

The *All of Us* Research Program

Association of Nurses in AIDS Care and
the American Academy of HIV Medicine



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January 26, 2021

Goals

- Describe the mission, objectives, and scientific framework of the *All of Us* Research Program
- Discuss approaches for external researchers to explore and access the data currently being collected within the program
- Discuss *All of Us* efforts to address COVID-19

Mission & Objectives

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

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

**Deliver the largest,
richest biomedical
dataset ever,**
making it as easy,
safe, and free to use
as possible

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

**Contributes to the
All of Us team &
consortium**

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

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



Two Methods of Enrollment



**HEALTH CARE PROVIDER
ORGANIZATIONS**



DIRECT VOLUNTEERS

Current Protocol



Enroll, Consent and Authorize EHR

Recruiting 18+ years old initially; plan to include children in future

Online, interactive consent

Includes authorization to share EHR data



Answering Surveys

Initial surveys:

- The Basics
- Overall Health
- Lifestyle
- Health Care Access & Utilization
- Family Medical History
- Personal Health History

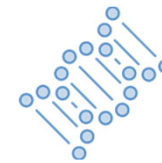
Additional surveys will be released on an ongoing basis.



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

Coming soon:

Integrated apps to track mood & cardio-respiratory fitness

Electronic Health Records

Participants are asked to authorize linkage of their EHR information.

Initial Data Types	Expanded Data Types (May Include)
<ul style="list-style-type: none">• Demographics• Visits• Diagnoses• Procedures• Medications• Laboratory visits• Vital Signs	<ul style="list-style-type: none">• Clinical Notes• Radiology, cardiology, and other reports• Mental Health Reports• Substance Abuse, Alcohol use, and Tobacco use• More laboratory results, potentially including genomics



Survey Modules

Surveys at enrollment:

1. The Basics
2. Overall Health
3. Lifestyle
4. Health Care Access and Utilization
5. Family Medical History
6. Personal Health History

New:

- COVID Participant Evaluation (COPE)

Many more in development:

- Diet
- Physical Activity
- Social Determinants of Health
- Mental Health and Wellbeing

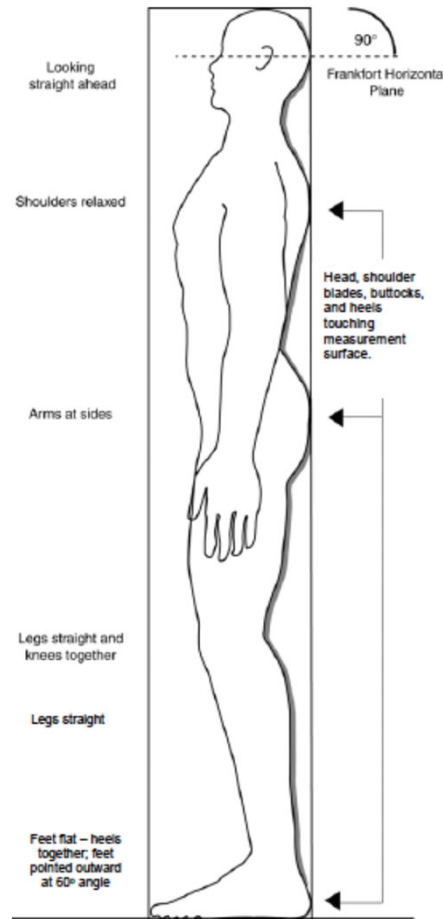
The screenshot displays a user interface titled "My Data". It features three tabs: "SURVEYS", "SNAP ANSWERS", and "MEASUREMENTS". The "SURVEYS" tab is active. Below the tabs, there are three cards representing completed surveys. Each card has a circular icon with a checkmark, the survey name, the completion date, and a "View & Compare Results" button.

Survey Module	Completion Date
The Basics	Completed On Apr 5, 2019
Overall Health	Completed On Apr 5, 2019
Lifestyle	Completed On Apr 5, 2019

Physical Measurements

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

Participants will have access to their physical measurements



All of Us

Thank you for taking part in the *All of Us* Research Program. By sharing your information, you're helping shape the future of health care. This form has your physical measurements from your visit today.

Date of Visit: _____

Height: _____ Weight: _____ Body Mass Index (BMI): _____

Hip Circumference: _____

Waist Circumference: _____

Blood Pressure (Systolic/Diastolic): _____ / _____

Heart Rate (Beats per Minute): _____

Adult Body Mass Index (BMI) Groupings:

BMI is less than 18.5	BMI is 18.5 to 24.9	BMI is 25 to 29.9	BMI is 30 or greater
underweight	normal	overweight	obese

(These apply to both men and women.)

You will see blood pressure and heart rate information on the right. This is to give you a broad sense of what is thought to be "normal" for an average person. Your "normal" may be different from this for many reasons. These reasons may include your age, level of fitness, and general health. Concerns or questions about your measurements? Please speak to your health care provider or contact the *All of Us* Support Center at 1-844-842-2855 or help@joinallofus.org.

The National Institutes of Health offers many resources to help people learn more about heart health. It also has tools to help people maintain a healthy weight.

Visit: <https://www.nhlbi.nih.gov/health>

Your preliminary findings suggest a potential concern with your blood pressure _____ / _____ or heart rate _____. We recommend an evaluation by a health care provider as soon as possible.

Normal Blood Pressure Range:

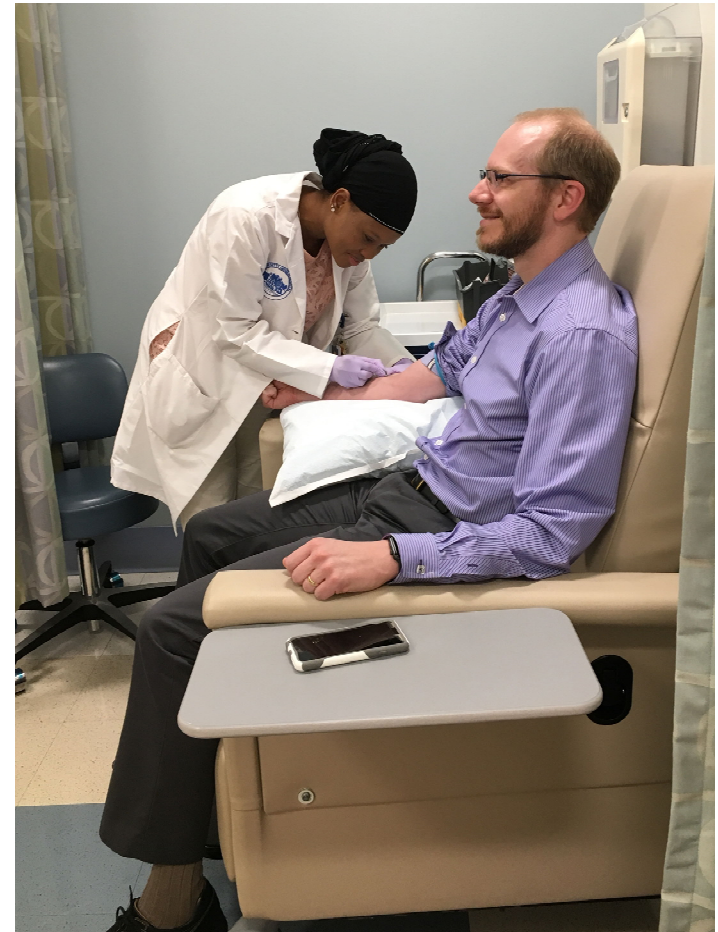
Normal Heart Rate Range:

Precision Medicine Initiative, NIH, 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.

