



Achieving Health Equity through the *All of Us* Research Program

Martin Mendoza, PhD
Director of Health Equity
October 18, 2022

Health Equity Innovation Summit
Texas A&M University Health



Goals

- Discuss importance of diversity and equity in biomedical research
- Share the **mission and goals** of the *All of Us* Research Program
- Discuss how *All of Us* is **advancing health equity and inclusion** in research
- Provide examples of how *All of Us* can serve as a **resource for addressing health disparities**

The Lack of Underrepresented Communities in Biomedical Research

Why Participate

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%

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

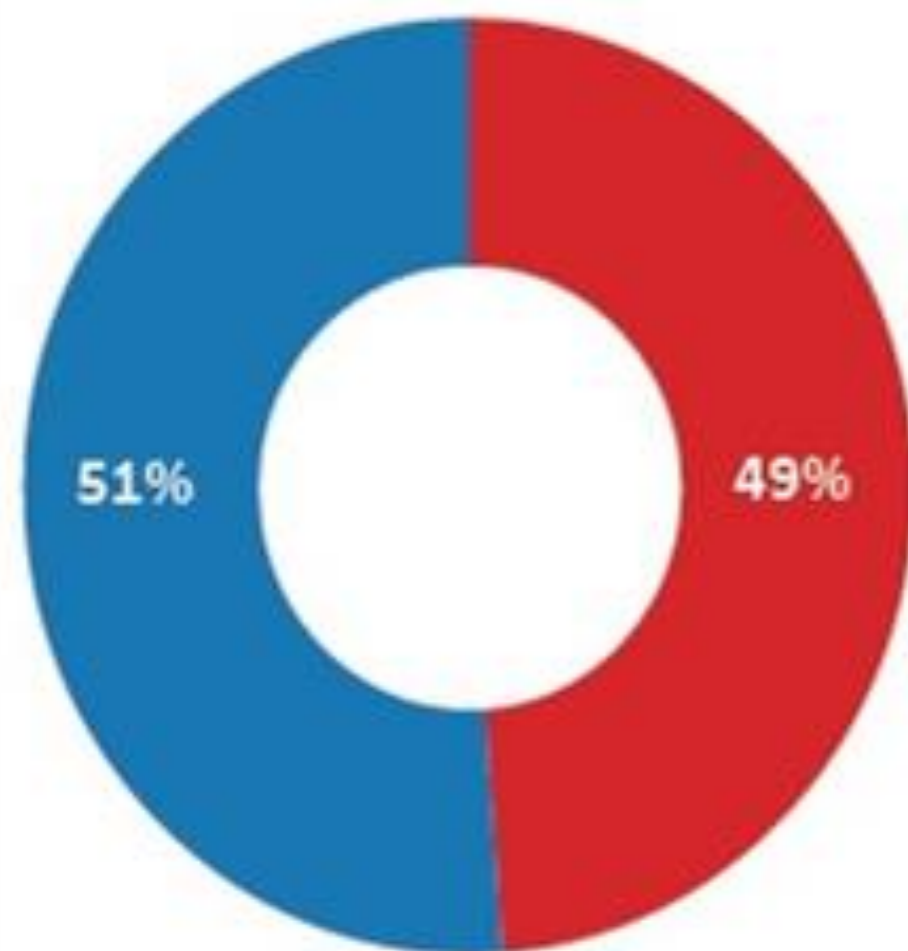
- 3.1% of NIH clinical trial participants nationwide
 - 2.7% of FDA novel drug trials

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

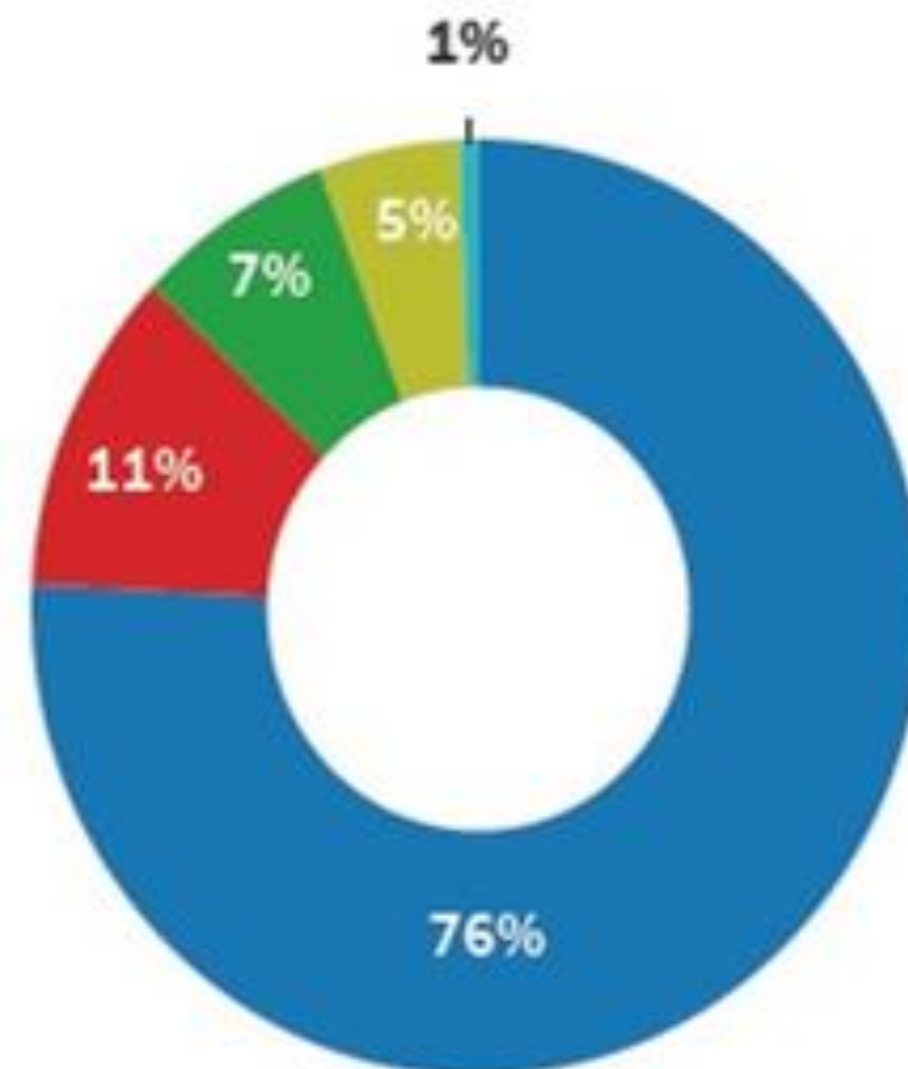
2015-2019: FDA Drug Trials Snapshots Summary Data

