

# *All of Us* Advisory Panel Meeting



December 09, 2021

# Agenda

Time	Topic	Presenter
11:00 a.m. – 11:30 a.m.	Program Update ( <b>Open session</b> )	<i>Josh Denny</i>
11:30 a.m. – 11:35 a.m.	<i>Closed Session Starts</i>	

Open session will be recorded.

# 2021 Updates

# All of Us Senior Leadership Additions



**Karriem Watson, DHSc**  
Chief Engagement Officer



**Holly Garriock, PhD**  
Chief Cohort  
Development Officer



**Geoffrey Ginsburg, MD, PhD**  
Chief Medical and  
Scientific Officer Designee



**Martin Mendoza, PhD**  
Director of Health Equity



**Andrea Ramirez, MD, MS**  
Senior Advisor to CEO

## *All of Us* Objectives for 2021 (Established Late 2020)

By the end of 2021, we will:

**1) Restart enrollment following COVID-19**

We will reestablish a national infrastructure enrolling 3k core participants per week.

**2) Enable Participant Enrollment for Anyone, Anywhere**

*We will be comfortable with* a national ad campaign that will result in enrollment, biospecimen donation, and data collection from anyone, anywhere.\*

**3) Enhance Participant Value**

Participants will perceive *All of Us* as a product that provides them value.

**4) Establish a Diversity of Researchers and Research**

We will have grown to an initial “critical mass” of diverse researchers and research that will return value to researchers and participants.

**When there are resource conflicts, we will use this priority order to resolve them.**

\*not children, incarcerated, on tribal lands, or decisionally impaired

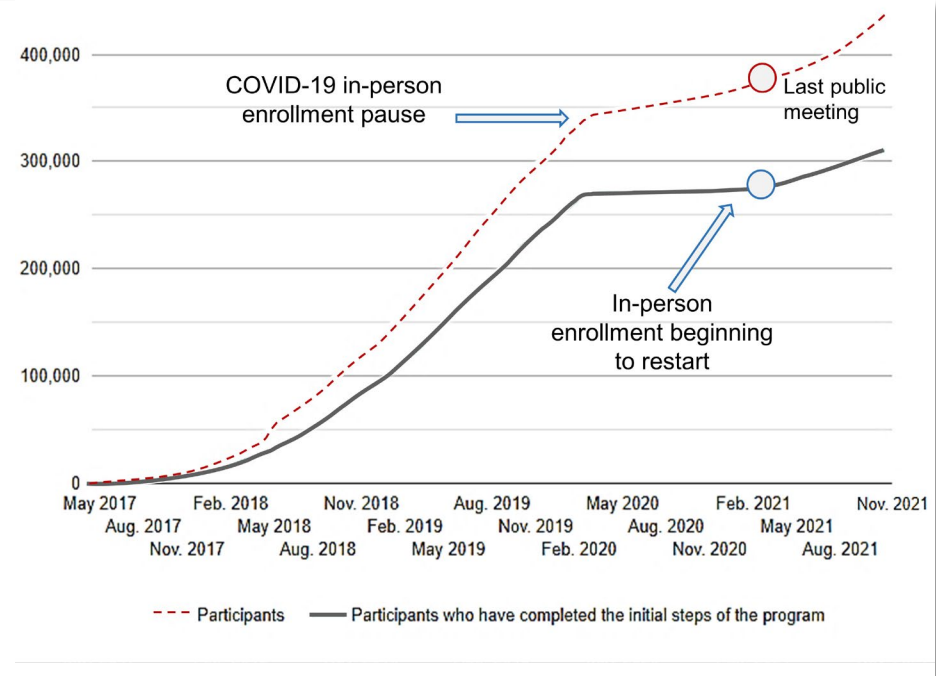
# Program Enrollment During COVID-19 Pandemic (As of December 7, 2021)

**439,000+**  
Participants

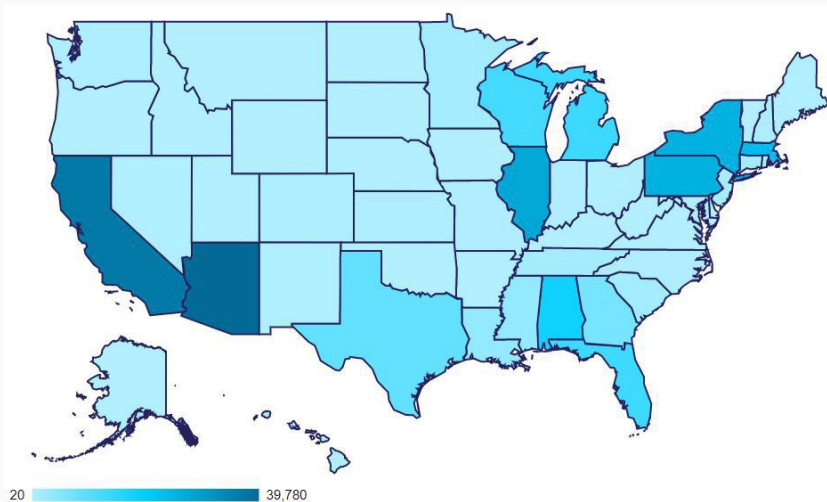
**263,000+**  
Electronic Health  
Records

