

ELSI Workshop
June 24, 2019

Creating a Platform to Enable ELSI Research

All of Us
RESEARCH PROGRAM

The
Future of
Health Begins
With You



National Institutes
of Health

Stephanie Devaney, PhD
Deputy Director, *All of Us* Research Program

If we harness the right data and information across a diverse group of one million of us – as *partners* – over many years, we will learn things about human health that will be game-changing

Our Mission

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

Nurture relationships

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

Deliver the largest, richest biomedical dataset ever,

making it as easy, safe, and
free to use as possible

Catalyze a robust ecosystem

of researchers and funders
hungry to use and support it

All of Us Research Program Core Values

Participation is **open** to all.

Participants reflect the rich **diversity** of the U.S.

Participants are **partners**.

Trust will be earned through **transparency**.

Participants have **access** to their information.

Data will be accessed **broadly** for research purposes.

Security and privacy will be of highest importance.

The program will be a catalyst for **positive change** in research.

One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday,
the fourth day of January, two thousand and sixteen

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and
for other purposes.

Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “21st Century
Cures Act”.

(b) TABLE OF CONTENTS.—The table of contents for this Act
is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID
ABUSE

Sec. 1001. Beau Biden Cancer Moonshot and NIH innovation projects.

Sec. 1002. FDA innovation projects.

Sec. 1003. Account for the state response to the opioid abuse crisis.

Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.

Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

Sec. 2011. Precision Medicine Initiative.

Sec. 2012. Privacy protection for human research subjects.

Sec. 2013. Protection of identifiable and sensitive information.

Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

Sec. 2021. Investing in the next generation of researchers.

Sec. 2022. Improvement of loan repayment program.

21st Century Cures Act

- H.R.34. (Pub. L. 114-255) enacted December 13, 2016
- Broad bi-partisan support
- Provides the Precision Medicine Initiative with \$1.455 billion over 10 years
- Provides flexible funding mechanism
- Language on:
 - Diversity
 - Data sharing
 - Privacy

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All of Us Research Protocol Evolution

- The Program will start by collecting a limited set of standardized data
- Data types will grow and evolve

V1 platform

Data
Samples
Analyses
Tools
Cohort

V2 platform

+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

V3 platform

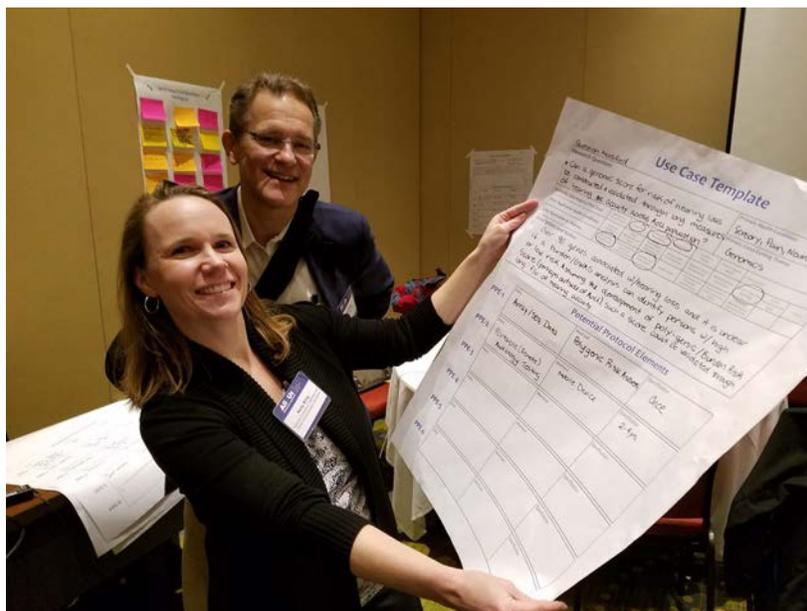
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

Vx platform...

...
...
...
...
...

National Research Priorities Workshop

Designed with our NIH
colleagues



514 use cases generated

Kinds of Questions *All of Us* Can 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?

