cohort collaborations!, appears on the screen.

## Mr. Dishman continues:

And the fourth and final way that—I suspect there’ll be some specific questions around this is—like, “Okay, Eric, we are a disease-focused organization. Like, what do we need to do to intersect with you?” And, you know, you may be a rare disease group and it’s like, hey, we understand that you can’t recruit all people with a particular rare disease that we have or that the national incident rates of people who signed up will be too small.

Well, one of the things that we’re trying to explore is what I call sort of a franchising model. And we’ve already had some groups come to us and were just like, “We want to do this at some point; we’re just not ready to do it.” So let’s just say, first of all, how do you help recruit people and get them into the *All of Us* resource?

But also let’s say you come and say, “Hey, we’ve got funding from a philanthropist or a foundation or NIH, and an NIH institute wants to do it on a specific disease. Can we figure out how to leverage the protocol that we have, the data properties and the platform that we have?” And instead of a million, it’s a million and 100,000, and that 100,000 is a specific cohort that you’re funding, but we’re doing it in a way that it’s completely comparable to the all million people that we get. And it may have some additional measures that you want to capture on those 1 million or 100,000 that we could never afford or practically be able to execute across a million people. So this is what I mean by a franchising model.

And then the other piece of this is a bunch of larger cohorts from around the world met at an event at Duke last month to start exploring this, both large and small, these cohort programs. How do we start sharing instruments across so you can more easily compare data across those? How do we, you know, make it easier for people to have access to folks with their rare disease that are in *All of Us* and VA and the UK Biobank so that they have a bigger sample size with which they can do it? So it’s partly a direct collaboration amongst the cohorts, but then it’s also opportunities to say, “Okay, we know that a lot of people want to be able to compare to this million people.”

How do we help you conduct your study in such a way that it’s going to be very comparable and, in many cases, even leveraged infrastructure that we’ve got at cost so that you can actually scale up on your own without us necessarily doing all the pieces for you?

So those are vision, and we’ve thought in more detail about what we have here today, but I just wanted to lay those out for you as we think about it.

## PowerPoint Slide 35, Key areas of collaboration with the advocacy community, appears on the screen.

## PowerPoint Slide 36, Am starting to be able to look beyond national launch to key collaborations, appears on the screen.

## Mr. Dishman continues:

So lastly, three kind of areas that relate to this—if I go back to that slide where I took our mission and I asked you a series of questions around each of those, you know, I think there's three opportunities for those that are research and disease and new patient advocacy organizations with us—continuing to help shape the science, that means identifying use cases and gathering requirements.

You know, if you’re an organization that comes to us and says, “Well, we don’t really know what we would want your million-person study to study,” that’s not very helpful. If you’re an organization that comes to us and is like, “Hey, we’ve done our own strategic planning, and we know very specifically some kinds of things that we think are affordable and scalable at a million-person scale,” that’s a whole different conversation. If you come and say, “Look, we and three or four other disease organizations have some common needs that we all need for data at a large scale, so if you put this in the cohort for a million people, you’re going to impact this disease and this disease and this disease,” even better. Like, that’s the process that our workshop was hoping to try to get to. But the more you can think that way as well, it’s like, “Okay, how can you advance your scientific area?” But the things that you need—what other scientific areas is going to advance? I think the more we all think that way and act that way and collect the requirements, the better.

The second is, please help us grow the cohorts. If you are willing, please do invite your members to join. Please invite their family members. Get the word out. You know, help other people; help us manage expectations.

There’s a lot of people, you know, even in the tech press who don’t understand that—let alone participants—who don’t understand the difference between, you know, a consumer genotype type that you get, but you bought a kit for Christmas, versus the whole-genome sequence. We all benefit from educational collateral that helps to educate the community that we’re trying to reach about expectations management around these things.

And then, lastly, it’s back to that ecosystem. How do we work together to bring your ecosystem of funders and researchers to leverage the resource once those things are actually in there or once just by natural recruitment? You know, “Look, holy cow, they have 180,000 people who have had this particular injury and recovered from it,” right? So that’s the challenges that I see as we go through in time here.

## PowerPoint Slide 37, Help shape the science by knowing & sharing your requirements, appears on the screen.

## Mr. Dishman continues:

So help shape the science—you know, where do you think the biggest breakthroughs of a billion-person diverse resource can help accelerate the science in your area, all the way down to, you know, what are the subset studies or ancillary studies that you can imagine can do this.

