All of Us Research Program: 2022 Institutional Onramp Event Introduction

October 3, 2022

Dr. Karriem Watson, Director of Engagement and Outreach
All of Us Research Program

National Institutes of Health

Goals of Today's Event

- Share the mission and objectives of the *All of Us* Research Program
- Highlight how institutions can leverage the *All of Us* Research Program to enhance research capacity
- Share resources available to institutions and researchers
- Hear from you!

One of the largest, richest, most diverse biomedical datasets of its kind

Inviting

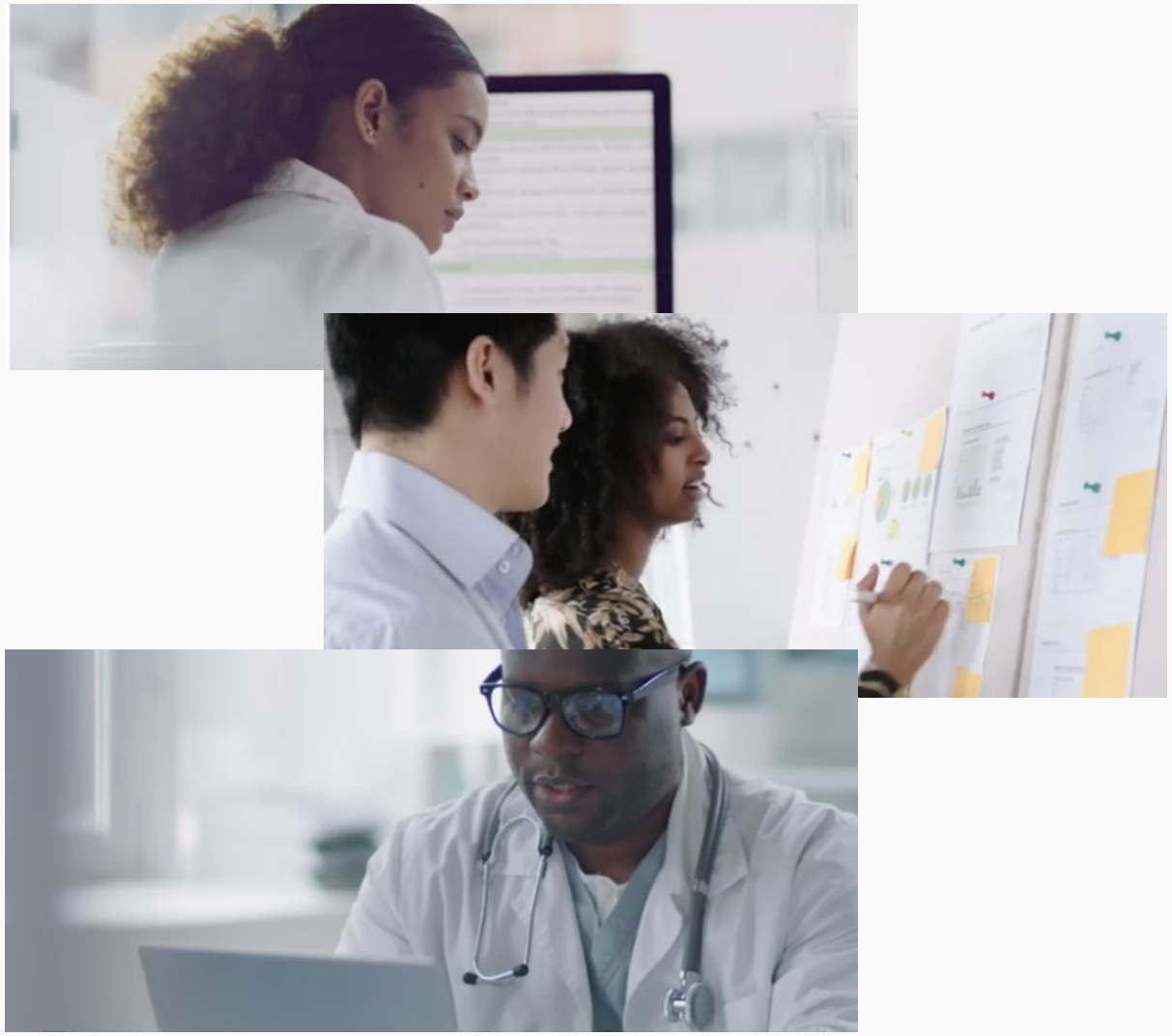
1 Million or more people across the United States

Data available from **372,000+** participants

80%
are from underrepresented communities

45%
are from racial and ethnic minority groups

Building a Diverse Researcher Cohort



- **Creating a demographically diverse researcher cohort** that promotes responsible and ethical use of data, returns value to participant communities, and accelerates research impact.
- **Encouraging student assemblies and early-stage investigators** to bring fresh, creative perspectives & innovative research outcomes.
- **Ensuring access for researchers from various institutions/organizations** to establish a truly equitable resource for all.

A dataset accessible to researchers across stages and settings

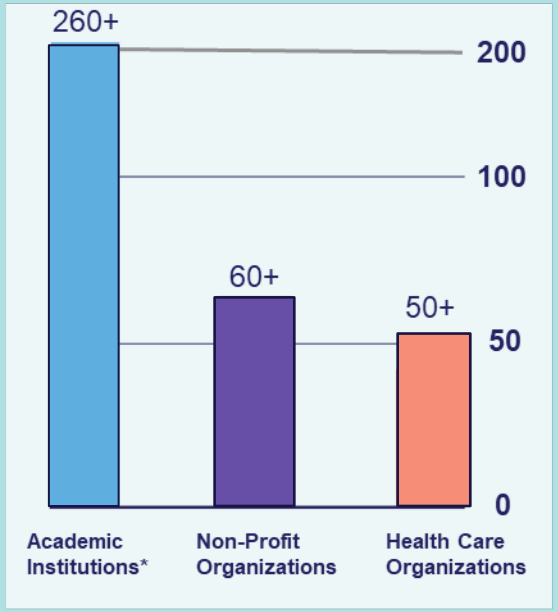
Our Researchers

3,000+

Registered Researchers
across a range of institutional roles and career stages

400+

Institutions



*Includes 42 Historically Black Colleges and Universities and Hispanic-Serving Institutions.

Figures accurate as of September 2022

Figures accurate as of September 2022

Research Currently Underway

2,400+
Active projects

65+
Publications in peer-reviewed journals

Top conditions being studied

In the Researcher Workbench include:

- Cardiovascular disease
- Hypertension
- Mental Health
- Cancer
- Diabetes

Figures accurate as of September 2022

The Researcher Workbench: Benefits for Researchers and Institutions

Available to all registered users

Resources

***All of Us* offers data and more.**

Registered users have access to:

- Platform and tools
- $300 in initial credit
- User support materials and staff
- Opportunities to showcase work

Platform Uses

***All of Us* is for publishing and more.**

- Team science
- Dissertation
- Thesis
- Poster presentations
- Class projects
- Self-practice (especially data science

All of Us support for institutions

All of Us related funding support

- Notice of Special Interest: Administrative Supplements to Advance Precision Medicine Using the *All of Us* Research program's Data
- Notice of Special Interest: Administrative Supplements to Support "All of Us" and Health Disparities-Related Pilot Research Projects at NIMHD-Funded Research Centers in Minority Institutions (RCMI)
- Educational Hub for Enhancing Diversity in Computational Genomics and Data Science (U24 Clinical Trials Not Allowed)

Introducing *All of Us* Chief Executive Officer, Dr. Josh Denny

Joshua C. Denny, MD, MS, FACMI
Chief Executive Officer
All of Us Research Program
National Institutes of Health