**311,000+**  
Participants who have  
completed initial steps  
of the program

**330,000+**  
Biosamples

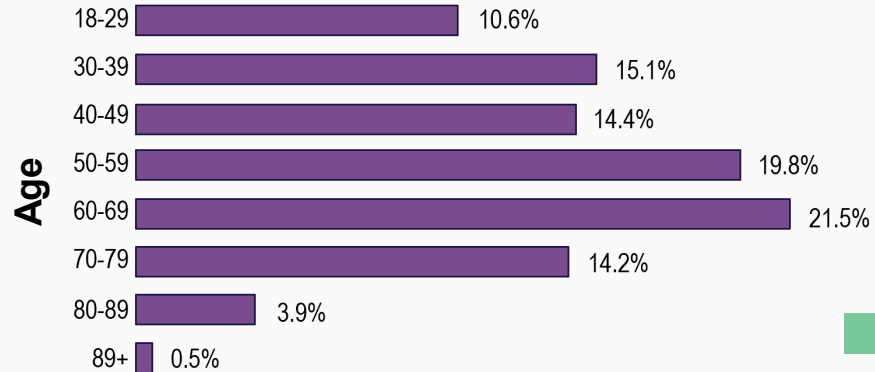
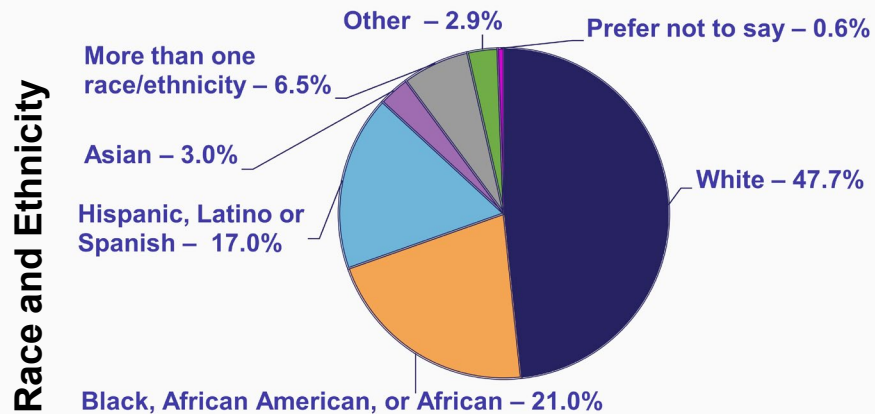


# Status of the Program



<https://www.researchallofus.org/data-tools/data-snapshots>

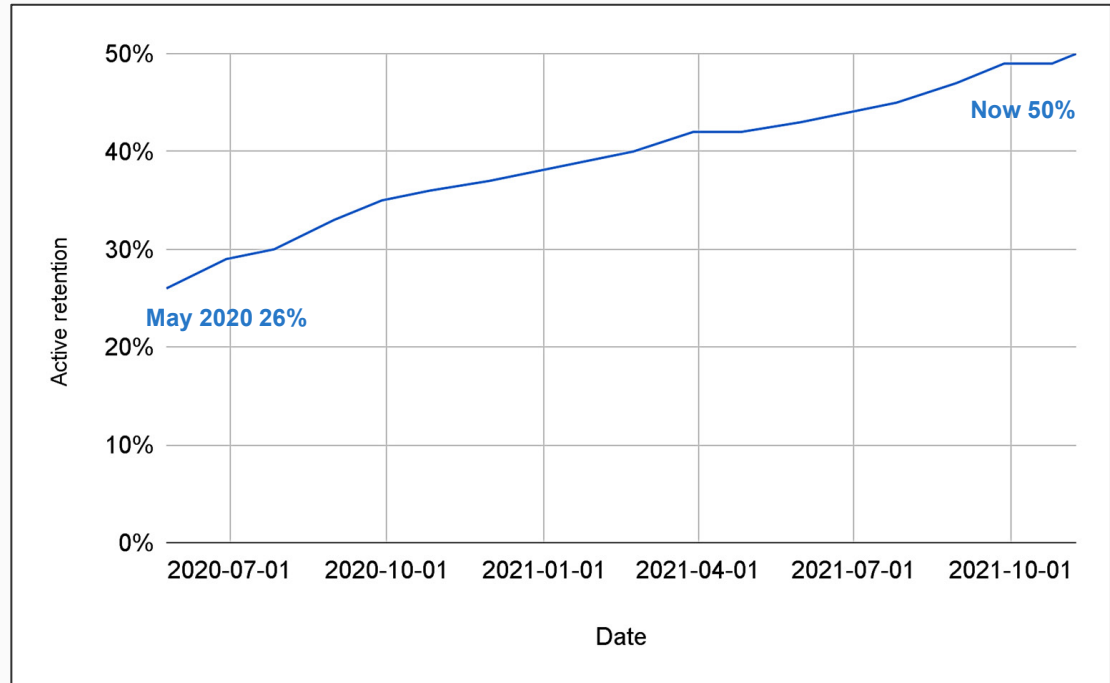
**Over 80% of *All of Us* participants are underrepresented in biomedical research**



