

The *All of Us* Research Program:

The future of health begins with you



National Institutes
of Health

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Polling Question

We are interested in understanding how familiar you already are with precision medicine. We want to know what kind of background you have and how we can increase your knowledge to best work together.

- 🗳 On Screen: How familiar are you with precision medicine?
- Not familiar
 - Somewhat familiar
 - Very familiar

All of Us
RESEARCH PROGRAM



precision medicine:
the right treatment
for the right person
at the right time

The Cost of Imprecise Medicine



Patients

- Health care is often targeted to the average patient, not the individual
- Health problems can take years to unravel, with significant trial and error



Providers

- Not enough research to draw on for clinical evidence, especially in diverse populations
- Medical records scattered in different places
- Not enough time to analyze one patient at a time



Researchers

- Enormous time and cost spent building IT systems vs. doing research
- Siloed data resources and funding opportunities
- Challenges acquiring large sample sizes
- Slow translation of data into knowledge

Polling Question

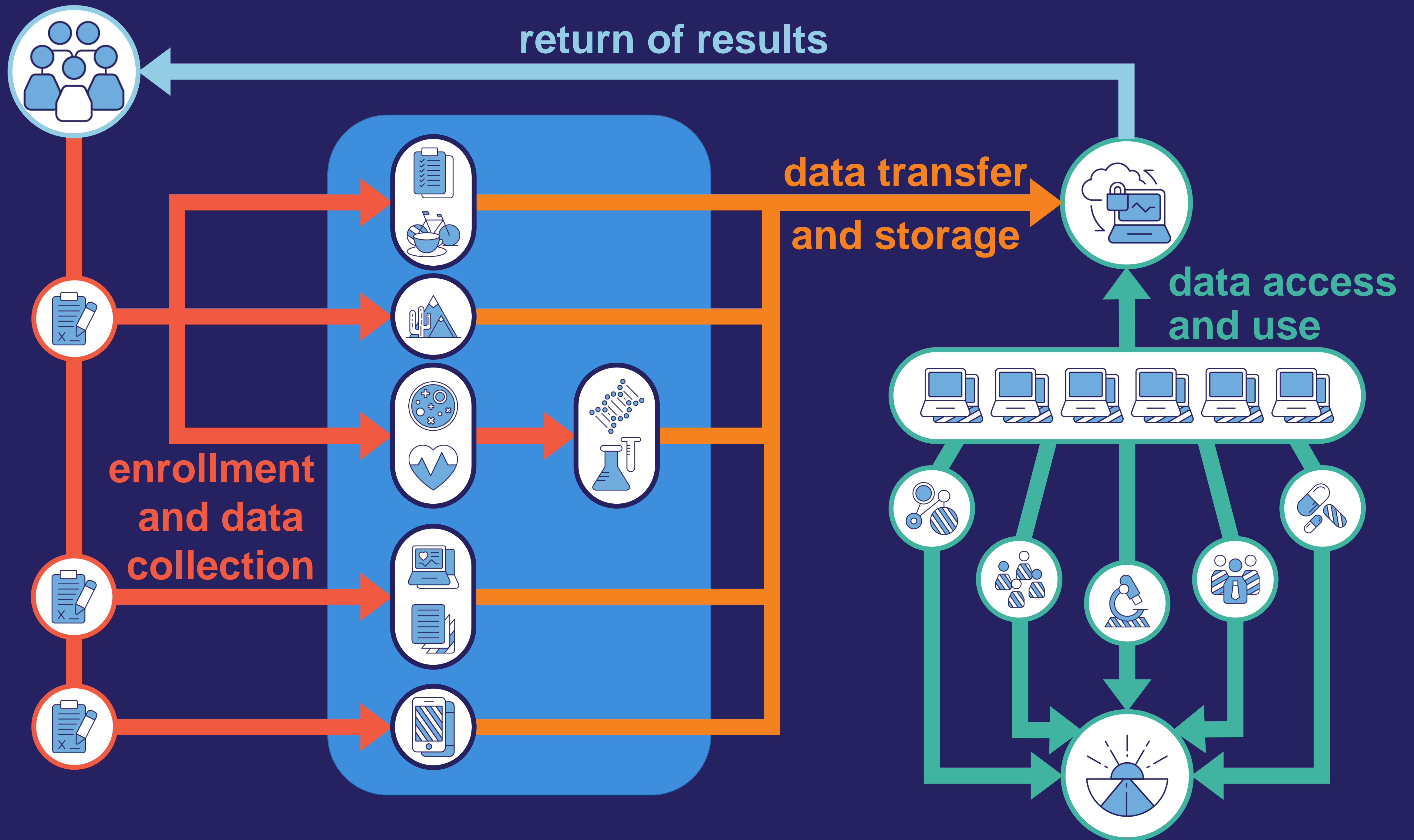
We are interested in understanding how familiar you already are with the *All of Us* Research Program. We want to know what kind of background you have and how we can increase your knowledge to best work together.

- 🗳 On Screen: How familiar are you with the *All of Us* Research Program?
- Not familiar
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What is the *All of Us* Research Program?

- ***Rich, Longitudinal Resource:*** Deliver a national resource of deep **clinical, environmental, lifestyle & genetic data** from 1 million participants who have consented & are engaged to provide data on an ongoing, longitudinal basis (10+ years!)
- ***Diversity of Participants:*** Reflect the broad diversity of the U.S.—**all ages, races/ ethnicities, sex, gender, SES, geographies, & health status**—by over-recruiting those underrepresented in biomedical research
- ***Diversity of Researchers:*** Build the tools & capabilities that make it easy for researchers **from community scientists to premier university labs** to make discoveries using the data & biosamples and through ancillary studies with the cohort





Two Methods of Enrollment



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**

Potential Activities Asked of Participants



Enroll, Consent and 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

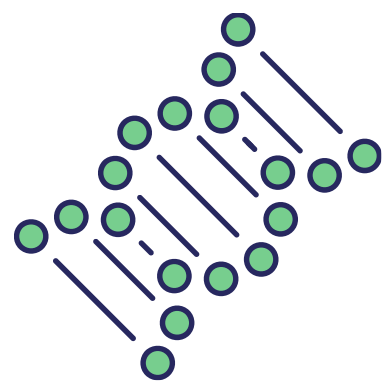
- Three initial surveys: The Basics, Overall Health & Personal Habits
- Additional surveys will be released on an ongoing basis.