All of Us Research Program: Making Precision Medicine a Reality for All

October 3, 2022

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

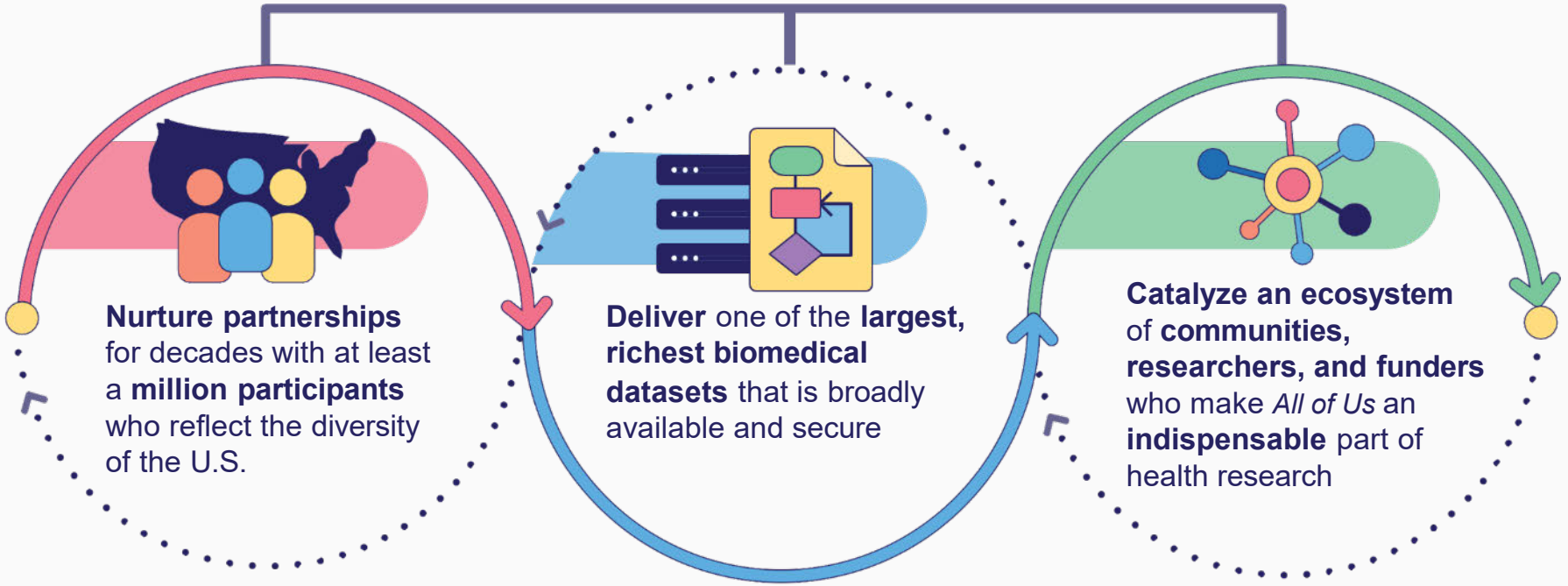
@AllofUsCEO

National Institutes of Health

All of Us Research Program Mission

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

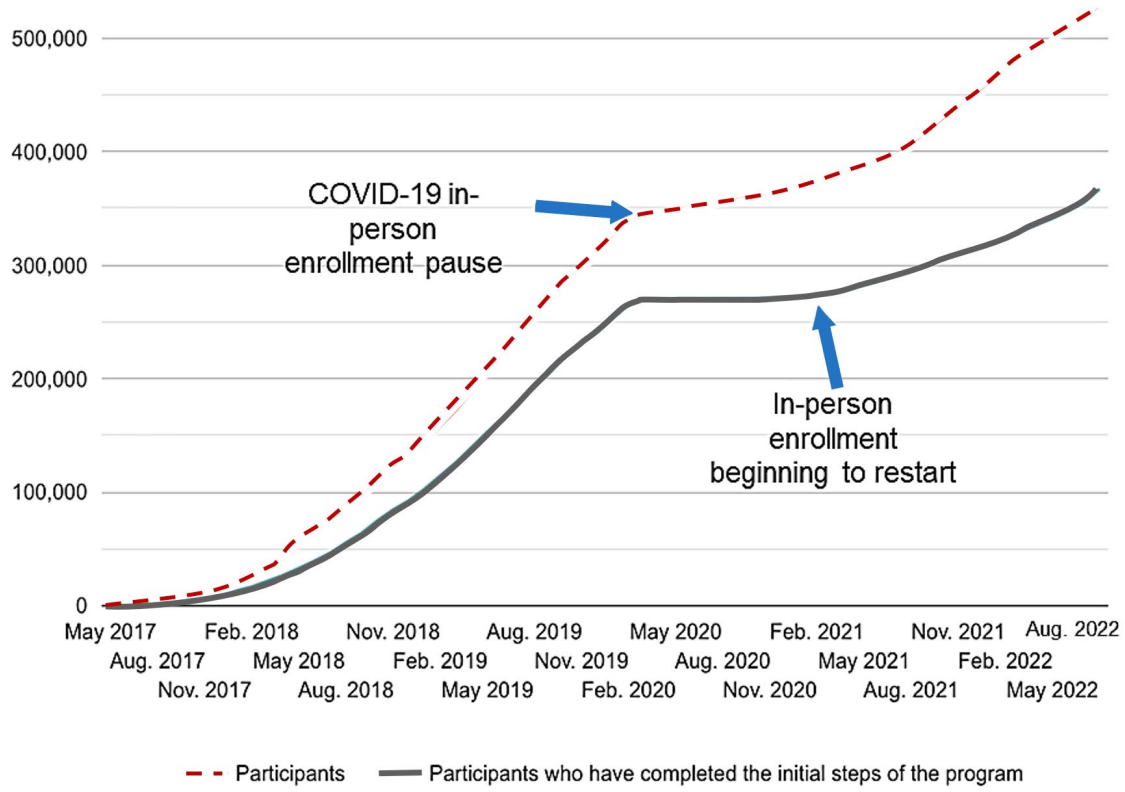
Enrollment Update

535,000+
Participants

324,000+
Electronic Health Records

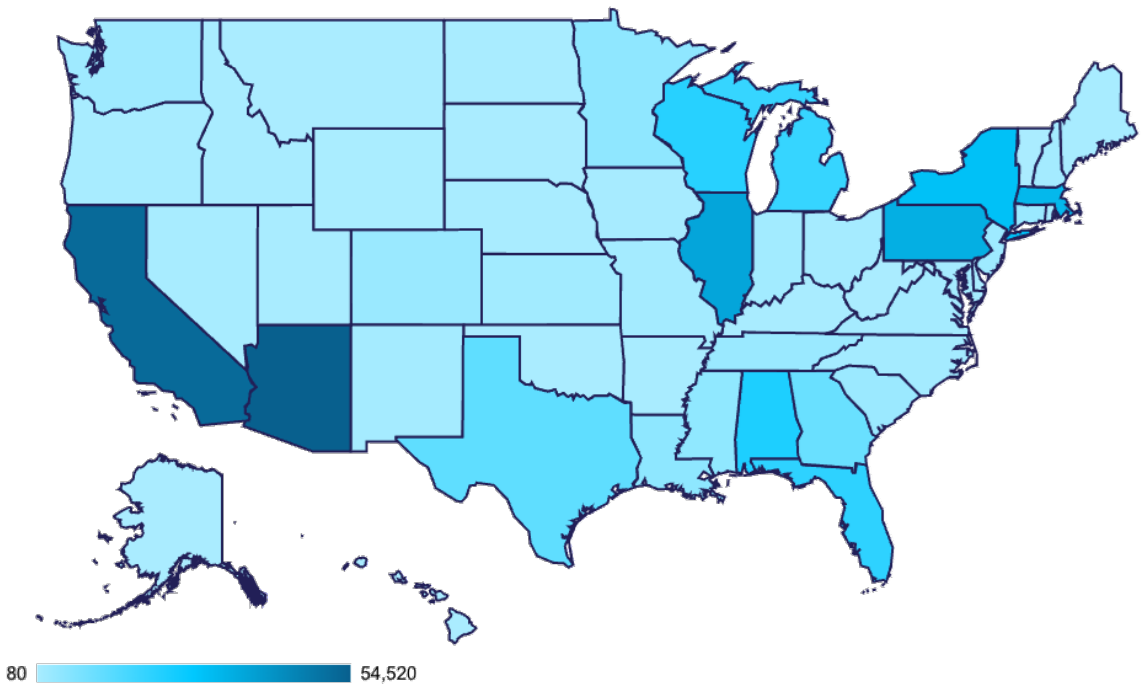
374,000+
Participants who have completed initial steps of the program

394,000+
Biosamples



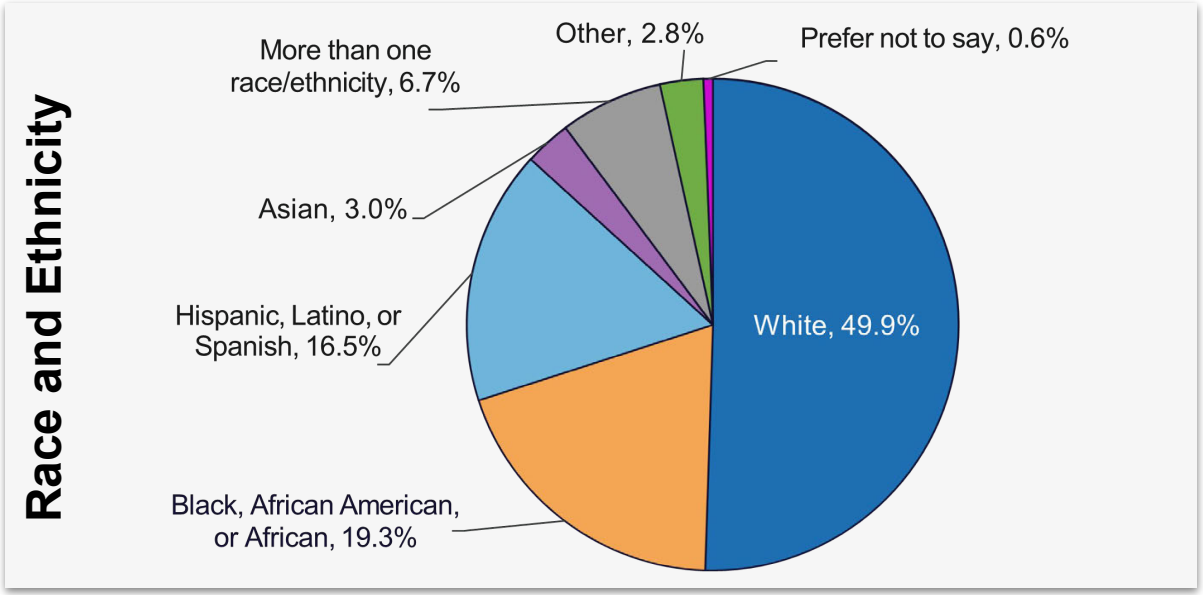
Numbers current as of September 30, 2022