# Focused on Increased Participant Engagement

- Increased outreach and capabilities to facilitate participant continued engagement
- Increased % of participants with EHRs from 55% to 79%

Participants completing new activities within last 18 months





# Completed Tribal Consultation; Focus on Next Steps

[Tribal Consultation Final Report](#) Published March 2021



## Forming Tribal Partnerships

- Forming **collaborative agreements** with Tribal Nations to **respect tribal sovereignty** and research regulations



## Providing Guidance and Resources

- **Added information** about consultation for participants in Portal
- **Clarifying engagement** with urban-based AI/AN individuals



## Developing Training and Resources for Researchers

- Promoting **cultural sensitivity** and **emphasizing avoidance of stigmatizing research**

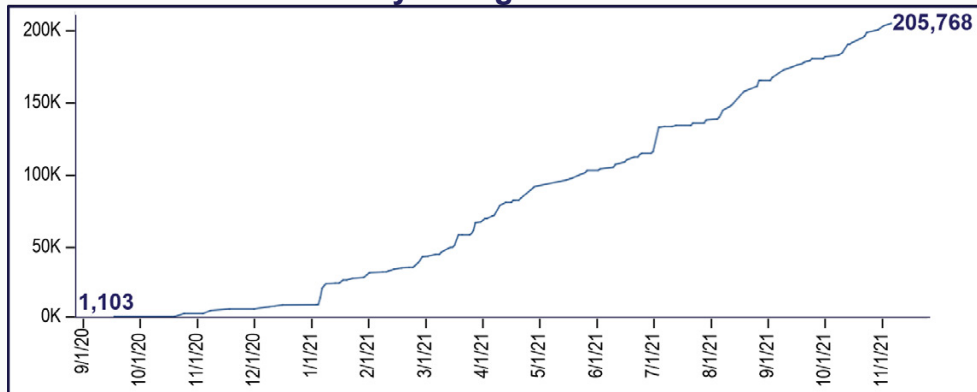


## Integrating AI/AN Data in the Research Hub

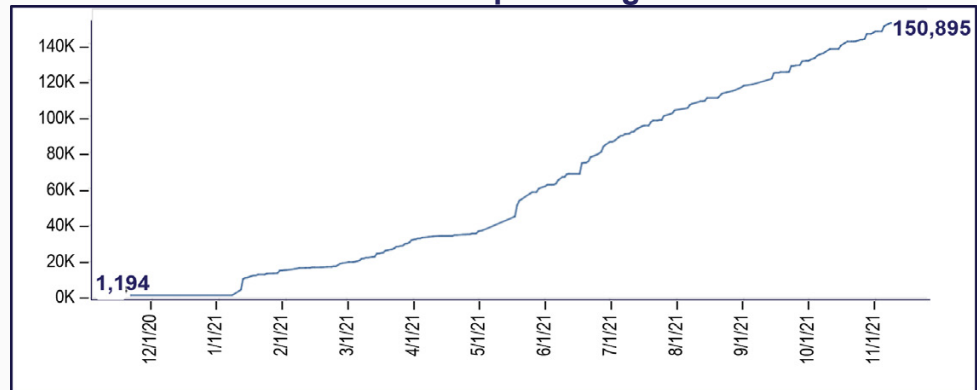
- **Data from AI/AN individuals** will be included in 2022
- **Tribal affiliation will not be displayed** without an agreement with the Tribe

