



National Institutes
of Health

All
of **Us**
RESEARCH PROGRAM

How the *All of Us* Research Program will impact health for all children

AAP 2024 NCE Plenary Session October 1, 2024

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Faculty Disclosure Information

I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.

I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Learning Objectives

At the end of our time together, we all will be able to

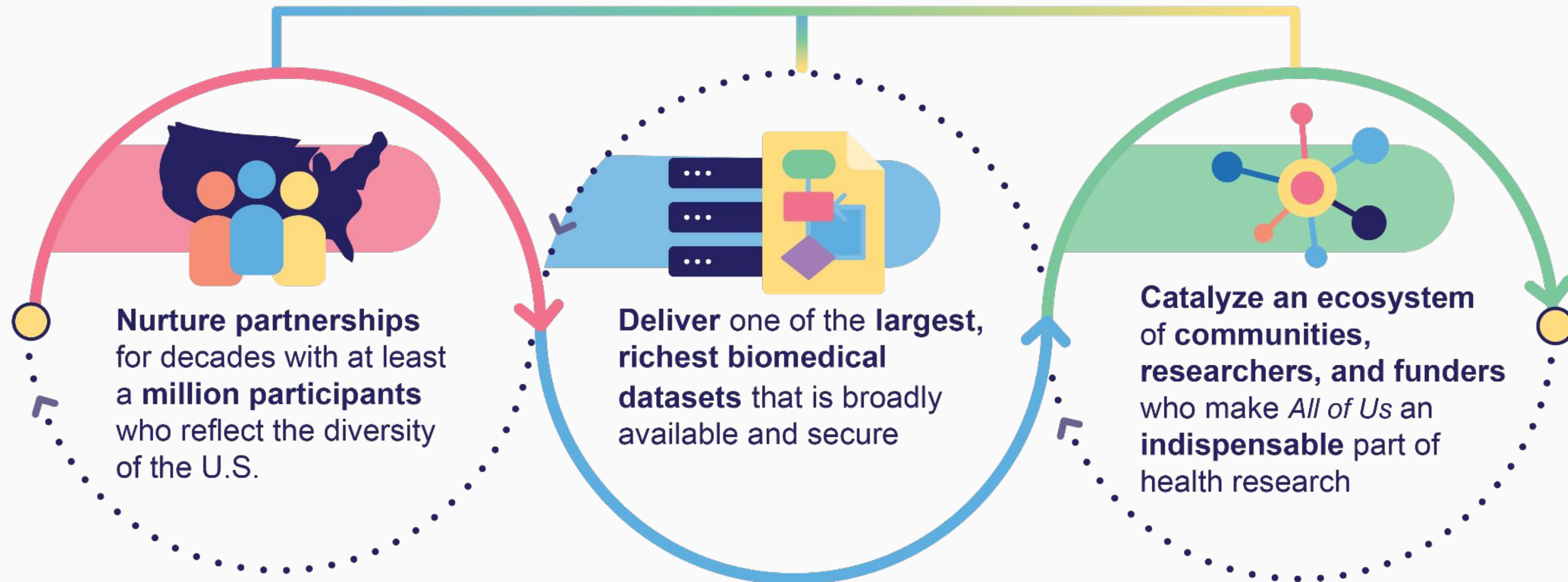
1. Describe the mission of the *All of Us* Research Program, which is to accelerate health research and medical breakthroughs for adult and pediatric populations.
2. Provide an example of the type of practice-changing questions researchers can answer now and in the future using data from *All of Us* participants.
3. Educate patients, families, colleagues, community members, and other relevant parties on the importance of including pediatric participants in the *All of Us* Research Program.

The *All of Us* Research Program



The *All of Us* Research Program 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

Data from participants is provided to researchers AND back to participants

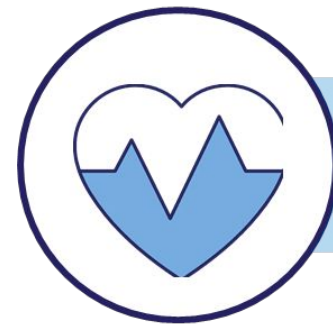
From Participants



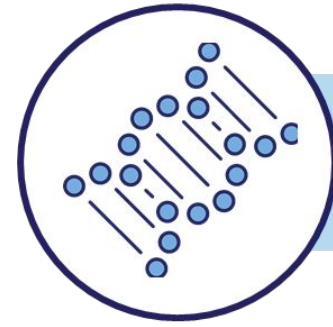
Consent and Electronic Health Records



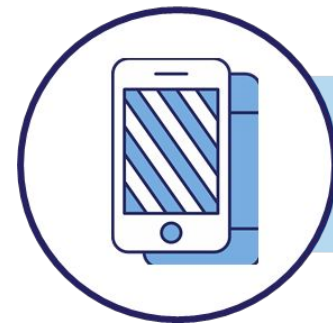
Participant surveys



Physical measurements



Biosamples



Mobile/wearable tech

To Researchers



413,350+

With survey responses

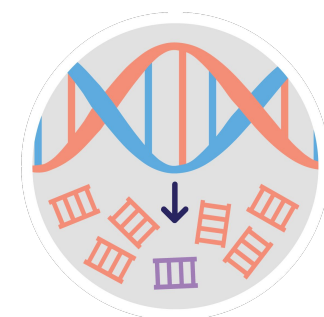


287,000+

With EHR data

25,000+

With pediatric EHR data



245,350+

With short-read whole genome sequences (WGS)



