

All of Us
RESEARCH PROGRAM

**The future
of health
begins
with you**



Pre-Launch Webinar
May 2, 2018



National Institutes
of Health

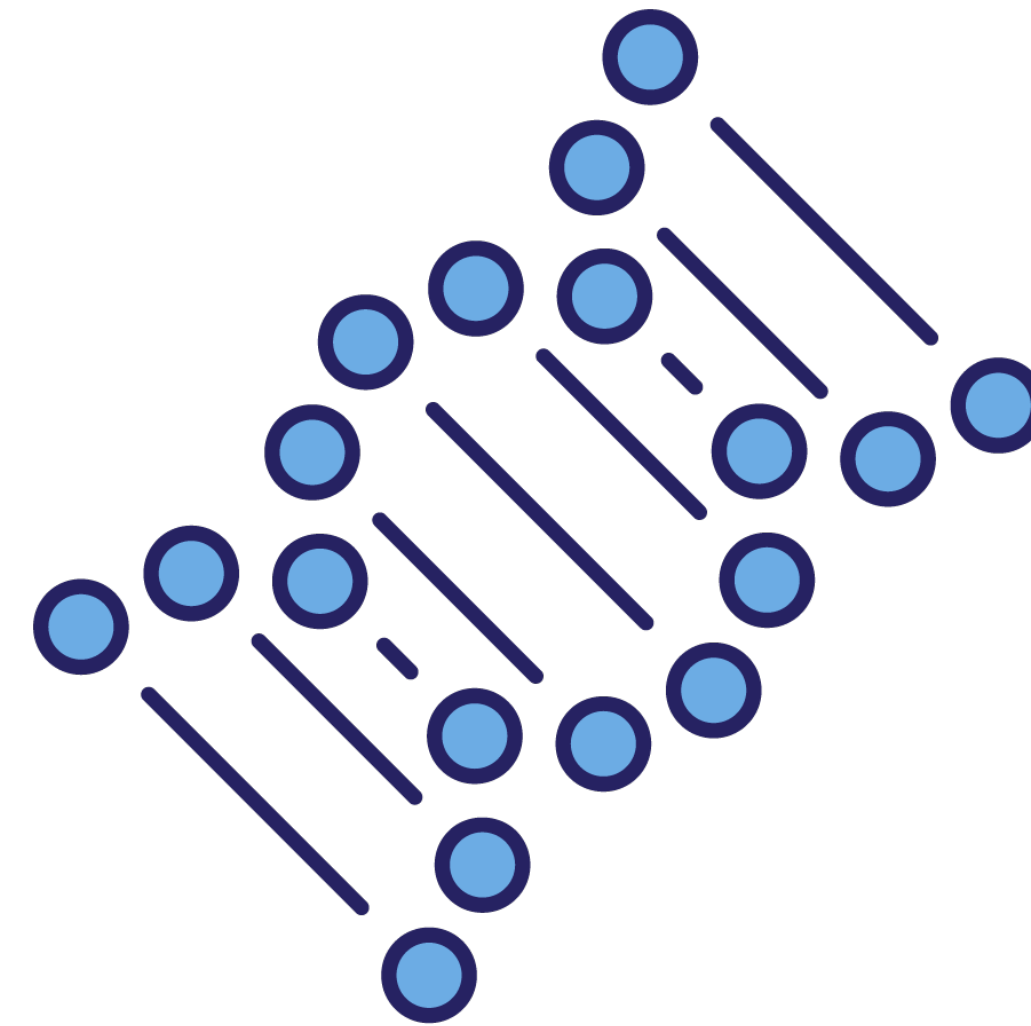
Agenda

- ① Overview of the *All of Us* Research Program
- ② National Launch of *All of Us*
- ③ Get Involved with *All of Us*

What Is Precision Medicine?

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, environment, and biological makeup.

It is a radical shift in how each of us can receive the best care possible based on our unique characteristics.