# Returning Genomic Results to Participants and More to Come

## Array data generated



## Whole Genome Sequences generated



## Non-Health Genetic Traits



Traits

Genetic Ancestry

Currently returning to participants

>64,000 participants have viewed traits or ancestry

## Health-Related Genetic Traits



Hereditary Disease Risk

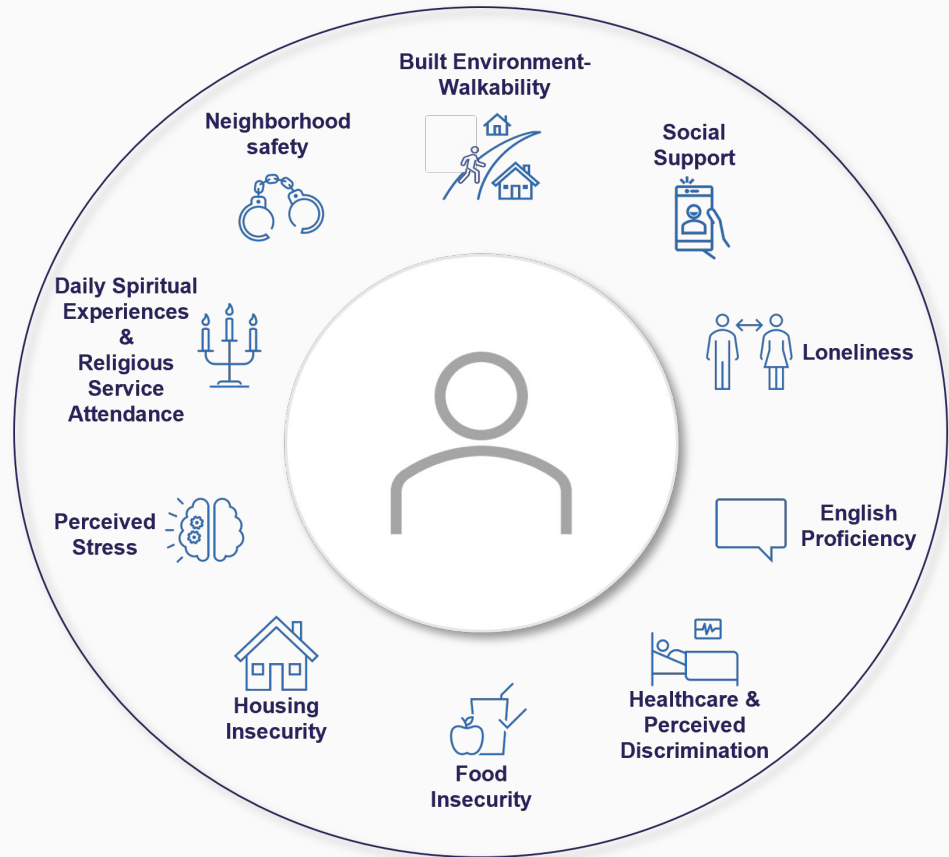


Medicine and Your Health

Launching in mid-2022

# Launched a Focused Social Determinants of Health Survey

- Launched on 11/04/2021
- Ties in with our work with UNITE
- >59,000 (15.6%) participants have completed, with more engagement efforts planned
- 81 questions including branching logic in one question
- Collaborated with experts from NIMHD, NHLBI, NIDDK, NICHD, OBSSR, ORWH, UCSF, Harvard and UC Berkeley



# Deliver an End-to-End Genetics Experience for Health-Related Genomics Results *Expected mid-2022*

All of Us  
RESEARCH PROGRAM

JANE DOE  
DOB: May 25, 1977  
ID: 123456

Specimen: Blood  
Barcode: 223 234234 2343  
Collected: September 15, 2018  
Report date: October 2, 2018

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.

Genes affect how we respond to medicine in many different ways

All of Us  
RESEARCH PROGRAM

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ID: 123456

Specimen: Blood  
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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?

- This result means that you are more likely than other people to get certain types of cancer.
- It does **not** mean that you have certain types of cancer.
- It does **not** mean that you will definitely get certain types of cancer.
- This result is important** and should not be ignored.

IMPORTANT!

This report comes from a research program so it is a **research result**. Your doctor will need to confirm these results with a clinical genetics test before using them in your care.

Share this report with your doctor.

IMPORTANT!

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.

The *BRCA1* gene

Women and men who have this result in the *BRCA1* gene have a higher chance of developing certain cancers in their lifetime compared to someone without this result. Women are at higher risk for breast cancer and ovarian cancer. They may also have a higher risk of pancreatic cancer. Men are at higher risk for male breast cancer and pancreatic cancer. They may also have a higher risk of prostate cancer.

Genome Center: XXXXX, CLIA #XXXXXXX  
Laboratory Director: XXXXXX

Hereditary Disease Risk Report: DNA and the risk for some diseases  
14

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

DNA

Confirm these results with a clinical DNA test.

You are eligible for a free clinical DNA test. Because these are research results, a clinical DNA test is needed for your doctor to use this information in your care.

Get Started

Doctors and health care providers sometimes use DNA information in a patient's care.

When deciding how often to check you for cancer or other diseases, doctors also think about other things, like your age or whether anyone else in your family had cancer or other diseases.

If your sex assigned at birth was female

Why does this matter?