15,600+

With Fitbit records

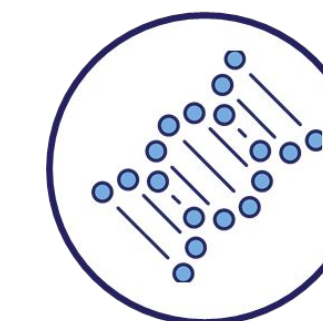
Back to Participants



Survey & EHR data



Physical measurements



DNA results



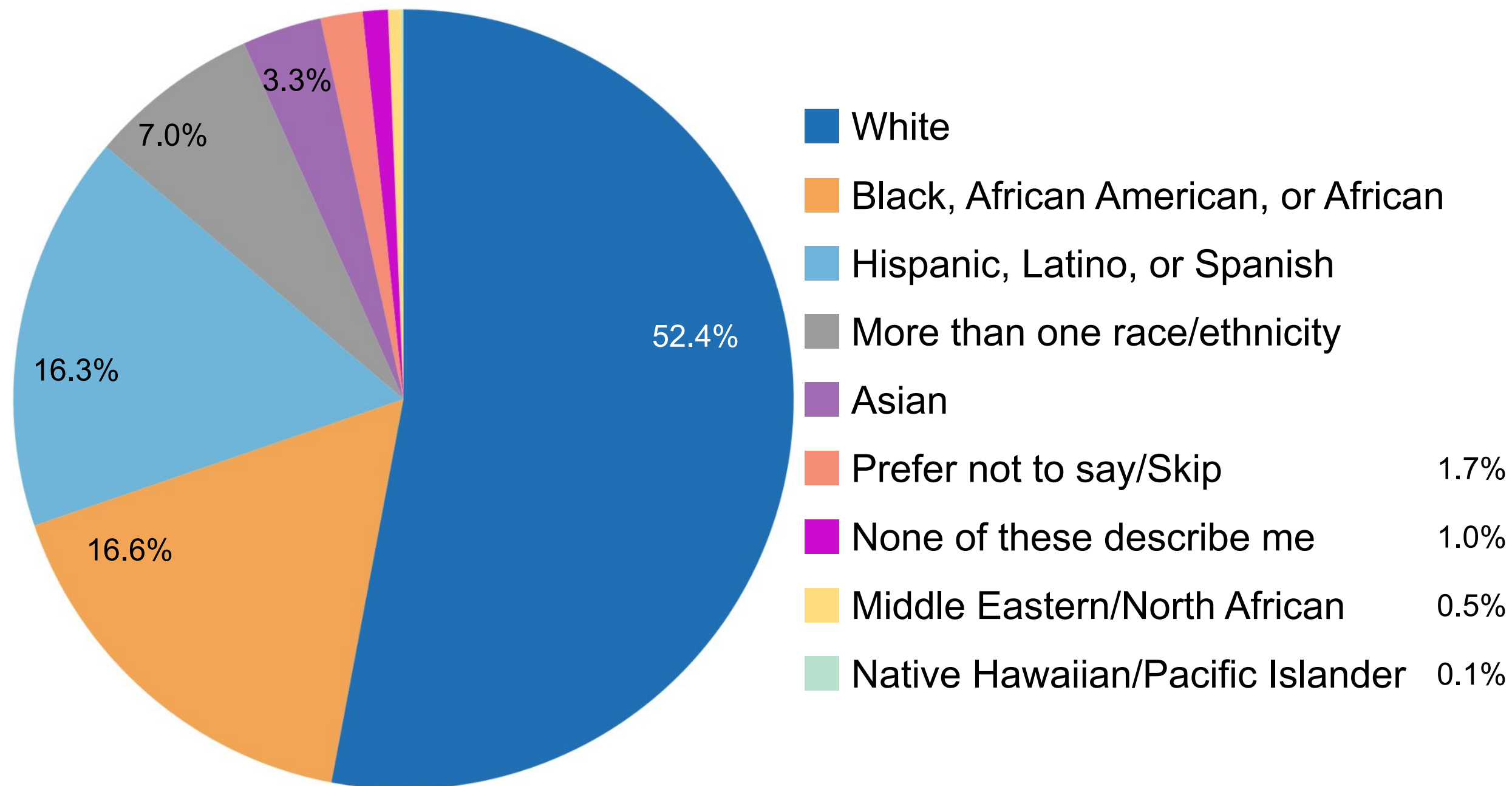
Scientific findings

(and more to come)