Precision Medicine in Real Life

Right treatment for the right person --



Prescription
Eyeglasses



Insulin Pump



Blood
Transfusions

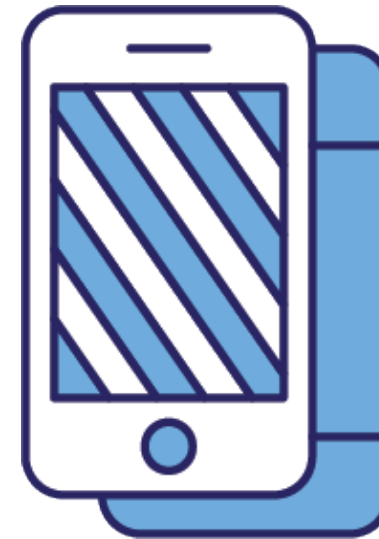


Hearing Aid

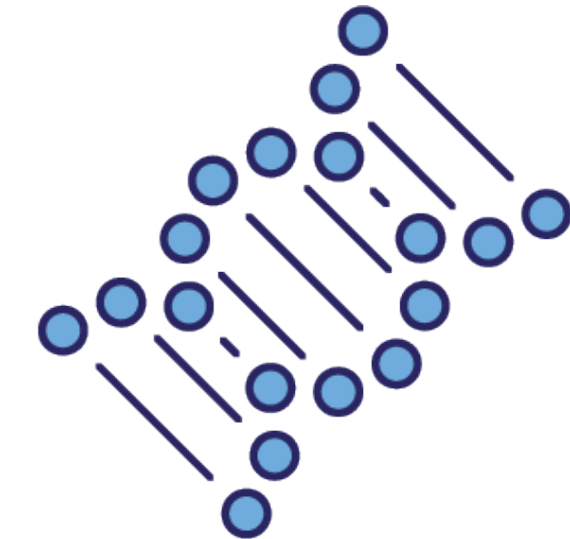
Why now?



We have technologies that
can collect
and crunch huge amounts
of data.



More people are engaged
in their health, and can
track and share their data
— like steps and sleep.



We have a greater
understanding of
human genes.

The time is right.

What is the NIH *All of Us* Research Program?



The *All of Us* Research Program is a historic, longitudinal effort to **gather data from one million or more people** living in the United States to **accelerate research and improve health**. By taking into account individual differences in **lifestyle, socioeconomic, environment, and biology**, researchers will uncover paths toward delivering **precision medicine – or individualized prevention, treatment, and care – for all of us**.



“All of Us is among the most ambitious research efforts that our nation has undertaken!”

***NIH Director Francis Collins,
M.D., Ph.D.***

All of Us Research Program: Mission and Objectives

Nurture relationships

with one million or more participants, from all walks of life, for decades

Our mission

To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us

Deliver the largest, richest biomedical data set ever

that is easy, safe, and free to access

Catalyze a robust ecosystem of researchers and funders hungry to use and support it



All of Us Values

- Participation in the *All of Us* Research Program will be **open** to interested individuals
- The program will reflect the rich **diversity** of America
- Participants will be **partners** in the program
- Trust will be earned through robust **engagement** and full **transparency**
- Participants will have **access** to information and data about themselves
- Data from the program will be broadly **accessible** to **empower research**
- The program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework
- The program will be a catalyst for **innovative research** programs and policies

What is the promise for participants?