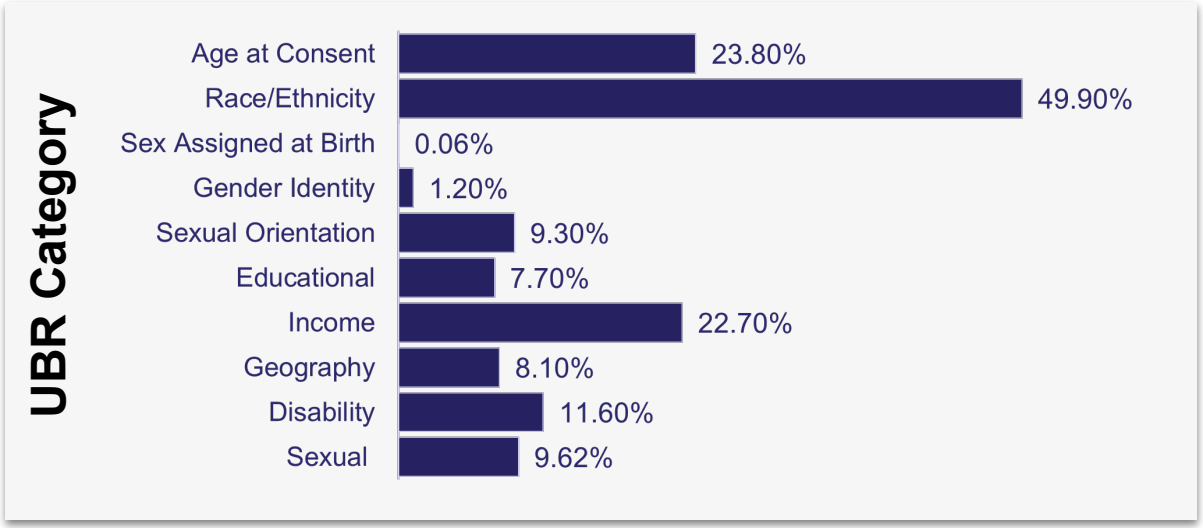
Status of the *All of Us* Research Program (as of September 30, 2022)



