



THE FUTURE OF HEALTH BEGINS WITH YOU

The  
Precision  
Medicine  
Initiative

## Update on the *All of Us* Research Program

Council of Councils Meeting  
September 6, 2019

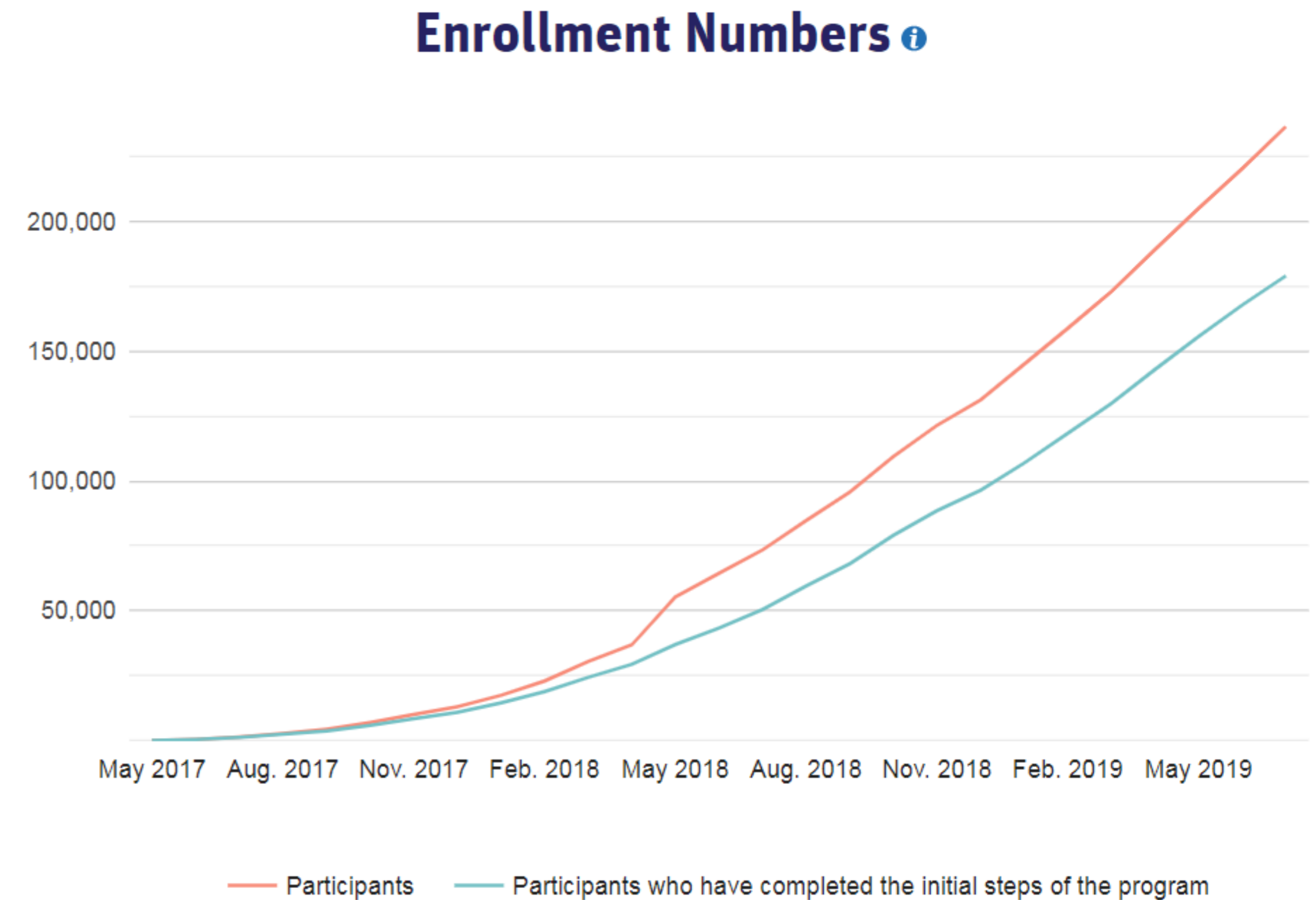


National Institutes  
of Health

Stephanie Devaney, PhD  
Deputy Director, *All of Us* Research Program

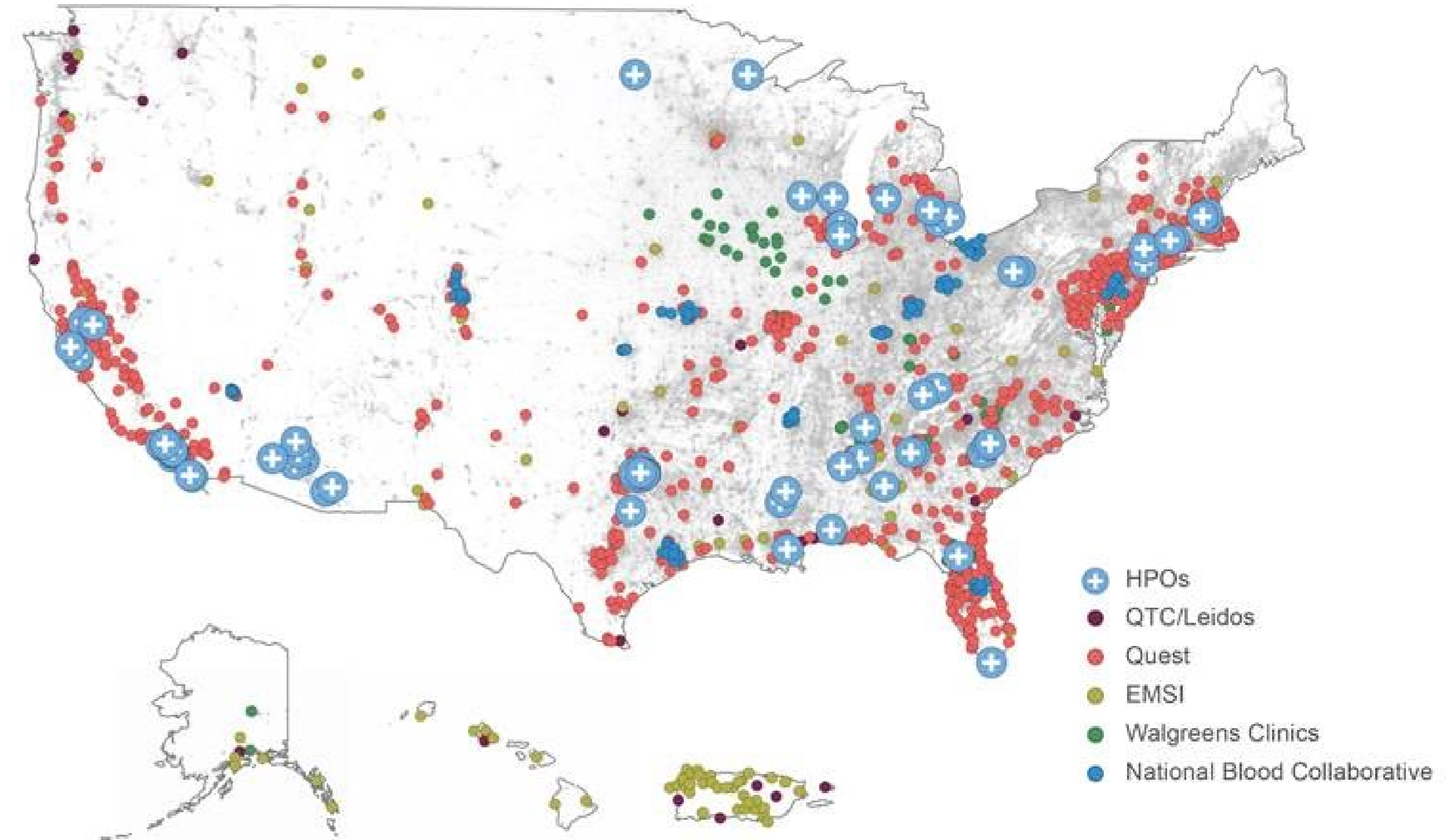
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  - >80% are underrepresented in biomedical research
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- *Participants from all 50 states*
- *Bilingual enrollment journey*

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- Celebrated our 1 year anniversary since national launch on May 6<sup>th</sup> with a symposium that was Facebook livestreamed
- Launched beta version of our Public Data Browser
- Published our marker paper in NEJM