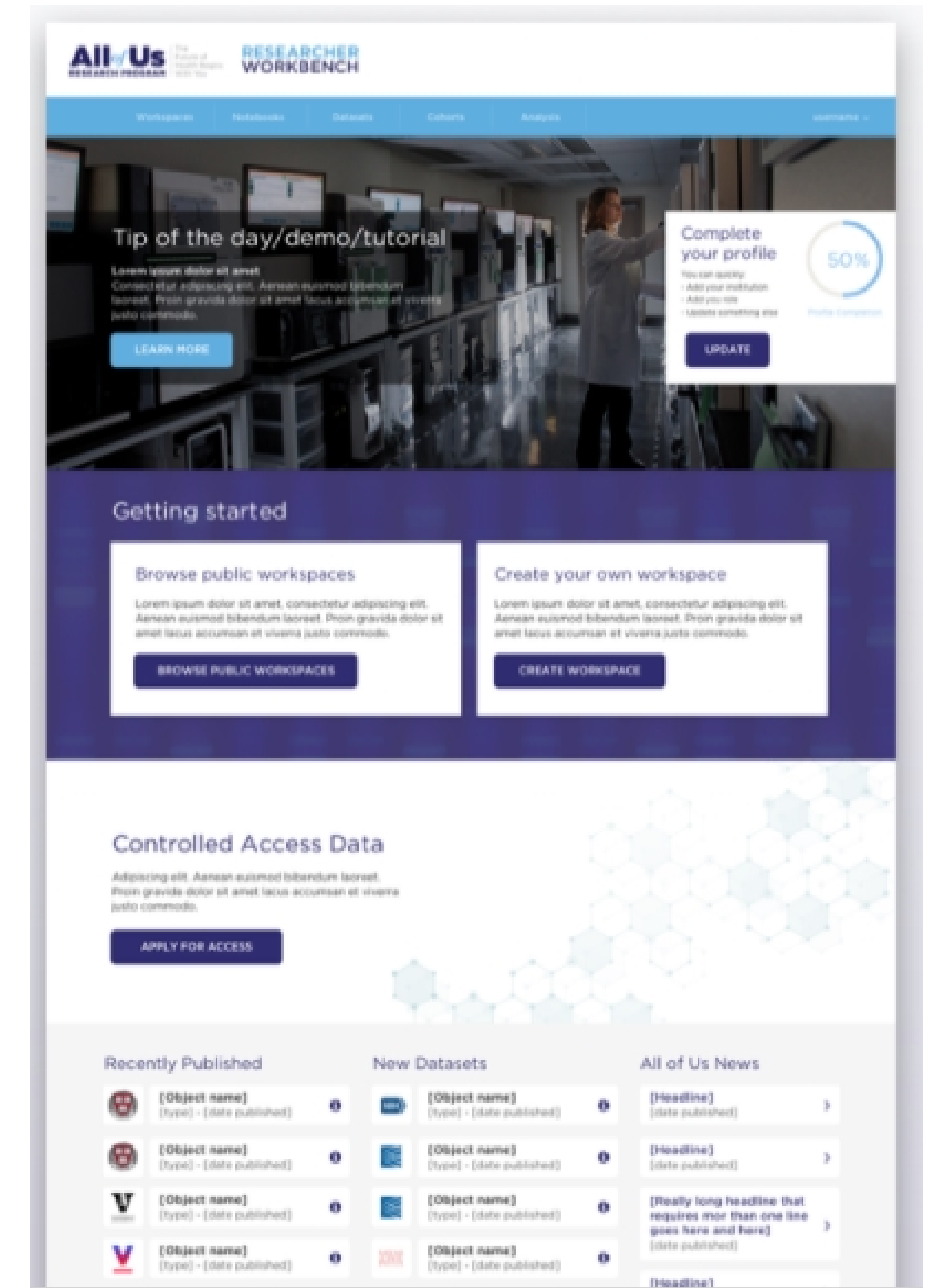
- An opportunity to help **fight disease** and improve the health of future generations.
- A chance to **learn about your own health**, including personalized risk factors or exposures.
- The ability and choice to **access your own data**, including increasingly rich health records.
- An opportunity to **ensure that your community is included** in the studies that lead to new understanding and new treatments.
- A chance to **learn about additional research opportunities** that may interest you.
- The choice to **meet others like you**, perhaps even joining some of them to propose & do research.



This is a long-term relationship and the value to participants (and researchers) will grow over time.

What is the promise for researchers?

- ① The opportunity to **save time and resources** and **accelerate your research breakthroughs** by leveraging:
 - A **rich resource of data**, including biospecimens and increasingly robust electronic health records.
 - A **longitudinal dataset** that will follow participants as they move, age, develop relationships, get sick, and try treatments.
 - A **diverse cohort of participants**, including people both healthy and sick, from all walks of life and all parts of the country.
 - Both raw data and data that is already **cleaned and curated**.
 - **Robust computing and analytic tools** to support complex data analyses in a **secure data environment**.
 - A group of **engaged participants** who may be eager to participate in ancillary studies.
- ② The ability to easily **share workspaces and analyses** with research partners and reviewers.
- ③ The chance to learn from the program's pilots and experiments and **leverage innovations** for other studies and cohorts.



As with most studies, we are collecting, evaluating, and curating initial datasets; availability in 2019.

What is the promise for providers?