If this result is confirmed by a clinical DNA test, your doctor might talk with you about:<sup>1</sup>

✔ Self-exams

If your sex assigned at birth was male

Why does this matter?

If this result is confirmed by a clinical DNA test, your doctor might talk with you about:<sup>1</sup>

✔ Self-exams

All Hereditary Disease Risk results will be returned through a genetic counselor, and we will offer confirmatory clinical genetic testing.

# All of Us COVID-19 Serology Study in Partnership with NCI, FNL, and NIAID

Clinical Infectious Diseases

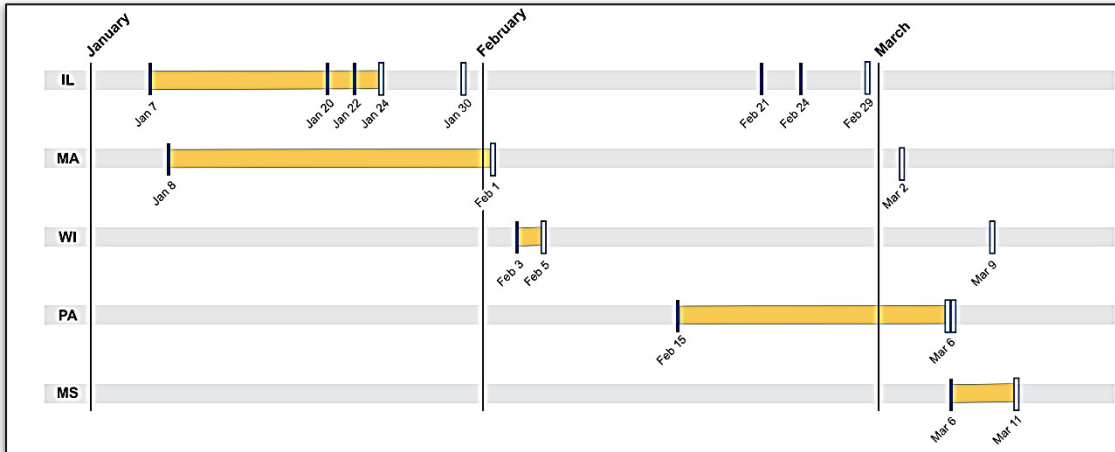
MAJOR ARTICLE



## Antibodies to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in All of Us Research Program Participants, 2 January to 18 March 2020

Keri N. Althoff,<sup>1,2</sup> David J. Schlueter,<sup>3</sup> Hoda Anton-Culver,<sup>4</sup> James Cherry,<sup>5</sup> Joshua C. Denny,<sup>2</sup> Isaac Thomsen,<sup>6</sup> Elizabeth W. Karlson,<sup>7</sup> Fiona P. Havers,<sup>8</sup> Mine S. Cicek,<sup>9</sup> Stephen N. Thibodeau,<sup>9</sup> Ligia A. Pinto,<sup>10</sup> Douglas Lowy,<sup>5</sup> Bradley A. Malin,<sup>8</sup> Lucila Ohno-Machado,<sup>11</sup> Carolyn Williams,<sup>12</sup> David Goldstein,<sup>13</sup> Aymone Kouame,<sup>6</sup> Andrea Ramirez,<sup>2</sup> Adrienne Roman,<sup>6</sup> Norman E. Sharpless,<sup>5</sup> Kelly A. Gebo,<sup>14,a</sup> and Sheri D. Schully<sup>2,a</sup>; on behalf of the All of Us Research Program

- Blood specimens collected between **January 2 and March 18, 2020**
- **9 cases** in **5 states** (IL, MA, WI, PA, MS) in 24,079 tested samples
  - 7 cases earlier than previously known in those states
  - Earliest case was January 7, 2020
- Results were returned to participants



# Launch of the Researcher Workbench: Registered Tier

## Researcher Workbench Launched on May 27, 2020

- Approved researchers have “passport access” to Workbench data – No individual project or IRB approval needed
- New researchers can start doing research in as little as 2 hours after application

The screenshot displays the All of Us Researcher Workbench interface. At the top, the logo reads "All of Us RESEARCHER WORKBENCH". Below the logo, a welcome message states: "Welcome to the RESEARCHER WORKBENCH The secure platform to analyze All of Us data". Three circular icons represent different features: a folder, a network of nodes, and a hand holding a document. The main content area is divided into two sections. The first section, titled "Workspaces +", contains four workspace cards. Each card has a title, a description, an "OWNER" button, and a "Last Changed" timestamp. The second section, titled "Recently Accessed Items", contains six notebook cards. Each card has a title, a description, a "Notebook" button, and a "Last Modified" timestamp.