Sex Distribution



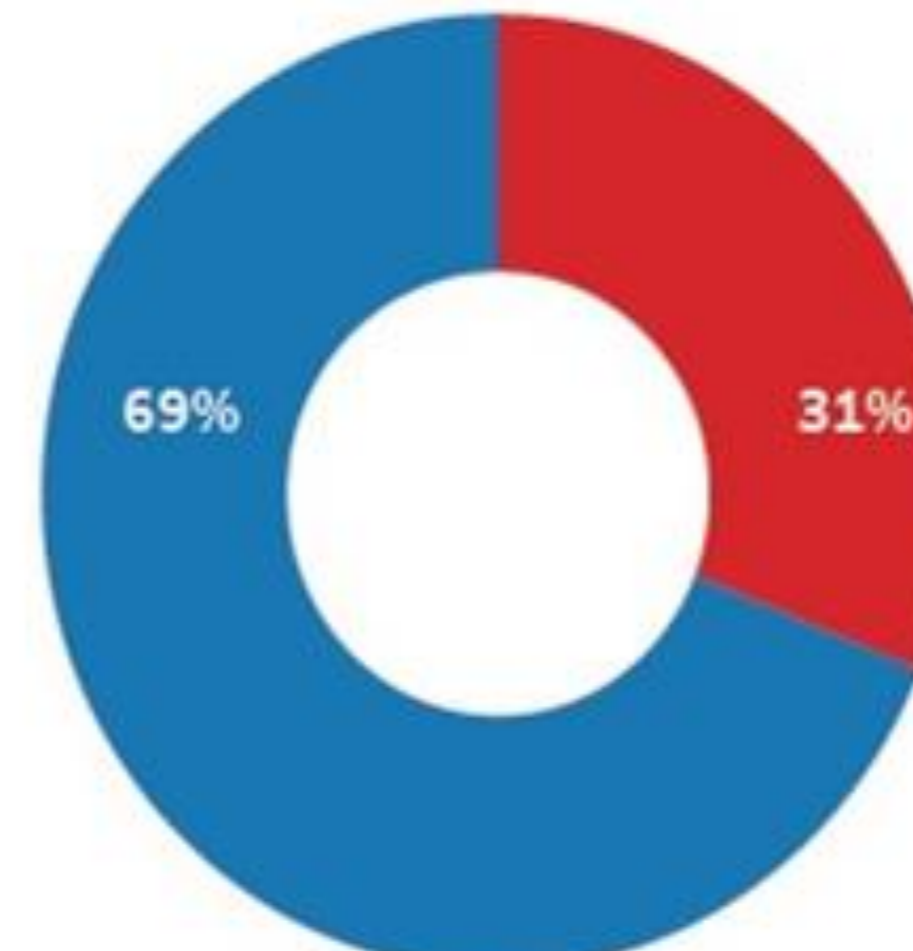
Female ■
Male ■

Race Distribution



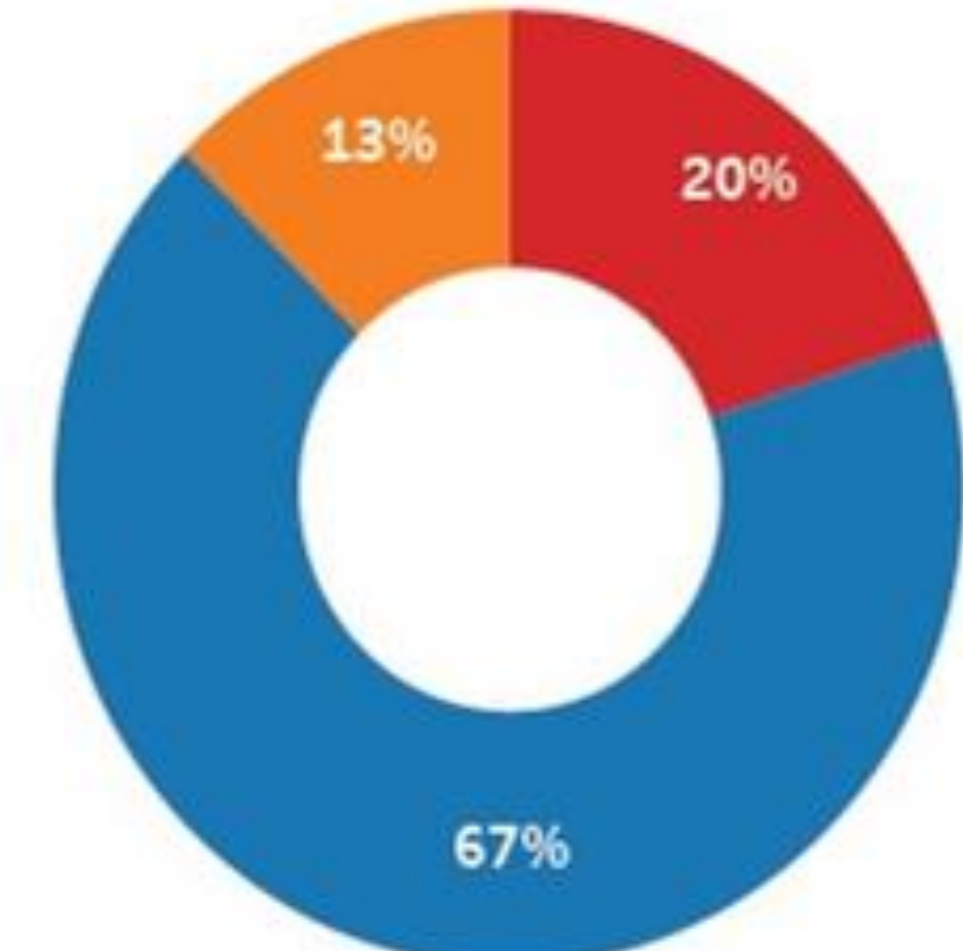
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

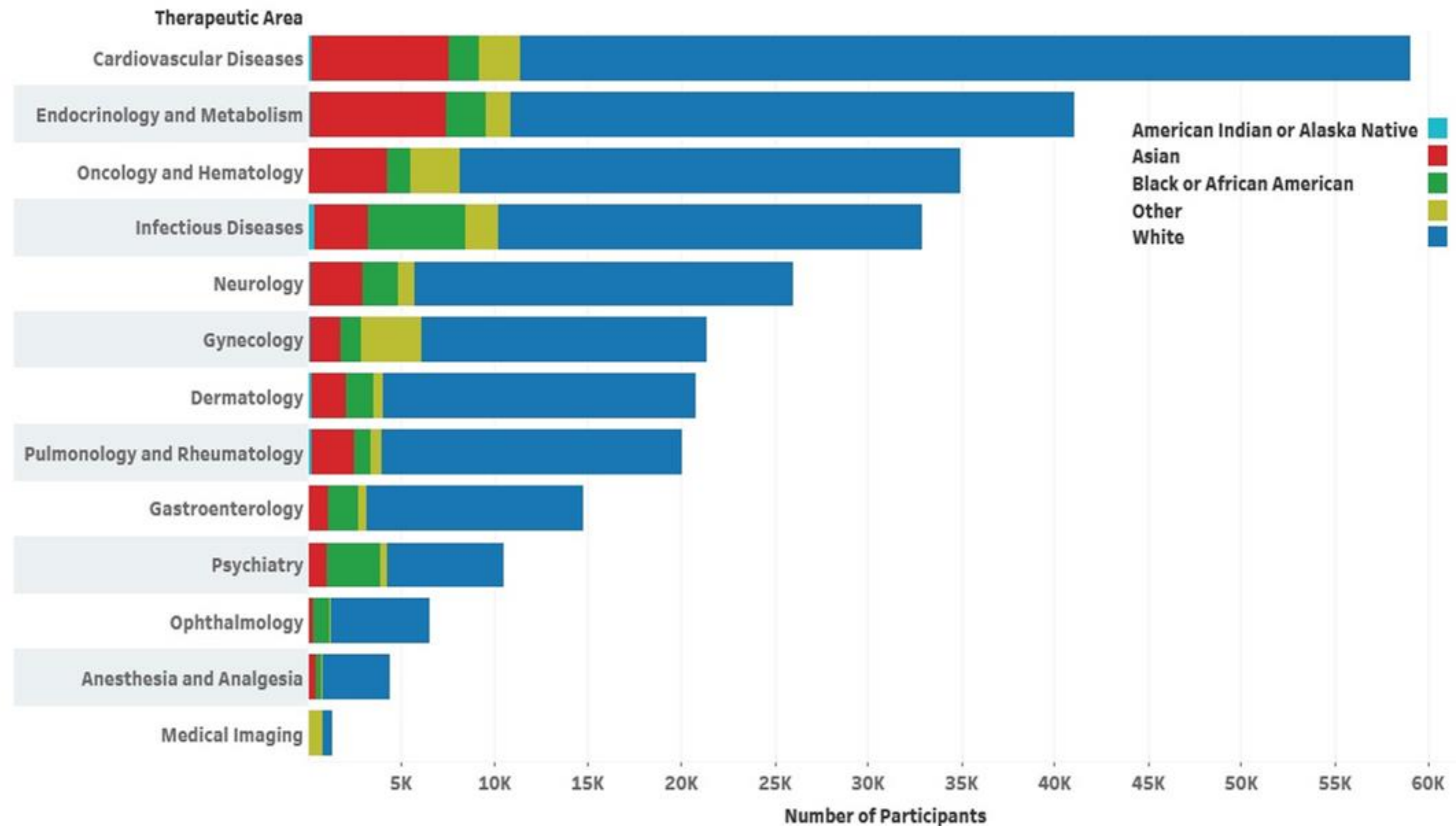
Ethnicity Distribution



Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

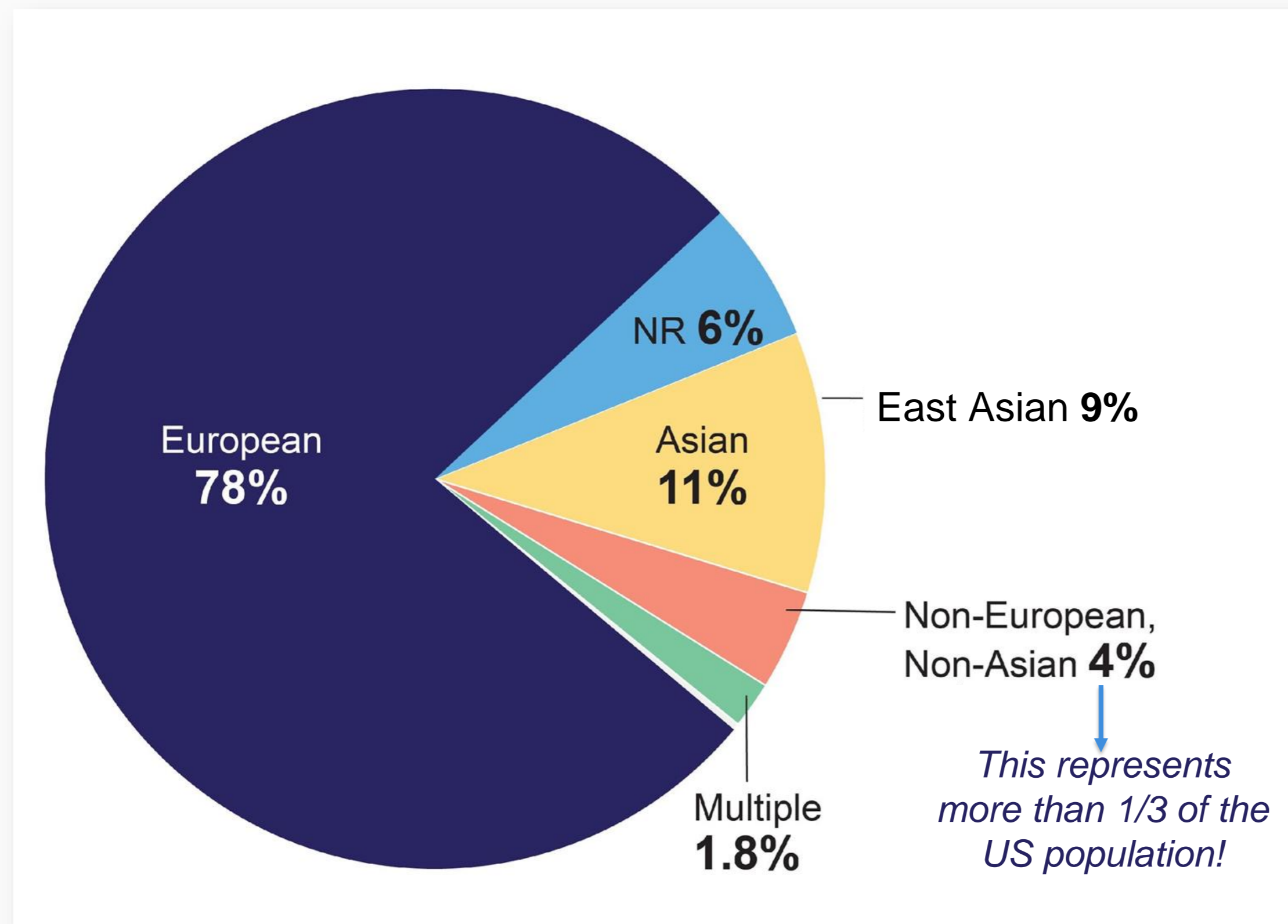
2015-2019: FDA Drug Trials Snapshots Summary Data