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

Pilots under development: richer EHR data, health apps, fitness wearables, and return of genetic info

core values

All of Us Research Program Core Values

1. Participation is **open** to all.
2. Participants reflect the rich **diversity** of the U.S.
3. Participants are **partners**.
4. Trust will be earned through **transparency**.
5. Participants will have **access** to their information.
6. Data will be accessed **broadly** for research purposes.
7. Security and privacy will be of **highest** importance.
8. The program will be a catalyst for positive **change** in research.

The *All of Us* Approach to Participation

Participants in the *All of Us* Research Program will be true partners—not patients—in the research process.

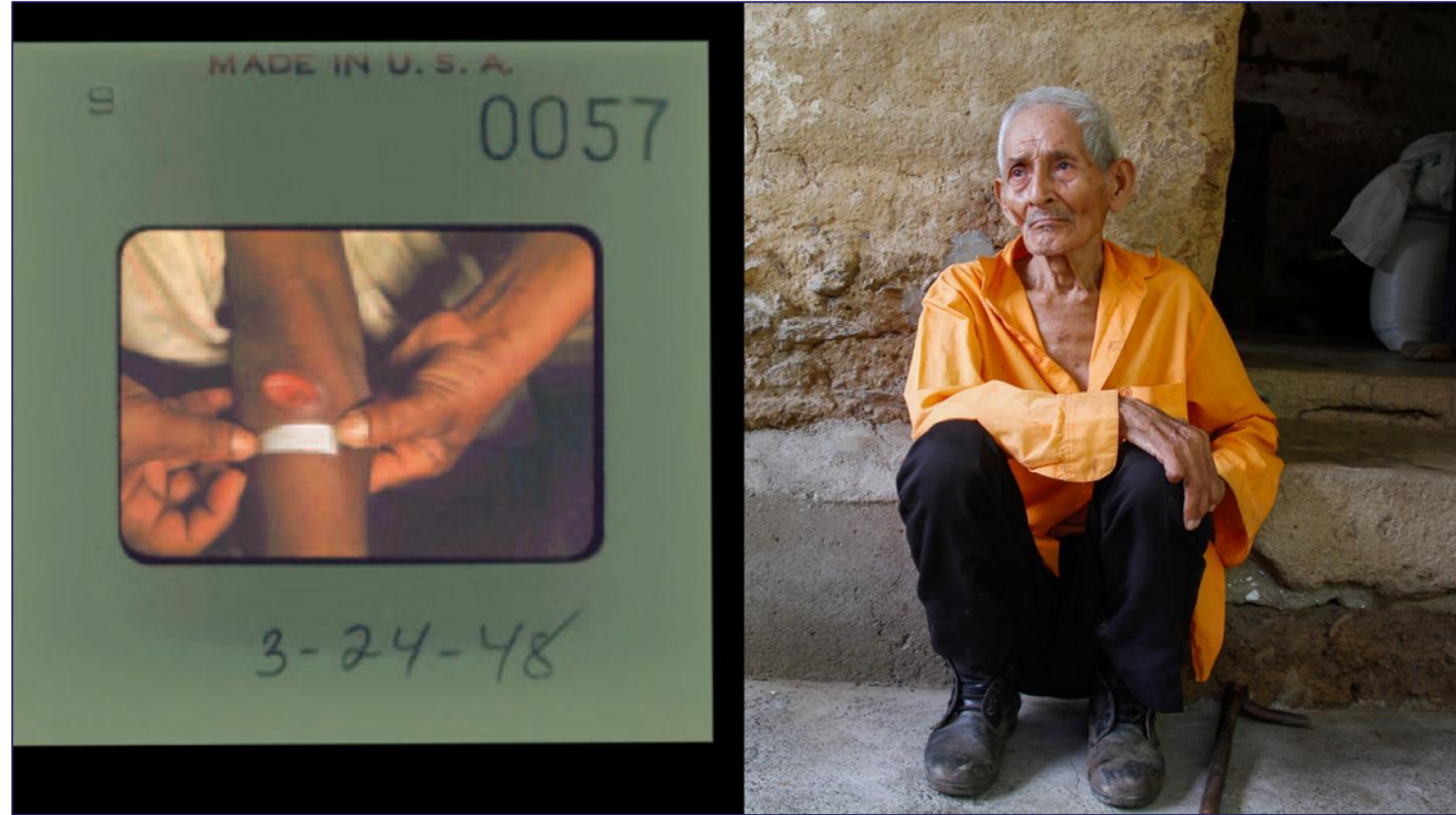
◎ Involved in program development:

- What **data** we collect
- What **lab analyses** we do
- What **research** is conducted
- How data is **returned**



**Trust will be earned through
robust engagement and full transparency.**

Disenfranchisement and Historical Abuses



Minorities make up
38%
of the U.S. population.

Minority population will rise to over
56%
of overall population.