## PowerPoint Slide 38, Help grow the cohort by getting word out & helping to manage expectations, appears on the screen.

## Mr. Dishman continues:

Help grow the cohort by getting the word out. I’m not going to go through all these, but these are some of our message challenges. I suspect some of you have had the same—I mean, the first two or the second is pretty unique to us. “Hey, we’re open for business!” You don’t need a special code to enroll anymore after May 6. But, you know, the promise of electronic health records. But the challenge of pulling all that together from an individual that’s holistic and complete toward the challenge of genomics and those kinds of things.

## PowerPoint Slide 39, Help woo an ecosystem to leverage this national resource in your domain, appears on the screen.

## Mr. Dishman continues:

And then, lastly, that ecosystem. And the way I tend to think about ecosystems—here’s your organization, whatever it may be, and, you know, are there institutes and centers at NIH that are partner organizations of yours already? You have relationships that have existed with them long before the *All of Us* Research Program ever existed and that sits within a body of NIH-funded research, which is the largest biomedical funder in the United States and arguably the world.

But then there’s other industry and foundation funders and commercial funders that you know about in your particular area that need to be part of that ecosystem map and part of that equation, and all of that’s embedded with the participants and stakeholders around your particular area that you probably, better than us, will always be best at sort of reaching out to and knowing their input and figuring out how to get that participant voice in there.

So that’s what I mean by kind of wooing an ecosystem and figuring out how do we coordinate between what you’re doing, what we’re doing, the priorities of those different organizations, and look at these for some common ground where we can scale up and have impact much more quickly than any of us alone could ever do by ourselves.

## PowerPoint Slide 40, Thank you, appears on the screen.

## Mr. Dishman continues:

So that’s the Dishman sermon today. I hope it was helpful. And I’ll just now invite the operator to just come back in and help us through the Q&A process. And then let me also ask the operator Mary, or anybody else who knows, for questions we don’t get to today, is there a mechanism by which people can be typing them in so that those are collected for future follow-up?

## Mary:

Absolutely, thank you, Eric.

We will now begin the question-and-answer session. If you’d like to ask a question, you may press star followed by the number 1. Please unmute your phone and record your name clearly when prompted. Your name will be needed to introduce your questions. And to cancel your request, you may press star followed by the number 2. Let’s wait for a moment for the first question.

At this point, there’s no questions on queue. Once again, participants, if you would like to ask a question, you may press star 1.

## PowerPoint Slide 39, Help woo an ecosystem to leverage this national resource in your domain, appears on the screen.

## Mary continues:

For other participants, you can also type in your questions on the WebEx. In that way, if in case your question will not be entertained, we can print it out and send it to the leaders.

Just a moment, please, for the first question. Eric and other speakers, we have our first question from Margaret Anderson. Margaret, your line is open.

## Ms. Anderson:

Yes. Hi Eric. Thank you so much for an amazing presentation. My question is about those research use cases. Can you talk a little bit about how the *All of Us* program and cohort will collect those examples as they start to kind of roll in? How will you kind of put that back out to the community to inspire even more research to be done, so each day it starts to happen?

## Mr. Dishman:

Yeah, it’s already started to happen. So we had opened an online platform even before we had our research priorities workshop, and there were already 800 use cases that people submitted. So it explains what a use case is. It gives them examples of them. I think there’s even a video of me talking about, “Hey, specificity is important.” And so we opened up that platform, sent out the word to everybody that we could find, and they gave advance before we even had the workshop. And then in the workshop, we invited participants and groups and scientists in different areas to come together and generate another 500 use cases. So we’re analyzing those now, and we’ll just put all of that information out, and we’re working on the platform to put a bunch of that back out so people can even comment on those that we’ve already generated.

Meanwhile, we’ll use likely that platform. I mean, none of these online platforms serve exactly the needs that we have. So we’re looking at, like, “Okay, how do we do this in an ongoing way,” but it’ll be a similar kind of process where either at workshops that are co-present and through online, people can submit those use cases, and then we’ll always sort of, you know, feedback out both the raw use cases as well as the analysis of the use cases. What will happen later this summer from those that we collected a few weeks ago is that there were already themes that were emerging within the workshop on the third day of the workshop and from those that were submitted beforehand, and we’ll be doing some follow-up on those particular themes with much smaller groups.