Race Breakdown Across Therapeutic Areas

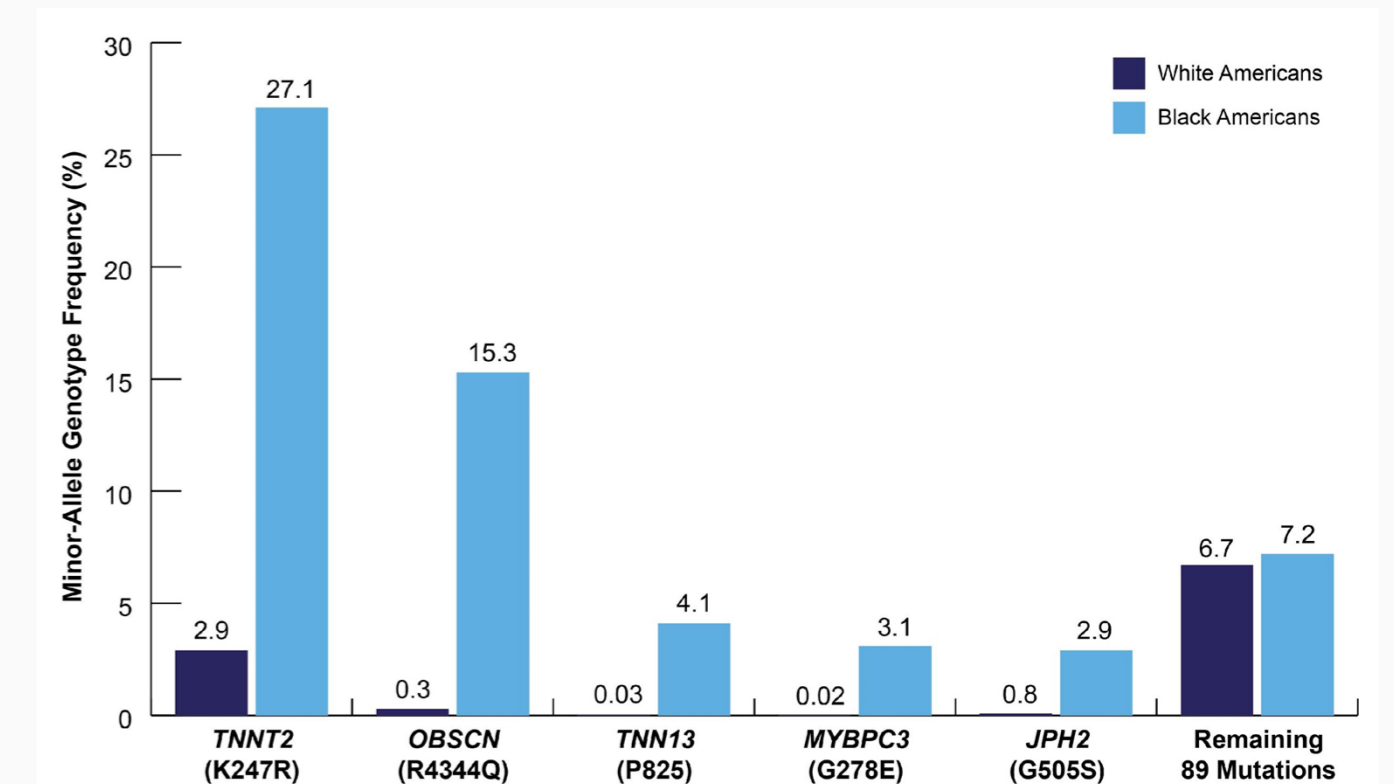


Precision Medicine is Expanding, but Genomic Studies Are Not Diverse

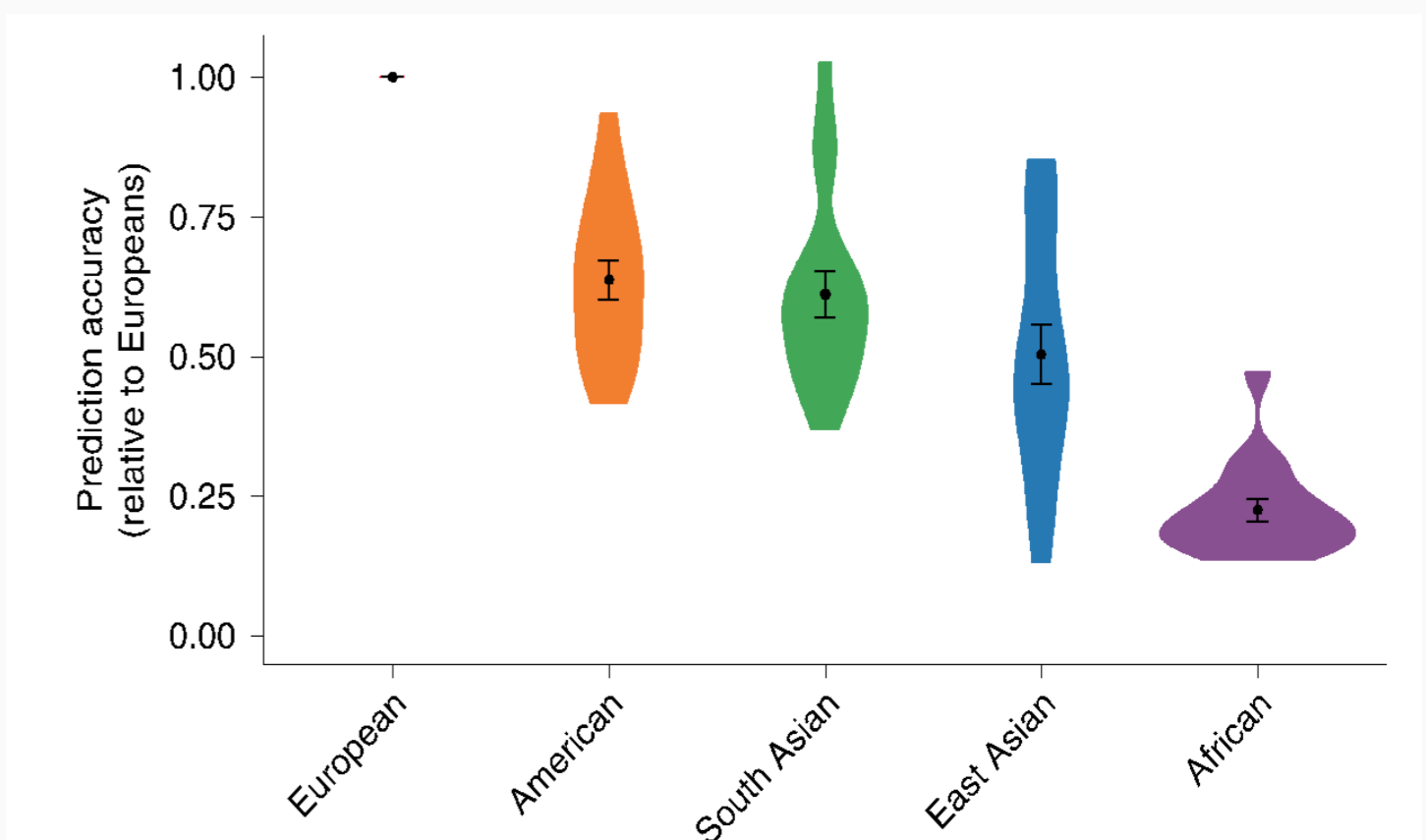
There is a lack of diversity in genome-wide association studies.



This affects interpretation of genetic variants...