joinallofus.org

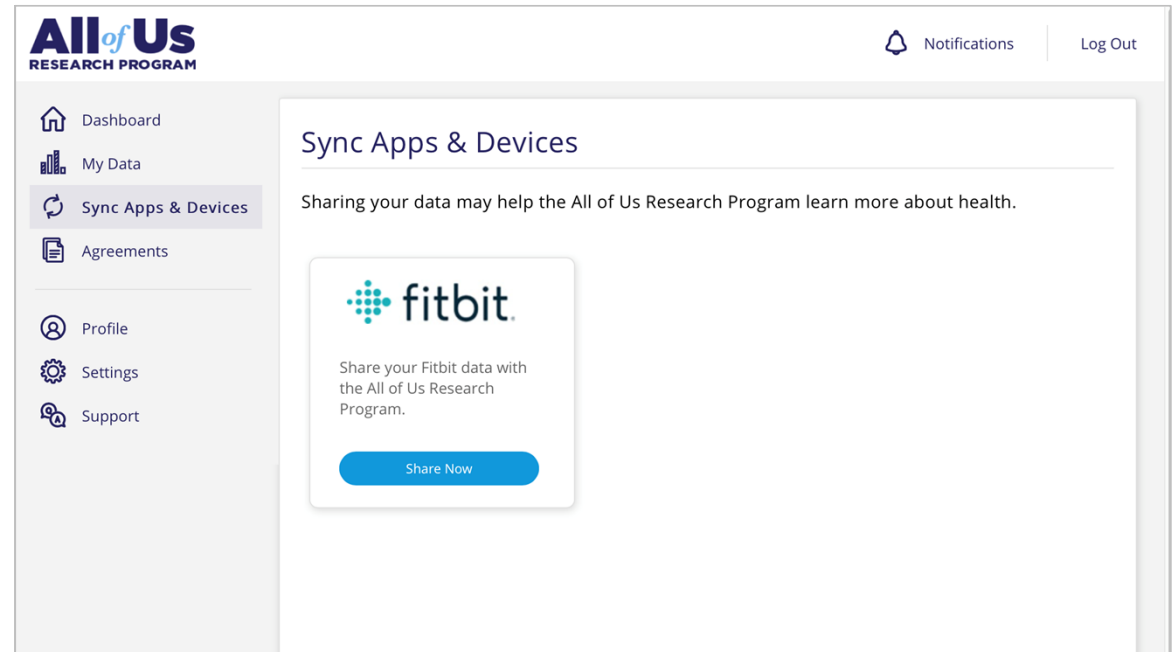
Biospecimen Collection

- ◎ Blood
 - DNA, plasma, serum, cfDNA, RNA
- ◎ Saliva (DNA), if blood draw is unsuccessful
- ◎ Urine



Wearables and Digital Apps

- “Bring your own device” (BYOD) program:
 - Fitbit (now)
 - Additional integrations in the future
- Pilots of specific smartphone-based apps in development



Genomics Plans

⦿ Infrastructure

- **Three Genome Centers:** to generate genotyping & whole genome sequencing for 1M participants
- **Genetic Counseling Resource:** to support the responsible return of information to interested participants

⦿ Return of Information

Over time, the program anticipates providing several kinds of information of interest to participants:

- Traits and ancestry
- Drug-gene interactions
- Genetic findings connected with risk of certain diseases



Genetics Engagement Module (GEM) with Color

Ancestry Analysis



Lactose Intolerance

Lactose intolerance means you have trouble digesting lactose contained in dairy products like milk or ice cream.

Linda, you are likely to be lactose intolerant.

What we looked at and why

A position in your DNA was analyzed that influences how much lactase your body makes. Lactase is an enzyme that breaks down lactose, a sugar found in milk and other dairy products.

- People who do not experience lactose intolerance produce enough lactase enzyme and are usually able to digest lactose

DNA marker	Gene	Your result
rs4988235	MCM6	GG

*Each of your parents provides you with a nucleotide at

Simple Traits

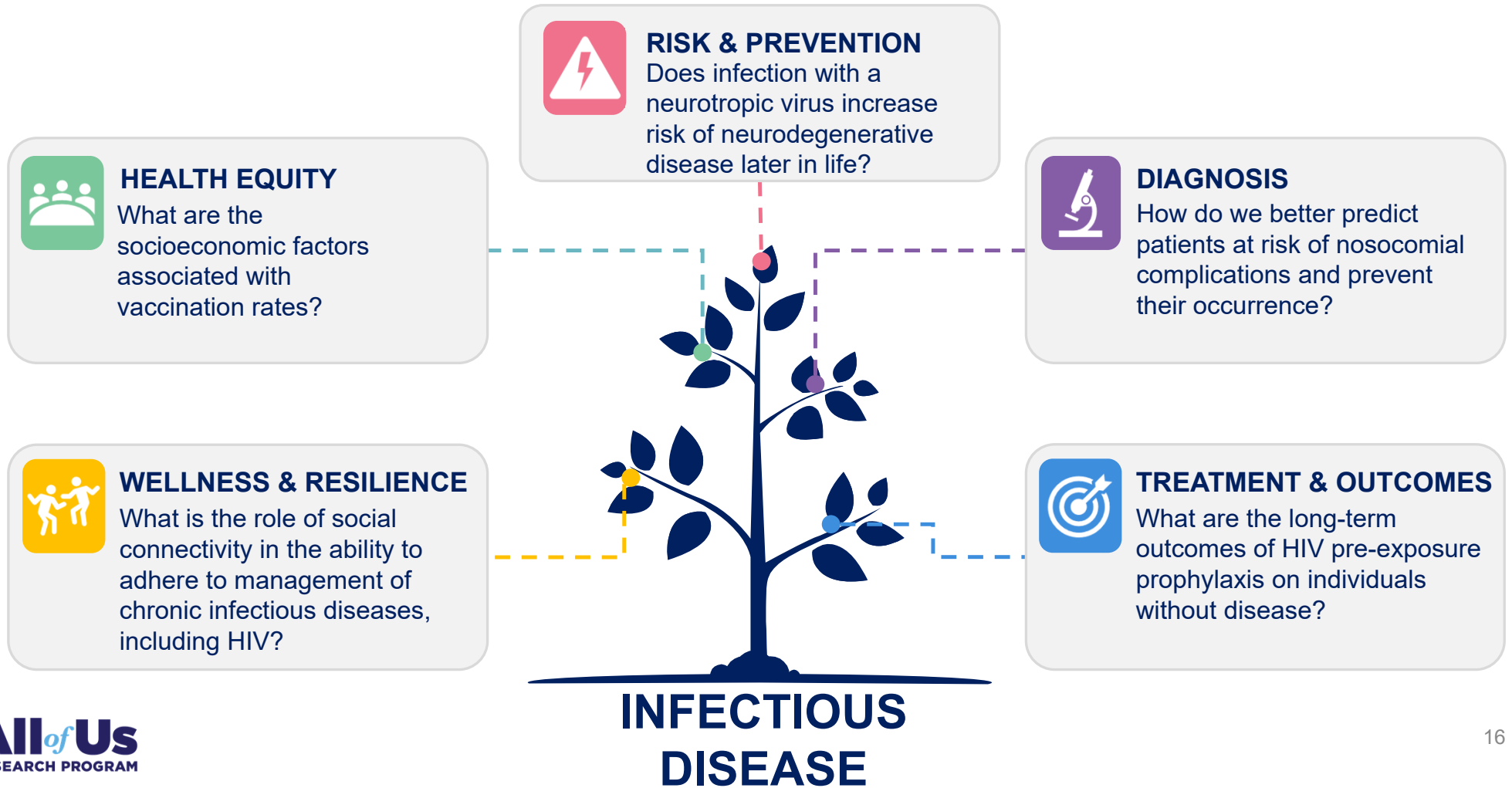
Scientific Framework

Scientific Framework

Enable research that will:

- Increase wellness and resilience, and promote healthy living
- Reduce health disparities and improve health equity in populations that are historically underrepresented in biomedical research (UBR)
- Develop improved risk assessment and prevention strategies to preempt disease
- Provide earlier and more accurate diagnosis to decrease illness burden
- Improve health outcomes and reduce disease impact through improved treatment and development of precision interventions

Example Use Case: Infectious Disease



Current Progress

- Opened doors nationally on **May 6, 2018**
- >272K participants have completed the full protocol, from all 50 states
 - >80% are underrepresented in biomedical research;
 - >50% are racial/ethnic minorities
- Built significant infrastructure to support the program:
 - 100+ academic, VA, FQHC, technology, & community partners
 - 350+ clinics enrolling participants and still expanding
 - Bilingual website, participant portal, app, and call center
 - Biobank with 24-hour shipping process and capacity for 35M+ vials
 - Interactive mobile exhibits that travel the country



