



The *All of Us* Research Program: Advancing Health Equity, Inclusion, and Diversity in Clinical Research

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Director of Health Equity

March 30, 2023

NIMHD Workshop on Inclusive Participation in Clinical Research



The Lack of Underrepresented Communities in Biomedical Research

Minorities make up about
38%
of the US population.

Minority populations to rise to over
57%
of overall population.

Minority enrollment in clinical trials
<10%

Why Participate

African American population = 13.4% of US population

- 6.7% of NIH clinical trial participants nationwide
 - 1.6% of FDA novel drug trials

Hispanic population = 18.5% of US population

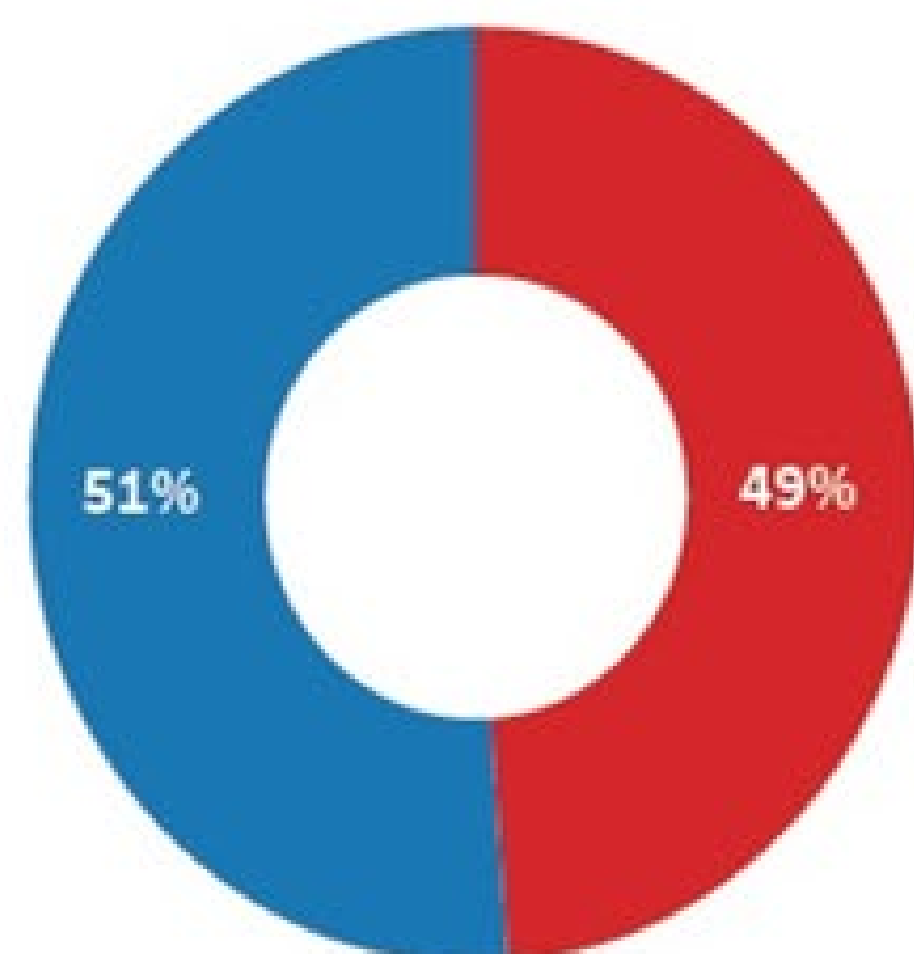
- 3.1% of NIH clinical trial participants nationwide
 - 2.7% of FDA novel drug trials

Asian American, Native Hawaiian, & Pacific Islander population = 6.1% of US population

- .1% of NIH clinical trial participants nationwide
 - 1% of FDA novel drug trials

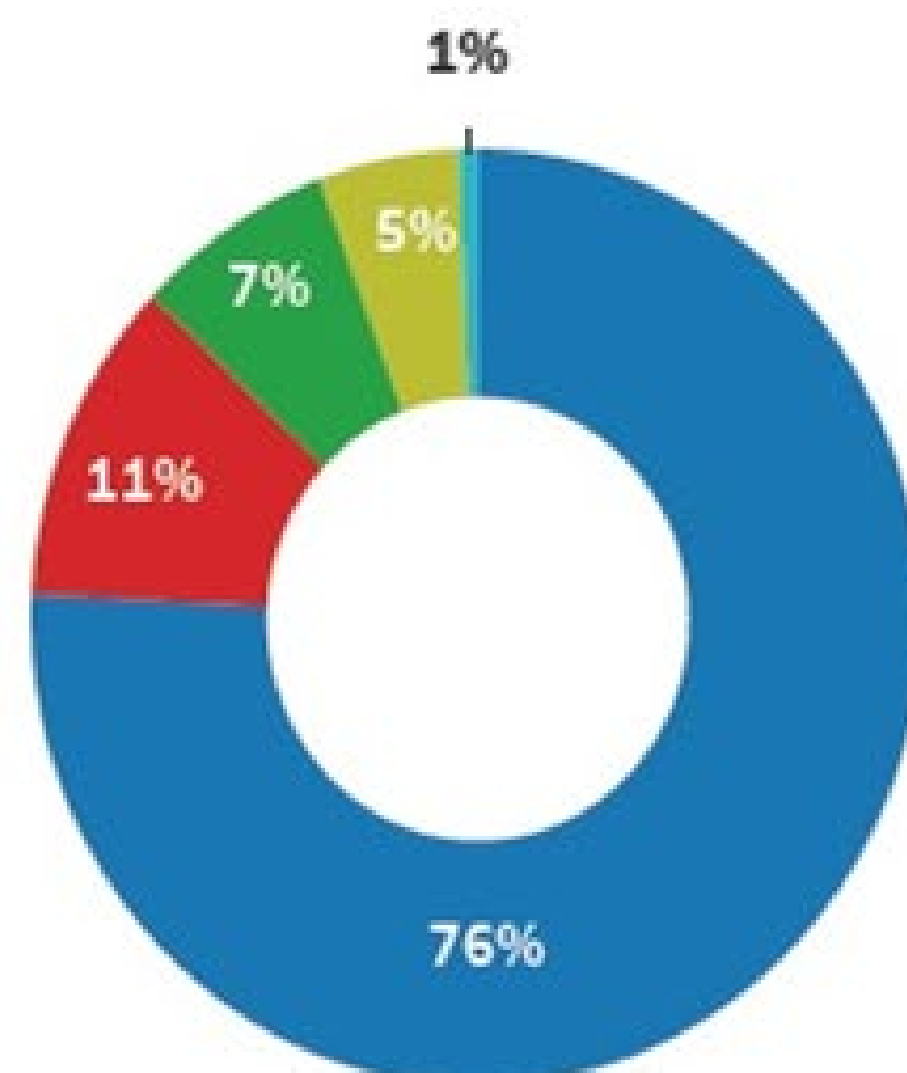
2015-2019: FDA Drug Trials Snapshots Summary Data