**Workspaces**

- Featured Workspace: Dem entia  
OWNER  
Last Changed: 02/11/20, 07:32 PM
- All of Us Survey Codebook and Frequency Distribution s  
OWNER  
Last Changed: 02/11/20, 07:51 PM
- Featured Workspace: Depr ession  
OWNER  
Last Changed: 02/11/20, 07:50 PM
- Featured Workspace - Type 2 Diabetes  
OWNER  
Last Changed: 02/11/20, 07:50 PM

**Recently Accessed Items**

- Case 1 Noteboo k  
Notebook  
Last Modified: Mar 06 2020
- Dementia Analy sis from Cohort Builder  
Notebook  
Last Modified: Feb 04 2020
- Ischemic Heart Disease Analysis  
Notebook  
Last Modified: Feb 04 2020
- Dementia Analy sis  
Notebook  
Last Modified: Feb 04 2020
- Type 2 Diabetes Analysis  
Notebook  
Last Modified: Feb 04 2020
- Ischemic Heart Disease Analysis  
Notebook  
Last Modified: Jan 31 2020

# Since the Launch of Researcher Workbench we have Expanded the Data



329,000+ Participants



267,600+ Physical Measurements



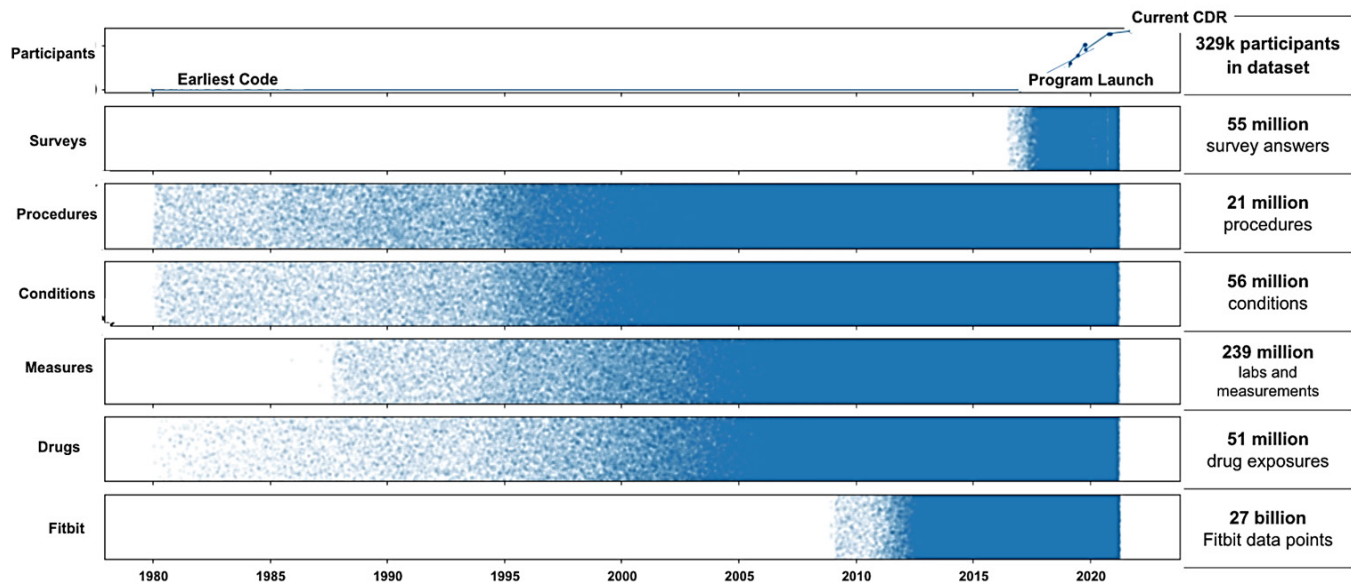
214,200+ EHRs



329,000+ Surveys  
(100,000 COPE Surveys)