All of Us Research Hub

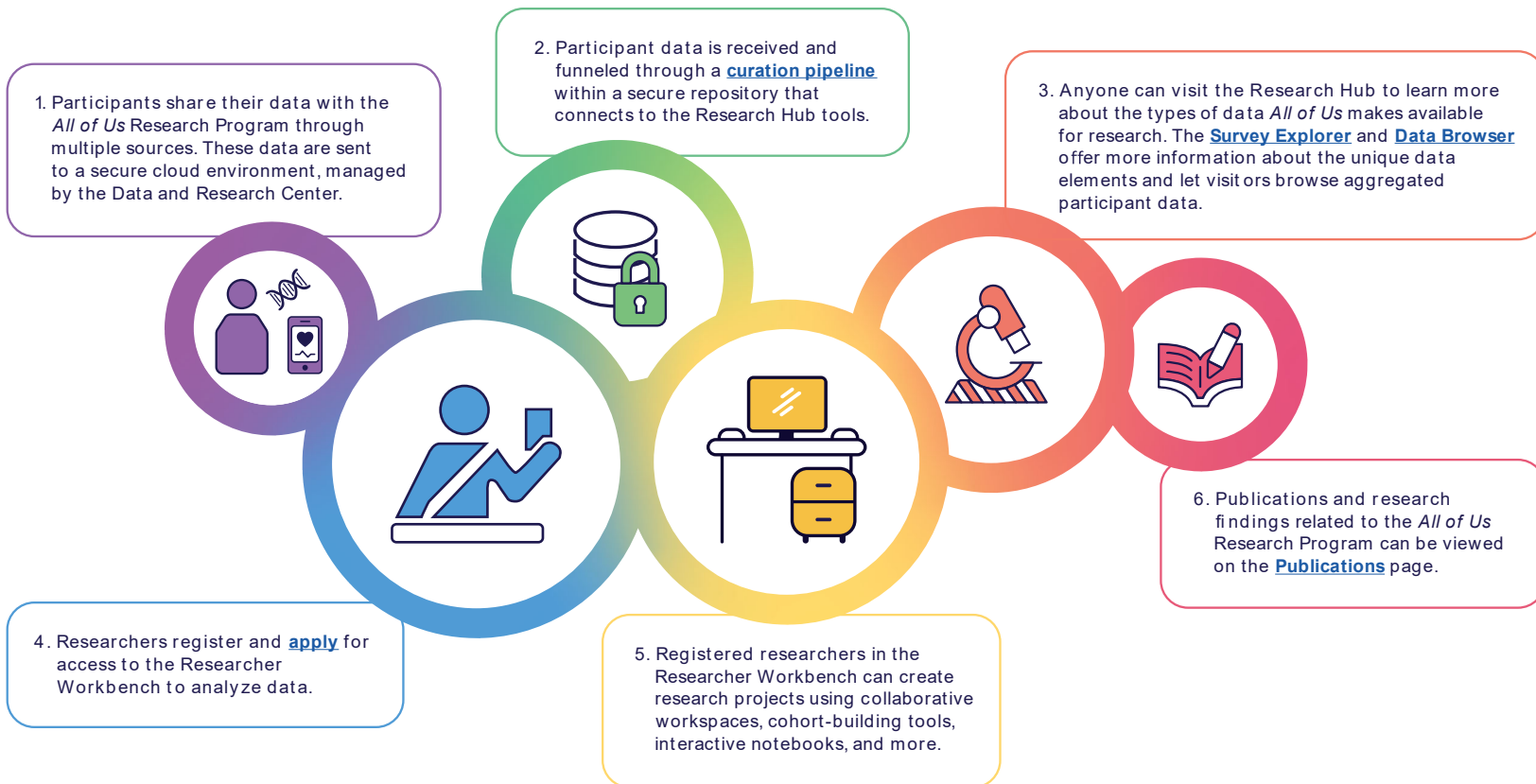
Research Hub Website

ResearchAllofUs.org

- Goal: To provide more information around program data and tools
 - **Data Snapshots:** broad cohort metrics
 - **Data Browser:** interactive tool
 - **Survey Explorer:** source information for participant-provided information
 - **Researcher Workbench:** restricted cloud-based platform designed to execute rapid, hypothesis-driven research

The screenshot displays the All of Us Research Hub website. At the top, there is a navigation bar with links for ABOUT, DATA & TOOLS, DISCOVER, FAQ, and APPLY. A RESEARCHER LOGIN button is also present. The main content area features a large header image of a woman looking at a computer screen. Below this, the text reads: "Welcome to the All of Us Research Hub" and "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 stores health data from a diverse group of participants from across the United States." A sub-section titled "Data Methodology" explains the program's approach to data quality, mentioning a "Data Curation Process" and an "Observational Medical Outcomes Partnership (OMOP) Common Data Model". Below this, the "Survey Explorer" section is visible, which describes the value of surveys in medical research and lists two types of surveys: "The Basics" and "Lifestyle".

How the Research Hub Works



Selected Data Snapshots

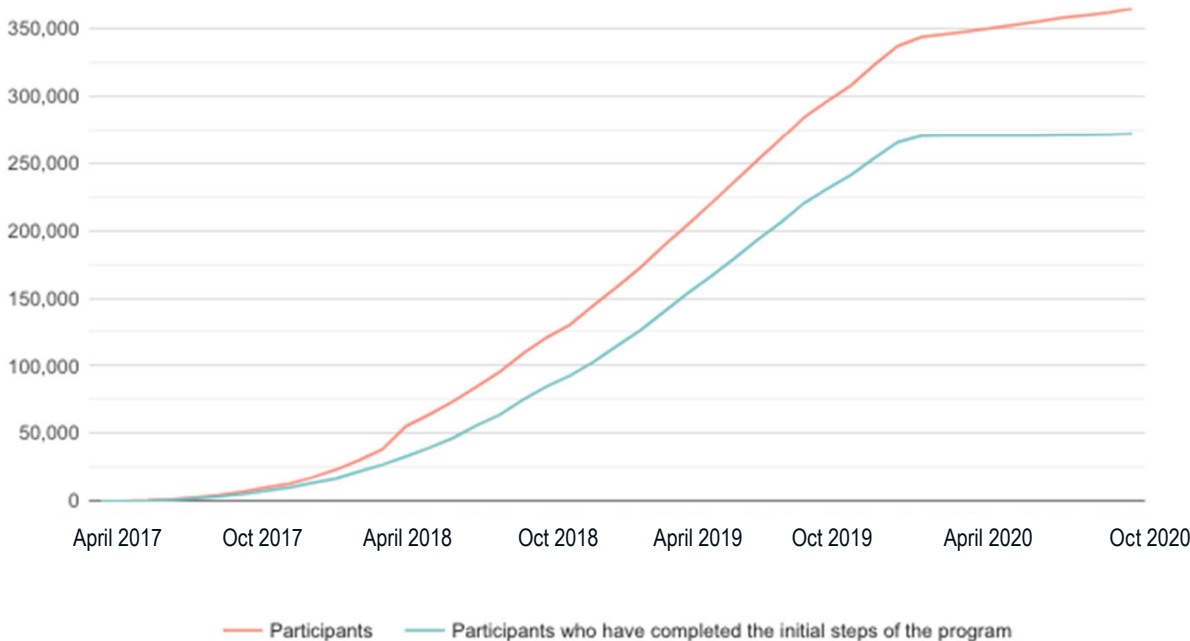
(Updated 1/12/21)



Enrollment Numbers

This graph represents participants who have consented to join the program and those who have completed all initial steps of the program. The initial steps are consenting, agreeing to share electronic health records, completing the first three surveys, providing physical measurements, and donating at least one biospecimen to be stored at the biobank.