Sex Distribution



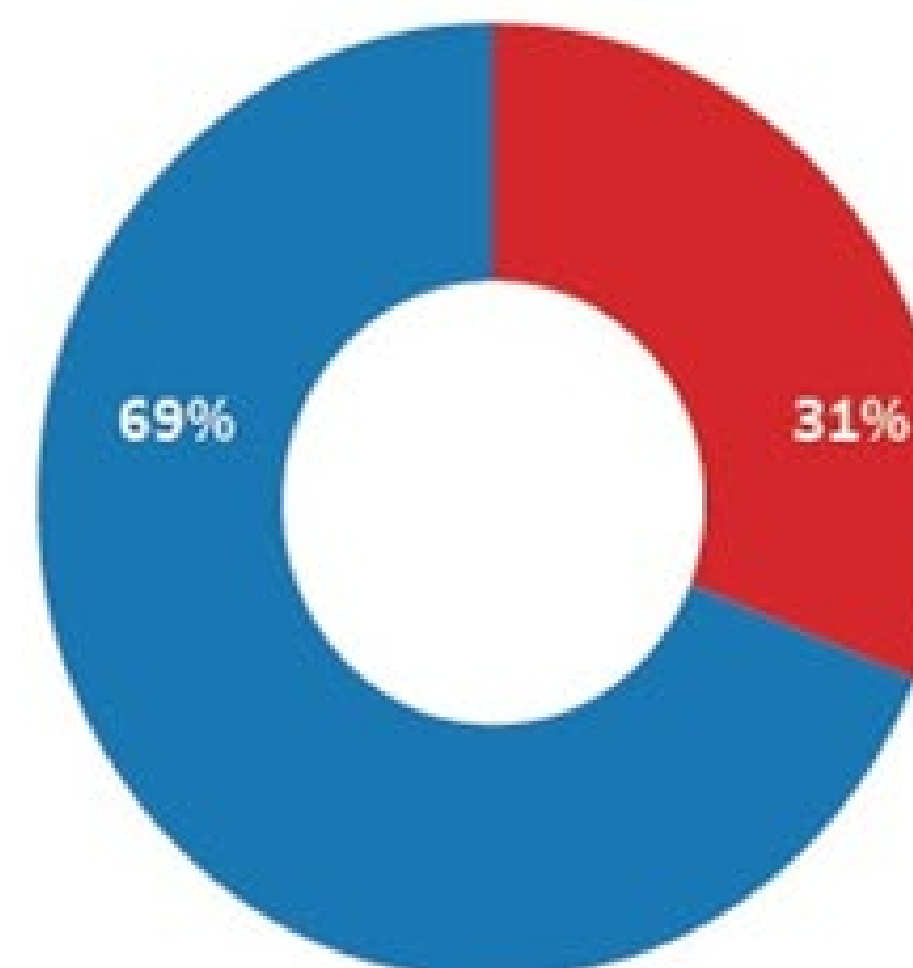
Female ■
Male ■

Race Distribution



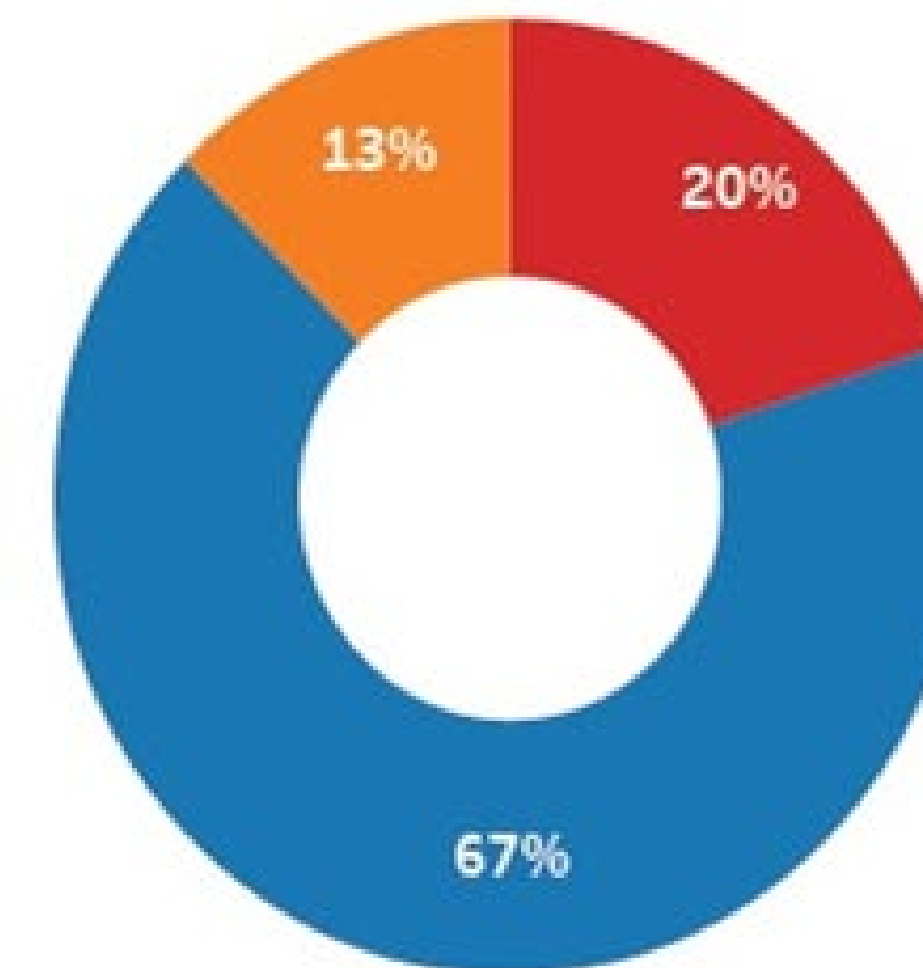
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