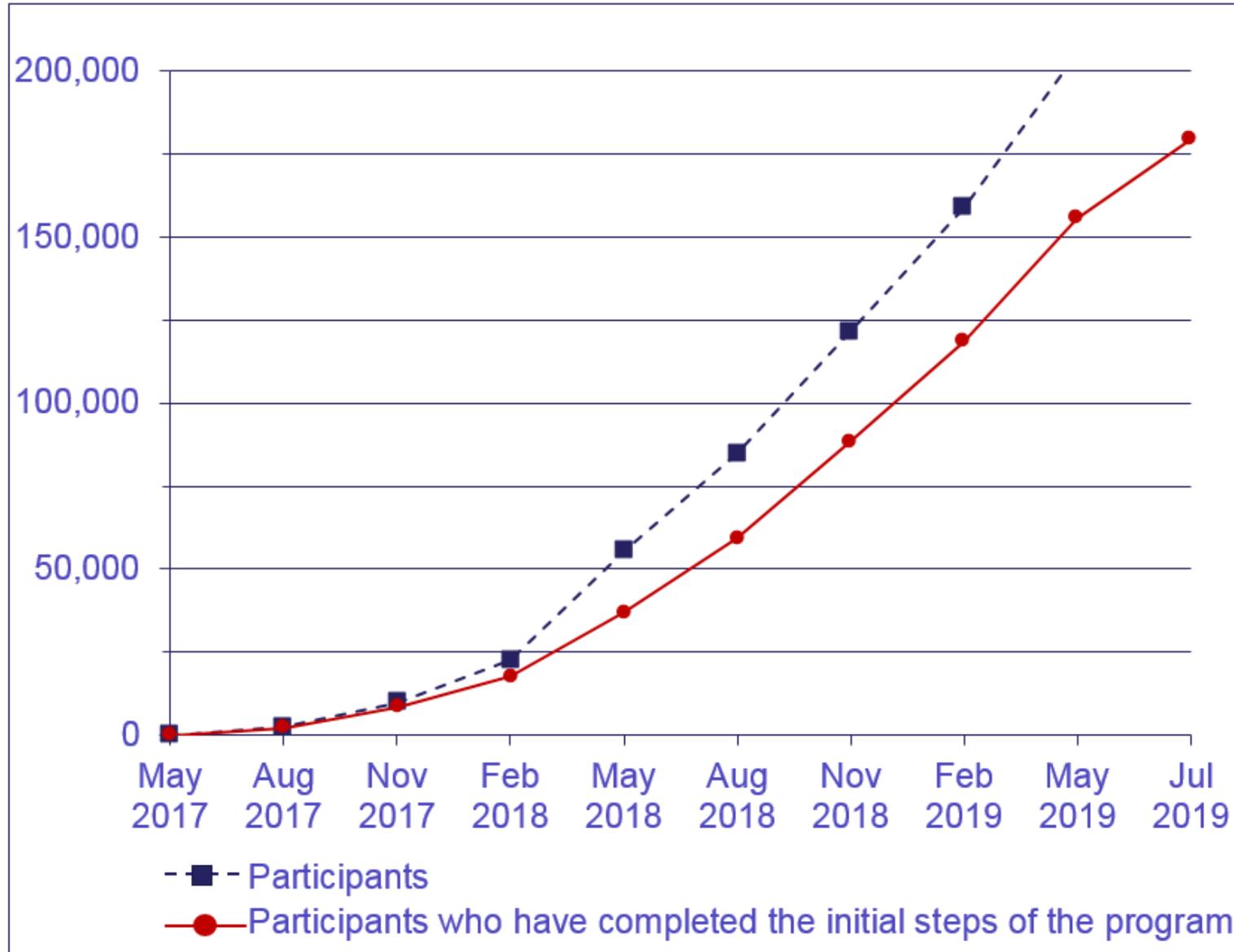
Or develop ***better treatments for diabetes***, which affects almost 10% of Americans—or ***prevent diabetes*** altogether?

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?

Or drive local ***disparities interventions*** that work sustainably?

Enrollment Numbers



TO DATE...

