Update on the *All of Us* Research Program

September 17, 2021

Josh Denny, MD, MS
Chief Executive Officer
All of Us Research Program

@AllofUsCEO

National Institutes of Health

All of Us Research Program Mission

Nurture relationships
with **one million or more** participant partners, from all walks of life, for decades

Our mission

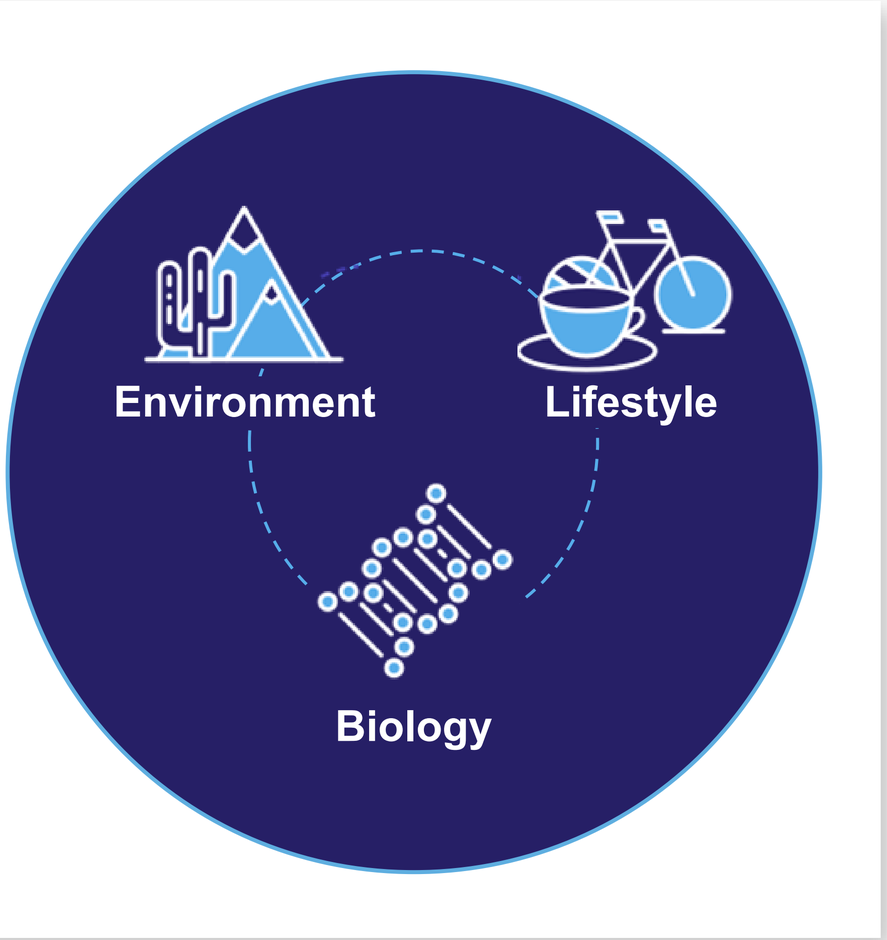
To accelerate health research and medical breakthroughs that enable individualized prevention, treatment, and care for all of us

Deliver one of the largest, richest biomedical dataset
that is secure and easy to access

Catalyze a robust ecosystem
of researchers and funders hungry to use and support it

The *All of Us* Research Program: An Innovative Research Effort

- **Diversity at the scale of 1 million people or more**
- **Focus on participants as partners,** with return of value as a priority
- **Longitudinal design,** ability to recontact participants
- **Multiple data types:** EHR, surveys, baseline physical measurements, biospecimens, genomics, and more
- **National, open resource for all:** broadly accessible to all researchers with open-source software & tools
- **Security and privacy safeguards** for all participants



All of Us Program Partners

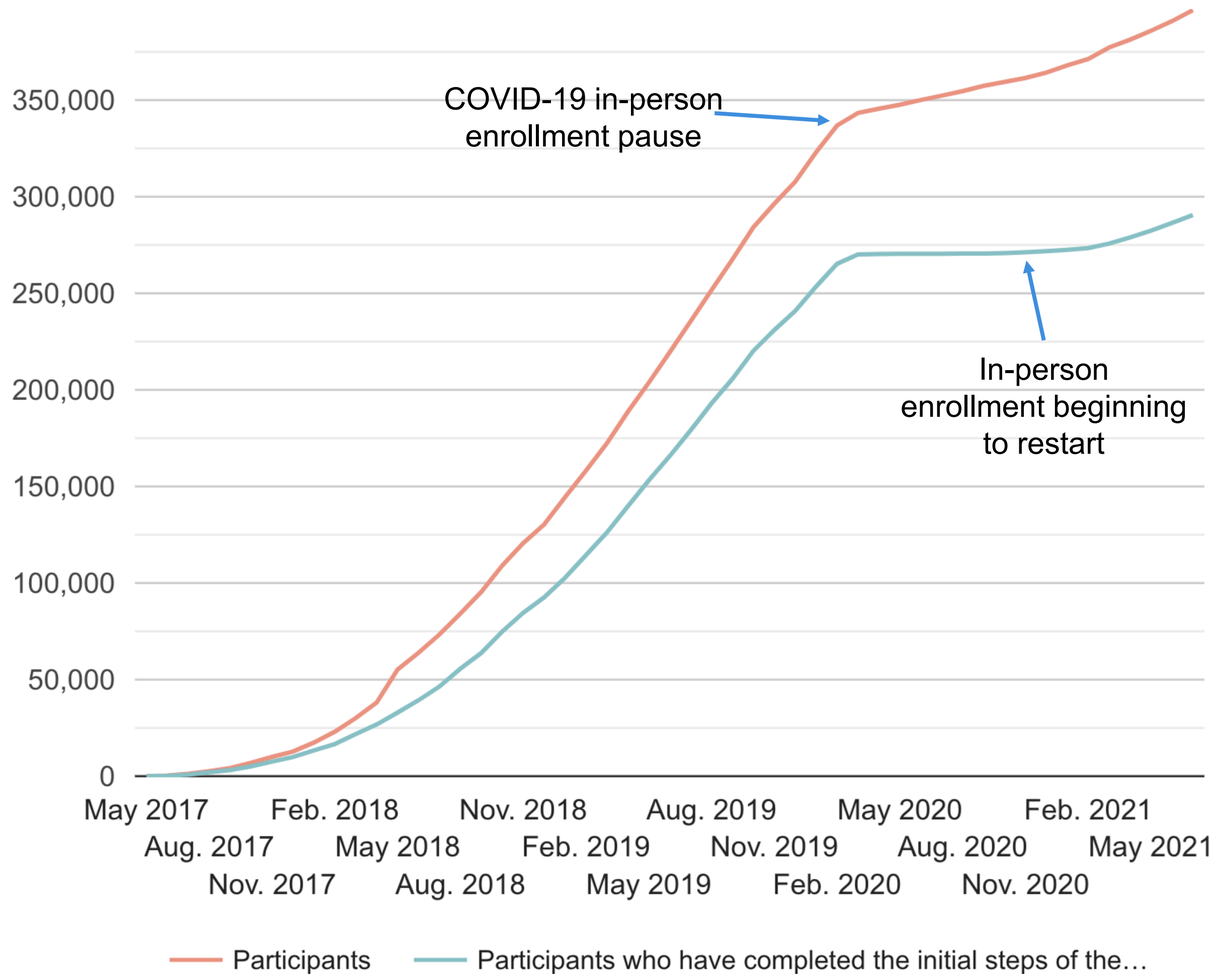
Status of the *All of Us* Research Program (as of September 6, 2021)