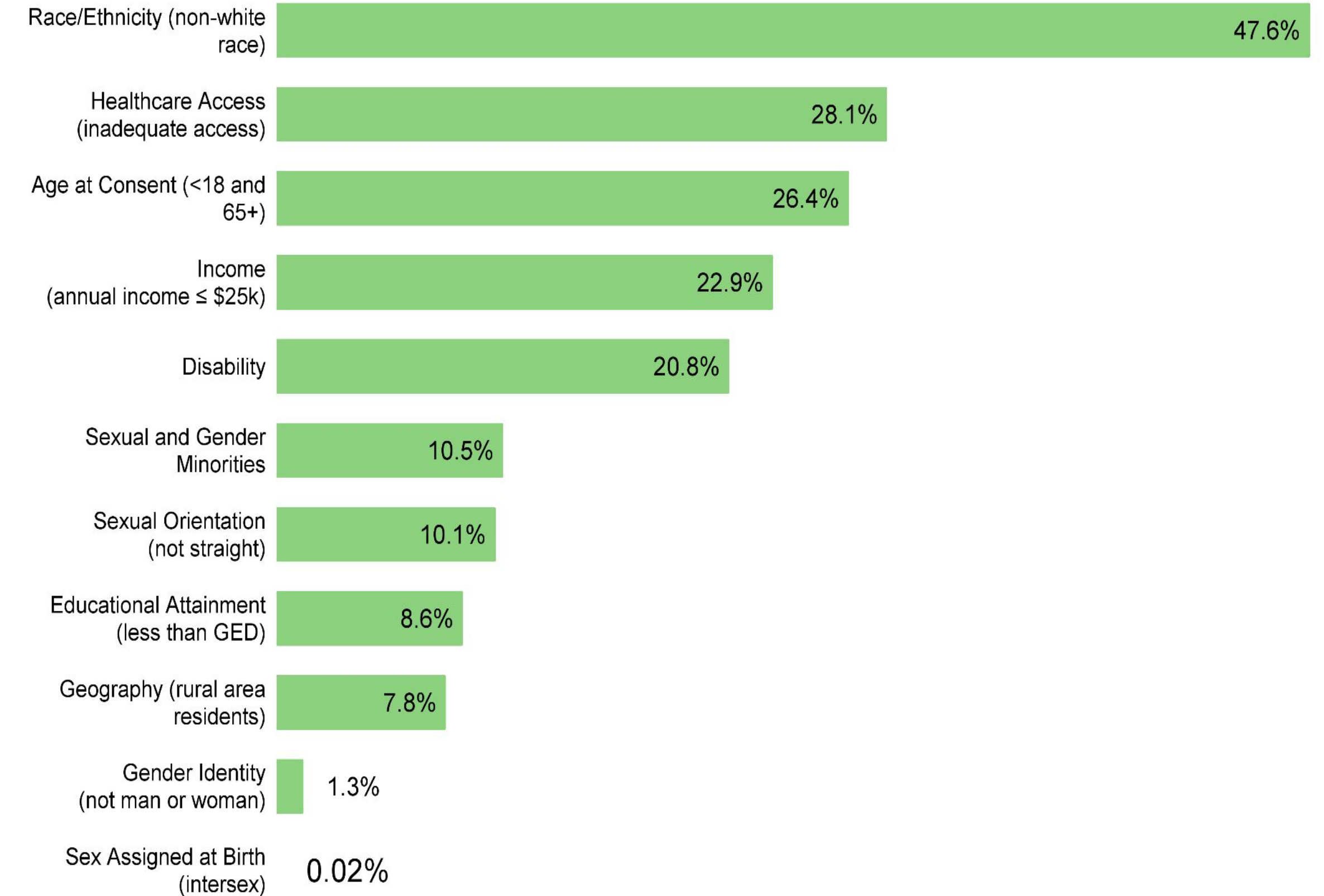
Data as of January 2024

All of Us includes robust participant diversity across many definitions and categories

Race & Ethnicity of Participants



UBR Category



Over 87% of All of Us participants are underrepresented in biomedical research

Numbers current as of September 3, 2024

Two examples of scientific findings from the *All of Us* dataset



Among **52,000** *All of Us* participants, those with high **resilience** at the beginning of the COVID-19 pandemic did not feel as depressed over time as participants with a low level of resilience, even if they experienced discrimination.

Cook et al (2023). *Front. Psychol.*

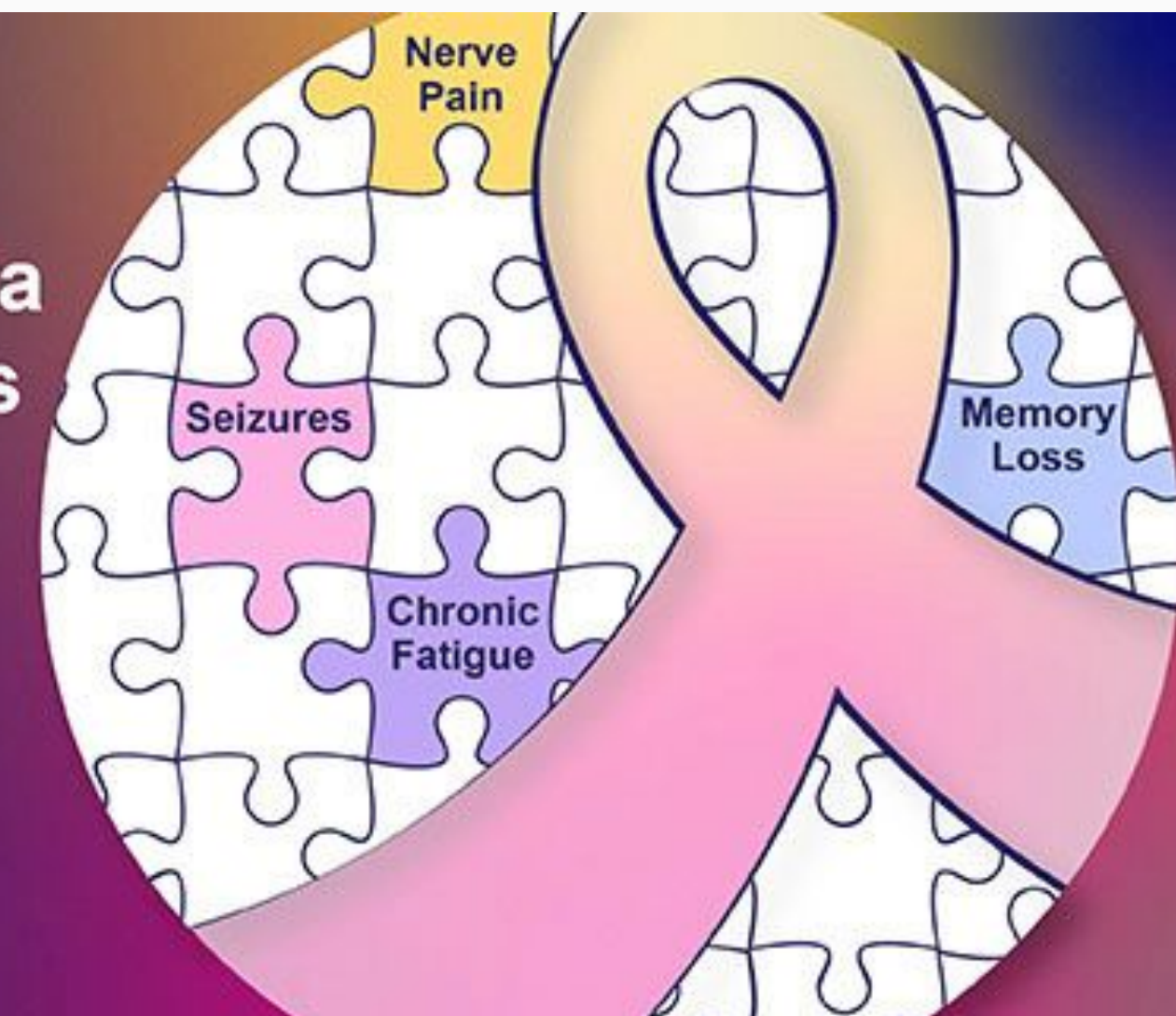
Among **4,000** *All of Us* participants, 4 conditions were more common in **teen and young adult cancer** survivors than those who never had cancer:

- Memory loss
- Nerve problems
- Chronic fatigue
- Seizures

Agapito et al (2023). *Cancer Med.*

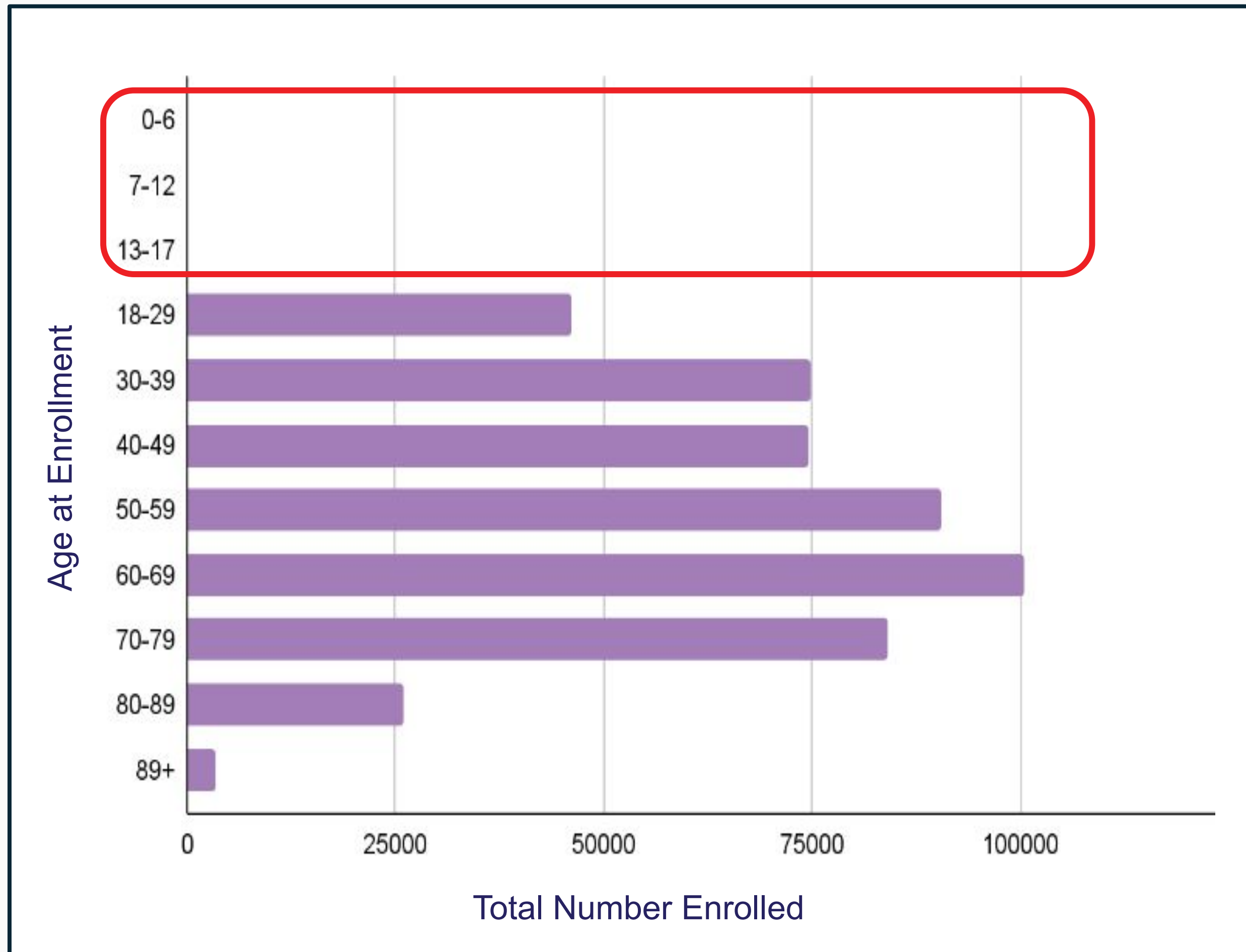
Participant Data
Puts the Pieces
Together

**All
of
Us**
RESEARCH PROGRAM



What is missing from the *All of Us* dataset?

Pediatric Participants



Pediatric Activities Update



Why must we include children in the *All of Us* dataset?

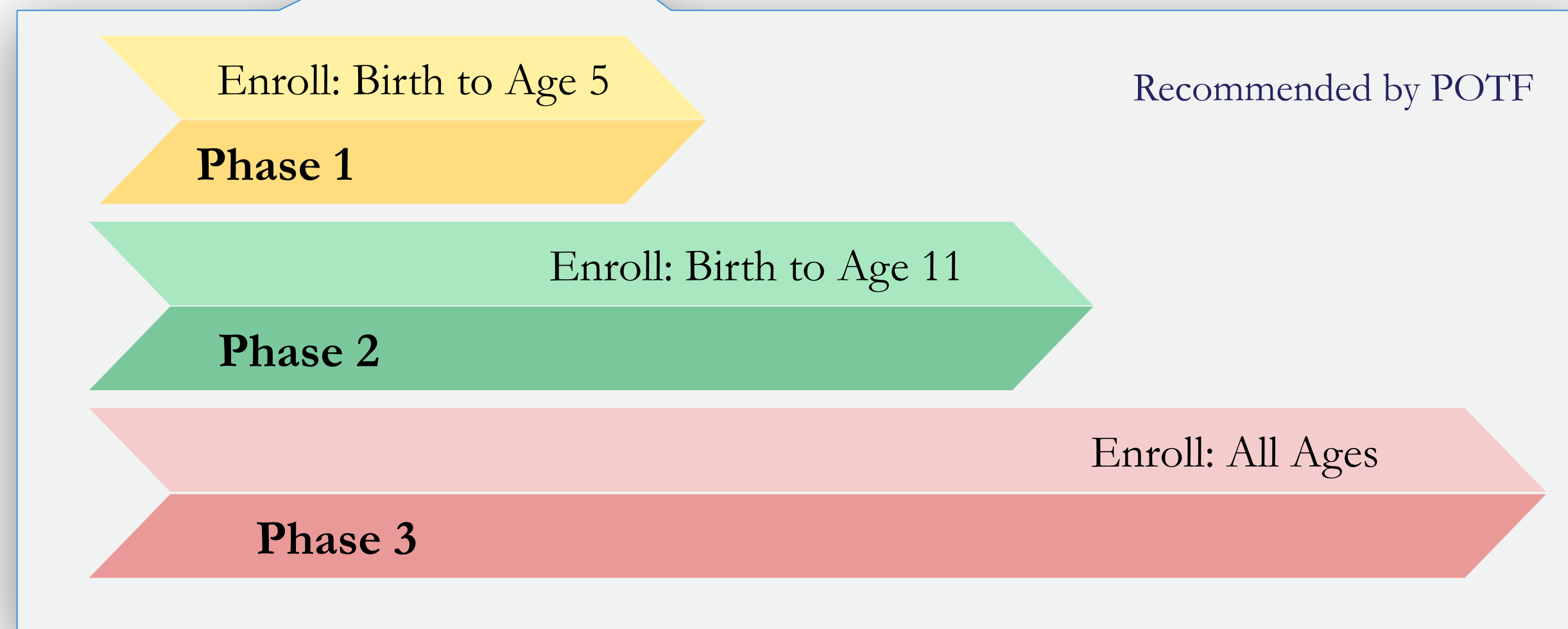
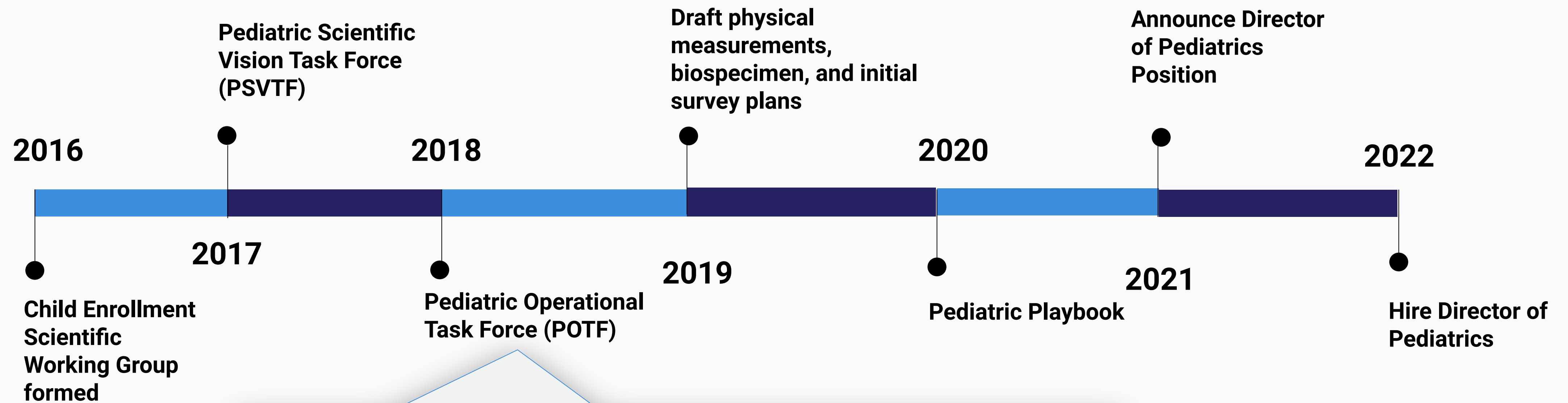
Why are pediatric participants important for *All of Us*?

