

The Future of Precision Health: Engaging Underrepresented Research Participant Communities and Achieving Responsible Return and Use of Genomic Results

Welcome! As you login, please note:

- You are on a secured mute upon entry
- The participant list is protected, so you should only see the panelists
- Submit questions to the Q&A channel (bottom right); please select 'Ask: All Panelists'
- This event is being recorded

Event organizer: Karyn N. Onyeneho, M.S., All of Us Research Program

All of Us
RESEARCH PROGRAM



National Institutes
of Health

Tuesday, October 27, 2020 5:00 pm-7:00 pm ET
**American Society of Human Genetics
(ASHG) All of Us Educational Session**

Today's Agenda and Speaker Lineup



**Joshua C. Denny, M.D.,
M.S.**
National Institutes of Health



**Consuelo Wilkins, M.D.,
MSCI**
Vanderbilt University Medical
Center



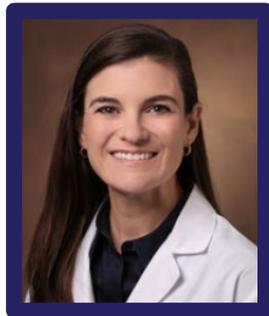
Richard Gibbs, Ph.D.
Baylor College of Medicine



Alicia Zhou, Ph.D.
Color Genomics



**Philip Empey, Pharm.D.,
Ph.D.**
University of Pittsburgh Medical
Center



Andrea Ramirez, M.D., MS
National Institutes of Health

Part I: All of Us Research Program Overview

- **All of Us Research Program Overview**
Joshua C. Denny, M.D., M.S.
- **Engaging Underrepresented Research Participant Communities in Genomic Research**
Consuelo Wilkins, M.D., MSCI
- **Innovative Sequencing and Array Technologies at All of Us**
Richard Gibbs, Ph.D.
- **Returning Ancestry and Traits at Population-Scale**
Alicia Zhou, Ph.D.
- **Pharmacogenomics (PGx) Framework and Approach for PGx Return of Results**
Philip Empey, Pharm.D., Ph.D.

● Q&A with Panel

Part II: Interactive Panel Discussion

- **Researcher Workbench Demonstration and Developing Tools for Genomic Analyses**
Andrea Ramirez, M.D., M.S.
- **Q&A with Panel**

Part I: *All of Us* Research Program Overview



Opening Remarks

Joshua M. Denny, M.D., M.S.

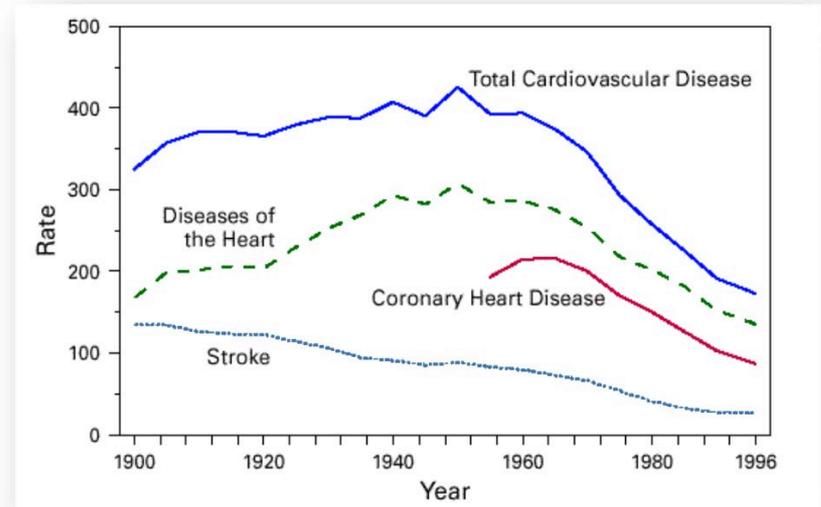
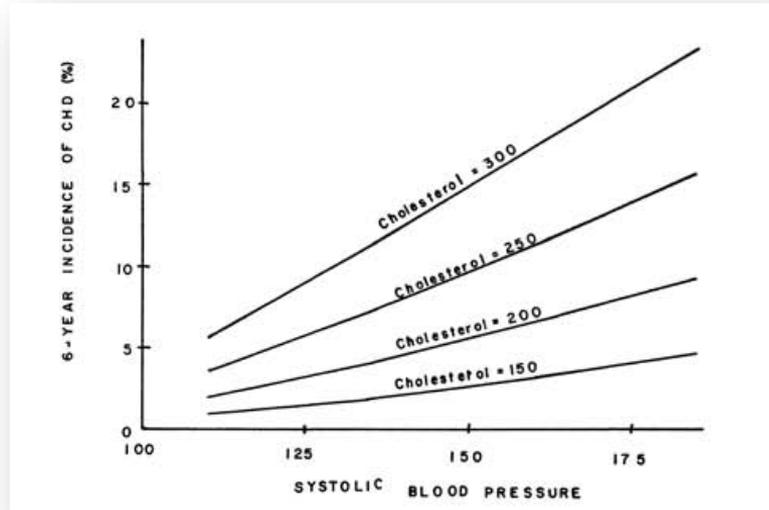
National Institutes of Health

Large Cohort Studies Have Transformed Disease Treatment



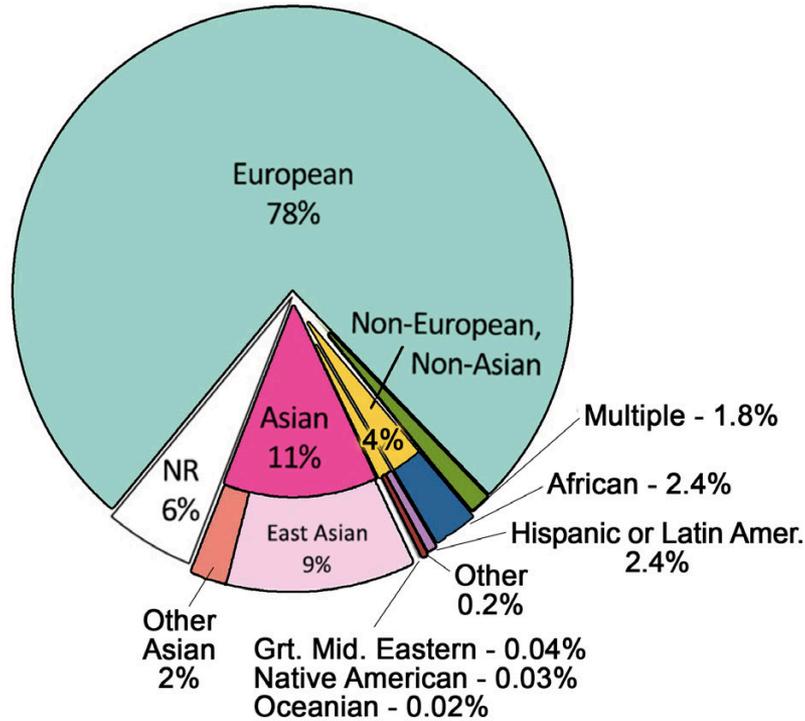
Framingham and other cohorts have taught us much about heart disease...

...and cardiovascular deaths have decreased



**Could we have a similar experience
with precision medicine in the next
40 years?**

There is a Lack of Diversity in Our Genome Science



A lack of diversity in genetics impoverishes:

- **Understanding of health disparities**
- **Discovery of variability in drugs like clopidogrel or tacrolimus**
- **Discovery of new drugs (e.g., PCSK9)**
- **Accuracy polygenic risk scores**
- **Classification pathogenicity of variants**

The *All of Us* Research Program

Nurture relationships

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

Catalyze a robust ecosystem

of researchers and funders hungry to use and support it



Deliver the largest, richest biomedical dataset

that is easy, safe, and free to access

Enrollment, Consent, and EHR Authorization



Enrollment, Consent, EHR Authorization

Participants must be 18
years or older

Online video consent

Includes authorization to
share EHR data with
researchers

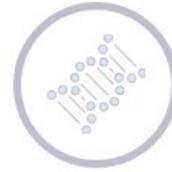
Plans to include children
in future



Participant Surveys



Physical Measurements



Biosamples



Mobile and Wearable Technologies

Current Data Collected: Surveys, Measurements, Biosamples



Enrollment, Consent,
EHR Authorization



Participant
Surveys

Current and future
surveys focused on:

- Lifestyle (e.g., Diet)
- Personal and Family Medical History
- Healthcare Access

Other surveys:

- C O V I D P a r t i c i p a n t E x p e r i e n c e (COPE)



Physical
Measurements

- Blood pressure
- Heart rate
- Height
- Weight
- BMI
- Hip circumference
- Waist circumference



Biosamples

- Blood
- Saliva (if blood draw is unsuccessful)
- Urine



Mobile and Wearable
Technologies

Future Data Collected: Mobile and Wearable Technologies



Enrollment, Consent,
EHR Authorization



Participant
Surveys



Physical
Measurements



Biosamples

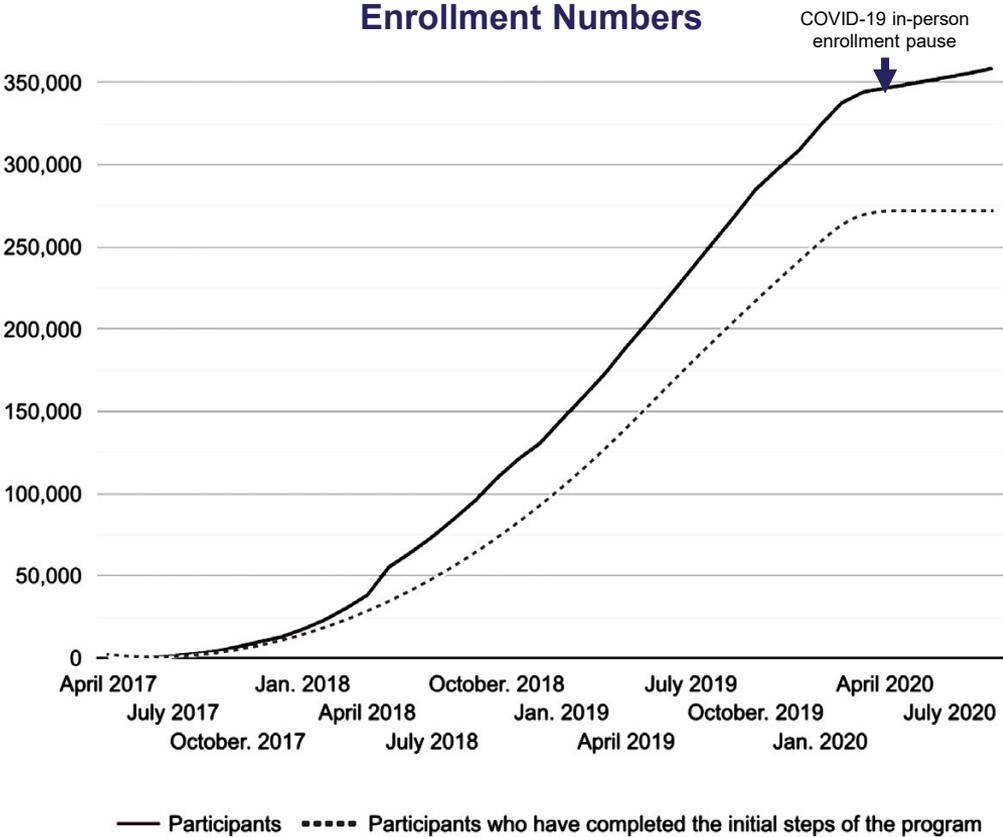
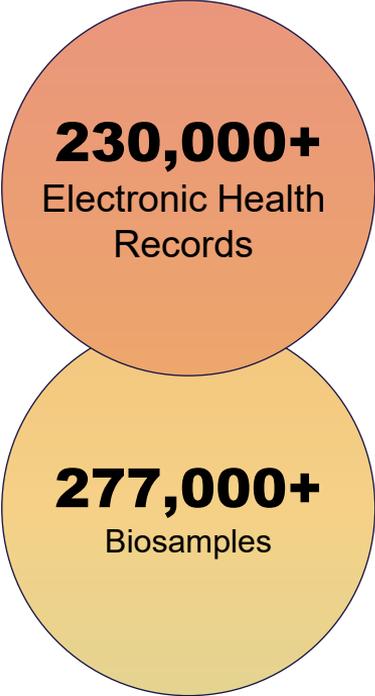
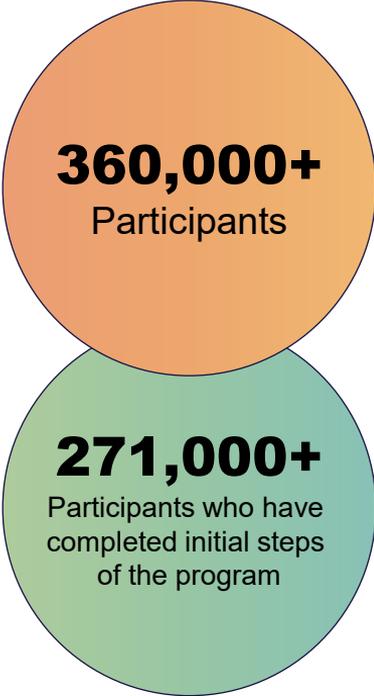


Mobile and Wearable
Technologies

Data from wearable fitness devices, starting with Fitbit and Apple HealthKit

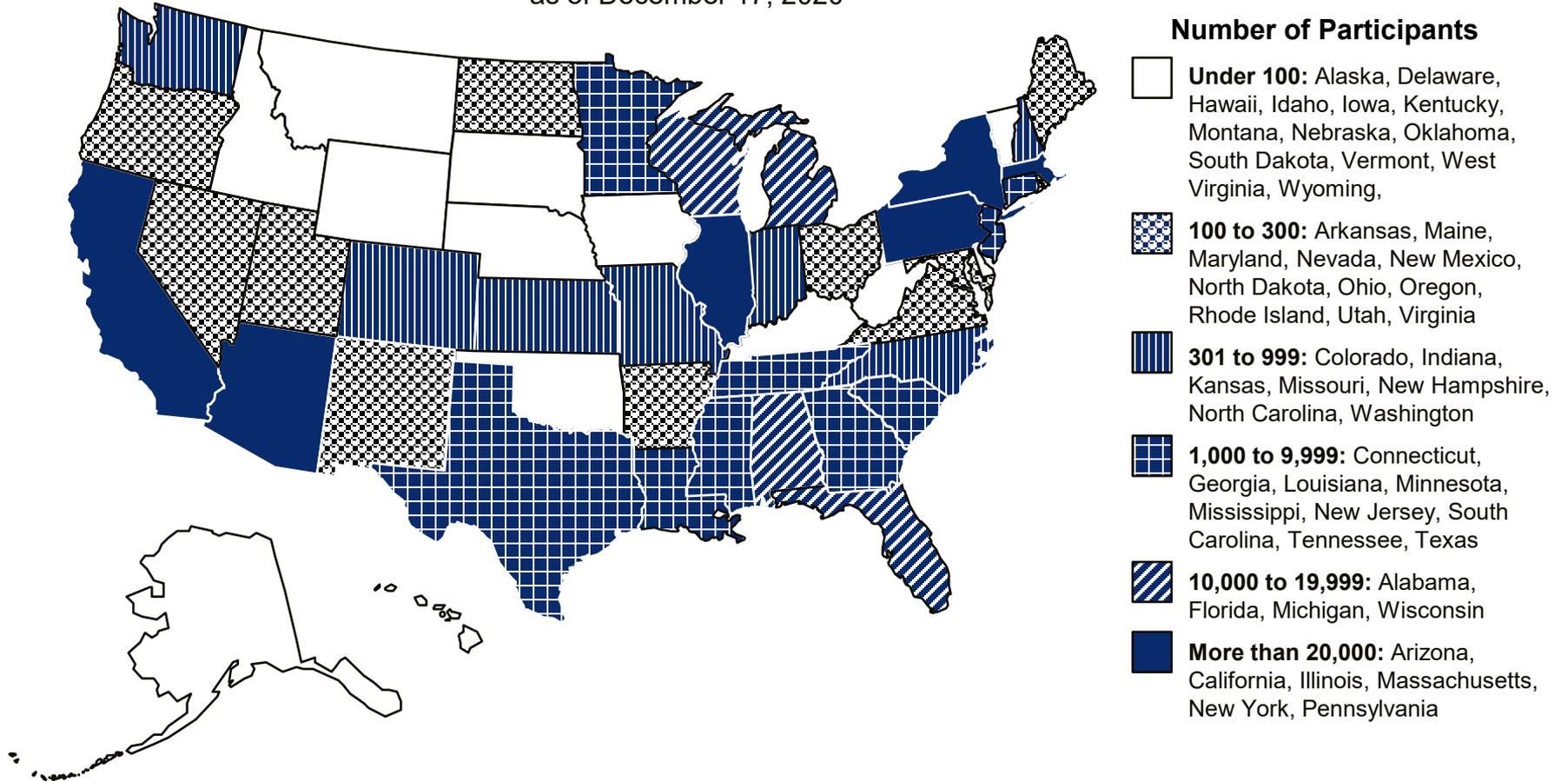
Other data collection from integrated apps that track mood and cardio-respiratory fitness

Status of the Program



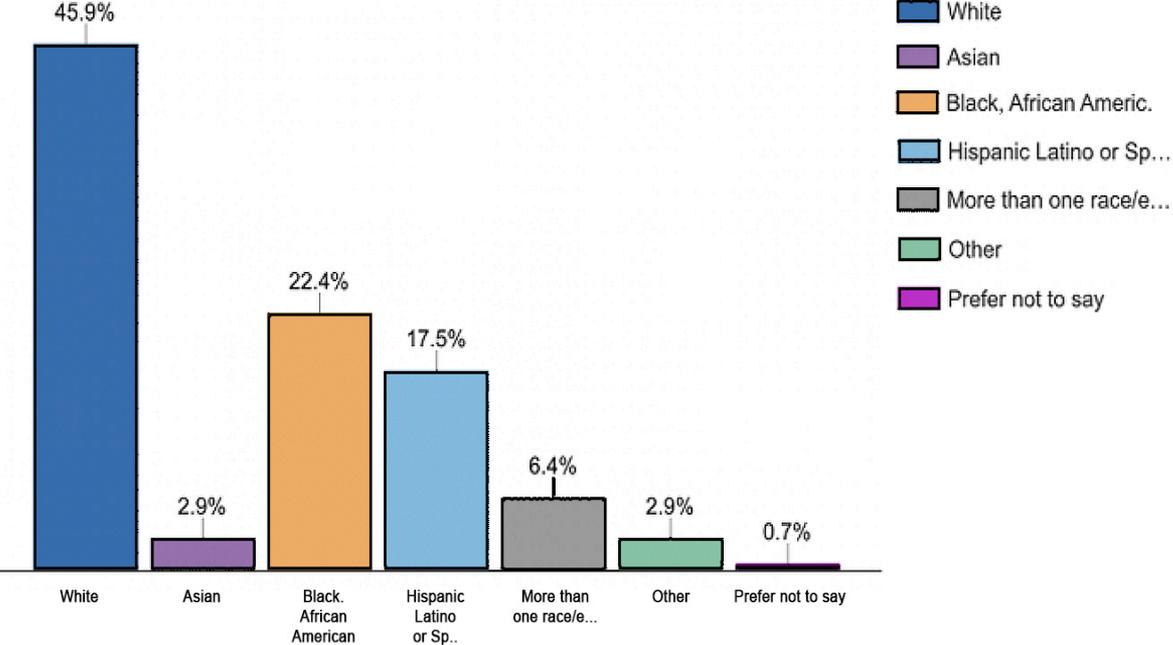
Participant Representation Across the U.S.

as of December 17, 2020

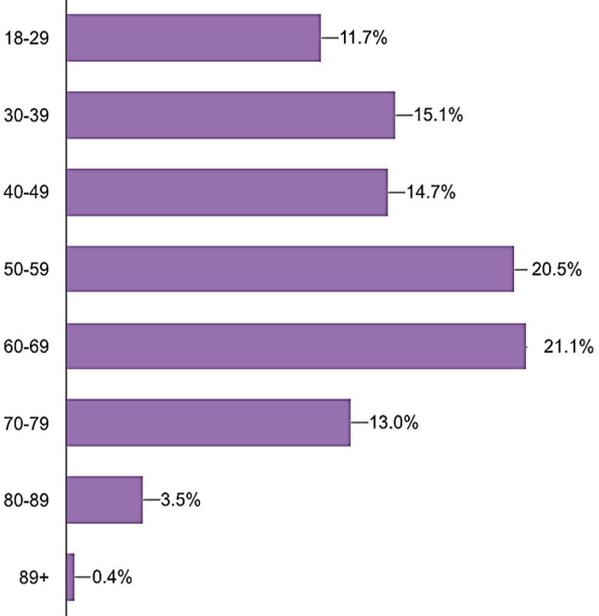


Status of the Program Continued

Race and Ethnicity



Age

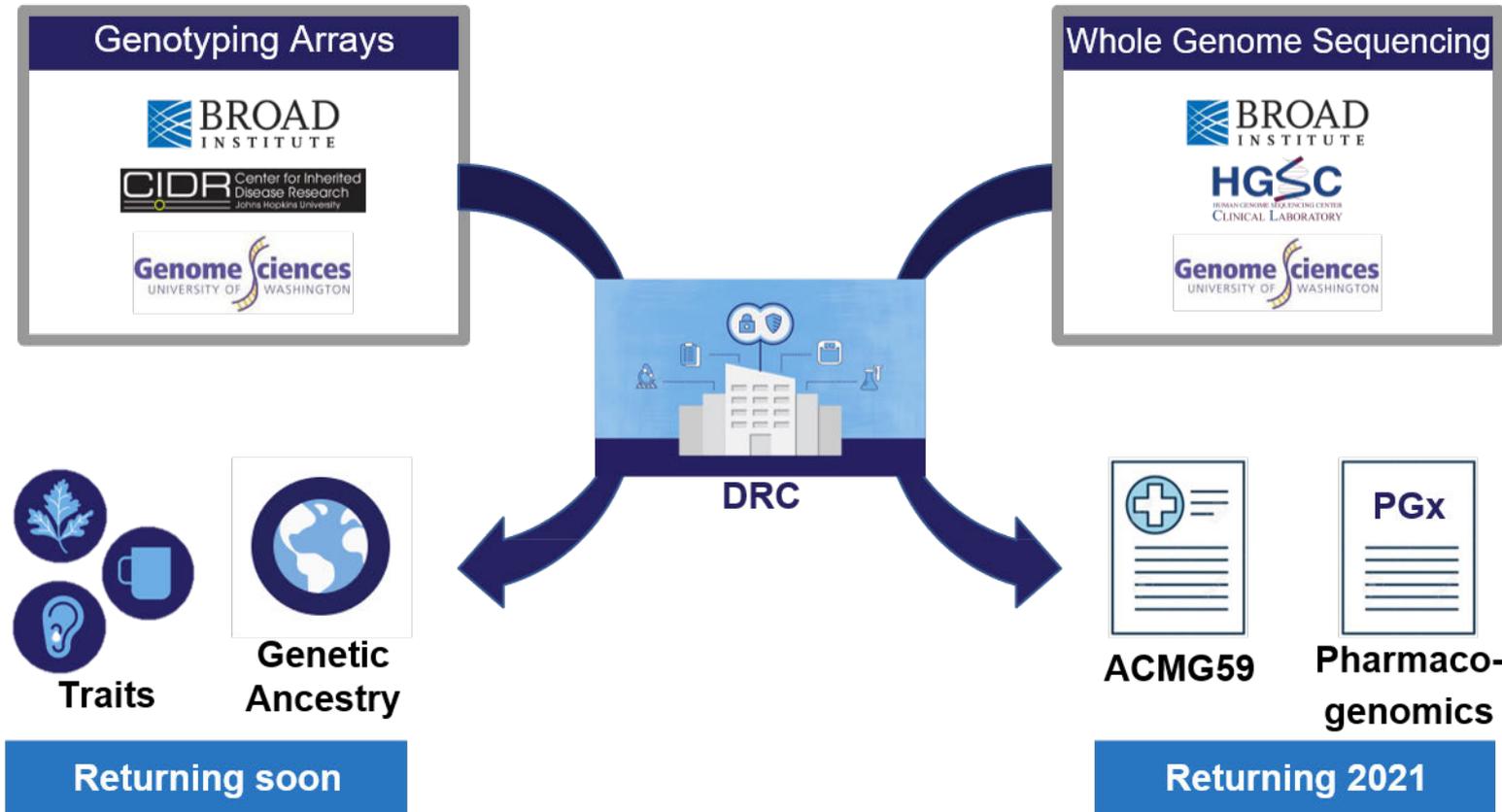


Over 80% of All of Us participants are underrepresented in biomedical research

Returning Value to Participants: Genetic Return of Results

Genetic Ancestry and Traits

Health-Related Genetics



Returning Value to Researchers: Research Hub

Public: Data Browser
DataBrowser.ResearchAllOfUs.org

Search Across Data Types

Keyword Search

Data includes 225,340 participants and is current as of 2/11/2020

FAQs | Introductory Videos | User Guide

EHR Domains:

- Conditions: 20,776 medical concepts, 113,200 participants in this domain
- Drug Exposures: 20,951 medical concepts, 104,500 participants in this domain
- Labs & Measurements: 10,049 medical concepts, 109,100 participants in this domain
- Procedures: 20,546 medical concepts, 102,340 participants in this domain

Survey Questions:

- The Basics: 16 questions available, 225,340 participants in this domain
- Overall Health: 21 questions available, 219,800 participants in this domain
- Lifestyle: 26 questions available, 219,500 participants in this domain
- Personal Medical History: 465 questions available, 39,320 participants in this domain
- Health Care Access & Utilization: 57 questions available, 45,820 participants in this domain
- Family Medical History: 1 question available, 41,600 participants in this domain



Restricted: Researcher Workbench
ResearchAllOfUs.org/Apply

All of Us RESEARCHER WORKBENCH

Welcome to the RESEARCHER WORKBENCH
The secure platform to analyze All of Us data

Workspaces

- Featured Workspace: Dem entia
- All of Us Survey Codebook and Frequency Distribution s
- Featured Workspace: Depr ession
- Featured Workspace - Type 2 Diabetes

Recently Accessed Items

- Case 1 Noteboo k
- Dementia Analy sis from Cohort Builder
- Ischemic Heart Disease Analysis
- Dementia Analy sis
- Type 2 Diabetes Analysis
- Ischemic Heart Disease Analysis

Summary statistics of participant data

- EHR Data, Survey Questions, Physical Measurements

Beta Launch on May 27, 2020

- Currently restricted to U.S. researchers with eRA Commons accounts

Part I: *All of Us* Research Program Overview

Engaging Underrepresented
Research Participant
Communities in Genomic
Research

Consuelo Wilkins, M.D., MSCI
Vanderbilt University Medical Center



Overview

- *All of Us* has a comprehensive approach to engaging participants, communities, and other stakeholders.
- Diversity in genomics is greatly needed and prior strategies have been had varying success.
- Race, a social construct, has been biologized. Ancestry and race are often conflated.
- Engaging groups who have been historically marginalized and underrepresented in research requires time, resources, training and cultural humility.

Comprehensive Engagement Strategy

- **All of Us** is engaging organizations across the U.S.
 - **Engagement Partners:** Trusted national and regional community organizations and health care provider organizations
 - Increase awareness of *All of Us*; some educate providers
 - **Champions:** Community and health advocacy organizations
 - Increase awareness of *All of Us*



Photo: CPGI meeting May 2019

All of Us Community and Provider Partner Network





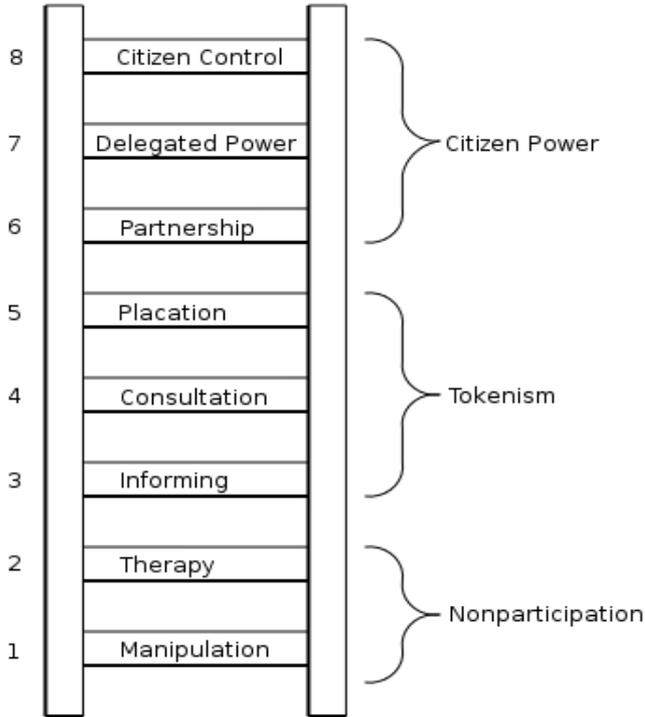
Engagement

≠



Recruitment

What is authentic engagement?



Increasing Level of Community Involvement, Impact, Trust, and Communication Flow

Outreach	Consult	Involve	Collaborate	Shared Leadership
Some Community Involvement	More Community Involvement	Better Community Involvement	Community Involvement	Strong Bidirectional Relationship
Communication flows from one to the other, to inform	Communication flows to the community and then back, answer seeking	Communication flows both ways, participatory form of communication	Communication flow is bidirectional	Final decision making is at community level.
Provides community with information.	Gets information or feed-back from the community.	Involves more participation with community on issues.	Forms partnerships with community on each aspect of project from development to solution.	Entities have formed strong partnership structures.
Entities coexist.	Entities share information.	Entities cooperate with each other.	Entities form bidirectional communication channels.	Entities have formed strong partnership structures.
Outcomes: Optimally, establishes communication channels and channels for outreach.	Outcomes: Develops connections.	Outcomes: Visibility of partnership established with increased cooperation.	Outcomes: Partnership building, trust building.	Outcomes: Broader health outcomes affecting broader community. Strong bidirectional trust built.

Sherry R. Arnstein, Ladder of citizen participation. 1969.

Reference: Modified by the authors from the International Association for Public Participation. DHHS. Principles of community-engagement. 2nd Ed. 2011.

http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf

Trust in Genomics Among Marginalized Racial and Ethnic Groups

- **History:** Eugenics movement & discrimination
- **Economic risk:** loss of benefits or income if linked to health condition
- DNA associated with **criminal justice system**
- Findings linked to genetics may **contradict cultural or ancestral beliefs**
- **Scientists insensitive** to cultural concerns about risks and harm



Eugenics

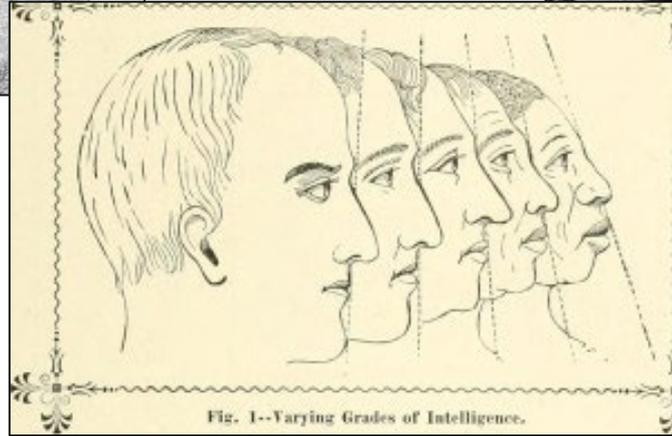
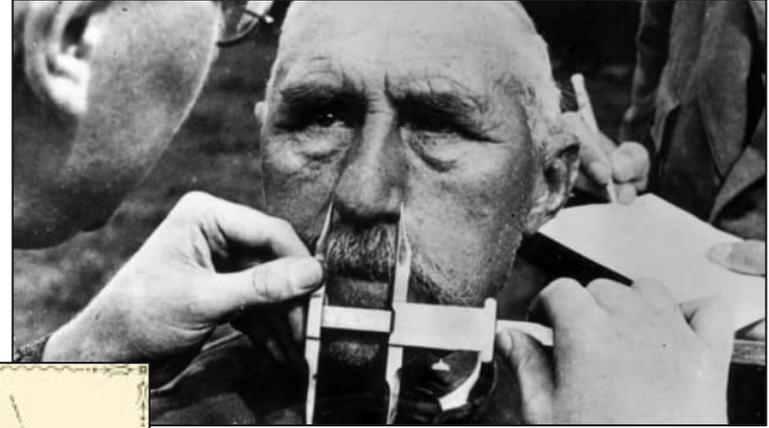
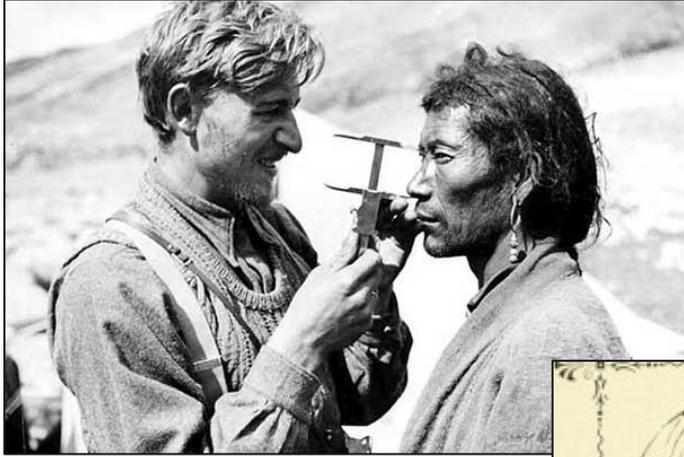


Fig. 1--Varying Grades of Intelligence.

After enslaved Africans were stripped of their culture and not allowed to be educated, they were then labeled as inferior.

Engagement Prior to *All of Us* Launch

Precision Medicine Initiative Pilot Community Engagement Studios (4/29/16 – 10/31/16)

- **77 Studios**
 - 60 were part of the Pilot
 - 17 with FQHCs (CT, TN, SC, NY, MS, CA)
- **654** community members
- Avg **8.5** community members/studio
- **46%** self-identified as a racial/ethnic minority
- **9%** self-identified as a sexual or gender minority



Joosten YA, Israel T, Williams NA, Boone LR, Schlundt D, Mouton CP, Dittus RS, Bernard G, Wilkins CH. Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input from Stakeholders to Inform Research. *Academic Medicine*. 2015 Dec; 90(12): 1646–50.

Johnson DA, Joosten YA, Wilkins CH, & Shibus CA. (2015) Case Study: Community Engagement and Clinical Trial Success: Outreach to African American Women. *Clinical and Translational Science*. 2015 Aug; 8: 388–390.

Vanderbilt PMI Pilot Community Engagement Studios

77 Studios; N= 654; Racial/Ethnic Minorities: 46%

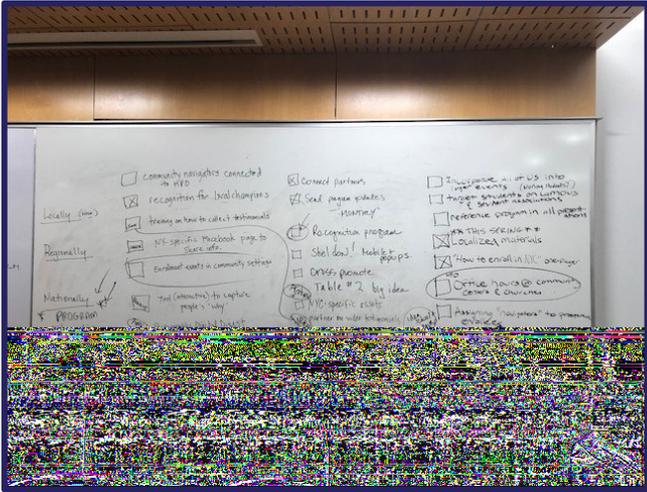
April 29, 2016 - October 31, 2016



Engagement Prior to *All of Us* Launch

September 2016 – National Community Partners meeting

Lead by: HCM Strategies and NYC Precision Medicine Consortium



Engagement Prior to *All of Us* Launch Continued

Inaugural Steering Committee Members
Selection process November 2016
Appointed early 2017



Patricia Butts



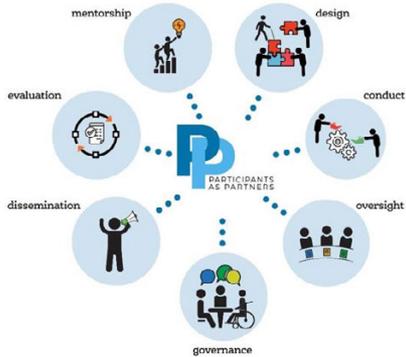
Steve Mikita



Karl Surkan

Effectively Engaging Participants as Partners

All of Us Research Program Engagement Core



Consuelo H. Wilkins MD, MSCI



Karriem S. Watson, DHSc, MS, MPH



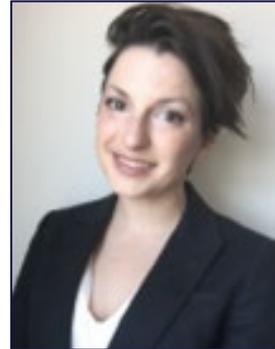
Elizabeth G. Cohn, PhD, RN



Alecia Fair, DrPH



Selena McCoy Carpenter, MEd



Catherine M. Hammack, MA, JD



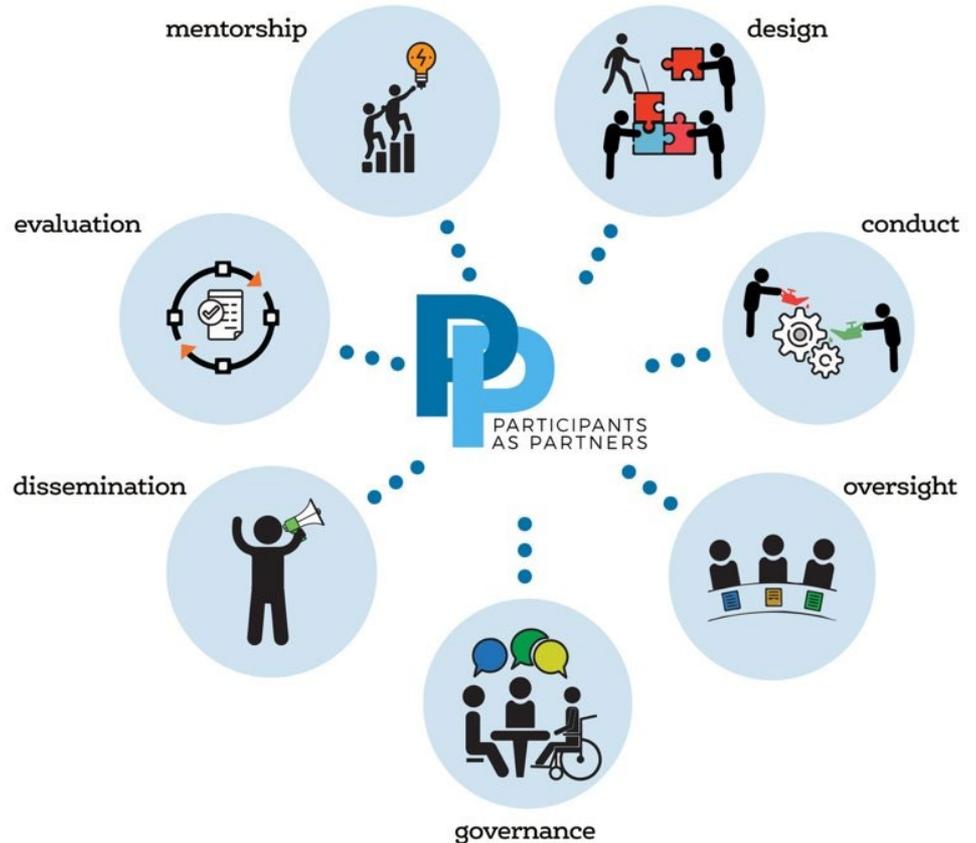
Amir Elraheb, BA



Melinda Aldrich, Ph.D., M.P.H.

Vision of the Engagement Core

Engage “participants as partners”
in the oversight, design, and
conduct of the *All of Us* Research
Program



All of Us Research Program Engagement Core

Specific Aims:

- Create infrastructure to fully integrate participants in all aspects of the research
- Identify and meaningfully engage diverse participants in governance
- Assess impact of engagement on research; develop metrics to inform *All of Us* as well as future large- scale research programs

Current Participant Partner Initiatives

2 Advisory
Panel Members

4 Steering
Committee
Members

24 Participant
Ambassadors

2 Executive
Committee
Members

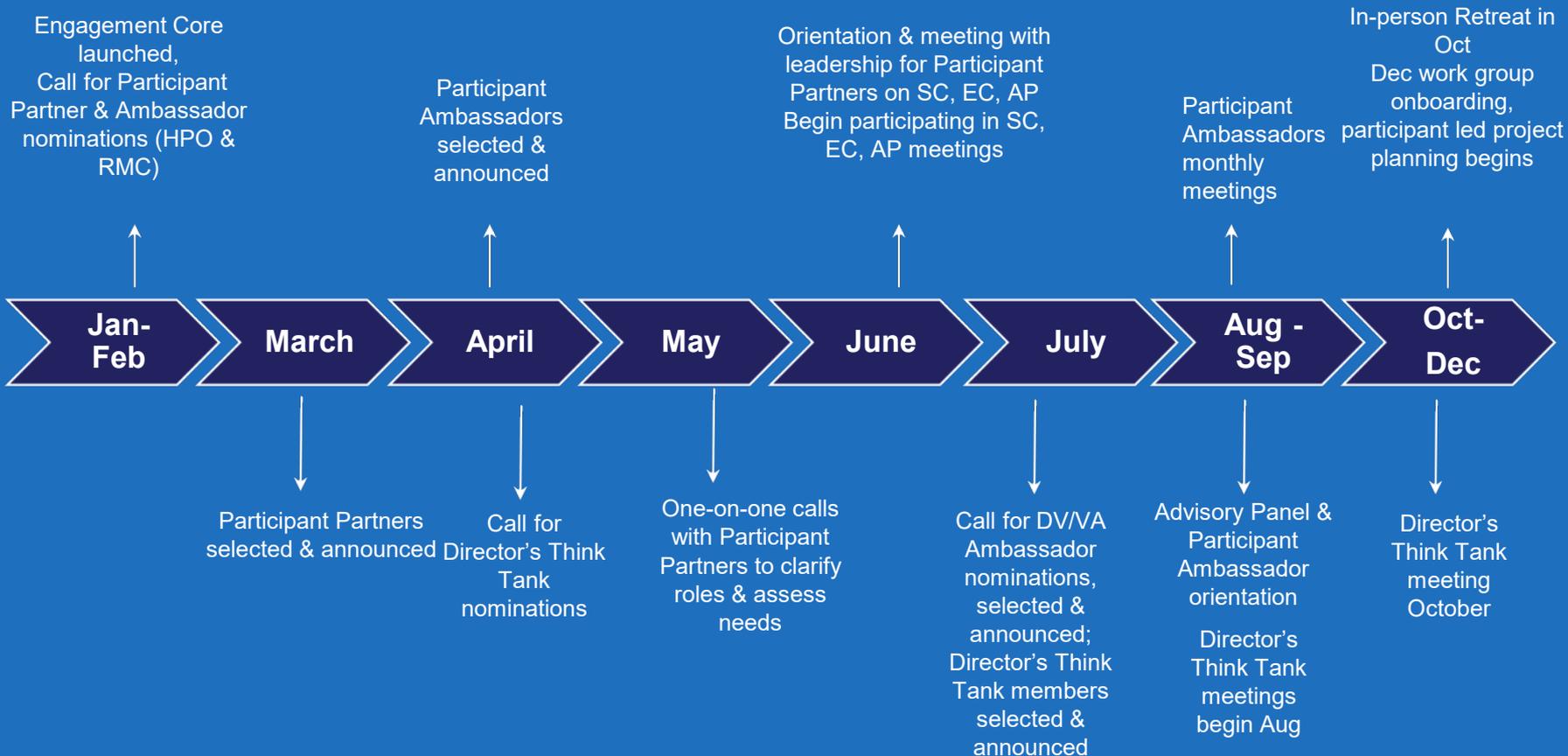
6 Think Tank
Members

Future initiatives

Community
Engagement
Studios

Participant
Polling

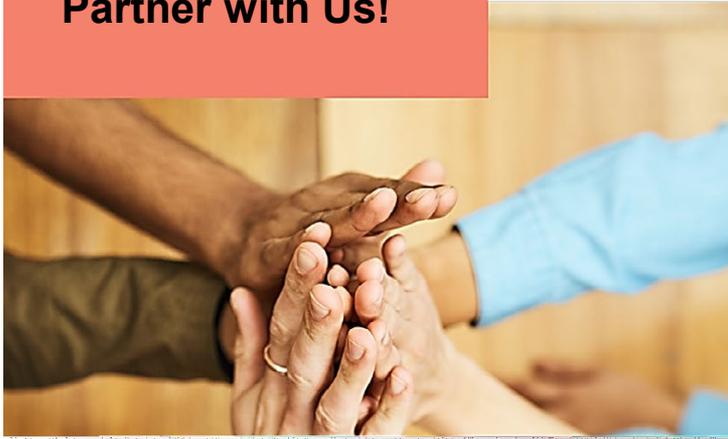
2018 Engagement Core Timeline



Selecting Diverse Participants to Engage



Partner with Us!



Why Diversity is Key: *All of Us* Newsletter, February 2018

We're doing research in a new way—with participants as our partners. We invite participants to take part in *All of Us* committees and working groups. We're looking for people who are excited about the future of health and enjoy working with people of different backgrounds.