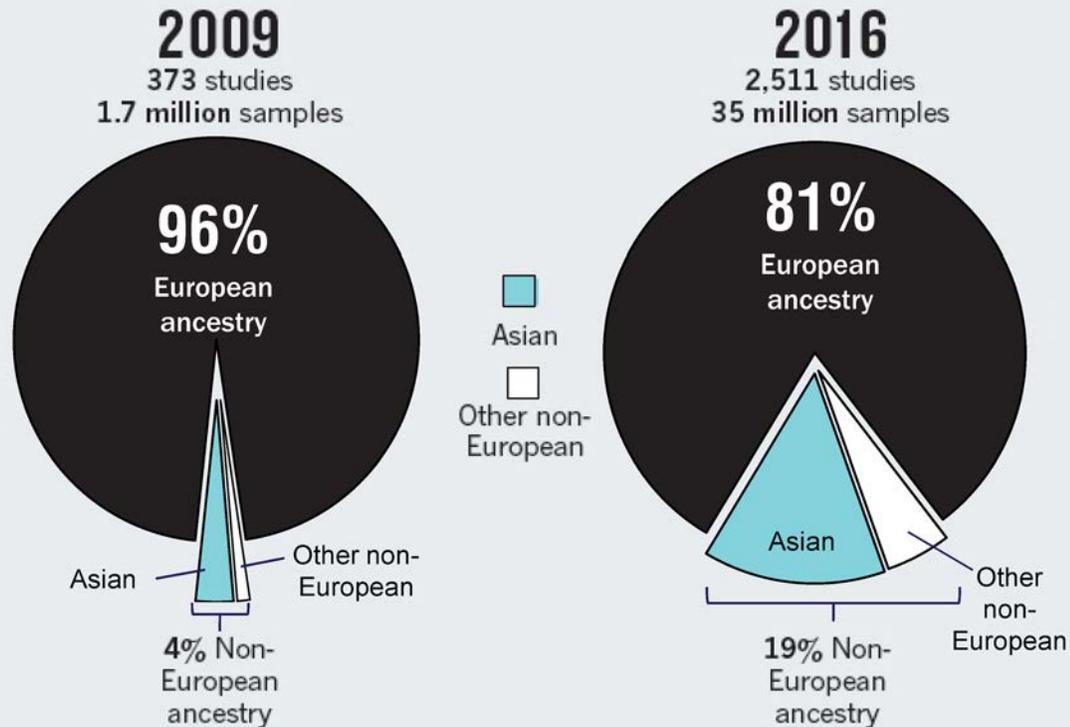
- Celebrated our **1 year anniversary** on May 6
- **>209,000** People have signed up from **all 50 states**
- **161,685** have completed the full protocol
- **>80%** are under-represented in biomedical research; **~51% R/E minorities**