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL REPORT

### The “All of Us” Research Program

The All of Us Research Program Investigators

SUMMARY

Knowledge gained from observational cohort studies has dramatically advanced the prevention and treatment of diseases. Many of these cohorts, however, are small, lack diversity, or do not provide comprehensive phenotype data. The All of Us Research Program plans to enroll a diverse group of at least 1 million persons in the United States in order to accelerate biomedical research and improve health. The program aims to make the research results accessible to participants, and it is developing new approaches to generate, access, and make data broadly available to approved researchers. All of Us opened for enrollment in May 2018 and currently enrolls participants 18 years of age or older from a network of more than 340 recruitment sites. Elements of the program protocol include health questionnaires, electronic health records (EHRs), physical measurements, the use of digital health technology, and the collection and analysis of biospecimens. As of July 2019, more than 175,000 participants had contributed biospecimens. More than 80% of these participants are from groups that have been historically underrepresented in biomedical research. EHR data on more than 112,000 participants from 34 sites have been collected. The All of Us data repository should permit researchers to take into account individual differences in lifestyle, socioeconomic factors, environment, and biologic characteristics in order to advance precision diagnosis, prevention, and treatment.

LONGITUDINAL COHORT STUDIES HAVE IMPROVED human health by characterizing natural histories of diseases, identifying their risk factors, and revealing new biomarkers. Advances in genomics and biosensors have set the stage for refined taxonomies of disease, which may

help to guide prognosis, improve existing treatments, and aid in the development of new therapies. Most important, advances in genomic analyses have helped to identify the underlying causes of disease in individual patients. However, many efforts have been hampered by an inadequate sample size and a lack of diversity among participants,<sup>1</sup> restrictive policies regarding data access, or failure to capture genotype and phenotype data comprehensively.<sup>2</sup> Collectively, these challenges have slowed the pace of medical discovery, decreased the generalizability of research findings, hindered reproducibility, and led to incorrect interpretations.<sup>3,4</sup> Population-based research, which requires large sample sizes and highly granular phenotypic data, benefits from access to populations of patients from various ancestries. The All of Us Research Program seeks to provide these data. Here, we describe the goals of the program and the extent to which they have been met.

In his State of the Union address in January 2015, President Barack Obama first announced the program (then called the Precision Medicine Initiative cohort program<sup>5</sup>), and the All of Us network of grant awardees received initial funding from the National Institutes of Health (NIH) in July 2016. A central goal of the program is to enroll at least 1 million persons who agree to share their electronic health record (EHR) data, donate biospecimens for genomic and other laboratory assessments, respond to surveys, and have standardized physical measurements taken. Participants will also have the opportunity to contribute data from sensors and mobile health devices and be contacted for future research opportunities. The All of Us cohort will thereby provide data for prospective, retrospective, and cross-sectional analyses. The program launched in May 2018; a year later, the program met more than one fifth of its recruitment goal of 1 million persons.

# Our Mission

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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

# *All of Us* Research Program Core Values

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Participation in **open** to all.

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

Participants are **partners**.

Trust will be earned through **transparency**.

Participants have **access** to their information.

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

**Security and privacy** will be of highest importance.

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

# Current protocol



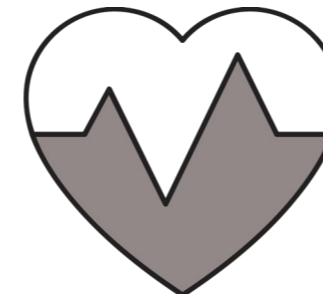
## Enroll, Consent & Authorize EHR

- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



## Answering Surveys

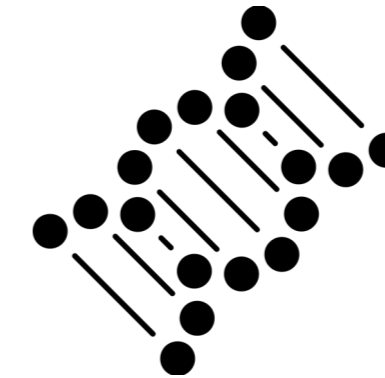
- Initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History
- Additional surveys released on an ongoing basis.