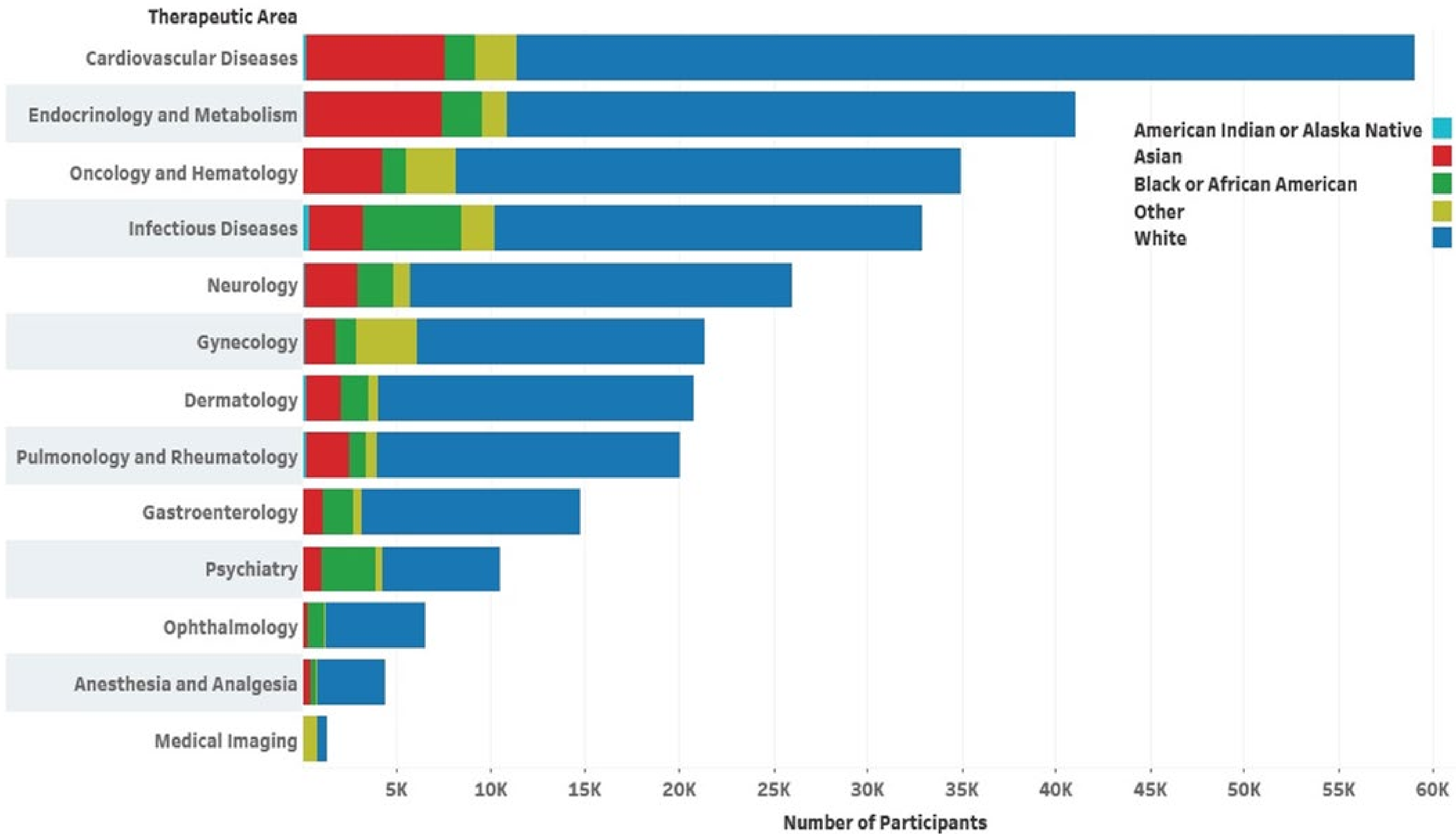
Ethnicity Distribution



Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

2015-2019: FDA Drug Trials Snapshots Summary Data

Race Breakdown Across Therapeutic Areas



“If you don’t see the light, you will soon see the fire” – Peggy Hamburg, Former FDA Commissioner

MARKETS BUSINESS INVESTING TECH POLITICS CNBC TV INVESTING CLUB PRO

HEALTH AND SCIENCE

FDA committee votes against Eli Lilly cancer treatment over concerns trials conducted only in China


PUBLISHED THU, FEB 10 2022 5:36 PM EST


Spencer Kimball
@SPENCEKIMBALL


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KEY POINTS

- The monoclonal antibody treatment, sintilimab, treats adults with non-small cell lung cancer in combination with chemotherapy.
- FDA committee members said the trial population of mostly Asian men did not represent the diversity of U.S. patients.
- Patients who develop lung cancer in the U.S. are split equally across genders and have diverse ethnic backgrounds.



**Squawk Box**


WATCH LIVE 

UP NEXT | **Squawk on the Street**
09:00 am ET [Listen](#)

TRENDING NOW



Jan. 6 Capitol riot committee to reveal new details showing Trump at center of effort to overturn Biden win



Biden announces standards to make

“Sponsors should prospectively address measures to ensure the representation of patients reflecting the population who will eventually use the product in the USA.”

- Rick Pazdur, Director FDA Oncology Center for Excellence (Feb 2022)

Equity, Diversity, and Inclusion Change is Possible!

**OCTOBER 2016: MENDOZA - FDA Recommendation:
Mandated Diversity Plan for Late Stage CTs**

**DECEMBER 2022 : FY 2023 Omnibus Legislation
Required Diversity Plan for Phase III CTs**

Contains Nonbinding Recommendations

**Collection of Race and Ethnicity Data
in Clinical Trials**

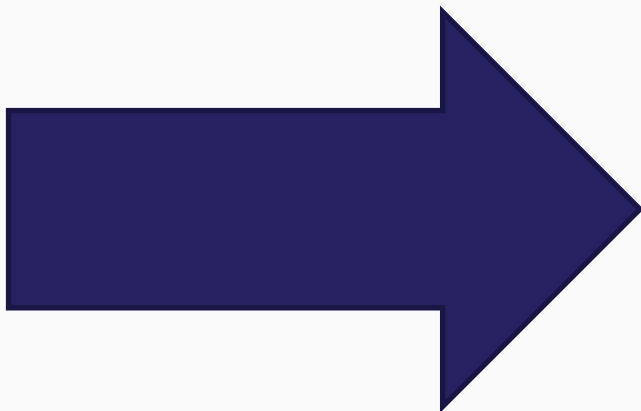
**Guidance for Industry and
Food and Drug Administration Staff**

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-5084 or omh@fda.hhs.gov.

U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Minority Health (OMH)
Office of Women's Health (OWH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)

October 2016
Clinical Medical



About *All of Us*

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**, we hope that researchers will one day uncover paths toward delivering **precision medicine – or individualized prevention, treatment, and care – for all of us**.

The *All of Us* Research Program is part of the broader Precision Medicine Initiative.

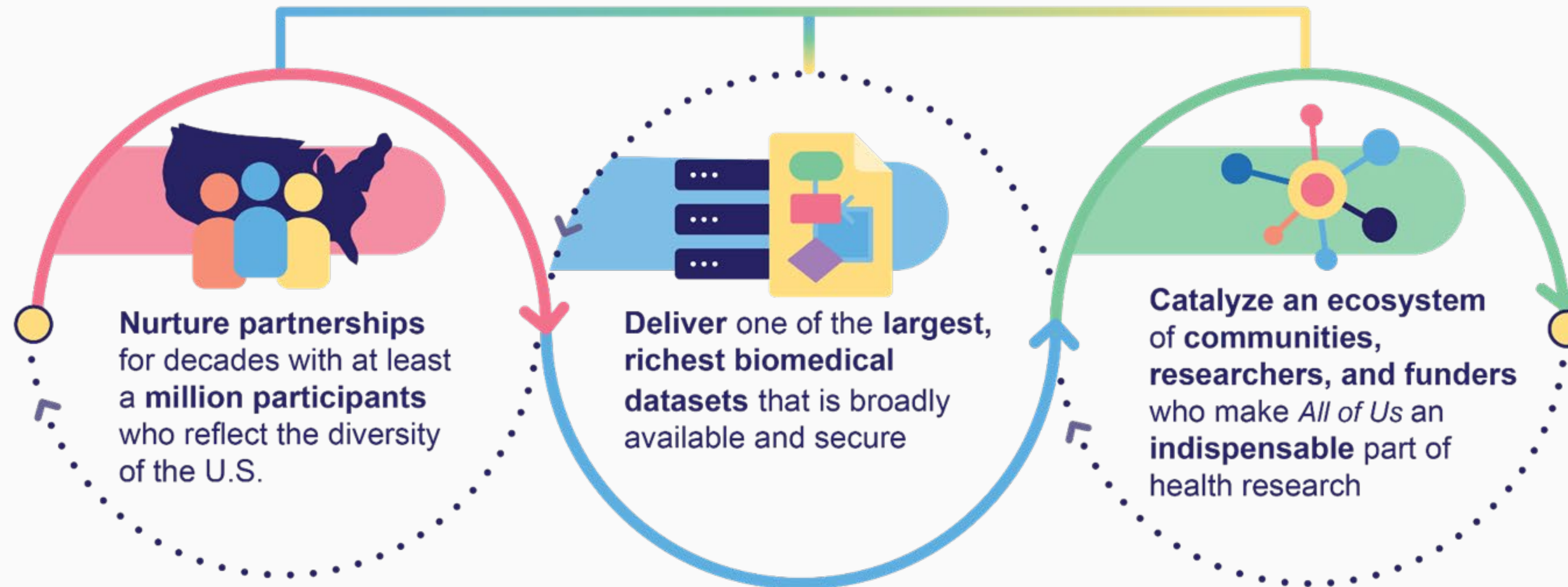


“All of Us is among the most ambitious research efforts that our nation has undertaken!”