- To live up to the “**all**” in *All of Us*
- To accelerate discoveries of the complex interplay of genetic, environmental and social factors influencing health *across the lifespan*
- To enable discovery of precision predictors and interventions for health conditions impacting children, families, and adults

How will pediatrics benefit from *All of Us*?

- Observational studies fuel much of the most impactful pediatric research
- An accessible, research-ready *All of Us* pediatric dataset will accelerate future discoveries
- Opportunity to collect deeper data via ancillary studies
- The large, multi-layered diverse data will catalyze practice-changing understanding of health and disease

Pediatric enrollment has been planned since the start of the program



Enabling pediatric participation was the #1 priority for the *All of Us* Research Program in 2023, and we achieved our goal of enrolling the first child



Pediatric Team

- Established the Pediatric Branch of Division of Cohort Development
- Coordinated across *All of Us*, NIH, and partner sites & organizations



Pediatric Protocol

- Wrote or amended protocol and appendices
- **IRB approved for participants birth to 5 years of age**



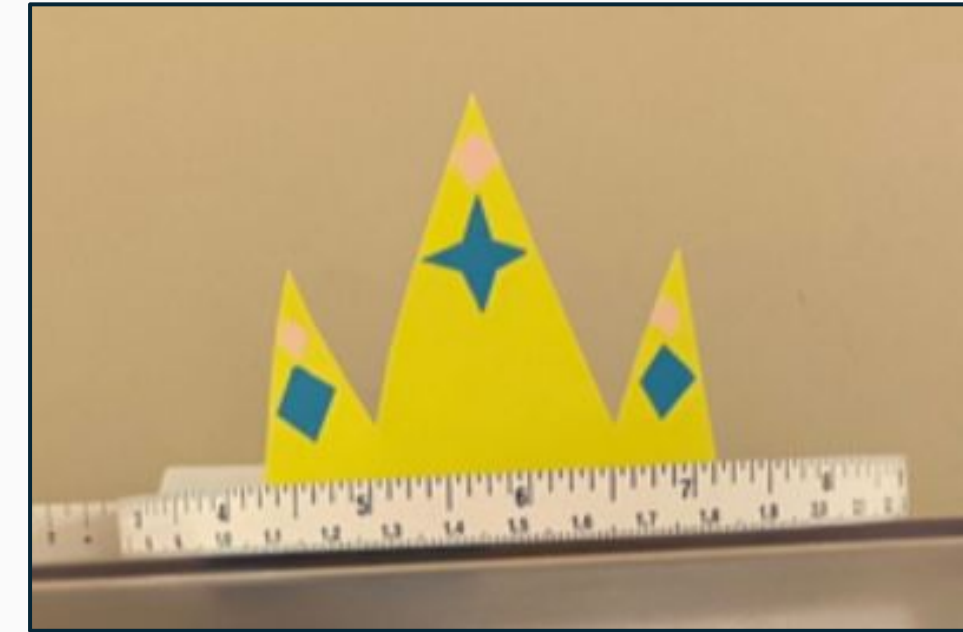
Participant and Staff Platforms

- **Adapted all tech** to support pediatric participation
- Data capture for surveys, physical measures, biospecimens