## Physical Measurements\*

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

*\*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
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

*Coming soon*

# Two Methods of Engagement

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[JoinAllofUs.org](https://JoinAllofUs.org)



**HEALTH CARE PROVIDER  
ORGANIZATIONS**



**DIRECT VOLUNTEERS**

# Some Areas of Focus for the Near Term and Beyond

- ⦿ Enroll & retain 1 million people
- ⦿ Improve the participant experience
  - Continue to innovate around the direct volunteer pathway
  - Diverse network of participants giving input, including AI/AN via consultation
  - Continuing great work on community and participant engagement
- ⦿ Launch genomics
- ⦿ Launch the Researcher Workbench

## *Deep program investments in engagement*

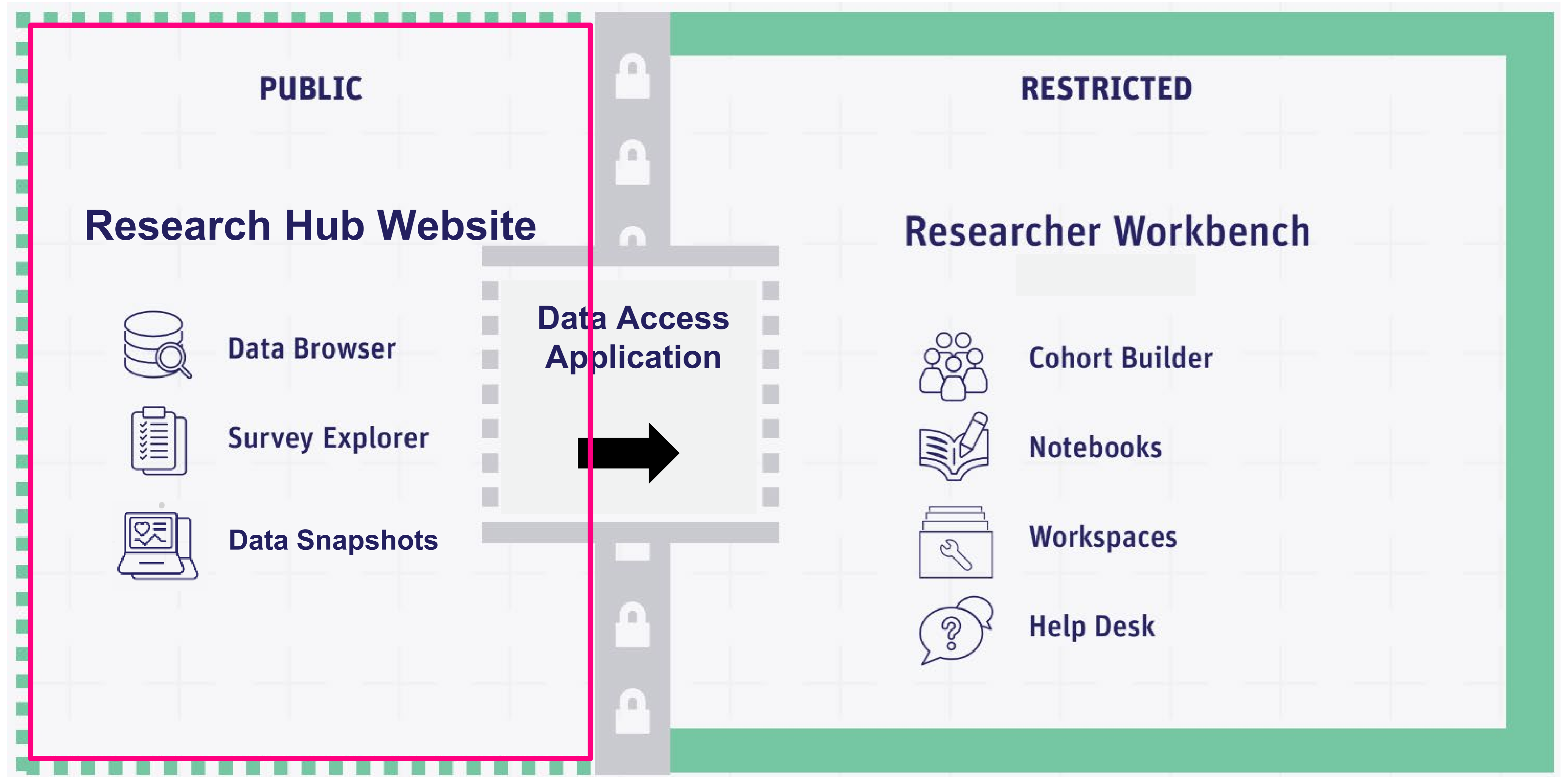


# Genomics plans: genotyping, WGS, “RROI”

- ◉ 3 genome centers awarded
- ◉ Genotyping & WGS for all 1M participants
- ◉ Genetic Counseling Resource awarded
- ◉ Initial pilot of 25,000 diverse participants will teach us responsible & effective ways to return information, IF a participant chooses!
- ◉ Over time, we will offer multiple options to receive:
  - Ancestry results
  - Health relevant findings
  - Pharmacogenomics
- ◉ Exact timing of pilot launch depends upon:
  - Genetic counseling resource in place & tested
  - Security, usability & sample quality testing
  - FDA & IRB approval of AOU process