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

researchallofus.org

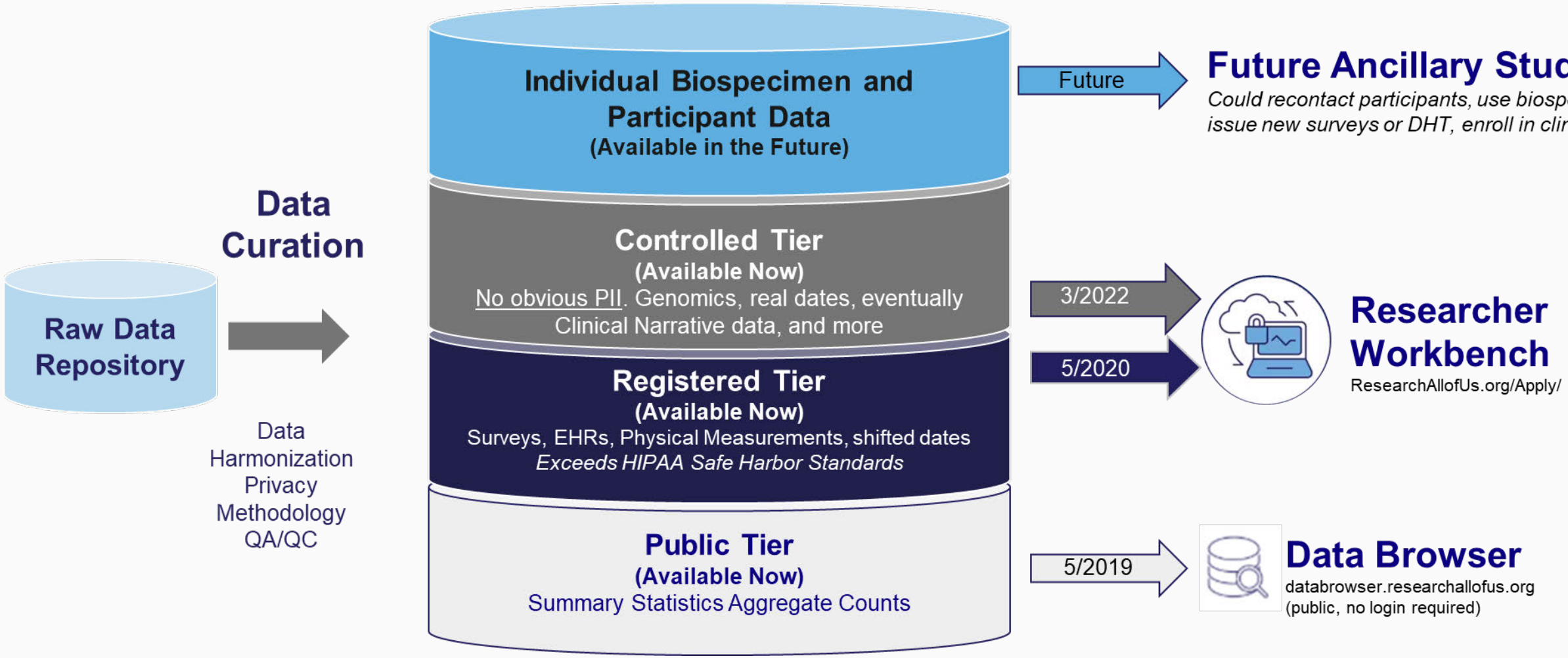




Data Collected from *All of Us* Participants

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

Researcher Data Access



Data on the Researcher Workbench is Diverse and Longitudinal

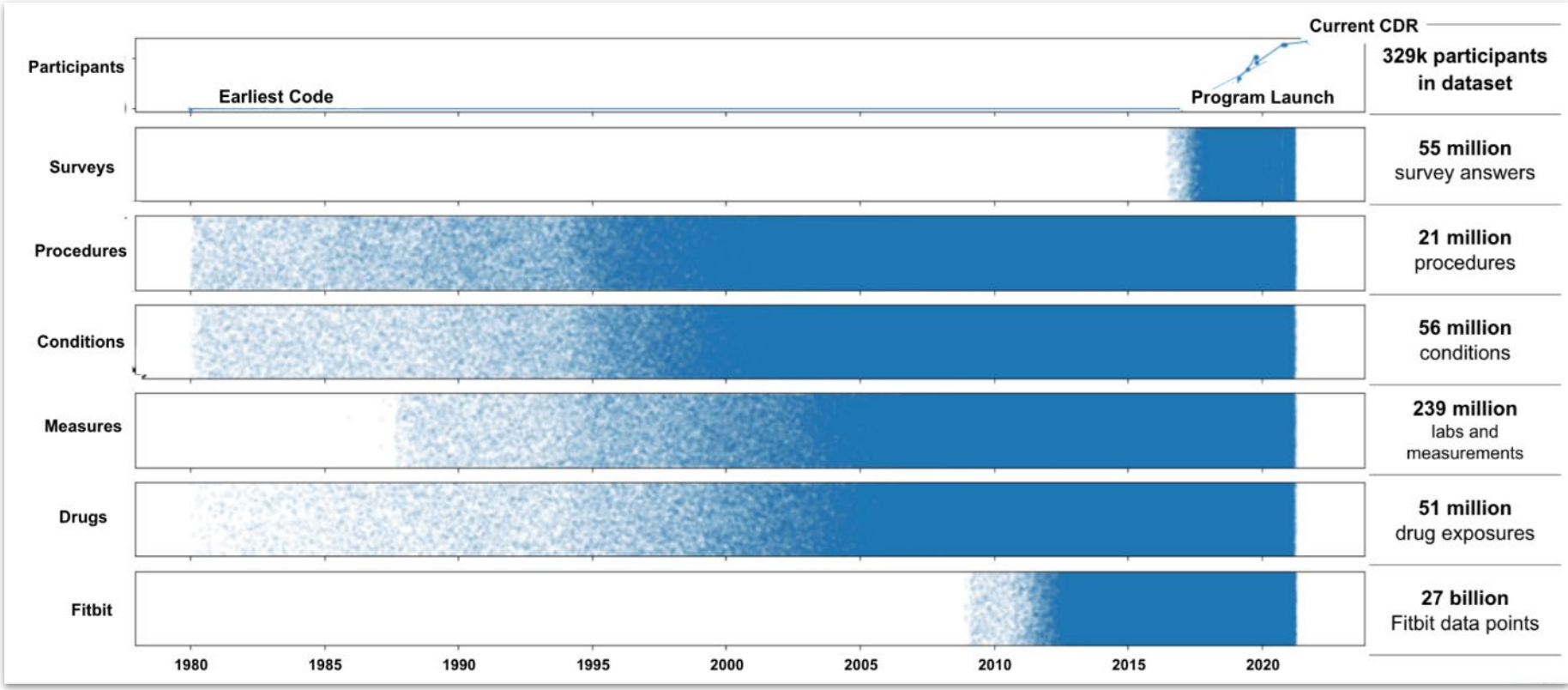
374,000+ Participants

311,000+ Physical Measurements

324,000+ EHRs

372,000+ Surveys

12,880+ Fitbit Records

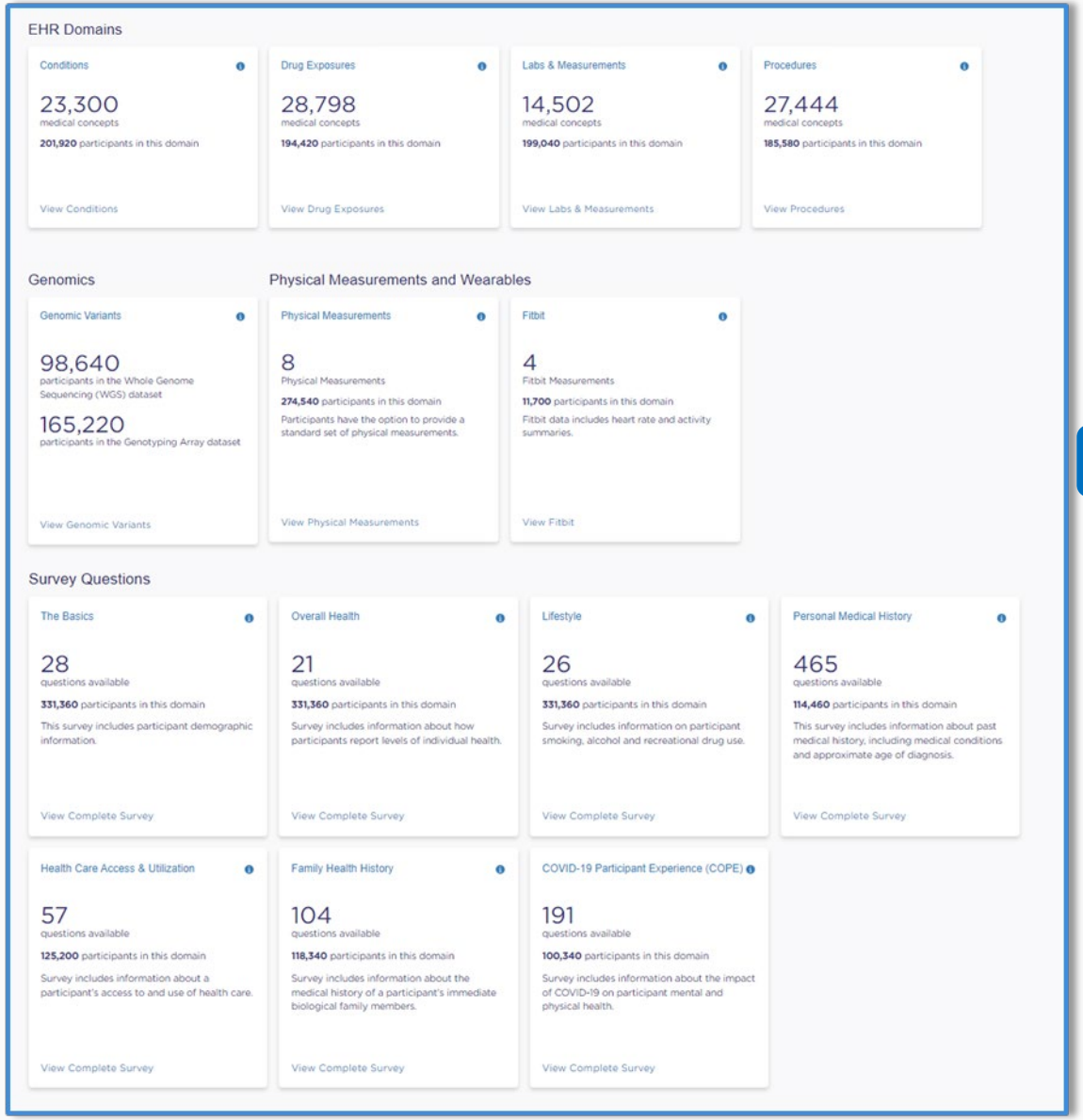


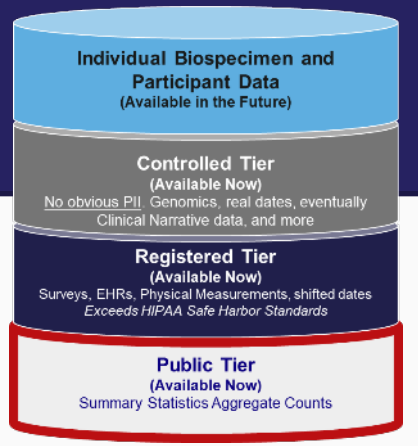
Plus: ~100k whole genomes + ~165K arrays launched in March

All of Us Research Hub: Public Data Browser

Summary statistics of:

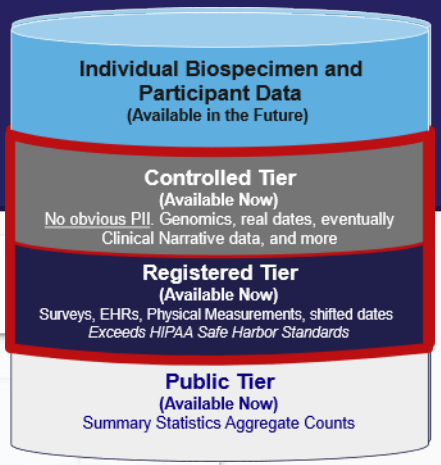
- EHR Data (Conditions, Drug Exposures, Lab & Measurements, Procedures)
- Genomic Variants
- Survey Questions (including COVID-19 surveys)
- Physical Measurements
- **Open Access (no login required)**





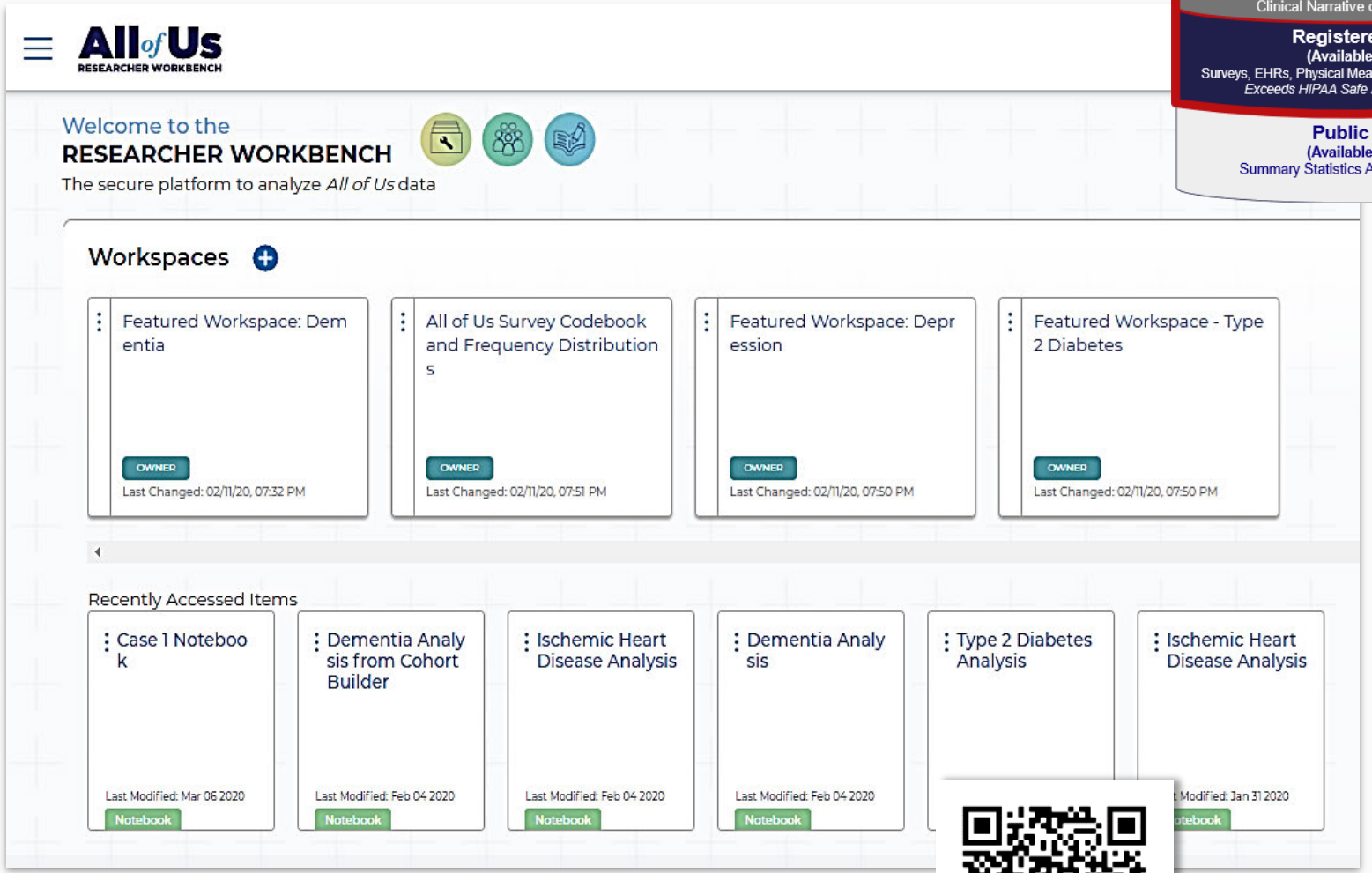
DataBrowser.ResearchAllofUs.org

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



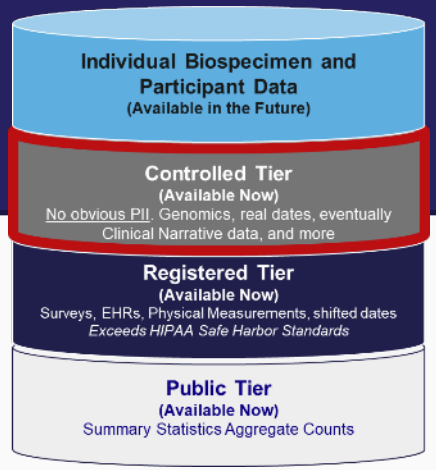
Researcher Workbench Beta

- Cloud based central resource
- **Passport access model** - just create, describe your workspace, and get to work! **No separate IRB approval needed.**
- Access open to US nonprofits, academic institutions, and healthcare organizations
- Currently, **>3170 researchers from >400 institutions**