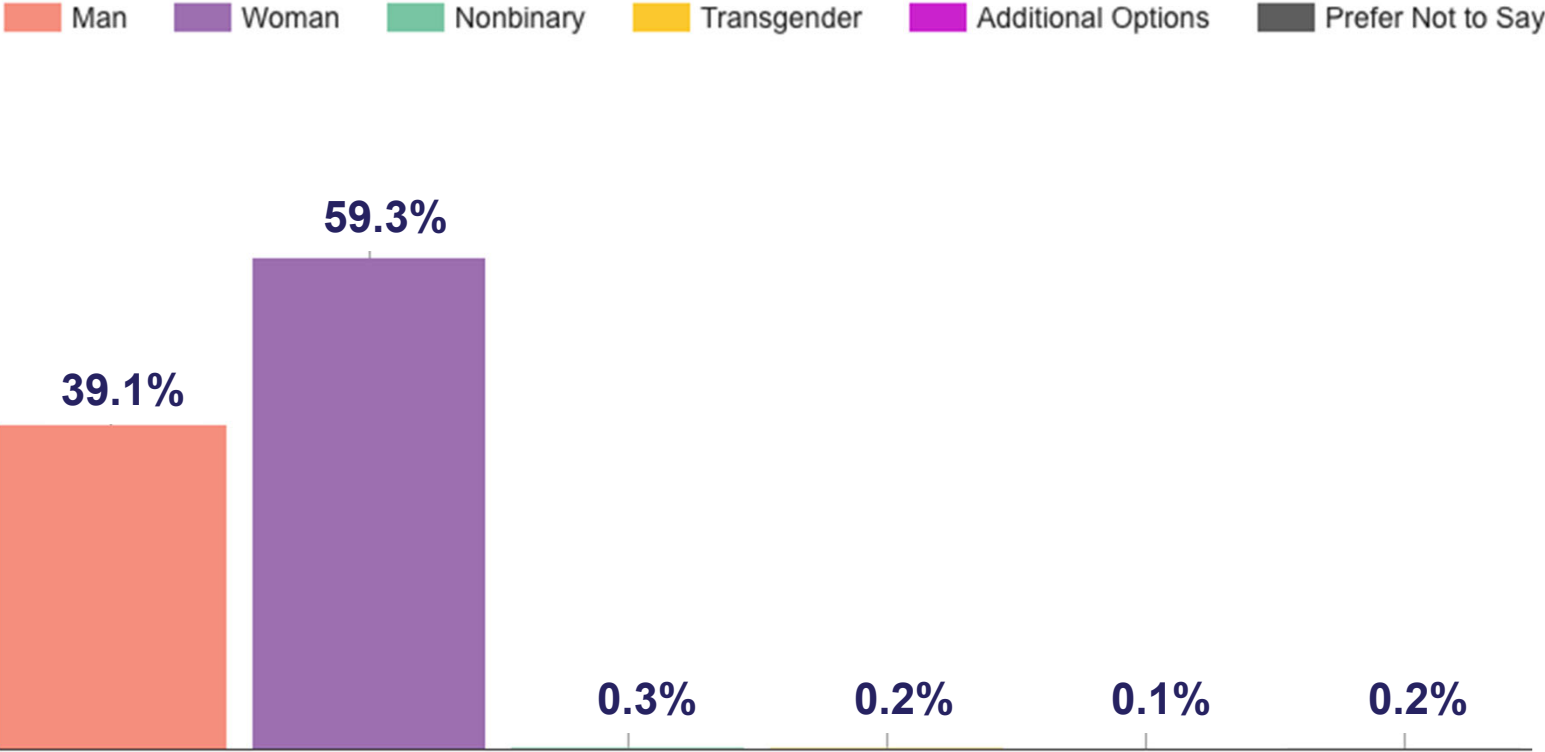
The following numbers are approximated to protect participants' privacy. Numbers are updated as of January 12, 2021.



Selected Data Snapshots

(Updated 1/12/21)

Gender Identity

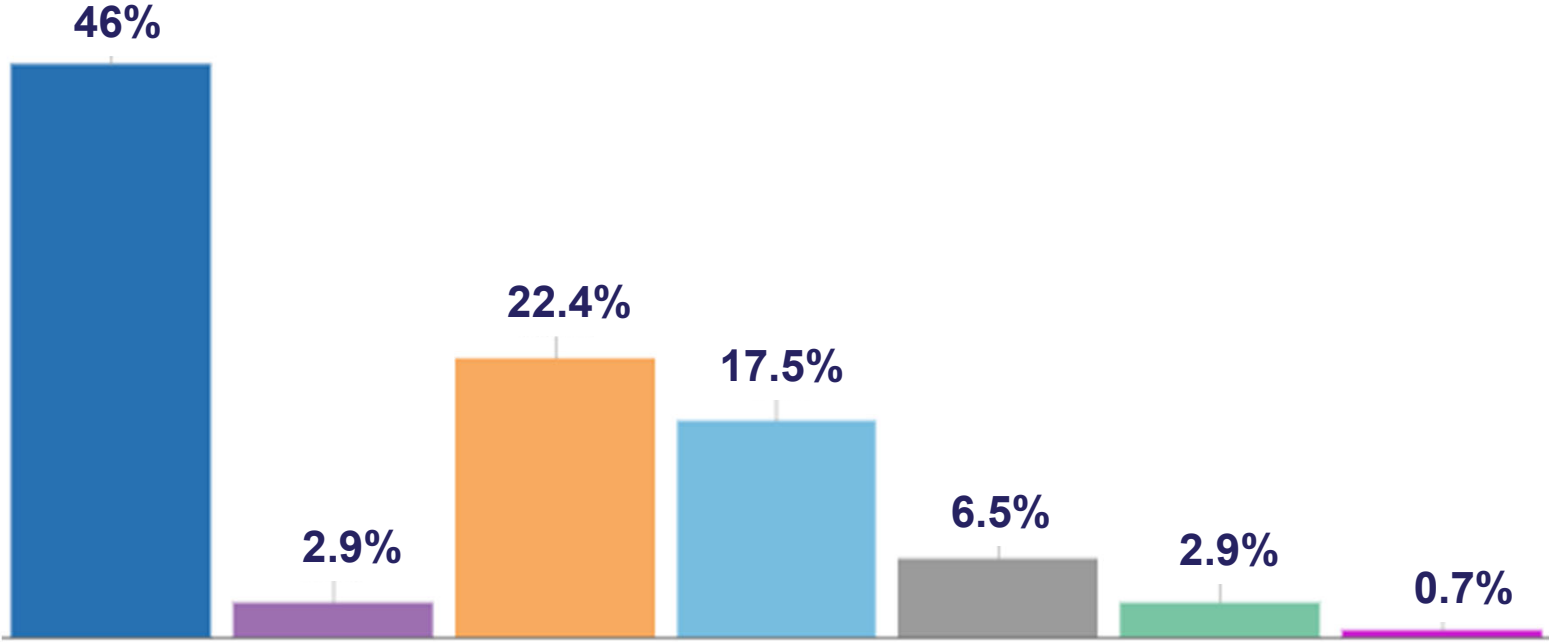


Selected Data Snapshots

(Updated 1/12/21)

Race & Ethnicity

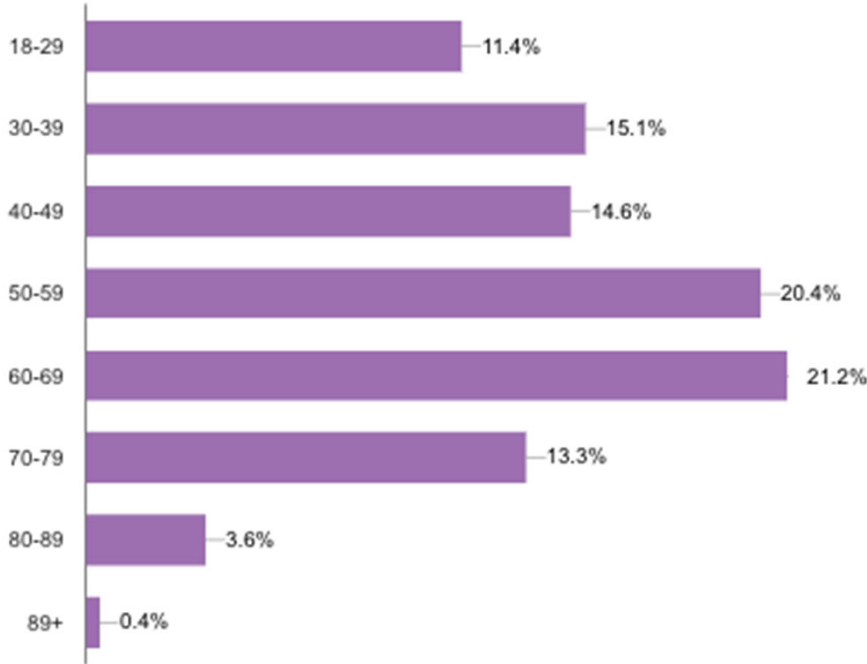
White Asian Black, African American or African Hispanic Latino or Spanish More than one race/ethnicity Other Prefer not to say