406,000+
Participants

253,000+
Electronic Health Records

295,000+
Participants who have completed initial steps of the program

310,000+
Biosamples



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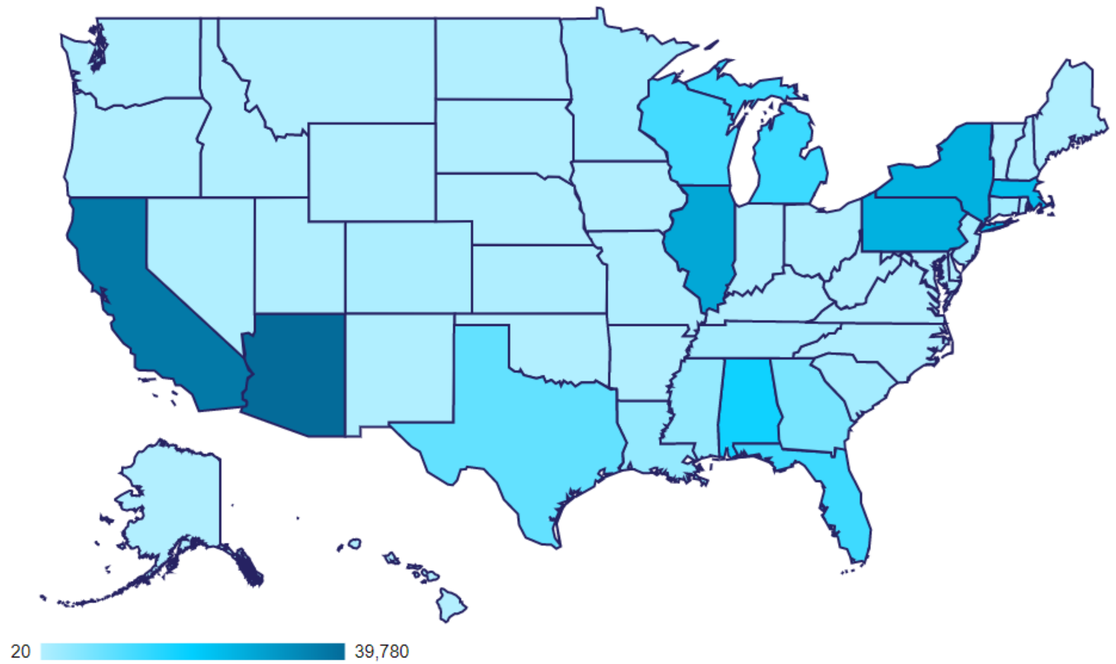
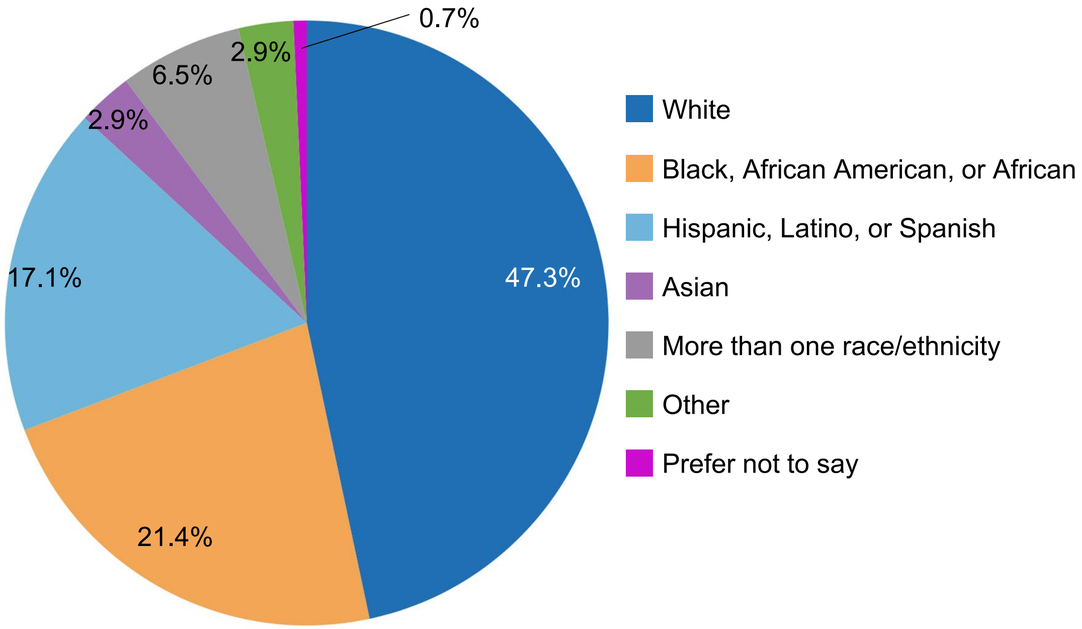
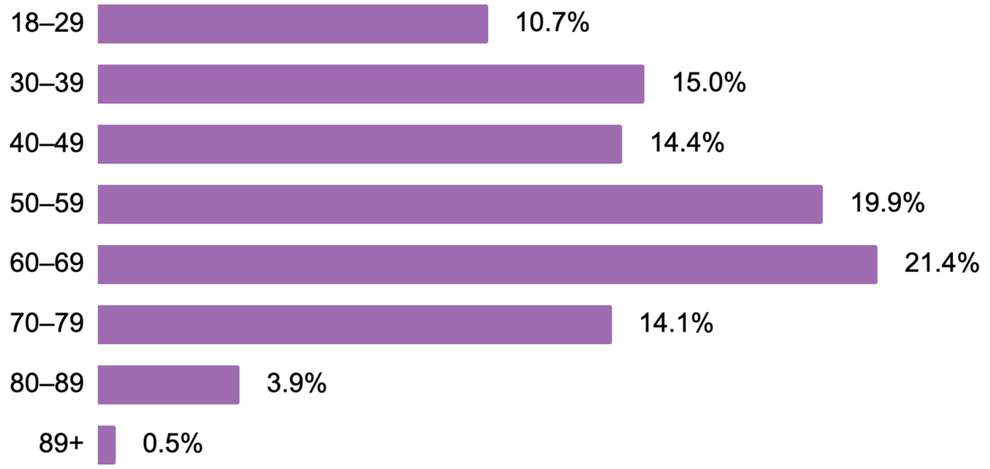


Over 80% of *All of Us* participants are underrepresented in biomedical research

Race and Ethnicity



Age



researchallofus.org

Data Collected from *All of Us* Participants

- Consent and Electronic Health Records
- Participant Surveys
- Physical Measurements
- Biosamples
- Mobile/Wearable Tech

Data Collected from *All of Us* Participants: Surveys

- Consent and Electronic Health Records
- **Participant Surveys**
- Physical Measurements
- Biosamples
- Mobile/Wearable Tech

Current surveys focused on:

- Demographics and Lifestyle
- Personal and Family Medical History
- Healthcare Access
- **CO**VID **P**articipant **E**xperience (**COPE**)

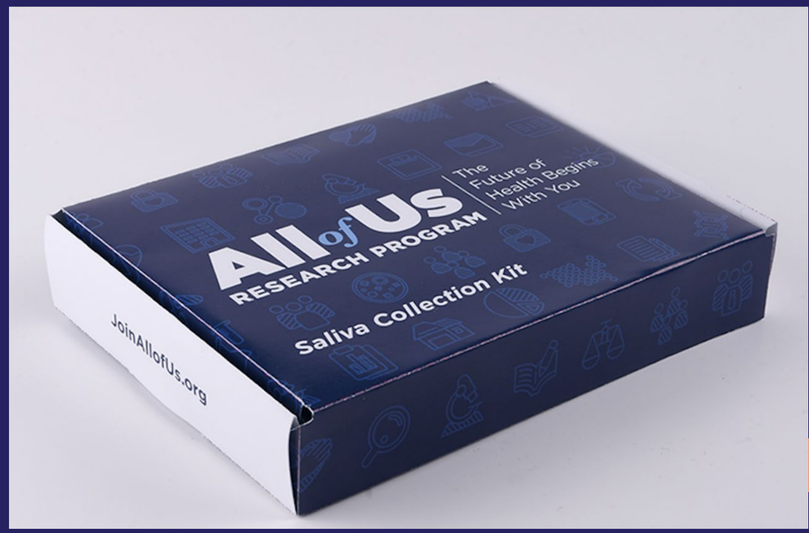
Next in queue:

- Social Determinants of Health

Data Collected from *All of Us* Participants: Biosamples

- Consent and Electronic Health Records
- Participant Surveys
- Physical Measurements
- **Biosamples**
- Mobile/Wearable Tech