Minority enrollment in clinical trials
<10%

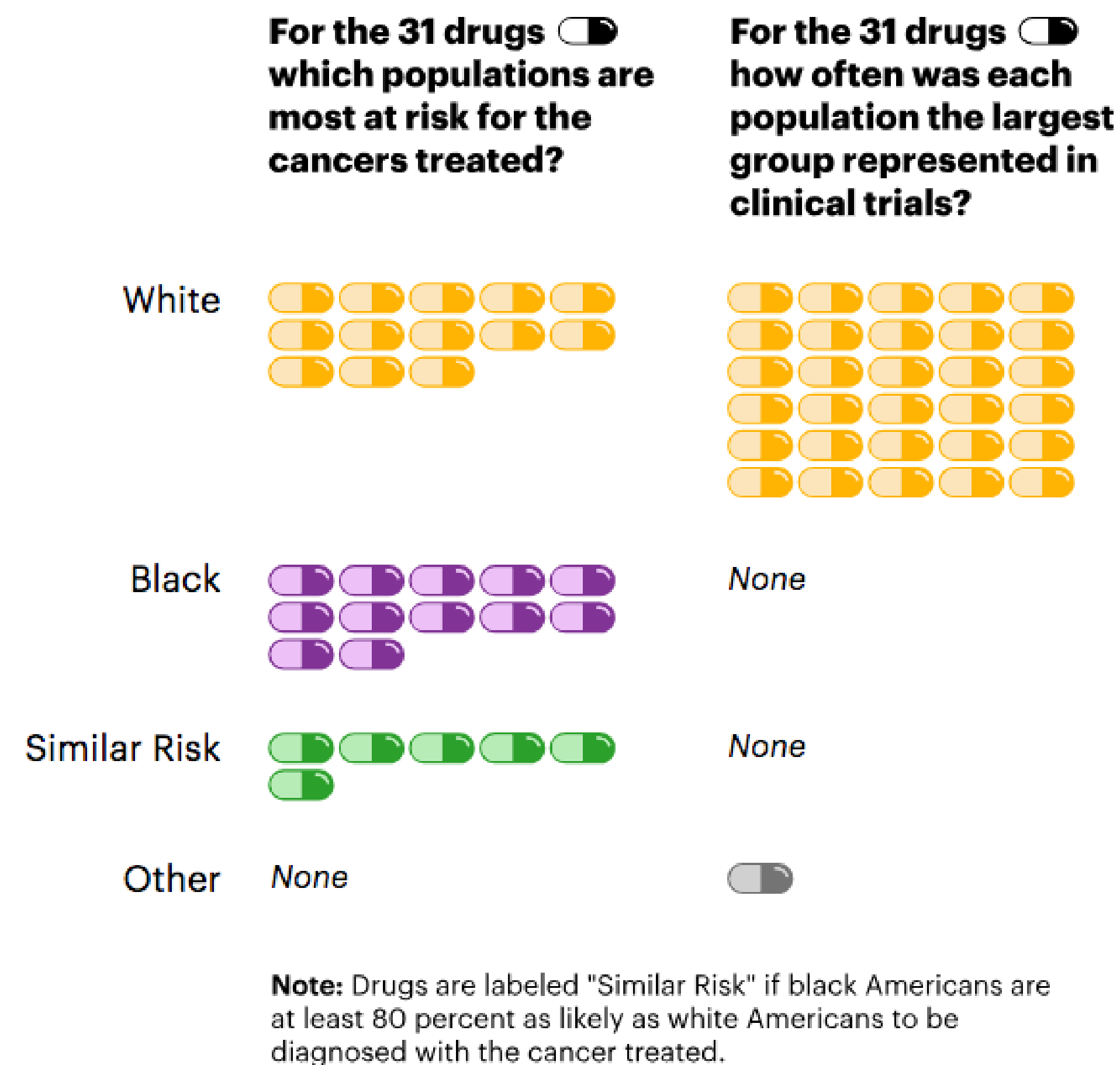
**Underrepresented in
biomedical research:
populations include
dimensions of race and
ethnicity, as well as
age, sex, gender,
sexual orientation,
income, education,
geography, access to
care and disability.**

Lack of Diversity in Biomedical Research can Impact Public Health

“Diversity in science is science done well. You need diversity in the research, diversity in who is being studied and diversity in the people doing the science. Otherwise you become an echo chamber – everyone looks and sounds just like us.”

- **Sam Oh, PhD, MPH**, epidemiologist and researcher at UCSF Center for Genes, Environment and Health.

Source: UCSF News Center; UCSF



Source: U.S. Food and Drug Administration; National Cancer Institute (Riley Wong for ProPublica)