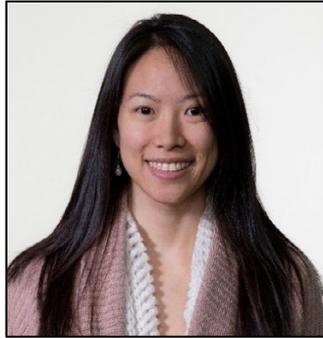
LEARN MORE AND APPLY TODAY

Participants as Partners

Steering Committee, Executive Committee, Advisory Panel



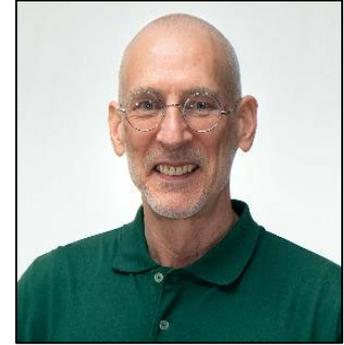
Michael Castro
Steering Committee Member



Katherine Chang, M.S.
Steering Committee Member



Michelle McNeely
Steering and Executive Committee Member



Richard Hochfelder
Steering and Executive Committee Member



Miriam Guzman, M.H.A.
Advisory Panel Member



Ana Carolina Dantas Machado, Ph.D.
Advisory Panel Member

Participant Ambassadors



Michelle Anderson
NE PMC
Boston, Massachusetts



Lottie Barnes
Direct Volunteer
Durham, North Carolina



John David Bean
Direct Volunteer
Hendersonville, Tennessee



Keisha Bellamy
Veterans Administration
Palo Alto, California



Craig Braquet
Direct Volunteer
La Place, Louisiana



Brian Bridges
Veterans Administration
Palo Alto, California



Joyce Brown
Illinois PMC
Chicago, Illinois



Daisy Burgos
Community Health Center, Inc.
Meriden, Connecticut



Hugo Campos
California PMC
Oakland, California



Ben Dorshorst
All of Us Wisconsin
Madison, Wisconsin



Sixto Escobar
Veterans Administration
Boston, Massachusetts



Miguel Flores, Jr.
University of Arizona
Tucson, Arizona



Michael Miller
UAB
Birmingham, Alabama



Evelyn Ortiz
New York City PMC
Yonkers, New York



Ana Pavon
Eau Claire CHC
Leesville, South Carolina



Gus Prieto
Direct Volunteer
Los Angeles, California



Marilyn Roman
Southeast Enrollment Center
Miami, Florida



Ellen Roy
Cherokee Health System
Knoxville, Tennessee



Elizabeth Rubinstein
Trans-American Consortium
Detroit, Michigan



Shawn Smith
University of Pittsburgh
Pittsburgh, Pennsylvania



Tyrone Thigpen
Jackson-Hinds CHC
Jackson, Mississippi



Vilma Velez
Hudson River Health
Cortland Manor, New York



Tiana Vargas
San Ysidro Health Center
San Diego, California

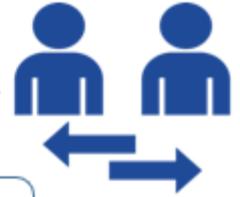


Karen Wall
Veterans Administration
Sante Fe, New Mexico

Lessons Learned

Defining roles up front

Understand the **time commitments** involved



"I was in the dark . . . with no complete picture of what was going to happen."

- Defining a **minimal level** of participation with **options** to do more
- Skills and contributions better utilized and **fully integrated** into **activities**
- **Bi-directional communication** with participant partners /colleagues
- **More education** and initial **onboarding support** to integrate the next cohort more seamlessly

October 2018

- Participant Partner Retreat
- Director's Think Tank In-person Meeting
- Joint Session with AoU Steering Committee



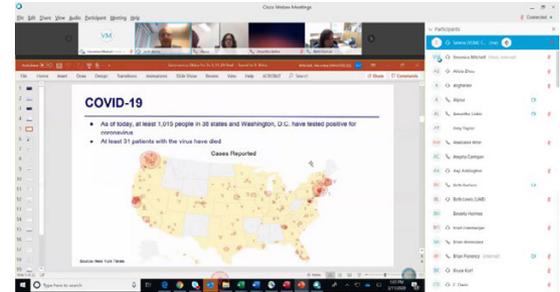
Minimizing Barriers for Engagement

- Face to Face in Bethesda
- Possible travel to other meetings
- Cash advances using GSA estimates
- Reporting must be submitted
- Monthly compensation: \$125
- Governance or extramural groups: \$500
- Not based on attendance
- Month lag time



Platforms used by Participant Ambassadors

- Webex for monthly meetings and governance group meetings
- Email
- Phone calls
- Texting (if requested)
- GroupMe



Participant Ambassador Placement in Workgroups

Governance Group	Participant Ambassador
Participant Evaluation and Assessment Board	Lottie Barnes and Gus Prieto
Omics	JD Bean
Special Populations Committee	Miguel Flores and Hugo Campos
Participant Provided Information (PPI)	José Iraheta
Science	Keisha Bellamy
Committee on Access Privacy and Security (CAPS)	Vilma Velez and Evelyn Ortiz
Electronic Health Records Committee	Tyrone Thigpen and Ana Pavon
Incident Notification Board (INB)	Michael Miller
Publications Board	Beth Rubinstein
Resource Access Board	Karen Wall and Marilyn Roman

Questions?

consuelo.h.wilkins@vumc.org

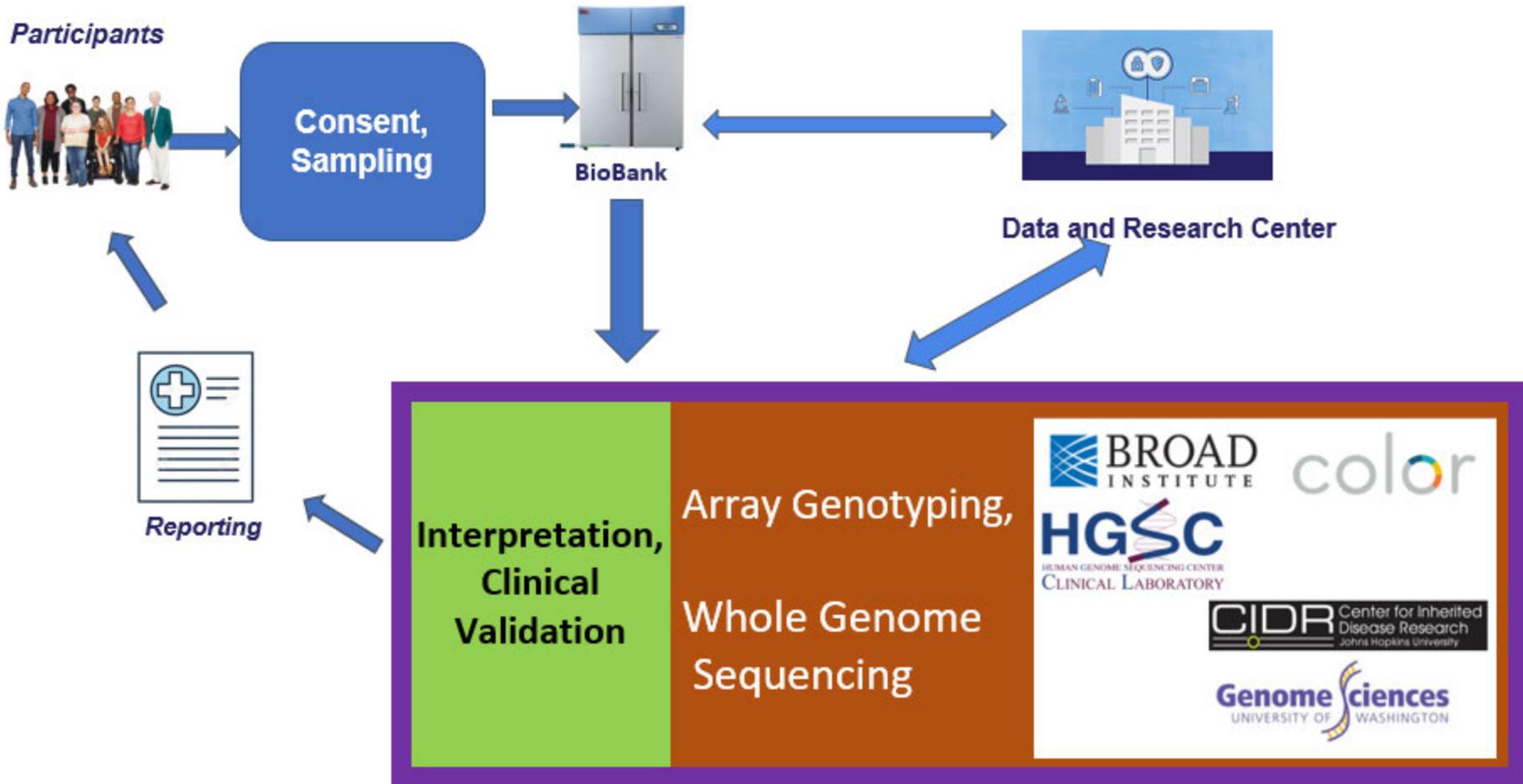
Part I: *All of Us* Research Program Overview

Innovative Sequencing and
Array Technologies at
All of Us

Richard Gibbs, Ph.D.
Baylor College of Medicine

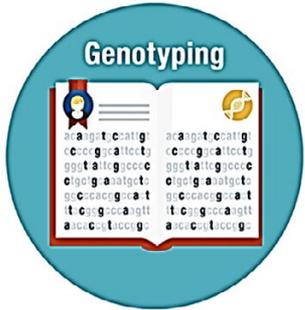


The 'Genomics Network': What's in the box?



What's in the box? Genotyping and Sequencing! Why both?

Array Genotypes vs. Whole Genome Sequencing



Array Genotyping

- Pre-determined sites in the Genome
- Inexpensive (\$10s per sample)
- Analysis is fast and easy

Whole Genome Sequencing

- Complete information
- Not as inexpensive (\$100s per sample)
- Analysis more involved



ARRAYS

- Predictable
- Limited
- Easier regulatory
- Superseded

Versus

GENOMES

- Uncertain
- Comprehensive
- Complicated
- Regulation
- Futuristic

What's on the box? Genotyping and Sequencing - NOT commodities!

Challenges:

- Scaling (one million!), cost, accuracy
- Content (arrays), primary analysis methods (WGS)
- Technical harmonization/coordination, Research versus Clinical use
- Compliance: Security, Synchronization with FDA requirements
- Methods evolution – when to add different data types?

**Interpretation,
Clinical
Validation**

Array Genotyping,

Whole Genome
Sequencing

 **BROAD
INSTITUTE**

color

HGSC
HUMAN GENOME SEQUENCING CENTER
CLINICAL LABORATORY

CIDR Center for Inherited
Disease Research
Johns Hopkins University

Genome Sciences
UNIVERSITY OF WASHINGTON

Workflow for Genomic Data Generation and RoR

Participants who have completed gRoR consent and provided a biospecimen

Genotyping Arrays
150,000*

Whole Genome Sequencing
100,000*

*estimates for 2021 sequencing and genotyping

Data and Research Center

Agree to gRoR for Ancestry and Traits

Agree to gRoR for Heredity Disease Risk Panel and PGx

PGx

All receive report

~2% positive for HDR (~1500 P/LP results)



color

The 'Genomics Network'



Heidi Rehm,
LMM/Broad Inst.



Stacey Gabriel,
Broad Inst.



Scott Topper,
Color Genomics



Alicia Zhou,
Color Genomics



Gail Jarvik,
U. Washington



Debbi Nickerson,
U. Washington



Evan Eichler,
U. Washington



Richard Gibbs,
BCM-HGSC



Kim Doheny,
JHU-CIDR



Eric Boerwinkle,
UT-HSC



	Genotype	Sequence	Clinical Validation	Harmonize
	✓	✓		✓
			✓	✓
		✓	✓	✓
	✓			
	✓	✓	✓	✓

Genomic Data/ Reporting Work Groups

I: Technical Operations



Stacey Gabriel,
Broad Inst.



Kim Doheny,
JHU-CIDR



Debbi Nickerson,
U.
Washington

- Sample Tracking
- Data Flow
- Protocol Harmonization
- Validation Protocols



Namrata Gupta,
Broad Inst.



Ginger Metcalf,
BCM-HGSC

II: Regulatory/ Compliance



Donna Muzny,
BCM-
HGSC



Niall Lennon,
Broad
Inst.



Tina Lockwood,
U.
Washington

- CAP/CLIA
- IRB
- FDA
- Data Security



Doreen Ng,
BCM-HGSC



Brian Shirts
U.
Washington



Scott
Topper,
Color
Genomics

III: Clinical Interpretation/ Reporting



Heidi Rehm,
LMM/Broad
Inst.



Gail Jarvik,
U.
Washington



Richard
Gibbs,
BCM-HGSC

- Overall Content
- Mechanics
- P vs LP vs VUS
- PGx



David Murdock,
BCM-HGSC



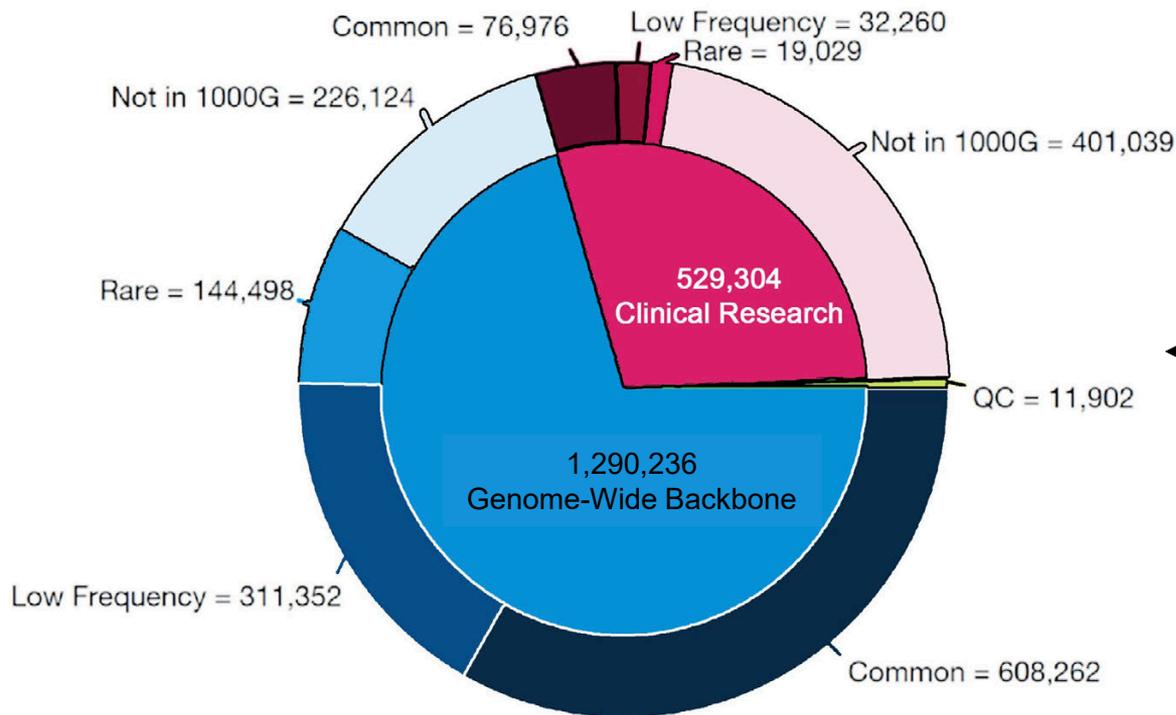
Philip
Empey,
IPM
Pittsburg



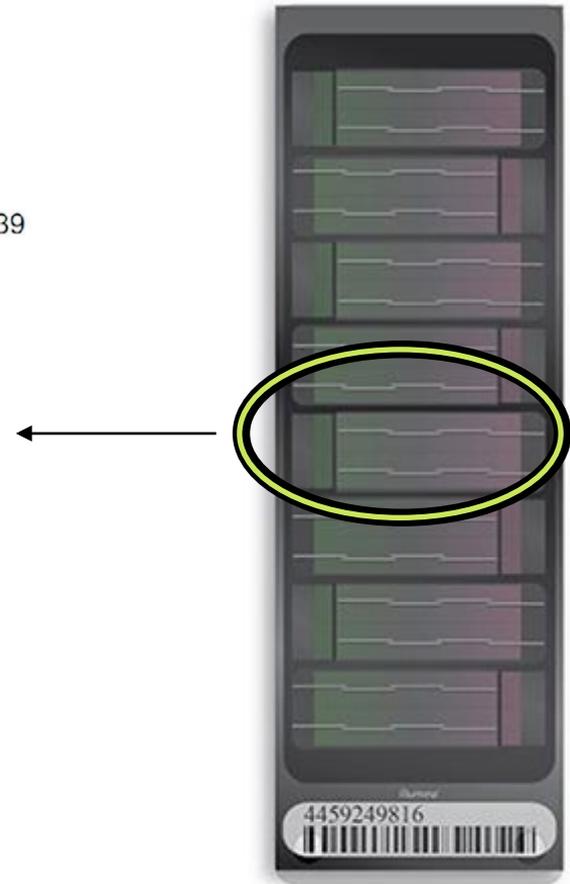
Eric
Venner,
BCM-
HGSC

Genotyping Array Content

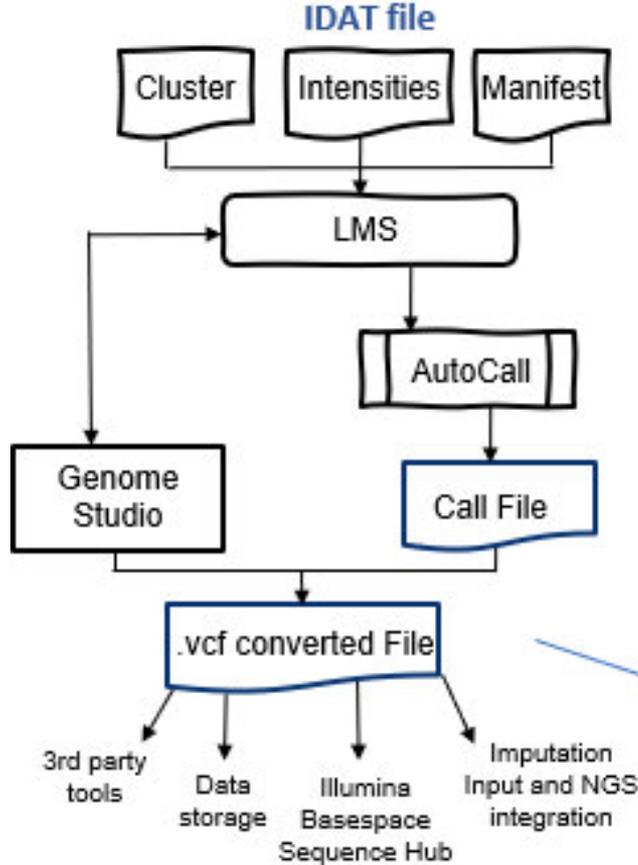
Illumina Infinium Global Diversity Array-8 v1.0



■ Genome-Wide Backbone ■ Clinical Research ■ QC



Genotyping



Uses of Array Data:

- QA/QC of WGS
- Validation of WGS
- SV calls
- Imputation when others use array

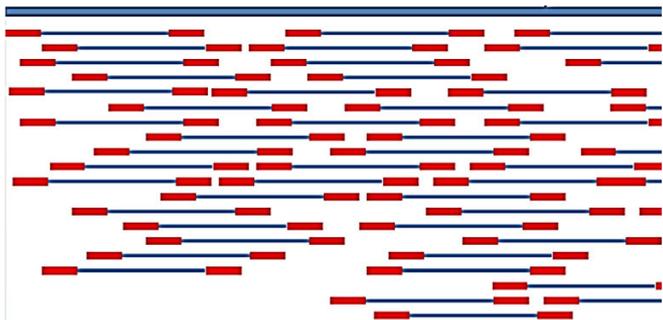
Data and
Research Center



Current Whole Genome Sequencing

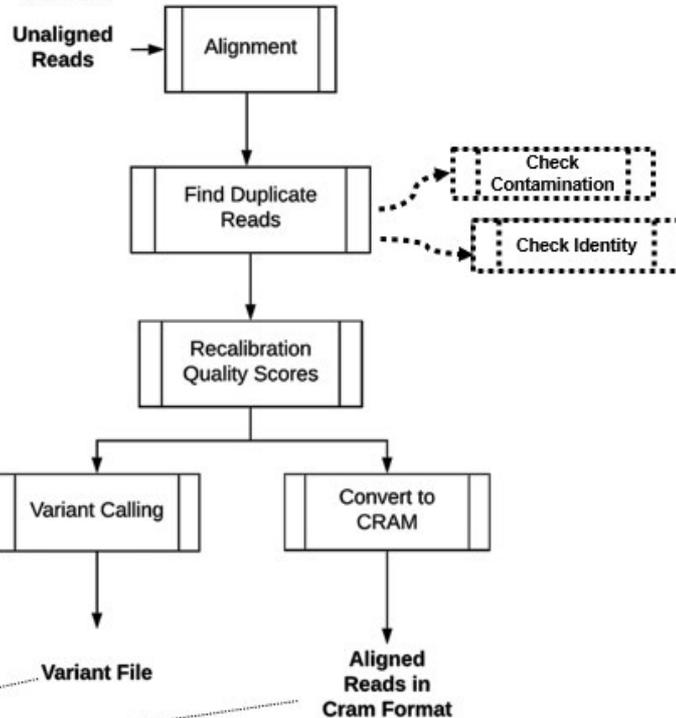


- *Mean* 30X coverage (clinical grade!)
- ~90 Billion Bases per sample
- 'short' 2 x 150 bp reads,



FastQ/
uBAM

Data Processing



Data and Research Center



Details and Decisions

- Many required for FDA IDE
- DNA quality metrics chosen
- Coverage/call rate minima established
- Genome reference builds for clinic vs. research
- Potential for new references?
- Methods for variant calling:
 - Several SNV alternatives with comparable performance
 - The Dragen Pipeline chosen as accessible for all Genome Centers

DRAGEN: SNVs and SVs

- DRAGEN Pipeline – originally from Edico
- Rapid analysis via specialized local hardware OR
- Cloud instances
- Same parameters for all users = harmonization
- Under discussion optimal SV calling

Summary of Minimal Genomic Deliverables

- Genotypes for all participants,
- WGS for all participants,
- What about alternative data types:
 - e.g., 'long reads' to better resolve SVs?
 - e.g., Hudson Alpha Long Read Pilot

HudsonAlpha Institute Long Read Sequencing Project

- Hudson Alpha Pilot 3,500-6,000 WGS with 'long reads',
- Evaluating Pacific Biosystems HiFi, Oxford Nanopore Technologies
- Evaluate SVs, 'difficult' loci – e.g. SMN1, SMN2, Cyp2D6
- Comparison with short reads