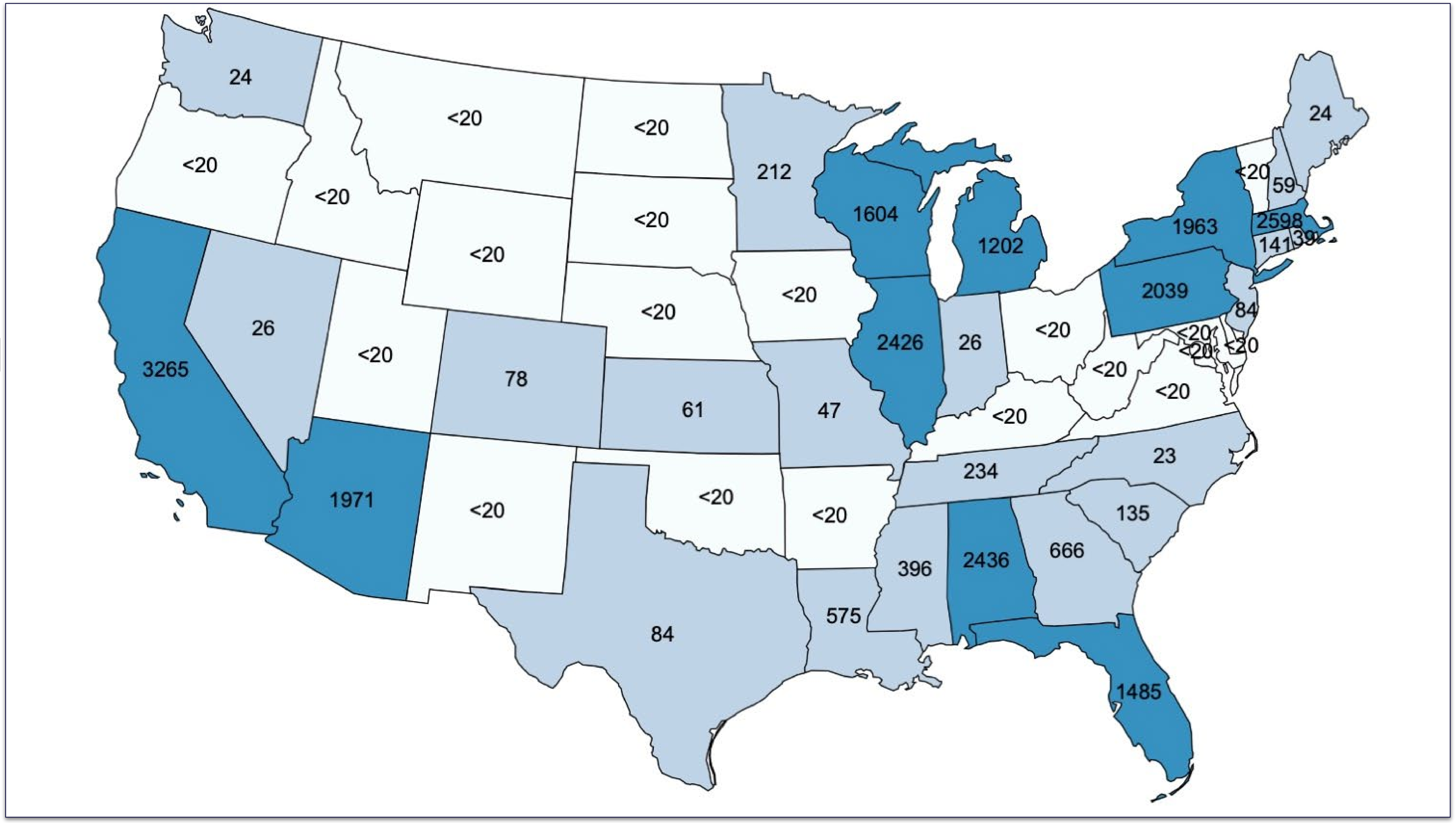
- Blood
  - DNA
  - RNA
  - cfDNA
  - Serum
  - Plasma
- Saliva kits (if not blood)
- Urine



COVID-19 Response - Serology Study

COVID-19 Serology Study

- Tested **24,079** blood specimens collected between **January 2** and **March 18, 2020**
- Tested spike and nucleocapsid antibodies on multiple platforms



SARS-CoV-2 antibodies identified prior to the first recognized cases in 5 U.S. states

COVID-19 Serology Study Published in *Clinical Infectious Diseases* (June 15, 2021)

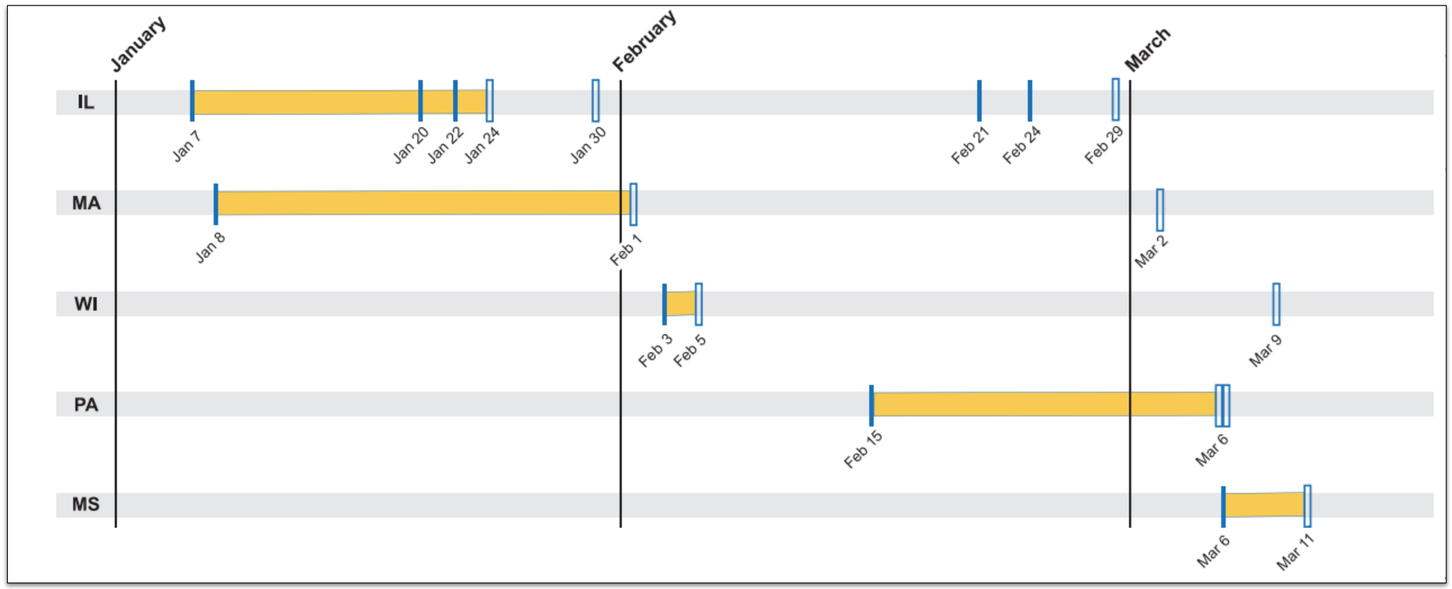
OXFORD ACADEMIC

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**

Press Coverage of the *All of Us* COVID-19 Serology Study

Sections | The Washington Post — Democracy Dies in Darkness | Carolyn Denny

Health

NIH study suggests coronavirus may have been in U.S. as early as December 2019

The Coronavirus Outbreak › | Maps and Cases | States Falling Behind Vaccine Goals | Vaccine Maps | Vaccines and Children

Scientists Report Earliest Known Coronavirus Infections in Five U.S. Sta

Blood drawn from nine people in the earliest days of the pandemic tested positive for the infection. But some experts questioned the results.

THE WALL STREET JOURNAL.

U.S.

Covid-19 Ranged From Illinois to Massachusetts Before States Reported First Cases

Blood samples show people in five U.S. states were infected early,

CNN health | LIVE TV

NIH researchers find more evidence Covid was circulating in the US in December 2019