- ◎ Over time, **increased scientific evidence and improved guidelines** to enable precision medicine opportunities for more people and conditions:
 - Better understanding of the **impact of environment and lifestyle factors** on health.
 - Increased knowledge of differences in risk factors and response to treatments among **diverse populations**.
 - More information on the development of conditions that will allow for **earlier detection**.
 - Deeper understanding of different conditions that may allow for **better stratification**.
- ◎ Innovations that may make it easier to **share electronic health records** with other providers and patients.
- ◎ New knowledge to help address **health disparities**, increase **patient engagement**, and understand the usefulness of **consumer health devices and apps**.



Help accelerate medical breakthroughs by sharing information about *All of Us* with your patients!

Kinds of Questions this Resource May Help Answer

How can we prevent the chronic pain that affects more than 100 million people across the U.S. each year?

Or develop better pain medicines that aren't addictive?

Or develop better treatments for diabetes, which affects almost 10% of Americans—or prevent diabetes altogether?

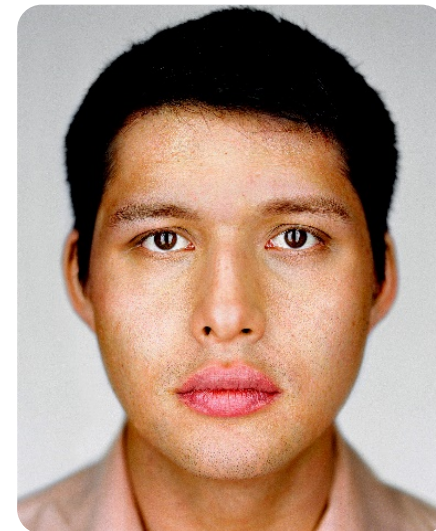
Or slow or even stop different kinds of dementia?

Or develop more cancer cures that will work the first time, so we can skip painful trial-and-error chemotherapy?

Transformational Approaches

A Transformational Approach to Diversity

Reflecting the country's rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.



People

Health
Status

Geography

Data
Types

UNDERREPRESENTED IN BIOMEDICAL RESEARCH

Build Trust
Create Value



A Transformational Approach to Participation

Participants in the *All of Us* Research Program will be true partners—not patients, not subjects—in the research process.