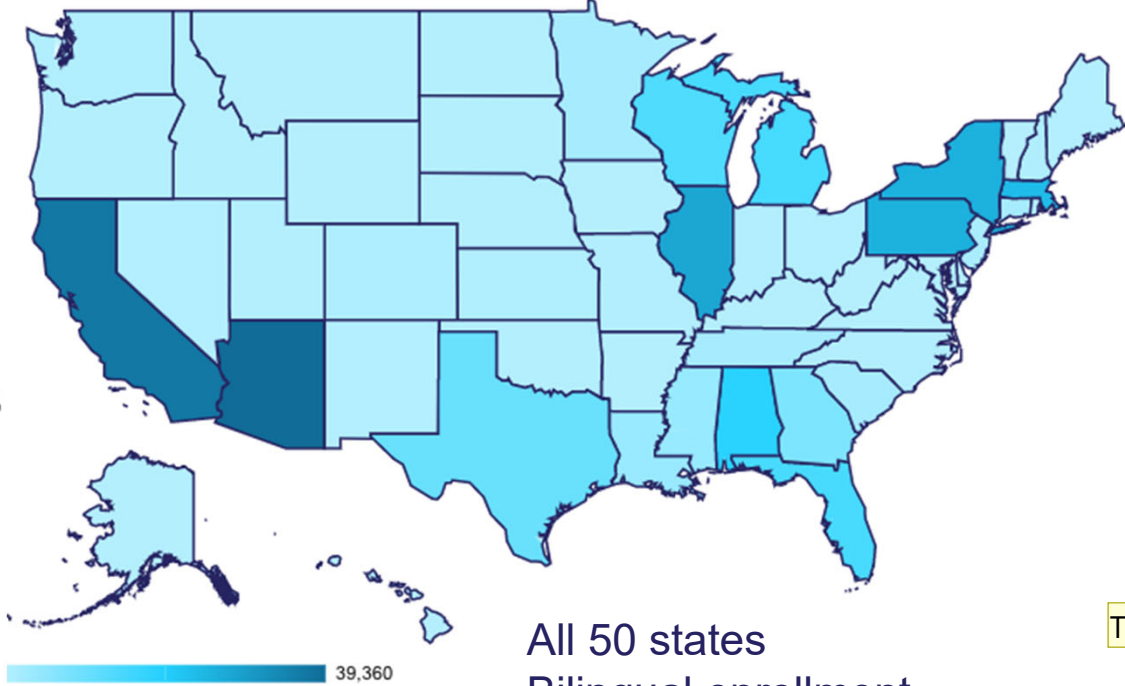
Selected Data Snapshots

(Updated 1/12/21)

Age



Geography



All 50 states
 Bilingual enrollment
 Interactive mobile exhibits*

TKC

*pre-COVID-19

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 "Keyword Search" input field. Below the search bar, it states "Data includes 316,760 participants and is current as of 10/1/2020." To the right of the search bar are three icons: a question mark in a circle (FAQs), a question mark in a document (Introductory Videos), and a database icon (User Guide). Below this is the "EHR Domains" section, which features four cards: "Conditions" (24,770 medical concepts, 192,000 participants), "Drug Exposures" (27,311 medical concepts, 174,660 participants), "Labs & Measurements" (13,631 medical concepts, 182,000 participants), and "Procedures" (27,702 medical concepts, 182,000 participants). Each card has a "View Top" link. Below the EHR Domains is the "Survey Questions" section, which features four cards: "The Basics" (28 questions available, 316,760 participants), "Overall Health" (21 questions available, 316,760 participants), "Lifestyle" (26 questions available, 316,760 participants), and "Personal Medical History" (465 questions available, 89,640 participants). Each card has a "View Complete Survey" link. A "Help" button is located in the bottom right corner.

A Quick Look at the Data Browser

PUBLIC DATA USE STATEMENT

Search Across Data Types

Keyword Search

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

FAQs **Introductory Videos** **User Guide**

EHR Domains:

Domain	Medical Concepts	Participants
Conditions	24,770	192,000
Drug Exposures	27,311	174,660
Labs & Measurements	13,631	182,000
Procedures	27,702	182,000

Survey Questions:

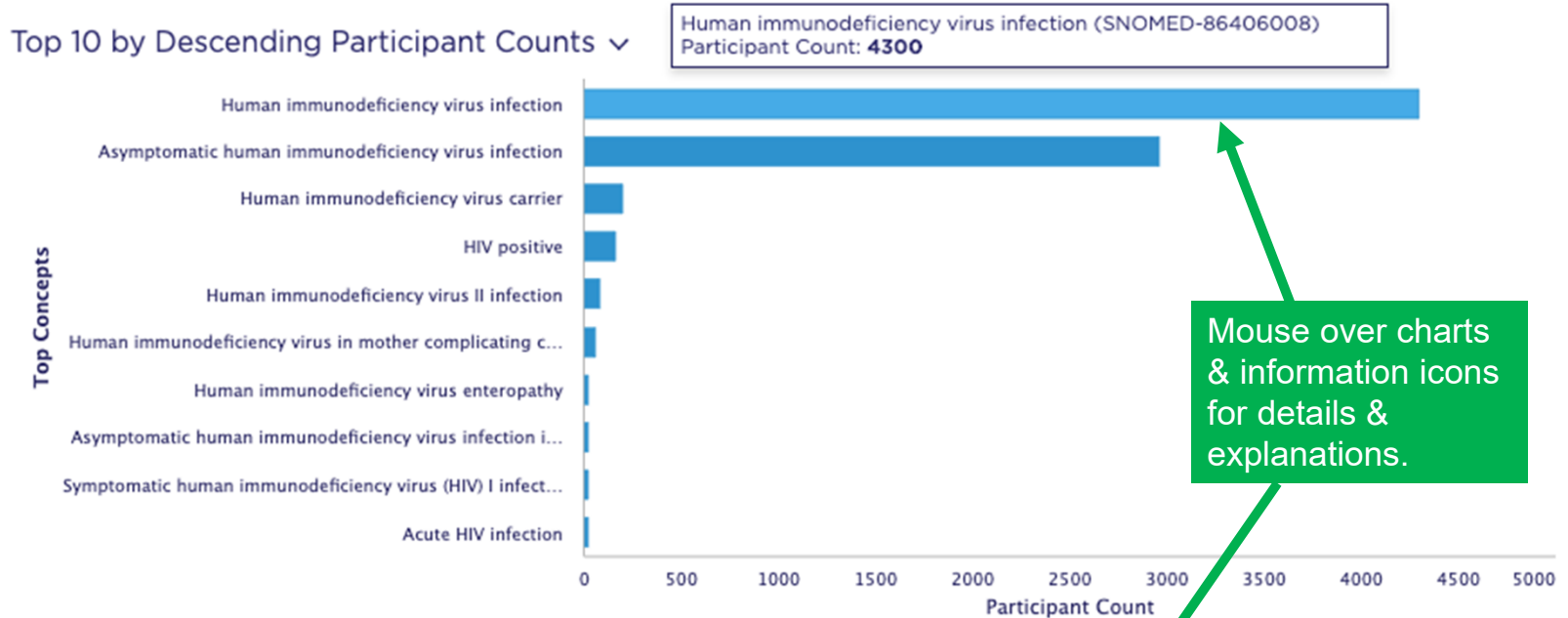
Category	Count
The Basics	165
Overall Health	
Lifestyle	
Personal Medical History	

Help

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

A Quick Look at the Data Browser: Conditions

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



Mouse over charts & information icons for details & explanations.