Polling Question

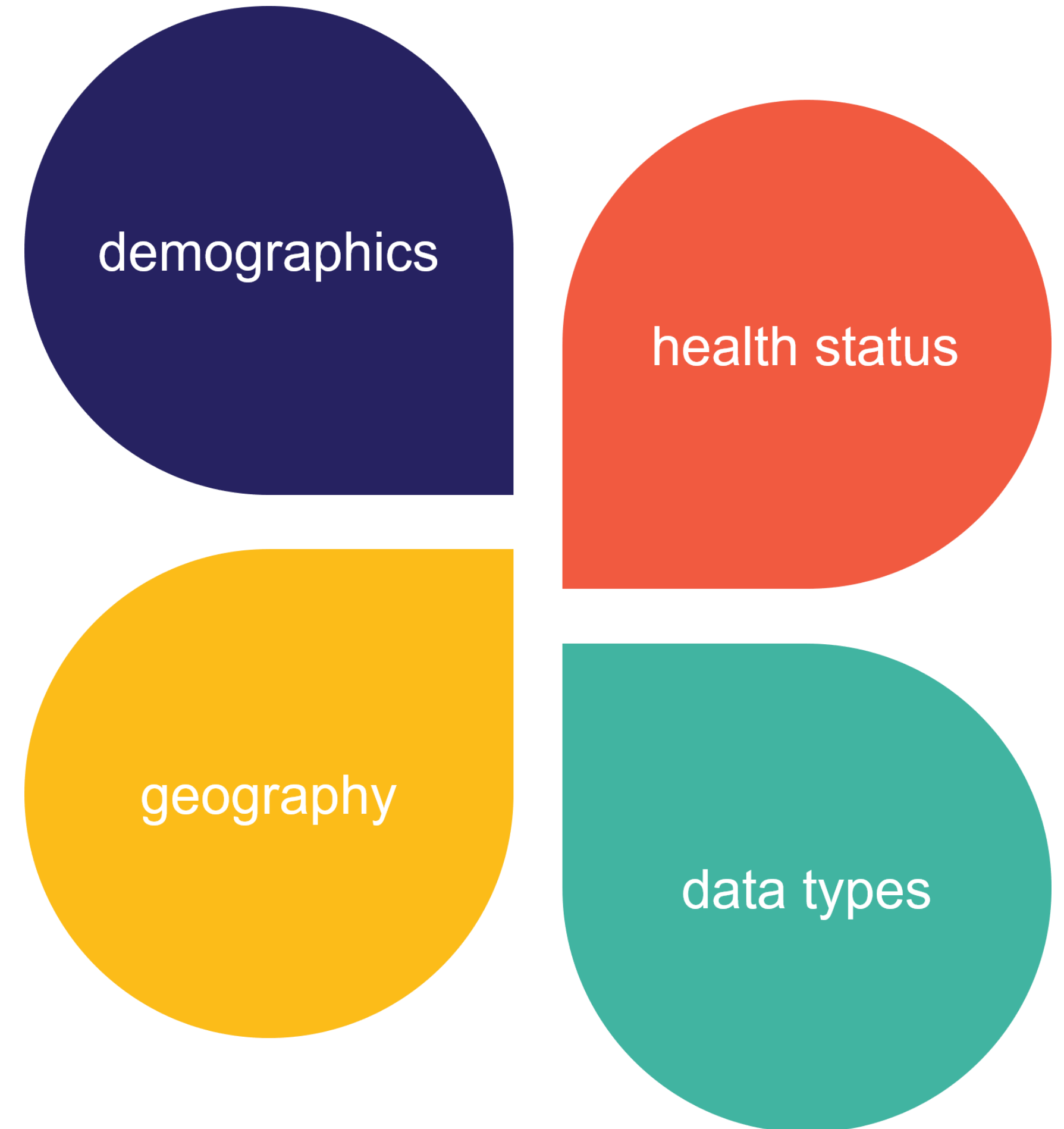
Now that you're more familiar with the connections between local, public health and precision medicine, we would like to understand if precision medicine connect to any current effort of you or your health departments. Please indicate if you believe that precision medicine might have implications for the work of you or your health department as noted below:

- ☒ On Screen: Precision medicine has implications for my work.
- Agree
 - Disagree
 - Unsure

The *All of Us* Approach to Diversity

Reflecting the country's rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.

- ① Develop a **national network of Health Care Provider Organizations (HPOs)** with incentives & methods to reach most diverse people & places
- ① Create **an innovative network of Direct Volunteer partners** to reach at least 90% of where all people live, within 20-45 minutes
- ① Build a **network of national & local Community Partners** to help build lifelong, trusted relationships with key communities & areas in the country
- ① Drive programs that **lead the way** for diverse communities to participate



All of Us Research Program Consortium

DATA AND RESEARCH CENTER

Big data capture, cleaning, curation,
& sharing in secure environment

Vanderbilt, Verily, Broad Institute

BIOBANK

Repository for processing, storing
& sharing biosamples (35+M vials)

Mayo Clinic

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web and phone-based platforms
for participants

Vibrent Health

PARTICIPANT CENTER / DV NETWORK

Direct volunteer participant enrollment,
digital engagement innovation &
consumer health technologies

*Scripps Research Institute
(with multiple partners)*

HEALTHCARE PROVIDER ORGS NETWORK

HPOs with clinical & scientific expertise,
enrollment & retention of participants

*30+ regional medical centers, FQHCs,
VA, and future awards to grow network*

COMMUNICATIONS & COMMUNITY NETWORK

Communications, marketing & design
expertise; engagement coordination &
community partners network

*Wondros, HCM, 29 community partner
organizations, and future awards to
grow network*

All of Us Consortium Members

DV Network

(Direct Volunteers)