11,600+ Fitbit Records



**Plus: ~90k whole genomes + ~165K arrays coming spring 2022**

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

## Research on the Researcher Workbench



**1300+**  
Registered  
Researchers



**900+**  
Active  
Projects

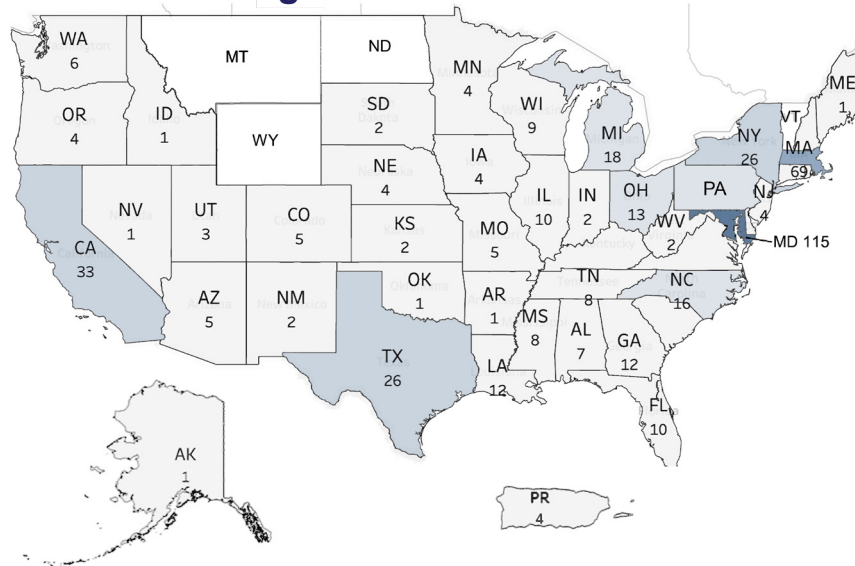


**45+**  
Publications  
using *All of Us*

## Institutional Agreements

**More than 280**  
registered institutions

**23%** are Historically  
Black Colleges and  
Universities,  
Hispanic Serving  
Institutions, or  
Non-Profits





# March 2021, Dr. Patrick Wu Defends His PhD Dissertation: Repurposing drugs using gene expression signatures and EHR data

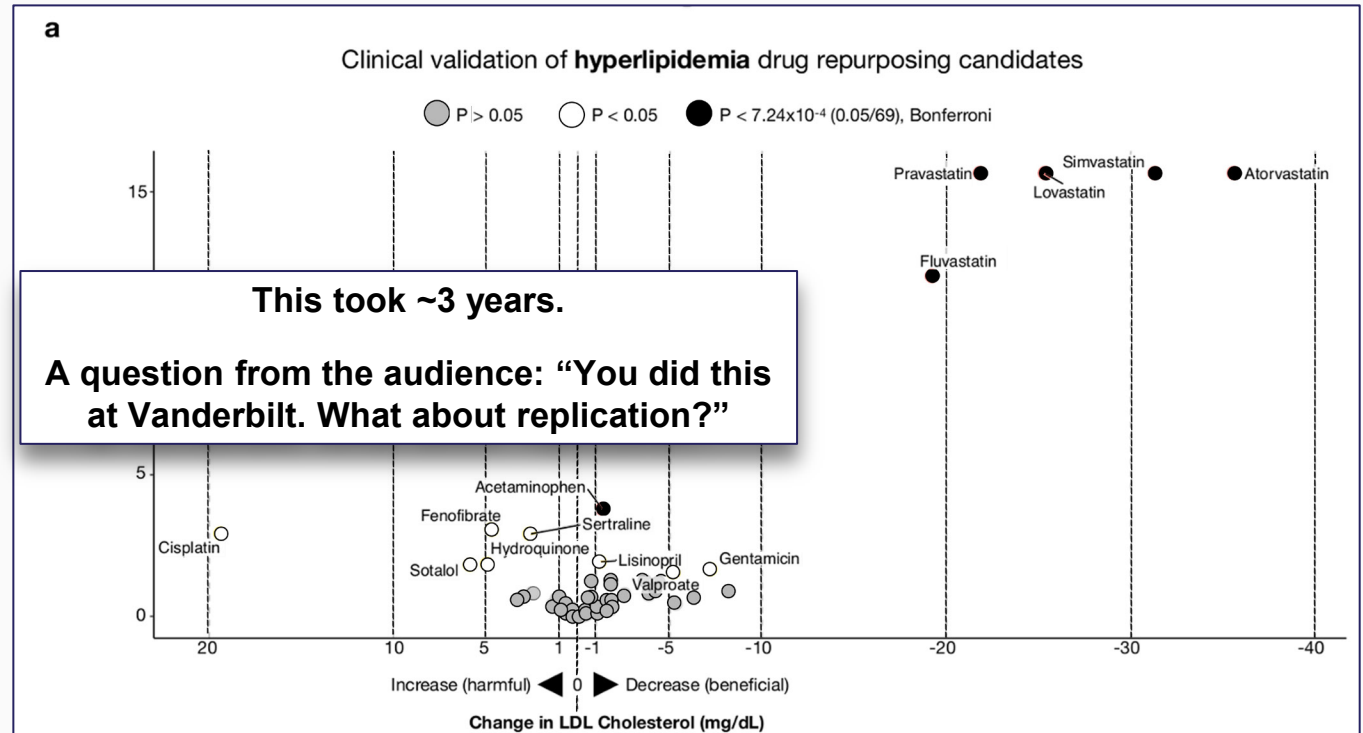
gene expression data identifies  
drugs that might lower  
cholesterol