By Maggie Fox, CNN

Updated 1:57 PM ET, Tue June 15, 2021

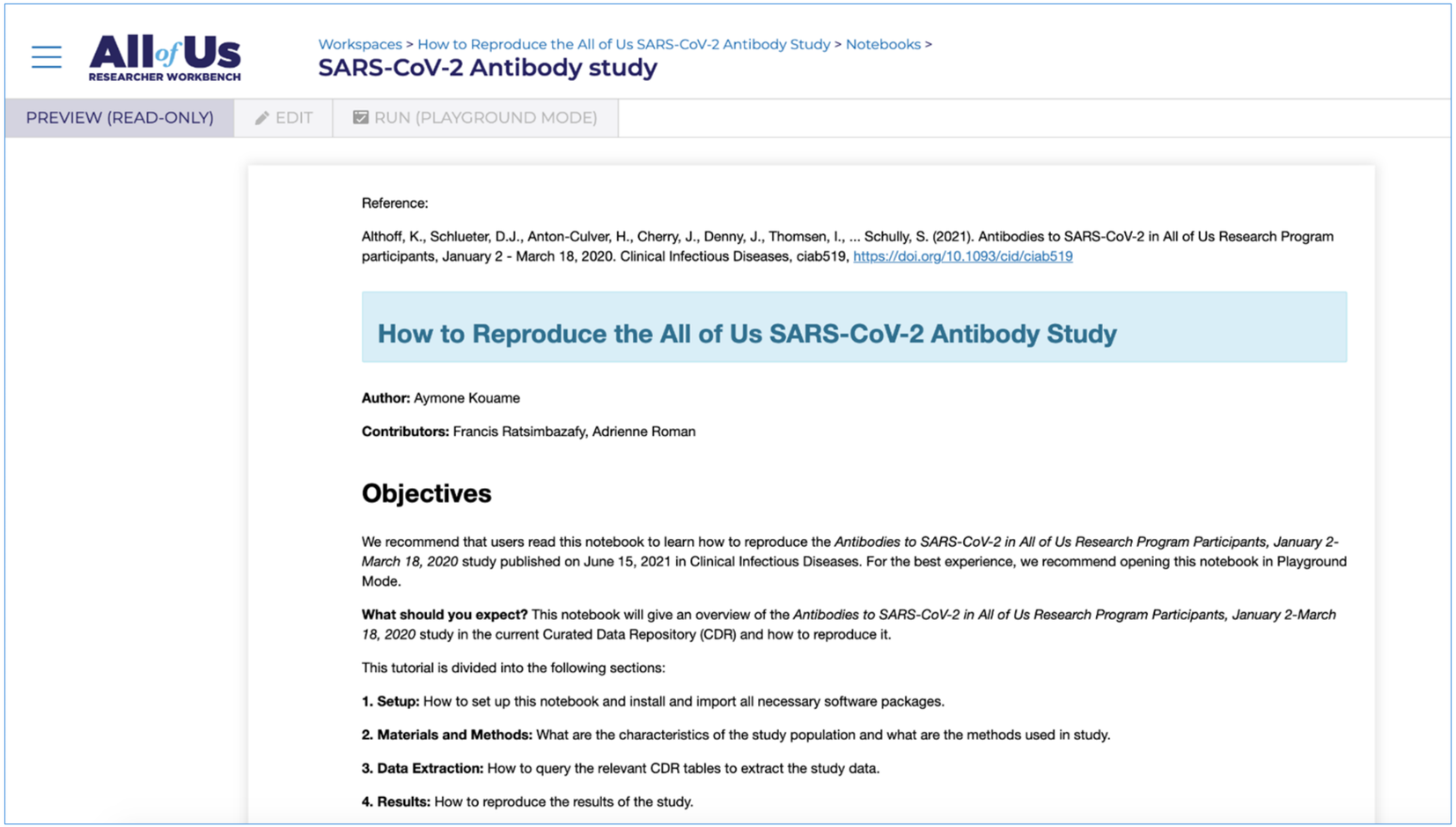
AP | More evidence suggests C... | Top Stories | Topics | Video | Listen

More evidence suggests COVID-19 was in US by Christmas 2019

By MIKE STOBBE June 15, 2021

Click to copy

Making Research Reproducible: Any Published *All of Us* Analysis Can Be Accessed by Any Other *All of Us* Researcher



[Notebook URL: https://bit.ly/3h7GnEF](https://bit.ly/3h7GnEF)

Any *All of Us* researcher can review and reuse the exact data and analyses used in the paper

All of Us Research Program Core Values
Return of information

Participation in **open** to all.

Participants have **access** to their information.

Participants reflect the rich **diversity** of the U.S.

Data will be accessed **broadly** for research purposes.

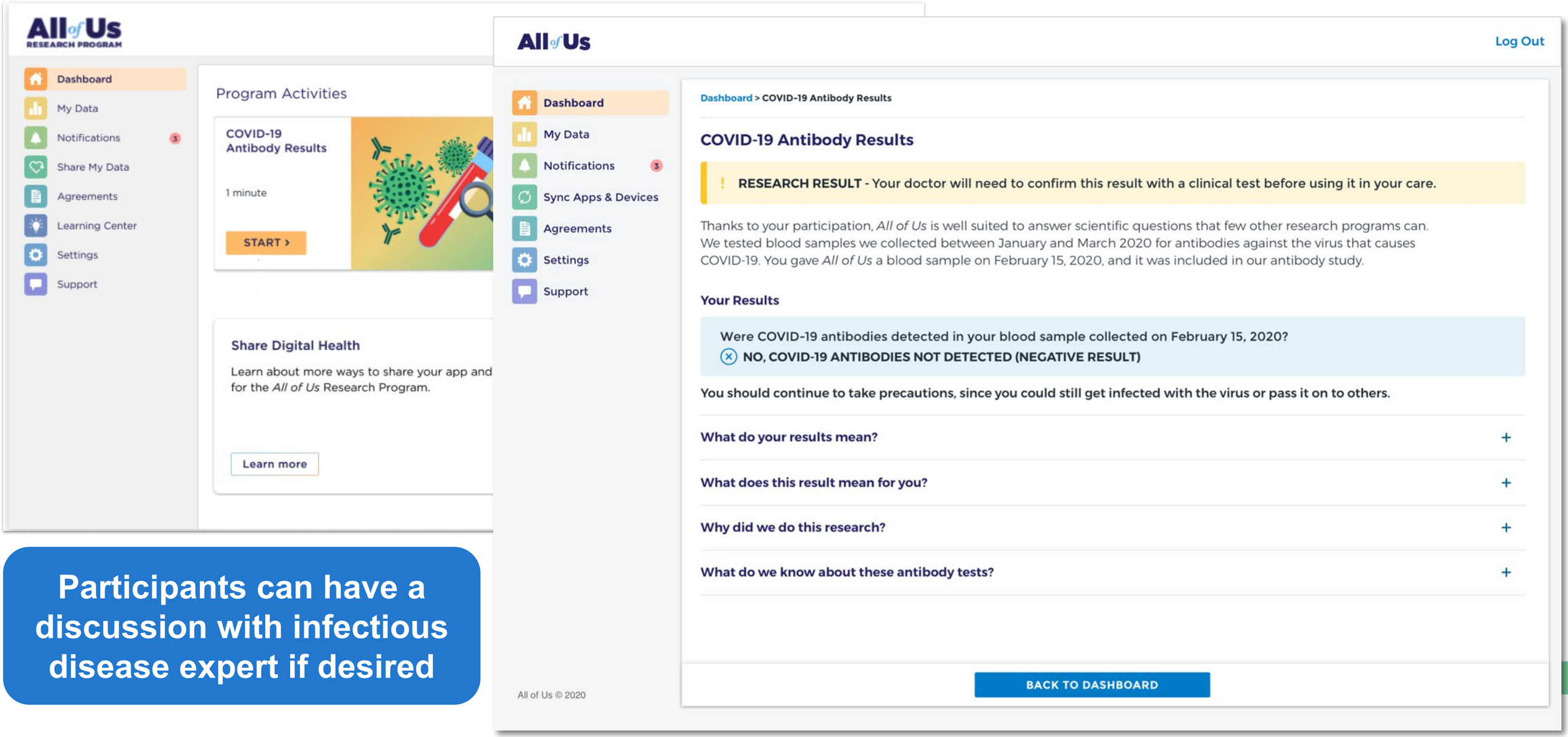
Participants are **partners**.

Security and privacy will be of highest importance.

Trust will be earned through **transparency**.

The program will be a catalyst for **positive change** in research.

We Returned Serology Results to Participants



Participants can have a discussion with infectious disease expert if desired

Current Data and Applications

Researcher Data Access

Raw Data Repository

Data Curation

Data
Harmonization
Privacy
Methodology
QA/CC

Individual Biospecimen and Participant Data
(Available in the future)

Controlled Tier
(Available in the future)
No obvious PII. Genomics, Clinical Narrative data, Data Linkages, Other Data Types

Registered Tier
(Available Now)
Surveys, EHRs, Physical Measurements
Exceeds HIPAA Safe Harbor Standards

Public Tier
(Available Now)
Summary Statistics Aggregate Counts

(future) → **Future ancillary studies**
Could recontact participants, use biospecimens, issue new surveys or DHT, enroll in clinical trials