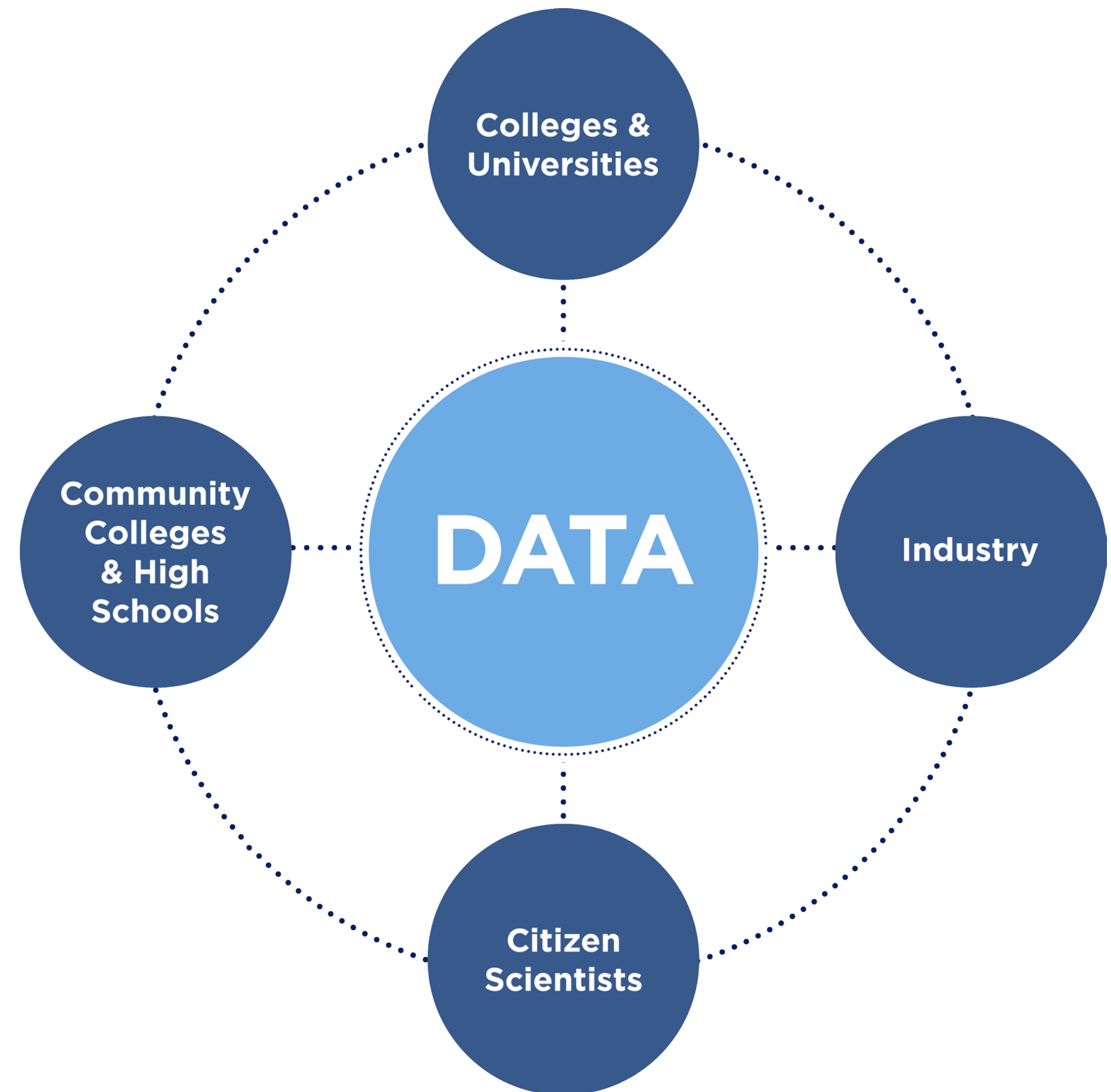
Involved in program development:

- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned



A Transformational Approach to Data Access

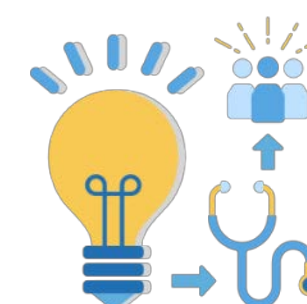
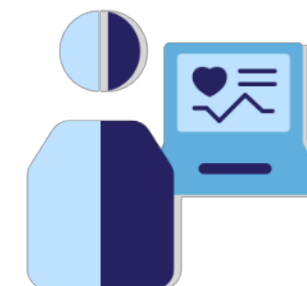
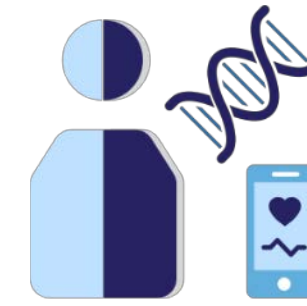
- ⦿ Data sharing will be a priority to both researchers and participants
- ⦿ Participants will have access to study information and data about themselves
- ⦿ Data collection will start small and will grow over time
- ⦿ Privacy and security will adhere to the highest standards
- ⦿ NIH will invest to level the playing field so diverse researchers can play



How will *All of Us* lead to discoveries?

Participants Share Data

Participants share health data online. This data includes health surveys and electronic health records. Participants also may be asked to share physical measurements and blood and urine samples.



Researchers Study Data

In the future, approved researchers will use this data to conduct studies. By finding patterns in the data, they may make the next big medical breakthroughs.

Researchers Share Discoveries

Research may help in many ways. It may help find the best ways for people to stay healthy. It may also help create better tests and find the treatments that will work best for different people.

Data Is Protected

Personal information, like your name, address, and other things that easily identify participants will be removed from all data. Samples—also without any names on them—are stored in a secure biobank.

Participants Get Information

Participants will get information back about the data they provide, which may help them learn more about their health.