... polygenic risk scores for diseases



... and many other impacts

FDA Clinical Trial Diversity Guidance

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

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

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

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

SHARE f t in e

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.

TV
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)



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.

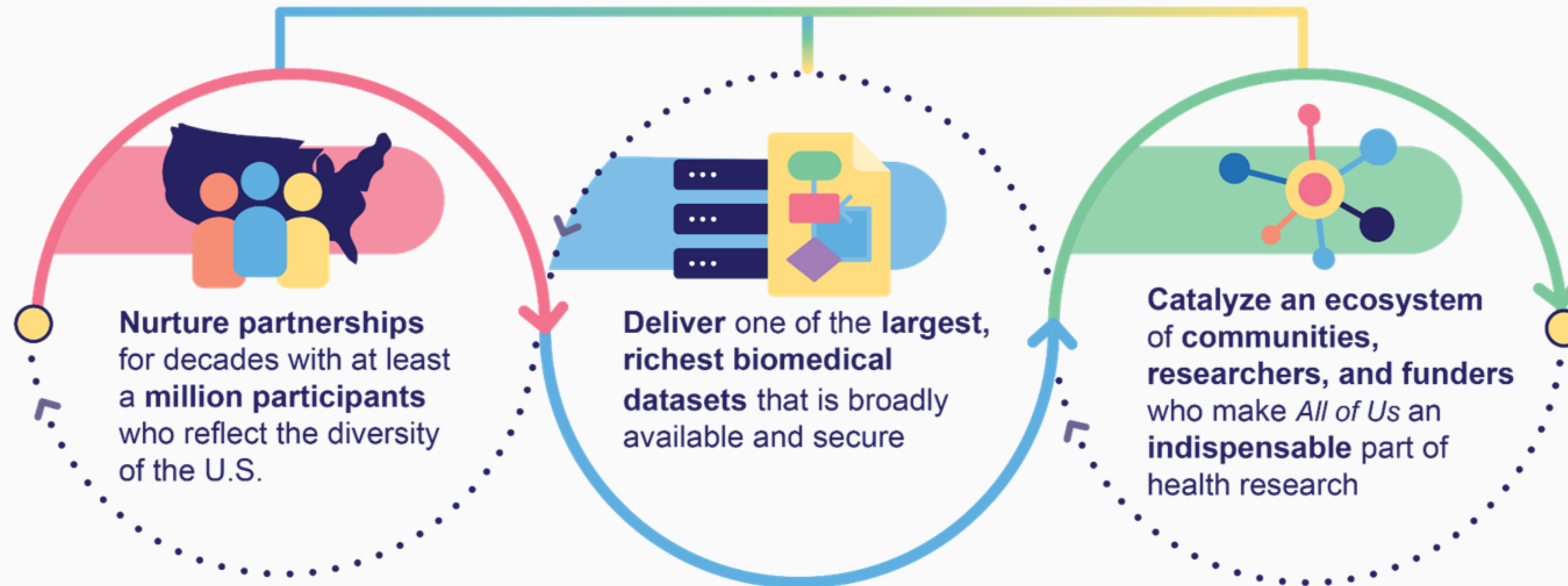


“All of Us is among the most ambitious research efforts that our nation has undertaken!”

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

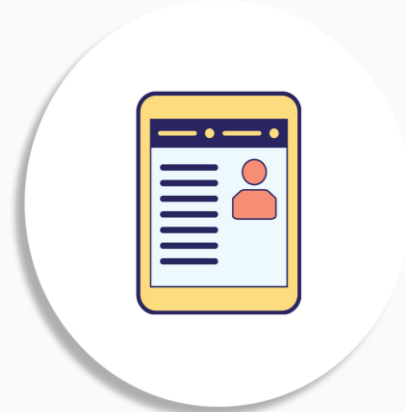


Made possible by a team that maintains a culture built around the program's core values

By the end of 2026 we will...



Enroll 1 million participants who reflect the diversity of the US, cover the lifespan, and have shared all baseline elements. Of these participants, 500,000 are actively engaged in the program.



Expand data available for 1 million participants, to include surveys, health data streams, a whole genome sequence, environmental data, and physical measures.



Develop and launch a scalable ancillary studies program that expands the cohort and delivers additional phenotypic, lifestyle, environmental, and biologic data.



Establish a diverse global community of 10,000 researchers productively using *All of Us* data.



Incorporate participant return of value into data collections and assess its impact, including return of information to participants on genomics and EHR.

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



All of Us Research: How it Works



Status of the *All of Us* Research Program (as of October 13, 2022)

539,000+
Participants

324,000+
Electronic Health
Records

378,000+
Participants who have
completed initial steps
of the program

397,000+
Biosamples

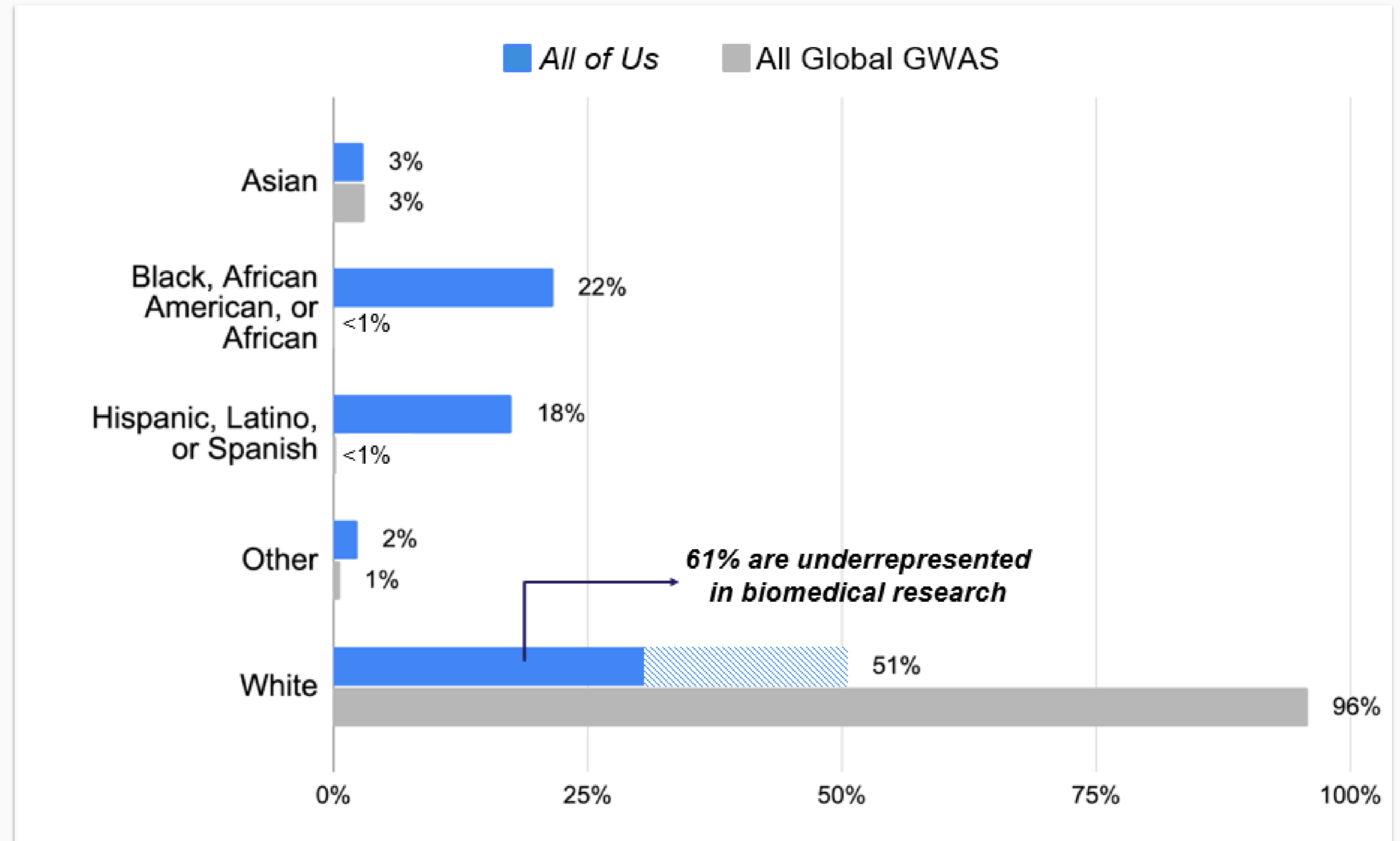
Participant Demographics	Percentages
At least one UBR	80.4%
Non-white race or Hispanic/Latino ethnicity	48.1%
Age \geq 65	25.3%
Less than GED	9.9%
Annual Income \leq \$25k	26.4%
Sexual and Gender Minorities	9.5%
Disability	11.3%

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

All of Us 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 is accessed **broadly** for research purposes.
- **Security and privacy** are of highest importance.
- The program may be a catalyst for **positive change** in research.



Engaging Underrepresented Communities through an Engagement Ecosystem



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



Ensuring Accessibility in Engagement Activities through the *All of Us* Journey

American Association on Health and Disability



The *All of Us Journey*, our Mobile Engagement Asset (MEA), is a traveling mobile exhibit that addresses access issues by going where the community is located.