(Winter 21/22) / (now) → **Researcher Workbench**
ResearchAllofUs.org/Apply/

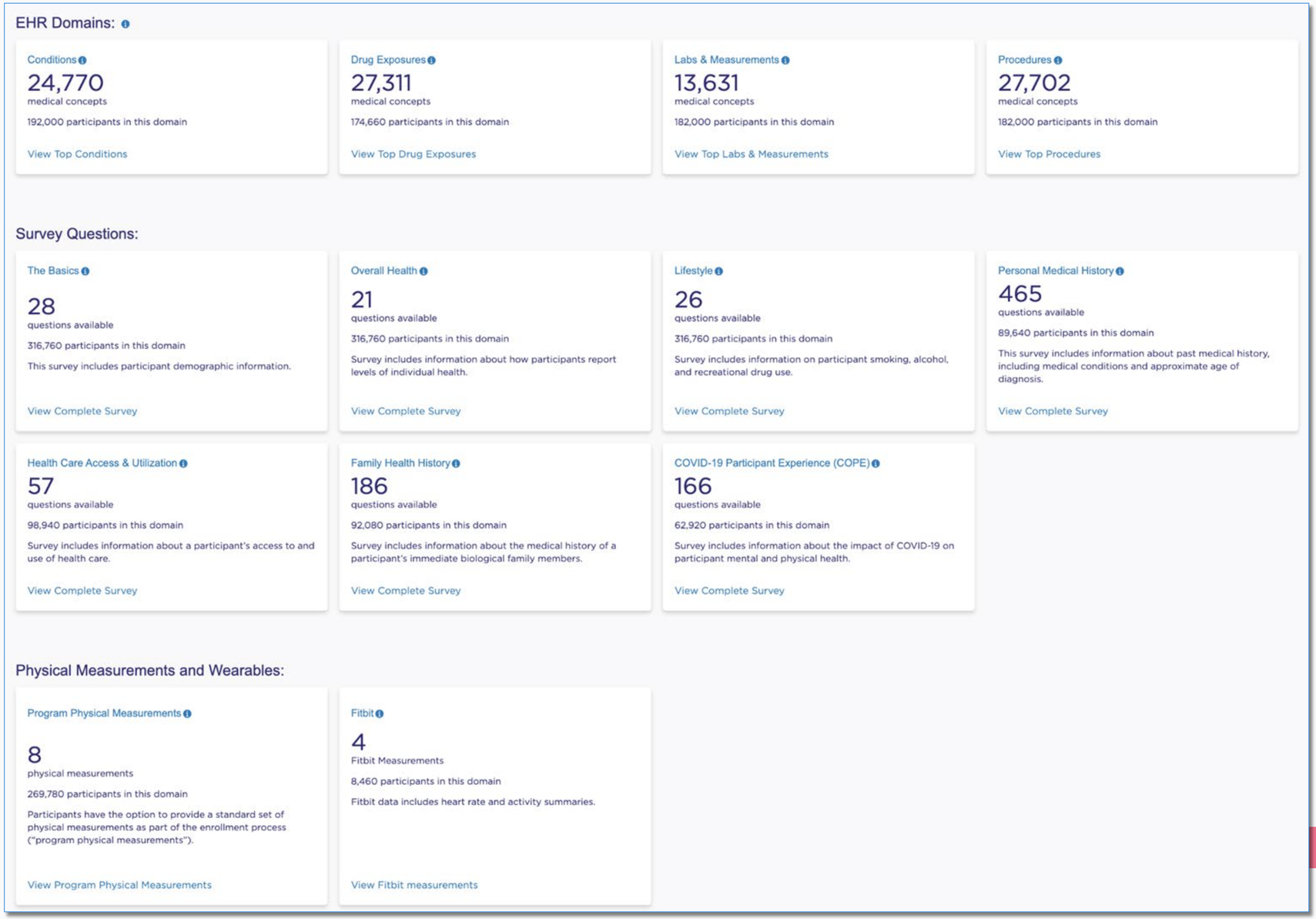
(now) → **Data Browser**
databrowser.researchallofus.org
(public, no login required)

All of Us Research Hub: Public Data Browser

Summary statistics of participant data

- **EHR Data** (Conditions, Drug Exposures, Lab & Measurements, Procedures)
- **Survey Questions** (including COVID-19 surveys)
- **Physical Measurements**
- **Open access** (no login required)

DataBrowser.ResearchAllofUs.org



All of Us Research Hub: Data Browser – EHR Conditions

Search Across Data Types

Type 2 Diabetes ×

Data includes 316,760 participants and is current as of 10/1/2020.

FAQs | Introductory Videos | User Guide

EHR Domains:

Conditions

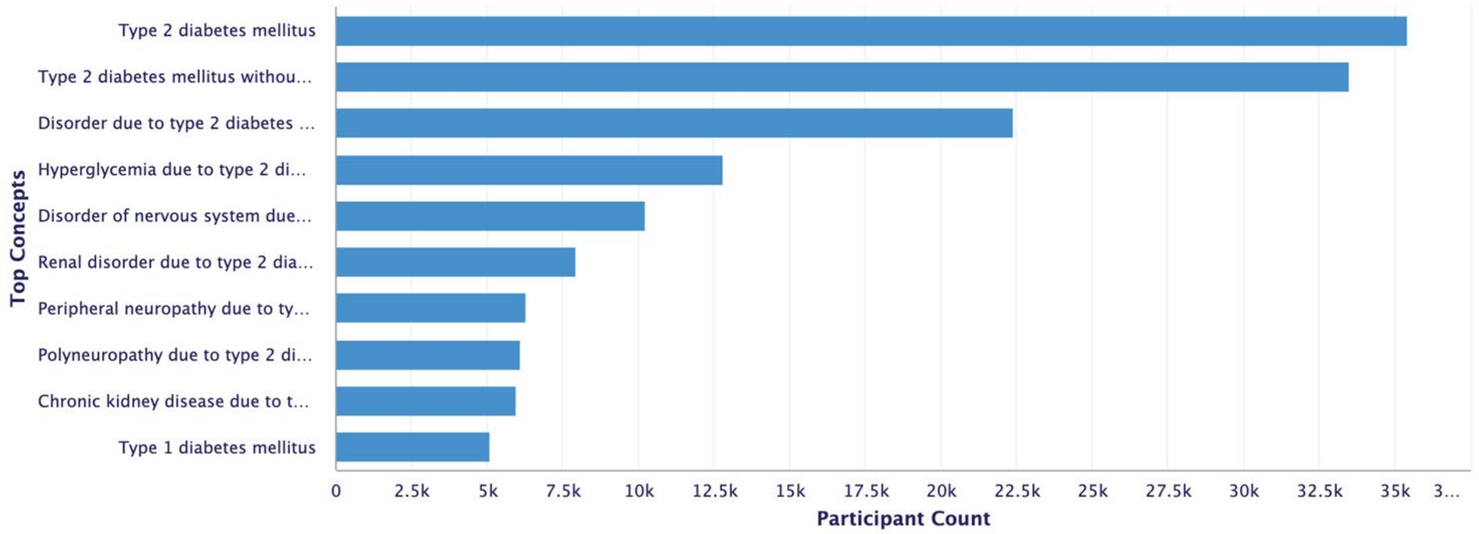
119
matching medical concepts

192,000 participants in this domain

View Results

DATA DISCLAIMER

Top 10 by Descending Participant Counts



Survey Questions:

No Survey Results. Please type in a new search term.

Physical Measurements and Wearables:

No Program Physical Measurement Results. Please type in a new search term.

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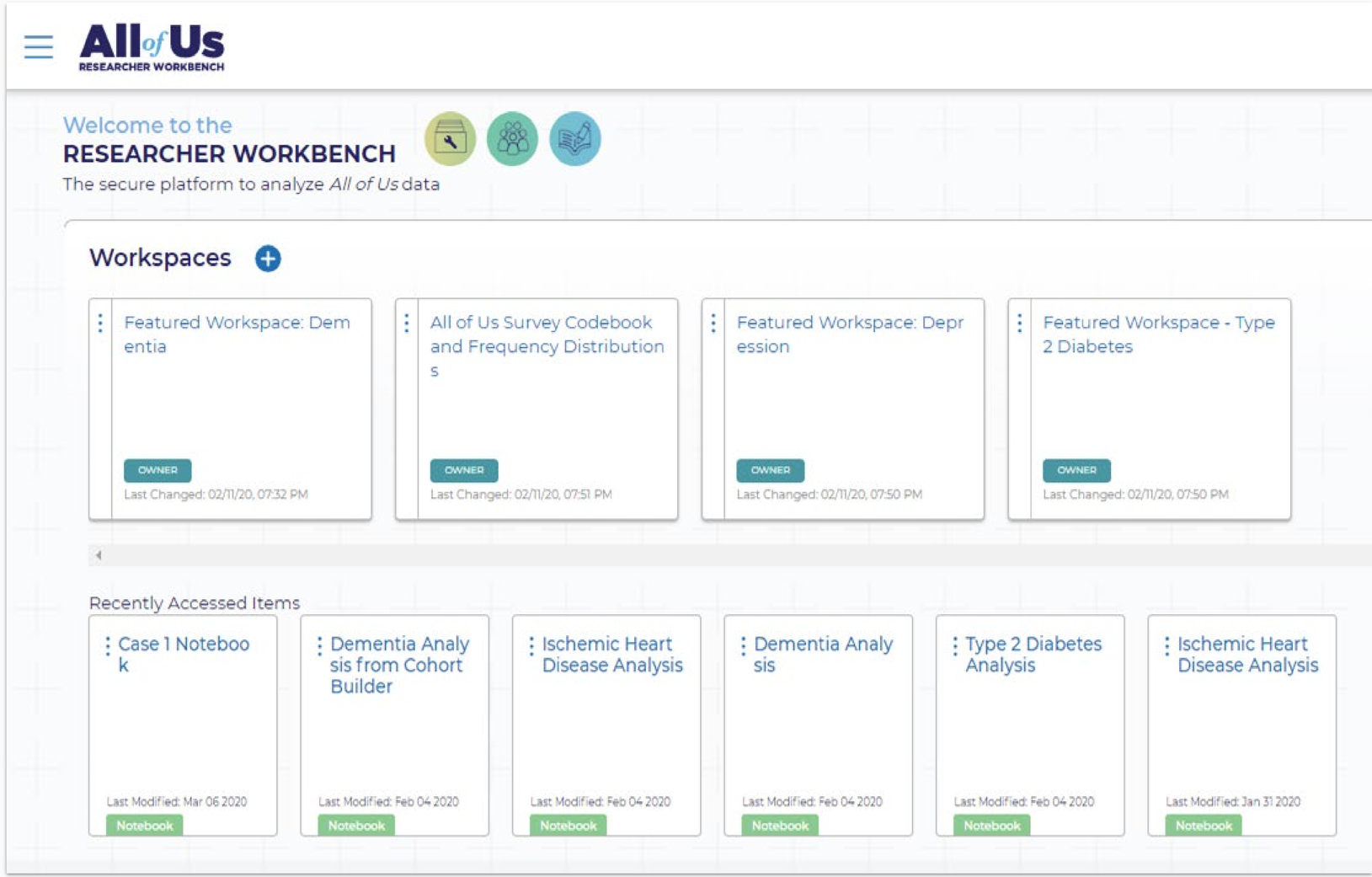
All of Us Researcher Workbench: Access to Row-Level Data for Analysis