Shawn Levy
Hudson
Alpha

Advisory Group



Fritz Sedlazeck
BCM



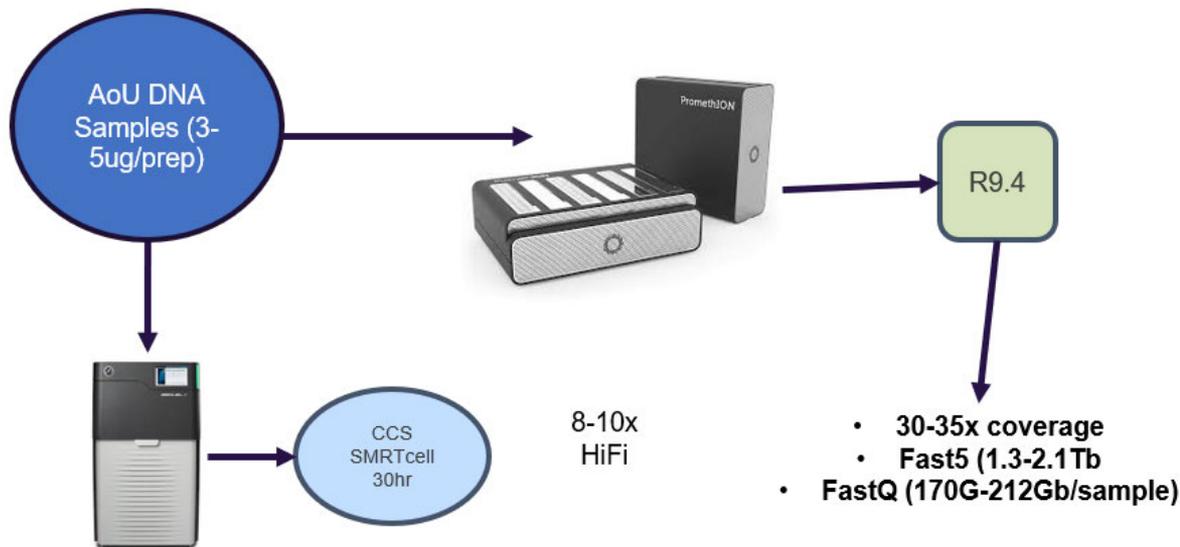
Medhat Mahmoud
BCM



Evan Eichler,
U. Washington



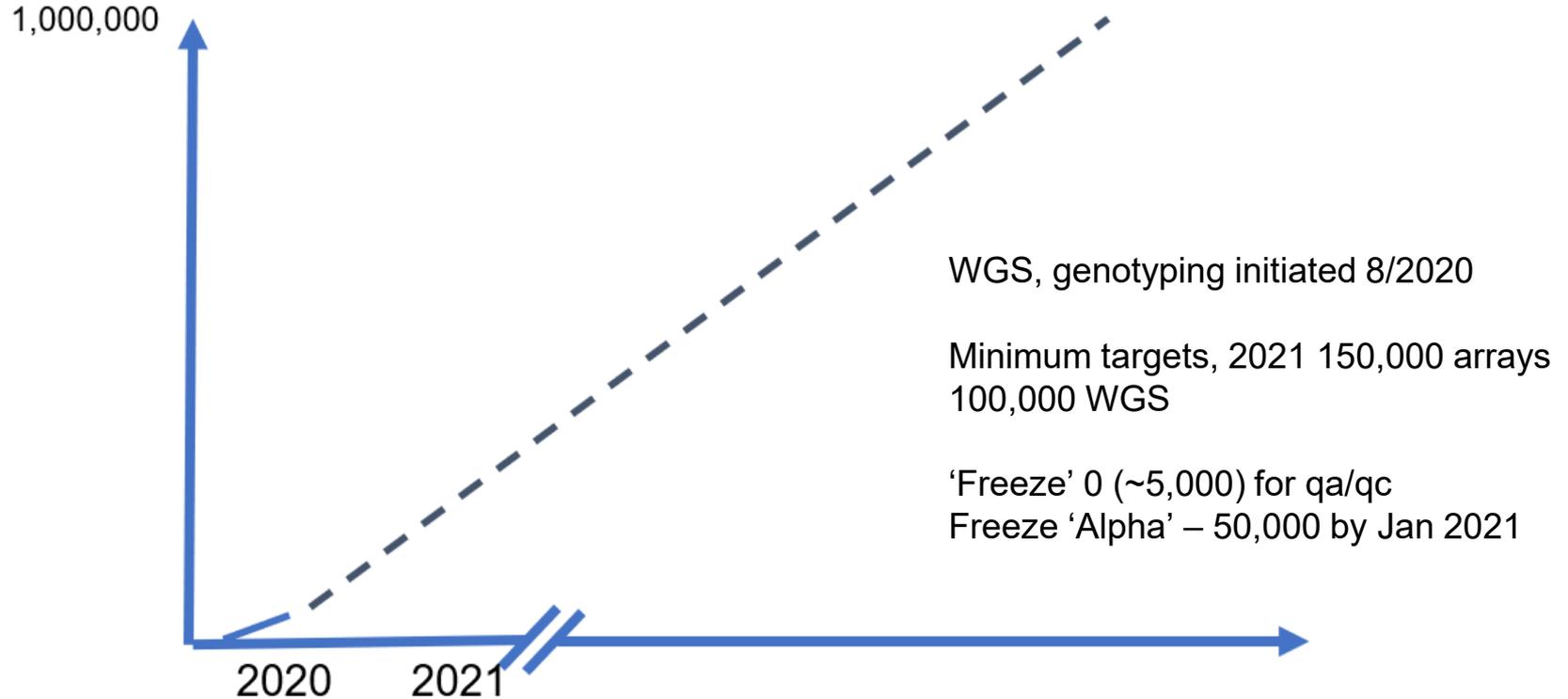
Peter Audano
U. Washington



All of Us Long Read Sequencing Progress

- Validated platform, sample types (saliva and blood)
- Determined sensitivity and precision over three variant classes for low coverage long read data:
 - Structural variants (>50nt)
 - Indel (1-49nt)
 - Single nucleotide variants
- So far:
 - not more than 20 x coverage required (good),
 - Indel calling improved greatly
 - A hybrid model?

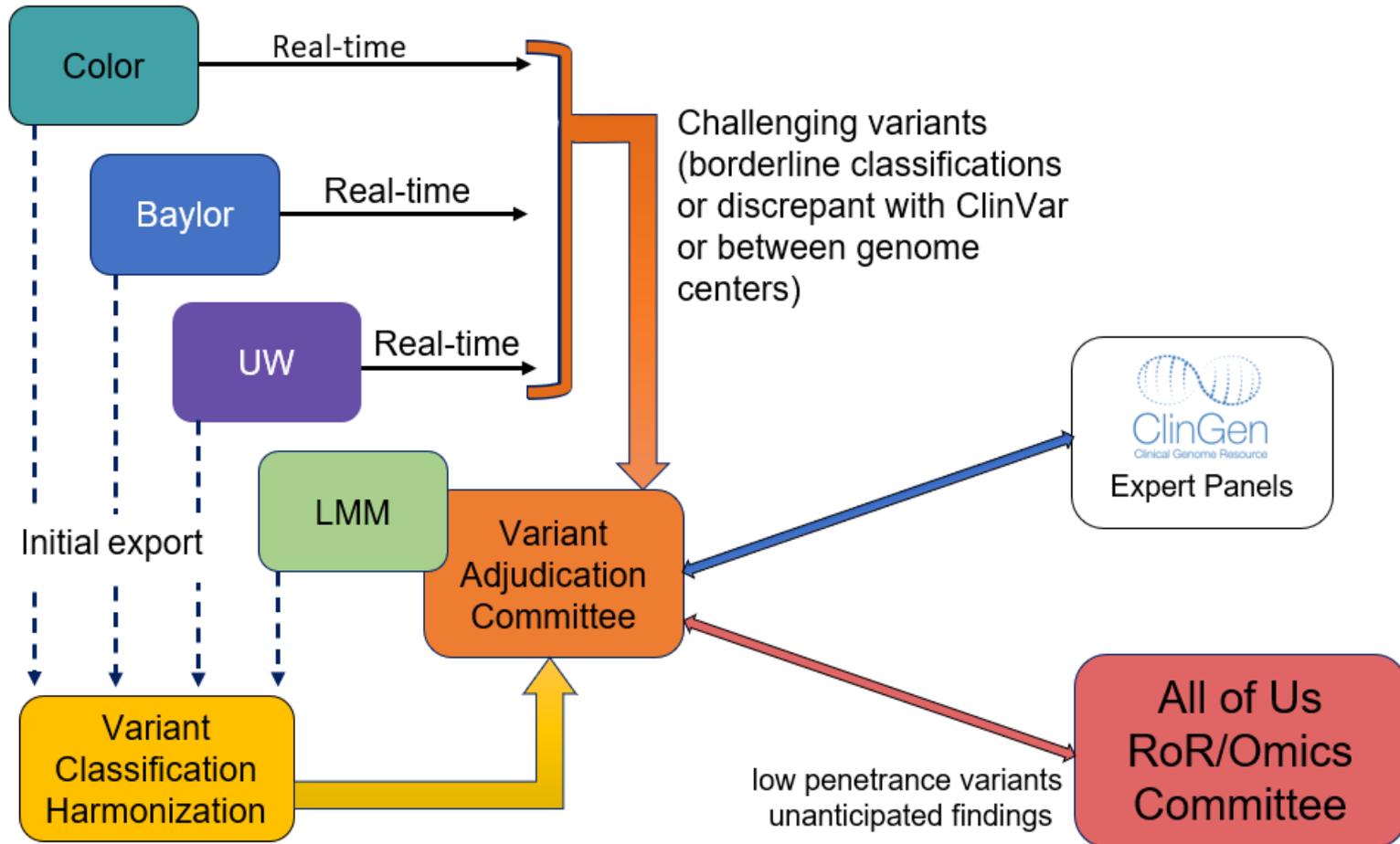
All of Us Data so far:



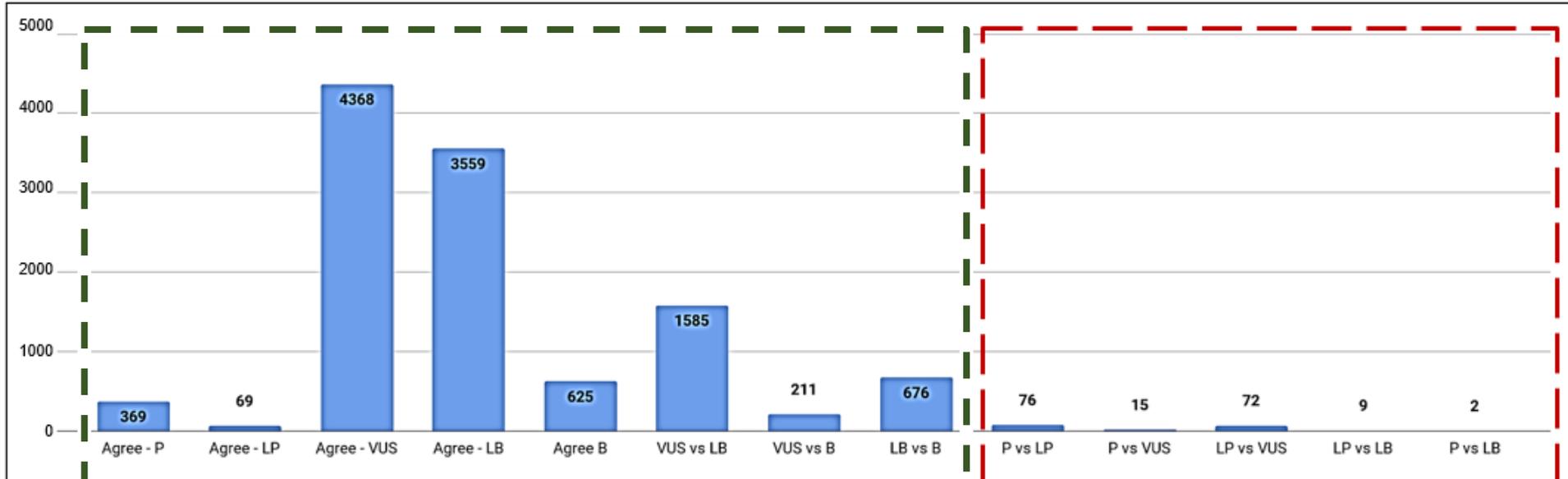
Objective – To Return Genetic Data to Participants

- Requires variant interpretation
- Coordinated, independent efforts at three clinical labs
- Harmonization at several points in pipelines

Variant Classification Harmonization



Comparison of 11,636 Variants Classified by ≥ 2 labs



98.5%

CONCORDANT at AoU reporting level
(11462/11636)

1.5%

DISCORDANT at AoU reporting level
(182/11636)

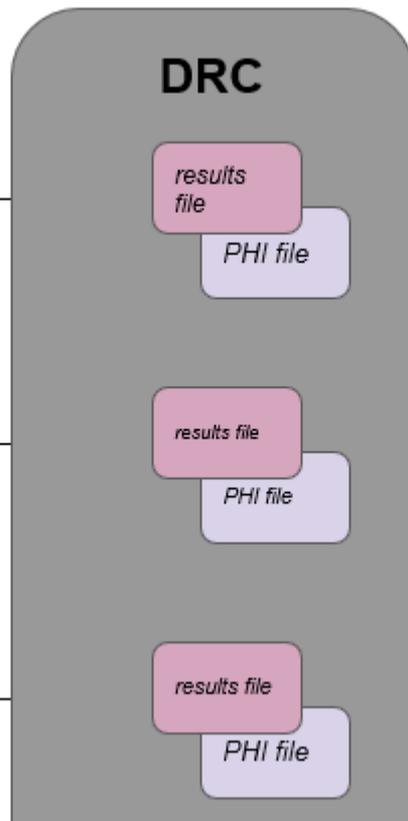
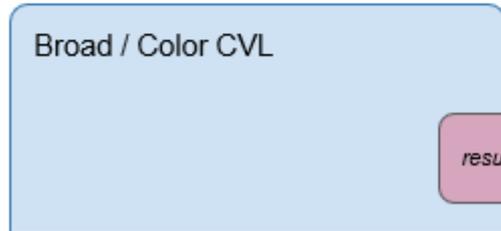
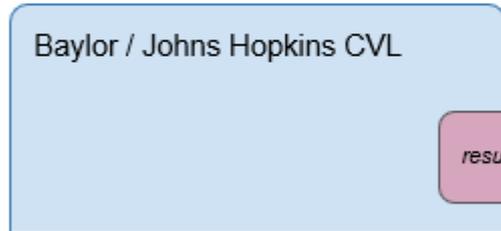
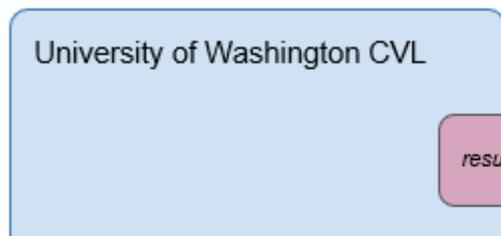
0.86%

have medically significant differences
(102/11636)

Mechanics of Report Signout



Independent CVLs



Whole Genome Sequencing and Genomic Return of Results

Whole Genome Sequencing



Clinical Validation



 Reporting and Harmonization Platform

*~2% positive for HDR
(~1500 P/LP results)*



Genetic Counseling Resource

Reporting and Harmonization Platform

Variant classifications from 4 clinical labs will be stored and regularly updated within the common reporting platform

A common sign-out environment will ensure reports have consistent content and variant classifications

Whole Genome Sequencing and Genomic Return of Results Continued

- New generation of Arrays designed, built, deployed
- Illumina 'short-read' WGS underway
- FDA clearance for health data return
- Novel 'long read' genomes under evaluation
- Variant interpretation and harmonization achieved at baseline
- Ongoing harmonization – see next presentation

Part I: *All of Us* Research Program Overview



**Returning Ancestry and
Traits at Population-Scale**

Alicia Zhou, Ph.D.

Color Genomics

Discussion Points

- **The *All of Us* Goal:** Returning Genetic Results from Research Data
- **The *All of Us* Framework:** Ethical and Regulatory Considerations
- **The *All of Us* GCR:** Technological Infrastructure and Genetic Counseling Services

The *All of Us* Goal:

Returning Genetic Results from Research Data

Participants Are Partners and Should Have Access to Their Information

- **Genetic information can be interesting and engaging**
 - 26+ million people have purchased at-home genetic ancestry tests
- **Genetic information can be useful to participants and their families**
 - Harbor important health information, such as indication of an individual's response to a medicine or specific measures of disease risk
 - Major professional societies (i.e., ASHG, ACMG, ESHG) have issued guidance around using data streams to opportunistically identify individuals at high risk of penetrant, treatable disorders

Returning Genomic Information Drives Program-level Goals

- **A broad, longitudinally-engaged population ultimately increases the research value of the database**
 - The promise of returned information **encourages recruitment** into the study
 - Ongoing engagement **drives retention and long-term participation**
 - Participants see the progress of the program in very personal ways, which **drives understanding of and advocacy for the program**

All of Us Genomic Return of Results Content Strategy

Engagement

Genetic ancestry and traits results



7 regions (21 subregions) and 4 traits

- Sub-Saharan Africa
- Europe
- Oceania
- Southern Asia
- Eastern and northern Asia
- The Middle East and North Africa
- The Americas
- Ear wax
- Bitter taste perception
- Cilantro preference
- Lactose intolerance

Health information

Hereditary Disease Risk Report



59 genes (SNVs + indels)

- Breast cancer
- Ovarian cancer
- Uterine cancer
- Colorectal cancer
- Prostate cancer
- Melanoma
- Brain cancer
- Pancreatic cancer
- Stomach cancer
- Familial Hypercholesterolemia
- Cardiomyopathies
- Arrhythmias
- Arteriopathies

Medicine and your DNA Report



7 genes

- *CYP2C19*
- *DPYD*
- *G6PD*
- *SLCO1B1*
- *NUDT15*
- *TPMT*
- *UGT1A1*

Genetic Ancestry and Trait Results

All of Us
RESEARCH PROGRAM

Get Help Antoinette Phillips

Hi Antoinette.
Genetic ancestry and trait results help you discover insights about yourself beyond genetic health risks. You'll receive new results on an ongoing basis.

Ancestry

 **Genetic Ancestry**
Where in the world did your genes come from? [View](#)

Traits

 **Bitter taste perception**
Learn what your genes can tell you about your ability to taste bitter things. [View](#)

 **Cilantro preference**
Smell and taste work together to influence your cilantro preference. [View](#)

 **Earwax type**
Flaky or sticky? Earwax type is encoded in your genes. [View](#)

 **Lactose intolerance**
Your genes code for lactase, which helps you digest milk. [View](#)

Have questions or concerns?
[1-844-842-2855](tel:1-844-842-2855) [Chat Live Now](#) help@joinallofus.org

Antoinette, learn what your genes say about your ancestry.



Sub-Saharan Africa	82% ▾
West Africa Such as Nigeria, Senegal, and Ghana	66%
Central and East Africa Such as Kenya, Uganda, the Congo Basin, and Angola	16%
Europe	18% >
All tested populations	>

Health-related Results: Hereditary Disease Risk and PGx

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

Genes affect how we respond to medicine in many different ways

What is this kind of information used for?

IMPORTANT!

Share this report with your doctor

Genome Center: XXXXX, CLLA: BRXXXX, Laboratory Director: XXXXXXX

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.

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.
- **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.

All of Us Log Out

My Data > DNA Results > Hereditary Disease Risk Results

Hereditary disease risk results

ACTIONS ▾

Your report Next steps Risk with **BRCA1** Discuss results

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

If you want to share your results with your doctor or health care provider

Your doctor will need to confirm these results with a clinical genetic test before using them in your care. This is because *All of Us* is a research program and the results are research results that cannot be used directly in clinical care.

You can also [download this information sheet](#) and take it with you to talk to your doctor about your results.

SHARE RESULTS > See a preview of what we will send to your doctor.

If you want to talk to your family about your results

It's up to you to decide whether to talk to your family about these results.

If you do decide to share this information, you should explain to your family that this is a research result that has not been confirmed. You are welcome to invite your family to join you on a call with an *All of Us* Genetic Counselor if they have questions.

Some useful information:

- If your doctor confirms this result, it means that this gene was most likely inherited from either your mother or father.
- This would mean that one of your parents has the same result. Your children, brothers, and sisters also have a 50/50 chance of having the same result. Cousins, aunts, uncles, and grandparents could have it too.
- Men are just as likely as women to pass the result on to their children.
- Daughters and sons are equally likely to inherit the result.

We've created a sample letter that you can send to your relatives. This can help start a conversation about what these results might mean.

The *All of Us* Framework:
Ethical and Regulatory Considerations

Return of Results Process for Health-related Results

All of Us Institutional Review Board (IRB)

- Ensuring that the rights and welfare of research participants are overseen and protected uniformly
- Charged with reviewing the protocol, informed consent, and other **participant-facing materials**
- **16 representatives** with diverse backgrounds, expertise, and perspectives

Food and Drug Administration (FDA)

- Responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, **medical devices**, our nation's food supply, cosmetics, and products that emit radiation
- OHT7: **Office of In Vitro Diagnostics and Radiological Health**, Office of Product Evaluation and Quality
- Investigational Device Exemption (IDE): **consent to return of health-related results**

Return of Results Process for Health-related Results

Clinical Standards (CLIA)

- **Sample collection** meets CLIA/CAP standards
- **Primary data** generation is at CLIA-certified Genome Centers (WGS + genotyping)
- **Interpretation and secondary confirmation** of positive results is at CLIA-certified Clinical Validation Laboratories

Research data is not a clinical test

- There is **no supervising physician**
- There is **no clinical test requisition**

The research program does not provide clinical care

- Clinical genetic tests are clinical care
- The program **does not** provide clinical care

Return of Results Process for Health-related Results

- Hold our practices to the highest standards
- Discourage against using the research data to guide clinical care
- Do use the research data to identify people who will very likely benefit from a clinical test

IMPORTANT!