Showing top 11 matching medical concepts ⓘ

Interested in general health information related to "hiv"?
[Search MedlinePlus](#)

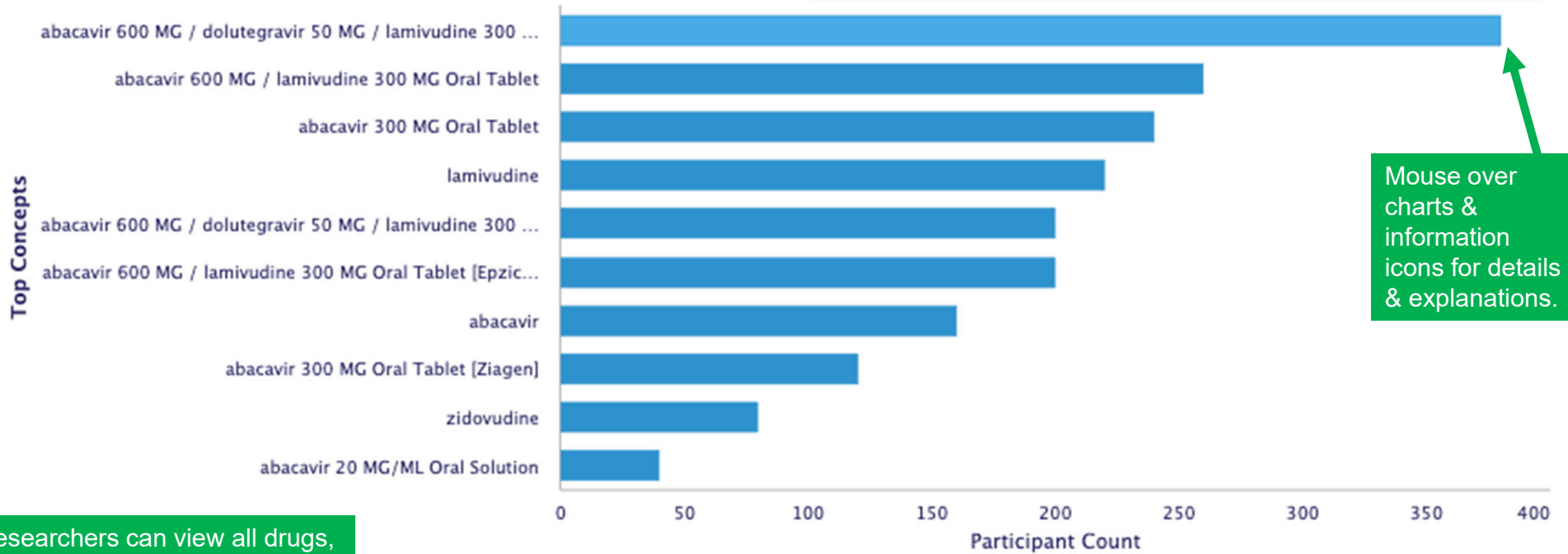
Conditions ⓘ	Participants of 192,000 ⓘ	% of 192,000 ⓘ	
1. Human immunodeficiency virus infection	4,300	2.24%	  
<i>Also Known As</i> ⓘ			
HIV infection, HIV - Human immunodeficiency virus infection, Human immunodeficiency virus infection... See More			

A Quick Look at the Data Browser: Drug Exposure

DATA DISCLAIMER

Top 10 by Descending Participant Counts ▾

abacavir 600 MG / dolutegravir 50 MG / lamivudine 300 MG Oral Tablet [Triumeq] (RxNorm-1546894)
Participant Count: **380**

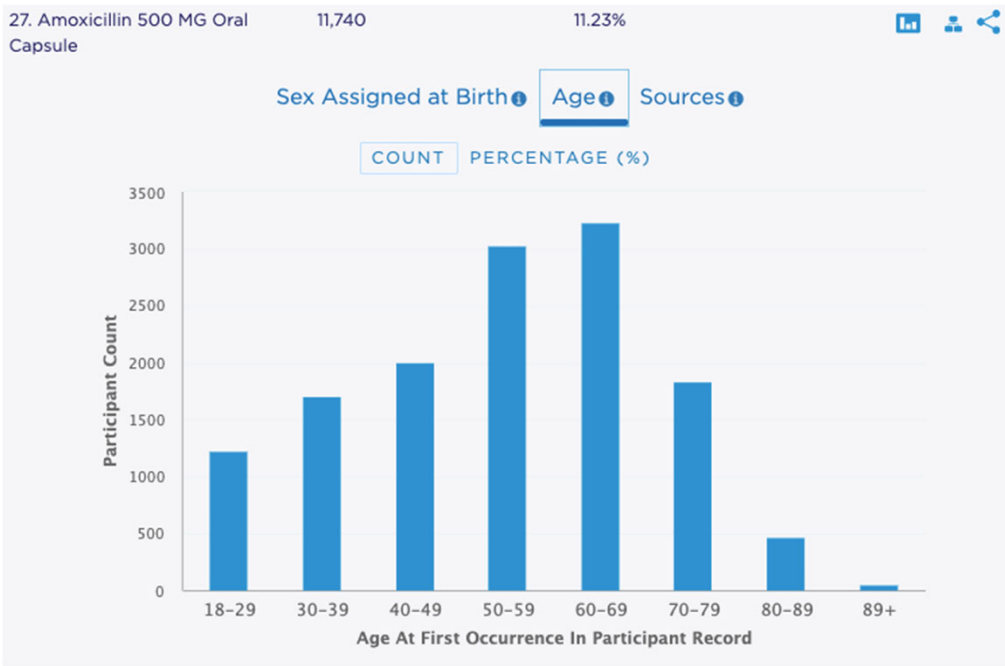
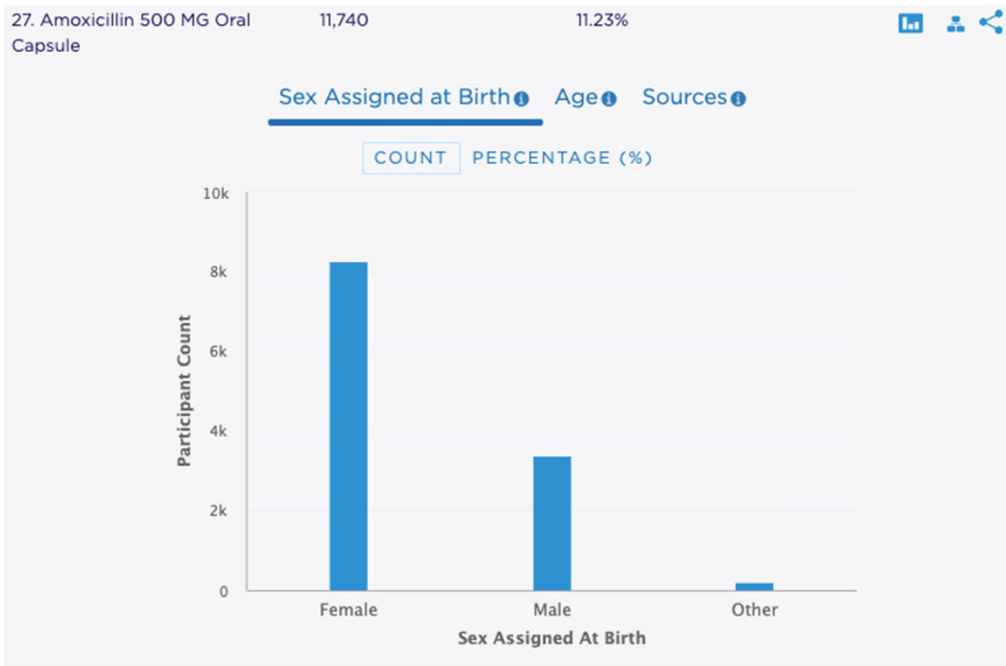


Mouse over charts & information icons for details & explanations.