Biobank



HPO Network

(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium

Illinois Precision Medicine Consortium

New England Precision Medicine Consortium

Trans-American Consortium for the Health Care Systems Research Network

New York City Precision Medicine Consortium

Southern All of Us Network

SouthEast Enrollment Center

UC San Diego Health



All of Us, Wisconsin

University of Arizona

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

VA Medical Centers



Communication & Engagement

WONDROS



Platform Development



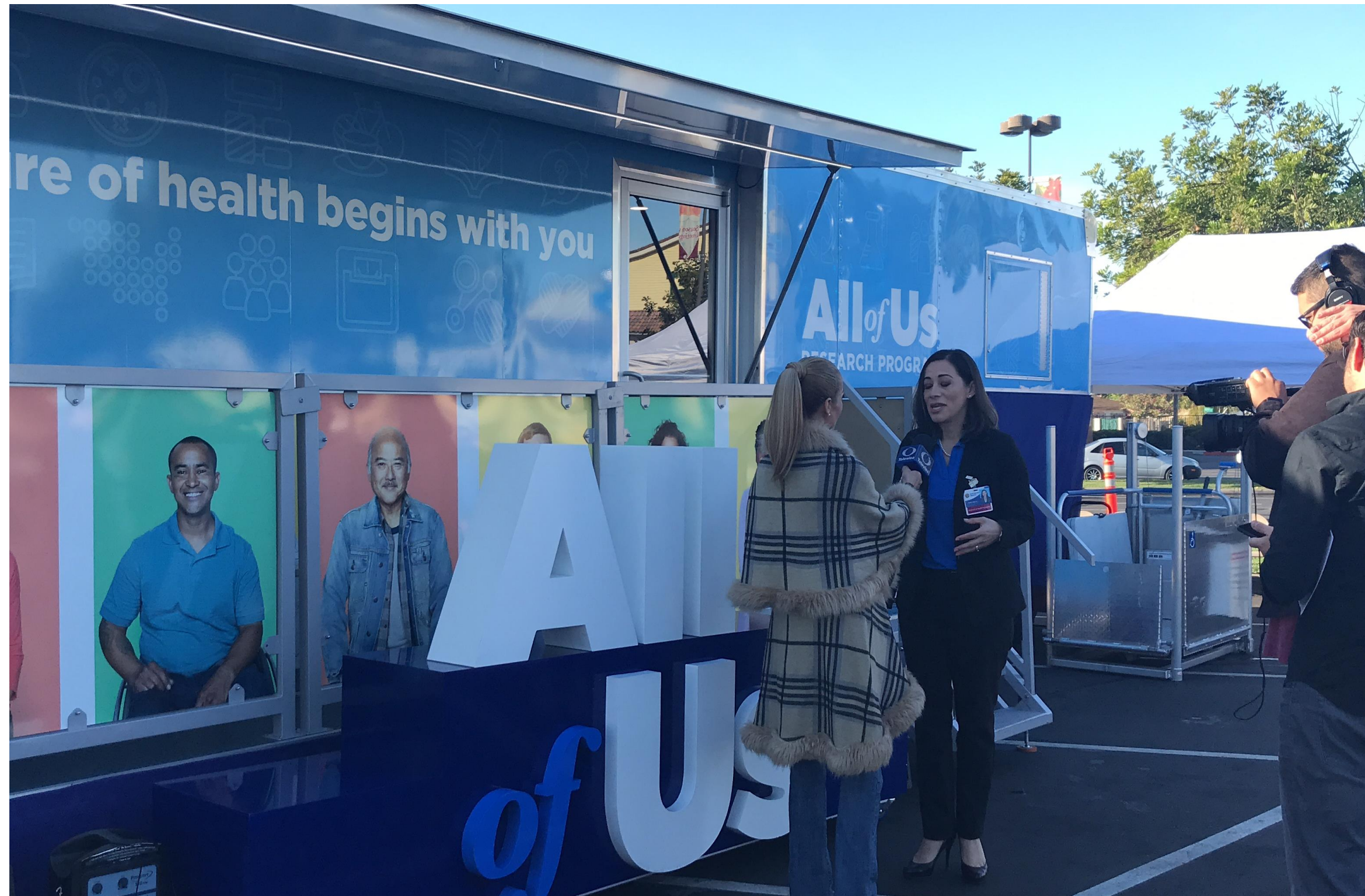
WONDROS



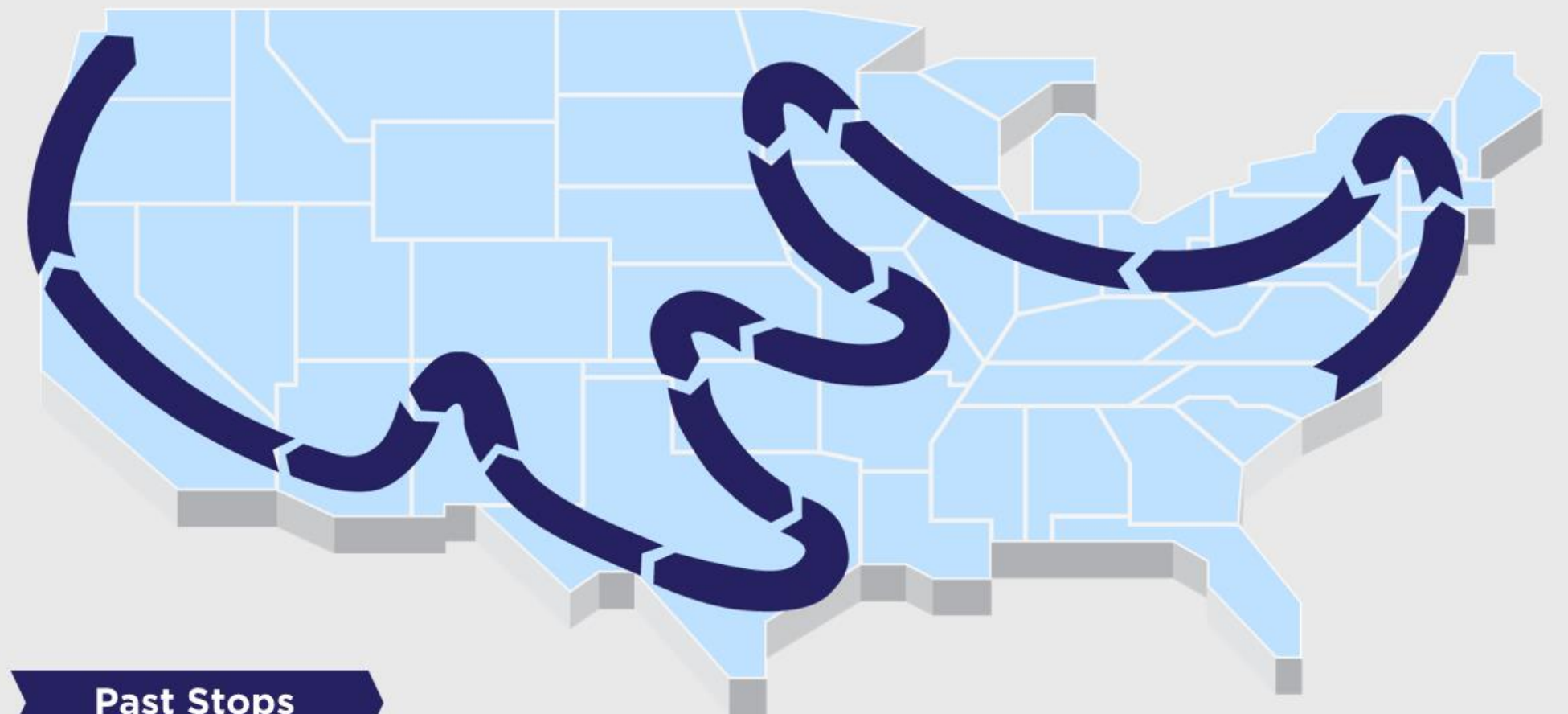
All of Us Community and Provider Partner Network