**Share this
report with
your doctor.**

- 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.
- **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 *All of Us* Genetic Counseling Resource:
Technological Infrastructure and Genetic Counseling
Services

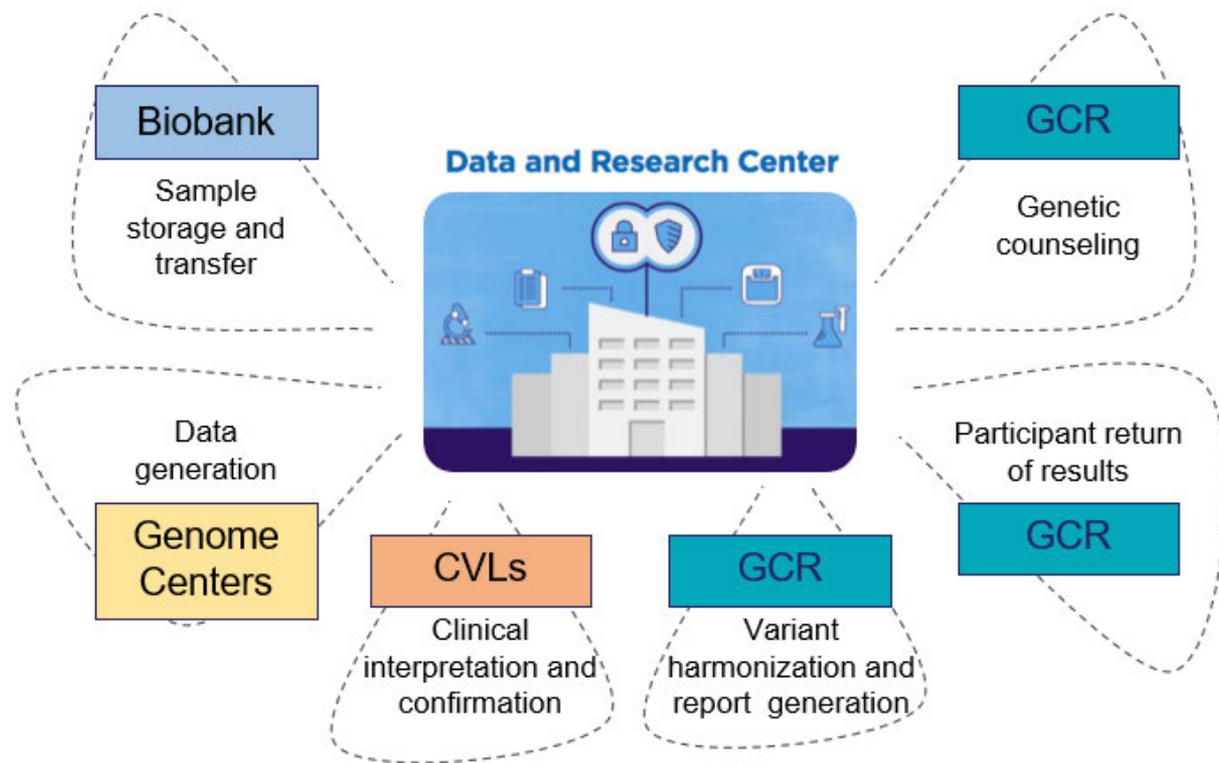
***All of Us* Genetic Counseling Resource**

The Genetic Counseling Resource will:

- Establish a network of genetic counseling professionals for the *All of Us* Research Program
- Deliver clinical reports to participants interested in receiving them about important medically-actionable genetic findings
- Provide computer- and phone-based genetic counseling services for participants and their health care providers
- Help advance technologies and approaches for population-scale genomic education and counseling for precision medicine delivery

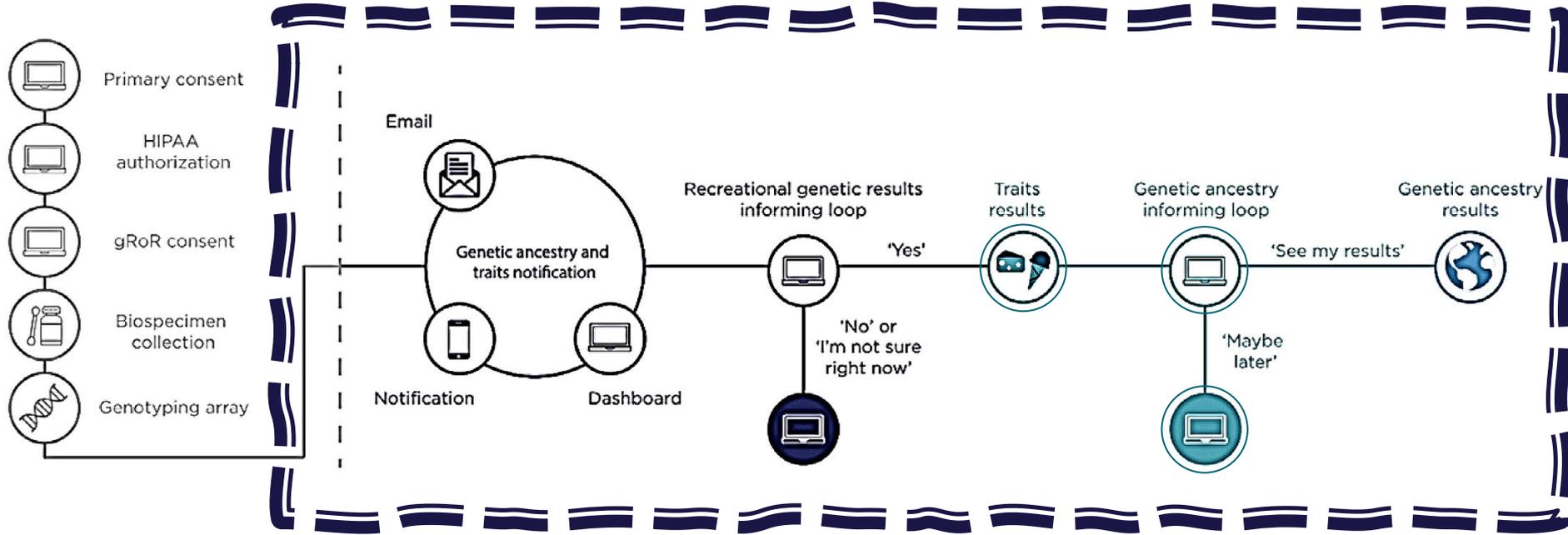
Genetic Counseling Resource facilitates the return of genomics results in a responsible fashion.

The *All of Us* Technological Infrastructure

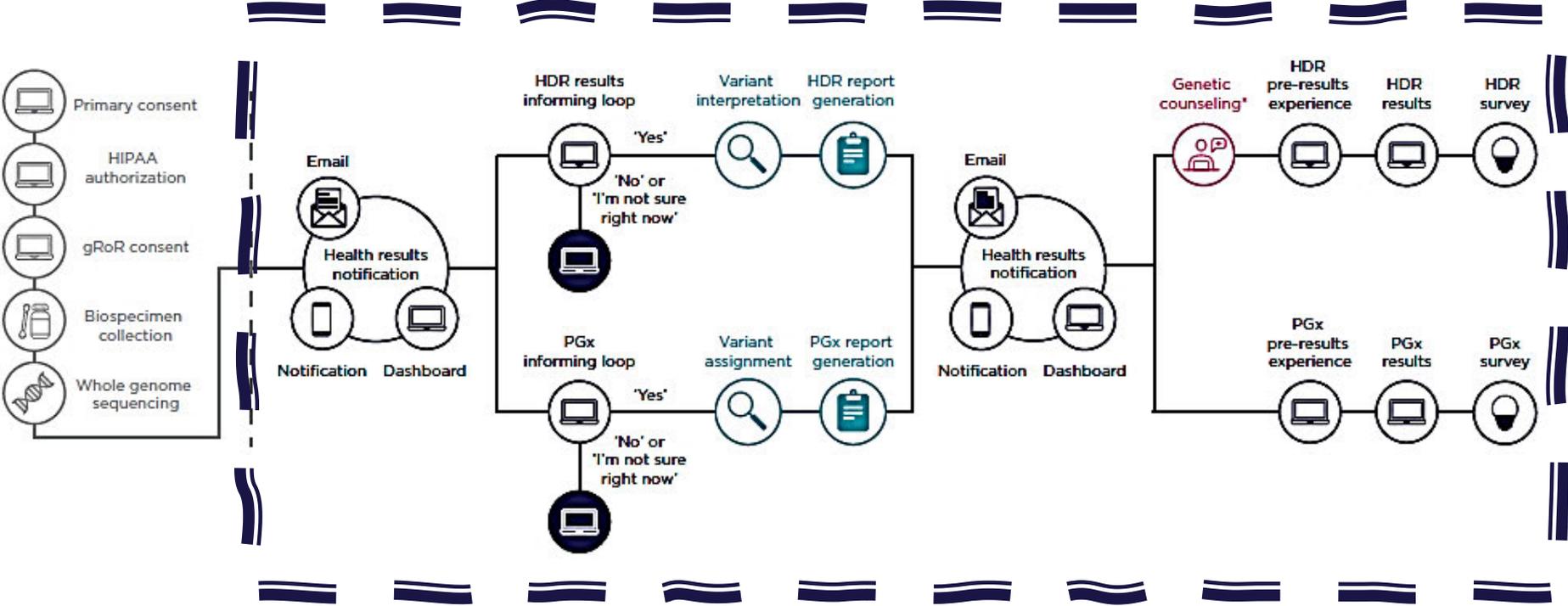


The DRC acquires, organizes, and provides secure access to datasets. The GCR manages content and information for return of genomic results to participants.

Return of Results Process for Genetic Ancestry and Trait Results



Return of Results Process for Health-related Results



Return of Results Process for Health-related Results Continued

All individuals will be...

- **Notified** when their results are almost ready
- Provided with an **online, educational “refresher” module** on the types of information they will receive
- Invited to provide personal and family history that can contextualize the results

Individuals with an ‘uninformative’ result...

- Will receive a notification that their **results are available to view**
- Can call the GCR if they have questions, but a genetic counseling session is **not required**

Individuals with a positive result will...

- Receive an invitation to **schedule a genetic counseling session**
- Have their **results released during the genetic counseling session**, wherein the genetic counselor will explain the significance of the result, answer questions, and discuss next steps
- Be **connected with a local specialist** and given opportunity to **share the results**

Genetic Counseling Resource

Primary aims of the *All of Us* Genetic Counseling Resource:

- Provide technological infrastructure, including software systems that can easily communicate with each other and standardized reporting system to make the results easy to interpret
- Help participants understand and appreciate the significance of their health-related genetic results
- Help participants understand what a “research result” is and is not
- Connect participants to accessible opportunities for follow-up care
- Educate and support the larger clinical network that receives *All of Us* participants into their care

Questions?

alicia@color.com

Part I: *All of Us* Research Program Overview

Pharmacogenomics (PGx) Framework and Approach for PGx Return of Results

Philip Empey, Pharm.D., Ph.D.

University of Pittsburgh Medical Center



Why Focus on Pharmacogenomics?

Variability in medication response is widely understood

Strong scientific evidence for impact on outcomes

Testing is feasible and has life-long value

Variants are common; most participants are expected to carry at least one variant

Already implemented in clinical practice

Why Focus on Pharmacogenomics? Continued

- Participants expect return of PGx results
- Return of Results = Return of value
- In the *All of Us* Research Program 77 community studios (n=654):

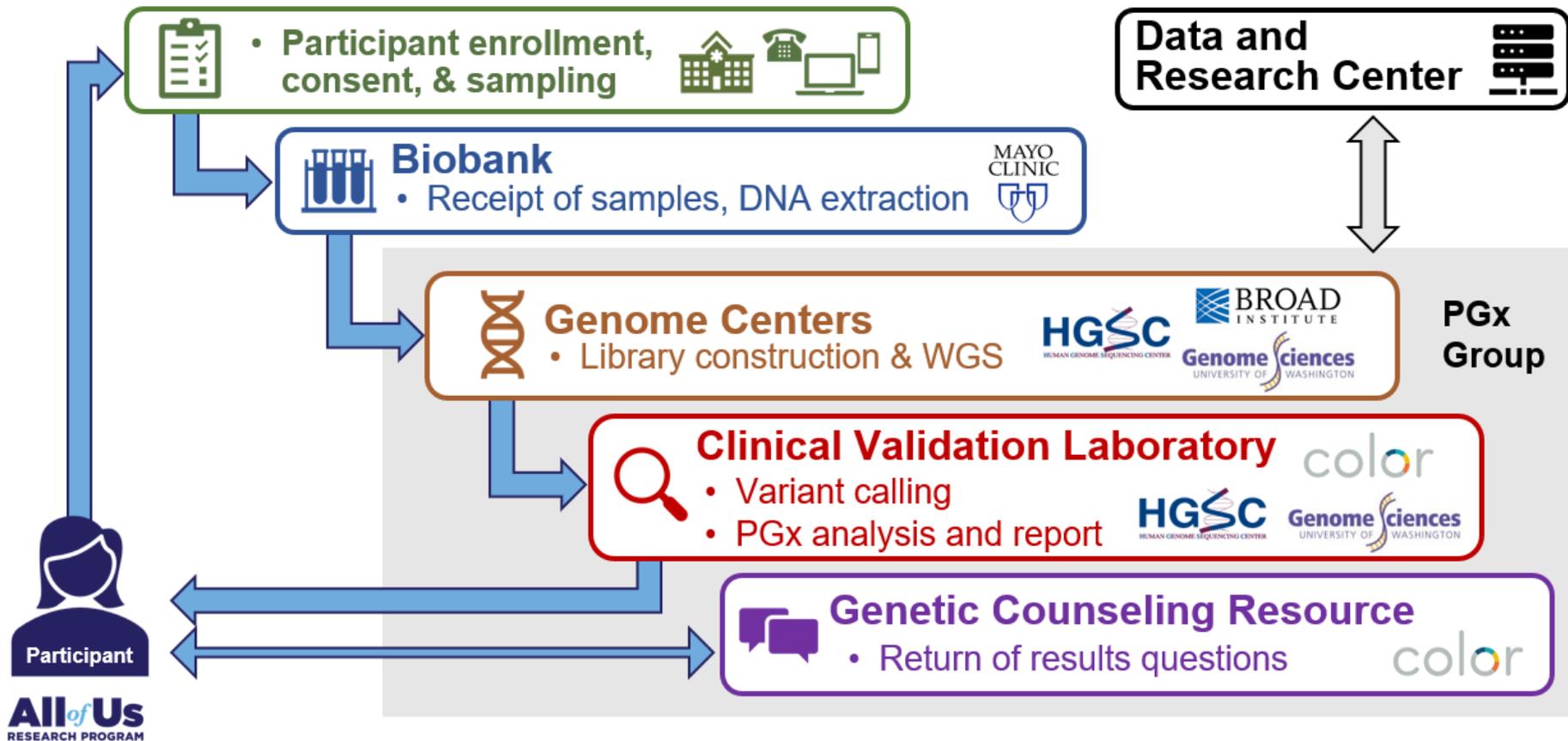
PGx data were ranked as most valuable to participants
(more than results about the genetic risk of disease)



Key features of the *All of Us* Research Program

- Participant-centered model for return of genomic results
- Needs to meet regulatory requirements
- Challenge of scaling to 1M+ participants
- Focus on diversity

PGx Testing at *All of Us* Genome Centers



Consent model

- Participants must agree to genomics return

The screenshot displays the user interface of the All of Us Research Program. On the left is a navigation sidebar with icons and labels for: Dashboard, My Data, Notifications (with a red notification badge), Sync Apps & Devices, Agreements (highlighted in light blue), Settings, and Support. The top right corner features a 'Log Out' link. The main content area shows a breadcrumb trail: 'Agreements > Manage Consent to Get DNA Results > Consent to Get DNA Results'. Below this is a progress bar. The primary question is 'Would you like us to check your DNA and tell you what we find?'. Three radio button options are presented: 'Yes, I want to learn some or all of my DNA results.' (which is selected), 'No, I do not want to learn about any DNA results.', and 'I'm not sure right now.'. Each option is followed by a bulleted list of terms and conditions.

All of Us
RESEARCH PROGRAM

Log Out

Dashboard
My Data
Notifications 5
Sync Apps & Devices
Agreements
Settings
Support

Agreements > Manage Consent to Get DNA Results > Consent to Get DNA Results

Would you like us to check your DNA and tell you what we find?

Yes, I want to learn some or all of my DNA results.

- I know *All of Us* will ask me later what specific types of DNA results I want. I get to choose.
- I know this means *All of Us* will tell me the kinds of results I choose to learn.
- I know this means I have to keep my contact information in *All of Us* up-to-date so that you can give me my results.
- I know this means that researchers can still use my DNA to make discoveries unless I stop participating in the program.

No, I do not want to learn about any DNA results.

- I know I can change my mind later.
- I know this means that researchers can still use my DNA to make discoveries unless I withdraw (quit).

I'm not sure right now.

- I know that until I decide, I will not learn about any of my DNA results.
- I know I can change my mind later.
- I know this means that researchers can still use my DNA to make discoveries unless I withdraw (quit).

All of Us
RESEARCH PROGRAM

Regulatory approval

- Investigational Device Exemption (IDE) required from the FDA
- Allows the return of certain findings from the investigational device to participants
- *All of Us* works closely with the FDA to enable PGx return of results safely and supported by the highest level of evidence
- IDE submission was refined through a series of pre-submissions and responses, in-person meetings, and teleconferences over a period of 18 months

Guiding Principles of Gene Selection

All of Us Genomics Committee (2018) and PGx Workgroup

- Focused on participant value and actionability
- Emphasis on gene-drug associations with the highest level of evidence
- Included genes impacting drug efficacy and adverse reaction potential
- Considers testing methods and AoU return of results model

Pharmacogenes for Initial Return

CYP2C19	Cytochrome p450 2C19
DPYD	Dihydropyrimidine dehydrogenase
G6PD	Glucose-6-phosphate dehydrogenase
NUDT15	Nudix hydrolase 15
SLCO1B1	Organic anion transporting polypeptide 1B1
TPMT	Thiopurine methyltransferase
UGT1A1	UDP Glucuronosyltransferase 1A1



Rigor of Allele/Variant Selection

Evidence review criteria

1. Selection of alleles with known functional consequence
2. Consideration of clinical testing “standards”
 - Tier 1 and Tier 2 AMP recommendations when available
 - Coverage by leading institutional/lab tests.
3. Identification of core variants necessary to call alleles per PharmVar
4. No absolute frequency cut-offs. Consideration of rare alleles that are specific to ethnic groups
5. Filtered for targets with available controls



Philip Empey
University of
Pittsburgh



Scott Topper
Color Genomics



Debbie Nickerson
UW



Joshua Smith
UW



Colleen Davis
UW



Eric Venner
BCM-HGSC



David Murdock
BCM-HGSC

Analytical Validation

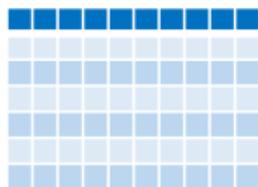
- Each Genome Center needed to achieve FDA IDE standards
- Completed a priori validation of PGx targets (desired variants when controls exist)
- **Accuracy of PGx calling:**
 - Blood-derived clinical samples (n= 159; orthogonally validated) = **100% concordance**
 - For rare alleles/no clinical controls: Get-RM cell lines (n = 135) = **99.8% concordance**
 - For those not in Get-RM, 1000 Genomes cell lines (n = 29) = **100% concordance**
- **Inter- and intra-lab equivalence >99%**
- **Precision of *All of Us* PGx calling = 99.3%**

Variant/Alele Selection

Gene	Alleles/variants
CYP2C19	*2,*3,*4,*6,*8,*9,*10,*16,*17,*22, *24,*35
DPYD	c.1905+1G>A (*2), c.1129-5923C>G, c.1679T>G (*13), c.2846A>T
G6PD	A-202A_376G; A-968C_376G; Asahi; Aures; Canton, Taiwan-Hakka, Gifu-like, Agrigento-like; Chinese-5; Ilesha; Kaiping, Anant, Dhon, Sapporo-like, Wosera; Kambos; Kalyan-Kerala, Jamnaga, Rohini; Mediterranean, Dallas, Panama, Sassari, Cagliari, Birmingham; Quing Yuan, Chinese-4; Seattle, Lodi, Modena, Ferrara II, Athens-like; Sibari; Ube Konan; Union, Maewo, Chinese-2, Kalo; Viangchan, Jammu
NUDT15	*2, *3
SLCO1B1	*5,*15,*17
TPMT	*2,*3A,*3B,*3C
UGT1A1	*6,*27,*28,*36,*37

Interpretation

Variants



Star allele “diplotype”

*1/*2



Predicted phenotype

CYP2C19
Intermediate
Metabolizer



- Translation translation tables
- Standardized phenotype terms (when available)

“Medicine and your DNA” Report Design

- Goal is to engage, inform, and achieve high participant comprehension
- Investigational device, “Research result”
- “If your doctor has prescribed medicine for you, keep taking it”
- Encourages sharing with the participant’s doctor and pharmacist.
- Includes normal results
- Emphasizes genetic information is just one piece of the puzzle

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. They do that in many different ways. Some genes help move medicines to the right part of the body. Some genes help break down medicines and clear them from your body. Some genes even change medicines into a form that makes them work properly.

This test looked at a few of the genes in your DNA that can affect how medicines are used. The technical term for this kind of information is “pharmacogenetics.”

What is this kind of information used for? Doctors and pharmacists use this kind of information when they consider why medicines work differently for different people.

But doctors and pharmacists don't make decisions based on just DNA. Some other important considerations can be age, weight, health, diet, and other medicines you are taking at the same time.

IMPORTANT!

- **If your doctor has prescribed medicine for you, keep taking it.** It can be dangerous to stop taking a medicine, or to change the dose or timing of it, without first asking your doctor.
- This report comes from a research program so **it is a research result.** That means that neither you nor your doctor should use it to make any changes to your medicines. Your doctor would need a separate clinical test if they wanted to use the information.

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

Pharmacogenetics: Medicine and your DNA
1/11

Reporting Drug Associations

- Guiding principle: *Including drug information provides value*
- Based on rigorous evidence review using:
 - CPIC guidelines/supplements
 - FDA-approved labeling and Table of PGx Associations
 - Primary literature
- Considers medication factors such as route of administration
- Highly iterative with FDA (CDRH/CDER)

Reporting Drug Associations Continued

Gene	Drug(s)
<i>CYP2C19</i>	amitriptyline (Elavil®), brivaracetam (Briviact®), citalopram (Celexa®), clobazam (Onfi®), clomipramine (Anafranil®), clopidogrel (Plavix®), doxepin (Sinequan®), escitalopram (Lexapro®), flibanserin (Addyi®), imipramine (Tofranil®), pantoprazole (Protonix®), sertraline (Zoloft®), trimipramine (Surmontil®), voriconazole (Vfend®)
<i>DPYD</i>	capecitabine (Xeloda®), fluorouracil (Adrucil®)
<i>TPMT/NUDT15</i>	azathioprine (Imuran®), mercaptopurine (Purinethol®), thioguanine
<i>SLCO1B1</i>	simvastatin (Zocor®)
<i>UGT1A1</i>	atazanavir (Reyataz®), belinostat (Beleodaq®), Irinotecan (Camptosar®)

Reporting Drug Associations Continued

Gene	Drug(s)
<i>G6PD</i>	chloramphenicol, dabrafenib (Tafinlar®), dapsone, hydroxychloroquine (Plaquenil®), local anesthetics, mafenide (Sulfamylon®), methylene blue, nalidixic acid (NegGram®), nitrofurantoin (Macrobid®, Macrochantin®, Furadantin®), pegloticase (Krystexxa®), phenazopyridine, primaquine, probenecid (Col-Benemid®), rasburicase (Elitek®), sodium nitrite, sulfacetamide, sulfamethoxazole/trimethoprim (Bactrim®, Septra®), sulfanilamide, sulfasalazine (Azulfidine®), tafenoquine (Krintafel®),

How This Implemented



JANE DOE
DOB: May 25, 1977
ID: 123456

Specimen: Blood
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Collected: September 15, 2018
Report date: October 2, 2018

RESEARCH RESULT – Do NOT use this result to make any changes to your medicines.

 **DNA and medicine**

In some cases, pharmacogenetic information may help doctors and pharmacists choose medicines and doses.

The table below points out some medicines that may be affected by your genetic results. If you are taking one of these medicines, talk with your doctor or pharmacist about whether ordering a clinical pharmacogenetic test is right for you.

These medicines MAY BE impacted by your genetics

Medicine	Gene
simvastatin (Zocor®)	SLCO1B1
amitriptyline (Elavil®)	CYP2C19
citalopram (Celexa®)	CYP2C19
clobazam (Onfi®)	CYP2C19
clomipramine (Anafranil®)	CYP2C19
clopidogrel (Plavix®)	CYP2C19
doxepin (Sinequan®)	CYP2C19
escitalopram (Lexapro®)	CYP2C19

Designed to encourage participant conversations with their providers by linking results to drugs:

“If you are taking one of these medicines, talk to your doctor or pharmacist to determine whether ordering a clinical PGx test is right for you”

“Medicine and Your DNA” Report User Comprehension



205

Genetic-testing naive, non-*All of Us* participants

- 59.5% ≥45 years old
- 63.5% female
- 48.0% non-white
- 52.5% had an associate degree or less education



97.6%

Comprehension of Genetic Knowledge

(i.e., “My DNA may impact how I respond to certain medicines”)



98.4%

Comprehension of Self- efficacy Concepts

(i.e., “I understand I should not change my medical care based on my DNA test results”)

Education/Support

How could finding out my DNA results help me?

Knowing your DNA results may help your healthcare provider take better care of you or you may learn something about yourself that you find interesting. Please watch this short video to proceed.