The Importance of Diversity



Program Infrastructure

Enrolling in *All of Us*



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**

All of Us Research Program Infrastructure

DATA AND RESEARCH CENTER

Big data capture, cleaning, curation, & sharing in secure environment

Vanderbilt, Verily, Broad Institute

BIOBANK

Repository for processing, storing, and sharing biosamples (35+M vials)

Mayo Clinic

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web and phone-based platforms for participants

Vibrent Health

PARTICIPANT CENTER / DV NETWORK

Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies

*Scripps Research Institute
(with multiple partners)*

HEALTHCARE PROVIDER ORGS NETWORK

HPOs with clinical & scientific expertise, enrollment & retention of participants

30+ regional medical centers, FQHCs, VA, and future awards to grow network

COMMUNICATIONS & COMMUNITY NETWORK

Communications, marketing, and design expertise; engagement coordination and community partners network

Wondros, HCM, 29 community partner organizations, and future awards to grow network

National Network of Inaugural Partners

National Partners

Regional Medical Centers

FQHCs

Community Partners



All of Us Consortium Members

DV Network (Direct Volunteers)





Biobank



HPO Network (Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium



All of Us, Wisconsin



Illinois Precision Medicine Consortium



New England Precision Medicine Consortium



Trans-American Consortium for the Health Care Systems Research Network



New York City Precision Medicine Consortium



Southern *All of Us* Network



SouthEast Enrollment Center



VA Medical Centers



FQHCs (Federally Qualified Health Centers)



Communication & Engagement

WONDROS



Platform Development



Community and Provider Partner Network



Potential Activities Asked of Participants (Protocol V1)



Enroll, Consent & Authorize EHR

- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



Answering Surveys

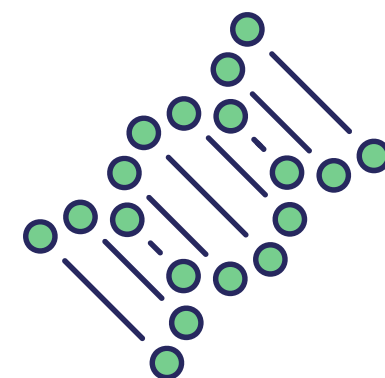
- Three initial surveys: The Basics, Overall Health, & Personal Habits
- Additional surveys will be released on an ongoing basis.



Physical Measurements*

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

**Based on diverse sampling and capacity*



Provide Biosamples*

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank

**Based on diverse sampling and capacity*



Wearables and Digital Apps

- Share data from wearable fitness devices, starting with FitBit
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

Coming soon

Pilots under development: richer EHR data, health apps, fitness wearables, and return of genetic info

Approach to Privacy and Security

- Guided by privacy, trust, and data security principles developed by experts with input from the public.
- Data warehouse is built with the most advanced security available.
- Experts have done and will continue to do rigorous security testing.
- Data is encrypted and direct identifiers are removed.
- Researchers must agree to a code of conduct before accessing the data.
- Participants' preferences will be respected.
- Protected by a Certificate of Confidentiality.
- Committed to transparency in the event of a data breach.



Safeguarding your identity and data to the best of anyone's abilities is our most important responsibility.