All of Us Journey

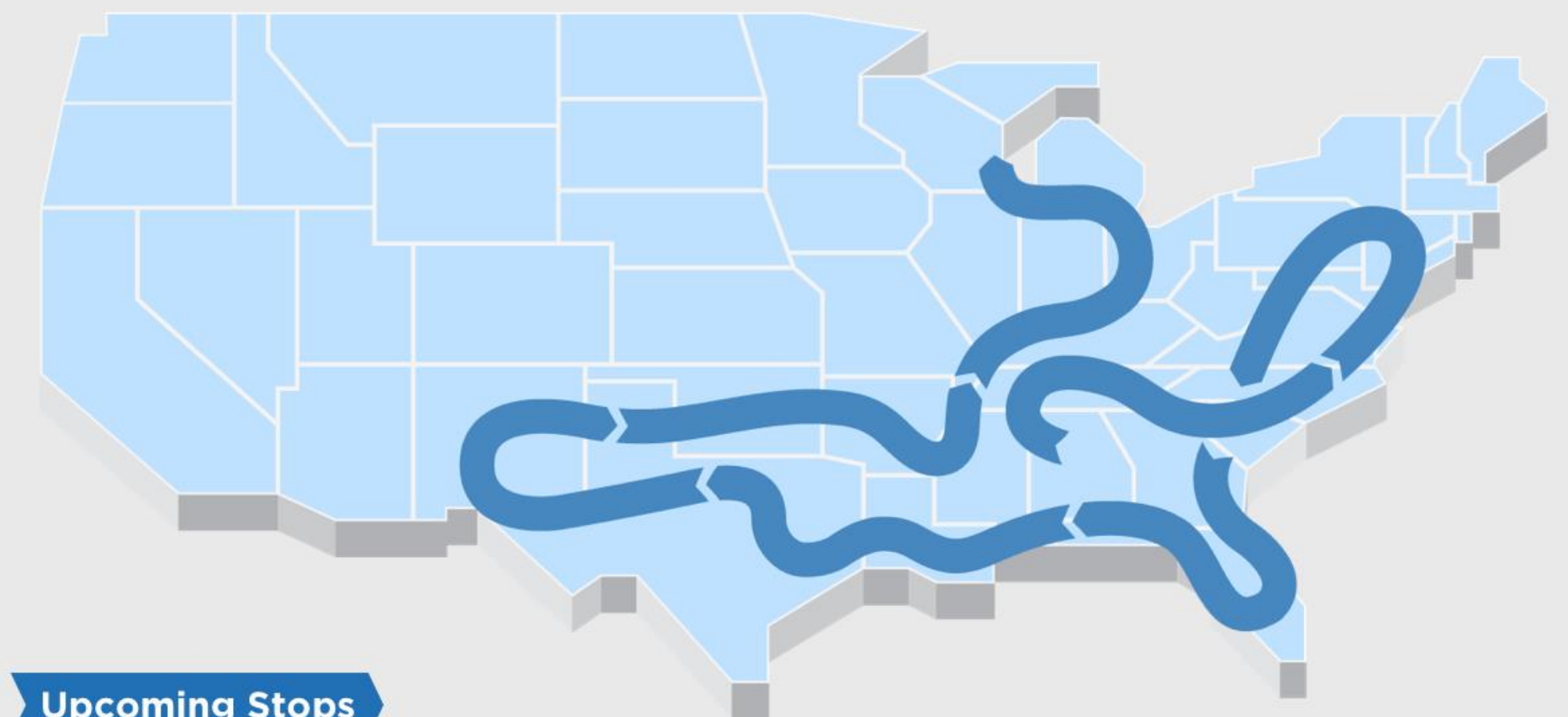


2017-2018



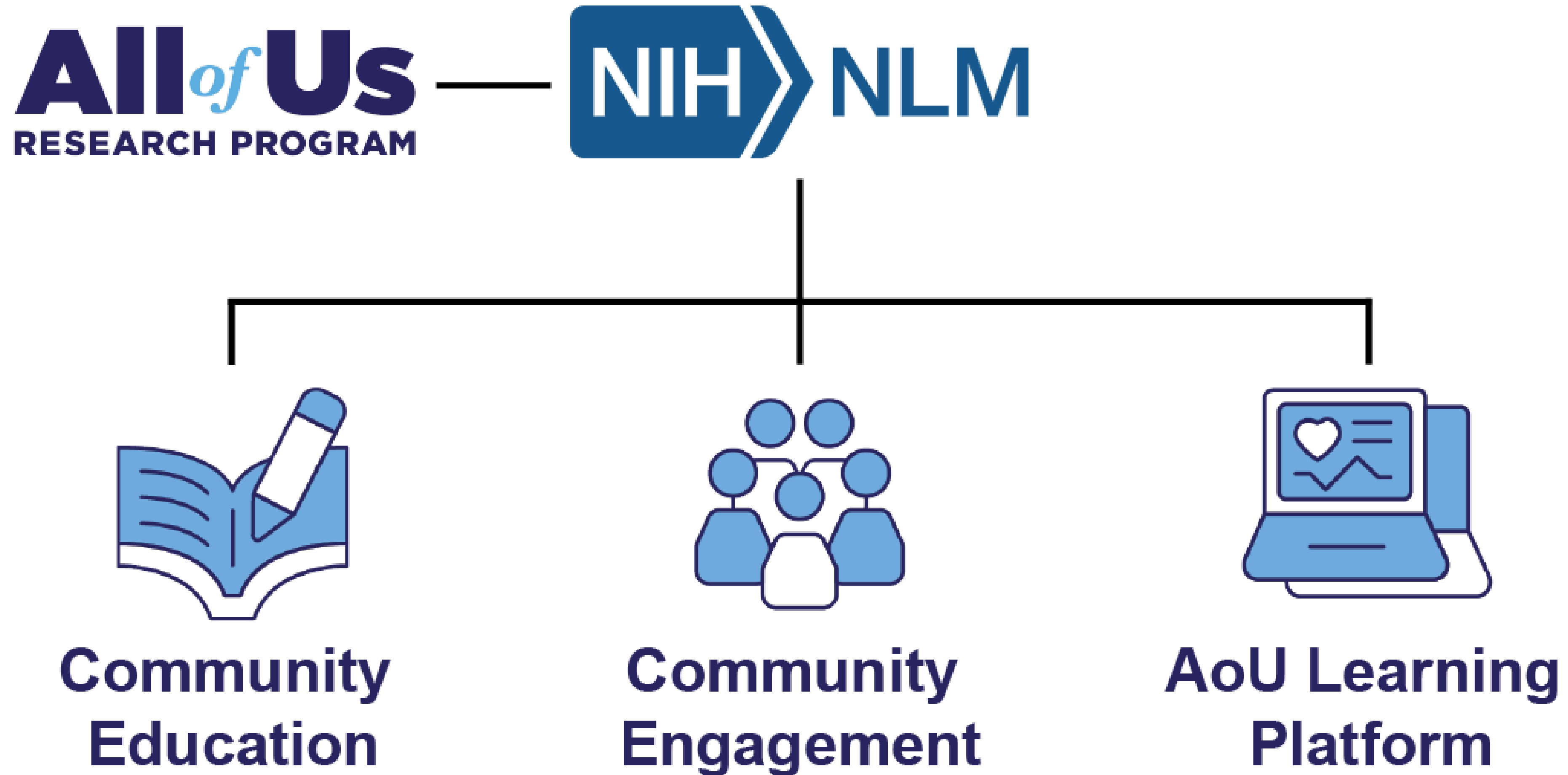
Past Stops

2018-2019



Upcoming Stops

Partnership Between *All of Us* and NLM



**The promise of *All of Us* for participants,
health care providers and researchers.**

What is the Promise for Participants?

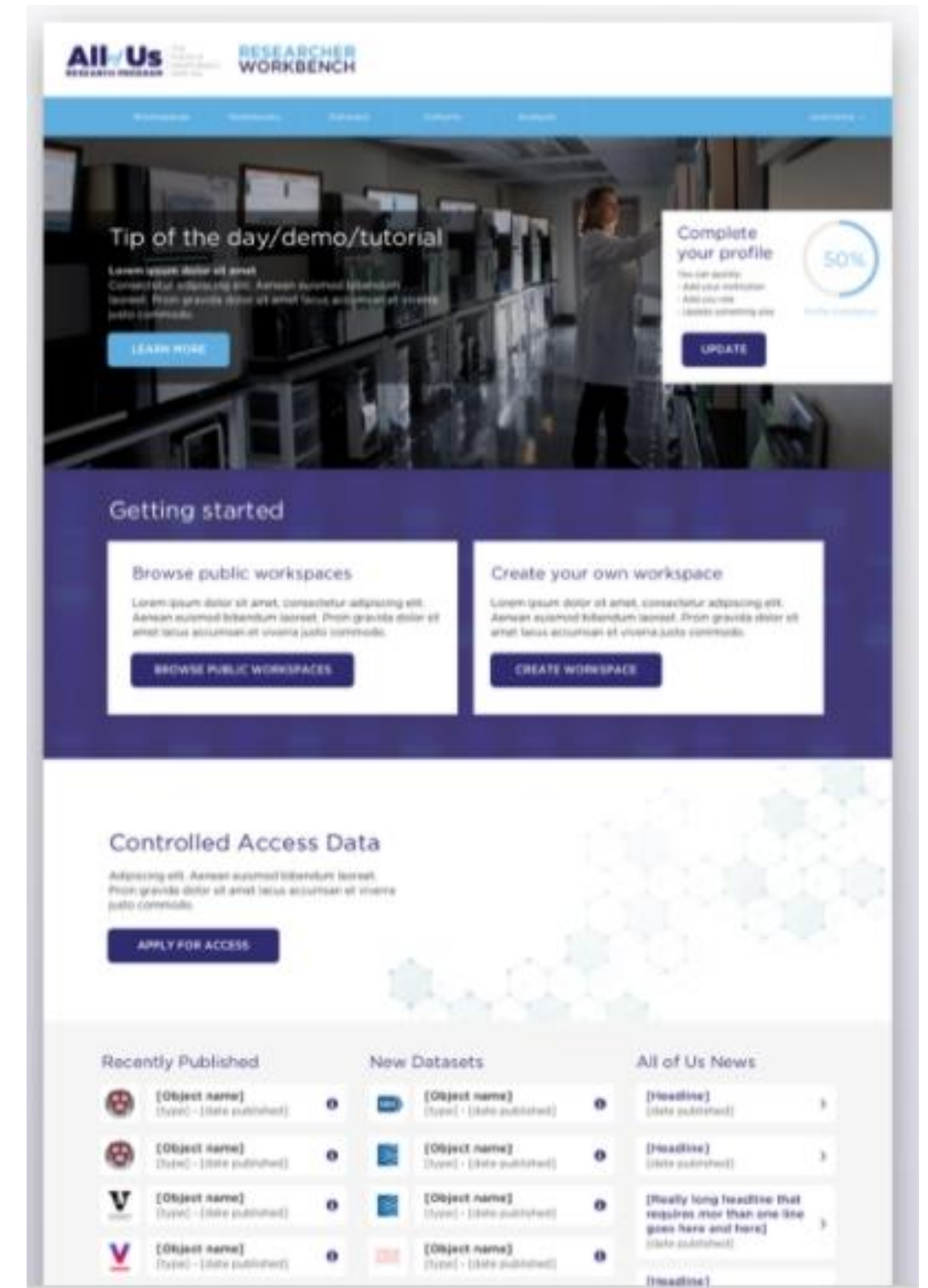
- An opportunity to **fight disease** and improve the health of future generations.
- The opportunity to **be part of a movement** to make our health care more precise, more personal and more effective.
- The opportunity to **ensure that your community is included** in the studies that may lead to new understanding and new treatments.
- An **opportunity to learn** some of your own health indicators and get your own data.