So, for example, well, let’s just stick with the blood pressure example I gave before, right? But there are, by the way, devices that already are used mostly in intensive care units to collect noninvasive blood pressure without a cuff. They’re called “time of life technology.” Let’s just say we needed to get smart about that particular area and understand, you know, “Okay, if we use these devices, collect blood pressure from folks, is it going to serve everybody’s needs? Or are there fine details in that data capture methodology that folks of cardiovascular risk?” We would need a different instrument there. It’s not a great example, or, you know, we may dive in into a particular workshop that’s around. Okay, those of you with all these great mental health use cases, we didn’t get a sense of the best priority out of all of those use cases. Can we open up the online resource and do a workshop that’s going to help us get better priorities? So the follow-ups will be as needed on all of those kinds of things.

## Ms. Jin:

So we also have some questions that have come in through the chat, which I would be happy to read if that would be helpful this time.

## Mr. Dishman:

Yup, go for it.

## Ms. Jin:

Ok. So someone on the chat asked, “What is the current thinking about including children and individuals with disabilities in the cohort?”

## Mr. Dishman:

So we have a Special Populations Committee within the consortium with expertise from all of these different areas and participants who are working through a series of more challenging or vulnerable populations and special populations who, right now, as we nationally launch and throughout the beta phase, we’ve been open to 18 and above; no other criteria beyond that other than the need to be able to do self-consent.

We have worked through a plan with a tribal working group and are working through a plan with regards to tribes. The furthest one along is the children’s working group. There’s a national report that they put out already with some recommendations or some opportunity areas, and then the consortium has taken that. And what I can tell you right now is, in fact, the Steering Committee just voted on this: We needed to break children up into segments. So the first segment that we’re going to focus on is 0 to 6, because what you can do that is enough variety of ethical and practical challenges of 0 to 6, but those are very different than inviting teenagers, for example, to be part of it. So we’re focusing especially on 0 to 6 right now, but there’s another subcommittee that’s looking beyond that, and we’re aiming for, sort of, the summer of 2019 to start enrolling children. But we’ve got to go through the whole process of getting the protocol written, feedback from different stakeholders, seeing if it’s affordable and doable at scale, and then, you know, getting the consortium to vote on it once we’ve sort of gone through those rounds of doing that. But they’re making great progress on that, and it’s obviously a commitment from the program to do that.

## Ms. Jin:

Great. We have another question that says, “What age range will be included in the version 1 platform?”

## Mr. Dishman:

Say that one more time.

## Ms. Jin:

The question was, “What age range will be included in the version 1 platform?”

## Mr. Dishman:

Yeah, so right now that’s related. So 18 and above is what the current protocol is focused on.

## Ms. Jin:

So, we have another question, and I realize this might be for Dara, which is, “Are there ways that community organizations can get involved in the launch activities in the seven sites or the Facebook events?”

## Dr. Richardson-Heron:

Yes, absolutely.

## PowerPoint Slide 41, Engaging with All of Us, appears on the screen.

## Dr. Richardson-Heron continues:

We would love for everyone to sign on and support our launch.

## PowerPoint Slide 42, All of Us Research Program Core Values, appears on the screen.

## Dr. Richardson-Heron continues:

If you haven’t already been in touch with one of our engagement counselors, we would love for you to be in touch with Kim Cantor, or you can reach her at [kim\_cantor@hcmstrategists.com](mailto:kim_cantor@hcmstrategists.com).

## PowerPoint Slide 43, Underrepresented in Biomedical Research: Build Trust, Be Authentic, and Create Value, appears on the screen.

## PowerPoint Slide 44, Engaging at Launch and Beyond, appears on the screen.

## PowerPoint Slide 45, Community Resources (JoinAllofUs.org), appears on the screen.

## Dr. Richardson-Heron continues:

We have a myriad of ways to get people involved in our program, and we would love to have many community organizations work with us to help get the word out about our launch and beyond. So please again, kim\_cantor—C‑A‑N‑T‑O‑R— @hcmstrategists.com.

## PowerPoint Slide 46, Questions, appears on the screen

## Dr. Richardson-Heron continues:

You can also go to our website, joinallofus.org. We have a few community resources that you can utilize to actually share with the members of your respective organizations so they can learn about the program and also serve as ambassadors for the work that we’re doing.