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

Our Mission

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



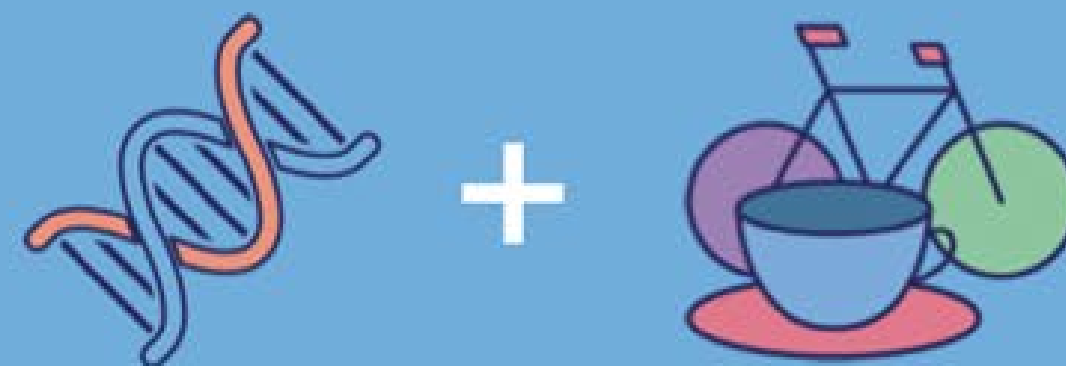
Made possible by a team that maintains a culture built around the program's core values

Enables research discoveries that drive more precise approaches to care

Engages **people & communities** who **have been left out of medical research** in the past



Combines **biological factors and social determinants** on a large, inclusive scale



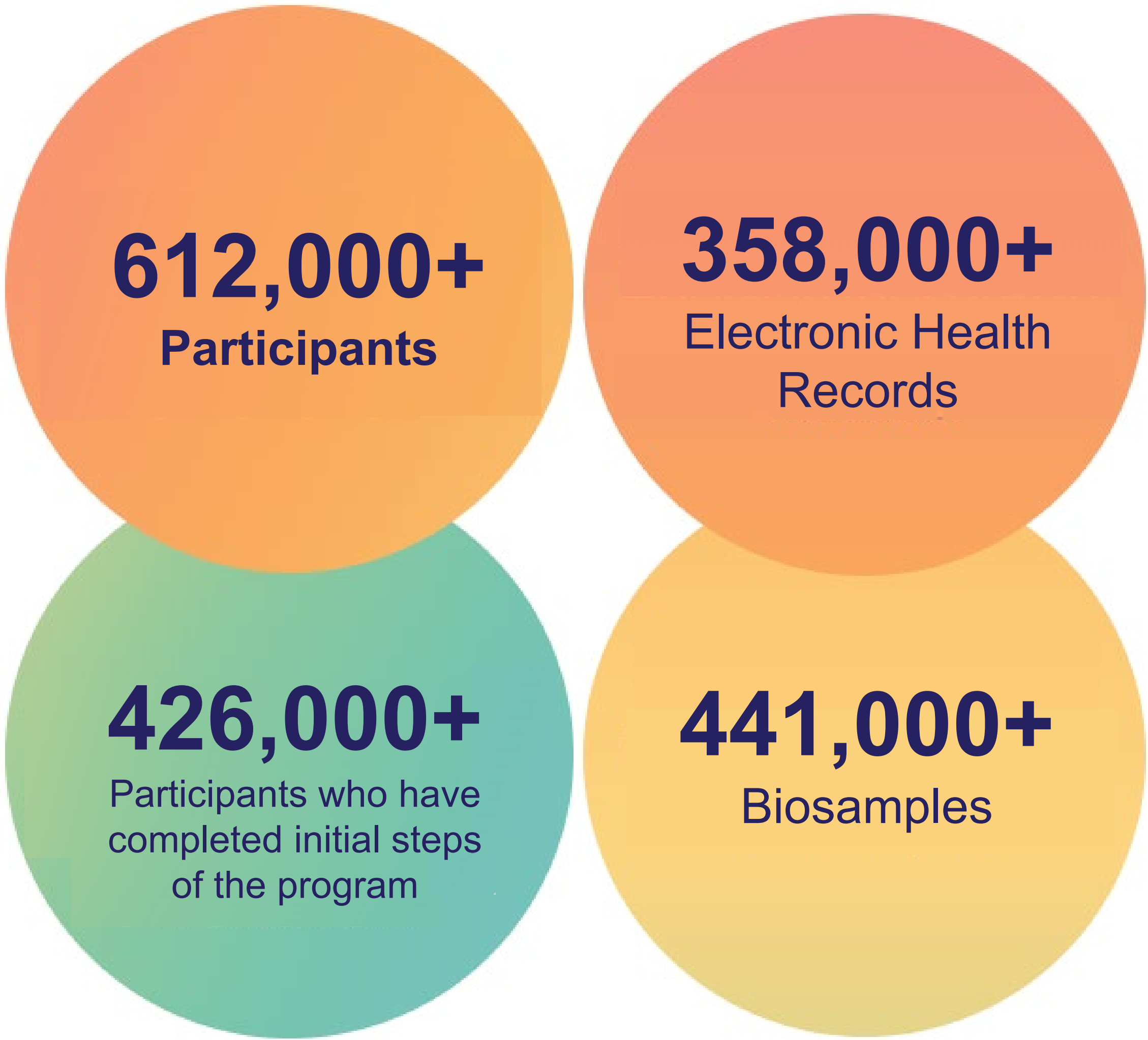
Easily accessible to any researcher with a secure internet connection