Researcher Workbench Beta
Launched on May 27, 2020

- Cloud based central resource
- Personally-identified information is removed
- **Passport access model** - just create, describe your workspace, and get to work! No separate IRB approval needed.
- During beta phase, access requires eRA commons ID and limited to US nonprofits



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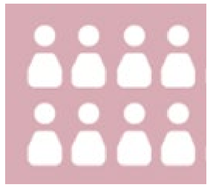
Researcher Workbench (Launched May 2020): By the Numbers

Data Available on the Researcher Workbench



329,000+ Participants

267,600+ Physical Measurements

214,200+ EHRs

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

11,600+ Fitbit Records

Researcher Workbench (Launched May 2020): By the Numbers

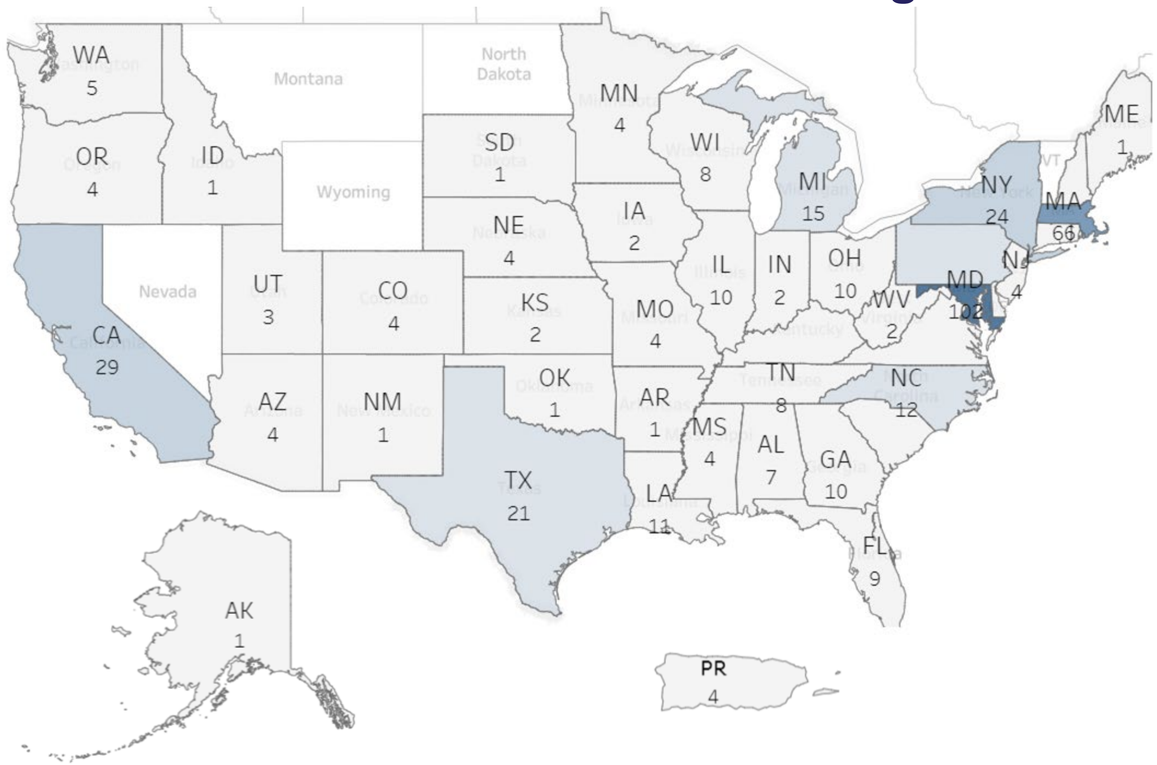
Research on the Researcher Workbench

1000+ Registered Researchers

660+ Active Projects

15+ Publications using *All of Us* data

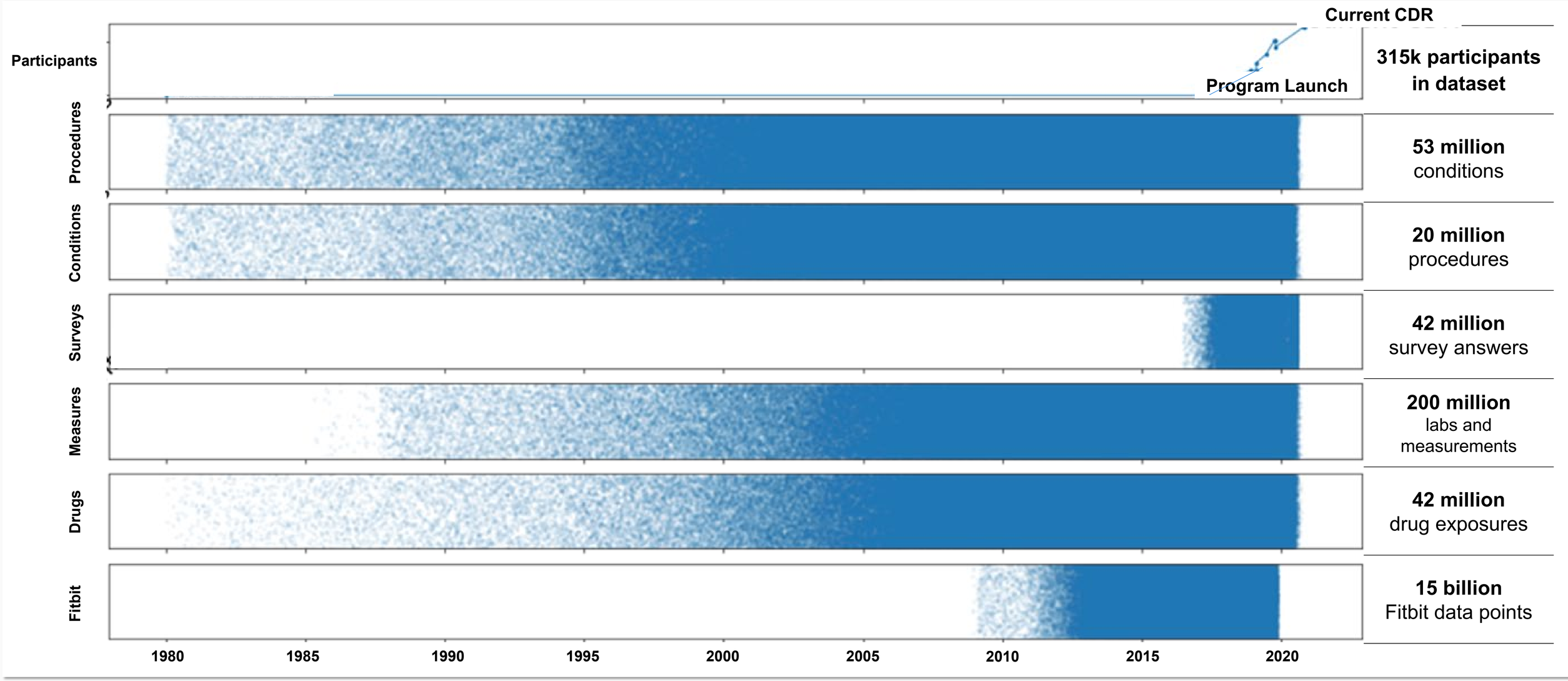
Institutional Agreements



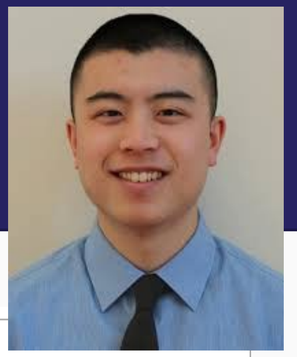
More than 240 registered institutions

Over 24% are Historically Black Colleges and Universities, Hispanic Serving Institutions, or Non-Profits