Status and Updates

- IDE approval milestone achieved in July 2020
- Planned content updates
 - Expanded validations as controls are identified
 - Planned PGx targets with structural variation (e.g. *CYP2D6*)
 - New guidelines (e.g., *CYP2C9*)



[This Photo](#) by Unknown Author is licensed under [CC BY-SA-NC](#)

Part I: Q&A with Panel

Part II: Interactive Panel Discussion

Researcher Workbench
Demonstration and
Developing Tools for
Genomic Analyses
Andrea Ramirez , M.D., M.S.
National Institutes of Health



All of Us Researcher Workbench

Presented to ASHG
October 27, 2020

Andrea H. Ramirez, MD, MS
andrea.h.ramirez@vumc.org



All of Us Research Program Objectives

Nurture relationships

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

Catalyze a robust ecosystem

of researchers and funders hungry to use and support it

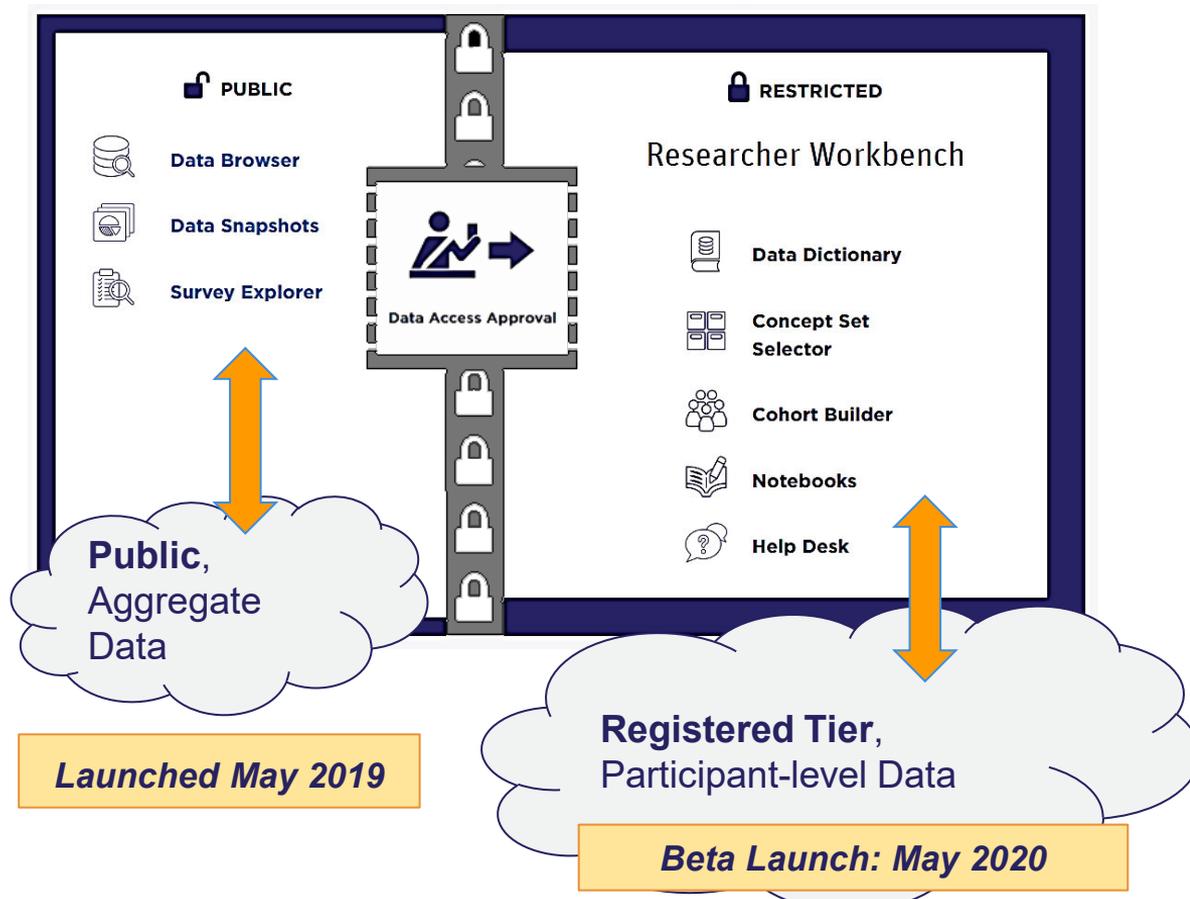


Deliver the largest, richest biomedical dataset

that is easy, safe, and free to access

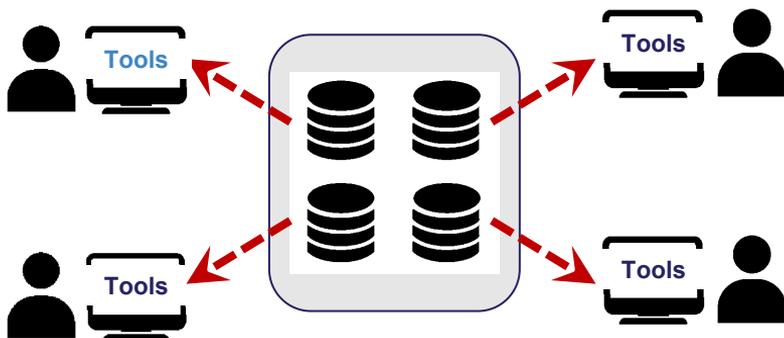
The Research Hub: Access & Analyze *All of Us* Data

<https://ResearchAllOfUs.org>



Traditional approach

Bring data to researchers



Discourages shared research

“Weakest link” security

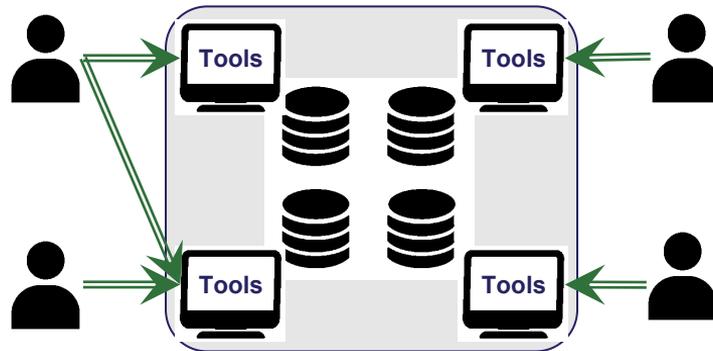
Huge infrastructure needed

Pay for multiple copies

Bespoke & unsupported tools

Cloud-centric approach

Bring researchers to data



Facilitates collaboration

Centralized security controls

Accessible to all researchers

Decreased cost of storage

Shared tool ecosystem

The Research Hub and Data Browser



Researchallofus.org: Public Tools for Browsing Aggregate Data

Search Across Data Types

Q Keyword Search

Data based on Curated Data Repository (CDR) dated 2/11/2020 with 225,360 total participants.

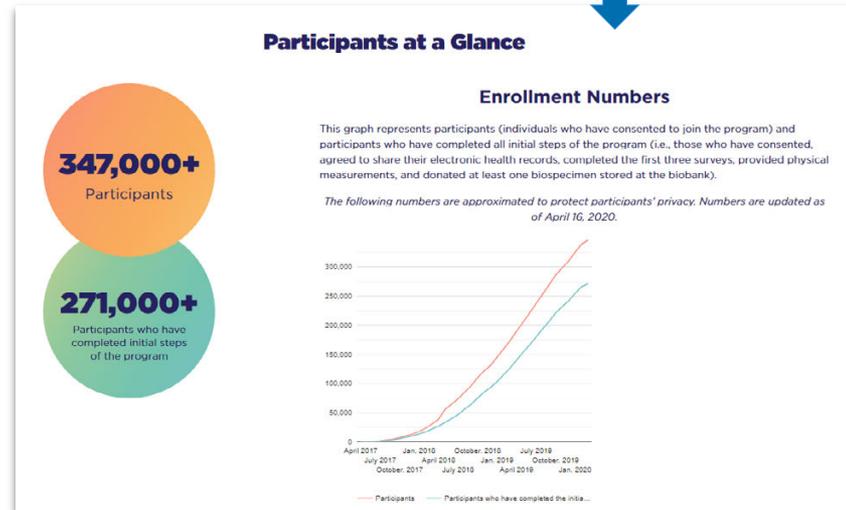
FAQs Introductory Videos User Guide

EHR Domains:

Conditions 20,782 medical concepts 113,280 participants in this domain View Top Conditions	Drug Exposures 20,955 medical concepts 104,580 participants in this domain View Top Drug Exposures	Labs & Measurements 10,050 medical concepts 109,180 participants in this domain View Top Labs & Measurements	Procedures 20,549 medical concepts 102,220 participants in this domain View Top Procedures
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← Data Browser

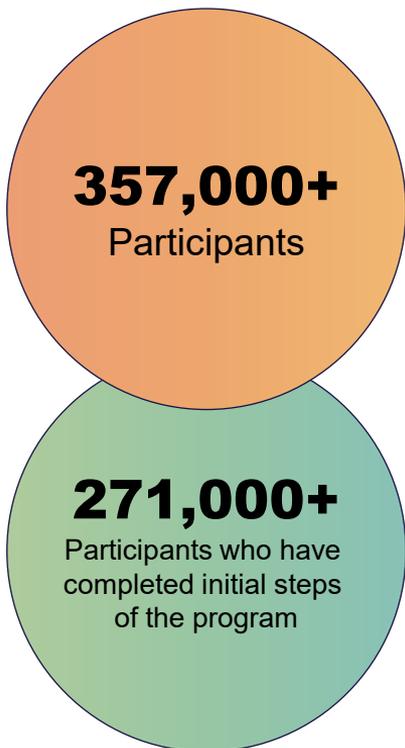
Data Snapshots



<h4>The Basics</h4> <p>This core survey (required for participation) asks basic demographic questions including questions about a participant's work and home.</p> <p>> View English version EXPLORE SOURCE MATERIAL > View Spanish version</p>	<h4>Lifestyle</h4> <p>This survey asks questions about a participant's use of tobacco, alcohol, and recreational drugs.</p> <p>> View English version EXPLORE SOURCE MATERIAL > View Spanish version</p>
<h4>Overall Health</h4> <p>This survey collects information about a participant's overall health including general health, daily activities, and women's health topics.</p> <p>> View English version EXPLORE SOURCE MATERIAL > View Spanish version</p>	<h4>Personal Medical History</h4> <p>This survey collects information about past medical history, including medical conditions and approximate age of diagnosis.</p> <p>> View English version EXPLORE SOURCE MATERIAL > View Spanish version</p>

← Survey Explorer

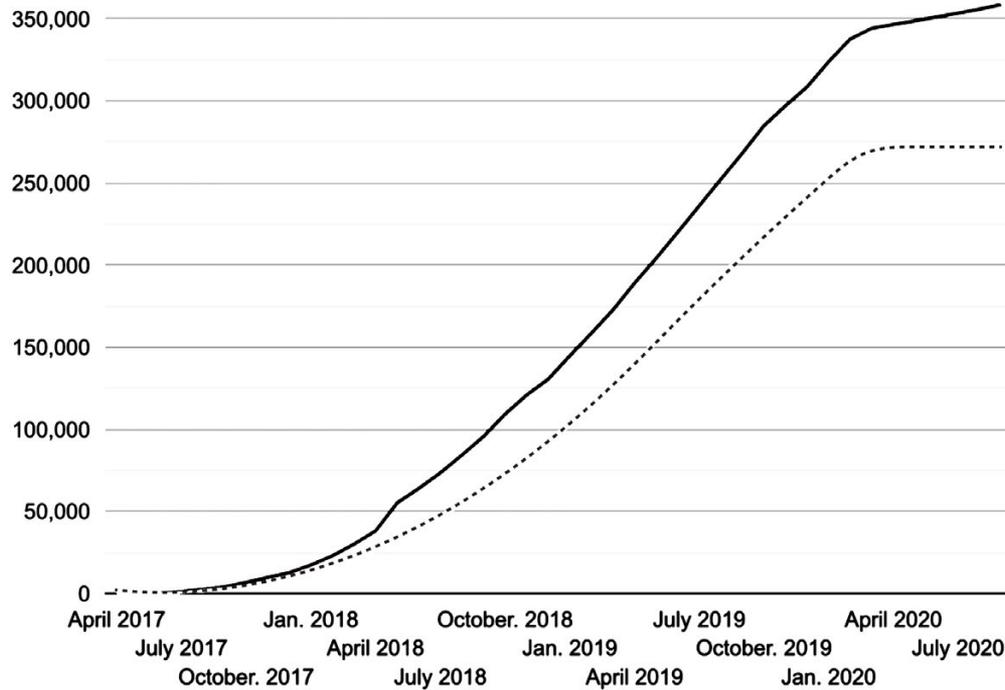
Participants at a Glance



Numbers are updated as of Sept. 10, 2020

In-person activities have been paused due to COVID-19

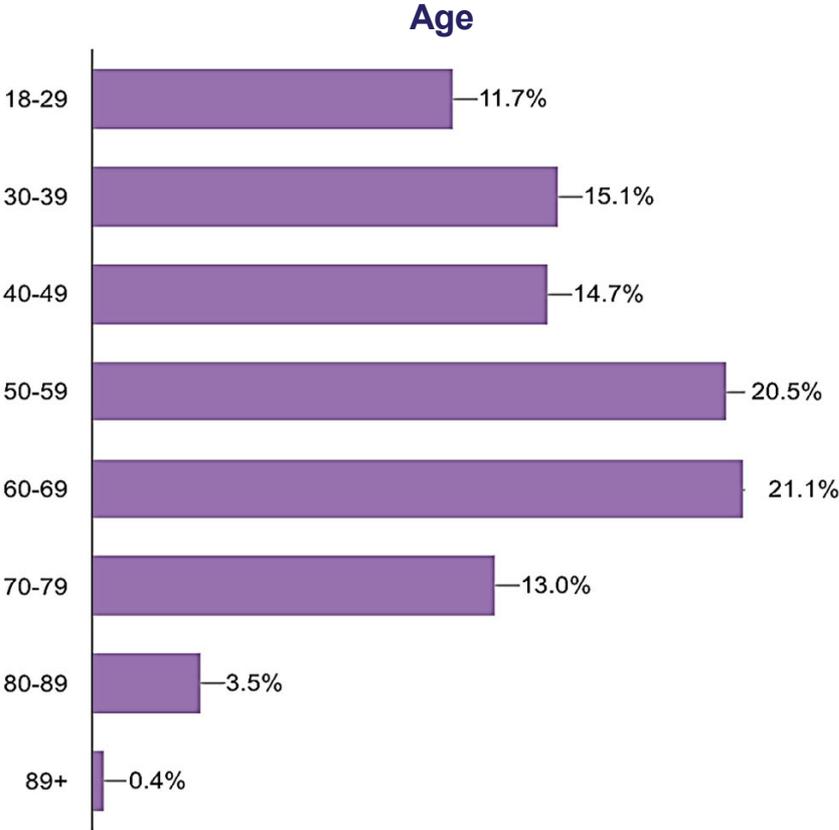
Enrollment Numbers



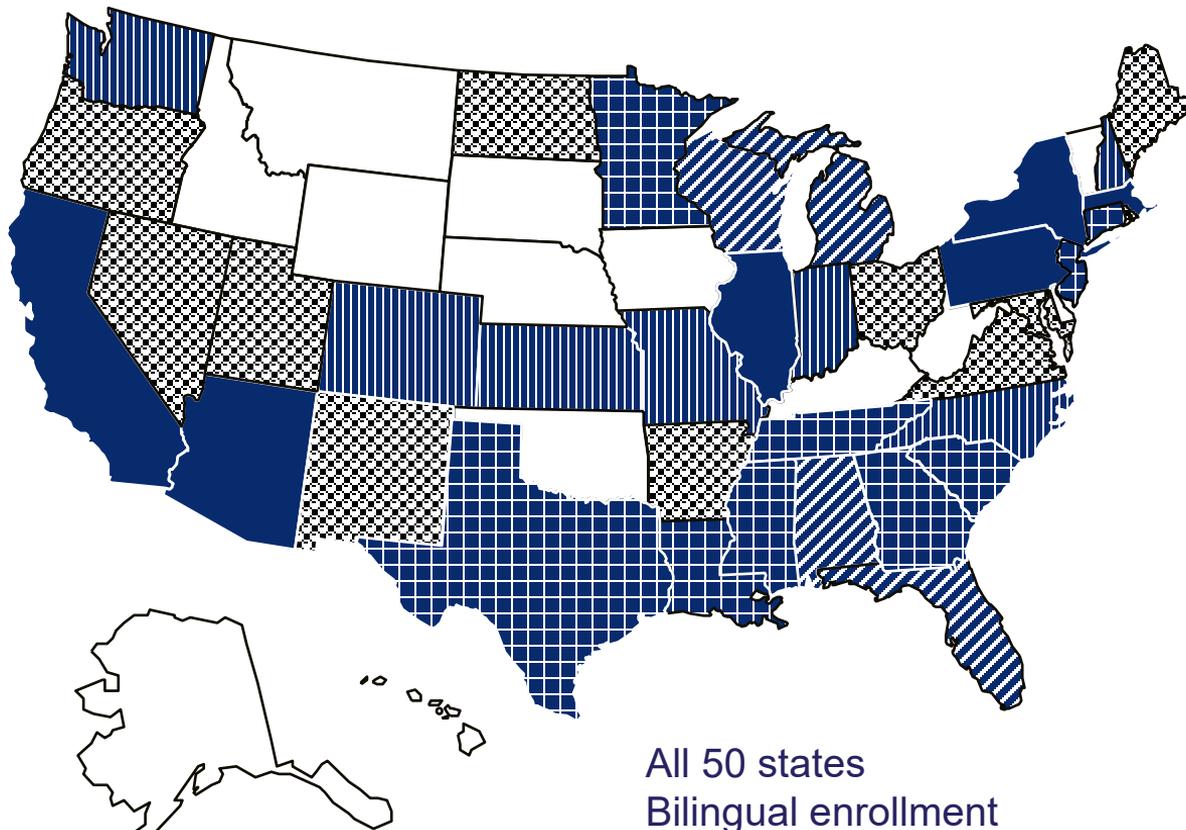
— Participants - - - - Participants who have completed the initial steps of the program

Selected Data Snapshots

(Updated 5/4/20)



Geography



Number of Participants as of December 17, 2020

-  **Under 100:** Alaska, Delaware, Hawaii, Idaho, Iowa, Kentucky, Montana, Nebraska, Oklahoma, South Dakota, Vermont, West Virginia, Wyoming,
-  **100 to 300:** Arkansas, Maine, Maryland, Nevada, New Mexico, North Dakota, Ohio, Oregon, Rhode Island, Utah, Virginia
-  **301 to 999:** Colorado, Indiana, Kansas, Missouri, New Hampshire, North Carolina, Washington
-  **1,000 to 9,999:** Connecticut, Georgia, Louisiana, Minnesota, Mississippi, New Jersey, South Carolina, Tennessee, Texas
-  **10,000 to 19,999:** Alabama, Florida, Michigan, Wisconsin
-  **More than 20,000:** Arizona, California, Illinois, Massachusetts, New York, Pennsylvania

All 50 states
Bilingual enrollment
Interactive mobile exhibits

All of Us Data Browser

- Interactive tool launched in beta on May 6, 2019
 - Provides summary statistics from the program's growing database
 - Open to everyone – no login!
 - Allows participants to understand the makeup of the cohort
 - Allows researchers to understand the characteristics of our participant population, explore the data types available, plan research questions

<https://DataBrowser.ResearchAllOfUs.org>

The screenshot displays the 'All of Us Data Browser' interface. At the top, there is a search bar labeled 'Search Across Data Types' with a search icon and the text 'Keyword Search'. Below the search bar, it states 'Data based on Curated Data Repository (CDR) dated 2/11/2020 with 225,140 total participants.' To the right of the search bar are three icons: 'FAQs' (a question mark), 'Introductory Videos' (a play button), and 'User Guide' (a document icon).

The main content is organized into several sections:

- EHR Domains:** This section contains four cards:
 - Conditions:** 20,776 medical concepts, 113,200 participants in this domain. View Top Conditions.
 - Drug Exposures:** 20,951 medical concepts, 104,500 participants in this domain. View Top Drug Exposures.
 - Labs & Measurements:** 10,049 medical concepts, 109,300 participants in this domain. View Top Labs & Measurements.
 - Procedures:** 20,546 medical concepts, 102,140 participants in this domain. View Top Procedures.
- Survey Questions:** This section contains four cards:
 - The Basics:** 16 questions available, 225,140 participants in this domain. This survey includes participant demographic information. View Complete Survey.
 - Overall Health:** 21 questions available, 219,800 participants in this domain. Survey includes information about how participant reports levels of individual health. View Complete Survey.
 - Lifestyle:** 26 questions available, 218,500 participants in this domain. Survey includes information on participant smoking, alcohol and recreational drug use. View Complete Survey.
 - Personal Medical History:** 465 questions available, 39,320 participants in this domain. This survey includes information about past medical history, including medical conditions and approximate age of diagnosis. View Complete Survey.
- Health Care Access & Utilization:** 57 questions available, 45,820 participants in this domain. Survey includes information about a participant's access to and use of health care. View Complete Survey.
- Family Medical History:** 67 questions available, 41,600 participants in this domain. Survey includes information about the medical history of a participant's immediate biological family members. View Complete Survey.
- Program Physical Measurements:** This section contains one card:
 - Physical Measurements:** 8 physical measurements, 192,900 participants in this domain. Participants have the option to provide a standard set of physical measurements as part of the enrollment process ("program physical measurements"). View Program Physical Measurements.

A Quick Look at the Data Browser

Search for specific keywords or browse using the different options underneath.

Search Across Data Types

Keyword Search

Data based on Curated Data Repository (CDR) dated 2/11/2020 with 225,140 total participants.