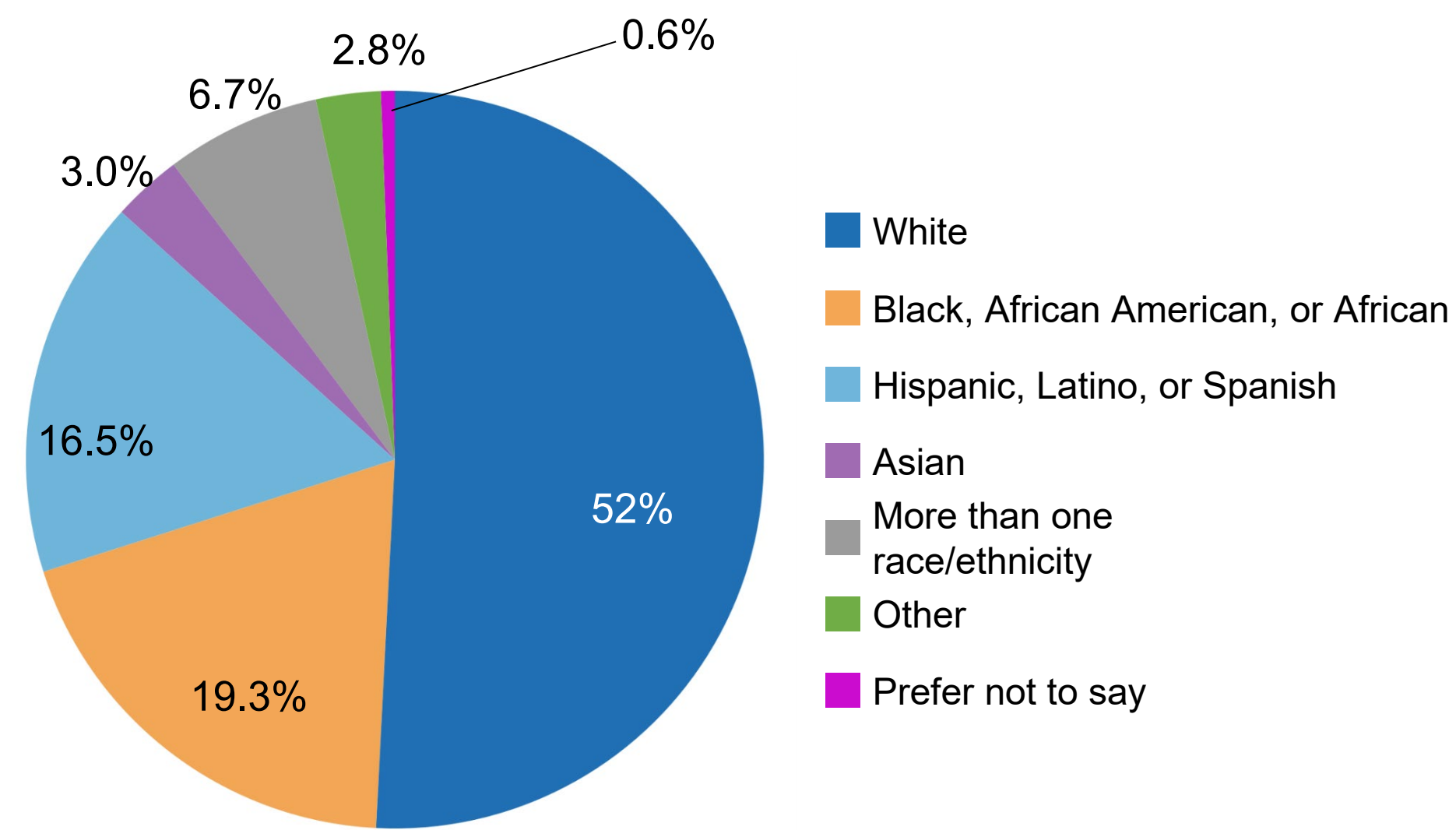
Follows participants as they move, age, and grow



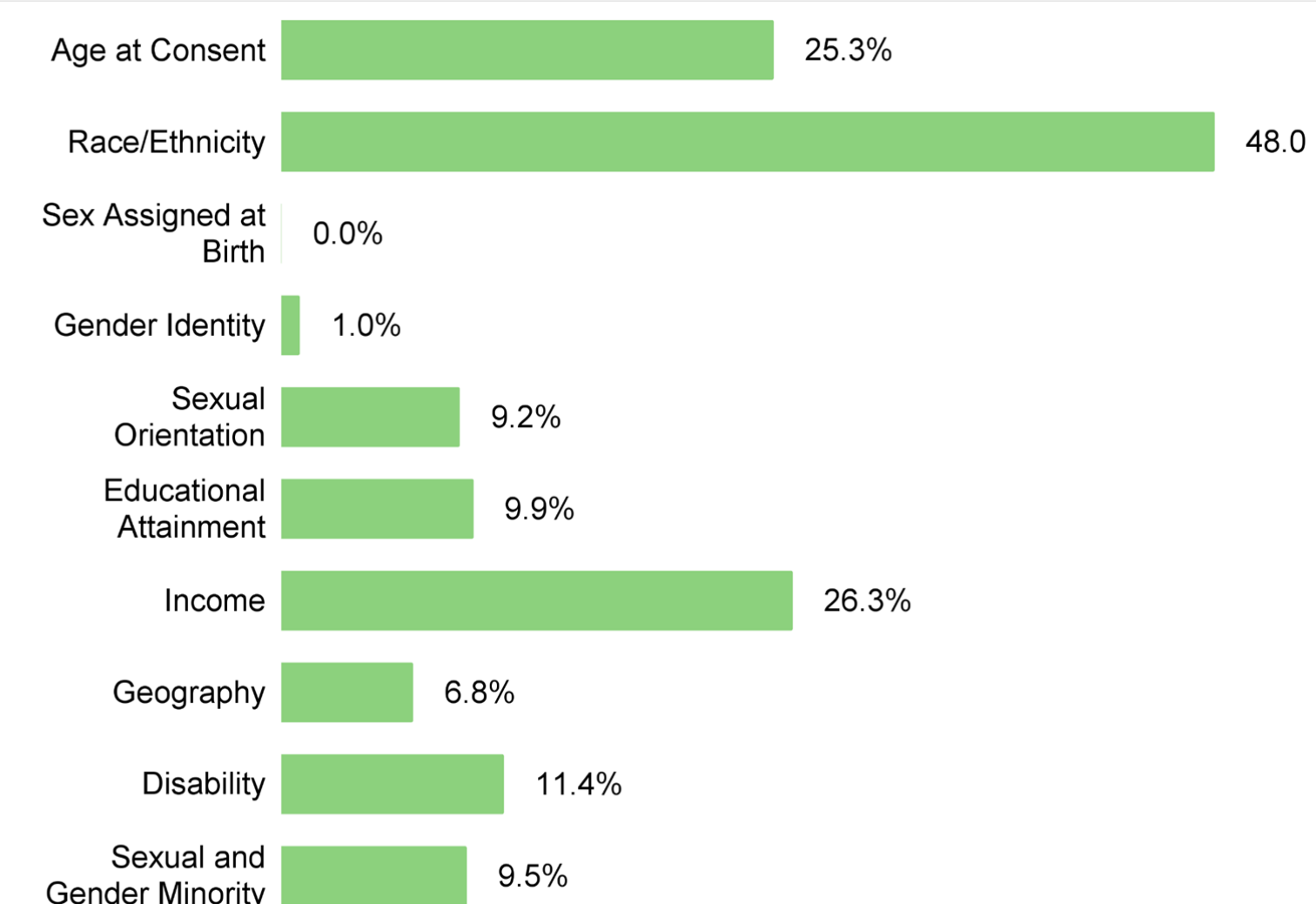
Status of the *All of Us* Research Program (as of March 15, 2023)