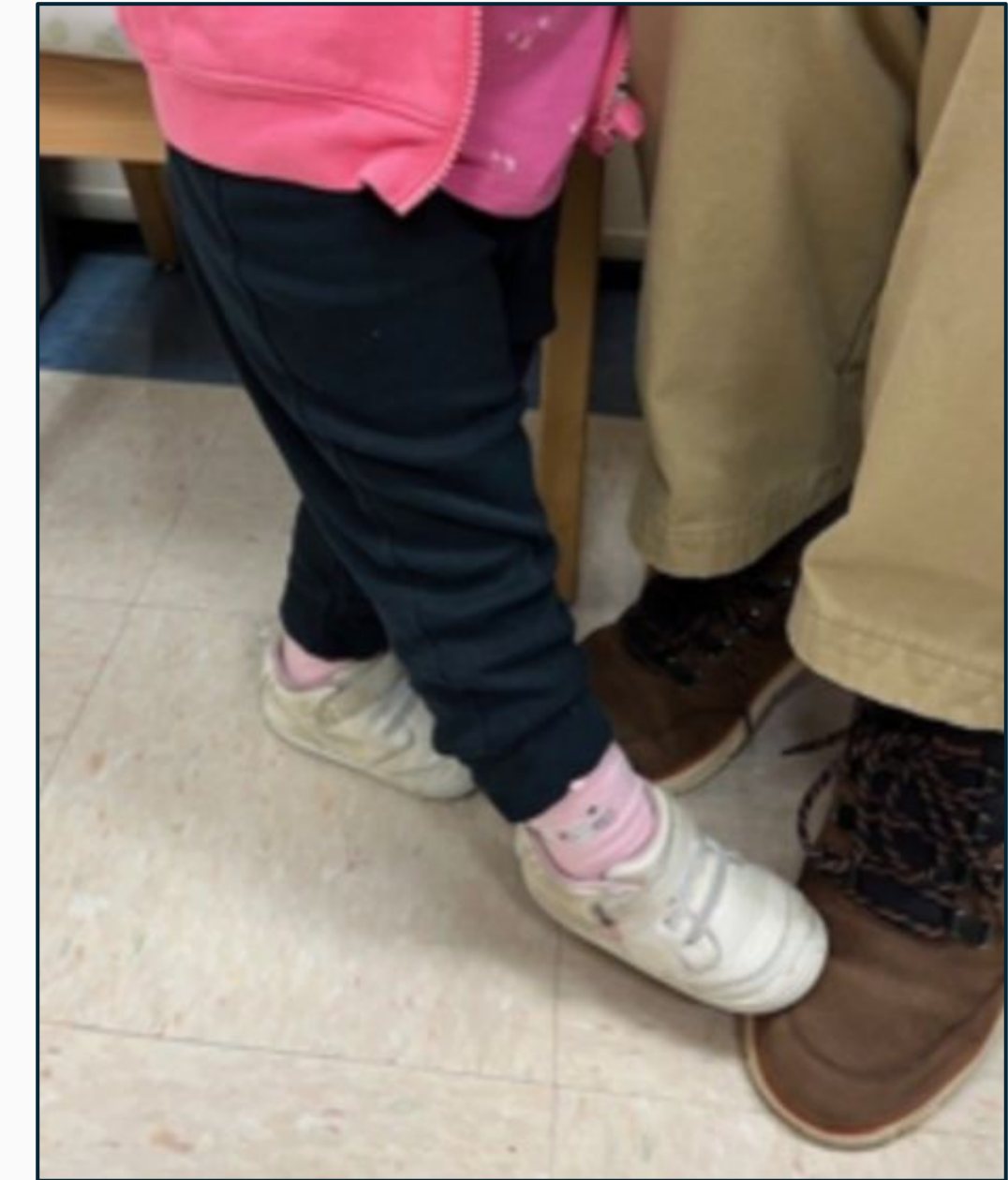
Site Selection, Onboarding, and Training

- Identified and onboarded **5 initial partner sites** for assessment of systems
- Deployed program and site-specific training

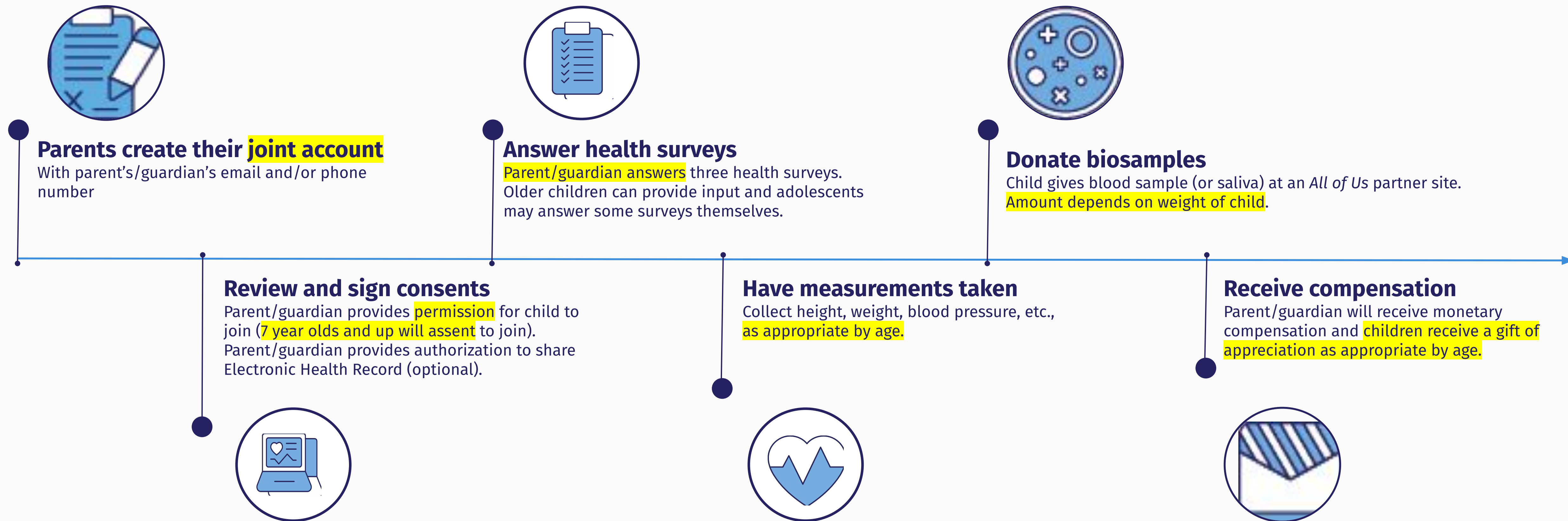


End to End Readiness Assessment

- Successful test of all systems and processes
- **Enrolled a small number of pediatric participants in 2023**



Many adaptations to the *All of Us* enrollment experience were required to enable pediatric participation



Yellow highlight indicates specific adaptations made for pediatric participation

Five strategically selected enrollment sites partnered with *All of Us* to enroll the very first pediatric participants

- 5 existing partner sites identified for **end-to-end assessment** of protocol, systems, and processes
- Goal: Enroll a small number of participants (up to 25), followed by a pause to assess protocols & procedures
- Outcome: Our enrollment goal was achieved, and we proceeded to post-launch review

Pediatric End-to-End Readiness Assessment



Current state in 2024: we are facing uncertainties due to the budget

The screenshot shows the NIH All of Us Research Program website. At the top left is the NIH logo and 'National Institutes of Health'. To the right are search, 'LOG IN', and 'Join Now' buttons. Below the navigation bar is the 'All of Us' logo and a menu with 'About', 'Get Involved', 'Funding and Program Partners', 'Protecting Data and Privacy', and 'News and Events'. The breadcrumb trail reads 'All of Us > News and Events > Program Announcements > From the All of Us CEO: Keeping Our Momentum Amidst Funding Uncertainties'. The main heading is 'From the All of Us CEO: Keeping Our Momentum Amidst Funding Uncertainties' with a date of 'April 23, 2024'. The text discusses the program's six-year anniversary and the impact of a 34% funding decrease from the 21st Century Cures Act, leading to a delay in pediatric enrollment and slower data collection. It concludes with a commitment to maintain momentum.