ResearchAllofUs.org/Data-Tools/Workbench/

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



Researcher Workbench's Controlled Tier
Launched March 2022

98,600+
Whole Genome Sequences

165,000+
Genotyping Arrays

Genomics Analysis Tools

Hail and PLINK in addition to R, Python, and Jupyter Notebooks

593,000,000+
Unique Variants

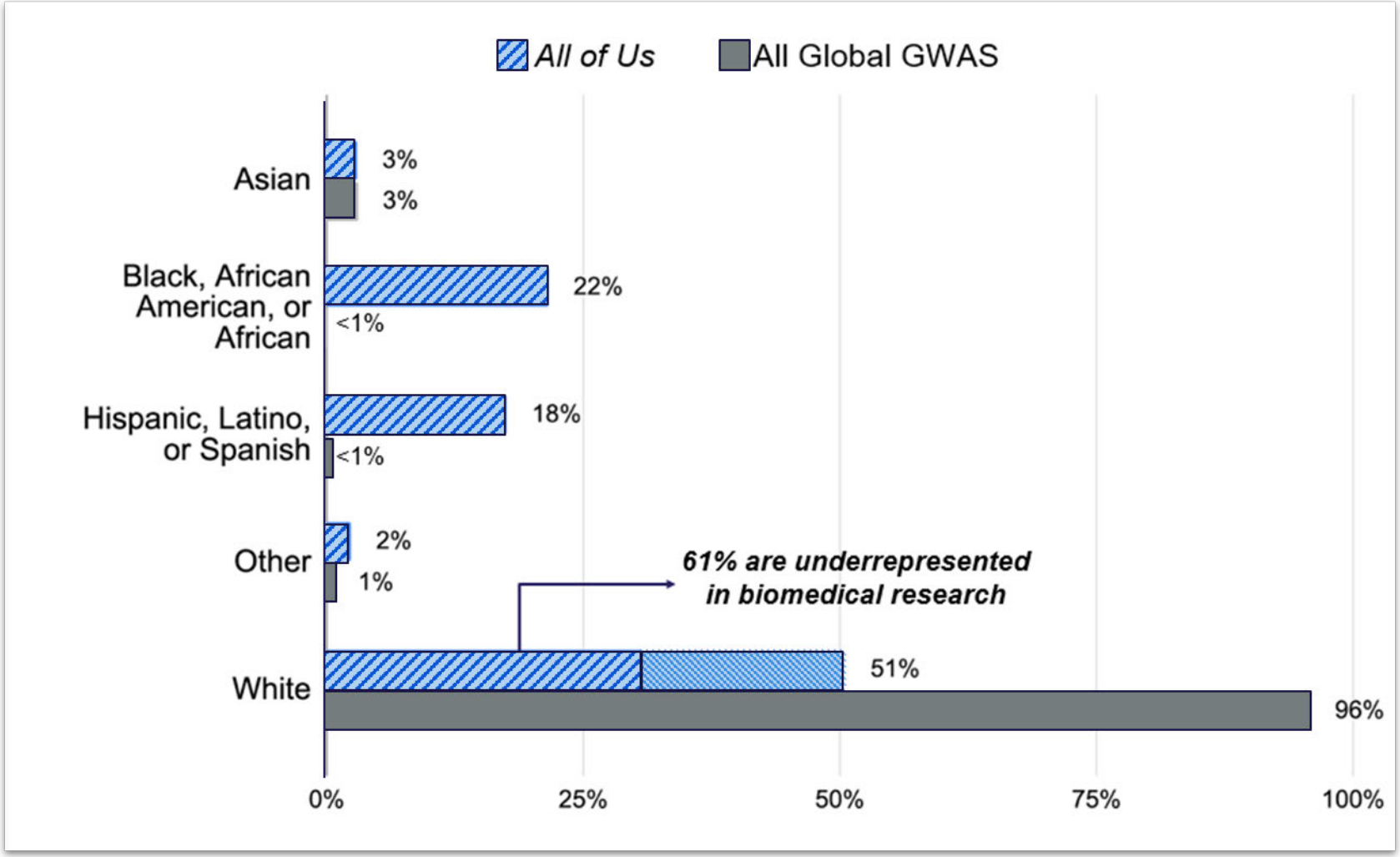
Includes 100M+ variants with ≥ 3 occurrences not seen in gnomAD 3.0

ResearchAllofUs.org/Data-Tools/Workbench/

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

Genomic Data Is Paired With Rich Phenotypic Data

81,000+ With

Whole Genome Sequences

Electronic Health Records

Physical Measurements

Survey Responses

98,000+ With

Whole Genome Sequences

Physical Measurements

Survey Responses

81,000+ With

Whole Genome Sequences

Electronic Health Records

3,500+ With

Whole Genome Sequences

Fitbit Records

Representing >30% of all participant Fitbit records

All of Us Data Includes a Wide Range of Diseases

Conditions	Domain	Participants
Heart Disease	Heart	63,860
Obesity	Endocrine	54,460
Type 1 Diabetes	Endocrine	3,260
Type 2 Diabetes	Endocrine	40,040
Any cancer	Cancer	36,740
Asthma	Pulmonary	36,400
Chronic Obstructive Pulmonary Disorder	Pulmonary	17,640
Epilepsy	Neuro	6,700
Stroke	Neuro	540
Rheumatoid Arthritis	Autoimmune	6,280
Osteoarthritis	Autoimmune	71,920

Conditions	Domain	Participants
Depressive Disorder	Mental Health	59,960
Bipolar Disorder	Mental Health	11,740
Dementia	Mental Health	4,020
Human Immunodeficiency Virus	Infectious Disease	4,340
COVID-19*	Infectious Disease	18,551*
Alcohol Abuse (AUDIT-C)	Abuse	100,468
Opioid Usage	Medication	126,000
Age Related Macular Degeneration	Eye	4,040
Hearing loss	Hearing	18,000
Falls	Aging/Nursing	4,060

***using combination of diagnosis code, lab test, and COVID survey answers**

Examples of type of research supported by *All of Us*

Topics we can study ***now***:

- Health disparities
- Historically underrepresented populations
- Associations between diseases, medications, behaviors, social determinants of health, mental health
- Associations with genomics and pharmacogenomics
- Health outcomes
- Environmental data linked at 3-digit zip level
- *Insert your topic here!*

Modalities of research we support

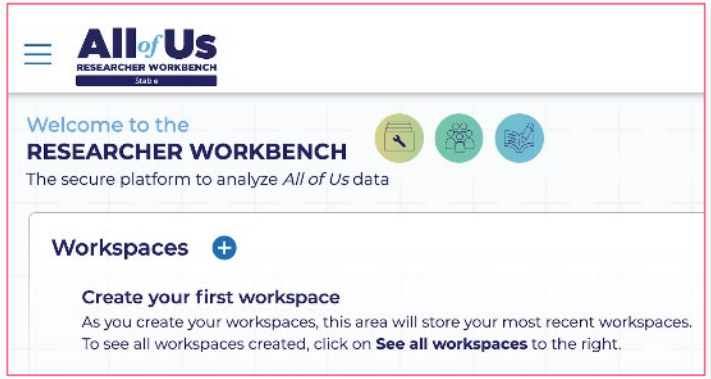
- AI/Machine Learning
- Risk stratification
- Predictive analytics
- Phenotype algorithms & cohort development
- Studies using Genomics/ Environmental/Lifestyle data
- Data QC and EHR variation
- Validation of other studies

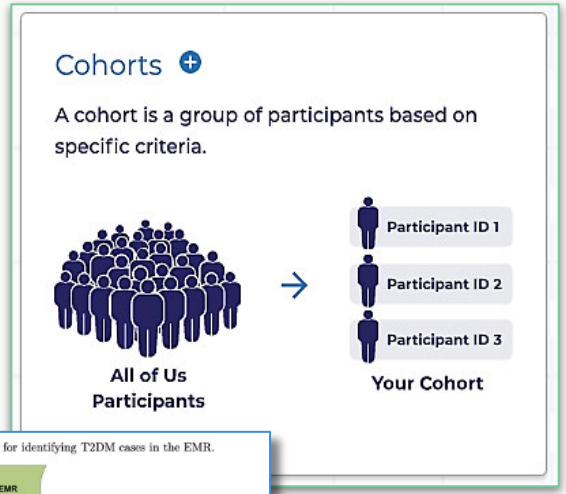
What we are not

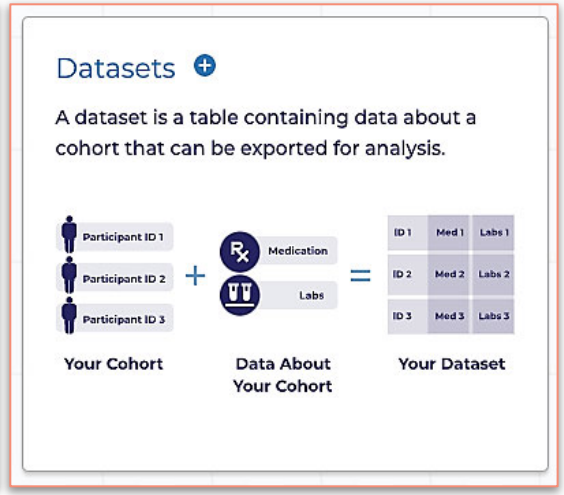
- A representative US sample
- A study with uniform follow-up of all variables

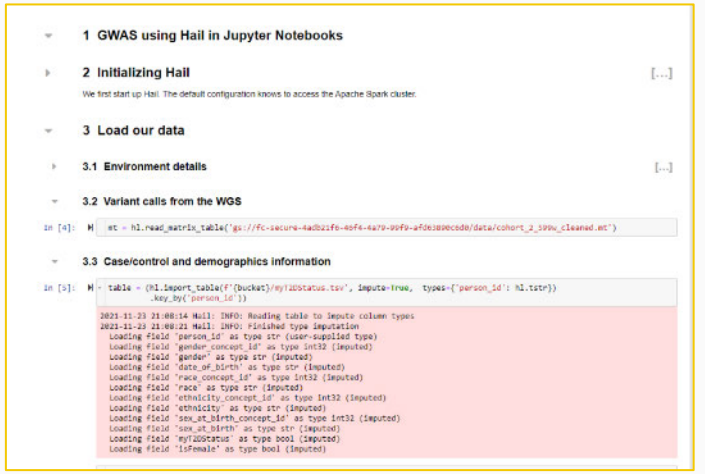
What Does It Look Like To Do an Analysis in *All of Us*?
A Genome Wide Association Study (GWAS) of Type 2 Diabetes