Race and Ethnicity



UBR Category

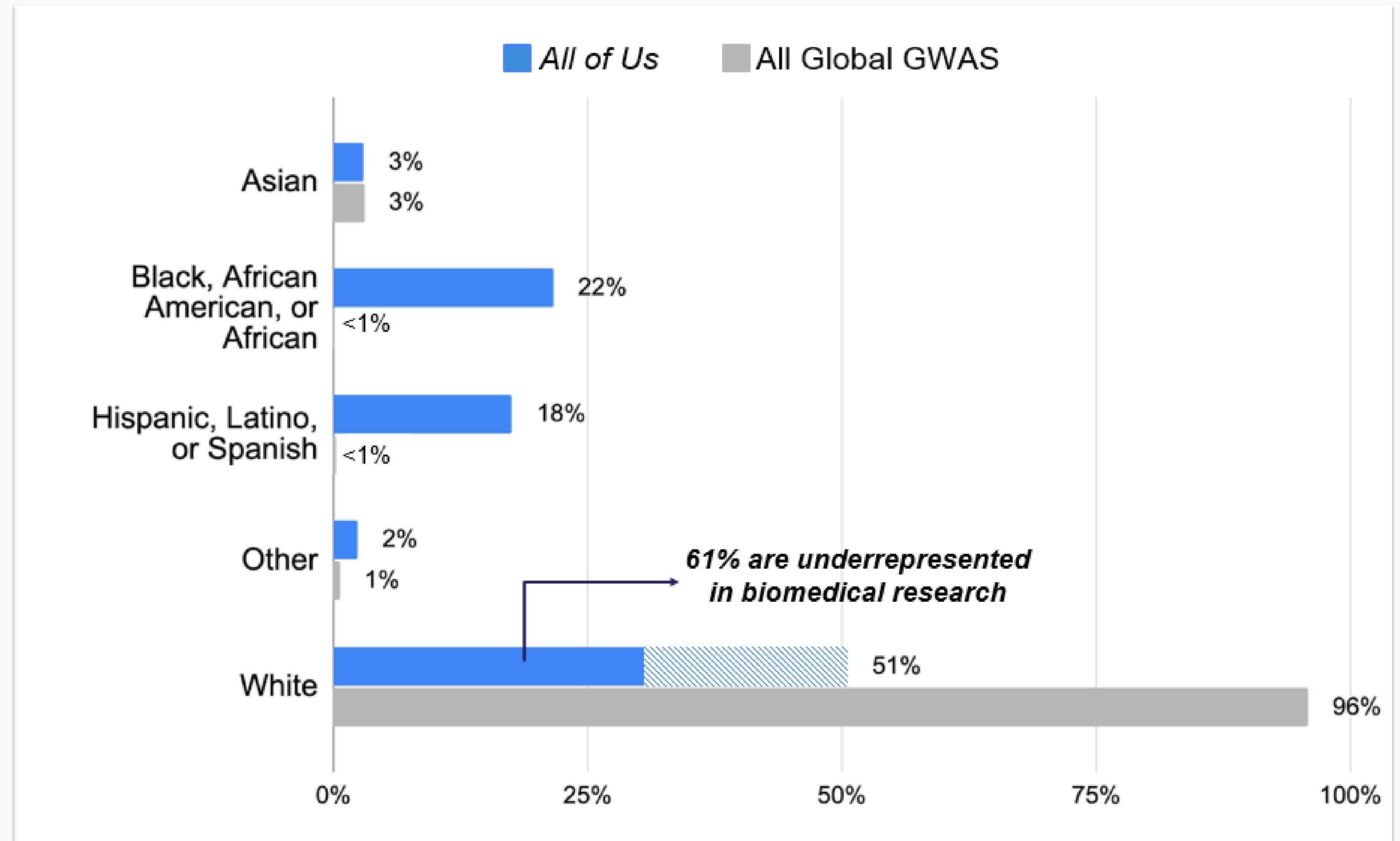


Enhancing Genomic Studies Through Inclusion

First genomic data set

~50% diverse by
race/ethnicity,

80% underrepresented in
biomedical research



All Global GWAS values from www.gwasdiversitymonitor.com. Values current as of February 17, 2022

Methods to Engage Underrepresented Communities in Biomedical Research

Engaging Underrepresented Communities through an Engagement Ecosystem



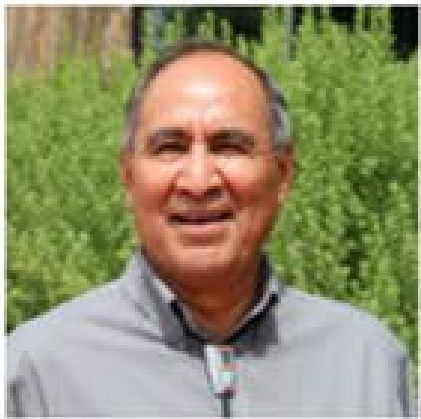
All of Us Community and Provider Partner Network (as of October 2021)



Engaging Communities Through Trusted Partners



Engaging Participants as Partners: *All of Us* Participant Ambassadors



Michael Allison
Arizona



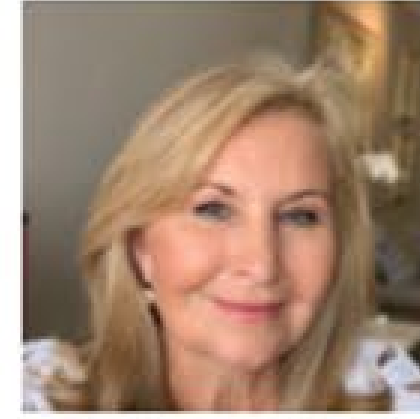
Michelle Anderson
Massachusetts



Carol Babcock
Missouri



Lottie Barnes
North Carolina



Joyce Bartle
New York



Keisha Bellamy
California



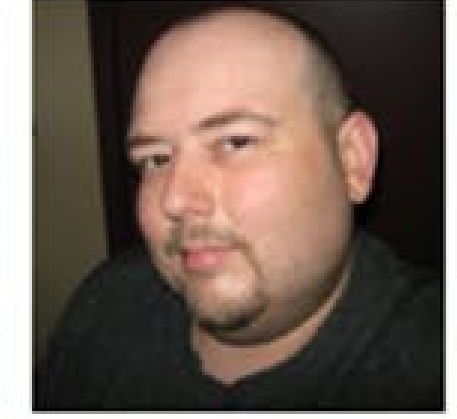
Craig Braquet
Louisiana



Randee Bloom
Michigan



Brian Bridges
California



Jeff Buchanan
Tennessee



Joyce Brown
Illinois



Daisy Burgos
Connecticut



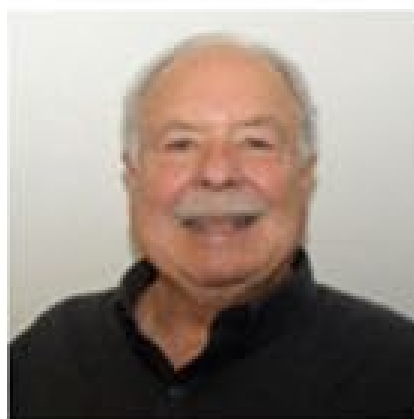
Hugo Campos
California



Ben Dorshorst
Wisconsin



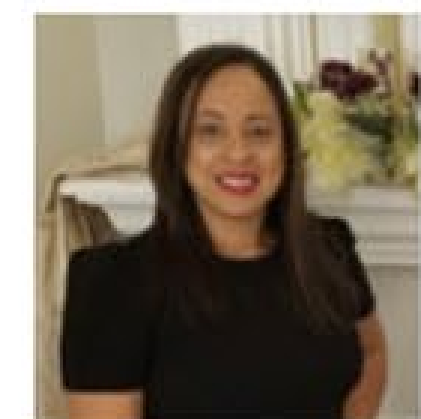
Sixto Escobar
Massachusetts



Roger Levine
California



Juana Mata
California



Aida Milian
New York



Michael Miller
Alabama



Evelyn Ortiz
New York



Valarie Paige
Mississippi



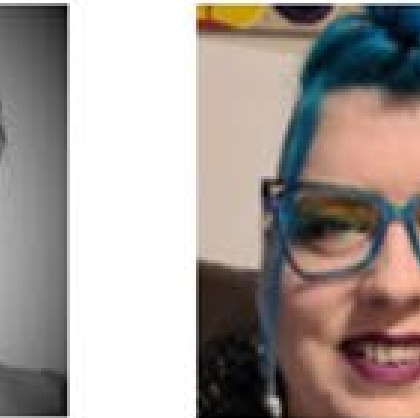
Gus Prieto
California



Marilyn Roman
Florida



Karla Rush
Arkansas



Lynz Sickler
Pennsylvania



Tyrone Thigpen
Mississippi



Tiana Vargas
California



Vilma Velez
New York



Joyce Bell Winkler
South Carolina

Return of Value to Participants


Genetic Ancestry and Traits (as of March 15, 2023)

DNA Results

You'll see all of your DNA results here when they're ready. See [options for your DNA results](#).