## Mr. Dishman:

And in fact I realize I screwed up. I was supposed to hand it back to Dara to go over exactly those things. So, Dara, if there’s any slides that you want me to pull back up—I was so relieved to being done with my talk that I kind of forgot where we were—so if there’s anything you want me to pull up, just let me know.

## Dr. Richardson-Heron:

Oh, you absolutely—you read my mind, because the most important thing is for people to be able to answer and ask you the questions. So you did perfectly as always.

## Ms. Jin:

And I see there are a couple of questions from people on the phone that are in the queue, so Mary, if you wouldn’t mind prompting the next questioner.

## Mary:

Thank you so much. Yes, we have our next question from Mr. Fred Stevenson. Fred, your line is open. Please go ahead.

## Mr. Stevenson:

Hello, I have about three questions: Where would the samples be stored, and who will have access and how?

## Mr. Dishman:

Yeah. All of the samples—so our biobank is a ward at the Mayo Clinic. The majority of the samples are stored in the biobank there. They do a certain amount as back-up in case, you know, freezers went down or electricity or a major catastrophe at one site, and they’re working on another backup site which is sort of normal large-scale biobank process. So all of the samples are shipped within 24 hours from around the country to the biobank. It’s challenging to do that, particularly for the West Coast just with the number of flights and courier routes very limited later in the day. So we’re still struggling with some of those time windows but continuing to focus on that.

Right now, our committee is working on access. They’ve started with data access. So we’re very clear and know what our approved data access policies are, they’re starting to work on access to samples as well as access to the cohort itself, which will be certainly part of the resource, so the way the aliquots of blood have been done and the samples with urine have been done is divided up in lots of ways, anticipating people making requests of those samples. We’re not ready for that. It will likely be after we launch the research portal in the first half of 2019, but by then we’ll have a lot more clarity about the policies that we can do that we’re really set up to facilitate and allow a lot of ancillary studies. But, as you can imagine, those are precious resources, so trying to sort through those, you know what—“Okay, what’s going to be the criteria that we’re going to use, and how are we going to decide how much we need to save for far future research that we can’t anticipate now versus go ahead and let folks have access to it?” Those are some of the issues.

We’re also sorting out right now what our first assay will be that we run and that we can try to afford to scale on all million people. We will be doing a pilot of that and there’s been lots of input sessions on that. So we’re trying to get certain amount of assays on the million people that we pay for and go ahead and do, and then that would help limit some of the cost that future folks need to do with regards to particular sample runs that they wanted to do.

## Mr. Stevenson:

Thank you. And then my last question was about whether or not—I’m sure they’ve been there, but the electronic health record companies, have they been at the beginning of this initiative and have partnered to provide mature tools to support the initiative.

## Mr. Dishman:

Yeah. Now I’m glad you asked that. I mean, I think a lot of people in the country still don’t understand that the challenge of getting thorough and holistic and longitudinal electronic health data both for us as patients—I mean, I struggled with it just to get through my own clinical trials—and then for research is still a big challenge.

So I’m happy to say that one of the pilots that we’ve been—that’s literally starting this week or next week is what we—a program that we call Sync for Science, and it’s five of the major electronic health record vendors who’ve been working with us from the beginning to develop an API, a programming interface, that make it relatively easier for a patient to go into their portal, if they have one provided by their provider, and say, “I want to share this data initially with the *All of Us* Research Program.” But everything’s been designed in a way that—our whole intent was like, “Let’s try to build this tool; we’ll test it on *All of Us*. We get it working, and then this is available.” So they’ve been fabulous at that.

Those pilots are starting at 13 sites, and those pilots will run between April and around July, and then we’ll be able to stop and look and say, “Was it technically doable? How did different patients in different parts of the country do it, managing to go in and give the authorization? Were there any things that need to be fixed?” And then we’ll probably have what I call—my boss used to call a success catastrophe. Assuming it’s successful, we’ll have a catastrophe trying to figure out, “Okay, how do you—how do you make this available to everybody?” Hopefully, all of those EHR vendors will just add that capability into their regular EHR updates. You know, over a year or two, those updates would just be there. And then it’s a matter of—and this is one I think we’re going to have to meet with a bunch of you about, you know, the *All of Us* program.