Next Steps for *All of Us*

Current Program Status

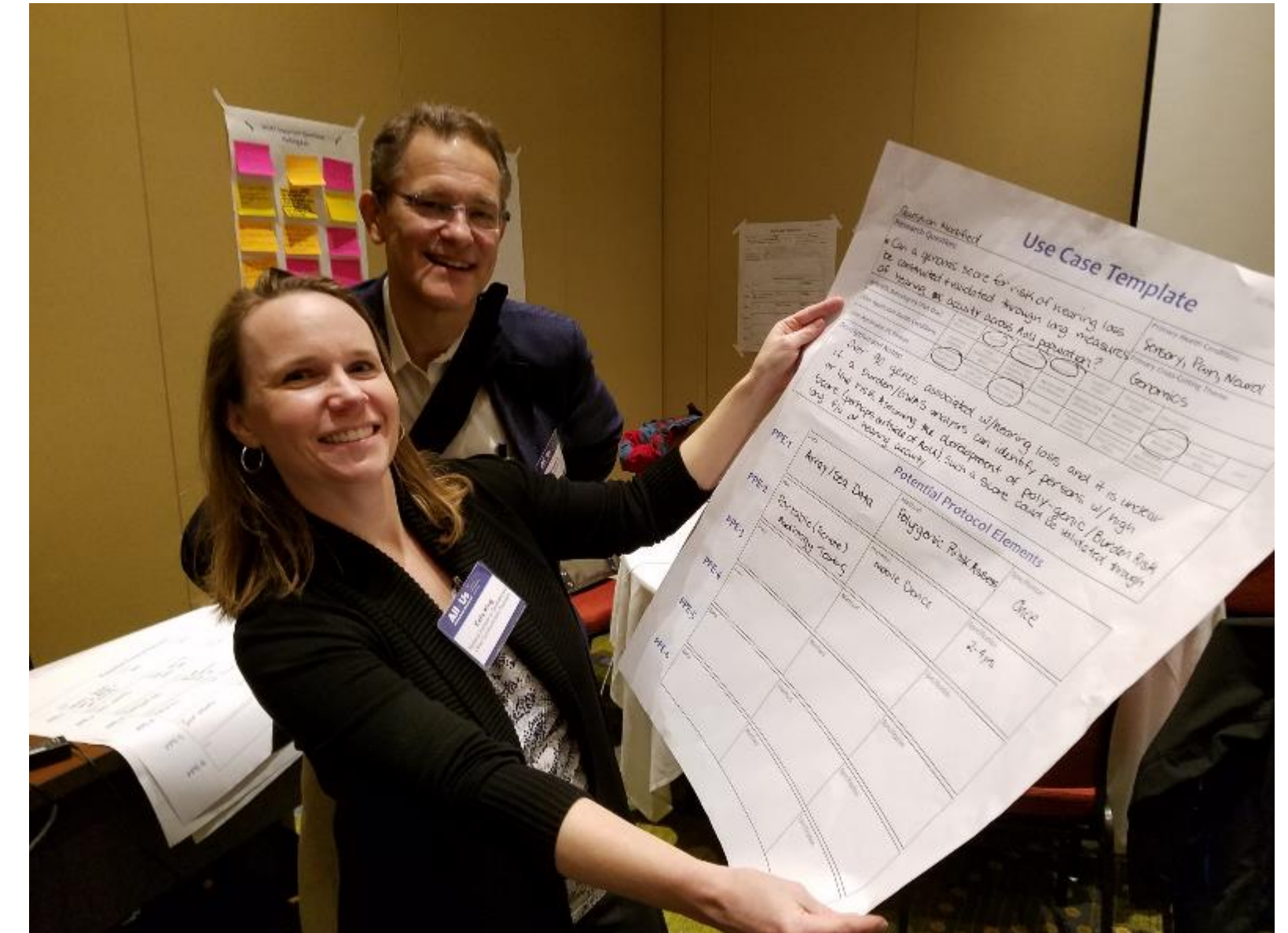
Since July 2016...

- ◉ Developed and updated protocol
- ◉ Completed a successful beta test with real participants, tools, and data
- ◉ Built robust network of 100+ academic, provider, technology, and community partners
- ◉ Launched 125+ clinics to enroll participants, with plans to expand to additional states and locations
- ◉ Developed participant-friendly and bilingual (English/Spanish) enrollment website, participant portal, app, and call center
- ◉ Built biobank and 24-hour shipping process with capacity for 35M+ vials
- ◉ Developed data warehouse with infrastructure to collect, clean, curate, de-identify, and eventually share the data
- ◉ Completed end-to-end security and usability testing
- ◉ Developed innovative pilots for testing electronic health record and wearables strategies
- ◉ Created interactive mobile exhibit that travels the country
- ◉ Development of the Research Portal is underway; expected to be open with initial public dataset in 2019



Recent Research Priorities Workshop

- Invited a broad array of stakeholders, including researchers, participants, professional societies, & advocacy groups to the Workshop in Bethesda, MD on March 21-23, 2018
- Purpose: Identify key research priorities that will capitalize on the *All of Us* Research Program's one million or more participants to help ensure optimal value for advancing precision medicine
- Collected use cases & requirements
 - 800+ in advance from the stakeholder community through IdeaScale crowdsourcing platform
 - 500+ at the workshop
- All of Us* team is currently reviewing & synthesizing the data we gathered
- Will have additional opportunities to submit use cases & requirements



National Launch: May 6, 2018

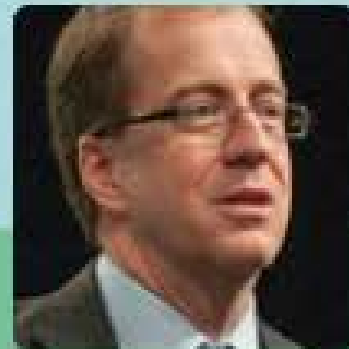


All of Us
RESEARCH PROGRAM

HOME SCHEDULE EVENT LOCATIONS ART EXPERIENCE

THE FUTURE OF HEALTH IS COMING. JOIN US.