Genetic ancestry and trait results

5 results

**Genetic ancestry**
Genetic ancestry can be very interesting, but you may also learn information you didn't expect.
[Learn more](#)

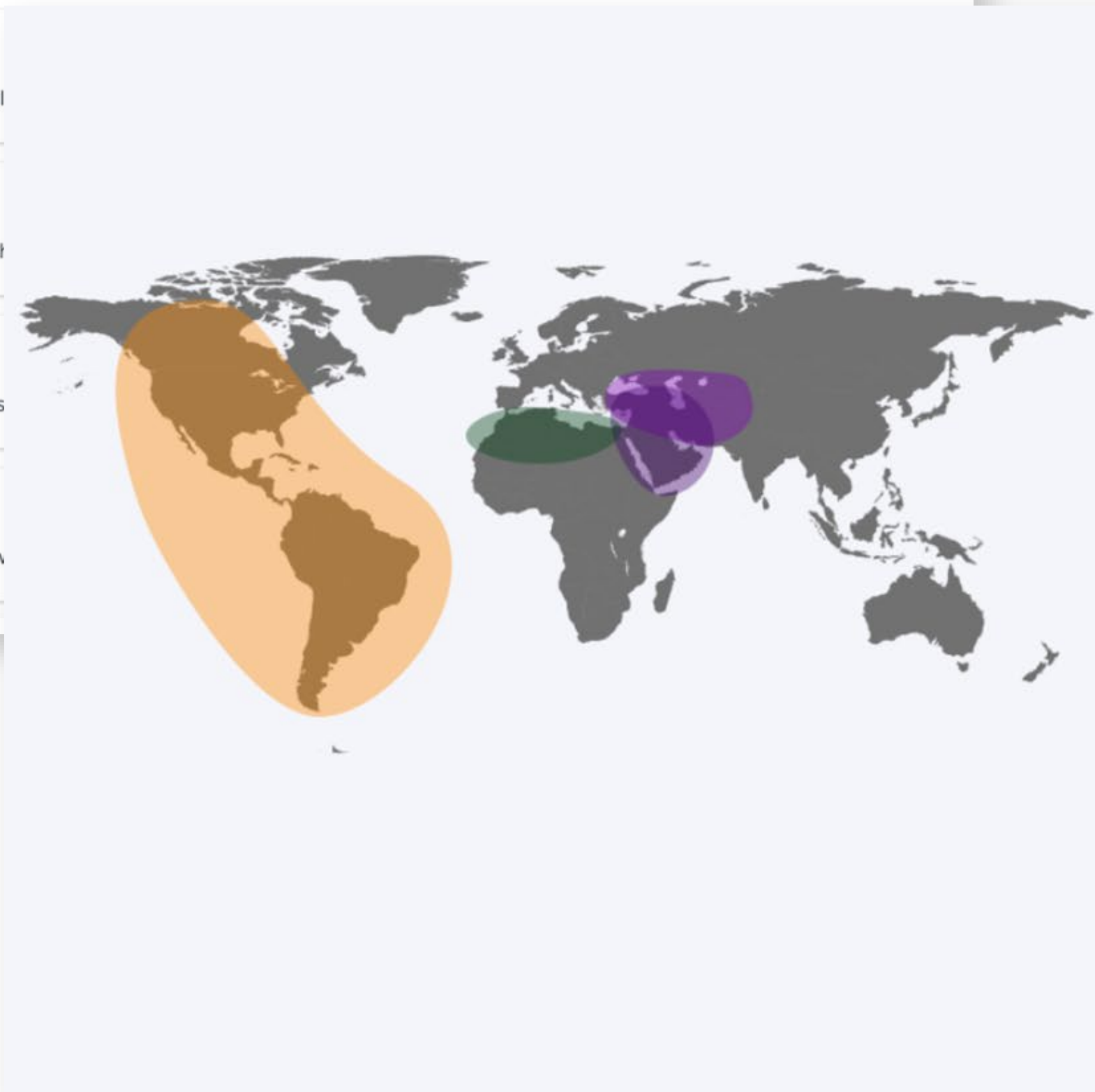
View Results

**Bitter taste perception**
Learn what your genes can tell

**Cilantro preference**
Your genes play a role in whetl

**Earwax type**
Flaky or sticky? Earwax type is

**Lactose intolerance**
Your genes have a say in how v




Over 182,000 participants sent notifications so far (email, push, and SMS based on participant preference) to choose if they want to receive results

The Americas	50% ▾
The Americas	100%
Such as North, Central, and South America	
The Middle East and North Africa	50% ▾
Northern Africa	10%
Such as Morocco, Algeria, and Egypt	
The Middle East	40%
Such as the Arabian Peninsula and Egypt	
Western Asia and the Caucasus	50%
Such as Turkey, Iran, Syria, Iraq, and the Caucasus	
See Other Ancestry Groups Tested	

- 70% complete genetic ancestry and traits informing loop choice (133k)
- 88% of those that view any result view any of the 4 trait results (116k)
- 98% of those that view any result viewed their genetic ancestry results (130k)

Genomic Health-Related Return of Results Released in December 2022

Hereditary Disease Risk (starting with ACMG59)



JANE DOE

DOB: January 1, 2000

ID: 2


Specimen: Whole Blood

Barcode: AOU 000 000 000 0002

Collected: January 1, 2022

Report date: September 29, 2022

RESEARCH RESULT - Your doctor will need to confirm this result with a clinical test before using it in your care.



Your result:

Something very important for your health was found in your *BRCA1* gene.

What does this mean?

- If confirmed by a clinical DNA test, this result means that you are more likely to get some types of cancers than other people.
- It does **not** mean that you have some types of cancers.
- It does **not** mean that you will definitely get some types of cancers.
- **This result is important** and should not be ignored.

IMPORTANT!

Share this report with your doctor.

- This report comes from a research program, so **it is a research result**. Your doctor will need to confirm these results with a clinical DNA test before using them in your care.
- **Do not change your medical care** before this result is confirmed by your doctor.
- **Results provided are from an investigational device**. An “investigational device” is a device that is the subject of a clinical study.


Genome Center: BCM

Laboratory Director: test

Hereditary Disease Risk Report: DNA and the risk for some diseases

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Medicine and Your DNA (Pharmacogenomics)



DOB:

ID:


Specimen:

Barcode:

Collected:

Report date:

RESEARCH RESULT — Your doctor will need to confirm this result with a clinical test before using it in your care.



Medicine and your DNA

Our genes affect how we respond to medicine.

They do that in many different ways. Some genes help move medicines to the right part of the body.

What is this kind of information used for?

Doctors and pharmacists use this kind of information when they consider why medicines work differently for different people.

But doctors and pharmacists don't make decisions based on just DNA.

Some other important considerations can be age, weight, health, diet, and other medicines you are taking at the same time.