Participant EHRs and Fitbit Provide Longitudinal Data



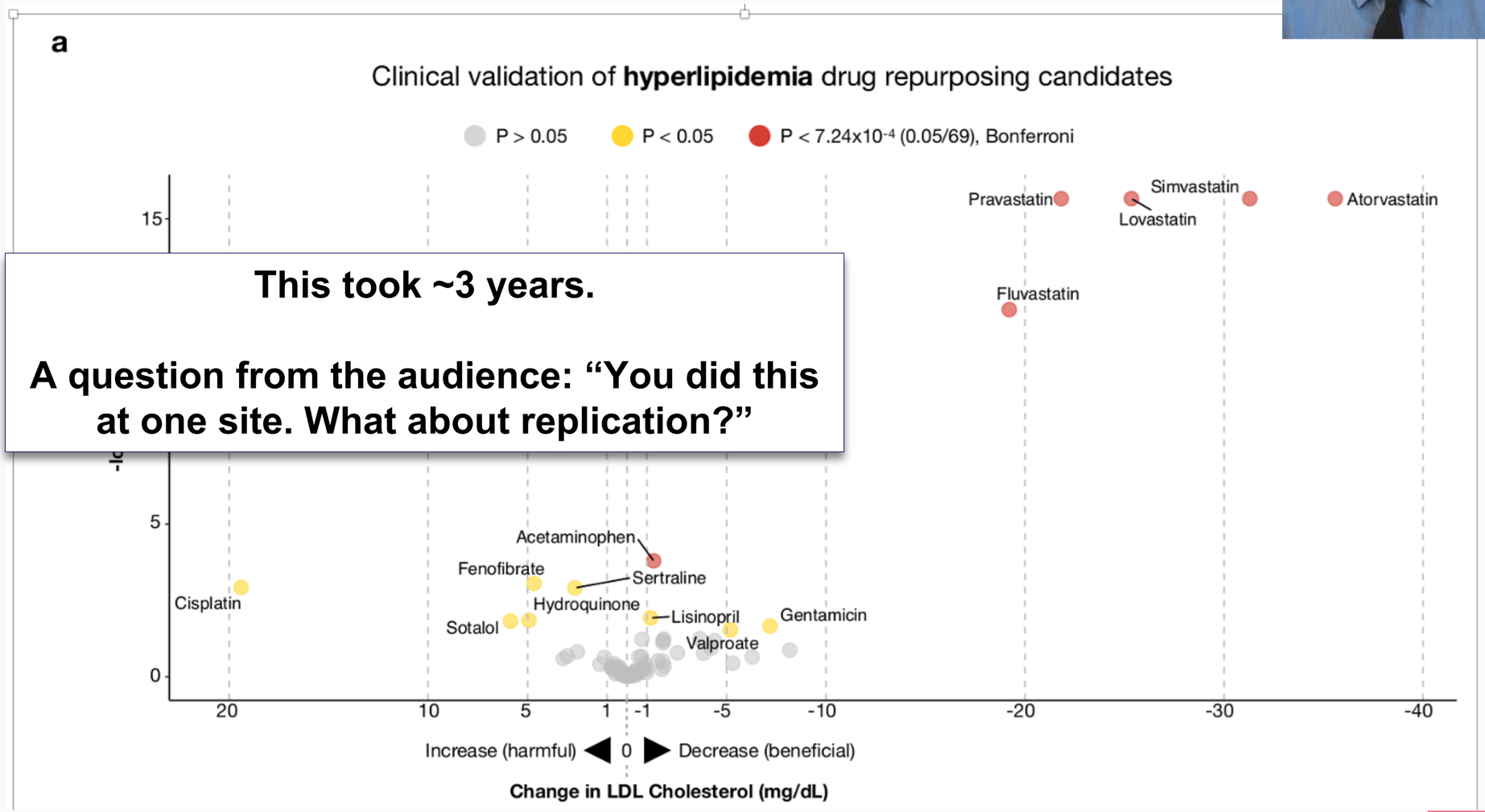
March 2021, Dr. Patrick Wu Defends His PhD Dissertation:
"Repurposing drugs using gene expression signatures and EHR data"



gene expression data identifies drugs that might lower cholesterol

found 69 candidate drugs

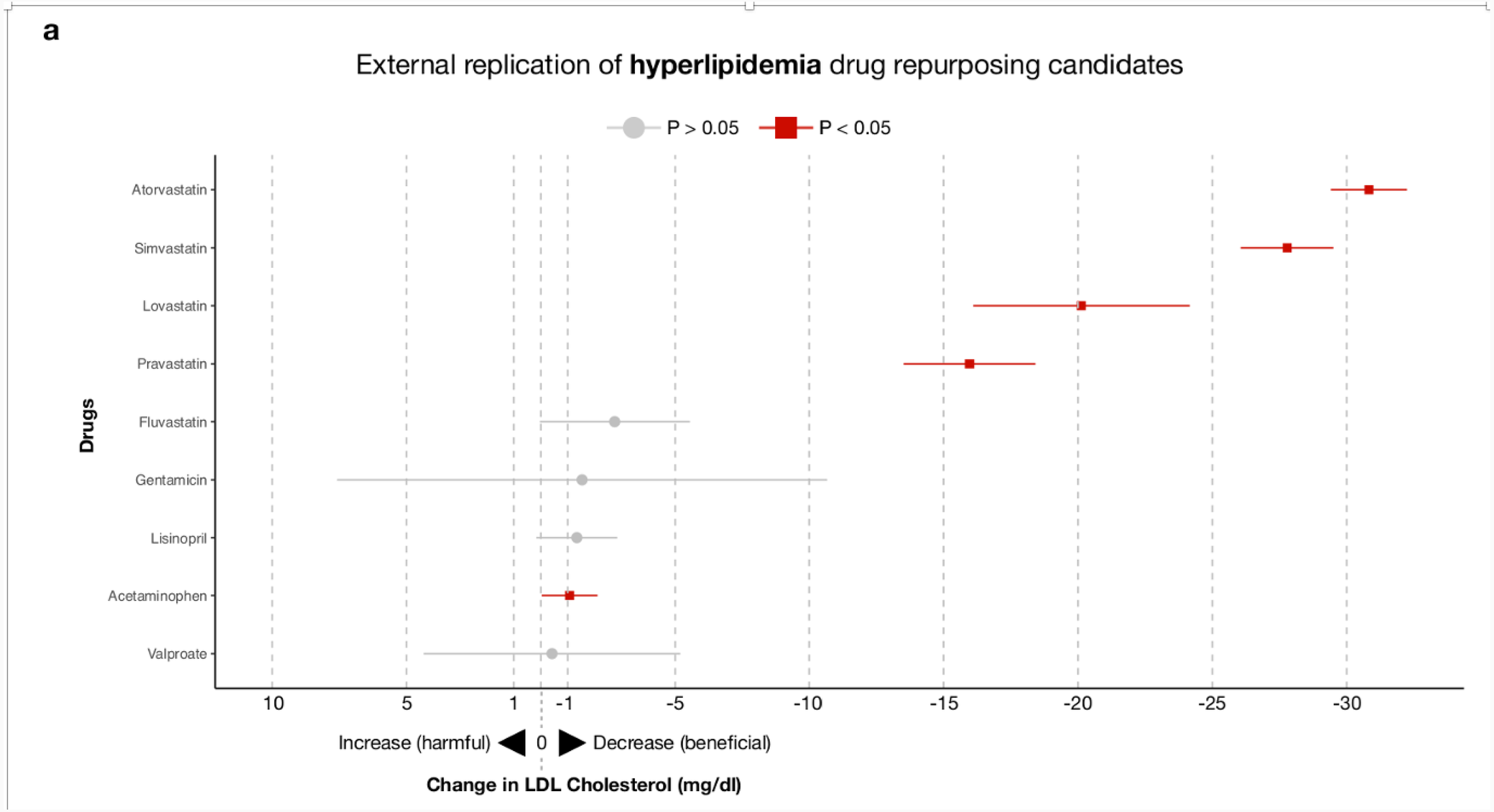
study those drugs in the Electronic Health Record data at Vanderbilt



This took ~3 years.