# All of Us Research Hub



# All of Us Public Data Browser

- Interactive tool launched in beta at our one year anniversary
  - 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

## DataBrowser.ResearchAllofUs.org

### Data Snapshots

Interested in quickly viewing the diversity of the *All of Us* Research Program participant data? Our Data Snapshots are the fastest way to view the diversity of the *All of Us* Research Program participant data set. Updated regularly, these snapshots provide visualizations of participant demographics, geographical distribution, and more.



245,000+

Participants



80,000+

Electronic Health Records



190,000+

Biosamples Received

[VIEW MORE DATA SNAPSHOTS](#)

### Data Browser

Ready to dive into the data?

Our interactive Data Browser lets researchers and participants view a curated subset of aggregate data stored in the *All of Us* Research Hub.

[EXPLORE THE DATA BROWSER](#)



Search Across Data Types ⓘ

Q Keyword Search

Data based on Curated Data Repository (CDR) dated 11/13/2018 with 116,460 total participants.



FAQs



Introductory  
Videos



User Guide

EHR Domains: ⓘ

Conditions ⓘ

15,679

medical concepts

36,620 participants in this domain

[View Top 100](#)

Drug Exposures ⓘ

14,967

medical concepts

33,860 participants in this domain

[View Top 100](#)

Measurements ⓘ

7,735

medical concepts

32,920 participants in this domain

[View Top 100](#)

Procedures ⓘ

13,238

medical concepts

35,680 participants in this domain

[View Top 100](#)

Survey Questions:

The Basics ⓘ

14

survey questions

104,440 participants in this domain

Survey includes participant demographic information.

[View Complete Survey](#)

Overall Health ⓘ

16

survey questions

101,420 participants in this domain

Survey provides information about how participants report levels of individual health.

[View Complete Survey](#)

Lifestyle ⓘ

7

survey questions

100,460 participants in this domain

Survey includes information on participant smoking, alcohol and recreational drug use.

[View Complete Survey](#)

Program Physical Measurements:

Physical Measurements ⓘ

Participants have the option to provide a standard set of physical measurements as part of the enrollment process ("program physical measurements").