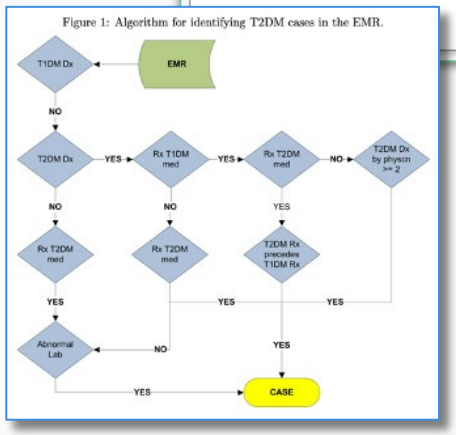
Workspace → **Cohort Builder** → **Concept Set Selector** → **Dataset Builder** → **Jupyter Notebook**



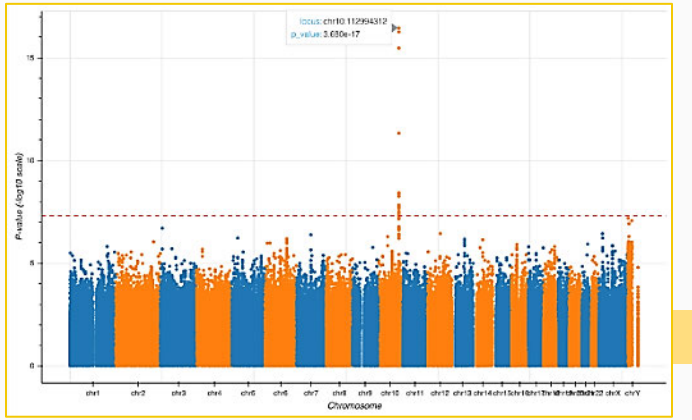




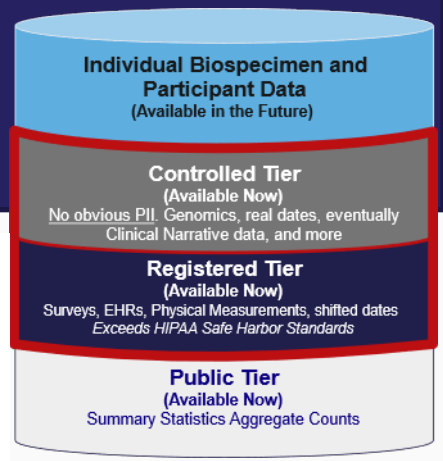




- ~23M SNPs
- ~20k participants
- GWAS runtime of ~20 minutes
- Cost $37



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



STEP 1

LEARN MORE ABOUT THE DATA AVAILABLE

Explore the data available through the Data Browser, which provides interactive views of aggregate-level participant data. Learn about individual-level data access tiers and the Researcher Workbench tools.

STEP 2

CHECK FOR YOUR INSTITUTION'S AGREEMENT

Before you can register, your institution must have a Data Use and Registration Agreement in place with *All of Us* to ensure data security.

STEP 3

CREATE A RESEARCHER WORKBENCH ACCOUNT

Complete your researcher profile, sign the Terms of Service, and agree to the Privacy Policy.

STEP 4

VERIFY YOUR IDENTITY USING LOGIN.GOV

Verify your identity using Login.gov. You may need to provide an SSN and a state-issued ID. Your institution may also require you to use an eRA Commons account. If so, contact your institution directly. Read more about Login.gov.

STEP 5

COMPLETE *ALL OF US* RESEARCH TRAINING

The mandatory training provides education on conducting responsible and ethical research with data from *All of Us* participants. Please allow at least one hour to complete.

STEP 6

SIGN THE DATA USER CODE OF CONDUCT

The Data User Code of Conduct is an agreement that outlines the program's expectations for researchers.

ResearchAllofUs.org/Data-Tools/Workbench/

Thank You!

All of Us

AllofUs.NIH.gov

JoinAllofUs.org

ResearchAllofUs.org

A big thank you to our 530,000+ participants!

@AllofUsResearch
@AllofUsCEO
#JoinAllofUs

All of Us RESEARCH PROGRAM

Panel Discussion

How Institutions can Benefit from Accessing the *All of Us* Database

KiTani P. Lemieux, PhD, MS
Associate Professor and PI,
- College of Pharmacy
- Division of Basic Pharmaceutical Sciences

Kaneisha Akinpelumi, MS
Associate Vice President
- Office of Research & Sponsored Programs

Baylor College of Medicine

DEPARTMENT OF MOLECULAR & HUMAN GENETICS

Debra Murray, PhD
Associate Professor and PI,
- **Co-Director** - Office of Community Engagement and Diversity
- **Director** - Education and Diversity Programs, Human Genome Sequencing Center

Laura Rosales, EdD, MBA
Administrator and Co-I, Department of Molecular and Human Genetics at Baylor College of Medicine

Kim Worley, PhD
Professor
- Vice Chair for Research Affairs - Basic and Translational
- Chair Elect - Faculty Senate, Baylor College of Medicine

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Data Use and Registration Agreements: An Overview

Data Use and Registration Agreements: An Overview

Cassie Springer, MPH
Senior Health Services Research Analyst
Data Research Center
Vanderbilt University Medical Center

All of Us RESEARCH PROGRAM | The Future of Health Begins With You

The *All of Us* Researcher Workbench Contracting Process

From Request to Completion

All of Us, the *All of Us* logo, and "The Future of Health Begins with You" are service marks of the U.S. Department of Health and Human Services.

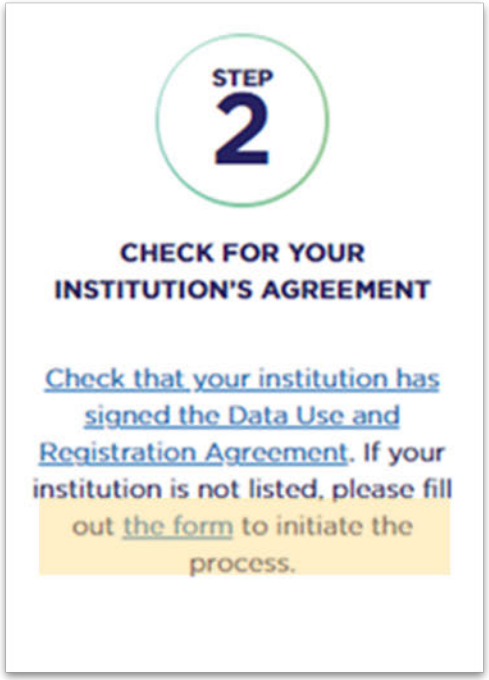
Presentation Overview

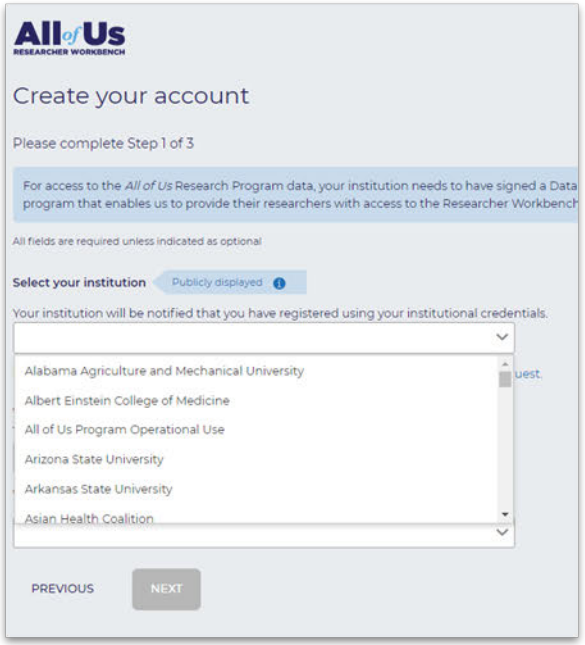
1. What is the DURA?
2. What is the DURA Contracting Process?
3. What does the Access Timeline look like?
4. What are the policy responsibilities of the signing institution, in order to remain compliant under the agreement?
5. What are typical stumbling blocks for access?
6. What are Frequently Asked Questions from Contracting Contacts?

1. What is the *All of Us* Data Use and Registration Agreement (DURA)?

- A completed Data Use and Registration Agreement (DURA) allows researchers to access the *All of Us* Researcher Workbench with institutional sign-off
- DURAs provide data access to any U.S.-based academic or health care institution, nonprofit organization, or government entity (such as NIH)
- There are 2 types: individual and institutional data use agreements
    - The rider for the controlled tier is optional
- Signed DURAs can be found here: *https://www.researchallofus.org/institutional-agreements/*
- If your institution is not listed, you can submit an *Access Request Form* and we will reach out to the contracting contact you provide

2. What is the *All of Us* DURA Contracting Process?





1. Researcher completes access request form

2. Access Team at Vanderbilt University Medical Center (VUMC) reaches out to the researcher's contracting contact with further information

3. Institution signs DURA; notifies the Access Team

4. Access Team adds institution to the Researcher Workbench

5. Access Team notifies researcher and provides next steps

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3. What is the Access Timeline for Registered & Controlled Tiers?

1-2 business days following request

1-2 days business days following processing

Timeline determined by institution

1-2 days business days following receiving partially executed DURA

1-2 business days following executed DURA

Researcher Submits Access Request Form

- The researcher can complete a request by selecting “submit a request” on the Institutional Agreements page of the Research Hub

Internal processing

- The VUMC Access Team process the request and shares it with their VUMC contracting officer

Contracting Contact outreach

- The VUMC contracting officer reaches out to the contracting contact provided in the request with background information, agreement template, and next steps.

Communication with Contracting Contact

- Until the VUMC contracting officer receives the partially executed agreement, they follow up with the researcher’s contracting contact every 2 weeks.

Execution of agreement and completion of registration form

- The researcher’s contracting contact sends the partially executed agreement and registration form to the VUMC contracting officer who will fully execute the contract.

Access Granted

- Upon executing the agreement, the VUMC access team adds the researcher’s institution to the Researcher Workbench and provides next steps to the original requester(s).