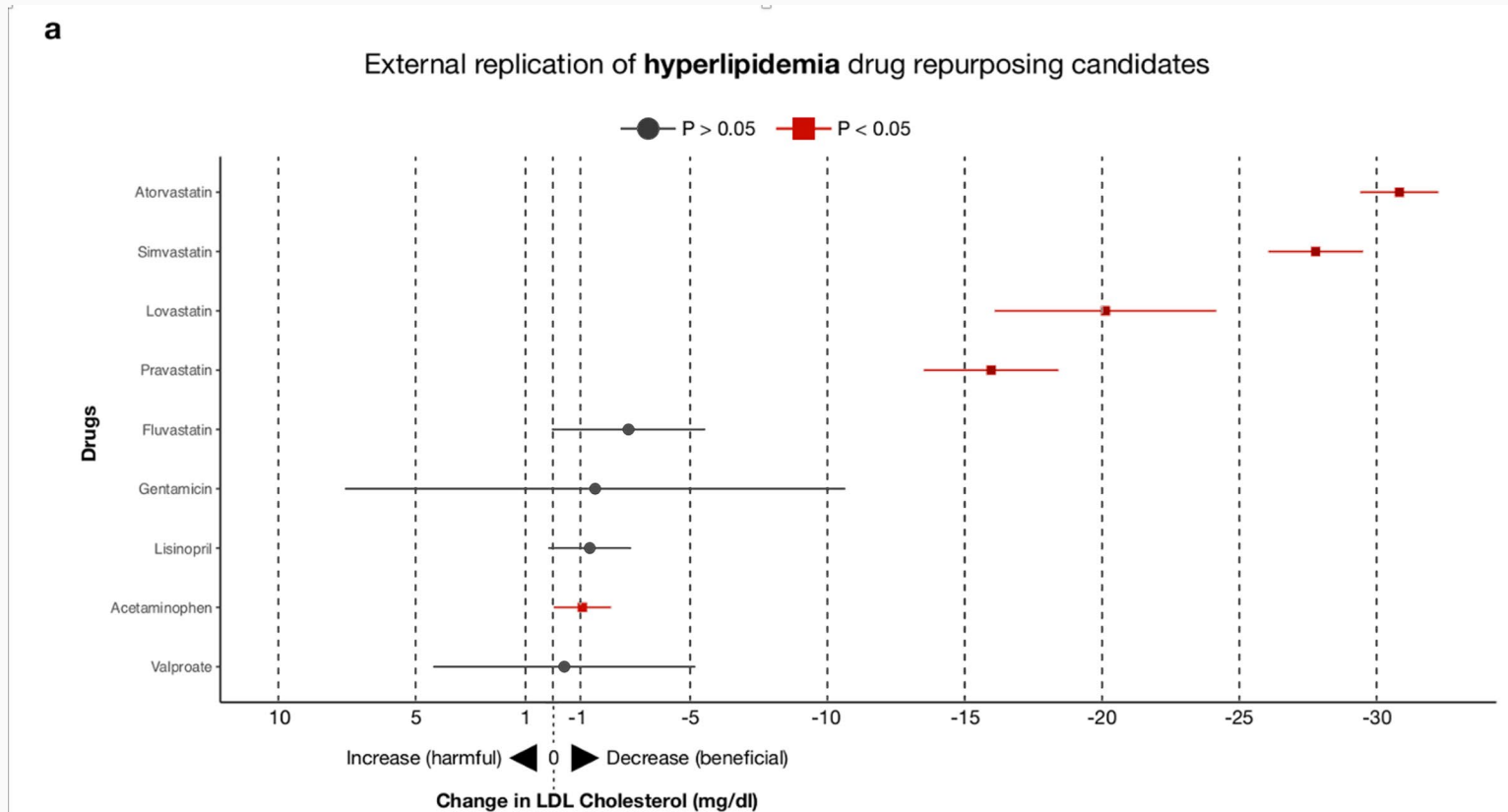
found 69 candidate drugs



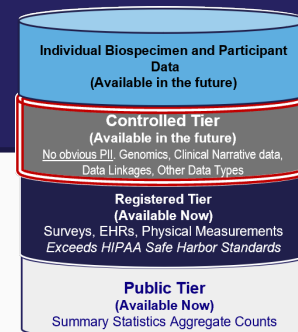
study those drugs in the  
Electronic Health Record data  
at Vanderbilt



# One Week Later: He emails me this figure from *All of Us*...



# Upcoming Controlled Tier Release by Spring 2022



## More granular data

- Expanded sociodemographic data
- Dates of services
- Expanded COVID-19 diagnoses and vaccination information and more COPE survey data



## New data types

- Derived social determinants of health
  - Socioeconomic statistics (SES) factors derived from census clusters and American Community Survey (ACS)
- Genomics: Expected ~90,000 WGS + ~165,000 arrays



# All of Us Data Roadmap