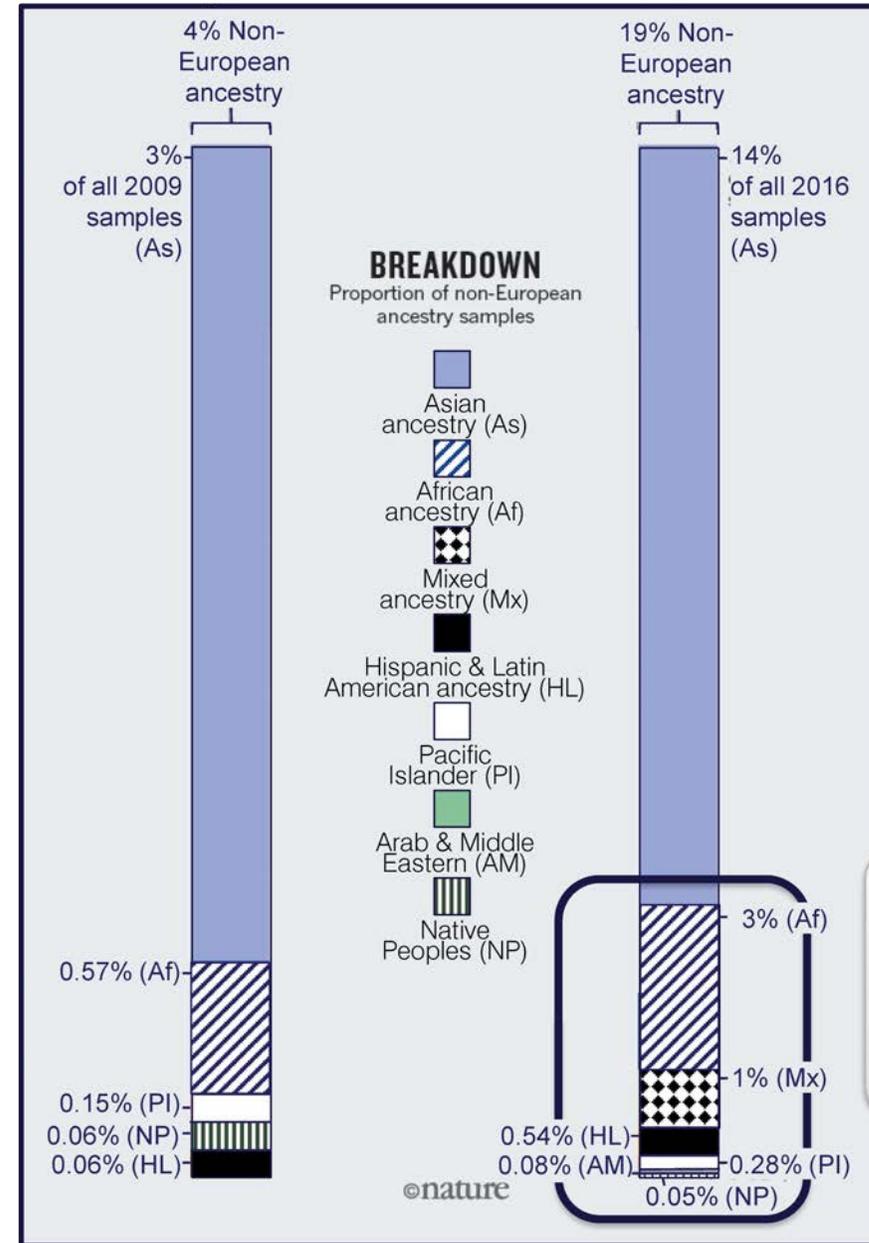
Why Diversity?

PERSISTENT BIAS

Over the past seven years, the proportion of participants in genome-wide association studies (GWAS) that are of Asian ancestry has increased. Groups of other ancestries continue to be very poorly represented.



Popejoy & Fullerton, *Nature* 2016



Terms for ethnicity are those used in the GWAS catalog. Some have changed between 2009 and 2016 as sampling has increased. Samples of European origin have the most specific descriptions of population ancestry.

4% GWAS represents >33% US population

Diversity | *Protected and Special Populations*

- Children
- American Indian/Alaska Natives
- Incarcerated Populations
- Individuals with Decisional Impairment
- Individuals with Physical, Linguistic, or Literacy Barriers to Participation