FAQs | Introductory Videos | User Guide

EHR Domains:

Conditions 20,776 medical concepts 113,200 participants in this domain View Top Conditions	Drug Exposures 20,951 medical concepts 104,500 participants in this domain View Top Drug Exposures	Labs & Measurements 10,049 medical concepts 109,300 participants in this domain View Top Labs & Measurements	Procedures 20,546 medical concepts 102,140 participants in this domain View Top Procedures
---	---	---	---

Survey Questions:

The Basics 16 questions available 225,140 participants in this domain This survey includes participant demographic information. View Complete Survey	Overall Health 21 questions available 219,800 participants in this domain Survey includes information about how participants report levels of individual health. View Complete Survey	Lifestyle 26 questions available 218,500 participants in this domain Survey includes information on participant smoking, alcohol and recreational drug use. View Complete Survey	Personal Medical History 465 questions available 39,320 participants in this domain This survey includes information about past medical history, including medical conditions and approximate age of diagnosis. View Complete Survey
--	---	--	--

Health Care Access & Utilization 57 questions available 45,820 participants in this domain Survey includes information about a participant's access to and use of health care. View Complete Survey	Family Medical History 67 questions available 41,600 participants in this domain Survey includes information about the medical history of a participant's immediate biological family members. View Complete Survey
---	---

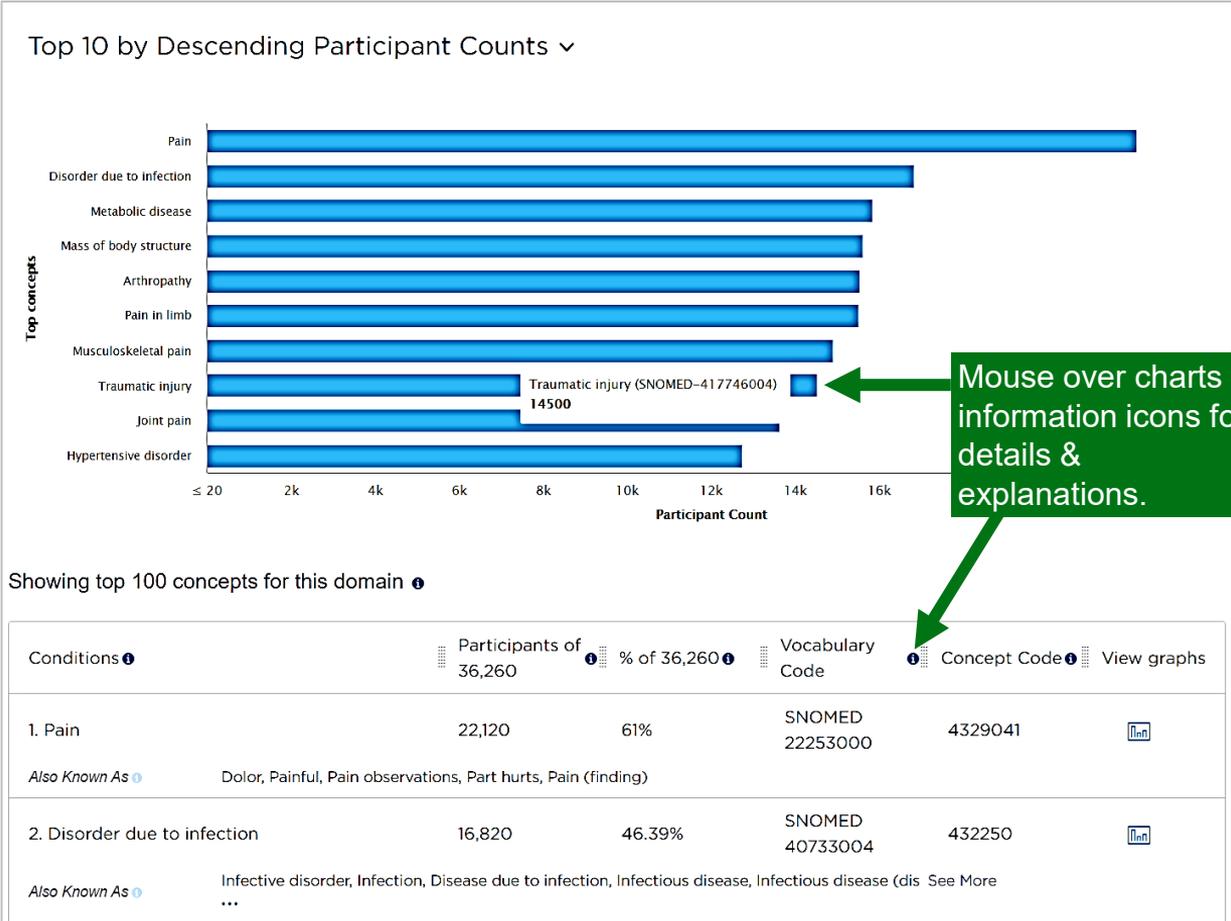
Program Physical Measurements:

Physical Measurements 8 physical measurements 192,900 participants in this domain Participants have the option to provide a standard set of physical measurements as part of the enrollment process ("program physical measurements"). View Program Physical Measurements

<https://DataBrowser.ResearchAllOfUs.org>

A Quick Look at the Data Browser

Available data gives insight into the participant cohort & research opportunities.



Mouse over charts & information icons for details & explanations.

A Quick Look at the Data Browser

Researchers can view the full surveys, including branching logic.



100,460

Participants completed this survey

7

Questions displayed

<https://DataBrowser.ResearchAllOfUs.org>

Question 1

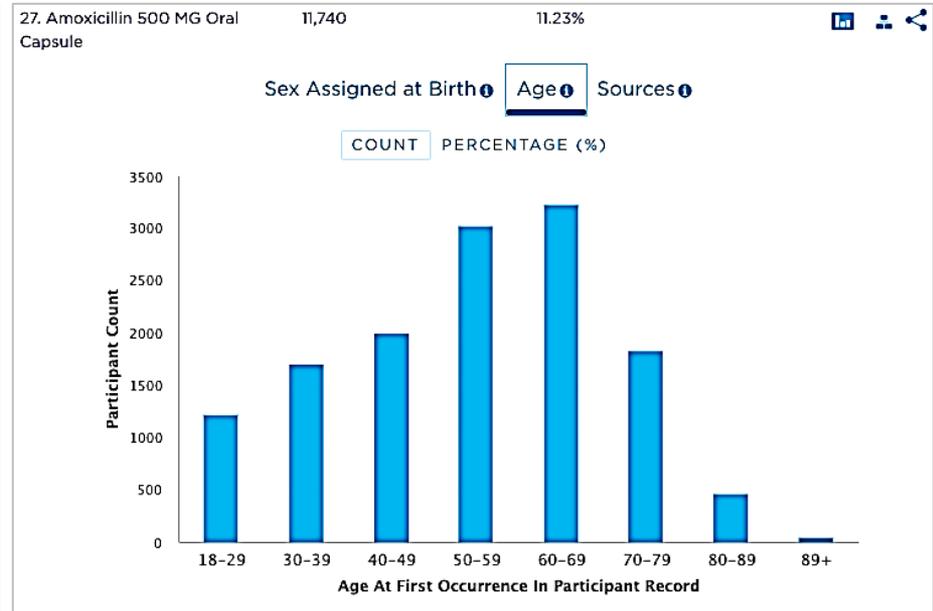
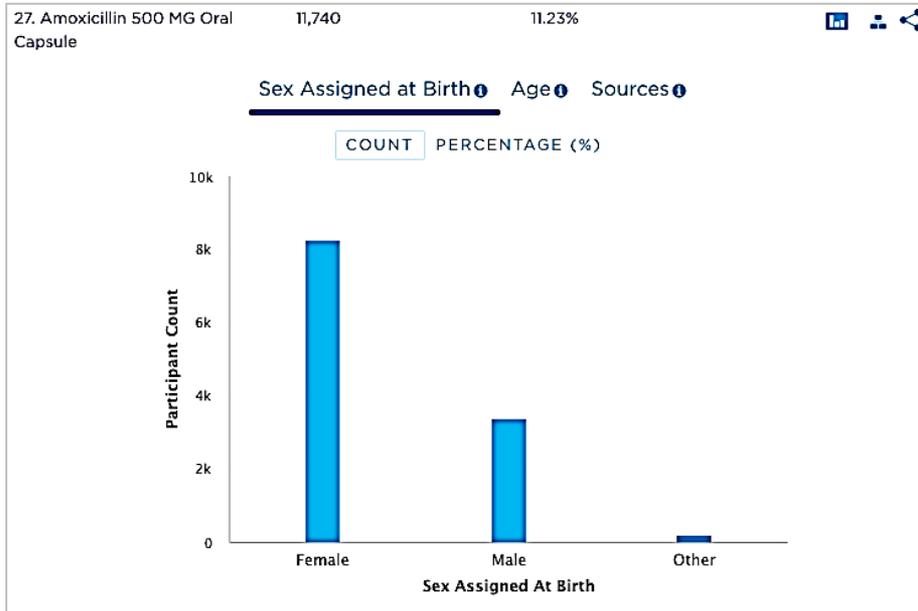
Have you smoked at least 100 cigarettes in your entire life? (There are 20 cigarettes in a pack.)

See Answers ▾

	Concept Code	Participant Count	% Answered	
No	1585859	59,140	58.87%	
Yes	1585858	39,060	38.88%	▾
↳ Do you now smoke cigarettes every day, some days, or not at all?				
ANSWER	Concept Code	Participant Count	% Answered	
Not at all	1585863	22,060	21.96%	
Every day	1585861	11,420	11.37%	
Some days	1585862	5,560	5.53%	
Prefer Not To Answer	903079	1,200	1.19%	
Skip	903096	340	0.34%	
Don't Know	903087	120	0.12%	
Did not answer	0	≤ 20	0.02%	
↳ In the past, have you ever made a serious attempt to quit smoking? That is, have you stopped smoking for at least one day or longer because you were trying to quit?				
ANSWER	Concept Code	Participant Count	% Answered	
Yes	1585868	33,340	33.19%	
No	1585869	5,780	5.75%	

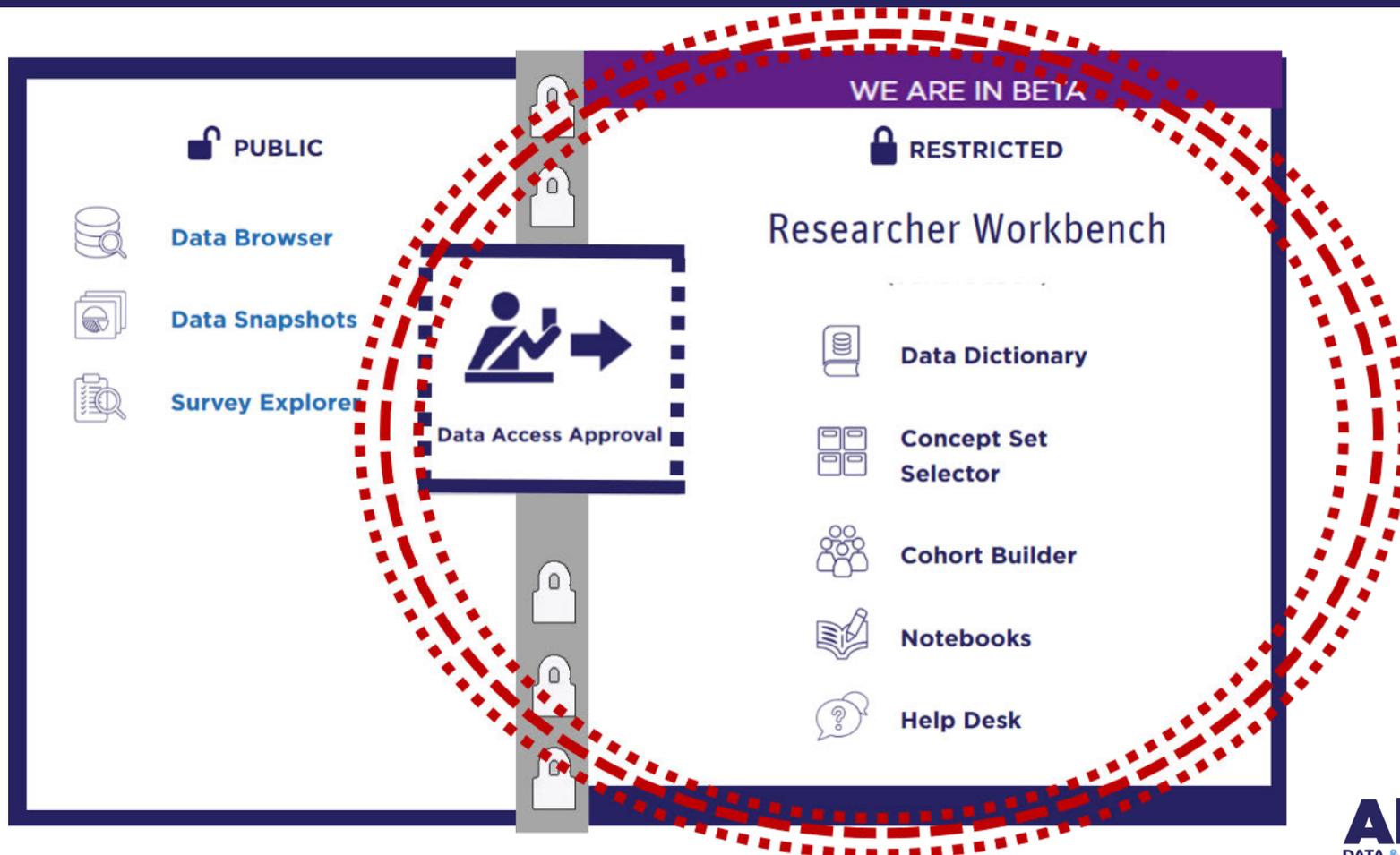
A Quick Look at the Data Browser

Explore data breakdowns by sex assigned at birth & age.



<https://DataBrowser.ResearchAllOfUs.org>

Research Hub → (Beta) Researcher Workbench



In May 2020 we launched the (Beta) Researcher Workbench

 | RESEARCHER LOGIN

[ABOUT](#) [DATA](#) [TOOLS](#) [DISCOVER](#) [FAQ](#)  [APPLY](#)

[WE ARE IN BETA](#) [LEARN ABOUT OUR BETA PHASE AND BEING A BETA TESTER >](#)

[Home](#) > [Apply](#)

Apply to be an *All of Us* Researcher

The Researcher Workbench is open to researchers [whose institutions have signed](#) a Data Use and Registration Agreement with the *All of Us* Research Program. Researchers at this time must also have an eRA Commons account and complete the *All of Us* Research Program data access process before they can access the Researcher Workbench and Registered Tier data. For more information, please visit the [Data Use Policies](#) page. If you are a researcher who does not have an eRA Commons account, please work with your institution to create one. Once your account is established, you may apply for access to the Researcher Workbench. For more information, visit the [eRA Commons](#) website.

About the Beta Researcher Workbench

Currently, an institutional agreement & eRA Commons account must be in place.

Feedback is welcome.

The tools will continue to evolve.

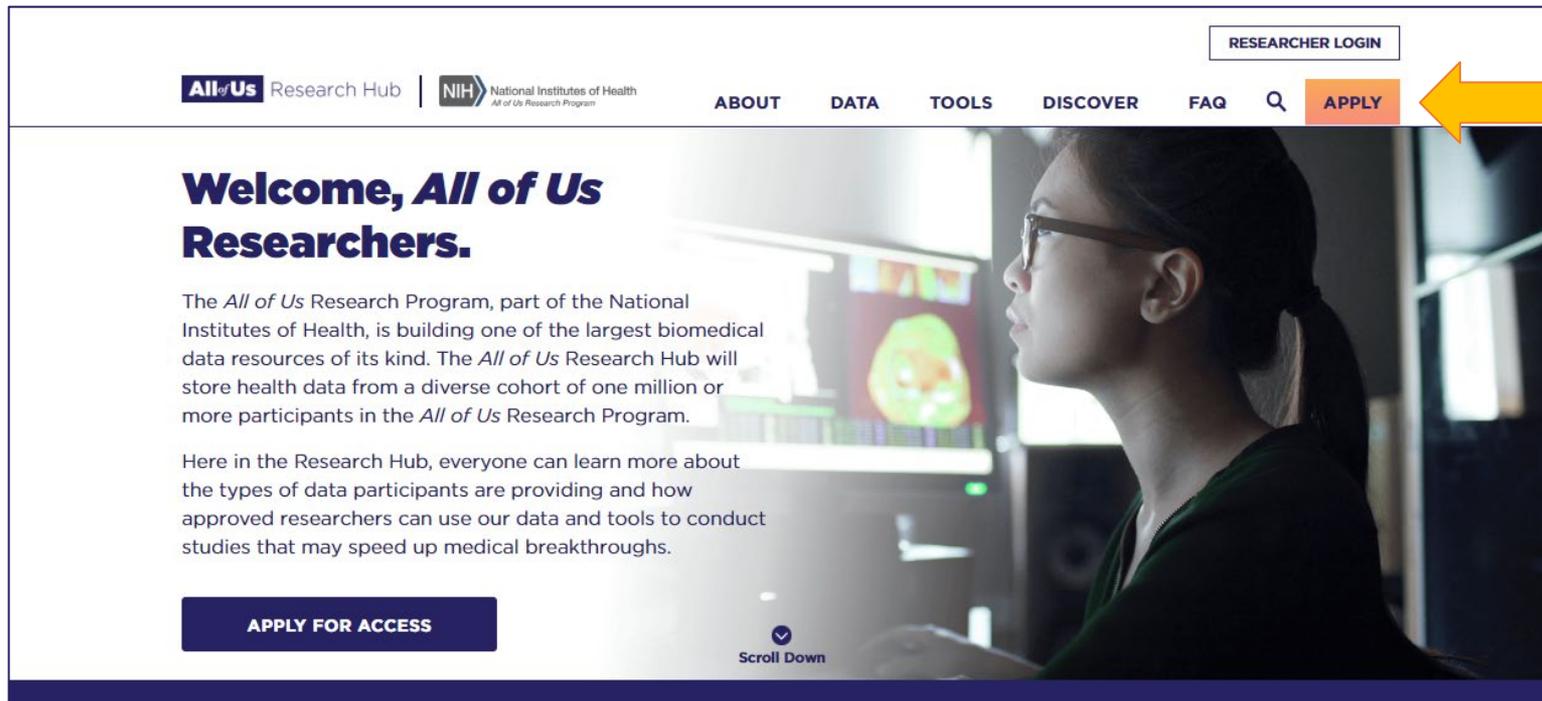
The program cohort is actively growing, and so is our data.

 Help



Interested in becoming a Beta Researcher?

Visit researchallofus.org to apply!



The screenshot shows the homepage of the All of Us Research Hub. At the top right, there is a "RESEARCHER LOGIN" button. The navigation menu includes "ABOUT", "DATA", "TOOLS", "DISCOVER", "FAQ", and "APPLY". A yellow arrow points to the "APPLY" button. The main content area features a large heading "Welcome, All of Us Researchers." followed by two paragraphs of text. At the bottom left, there is a dark blue button labeled "APPLY FOR ACCESS". At the bottom center, there is a "Scroll Down" button with a downward arrow icon. The background of the page is a photograph of a woman with glasses looking at a computer monitor displaying a colorful 3D model of a cell or organ.

All of Us Research Hub | **NIH** National Institutes of Health
All of Us Research Program

RESEARCHER LOGIN

ABOUT DATA TOOLS DISCOVER FAQ **APPLY**

Welcome, *All of Us* Researchers.

The *All of Us* Research Program, part of the National Institutes of Health, is building one of the largest biomedical data resources of its kind. The *All of Us* Research Hub will store health data from a diverse cohort of one million or more participants in the *All of Us* Research Program.

Here in the Research Hub, everyone can learn more about the types of data participants are providing and how approved researchers can use our data and tools to conduct studies that may speed up medical breakthroughs.

APPLY FOR ACCESS

Scroll Down

All of Us Data Access: “Share Widely and Wisely”

- End-goal is broad access
- Stepwise approach to minimize risk and to allow for learning



- **Multi-step access process involving**
 - Institutional Oversight
 - Researcher identity verification (eRA Commons ID)
 - Responsible Conduct of Research Training
 - Data User Code of Conduct

End of Research Hub and Data Browser Demo



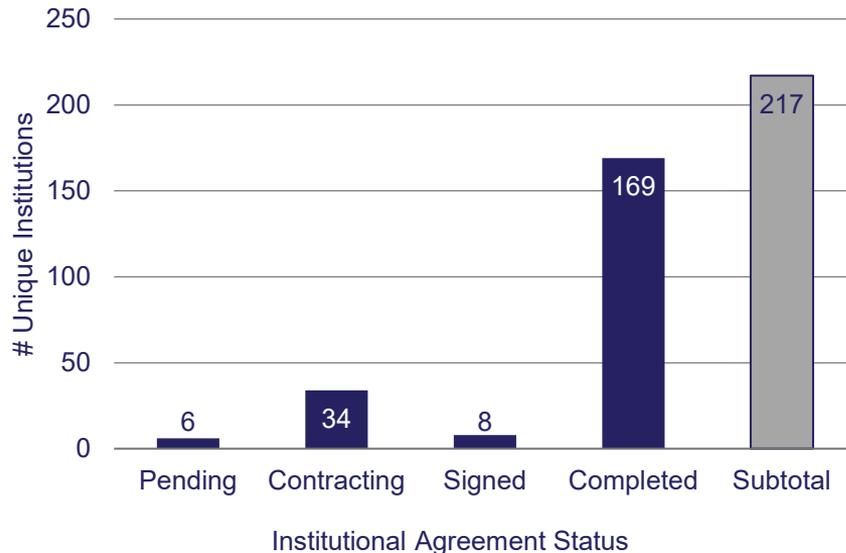
Registration and access processes are rapid.



Rapid Institutional Agreement Process.

Lightweight master contract developed collaboratively with CTSA contracting workgroup.

The median time to complete master contracting is 24 days.



Rapid Individual Onboarding Process.

The median time to complete all registration and access steps is ~ 2hrs.



Our Data are Growing. Here are the Current Data Types



Enroll, Consent and Authorize EHR

- Recruiting 18+ years old initially; plan to include children in future
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



Answering Surveys

- Initial surveys: The Basics, Overall Health, Lifestyle, Health Care Access & Utilization, Family Medical History, Personal Health History
- Additional surveys will be released on an ongoing basis.



Physical Measurements*

- Blood pressure
- Heart rate
- Height
- Weight
- BMI
- Hip circumference
- Waist circumference

**Based on diverse sampling and capacity*



Provide Biosamples*

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank

**Based on diverse sampling and capacity*



Wearables and Digital Apps

- Share data from wearable fitness devices, starting with Fitbit
- More integrations to come. E.g., integrated apps to track mood & cardio-respiratory fitness

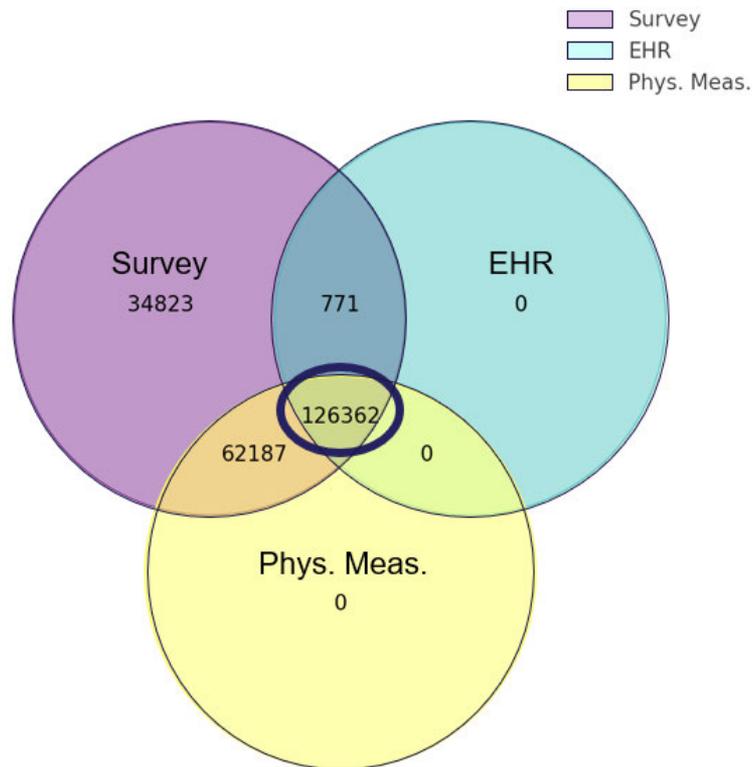
Available in the Current Dataset

Research Data Available Now

Data Type	Participant Count
Survey	>224,000
Physical Measurement	>188,000
Electronic Health Record	>127,000

*Counts reflect unique participants with ANY of data of the specified type.