It all sounds big, but we’re not even like a large NIH or a startup team with a consortium. How does the larger NIH, as well as lots of other funding organizations, come together so that once those APIs are out there, people can tap into them and program to them and say, “Hey, now there’s a choice to send your data to this study if you want to and to do this study.” So I’ve got lots of hope for that pilot and it looks very promising, but, as with all things, let’s test it first and then, if it’s successful, we’ll figure out how to scale that out.

The other thing that we’re doing is we will be doing some pilots of other approaches of collecting electronic health record data. So right now we’re receiving health EHR data from those health provider organizations who are part of our consortium. In fact, when they applied, they had to show that they could send the data over in a standard of the initial data types that we were trying to capture. So that’s happening right now.

But for a lot of the folks, especially on launch day, who will come in and they may not be associated with one of those, it will be programs like Sync for Science or some of these other areas that we’re piloting right now, like what’s called an aggregator approach. This is incredibly expensive to do. There’s no way we can afford to do this for a million people yet, but we’re going to go ahead and pilot that with like 15 to 25,000 people who aren’t affiliated with an HPO to see how good that data is and what you would need to do over time to reduce that cost so you could scale it up.

So I think one of the contributions we’ll be making to the field over the next year—yeah, you’ve got to wait for a while for lots of data to build up before you’re going to accelerate massive scientific breakthroughs. But I think we’re going to learn very practical things in the next 18 months from these pilots of different approaches comparing the value of EHR data that you get by these different methods that hopefully will help *All of Us* learn and move that forward.

## Mr. Stevenson:

Thank you.

## Ms. Jin:

Thank you. Mary, could you prompt the next person who has the question by phone?

## Mary:

Thank you. We have Rosanna Watervich. Rosanna, your line is open.

## Ms. Watervich:

Hi there. Thank you. This is the first time I’ve heard about the *All of Us* research in a presentation. So I’m happy to see it. I’ve done research before with NHANES secondary analysis, and I’m just curious how the *All of Us* program might interface with NHANES or potentially combine with NHANES, if this will be kind of redundant to what they’re doing or what that will all look like.

## Mr. Dishman:

Yeah, and we’ve certainly been engaged with them, and we are trying to not invent anything that we don’t have to, so even those three surveys that are out there are primarily NHANES instruments, but, because we are pushing for a level of diversity in pushing for a sixth-grade and then a fifth-grade reading level, we’ve had to take a lot of those and other accepted instruments and develop simpler questionnaires and then test those before we actually rolled those out.

So I mean we’re certainly not redundant with what NHANES is doing. I mean, they’re doing very different things than we are. But figuring out with them how we can continue to lower the literacy level of these instruments and then leverage data that they may even have eventually on some of the same people. I mean, those are conversations that we’re certainly having, but right now, we just focused on, “Okay, let’s get those first survey instruments out there.”

It’s kind of like a general health sort of basic demographics, but we’re already working on some on, for example, medication. And in all these cases—in some cases, as many of you who are parts of organizations have let us know about instruments, and I think you probably all know this but it’s worth saying out loud. I mean, there’s no way that we can create so much participant burden. And we’ve probably had requests to put in 150 different survey instruments already, and we can’t do that right for our participants, especially those which are focused on all million people.

I think the point that we’re going to get to is both how do we insert some of the key elements of some of these instruments and instruments that are more manageable from a burden of both analysis and to the participant. But, at the same time, this will be part of the process as we figure out how to do it if somebody coming to us and says, “Hey, can you send our depression scale instrument to, you know, 2,000 people with these particular criteria?” That’s exactly what we’re being set up to do. Of course, you know that’s going to need the researcher portal and all of that which, again, is in the 2019 timeframe or the first half of 2019 to do that.

## Ms. Watervich:

Thank you.

## Mr. Dishman:

Yup, thank you.

## Ms. Jin:

So, Eric, we will take a couple more questions from the chat. The first one is, “How do we find out what diseases are in the database?”

## Mr. Dishman:

Yeah. So it’s a point in which we open up the researcher portal, you’ll be able to—there’ll be basically a sort of cohort builder tool that you can use to go in and just, you know, sort of ask those basic questions. In fact, much of that will be the public part of the dataset that you don’t need to log in. You don’t need any credentialing to do to just run what’s in there kinds of analyses. And we’ll have a bunch of those analyses already set up for people to try to make it easy for them.

So once we launch the researcher portal next year—I mean, I’ve challenged the team to say, “Hey, if you could pull in when we launch the public part, it doesn’t need all of that extra credentialing and tracking of, you know, somebody, whether they’ve taken their online training or not around human subjects.” We might be able to do some of that earlier. But that’s when it will really start to take place is when the researcher portal launches.