Community partners like the National Alliance for Hispanic Health (NAHH) and American Association on Health and Disability (AAHD), have partnered with the MEA as a way to ensure no community is left behind.

National Alliance for Hispanic Health



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



Michael Allison
Arizona



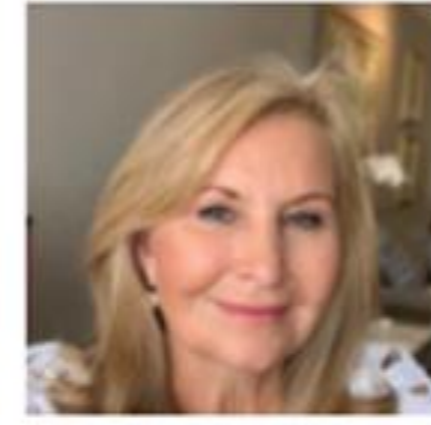
Michelle Anderson
Massachusetts



Carol Babcock
Missouri



Lottie Barnes
North Carolina



Joyce Bartle
New York



Keisha Bellamy
California



Craig Braquet
Louisiana



Rande Bloom
Michigan



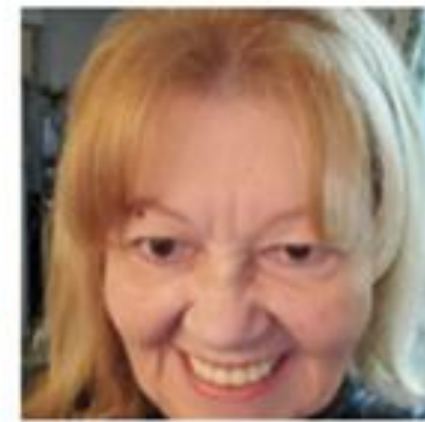
Brian Bridges
California



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



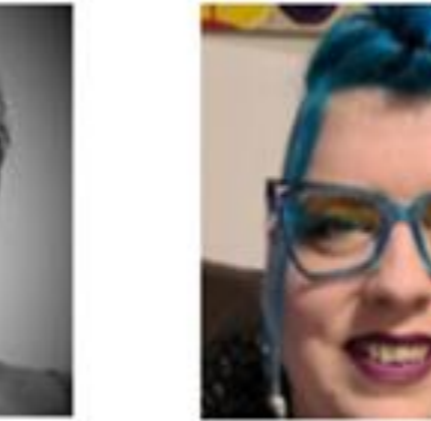
Gus Prieto
California



Marilyn Roman
Florida



Karla Rush
Arkansas



Lynz Sickler
Pennsylvania



Tyrone Thigpen
Mississippi



Tiana Vargas
California



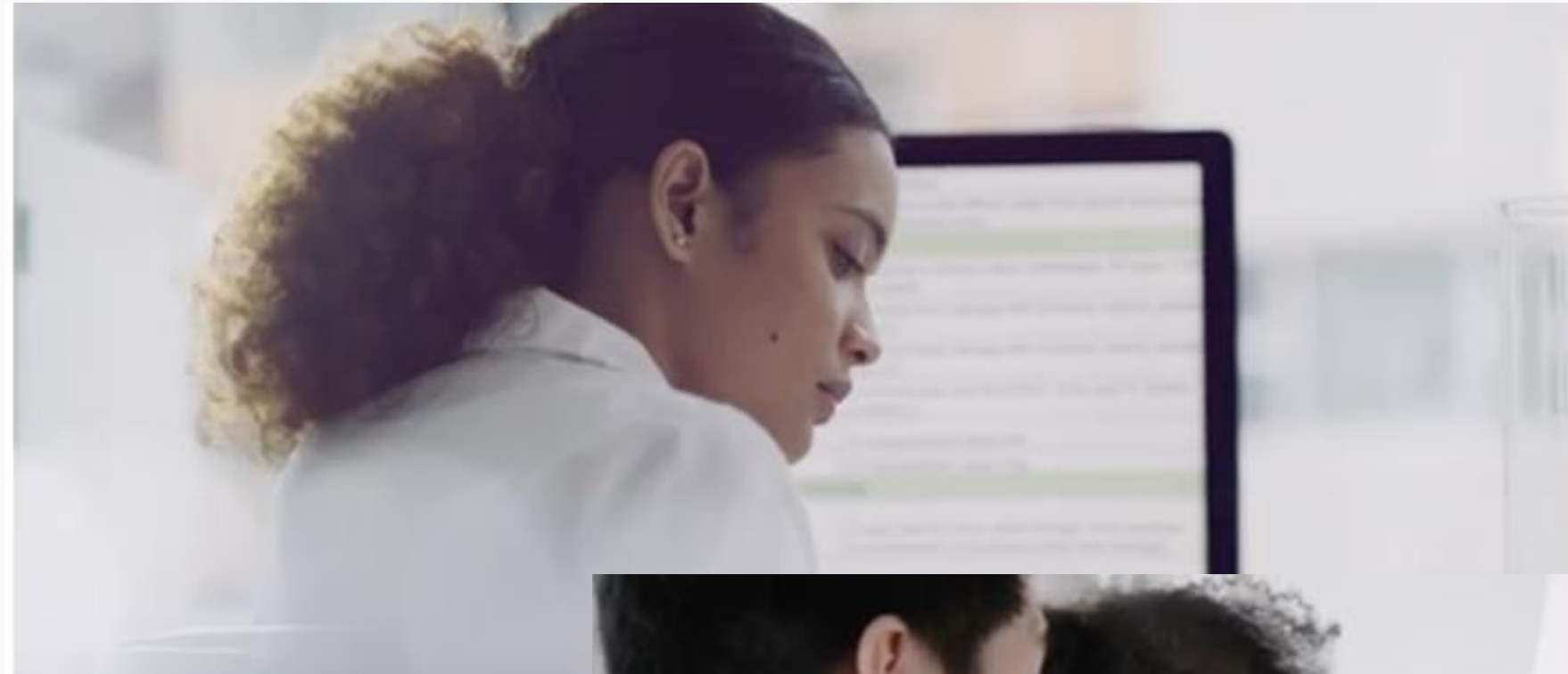
Vilma Velez
New York



Joyce Bell Winkler
South Carolina

Researcher Diversity

We Bring Together a Diverse Cohort of Researchers



The *All of Us* Research Program:

- **Has created a demographically diverse researcher cohort** that promotes responsible and ethical use of data, returns value to participant communities, and accelerates research impact.
- **Encourages student assemblies and early-stage investigators**, fostering fresh, creative perspectives, and innovative approaches to research.
- **Ensures access for researchers from various institutions/organizations** to establish a truly equitable resource for all.

Engaging a Diverse Researcher Community through Outreach



REGISTER TODAY
All of Us Research Program
Researchers Convention

March 31 - April 1,
2022



How *All of Us* Engages with Diverse Researcher Communities:

- **Partnership with Baylor College of Medicine:** *All of Us* Evenings with Genetics Research Program series with Dr. Debra Dianne Murray
- **Partnerships with HBCUs through CPGI Network:** Xavier University of Louisiana
- **Creating a pipeline for students:** The *All of Us* Minority Student Research Symposium (MSRS)

All of Us Research Program Researchers Convention: March 31–April 1

The Minority Student Research Symposium (MSRS), March 31

Poster presentations from student researchers and a keynote conversation about the power of mentorship.

- MSRS student researchers are undergraduate, graduate, and professional degree (medical, dental) students from minority communities
- MSRS student researchers were paired with a mentor during their research process.

Science Day, April 1

Panel discussions with registered Researcher Workbench users about their research and how it aligns with the goals and values of the All of Us Research Program



The poster features a collage of images: a group of three young women, a woman in a lab coat, a woman in a lab coat with blue gloves, and a man in a lab coat. The text on the poster includes:

All of Us
RESEARCH PROGRAM

REGISTER TODAY

**All of Us Research Program
Researchers Convention**

March 31 - April 1,
2022

**Researchers
Convention**

inority Science Day

All of Us
RESEARCH PROGRAM

Researcher Workbench: By the Numbers *(Since Launch in May 2020)*

Research on the Researcher Workbench



3,270+
Registered
Researchers



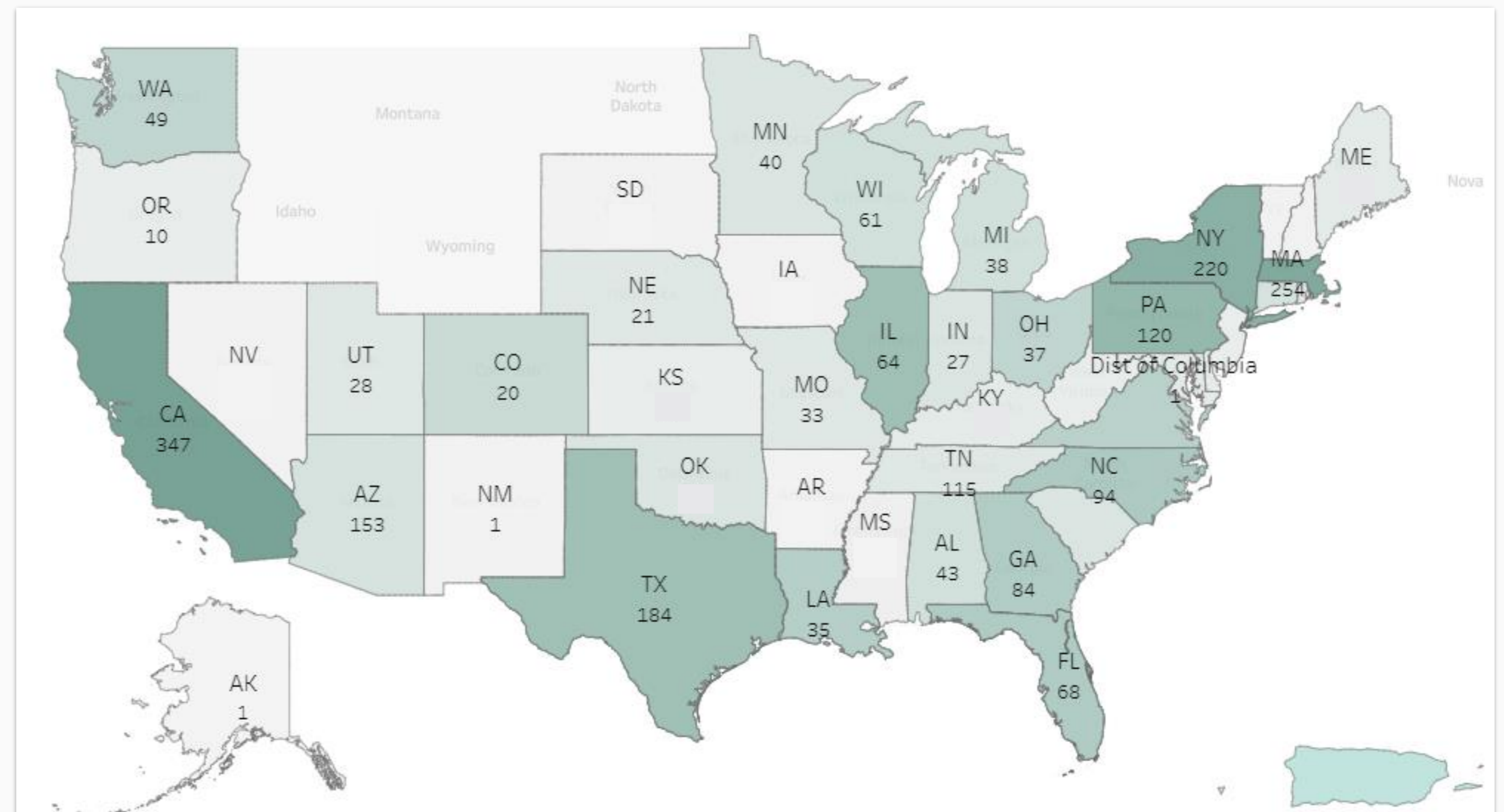
2,690+
Active
Projects



65+ Publications
using *All of Us*

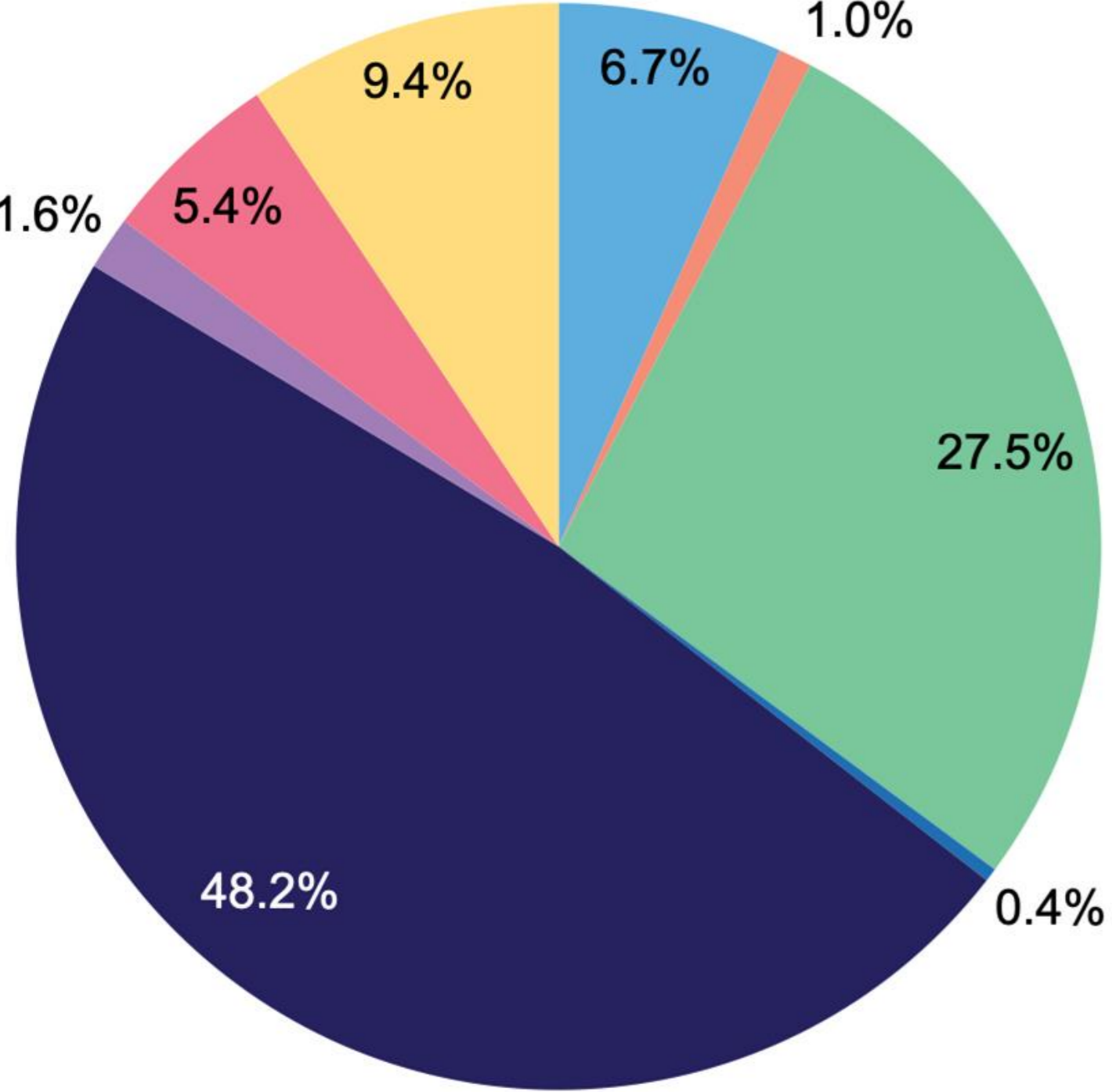
400+ Organizations:

- 24 Historically Black Colleges & Universities
- 30 Hispanic Serving Institutions



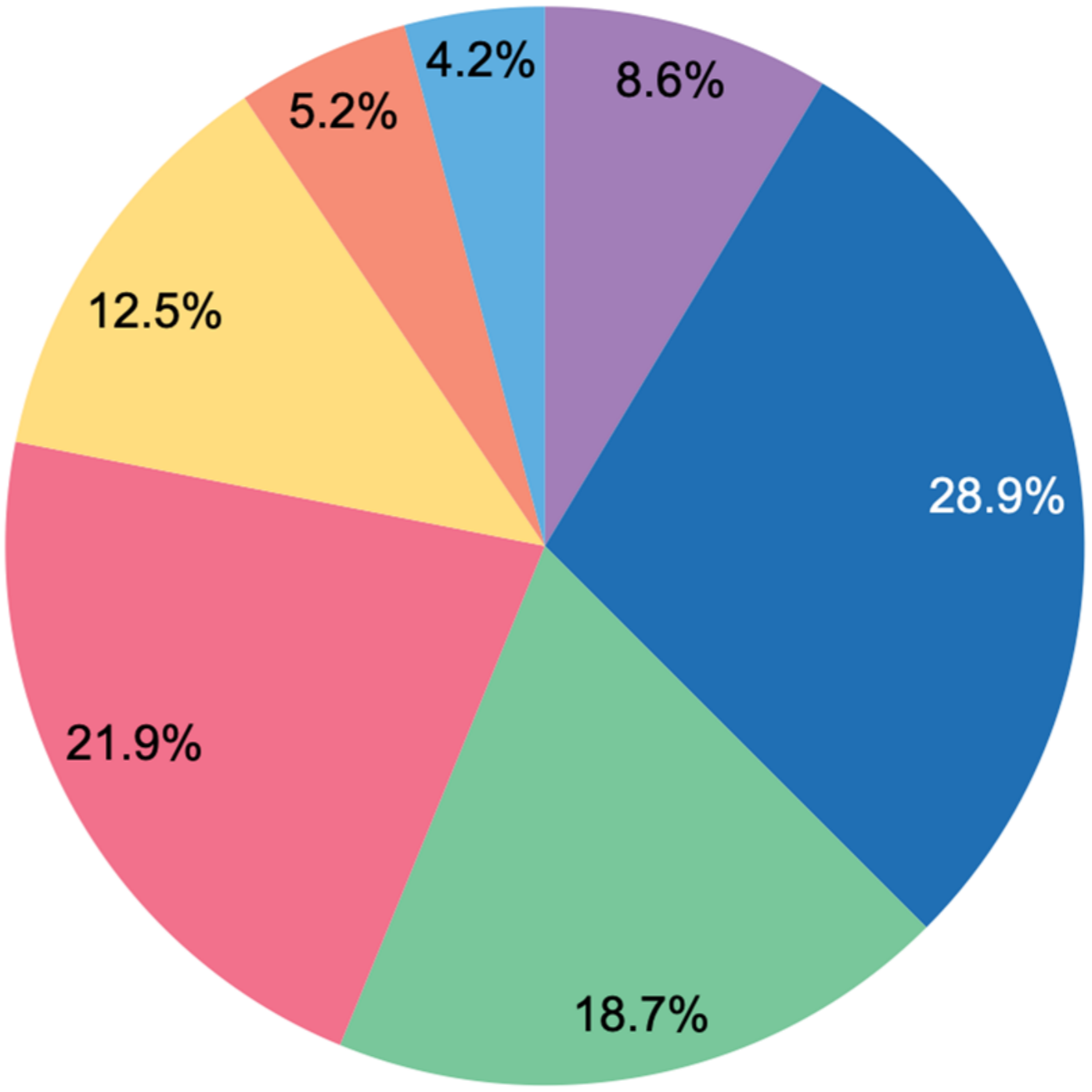
Diversity of Research Workbench Community