Researchers can view all drugs, including vaccines.

A Quick Look at the Data Browser

Explore data breakdowns by sex assigned at birth & age.



Survey Example: COVID-19 Participant Experience (COPE)

Total unique participants

62,920

Participants completed this survey

151

Questions Available

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

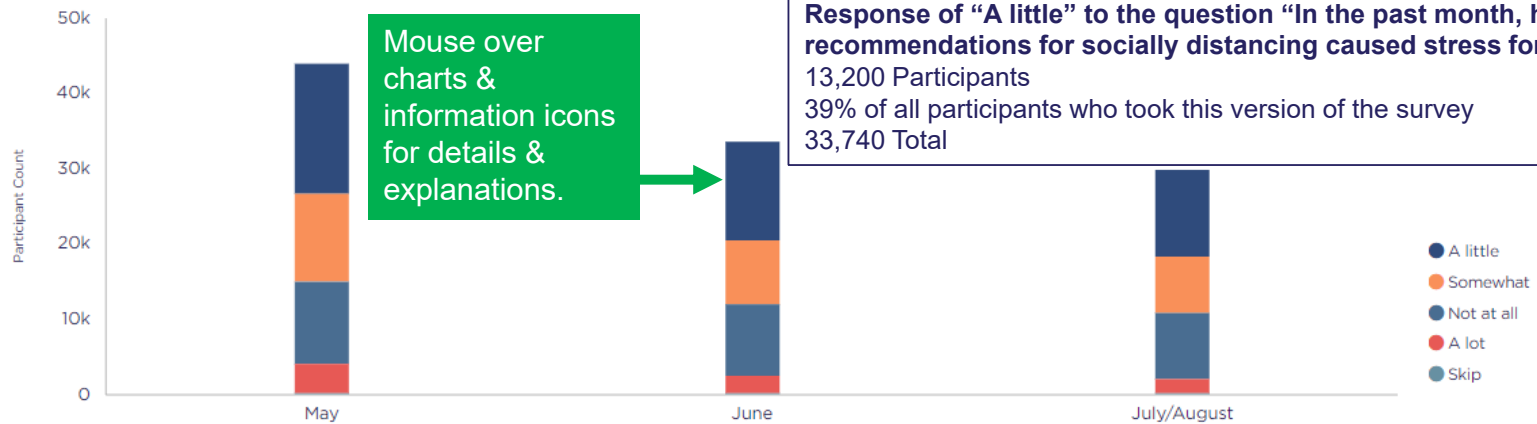
Survey versions

Month	Participants	Number of Questions	Download PDF
May	44080	148	Survey as PDF
June	33700	149	Survey as PDF
July/August	29920	148	Survey as PDF

Download different versions of the survey as PDFs

In the past month, have recommendations for socially distancing caused stress for you?

See Answers



COPE: Explore the survey

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


ABOUT DATA & TOOLS DISCOVER FAQ Q APPLY

Home > Data & Tools > Survey Explorer > COPE Survey

Participant Surveys: COPE

The coronavirus disease 2019 (COVID-19) is having widespread and wide-ranging effects on *All of Us* participants and their communities. *All of Us* created the COVID-19 Participant Experience (COPE) survey to learn more about the way the pandemic is affecting people's lives, particularly their mental health. The survey included questions about social distancing, general well-being, mood, stress, and more.

The first COPE survey was offered May 7, 2020. More surveys went out in May, June and July, and stayed up until late September. A shorter version of the survey will be available in November, December, and January.

In the past month, have recommendations for socially distancing caused stress for you? 

Original source question text
Have recommendations for socially distancing caused stress for you?

From which existing source was this question derived?
CDC COVID-19 Community Survey Question Bank

Year of Original Source
2020

Brief Description
The CDC COVID-19 Community Survey Question Bank, an online resource maintained by the U.S. Centers for Control and Prevention, contains community survey questions made available for use in COVID-19 research efforts.

URL
<https://cde.nlm.nih.gov/formView?tinyId=Kcceysolt>

Research Hub Components

PUBLIC



Data Browser



Data Snapshots



Survey Explorer



Help Desk

Launched May 2019



Data Passport Model

RESTRICTED

Researcher Workbench



Data Dictionary



Concept Set Selector



Cohort Builder



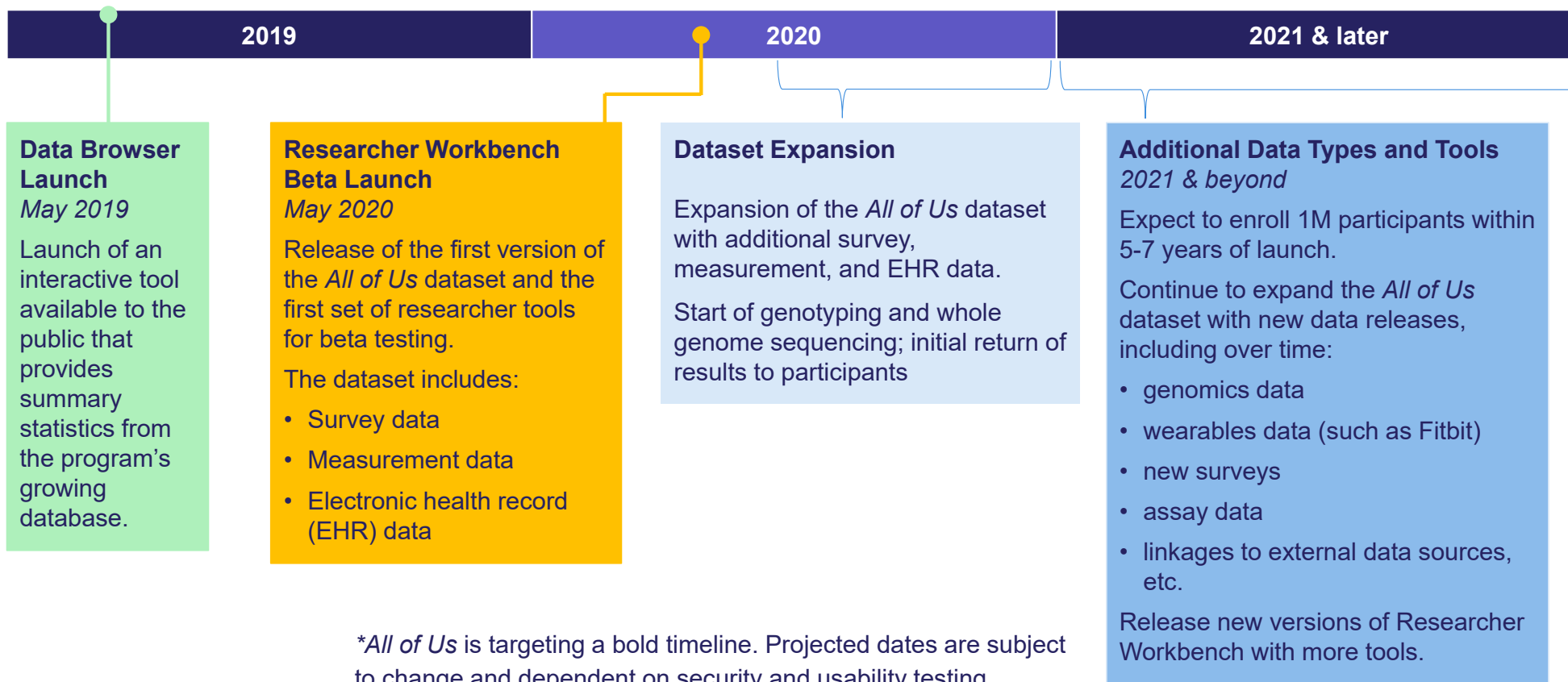
Notebooks



Help Desk

Beta Launch: May 2020

Data Release Timeline



The *All of Us* Research Program Researcher Workbench is Open for Beta!

- ◎ This moment is an important step in our effort to accelerate new discoveries.
- ◎ We want to build this platform together with the research community.
- ◎ We need researchers' input to make it more robust and to learn how well the data, tools, and policies are working.