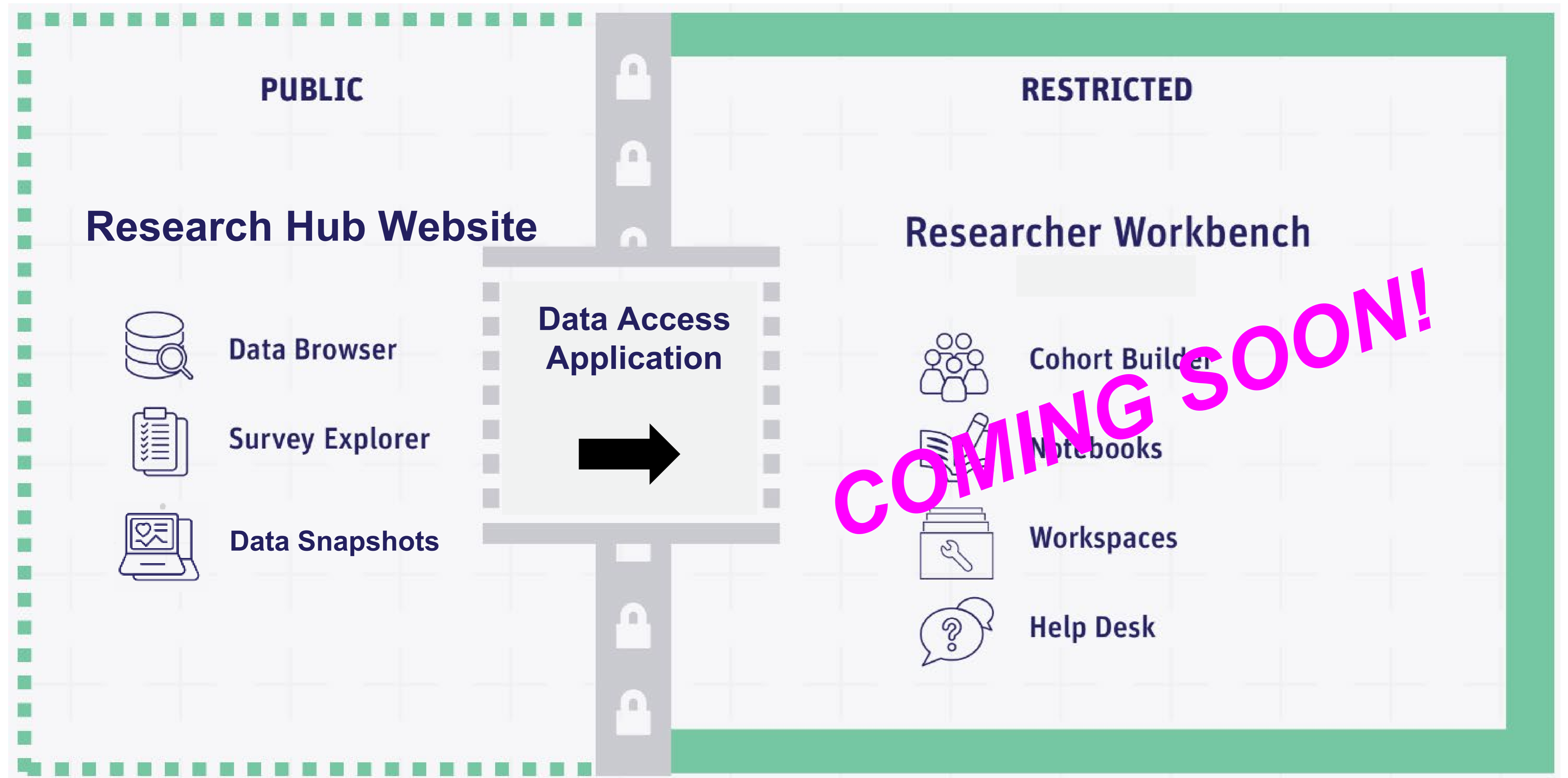
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physical measurements

[View Program Physical Measurements](#)