Race/Ethnicity



- African American
- American Indian/Alaska Native
- Asian
- White
- Two or More Races (Including White and Asian)
- None of These Describe Me (Race)
- Hispanic or Latino

Career Level



- Undergraduate Trainee
- Graduate Trainee
- Research Fellow
- Early Career Tenure Track Researcher
- Tenure Track Researcher
- Mid-Career Tenure Track Researcher
- Late Career Tenure Track Researcher
- Senior Researcher

We Support Researchers

- Training workshops/webinars
- Office hours
- *All of Us* Ambassadors for NIH ICs to help researchers navigate their research on Researcher Workbench
- Help available on the workbench:
 - How-to videos
 - Reusable demo phenotypes, cohorts, & notebooks
 - Data dictionaries
 - Community Forum
 - FAQs
 - Help desk

The screenshot shows the All of Us Researcher Workbench interface for the Major Depression Study. The header includes the All of Us logo and navigation tabs for DATA, ANALYSIS, and ABOUT. The main content area features two panels: 'Cohorts' and 'Datasets'. The 'Cohorts' panel explains that a cohort is a group of participants based on specific criteria, showing a transition from 'All of Us Participants' to 'Your Cohort' with three individual participant IDs. The 'Datasets' panel explains that a dataset is a table containing data about a cohort that can be exported for analysis, showing a flow from 'Your Cohort' (with participant IDs) and 'Data About Your Cohort' (with medication and lab icons) to 'Your Dataset' (a table with columns for ID, Med, and Labs).

Workspaces > Major Depression Study

DATA ANALYSIS ABOUT

Cohorts +

A cohort is a group of participants based on specific criteria.

All of Us Participants → Your Cohort

Participant ID 1
Participant ID 2
Participant ID 3

Datasets +

A dataset is a table containing data about a Cohort that can be exported for analysis.

Your Cohort + Data About Your Cohort = Your Dataset

Participant ID 1
Participant ID 2
Participant ID 3

Medication
Labs

ID	Med	Labs
ID 1	Med 1	Labs 1
ID 2	Med 2	Labs 2
ID 3	Med 3	Labs 3

Show: Show All Cohorts Cohort Reviews Concept Sets Datasets

Current Research on the *All of Us* Platform

What Kind of Research Can *All of Us* Support?

Example studies in *All of Us*

- Associations between diseases, medications, behaviors, SDOH, genomics
- Health disparities
- Historically underrepresented populations
- Genomics and PGx (soon)
- Drug target discovery
- Early disease detection
- Geospatial linkages (future)
- ***Insert your topic here***

Modalities of research *All of Us* supports

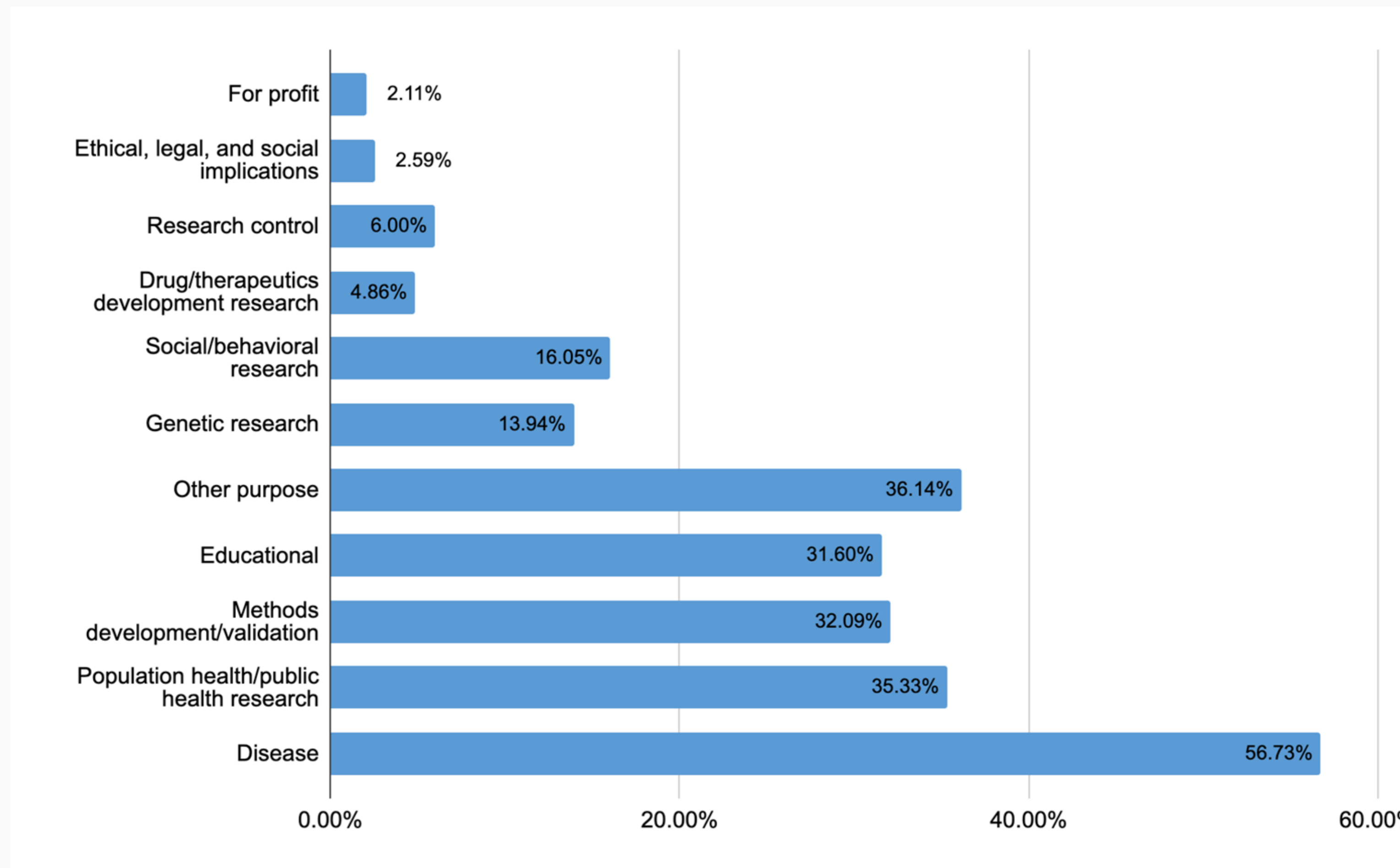
- AI/ML
- Risk stratification
- Predictive analytics
- Phenotype algorithms & cohort development
- Novel method development
- Basic EHR investigations
- Validation of other studies

All of Us is not

- A representative US sample
- A study with uniform follow-up of all variables

Researcher Workbench: Over 2,500 Active Projects

Total Workspaces by Research Purpose



*Note that researchers can multi-select any of the above purposes which apply to their workspace, so totals add to >100%

Scientific Framework Example: Blood Pressure



RISK & PREVENTION

How do age-related changes in blood pressure in children and young adults impact the development of hypertension and hypertension-related conditions in adulthood?



HEALTH EQUITY

What is the impact of economic stability on rates of screening, likelihood of receiving treatment, and blood pressure levels?



WELLNESS & RESILIENCE

What genomic, environmental, and lifestyle factors underlie the different patterns in age-related trajectories of blood pressure, thereby increasing or reducing the risk of high blood pressure?



DIAGNOSIS

Does blood pressure from ambulatory blood pressure monitoring (ABPM) or home blood pressure monitoring (HBPM) provide a more accurate estimate of cardiovascular risk?



TREATMENT & OUTCOMES

What are effective and scalable community-based interventions to improve blood pressure levels, medication prescription, and medication fill rates?