Join us for the official launch of the *All of Us* Research Program. Help us advance precision medicine.

Watch live on Sunday, May 6, 2018.

SPEAKERS INCLUDE


Francis Collins,
M.D., Ph.D.

Dara Richardson-Heron, M.D.

Eric Dishman

WATCH OUR WELCOME VIDEO

Community Artwork for All Of Us by Ariel Wilson, San Diego, CA



How Can You Take Part in the Event?

Get Involved with *All of Us*

Learn More about All of Us



JoinAllofUs.org



@AllofUsResearch
#JoinAllofUs

National Launch Site (<https://launch.joinallofus.org>)

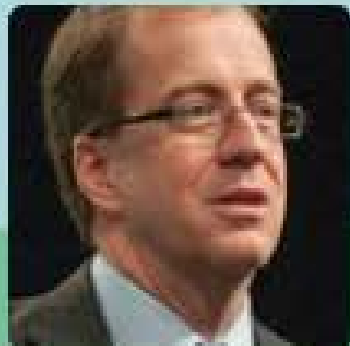


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How Can You Take Part in the Event?


NIH All of Us Site (https://allofus.nih.gov)

 U.S. Department of Health & Human Services


National Institutes of Health


 National Institutes of Health
All of Us Research Program

[ABOUT](#) 

[FUNDING](#) 

[NEWS, EVENTS, & MEDIA](#)

[JoinAllofus.org](#) 





The future of health begins with you

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[WATCH VIDEO](#) 



National Launch: May 6, 2018

Seven sites host half-day, simulcasted events that include:

- **Speakers program:**
 - One-hour livestreamed program at all sites
 - Representative of local community – participants, cultural performances, luminaries
 - Dr. Francis Collins, Eric Dishman, Dr. Dara Richardson-Heron at two sites, remarks simulcasted live
- **Community educational fair:**
 - Interactive *AOU* booth - engage with program staff, begin digital enrollment, branded giveaways
 - Local vendors: farmer's market, cooking demonstration, health screenings
- **Art activation:**
 - One local artist at each site creates interactive, collaborative community portrait



The simulcasted events will be supported by:

- **Facebook Live speakers program:** produced like broadcast television, to occur before streaming of simulcasted sites
- **Community events:** organized by many NIH champions, *AOU* consortium members, advocates, etc.
- **National & local print, broadcast, and social media strategy**



Engaging at Launch and Beyond

- 🕒 Post program information on your organization's social media channels
- 🕒 Follow *All of Us* on social media (Twitter, Facebook, YouTube and Instagram) and share program content; use the hashtag **#JoinAllOfUs**
- 🕒 Include information about *All of Us* in a weekly or monthly digital newsletter
- 🕒 Write and post a blog about the importance and value of *All of Us*
- 🕒 Host an in-person community event or conference call/webinar with network or partners
- 🕒 Distribute *All of Us* info flyers, posters, etc. at a meeting, conference, or event
- 🕒 Promote the national launch online experience including the live webcast
- 🕒 Share a recap about the national launch in digital or print newsletters

Twitter Accounts to Follow

We suggest following the below accounts, in addition to other *All of Us* consortium member accounts, to keep you in the know on the *All of Us* Research Program.

Person/Organization	Twitter Handle
<i>All of Us</i> Research Program	@AllofUsResearch
Eric Dishman	@EricDishman
Francis Collins	@NIHDirector
NIH	@NIH

Community Resources (JoinAllofUs.org)

[illegible]

THANK YOU!

Questions/Share Ideas:

Lydia_Kuykendal@hcmstrategists.com



National Institutes
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