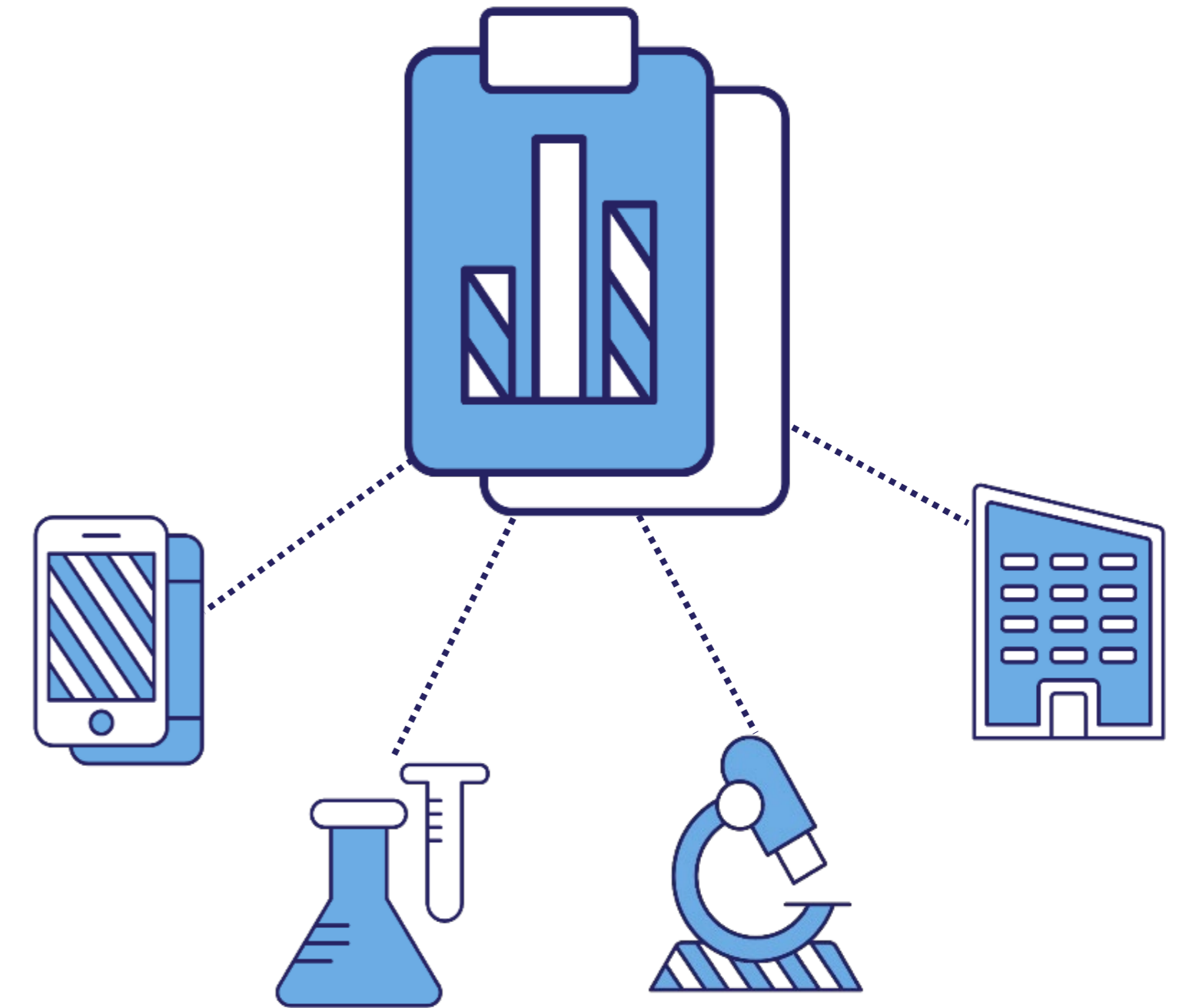
Conditions 	Participants of 36,620 	% of 36,620 	Vocabulary Code 	Concept Code 	View graphs 																		
1. Pain	22,120	60.4%	SNOMED 22253000	4329041																			
<i>Also Known As</i>  Dolor, Painful, Pain observations, Part hurts, Pain (finding)																							
Sex Assigned at Birth  <u>Age </u> Sources 																							
 <table><caption>Age at First Occurrence in Participant Record</caption><tr><th>Age Range</th><th>Count</th></tr><tr><td>18-29</td><td>~3,900</td></tr><tr><td>30-39</td><td>~5,100</td></tr><tr><td>40-49</td><td>~7,000</td></tr><tr><td>50-59</td><td>~8,800</td></tr><tr><td>60-69</td><td>7,120</td></tr><tr><td>70-79</td><td>~3,100</td></tr><tr><td>80-89</td><td>~600</td></tr><tr><td>89+</td><td>~100</td></tr></table>						Age Range	Count	18-29	~3,900	30-39	~5,100	40-49	~7,000	50-59	~8,800	60-69	7,120	70-79	~3,100	80-89	~600	89+	~100
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70-79	~3,100																						
80-89	~600																						
89+	~100																						
2. Disorder due to infection	16,820	45.93%	SNOMED 40733004	432250																			
<i>Also Known As</i>  Infective disorder, Infection, Disease due to infection, Infectious disease, Infectious disease (dis <a href="#">See More ...</a>																							
3. Metabolic disease	15,820	43.2%	SNOMED 75934005	436670																			
<i>Also Known As</i>  Metabolic disorder, MD - Metabolic disorders, Metabolic disease (disorder)																							
4. Mass of body structure	15,600	42.6%	SNOMED 300848003	410211																			
<i>Also Known As</i>  Observation of a mass, Lump, Mass, Mass of body structure (finding)																							

# All of Us Research Hub



# Principles of data access

- ◉ **Broad access** (more scientific brainpower per problem!)
- ◉ Researcher-based **data passport** model
- ◉ Researchers must apply, take **ethics & data use training**, agree to code of conduct
- ◉ Access will be granted by **data tiers**
- ◉ Data use will be **audited and reported publicly**
- ◉ **Data stored and used in secure enclave** in cloud; cannot be downloaded
- ◉ Potentially **stigmatizing research** will be **addressed by**:
  - **Transparency** on data uses
  - **Regular assessment**
- ◉ Consortium researchers have **no special or early access** to the full dataset

