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

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NIMHD Workshop on Inclusive Participation in Clinical Research

National Institutes of Health
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 51%, Male 49%
- **Race Distribution**: White 76%, Asian 11%, Black or African American 7%, Other 5%, American Indian or Alaska Native 1%
- **Age Distribution**: < 65 Years 69%, >= 65 Years 31%
- **Ethnicity Distribution**: Hispanic or Latino 13%, Not Hispanic or Latino 20%, Missing 67%
2015-2019: FDA Drug Trials Snapshots Summary Data

Race Breakdown Across Therapeutic Areas

- Cardiovascular Diseases
- Endocrinology and Metabolism
- Oncology and Hematology
- Infectious Diseases
- Neurology
- Gynecology
- Dermatology
- Pulmonology and Rheumatology
- Gastroenterology
- Psychiatry
- Ophthalmology
- Anesthesia and Analgesia
- Medical Imaging

Number of Participants

- American Indian or Alaska Native
- Asian
- Black or African American
- Other
- White
“If you don’t see the light, you will soon see the fire”
– Peggy Hamburg, Former FDA Commissioner

“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
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, socioeconomics, 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.
The *All of Us* Mission

Our Mission

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

- **Nurture partnerships** for decades with at least a million participants who reflect the diversity of the U.S.
- **Deliver one of the largest, richest biomedical datasets** that is broadly available and secure
- **Catalyze an ecosystem of communities, researchers, and funders** who make *All of Us* an indispensable part of health research

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

Enables research discoveries that drive more precise approaches to care
Status of the *All of Us* Research Program (as of March 15, 2023)

- **612,000+** Participants
- **358,000+** Electronic Health Records
- **426,000+** Participants who have completed initial steps of the program
- **441,000+** Biosamples

**Race and Ethnicity**
- White: 52%
- Black, African American, or African: 19.3%
- Hispanic, Latino, or Spanish: 16.5%
- Asian: 3.0%
- More than one race/ethnicity: 6.7%
- Other: 2.8%
- Prefer not to say: 0.6%

**UBR Category**
- Age at Consent: 25.3%
- Race/Ethnicity: 48.0%
- Sex Assigned at Birth: 0.0%
- Gender Identity: 1.0%
- Sexual Orientation: 9.2%
- Educational Attainment: 9.9%
- Income: 26.3%
- Geography: 6.8%
- Disability: 11.4%
- Sexual and Gender Minority: 9.5%
First genomic data set

~50% diverse by race/ethnicity,
80% underrepresented in biomedical research
Methods to Engage Underrepresented Communities in Biomedical Research
Engaging Underrepresented Communities through an Engagement Ecosystem

All of Us Engagement

- Community Partners National/Local
- Researchers
- Community & Provider Gateway Initiative (CPGI)
- Engagement Innovators
- Participant Partners (Engagement Core)
- Network of the National Library of Medicine (NNLM)
- Local CABs/PABs
- Engagement & Retention Leads
- All of Us Journey
- Front Line Staff

The Genetic Science Learning Center (GSLC) at the University of Utah
Research Triangle Institute
All of Us Community and Provider Partner Network (as of October 2021)
Engaging Communities Through Trusted Partners

Connections

Mobile

Legacy

Togetherness

Outreach

Education

Trust
Engaging Participants as Partners: *All of Us* Participant Ambassadors
Return of Value to Participants
Genetic Ancestry and Traits (as of March 15, 2023)

- Over 182,000 participants sent notifications so far (email, push, and SMS based on participant preference) to choose if they want to receive results
- 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)
The text describes a program for releasing genomics-related results to participants. The program includes:

1. Participants can choose results they want.
2. Interpretation begins at Clinical Validation Laboratories.
3. All results are supported by Genetic Counselors.
4. 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.
Thank you to our 610,000+ participants!

@AllofUsResearch
@AllofUsCEO
#JoinAllofUs

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