A question from the audience: "You did this at one site. What about replication?"

<u>One Week Later</u>: He has applied for the first time to use *All of Us*, completes his onboarding, and has replicated his results in *All of Us*...



What's coming next: Controlled Tier Researcher Data Access

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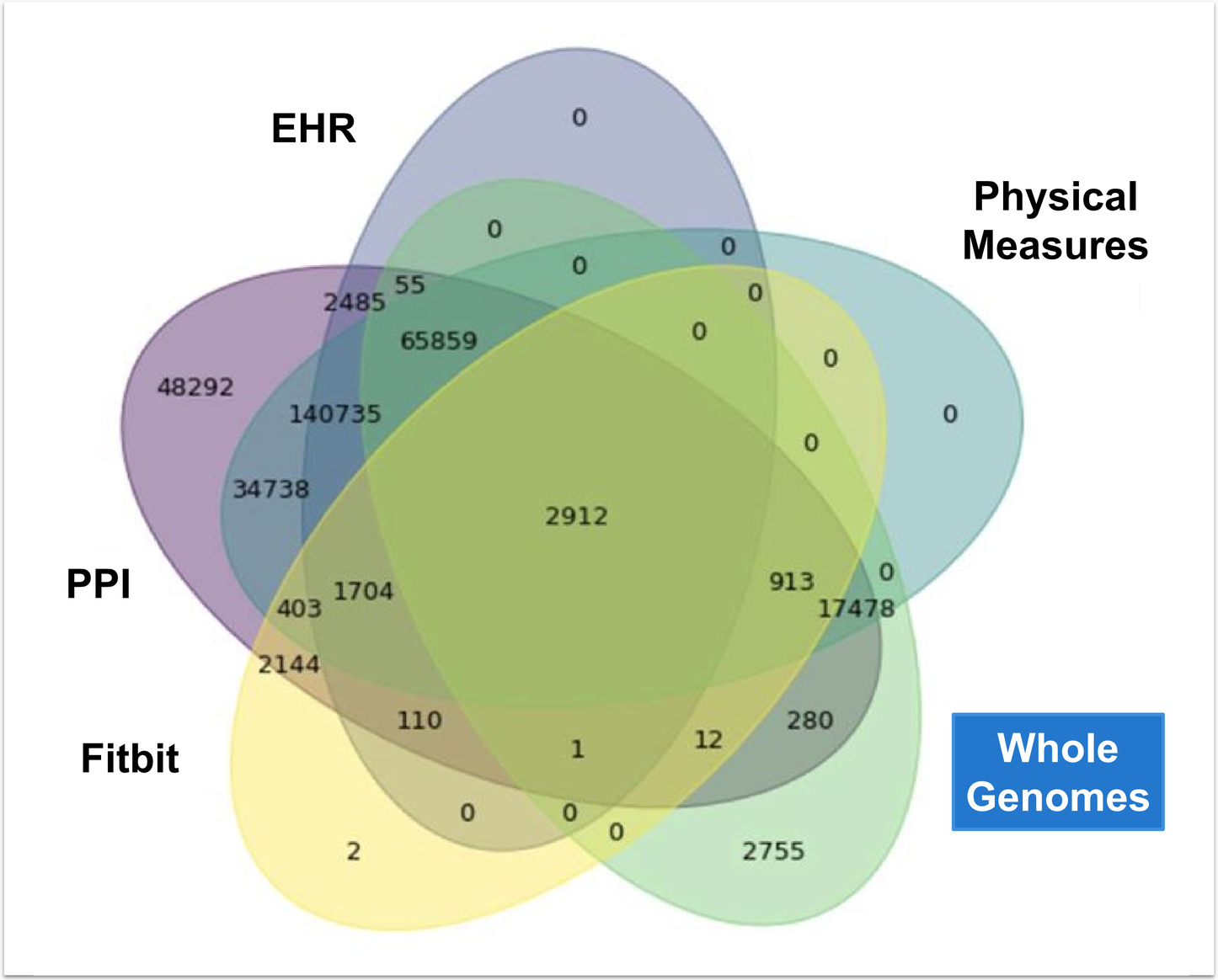
First Genomics Data Release is coming Winter 2021/2022



- Expected **90,000 WGS + 130,000 arrays**
  - >40% non-White
- More COVID-19 data
- More detailed demographic & EHR data

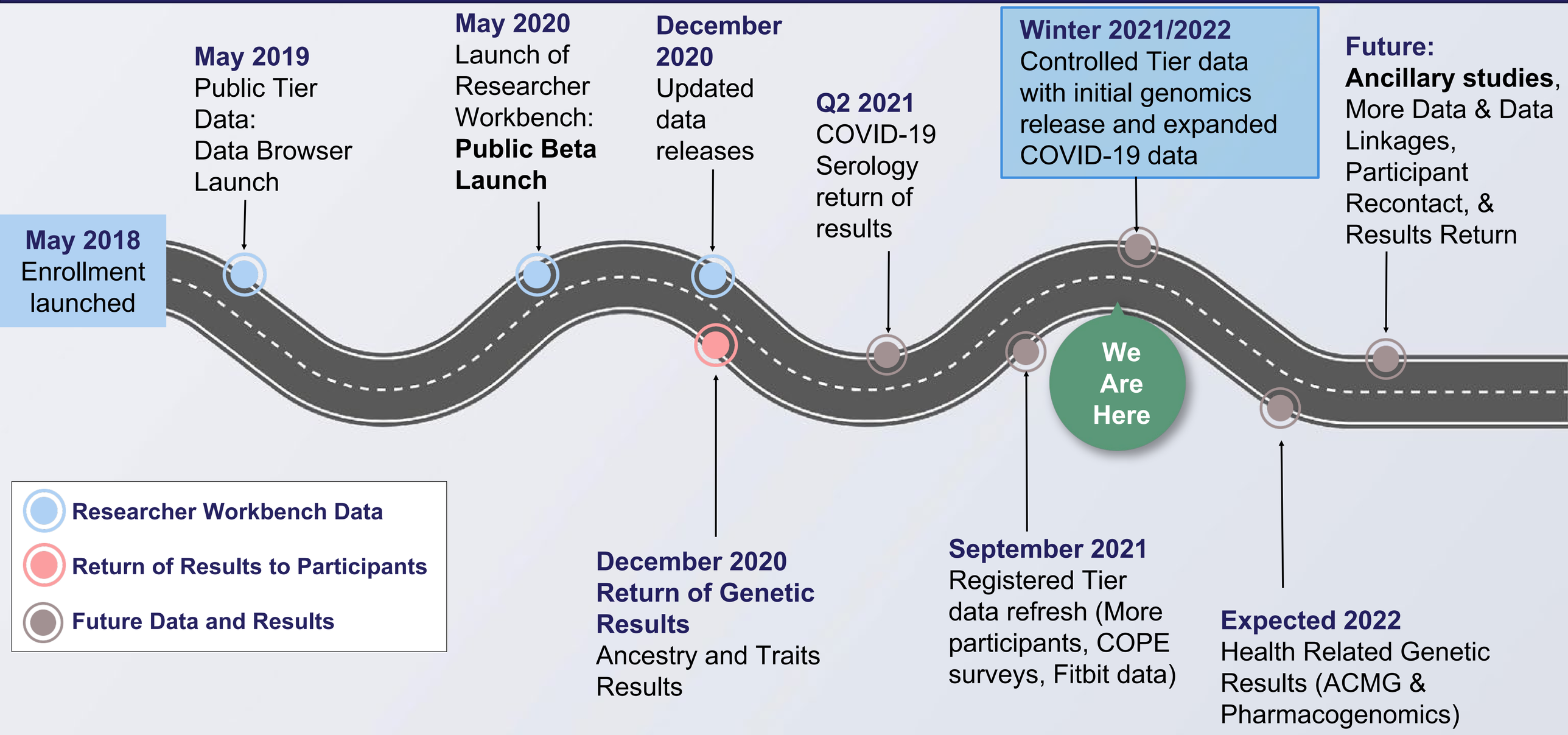
First Ancillary Study: Nutrition for Precision Health

Nutrition for Precision Health
Powered by the *All of Us* Research Program

Goal: Enroll 10,000 *All of Us* participants to study to develop algorithms to predict individual responses to foods and dietary patterns

- Build on *All of Us* to add a comprehensive set of microbiome, physiological, metabolic, behavioral, cognitive, contextual, survey, and environmental data
- In large and diverse population of participants

All of Us Roadmap



Thank You!

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