4. What are the Policy Responsibilities of the Signing Institution?

- Through the DURA, your institution accepts responsibility for the actions of data users from your institution, including their compliance with the program rules outlined in the Data User Code of Conduct (DUCC).
- Your institution also accepts additional responsibilities to help protect *All of Us* participant privacy.
- If someone from your institution violates the DUCC, we may notify your institution to make you aware of any penalties they may be subject to or remediation steps they must take.
- As the institutional point of contact, you are expected to communicate with *All of Us* and users as needed on DUCC compliance-related issues.

5. What are Typical Stumbling Blocks for Access?

- Researchers provide a contracting contact that is unresponsive to the Access Team or do not know why they are contacted
- Contracting teams take significant time internally to discuss the agreement
- Contracting contacts change, retire, switch roles
- Researchers lose interest in the data set over time
- Researcher cannot complete ID verification via Login.gov during registration

6. What are Frequently Asked Questions from Contracting Contacts?

- If my institution signed an institutional agreement, how do researchers from my institution access the Researcher Workbench?
- Can my institution specify different acceptable email domains for the Registered and Controlled Tiers?
- How do I know which researchers from my institution are using the Researcher Workbench? How do we monitor authorized data users accounts under our institutional agreement?
- What registration steps do authorized data users need to complete to gain access to the *All of Us* Dataset?

Questions?

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Breakout Rooms

Breakout Rooms

Breakout Rooms	Moderators
1. Troubleshooting the DURA Process	Cassie Springer & Ryan Hale
2. Leveraging the *All of Us* Dataset to Enhance Research Capacity at Your Institution	Danielle Wilfong & Rubin Baskir
3. Utilizing the Researcher Workbench	Ashley Green & Gage Rion

All of Us

Institutional Onramp Event

October 3, 2022

Breakout Room #2

Leveraging the *All of Us* Dataset to Enhance Research Capacity at Your Institution

Presented by Rubin Baskir, PhD. and Danielle Wilfong, M.S.

Benefits of Registration to Researchers

Available to all registered users

Resources

***All of Us* offers data and more.**

Registered users have access to:

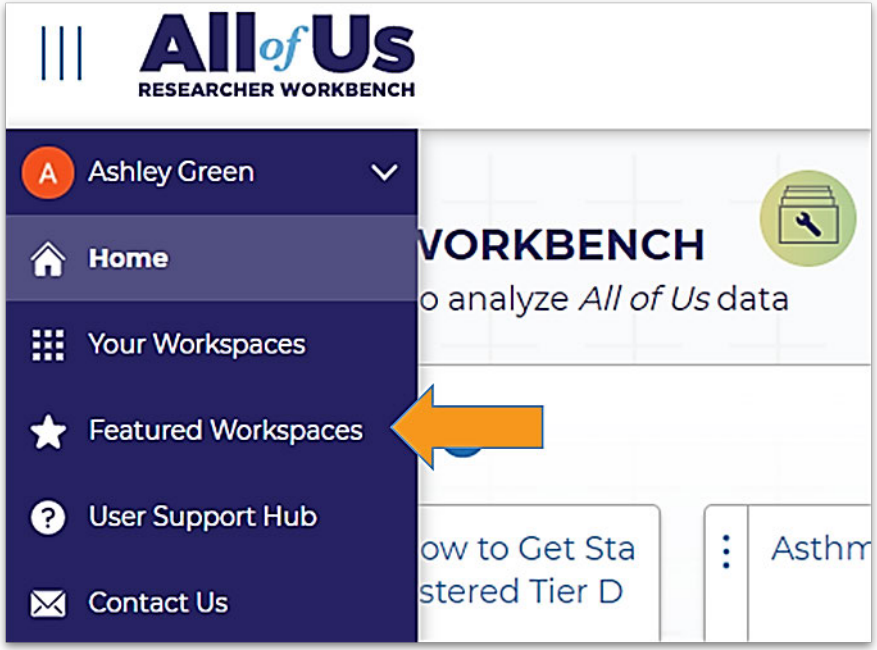
- Platform and tools
- $300 in initial credit
- User support materials and staff
- Opportunities to showcase work

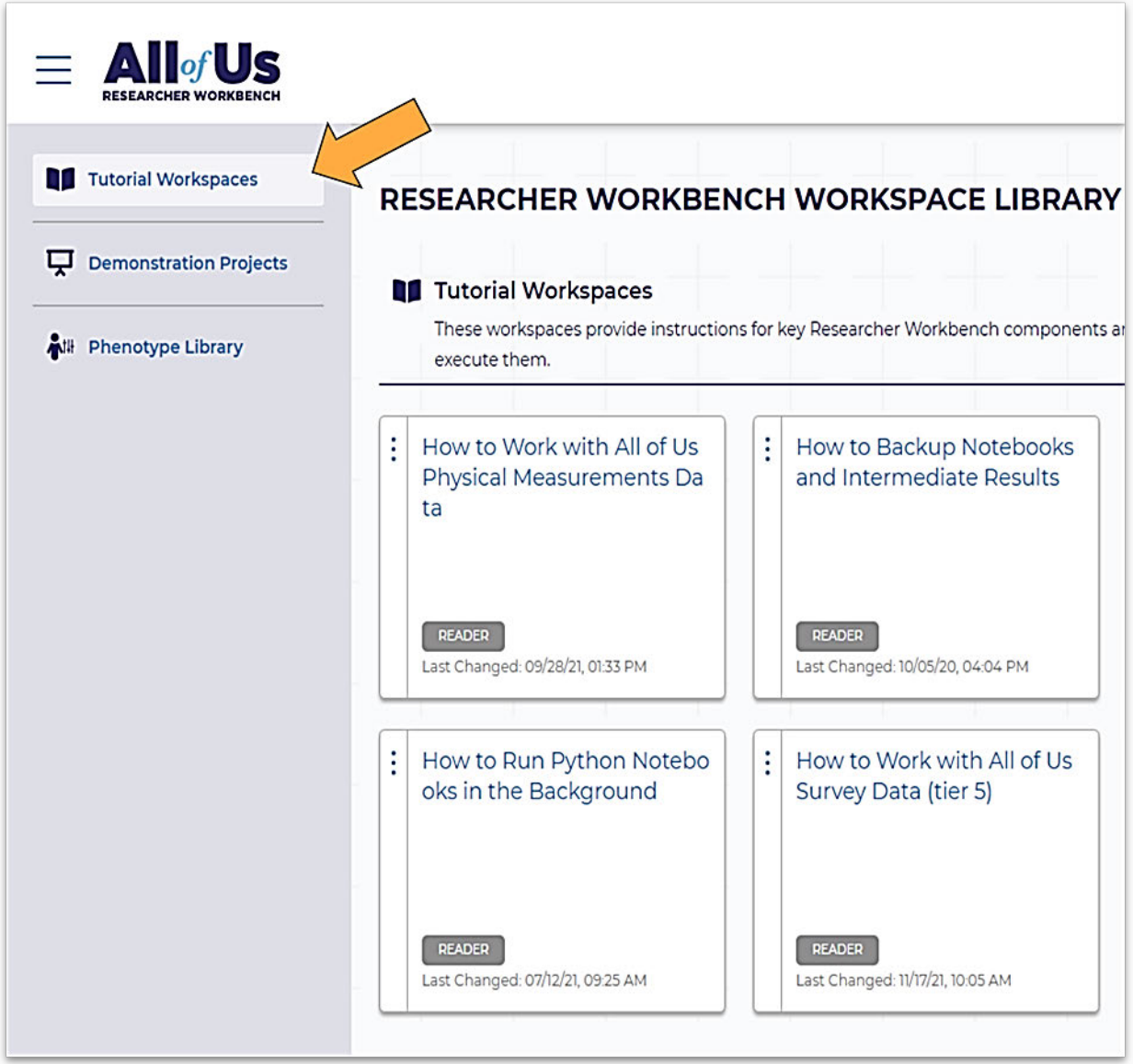
Platform Uses

***All of Us* is for publishing and more.**

- Team science
- Dissertation
- Thesis
- Poster presentations
- Class projects
- Self-practice (especially data science)

The Featured Workspaces can help you during your research





We also provide regular office hours & webinars

Support Desk

Send us your questions.

Email us or use our “Help” icon to:

- Resolve technical issues
- Ask questions about our data or the research program
- Give us feedback or make suggestions
- and more…

Response in 1-2 business days
support@researchallofus.

New User Orientation

Zoom in for a live orientation.

Webinar objectives:

- Understand data & data organization
- Learn how to get started on Researcher Workbench
- Learn how to utilize the User Support Hub

Monthly
link emailed to all registered users

Office Hours

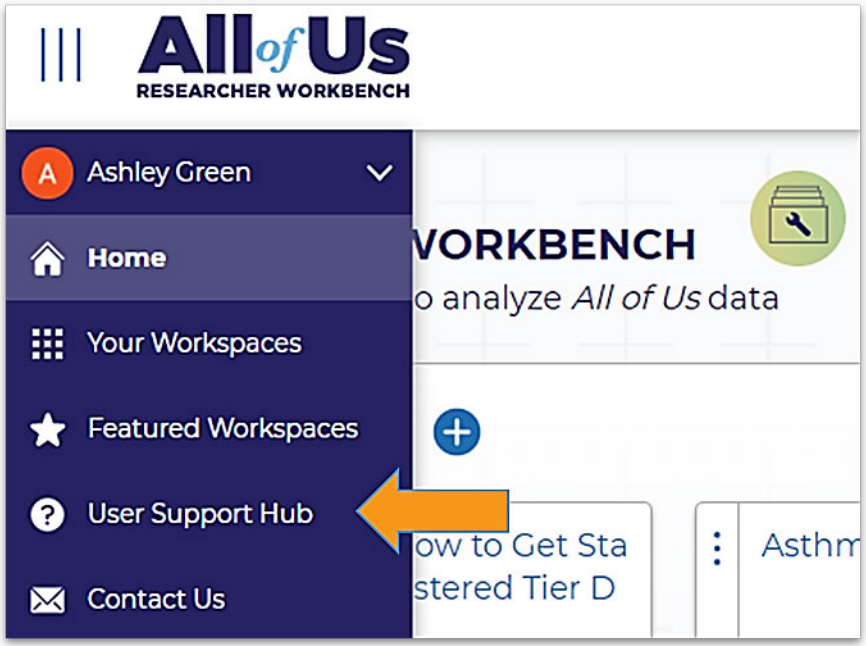
Get live, virtual help with questions.