NIH National Institutes of Health

LOG IN Join Now

About Get Involved Funding and Program Partners Protecting Data and Privacy News and Events

All of Us > News and Events > Program Announcements
> From the All of Us CEO: Keeping Our Momentum Amidst Funding Uncertainties

From the All of Us CEO: Keeping Our Momentum Amidst Funding Uncertainties

April 23, 2024

As we approach the six-year anniversary of the All of Us Research Program's national launch, I find myself reflecting on how far we've come in a few short years. Our program - once just a visionary idea - has become an integral part of the scientific enterprise, powering research around the world to advance personalized prevention, treatment, and care.

As part of the National Institutes of Health, All of Us is publicly funded. Last month, Congress passed appropriation bills for the 2024 fiscal year, providing funding through September 30, 2024. Due to a drop in funding from the 21st Century Cures Act, All of Us received \$357 million for this fiscal year, representing a decrease of \$184 million (34%) compared to last year's appropriation. This will mean a reduction in most program awards, which will result in several impacts: a decrease in the rate of new enrollments, a delay in the launch of pediatric enrollment, and a slowing of new data collection.

While these are difficult choices, we will maintain momentum to build on the program's many accomplishments to date:



[Read the full Announcement](#)

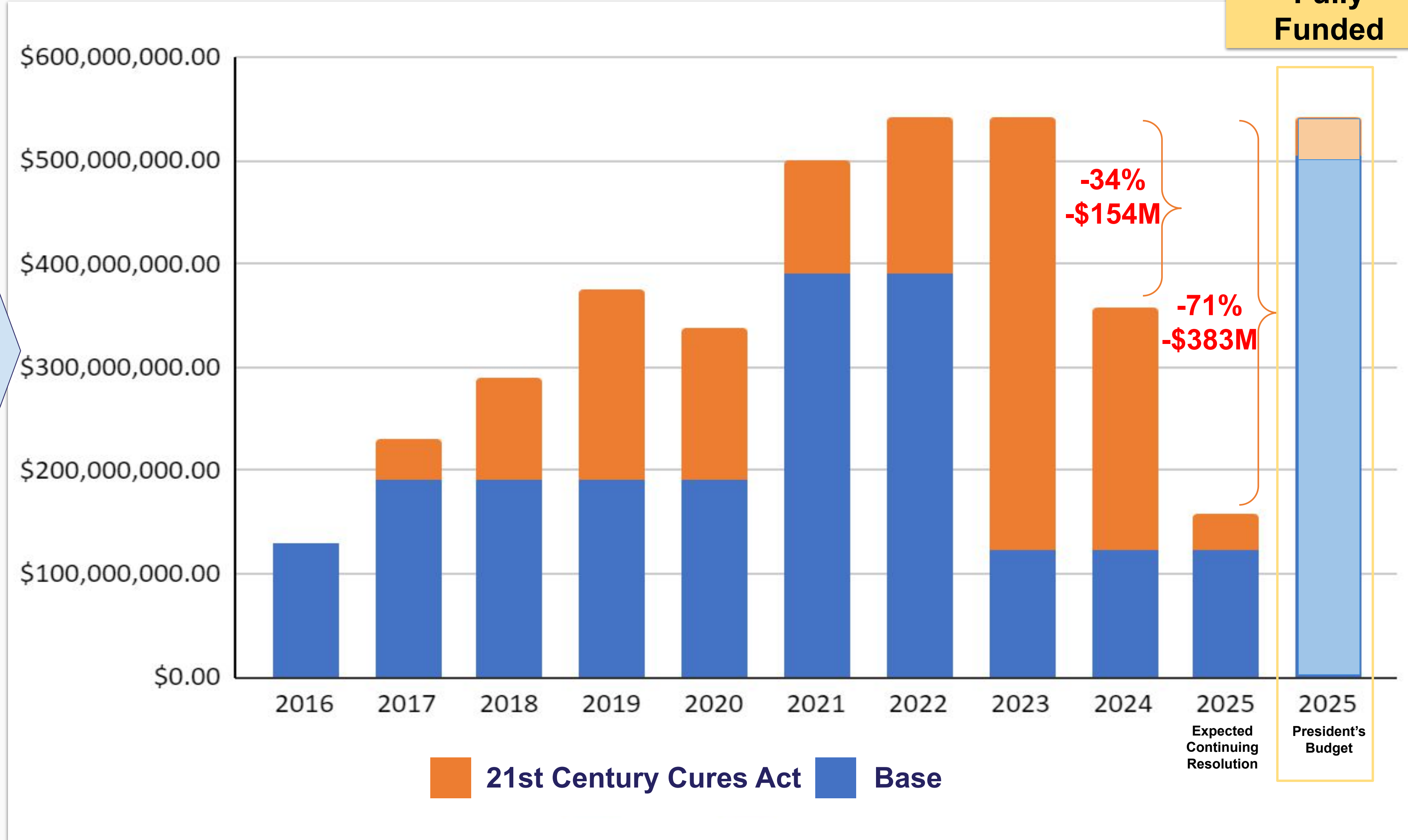
The *All of Us* Research Program's budget

Fully Funded

FY25 President's Budget Request: \$541M

Senate FY25 Labor-HHS bill **restored funding** for the program to the FY23 enacted level of \$541M.

If the base allocation stays flat, when the Cures Act funding drops, **the program's budget will be cut an additional 56%.**



*During the Aug. 1st FY25 L-HHS markup, Subcommittee Chair Tammy Baldwin (D-WI) and Ranking Member Shelley Moore Capito (R-WV) strongly supported advancing precision medicine by restoring full funding to *All of Us*.

Given this uncertainty, how do we maintain momentum for pediatric efforts in *All of Us*?