BLOOD PRESSURE

All of Us COVID-19 Serology Study Identified Some of Earliest U.S. Cases

OXFORD
ACADEMIC

Clinical Infectious Diseases

ACCEPTED MANUSCRIPT

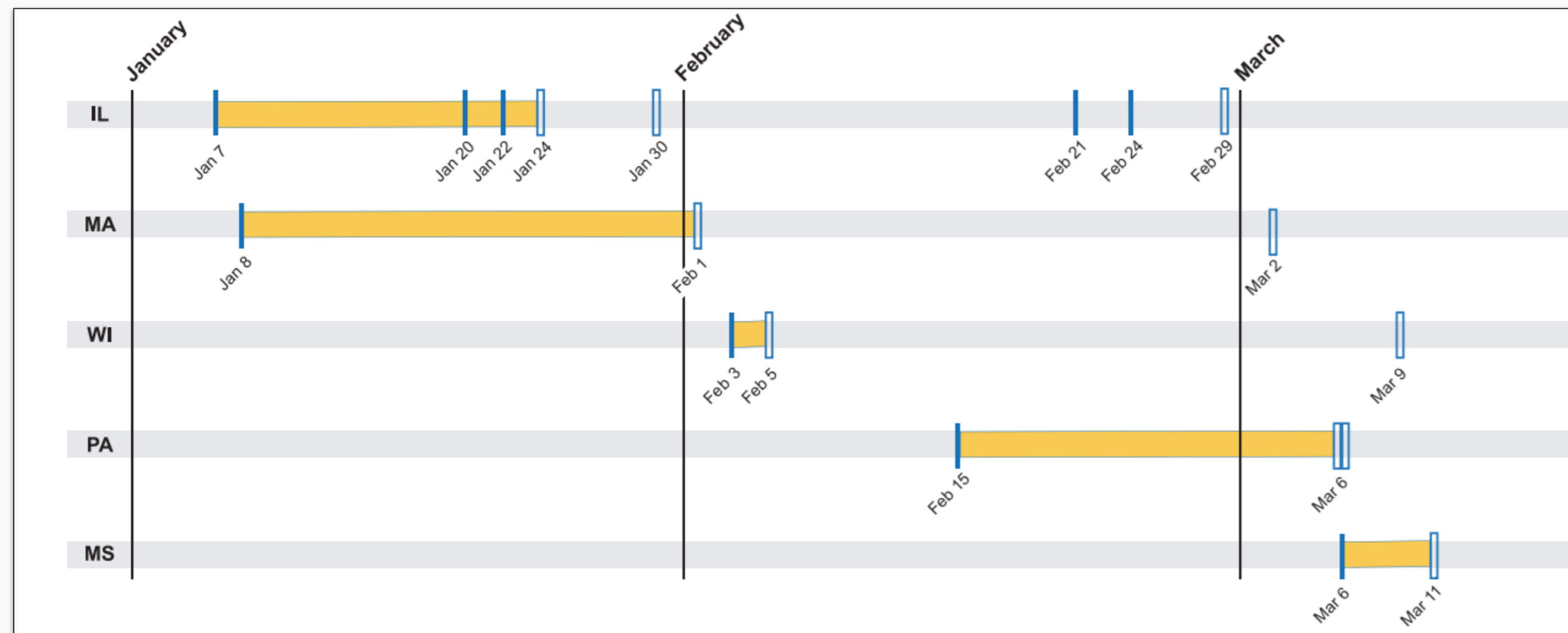
Antibodies to SARS-CoV-2 in All of Us Research Program Participants, January 2–March 18, 2020 FREE

Keri N Althoff, PhD, MPH ✉, David J Schlueter, PhD, Hoda Anton-Culver, PhD, James Cherry, PhD, Joshua C Denny, MD, MS, Isaac Thomsen, MD, MSCI, Elizabeth W Karlson, MD, MS, Fiona P Havers, MD, MHS, Mine S Cicek, PhD, Stephen N Thibodeau, PhD ... Show more

9 cases in 5 states (IL, MA, WI, PA, MS) in 24,079 tested samples

7 earlier than known cases in those states

Earliest case January 7, 2020



All of Us Team member handles participant samples in the lab

Making Research Findable, Accessible, Interoperable, and Reusable (FAIR)...In Practice!

The screenshot shows the All of Us Researcher Workbench interface. At the top left is the logo for All of Us Researcher Workbench. The breadcrumb trail reads: Workspaces > How to Reproduce the All of Us SARS-CoV-2 Antibody Study > Notebooks > SARS-CoV-2 Antibody study. Below the breadcrumb trail are three tabs: PREVIEW (READ-ONLY), EDIT, and RUN (PLAYGROUND MODE). The main content area displays a notebook page with the following text:

Reference:
Althoff, K., Schlueter, D.J., Anton-Culver, H., Cherry, J., Denny, J., Thomsen, I., ... Schully, S. (2021). Antibodies to SARS-CoV-2 in All of Us Research Program participants, January 2 - March 18, 2020. *Clinical Infectious Diseases*, ciab519, <https://doi.org/10.1093/cid/ciab519>

How to Reproduce the All of Us SARS-CoV-2 Antibody Study

Author: Aymone Kouame
Contributors: Francis Ratsimbazafy, Adrienne Roman

Objectives

We recommend that users read this notebook to learn how to reproduce the *Antibodies to SARS-CoV-2 in All of Us Research Program Participants, January 2-March 18, 2020* study published on June 15, 2021 in *Clinical Infectious Diseases*. For the best experience, we recommend opening this notebook in Playground Mode.

What should you expect? This notebook will give an overview of the *Antibodies to SARS-CoV-2 in All of Us Research Program Participants, January 2-March 18, 2020* study in the current Curated Data Repository (CDR) and how to reproduce it.

This tutorial is divided into the following sections:

- 1. Setup:** How to set up this notebook and install and import all necessary software packages.
- 2. Materials and Methods:** What are the characteristics of the study population and what are the methods used in study.
- 3. Data Extraction:** How to query the relevant CDR tables to extract the study data.
- 4. Results:** How to reproduce the results of the study.

<https://bit.ly/3h7GnEF>

Approved researchers can review and access the data and exact analyses used in the paper from the Workbench.

All of Us Discoveries: Analyzing Barriers to Healthcare Access Among Cancer Survivors



Jie Chen, PhD

Professor and Division Chief, Biostatistics and Data Science at Augusta University

Health care access and utilization among adult cancer survivors: Results from the National Institutes of Health "All of Us" Research Program

Steven S Coughlin ^{1 2}, Jie Chen ¹, Jorge E Cortes ^{3 4}

Affiliations + expand

PMID: 33942535 PMCID: [PMC8178490](#) DOI: [10.1002/cam4.3924](#)

Scientific Question Being Studied: What are the racial and ethnic disparities in healthcare among cancer survivors? What barriers to healthcare access do cancer survivors face?

Methods: Analyzed *All of Us* data about demographic factors and other personal characteristics, personal medical history of cancer, healthcare utilization, and access to care.

Findings: A minority of cancer survivors who participated in the *All of Us* Program had difficulty paying for health care in the past 12 months.

Join *All of Us*

Apply to be an *All of Us* Researcher

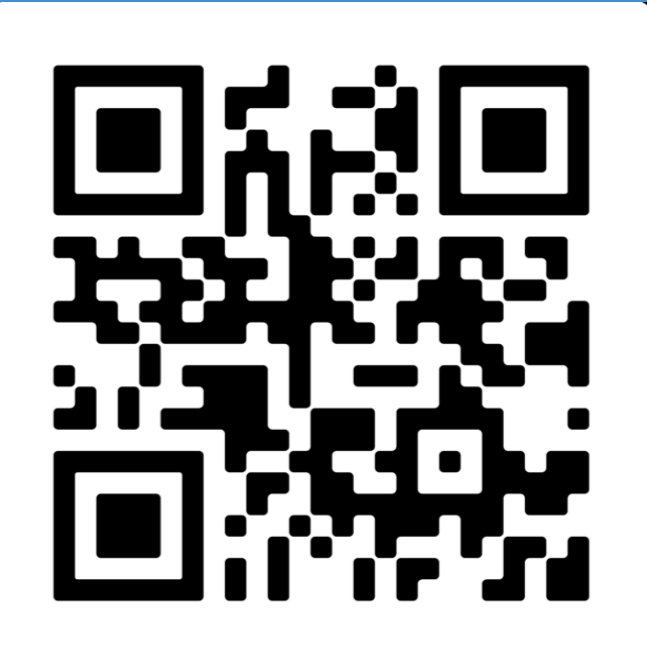
<p>STEP 1</p> <p>LEARN MORE ABOUT THE DATA AVAILABLE</p>	<p>STEP 2</p> <p>CHECK FOR YOUR INSTITUTION'S AGREEMENT</p>	<p>STEP 3</p> <p>REGISTER AS A RESEARCHER</p>
<p>STEP 4</p> <p>VERIFY YOUR IDENTITY</p>	<p>STEP 5</p> <p>COMPLETE <i>ALL OF US</i> RESPONSIBLE CONDUCT OF RESEARCH TRAINING</p>	<p>STEP 6</p> <p>SIGN DATA USER CODE OF CONDUCT</p>

APPLY NOW



Stay in touch to learn more

SUBSCRIBE to our quarterly email newsletter and receive the latest news and insights from the *All of Us* Research Hub.



Thank You!



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ResearchAllofUs.org



National Institutes
of Health

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@AllofUsResearch
#JoinAllofUs