Ask your questions live:

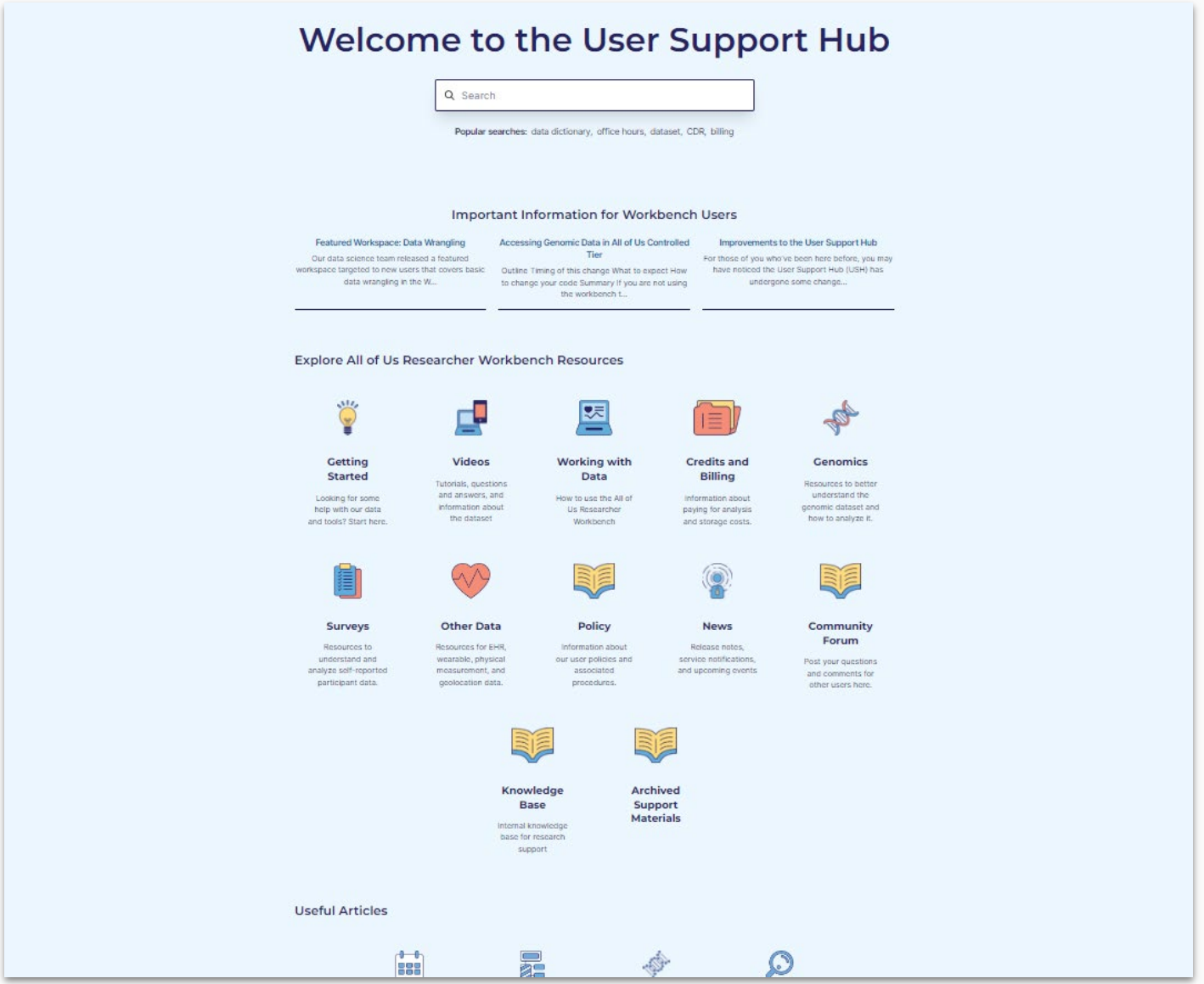
- Workflow implementation questions
- Data refreshers and updates
- Billing questions
- and more…

Bi-Weekly (Tues., Fri. 1-2pm CST)
link emailed to all registered users
(recordings are also available)

The Support Hub and Team are here to help you!



https://aousupporthelp.zendesk.com/hc/en-us



Early Efforts in Increasing Access to a Diverse Researcher Community

- *All of Us* invested $500,000 in **2** Administrative Supplement Funding to Support RCMIs
- *All of Us* Academy (administered by partner, Research Triangle Institute) issued grants to **6 HBCUs** totaling $425,000
- Partnered with Delta Research & Educational Foundation to award $439,000 towards capacity building for **10 HBCUs**
- Partnered with Pyxis Partners and granted $250,000 toward Researcher Engagement

Engaging a Diverse Researcher Community using the Researcher Workbench (Examples)

with Dr. Lemieux & MSRS Research Scholar, Jaelyn Stepter

Baylor's UBR Faculty Summit

RTI INTERNATIONAL

Community-Campus Partnerships for Health
Promoting Health Equity and Social Justice

North Carolina Agricultural and Technical State University

1867 Howard University

Tuskegee University

Morgan State University

SUNO Southern University at New Orleans

NCCentral University

Ensuring Data Access to Researchers at *ALL* Levels:

- Partnering with the University of Utah to develop *All of Us* data curriculum for high school students
- Engaging, mentoring, and supporting nearly 30 minority students through the Research Scholars Program and 2021 Minority Student Research Symposium
- Working with Baylor College of Medicine to build and support multidisciplinary research teams
- Facilitating research opportunities for community and citizen scientists with National Library of Medicine

Baylor College of Medicine's UBR Faculty Summit

UBR Faculty Summit by The Numbers

34 scholars from **26** institutions **34** accounts on the *All of Us* Researcher Workbench

17 institutions with fully executed Data Use and Registration Agreements And **9** that are pending

NIMHD/*All of Us* Research Program Notice of Special Interest Award

Hispanic/Latinxs coexisting chronic health conditions, mental illness and social determinants of health
PI: Jose Torres-Ruiz

Black Bodies Matter: An examination of Diabetes, Peripheral Artery Disease and Limb Amputation Disparities in Black and White participants of the All of Us Research Program
PI: Gene D'Amour

Howard University Research Center for Minority Health and Health Disparities
PI: William Southerland

Open Opportunities

Baylor Seed Funding

Baylor College of Medicine

DEPARTMENT OF MOLECULAR & HUMAN GENETICS

1. **UBR Faculty Summit Seed Awards**

   UBRFS multidisciplinary research teams

   - Track 1-**Project Initiation Awards** ($30K) (up to 3 awards)
   - Track 2-**Community Engagement Awards** ($15K) (up to 2 awards)
   - Track 3-**Collaboration Sustainability Awards** ($2K) (up to 12 awards)

2. **External Pilot Awards** ($30K) (up to 3 awards)

   "Established" Diverse College and University research teams

Research Opportunity Announcement: NIH All of Us Engagement, Communications, and Enrollment Partnerships

Research Opportunity Announcement (ROA): NIH All of Us Engagement, Communications, and Enrollment Partnerships

Note: There have been new actions to this contract opportunity. To view the most recent action, please click **here**.

ACTIVE

Contract Opportunity

Notice ID
OTA-22-006

Related Notice

Department/Ind. Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF
Sub-tier
NATIONAL INSTITUTES OF HEALTH
Office
NIH OFFICE OF THE DIRECTOR

The purpose of this announcement is to fund organizations who can help *All of Us* build its cohort of volunteers who reflect the rich diversity of the United States and are actively engaged as partners. These funded organizations will help design and implement strategies to raise awareness of the program through community and health care provider organizations, drive increased enrollment of participants, foster regular communication with participants, and engage the research community to use the data being gathered.

Award Project Duration: Award periods are anticipated to be up to five (5) years but may be shortened or extended as needed.

Pre-Submission Webinar: A webinar will be conducted on June 27, 2022 at [Time TBD]. Registration information will be posted here once it is available.

White Paper Deadlines: This ROA will remain open for three (3) years from its issue date, unless otherwise updated via an amendment, and includes multiple white paper (WP) submission deadlines. **All WP deadline times are 3:00 PM Eastern Time:**

Area 2: Engage researchers from diverse backgrounds, including those from underrepresented groups, to utilize the *All of Us* data resources to advance precision medicine	Up to $1M

Calendar Year 2022 WP Deadlines
– Nov 30, 2022

Calendar Year 2023 WP Deadlines
– Feb. 28, 2023
– May 31, 2023
– Aug. 31, 2023
– Nov. 30, 2023

New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research (R01 Clinical Trial Optional)

New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research (R01 Clinical Trial Optional)

RFA-HG-21-041

This Funding Opportunity Announcement (FOA) solicits R01 grant applications that propose independent research projects that are within the scientific mission areas of the National Human Genome Research Institute (NHGRI), National Institute of Biomedical Imaging and Bioengineering (NIBIB), and *All of Us* Research Program (*All of Us*). This program is intended to support Early Stage Investigators and New Investigators from diverse backgrounds, including those from groups underrepresented in the health-related sciences.

Submission Due Date:

February 22, 2023

February 22, 2024

5:00 PM Applicant's time zone