Pharmacogenetics: Medicine and your DNA

Genome Center: Broad Institute of MIT and Harvard, CLIA #22D2055652

Laboratory Director: Heidi L. Rehm, PhD, FACMG

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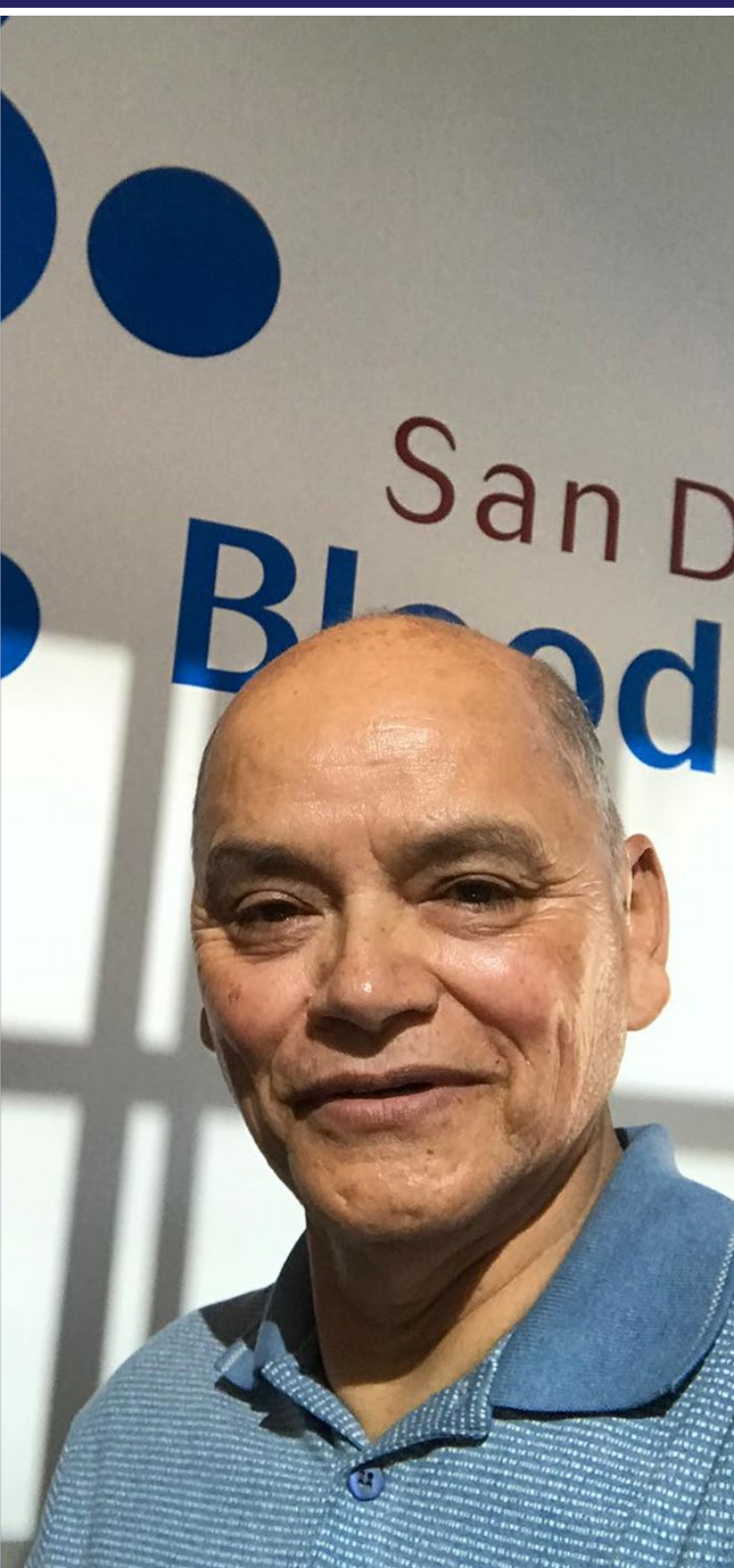
- Participants can choose results they want
- Interpretation begins at Clinical Validation Laboratories
- All results supported by Genetic Counselors
- **As of March 15, 2023:**
 - **37,235 participants** have been **notified** of their results
 - **>9,640 participants** have **completed** the Hereditary Disease Risk and/or the Medicine and Your DNA informing loops
 - Currently ramping up to notify another **155,000 participants**



AllofUs.NIH.gov

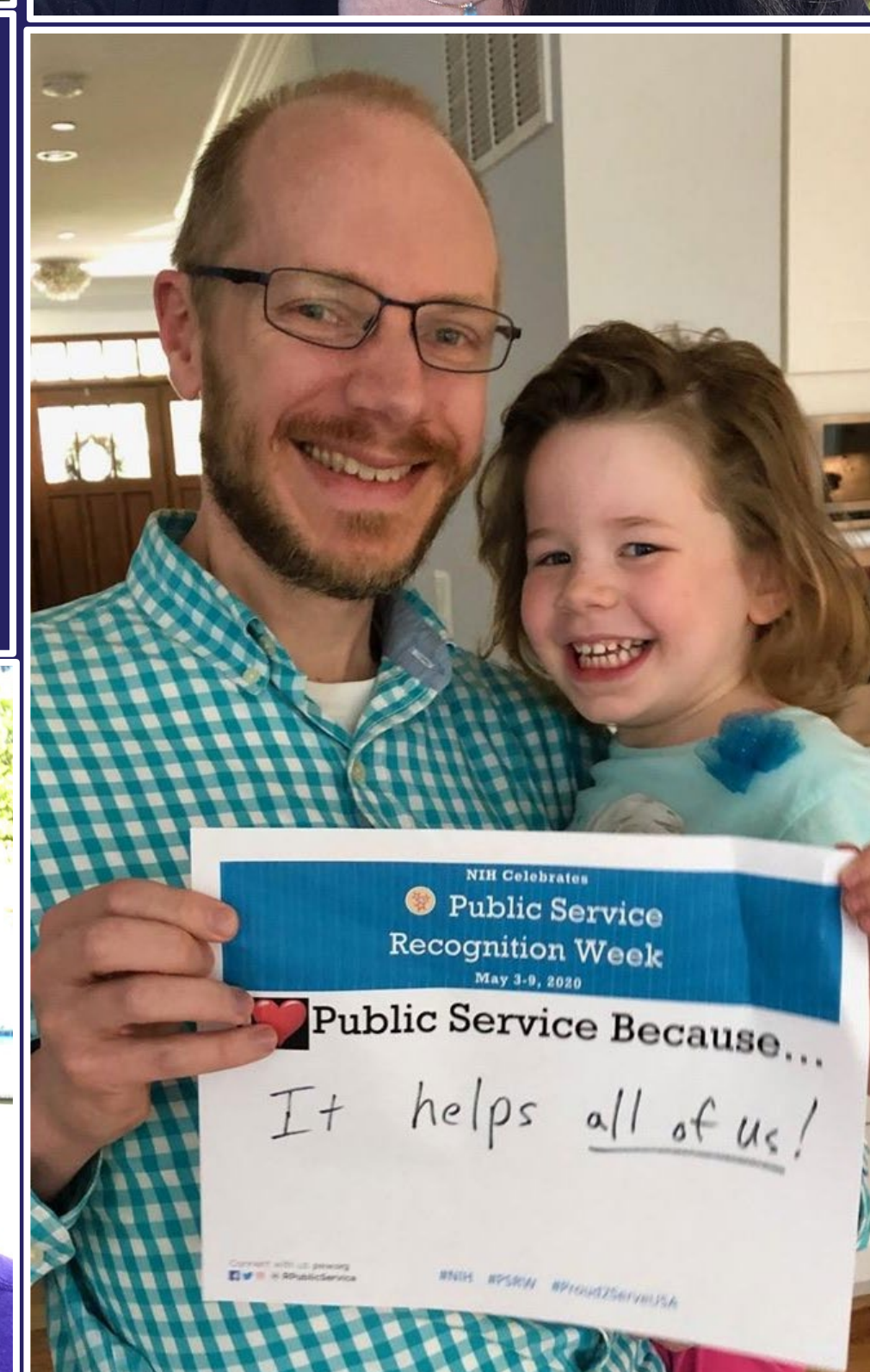
JoinAllofUs.org

ResearchAllofUs.org



Thank you!

    @AllofUsResearch
@AllofUsCEO
#JoinAllofUs



Thank you to our 610,000+ participants!