## Ms. Jin:

Thank you, Eric. Another question that we have is, “Is mental health included?”

## Mr. Dishman:

Yeah. Okay, now I’m going to confuse myself on this one, so any of my staff listening can help.

Initially, what we’re drawing—we’re going through a lot of effort to help people truly understand what may be in their EHR, so when you go through our consent process, some people are complaining about how long it takes, but it’s like we are truly trying to aim for a level of informedness that a lot of studies don’t have.

I’ve given both my genetic data and my EHR data to lots of studies, and pretty much what they said to me about my EHR data was like, you know, “Will you authorize us to use your EHR data?” And we’re trying to be much better than that and show people that it’s like, “Hey, there may be what you think of as stigmatizing things from mental health, from substance abuse, and all of those.”

So we’re not, unless anybody on my team corrects me, we’re not pulling any of that information yet in the initial draw from what we’re pulling in is the basic information from the EHR data. We want to get there. And this is, again, it’s kind of like some people are like, “Well, why haven’t you started whole genome sequencing out of the gate?” Well, first of all, there’s not enough capacity in place. The cost hasn’t come down enough, and there’s not enough genetic counseling available to support our needs yet. We’re working with partners to facilitate all that.

But in these areas, particularly where stigmatizing research or the challenge of genomics, we wanted to get enough participants in our actual data phase, and that’s more than 40,000 people in the process and 25,000 of them or so having finished it, we have that to start getting their feedback about what’s the right way that we should handle the pulling in of mental health data or the responsible return of genetic information, and that’s helpful now to have not just proxies for people that may end up being a participant, but actual participants being able to help us do that.

## Ms. Jin:

Thank you. I see that we have another question in the queue by phone, so let’s go ahead and take that. But Mary, can you also remind everyone if they do have a question they want to—they want to bring up by phone how they would do so?

## Mary:

Certainly, thank you. Again, once again, participants who would like to ask any questions you may press star-zero—I mean, star-one on your phone. Now, if you would like to chat questions over the WebEx, we can definitely do that and send the questions over to Dara or Eric Dishman so they can answer it to you via e-mail. Once again, star-one for any participants who would like to ask a question.

Now we have Michael Weiss on the phone who would like to ask a question. Michael, your line is open. Please go ahead.

## Mr. Dishman:

Michael, are you on mute? Michael, we’re not getting your question. Or I’m not. I will make sure I’m still on now. Now I’m nervous that I’ve been dropped off.

## Ms. Jin:

We can still hear you, Eric.

## Mr. Dishman:

Okay, all right.

***Crosstalk.***

## Mary:

Michael, this is Mary, the operator. Kindly check if your phone is on mute.

## Ms. Jin:

Let’s go to the next question.

## Mary:

Okay. Thank you. We have Antonio Garcia from University of Texas. Antonio, your line is open.

## Mr. Garcia:

Hi. Hello, everybody. My question is, do you guys really have any genomic data?

## Mr. Dishman:

No. The genomic data—we’ll start collecting genotyping and whole-genome sequencing later this year. There’s a Notice of Intent out for our genome centers that talks publicly about what our plans are, so we are planning to do both genotyping and whole-genome sequencing data capture. But as I mentioned a little bit before, we’re going to be doing a pilot of how do you responsibly return that information to people with 20,000 people that will start later this year and go into 2019. So it’ll be towards the fall and winter before those awards are awarded.

We’ve tested all the pipelines. We’ve got our return of information, different things that we want to try to compare, and then that gets going late this year. It will really take into ‘19 and 2020 before those things ramp up to scale up of like 200,000 samples per year.

## Mr. Garcia:

Okay. One more question. Do you have any funding mechanism for institutions that already have set record of genotyping publications?

## Mr. Dishman:

No, not really. So it’s important that everybody understand. We made a strategic choice, and this was the recommendation by the original group that said, “you know, here’s the instructions and setting this up.” We either we’re going to start fresh with the whole new cohort from day one and collect the same data on all million people to the degree possible or we were going to try to go stitch together a bunch of existing cohorts. And we very much decided on the first, right, because the technology of using genomics is changing that we needed to make sure that we had consistent pipelines, consistent ways of trying to capture EHR data, consistent ways of trying to capture mobile health and phone data and fitness device data and those kinds of things. So the whole cohort will be brand new.