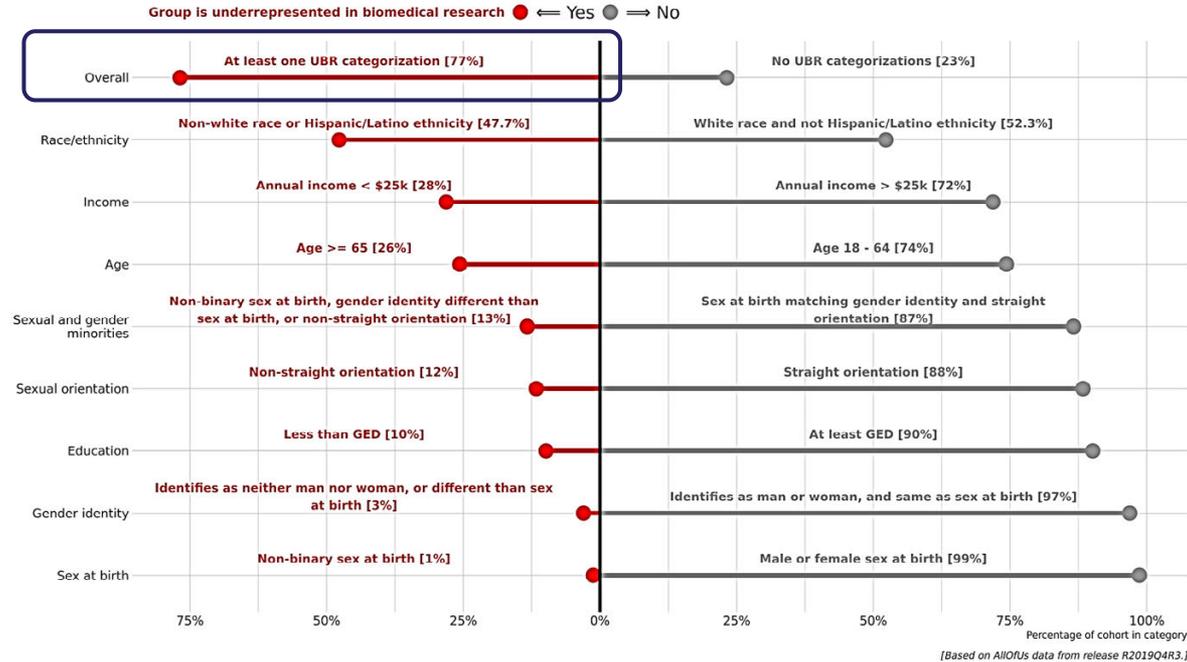
Count of participants with multiple data types



Participants included in this dataset are diverse.

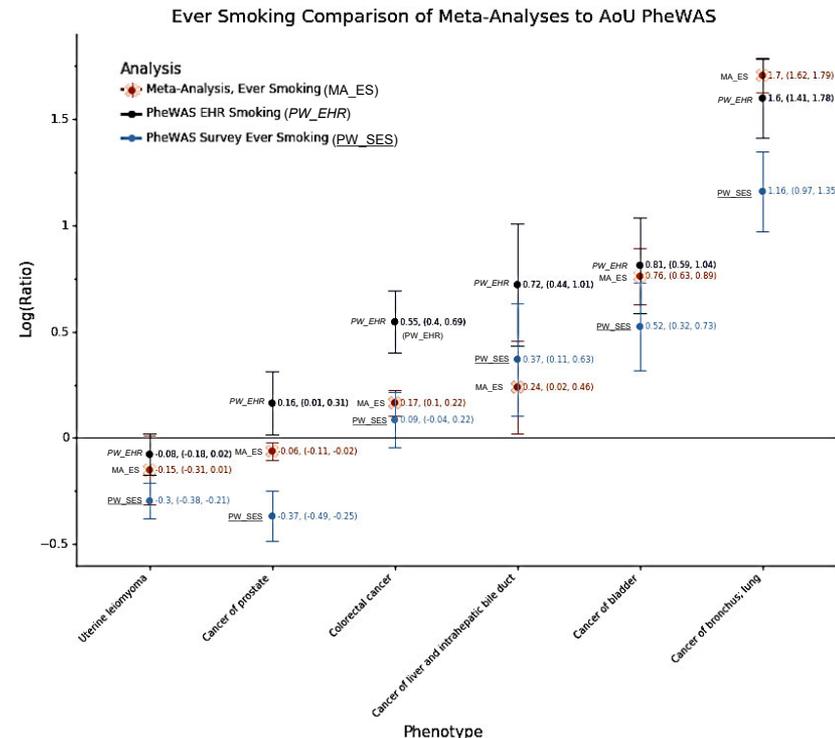
Cohort diversity: underrepresented groups in biomedical research

Categorizations based on explicit responses to survey questions.



This dataset reproduces known associations.

Description	EHR Ever Smoking OR (95% CI)	Survey Ever Smoking OR (95% CI)
Top 3 Increased risk effects		
Cancer of the bronchus; lung	4.94 (4.11, 5.95)	3.19 (2.65, 3.84)
Cancer within the respiratory system	4.94 (4.12, 5.92)	3.15 (2.62, 3.78)
Malignant neoplasm of bladder	2.36 (1.87, 2.98)	1.76 (1.42, 2.18)
Top 3 Decreased risk effects		
Vascular hamartomas and non-neoplastic nevi	0.51 (0.42, 0.62)	0.55 (0.48, 0.64)
Nevus, non-neoplastic	0.52 (0.43, 0.64)	0.57 (0.49, 0.66)
Benign neoplasm of skin	0.53 (0.49, 0.58)	0.62 (0.58, 0.66)



Want to learn more?

The screenshot shows the top of a medRxiv preprint page. The header includes the medRxiv logo, the text "THE PREPRINT SERVER FOR HEALTH SCIENCES", and logos for CSH, Cold Spring Harbor Laboratory, and BMJ Yale. A search bar is located in the top right. The main title of the preprint is "The All of Us Research Program: data quality, utility, and diversity". Below the title is a list of authors and a disclaimer: "This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice." Navigation options for Abstract, Info/History, Metrics, and a Preview PDF button are visible at the bottom of the page.

The screenshot shows the navigation menu of the All of Us Researcher Workbench. The menu is dark blue with white text. The items listed are: Home, Your Workspaces, Featured Workspaces (highlighted with an orange box), User Support, and Contact Us. The background of the workbench interface is partially visible, showing a grid layout with a search bar and a "WORKBENCH" header.

A. Ramirez, L. Suleiman, D. Schlueter, et al., *The All of Us Research Program: data quality, utility, and diversity*, medRxiv 2020.05.29.20116905; doi: <https://doi.org/10.1101/2020.05.29.20116905>

Coming Soon...

Winter 2020

Refreshed Public, Registered Tier
(w/ COVID-19 + Fitbit data)

2021

Controlled Tier Launch
(w/ Genomic Data)

May 2020: Registered Tier
Data Public Beta Launch

Nov 2019 Registered Tier
Data Alpha Launch

May 2019 Public Tier - Data
Browser Launch

Research Data Available Soon (Winter 2020)

Data Type	Participant Count*	
Survey	>315,000	~40% increase
COPE Survey	>63,000	New!
Physical Measurement	>260,000	~38% increase
Electronic Health Record	>204,000	~60% increase!
FitBit	<8,000	New!

*Counts reflect unique participants with ANY of data of the specified
Counts are approximate and subject to change upon final release of the dataset.

What is the Researcher Workbench?



Welcome to the Researcher Workbench



Welcome to the
RESEARCHER WORKBENCH



The secure platform to analyze *All of Us* data

Workspaces +

See all Workspaces

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

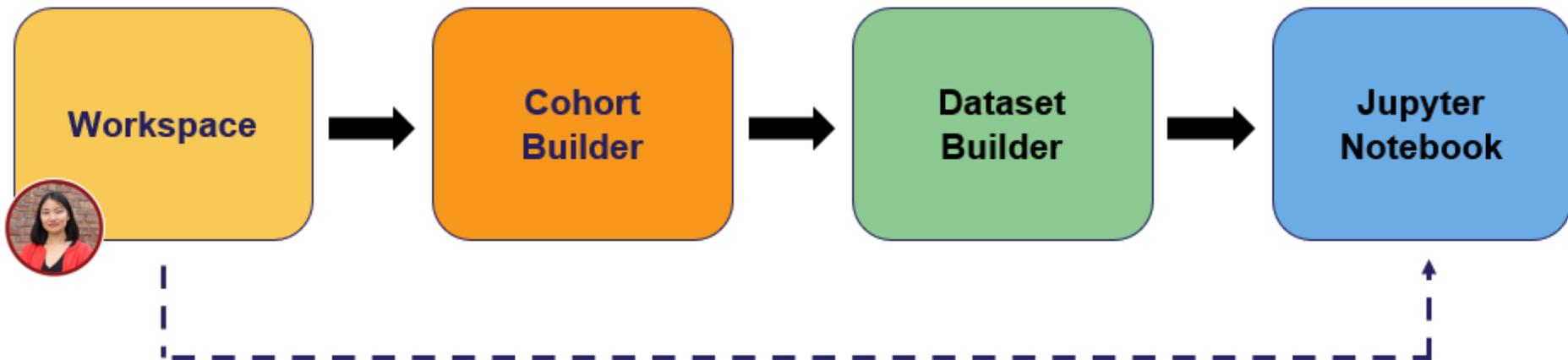
Recently Accessed Items

- 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

Quick Tour and Videos



Within the Researcher Workbench, a researcher (and their research team) collaborate in “workspaces.” The workflow is flexible & collaborative.



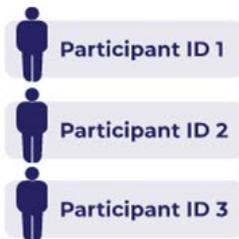
Point & Click Tools for Building Cohorts & Datasets

Cohorts +

A cohort is a group of participants based on specific criteria.



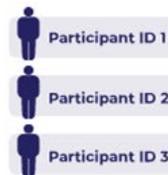
All of Us
Participants



Your Cohort

Datasets +

A dataset is a table containing data about a Cohort that can be exported for analysis.



Your Cohort



Data About
Your Cohort



ID 1	Med 1	Labs 1
ID 2	Med 2	Labs 2
ID 3	Med 3	Labs 3

Your Dataset

Workspace



Cohort
Builder



Dataset
Builder

Notebooks: Powerful, Flexible Tools for Reproducible Science

The screenshot displays the All of Us Researcher Workbench interface. At the top left is the 'All of Us RESEARCHER WORKBENCH' logo. The breadcrumb navigation shows 'Workspaces > Medications pathway (sequences) - Phase 1 > Notebooks > Duplicate of Medication sequences _ Paper'. Below this is a Jupyter Notebook interface with a menu bar (File, Edit, View, Insert, Cell, Kernel, Navigate, Widgets, Help, Snippets) and a toolbar with icons for file operations, running, and cell execution. The notebook content is titled 'Duplicate of Medication sequences _ Paper' and features a 'Contents' sidebar on the left. The sidebar lists sections: 1 Medication Sequences (1.1 Authors), 2 Introduction (2.1 Demonstration Goals, 2.2 Background: Medication, 2.3 Background: All of Us Data, 2.4 Methods: Tools, 2.5 Methods: Phenotype Characterization, 2.6 Methods: Exposure Variability), 3 Analysis Setup (3.1 Study Variables, 3.2 Define Functions for use), and 4 Type 2 Diabetes Medication (4.1 Define OMOP ancestor codes, 4.2 Extract participants with OMOP codes, 4.3 Extract the ATC5th and 6th digits). The main content area shows the text for section 2.1 'Demonstration Goals', which states that the notebook is part of a series of example analyses from the All of Us Research Program Demonstration Project. It lists two goals: to demonstrate how to implement a medication sequence for diseases including type 2 diabetes, depression and hypertension within the All of Us Researcher Workbench, and to demonstrate use of heterogeneous data sources within the All of Us research dataset. Section 2.2 'Background: Medication Sequencing' explains that medication sequencing was developed by researchers at Columbia University and the OHDSI network to characterize treatment pathways. It notes that the notebook demonstrates implementation of these algorithms on the All of Us research dataset to show how various data sources can be used for large-scale characterization. It concludes by stating that separate analyses will be performed for three common, complex diseases: 1. Type 2 Diabetes.

Workspace

Cohort
Builder

Dataset
Builder

Jupyter
Notebook

Featured Workspaces: Tutorials, Phenotypes, Ex. Analyses

All of Us
RESEARCHER WORKBENCH

K Kelsey Mayo

- Home
- Your Workspaces
- Featured Workspaces**
- User Support
- Contact Us

All of Us
RESEARCHER WORKBENCH

Workspaces > Medications pathway (sequences) - Phase 1 > Notebooks > Medication Sequences Code

Jupyter Medication Sequences Code

File Edit View Insert Cell Kernel Navigate Widgets Help Snippets

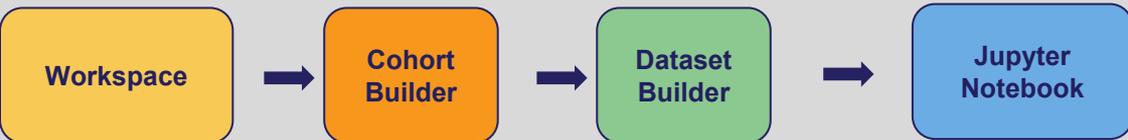
Code

In the following Sunburst plot, we only show the first two medications only.

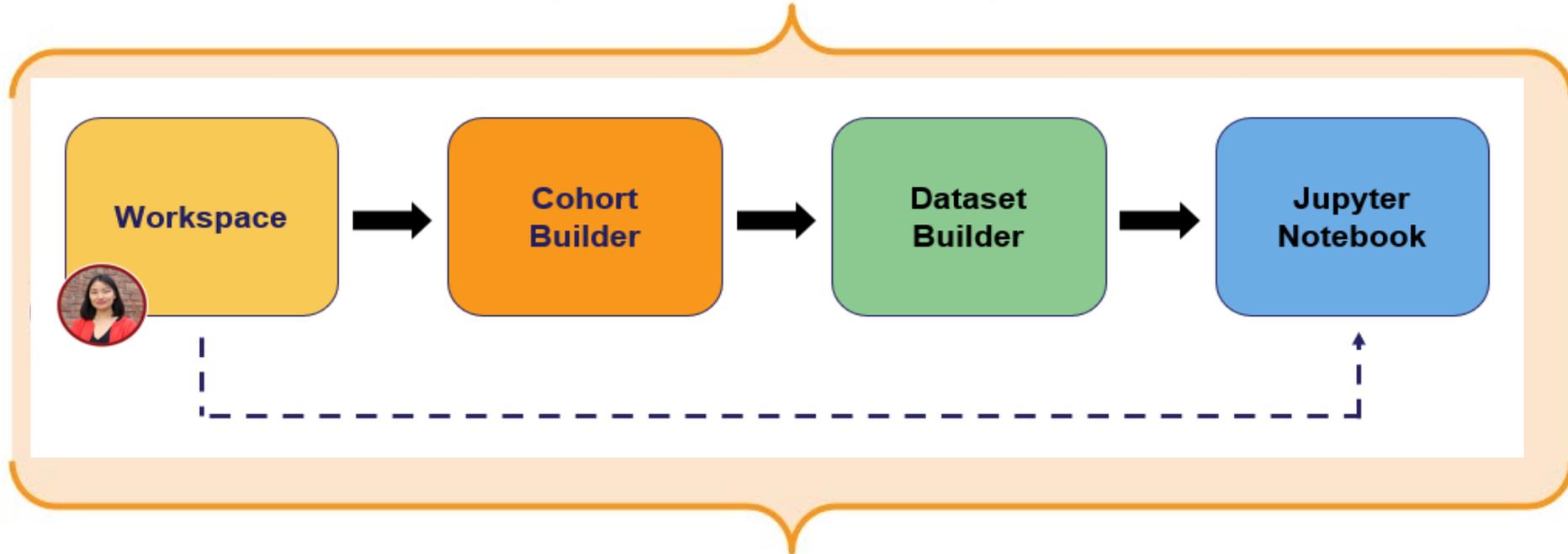
```
In [61]: fig = px.sunburst(filling_up_seq_df, path=['Med1', 'Med2'], values='count')
fig.show()
```

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All of Us Phenotype Library



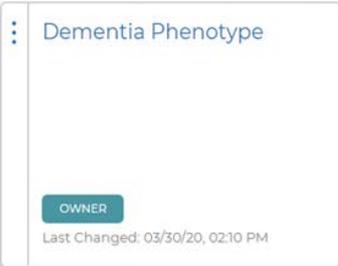
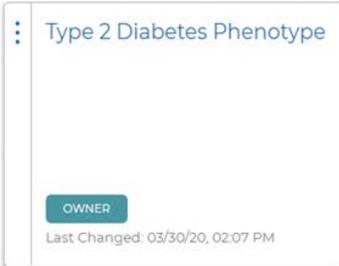
 Phenotype Library

 Tutorial Workspaces

RESEARCHER WORKBENCH WORKSPACE LIBRARY

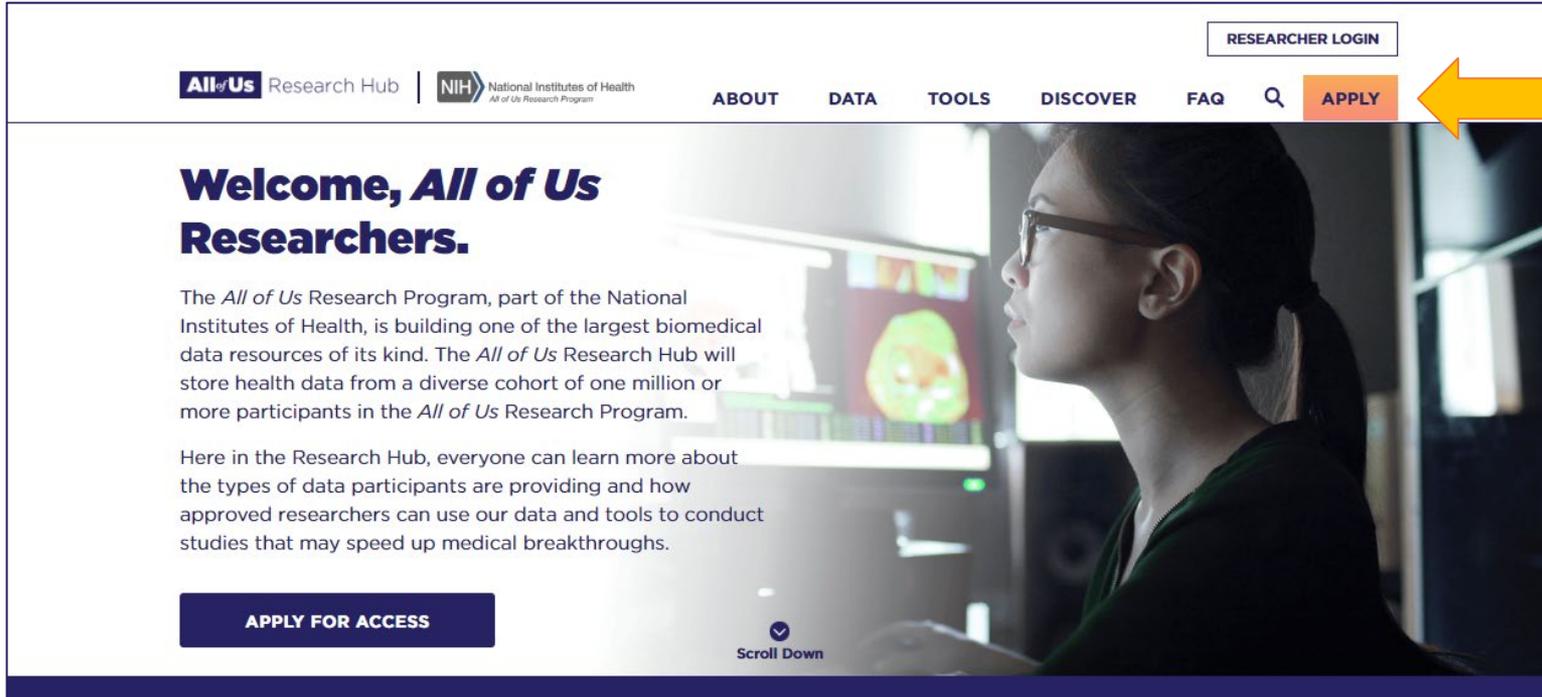
Phenotype Library

These workspaces demonstrate how computable electronic phenotypes can be implemented within the *All of Us* dataset using examples of previously published phenotype algorithms. You can open the workspaces to view them or "duplicate" the workspaces to edit and execute the algorithms.

 <p> Dementia Phenotype</p> <p> OWNER</p> <p>Last Changed: 03/30/20, 02:10 PM</p>	 <p> Depression Phenotype</p> <p> OWNER</p> <p>Last Changed: 03/30/20, 02:12 PM</p>	 <p> Ischemic Heart Disease Phenotype</p> <p> OWNER</p> <p>Last Changed: 03/30/20, 02:14 PM</p>	 <p> Type 2 Diabetes Phenotype</p> <p> OWNER</p> <p>Last Changed: 03/30/20, 02:07 PM</p>
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The screenshot shows the top navigation bar of the All of Us Research Hub website. The navigation menu includes links for ABOUT, DATA, TOOLS, DISCOVER, FAQ, and a search icon. The 'APPLY' button is highlighted in orange and is pointed to by a large yellow arrow from the right. Above the navigation menu is a 'RESEARCHER LOGIN' button. The main content area features a large heading 'Welcome, All of Us Researchers.' followed by two paragraphs of introductory text. At the bottom of the main content area is a dark blue button labeled 'APPLY FOR ACCESS' and a 'Scroll Down' indicator with a downward arrow icon.

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All of Us Research Program

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Welcome, *All of Us* Researchers.

The *All of Us* Research Program, part of the National Institutes of Health, is building one of the largest biomedical data resources of its kind. The *All of Us* Research Hub will store health data from a diverse cohort of one million or more participants in the *All of Us* Research Program.

Here in the Research Hub, everyone can learn more about the types of data participants are providing and how approved researchers can use our data and tools to conduct studies that may speed up medical breakthroughs.

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SAVE THE DATE!

All of Us Researcher Onramp

November 12 | 11 AM - 3 PM EST

Researchers interested in learning more about the *All of Us* Researcher Workbench are invited to tune into a virtual gathering on November 12th to:

- Learn about the program's vision
- Experience a demonstration of the workbench
- Hear directly from users
- Learn how to register, access, and analyze data

All of Us
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<https://allofus.nih.gov/news-events-and-media/announcements/all-us-researcher-onramp-event>

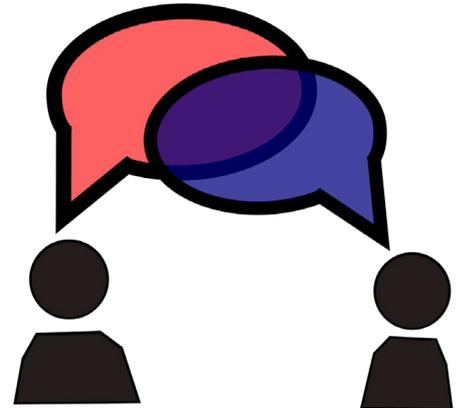
Please help us spread the word!

**Can you help us reach out to other early stage investigators,
trainees, bioinformaticians, and data science researchers?**

We'd love to connect with your community.

We are happy to arrange additional webinars and trainings.

Please email adrienne.s.roman@vumc.org



Thank you Data and Research Center (DRC) team!



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All of Us Researcher Onramp Event

What: Researchers interested in learning more about the *All of Us* Researcher Workbench and how to leverage its powerful analytic capabilities and are invited to tune in to this virtual gathering to:

- **Learn about the program's vision** from *All of Us* CEO Josh Denny, M.D., M.S., and University of California San Diego Professor of Medicine Lucila Ohno-Machado, M.D., Ph.D.
- **Experience a demonstration of the Workbench** by Kelsey Mayo, Ph.D., of Vanderbilt University
- **Hear directly from beta users** at leading research institutions about how they leveraged *All of Us* data and tools to power their studies
- **Learn how to register, access, and analyze data** within the *All of Us* Researcher Workbench

When: Thursday, November 12, 2020 | 11 a.m.–3 p.m. ET

Workshop registration is on a first-come, first-served basis. Register now!

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All of Us Research Hub

For individual demonstration requests, please email adrienne.s.roman@vumc.org

Part II: Q&A with Panel