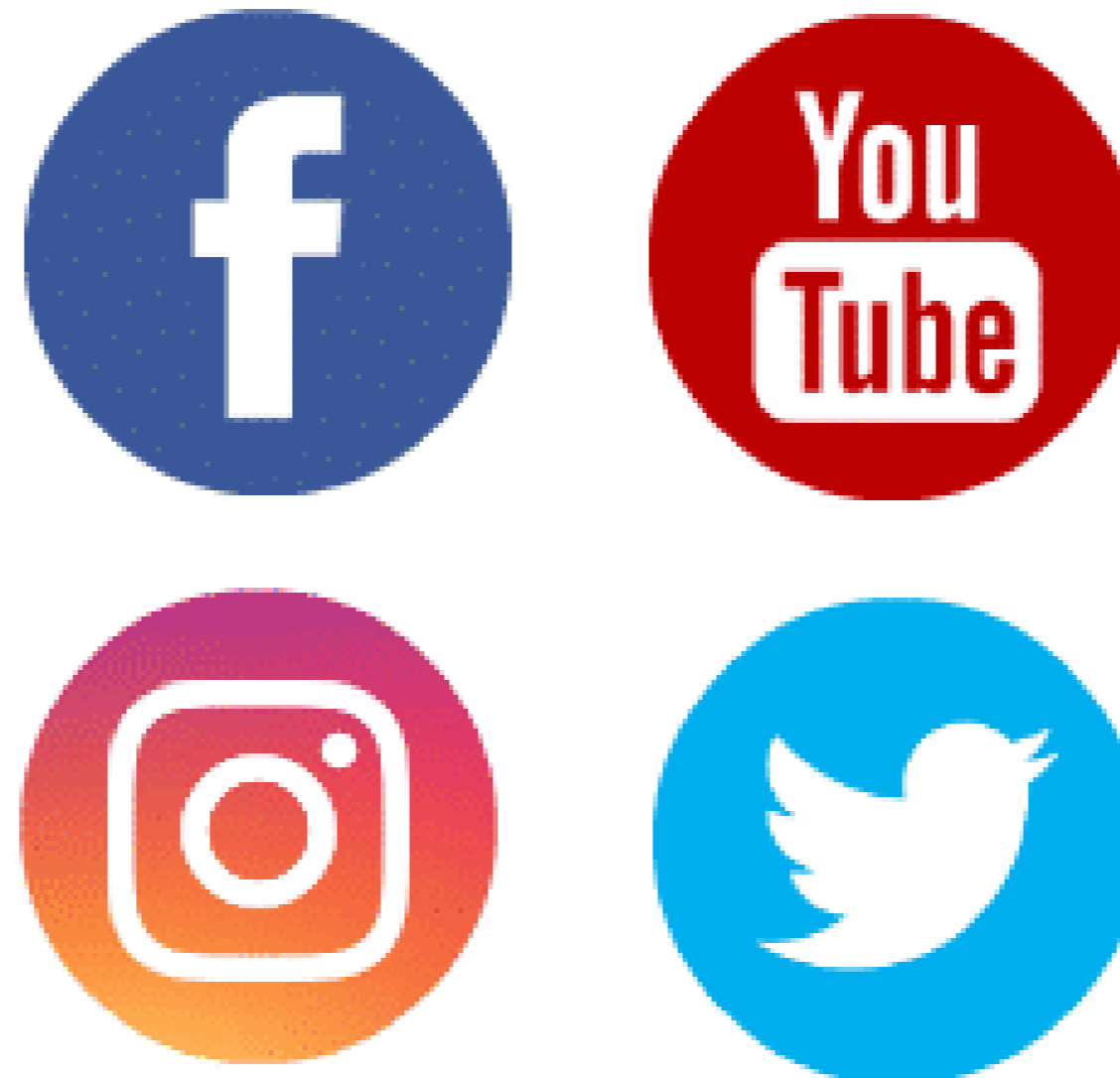


# For more information...

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[ResearchAllofUs.org](https://ResearchAllofUs.org)



**@AllofUsResearch**  
**#JoinAllofUs**



National Institutes  
of Health

[AllofUs.nih.gov](https://AllofUs.nih.gov)