That doesn’t mean that people might not want to join themselves or others joined from an existing cohort, and we’ll look for opportunities in the future to be able to create linkages wherever possible between those existing studies. But right now, we’ve got to focus first and foremost on capturing the new clean data set in a consistent way with a million people from across the country.

## Mr. Garcia:

One final question.

## Mr. Dishman:

Yeah.

## Mr. Garcia:

Are you guys are recruiting families so you can get the pedigree, or it's just—

## Mr. Dishman:

So that’s part of what our children’s evaluative group committee are actually looking at. We’ve had lots of great input both in our, I mean, literally three years now, and you know, when there were listening sessions before the consortium even kicked off. So we’re definitely looking at that. We’re not doing family recruits right now, but it’s something that we’re considering as part of our children launch when we do that in 2019.

## Mr. Garcia:

Okay, thank you very much.

## Mr. Dishman:

You’re welcome. Thank you.

## Ms. Jin:

So I see that Michael has connected again, so Mary, can you help us try to get Michael in the queue again for a question?

## Mary:

Definitely. Michael, your line is open.

## Dr. Weiss:

Hi. Thank you. Sorry about that earlier. I had some questions about just incentivization on the side of participants. Can you give in the short?—you know, talked about returning data to people, which is great over the long term. But can you discuss a little bit about the short-term incentivization on, you know, encouraging people to participate and continue participating and maybe, you know, highlight, is there some kind of compensation provided and maybe also touch on accessibility? Is there support to get people to study centers so that they can provide those samples, transportation or other things like that? Anything you can share would be very helpful.

## Mr. Dishman:

Sure. Okay, I think I’ll try to remember all those pieces. So in terms of the very practical issue, each of the sites has tried to develop a strategy that’s local to them about like let’s, you know, if you can make parking free, make parking free. You know for some, this is very easy to do, and others are in like urban New York and they’re like, “Yeah, good luck on that,” right? So all of the folks from a sort of philosophy and from a principles of the program are trying to ease the transportation burden as much as possible.

In terms of financial compensation, the way I tell people this is, look, remember everything we’re going to do is times a million. So the only financial compensation is for those who are invited in to do physical measurements and biospecimen capture. We offer 25 dollars to try to help compensate for some of their transportation costs for getting there. You know, the IRB helped us think this, and we had lots of input from folks around the country, you know, into this. And that was like the reality of it is, I mean, even that you think about like, if everybody accepts it, that’s 25 million dollars. So what we’ve really tried to do is figure out creative relationships between those local partners to try to ease the burdens on people to be able to get there as much as possible.

One of the things that we have and a capability that we have in our direct volunteer network is a company called BMSI, who can and do in-home visits for blood and other purposes. They service almost every insurance company in existence. You know, you can imagine that’s an incredibly expensive way to help get to somebody. But we even have that reimbursed, and we’re piloting it and trying to figure out, okay, how do we use that for people with mobility challenges or who may be, quite frankly, heading to the site that they have near them would be unsafe to do so from a walking perspective or whatever.

So we’re doing all of the things that we can, but that’s the sort of compensation model. It’s for those who come in and do a physical, the whole journey, doing that 25 dollars to try to help compensate for some of their costs. In some communities, it’s like nothing for them to get there. The others, 25 dollars doesn’t even begin to pay it if they have to take a Lyft to get there. But that’s what we’re able to do right now.

In terms of the other incentives, I mean, part of what I can tell you is what we’re hearing from participants about their different motivations for having joined, both in surveys we did before we even got started, as well as what we’re hearing from participants now. Certainly, a lot of participants are just driven by, “I want to do this for my own community, and I want to do this for my own family.”

The communities who really understand that they’ve been left out of traditional biomedical research and that there are huge data, science, evidence, and thus cure gaps for communities who have been left behind in scientific literature are really excited about the focus on underrepresented in biomedical research. And we certainly have to deal with the trust issues with them, because they’ve been harmed—many of them have been harmed in the past, in the name of federal research. But they get it, and they’re getting the word out to their communities, saying, “If we’re left behind in the research then we may be left behind in the cures.”

At the same time, you know, there are a lot of people that are coming in there like, “I want my information about myself. I want to know.” And they get it. They understand that what they’re going to get initially is pretty crude. But at that point, like, if they’re invited to do just a biosample, then they are going to get both their whole-genome sequence data and their genotyping data. So for some people that’s their biggest motivation to do it.