Despite a delay in the planned launch of pediatric enrollment, we are:

Preparing

Further developing the protocol and plans for future pediatric enrollment (from birth to age of majority) to support pediatric precision medicine research to benefit *all children*.

Enrolling

Continuing to enroll a limited number of pediatric participants at strategically selected sites to inform our future plans.

Energizing

Engaging and educating pediatric communities and key partners about the value of this program and the importance of stable funding so that we can launch and sustain pediatric participation.

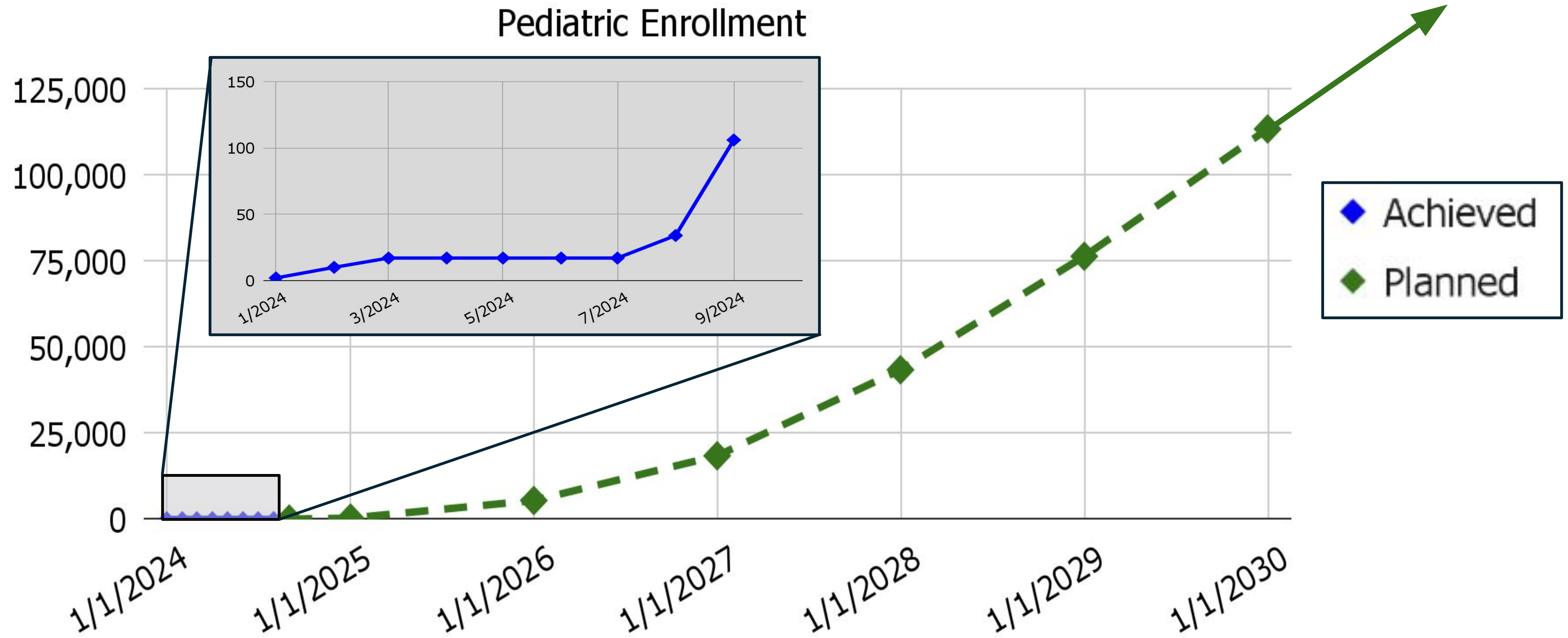
“Data from children and parents will allow researchers to elucidate the biological, social, and environmental influences that impact our health over time.”



[Read the
Press
Release](#)



The take home message: The Pediatric Program within *All of Us* is growing



Changes you may wish to make in practice

Looking forward, you may

1. **Sign up** for regular updates from the *All of Us* Research Program to remain up to date on our activities and how we are meeting our mission.
2. **Provide feedback** now and in the future regarding the practice-changing questions you need researchers to answer.
3. **Share** what you know about the *All of Us* Research Program with interested or relevant parties, including the importance of continued work to include pediatric participants.
4. **Anticipate** (as funding permits) a robust national pediatric cohort that reflects the diversity of our patients and supports individualized prevention, treatment and care for all children and families.



[Research Roundup
Newsletter](#)



[Join All of Us website](#)



[Researcher
Workbench](#)

References

***All of Us* Research Program Information**

General Information: <https://allofus.nih.gov/>

Information for Participants: <https://www.joinallofus.org/>

Researcher Hub: <https://www.researchallofus.org/>

Download Pediatric Supplemental Protocol from: <https://allofus.nih.gov/about/all-us-research-program-protocol>

Sign up for the *All of Us* Research Roundup Newsletter: <http://allof-us.org/RRSignup>

Works Cited

- Cook SH, Wood EP, Risner E, Weng CA, Xin Y. A national examination of discrimination, resilience, and depressive symptoms during the COVID-19 pandemic: the All of Us Research Program. *Front Psychol.* 2023 Sep 26;14:1175452. doi: 10.3389/fpsyg.2023.1175452. PMID: 37823074; PMCID: PMC10562571.
- Agapito I, Ng DQ, Milam J, Ziogas A, Anton-Culver H, Chan A. Neuropsychiatric complications and associated management in adolescent and young adult cancer survivors: An All of Us study. *Cancer Med.* 2023 Nov;12(22):20953-20963. doi: 10.1002/cam4.6641. Epub 2023 Oct 30. PMID: 37902258; PMCID: PMC10709746.

Thank You!

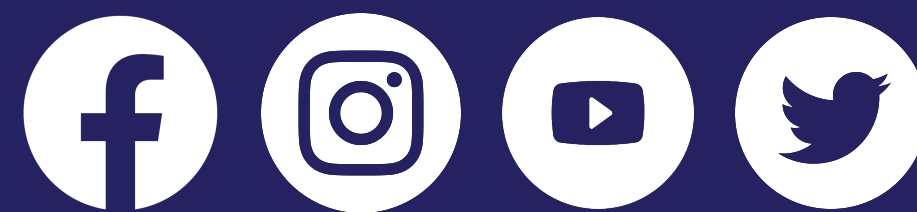


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#JoinAllofUs