Using the Researcher Workbench During Beta

Current components:

- Data: physical measurements, survey data, and some EHR data - much more to come (e.g., genomics, digital health technology)
- Tools: Dataset Builder, Cohort Builder (more to come!)
- Help Resources: FAQs, sample notebooks and workspaces, documentation, Help Desk



Access and Security

- *All of Us* employs a “data passport” model for this access tier, to grant researchers broad permission to explore the data for a wide range of studies
- Beta testing access is available to researchers with eRA Commons accounts *if* their institutions have signed a data use agreement. In the future, we’ll open the platform more broadly
- To facilitate collaboration and keep participant data secure, the Researcher Workbench is hosted in a Cloud-based system
 - All tools and data are in one place
 - Data downloads onto your local machine are not allowed
 - During the Beta testing phase, researchers will receive free credits to cover computing and storage costs

Workspace

The screenshot shows the All of Us Researcher Workbench interface. At the top left is the logo "All of Us RESEARCHER WORKBENCH". Below it is a welcome message: "Welcome to the RESEARCHER WORKBENCH The secure platform to analyze All of Us data". There are three circular icons representing different features. The main section is titled "Workspaces" and contains a grid of workspace cards. Each card has a title, a "OWNER" button, and a "Last Changed" timestamp. The workspaces shown are: "Featured Workspace: Dementia", "All of Us Survey Codebook and Frequency Distributions", "Featured Workspace: Depression", and "Featured Workspace - Type 2 Diabetes". Below the workspaces is a "Recently Accessed Items" section with a grid of notebook cards. Each card has a title, a "Notebook" button, and a "Last Modified" timestamp. The notebooks shown are: "Case 1 Notebook", "Dementia Analysis from Cohort Builder", "Ischemic Heart Disease Analysis", "Dementia Analysis", "Type 2 Diabetes Analysis", and "Ischemic Heart Disease Analysis". At the bottom is a "Quick Tour and Videos" section with three video thumbnails: "Workbench Quick Tour", "Cohorts Overview", and "Notebooks Overview".

- First, you will create a workspaces where you will store all of the data and analyses for a specific project
- Your cohorts (participants), concept sets (variables), cohort reviews, datasets, and notebooks (where analyses are run) for a project will live in one shareable workspace

Tools to Build Cohorts and Datasets

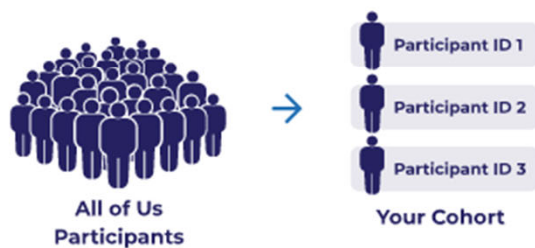
DATA

ANALYSIS

ABOUT

Cohorts +

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



Datasets +

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



Concept Sets

Concept sets are a set of medical concepts (eg: blood pressure) that are of interest for a research study.



All of Us Research Support

- **User Support Hub**

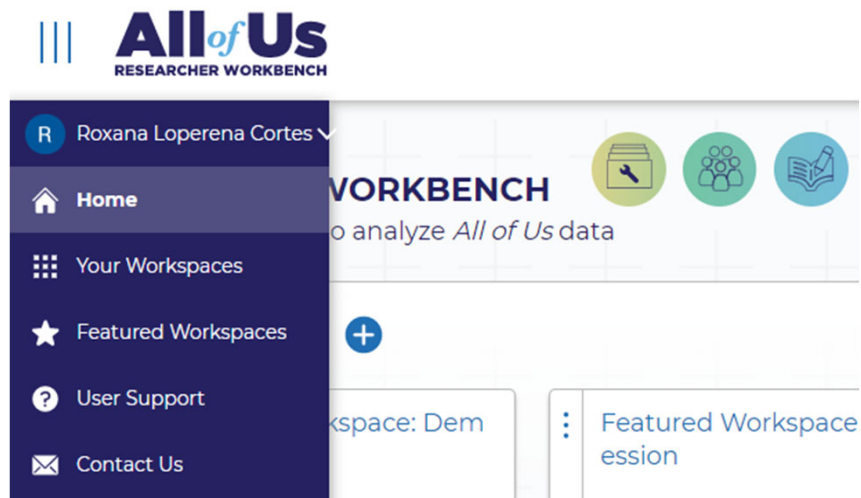
- Tool user guides
- Instructional videos
- Data model tutorials
- Knowledge Base
- Data Dictionary
 - PDF as part of detailed data documentation
 - Integrated directly within Workbench tools

- **Researcher Workbench**

- Featured Workspaces (example analyses, Phenotype Library)
- Reusable “code snippets”
- Demonstration Projects
- Help Tips

- **Help Desk Form**

- Specialized forms
 - Ask a question or get help
 - Feedback
 - Publication
 - Billing credits
 - Privacy concerns



***All of Us* COVID-19 Scientific Activities: Overview**

- The research community is collaborating in an unprecedented way to address COVID-19 and inform future pandemic preparedness.
- With its scale and diversity, *All of Us* is well-positioned to make special contributions to these efforts.
- In collaboration with national and international partners, we are addressing COVID-19 through three key initiatives,



Collectively, these efforts will help researchers learn more about COVID-19 and its impact on diverse communities across the U.S.

All of Us COVID-19 Scientific Activities: Priorities

- ◉ **Antibody testing:**

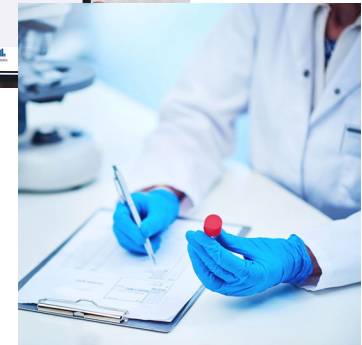
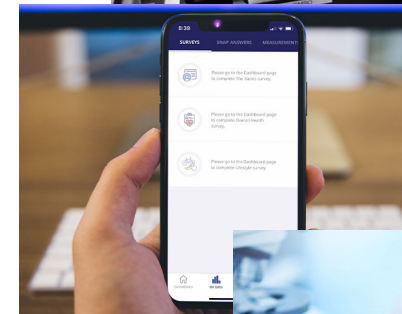
Supporting antibody testing on samples from recently-enrolled participants to better understand COVID-19's origins and spread.

- ◉ **COVID-19 Participant Experience (COPE) survey:**

Surveying all participants to measure impacts of the pandemic on physical and mental health, employment and income, substance use.

- ◉ **EHR data standards:**

Standardizing data from electronic health records to better detail symptoms, and effects of different medicines and treatments.



Data gathered from these activities will be made available in our Researcher Workbench in the future

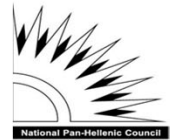
Limitations

- ⦿ While *All of Us* reflects the broad diversity of the US, it is not nationally representative
- ⦿ Data is not comprehensive; will be continuing to expand in depth and breadth as the program grows
- ⦿ Not all participants will have all data types available

Conclusions

- ⦿ Assembling the most diverse large-scale cohort of its kind with plans for genomic data and comprehensive clinical information
- ⦿ Successfully engaging participants as partners
- ⦿ New data types continuing to be rolled out
- ⦿ Ancillary studies of specific populations or disease states possible
- ⦿ Will facilitate research across multiple disease states and could serve as controls for disease-specific studies that lack healthy controls

All of Us Community and Provider Partner Network (as of December 2020)



All of Us Consortium Members *(beyond community partners, as of December 2020)*

The Participant Center



HPO Network

(Health Care Provider Organizations)



Participant Technology Systems Center (PTSC)



Biobank



Data & Research Center (DRC)



Genomics Partners



For more information...



ResearchAllofUs.org
(includes the Data Browser)
JoinAllofUs.org



[@AllofUsResearch](https://twitter.com/AllofUsResearch)
[#JoinAllofUs](https://twitter.com/AllofUsResearch)



National Institutes
of Health

AllofUs.nih.gov

Questions?

It takes *All of Us*....