Others who don’t have any access to their EHR data at all are excited, saying, “Look, I want to start to know what my medical history has been, and it’s been too hard for me to get it in there. “ And it’s certainly true that as we figure out these strategies to get people richer, more holistic health records, and we do these investments with these large players to go do this. I think you know one of the value propositions we’ll have to offer to people is you’re going to get a richer and more complete record.

At some point, we’re going to still try to figure out how to get everybody’s dental records in and their eye doctor records in so that they too can have a more holistic record that they’re going to do. But we have to admit that that takes time to do that. All right. So this is one of the areas where I was mentioning like I need all of your help to help everybody understand that EHR is not a solved problem. And even if you’re one of our health provider organizations, you may have only been there getting your care there for a year, so they may have a very tiny window of data that they’re able to pull into you. So this is a journey that *All of Us* is going to be on and our participants are going to be on for a long time.

Many others who have a particular condition and disease are excited and eager to be invited to follow-up ancillary studies or clinical trials that are related to their particular condition. So they’re pushing a different thing, “When can you get that available?” We’ve got to get the researcher portal in place and all those policies, but that’s very much what we’re designed to do as we go forward.

So yeah, it’s been kind of like there’s, you know, we keep saying one of the things we’re trying to do is to help reduce one-size-fits-all medicine. It has not been one-size-fits-all value propositions, but those are a lot of the common themes that we’ve been hearing back from participants that have given us feedback so far.

## Ms. Jin:

So I see we’re getting close to the hour, so we’ll take one more question, and then we’ll hand it over to Dara to close. The final question comes in from the chat. And it’s, “When will the researcher portal be open, and will it be open to college students and laypersons?”

## Mr. Dishman:

Yes. So when the researcher portal opens in the first half of 2019, it will be open to everybody at the same time—so college students, high school students, your mom. Now it has these three tiers of access that I talked about before, but there’ll be a public pier that you don’t even need to log into. You know, it’s just like, “Hey, go use this tool to start understanding what kind of knowledge and what kind of people and what kind of conditions are in there.” Obviously, you can’t go look up anybody’s address or any identifying information like that. I can’t even do that. That’s all kept in a completely different place with the people who have the encrypted key to get it.

The next tier up would be, you know, kinds of data where there’s a little bit more risk of somebody being able to re-identify somebody. So in that case, you have to basically go through a process that makes a commitment. You’re going to sign a pledge that says you’re not going to use data in bad ways, a little bit of training online. And then a third tier, which would be the highest risk, like your whole genome data. There you’re going to have to have some sort of, right now, institutional affiliation who can help hold people accountable if they behave badly. We’re working on that; nobody has a good solution yet. And if you have one, please email us.

We want citizen scientists to eventually be able to have access to all levels of data as well. For citizen scientists who have a partnership and may be even affiliated with a university, because that’s how they got their science done, that’s not hard for us. But there’s many more citizen scientists that don’t have access to any kind of institutional affiliation like that. That’s a big open question. How are we going to credential those people and, most importantly, hold them accountable should they start to do bad things with the data?

But, again, you’re coming to a secure environment to use the data. You’re not just copying it to wherever you want. So that gives us some ability to audit and control and make sure that you know people aren’t doing things that’s against the pledge of what they committed to do to protect participant privacy.

## Ms. Jin:

Great, thank you. We are at the hour, so I will hand it over to Dana for some closing remarks.

## Dr. Richardson-Heron:

First of all, I want to thank everyone for joining us and also thank Eric for the really, really amazing presentation. I think, you know, we know how much each of you are investing into your organizations and the work that you do. So we know that in order for us to be successful, we have to work together.

As we mentioned in the beginning, this is just the beginning of our work together and the beginning of our conversation. If you do have an interest in learning more, please go to our website, joinallofus.org. And also, please, if you’re interested in having your organization get more connected, I want to just restate the email address of one of our engagement counselors, Kim Cantor. It’s kim\_cantor@hcmstrategists.org.

Please also go to our website to see the resources that we have that you can share with your constituents. So we thank you again for your time. Thank you for your attention and, most importantly, thank you for all the great work that you do each and every day to advance health and health care literally and figuratively for *All of Us*. Have a great day. Thank you.