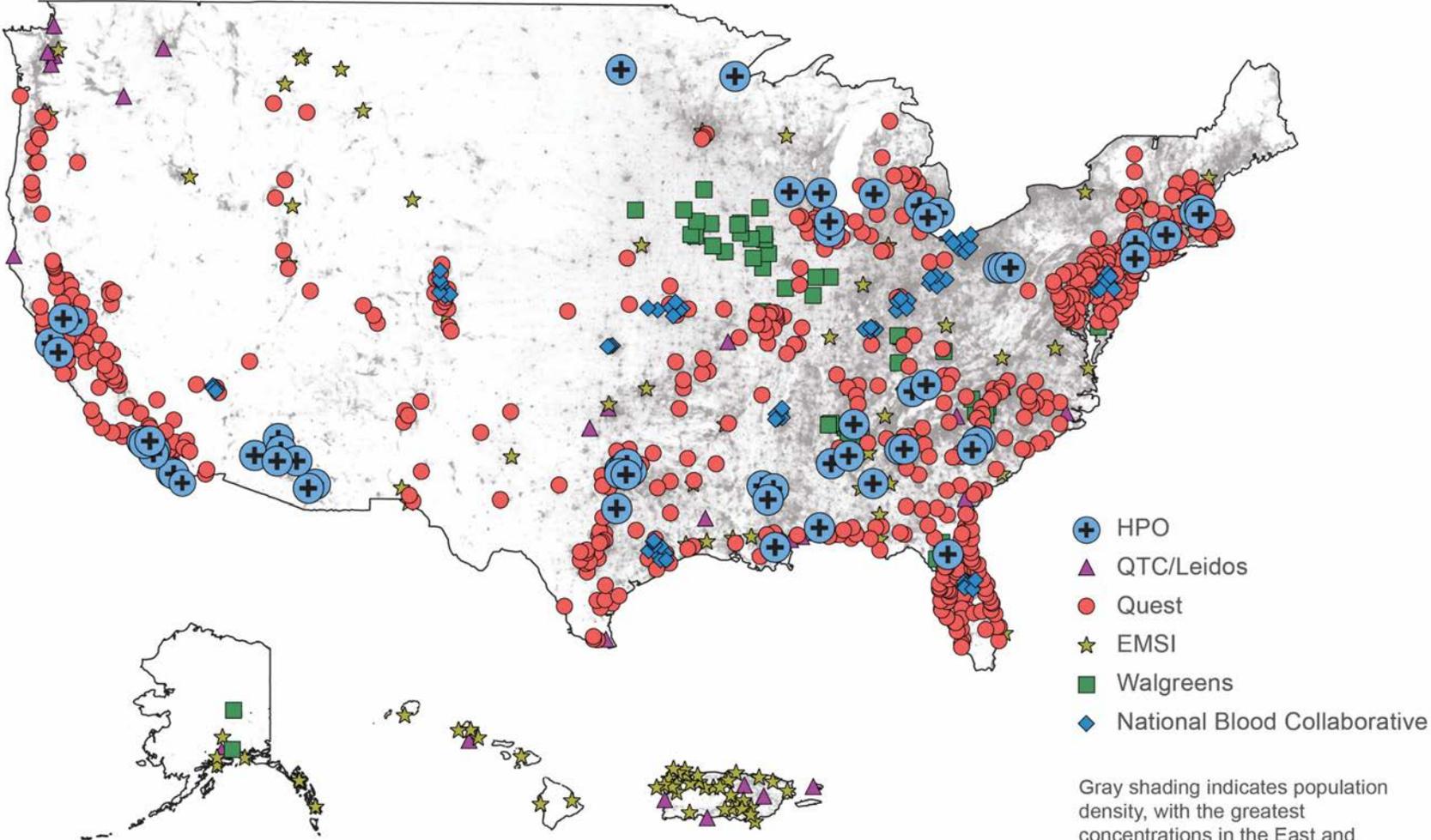


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- **358 sites** now enrolling



358 Sites Launched



Gray shading indicates population density, with the greatest concentrations in the East and South, from the Atlantic coast to as far west as Minnesota and Central Texas, and along the Pacific Coast in Washington State, Oregon, and Southern California.

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- Launched beta version of our **Public Data Browser**;
DataBrowser.ResearchAllOfUs.org



Two Methods of Engagement



JoinAllofUs.org



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**

Current protocol



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

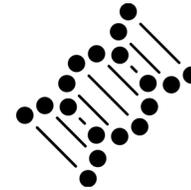
- Initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History
- Additional surveys released on an ongoing basis.



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

Genomics plans: genotyping, WGS, “RROI”

- Genotyping & WGS for all 1M participants
- Genetic Counseling Resource
- Pilot of return of results with 40k diverse participants
- **What to return?**
 - Begin with medically actionable genomic results return
 - **Facilitated return:** Medically actionable monogenic variants (AoU Medically Actionable Panel (AoUMAP)) via the Genetic Counseling Resource
 - **Access:** Uninformative AoUMAP results
 - **Access:** Typical and atypical pharmacogenomic CPIC A variants



Opportunities for return of value in the next-term

- Saliva pilot for existing participants who can't get to an enrollment center
- Genomics return of results pilot
- Mood module & mental health campaign
- Useful health information:
 - My medical minutes
 - Participant insights

**Thank you for
sharing your time,
insights, and
perspective with us**

The Team

DV Network

(Direct Volunteers)



Biobank



HPO Network

(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium

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

UC San Diego Health



All of Us, Wisconsin

University of Arizona

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

VA Medical Centers



Communication & Engagement

WONDROS



Platform Development



WONDROS



The Team