This is a long-term relationship and the value to participants (and researchers) will grow over time.

What is the Promise for Researchers?

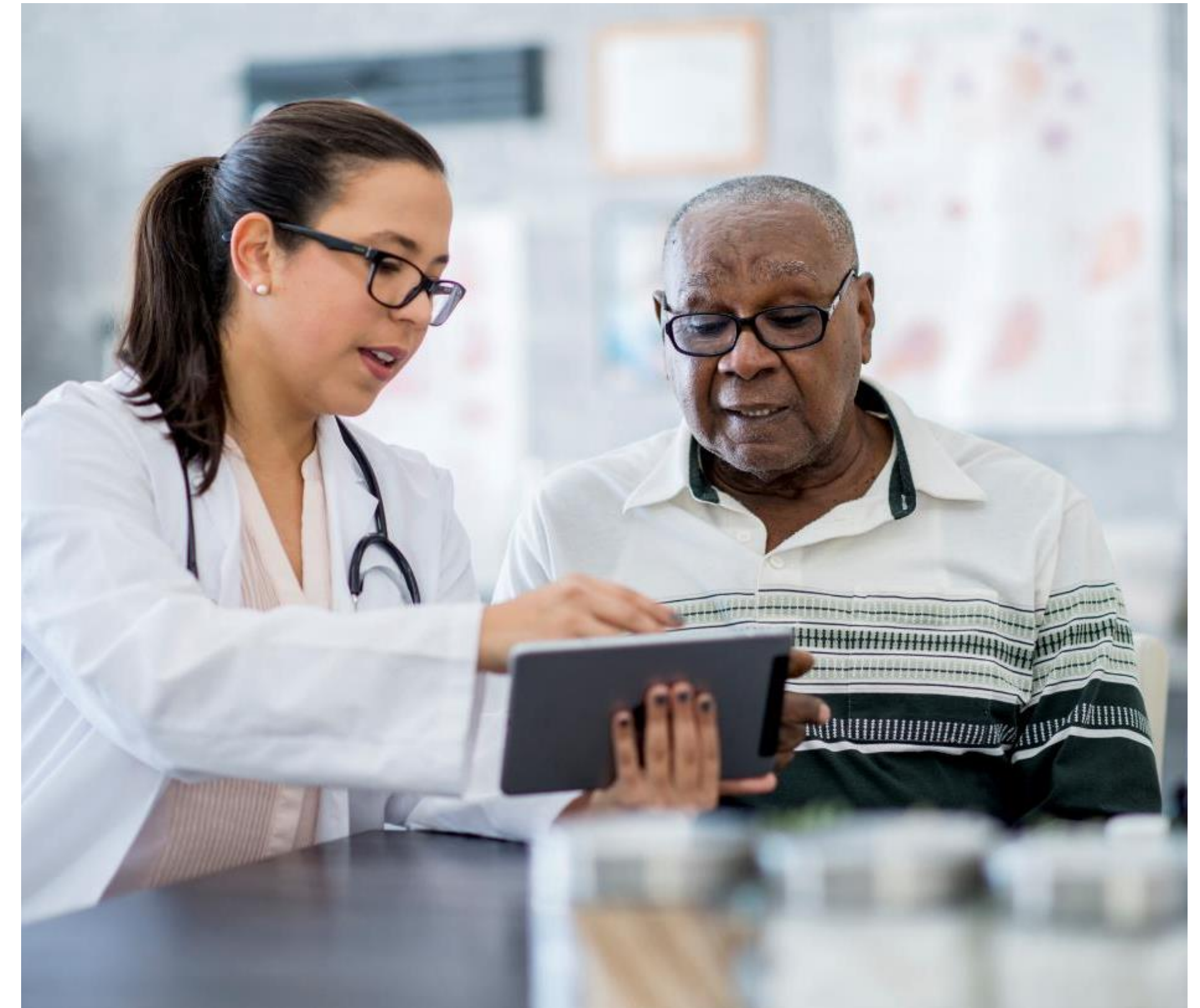
- ① The opportunity to **save time and resources** and **accelerate your research breakthroughs** by leveraging:
 - A **rich resource of data**, including biospecimens and increasingly robust electronic health records.
 - A **longitudinal dataset** that will follow participants as they move, age, develop relationships, get sick and try treatments.
 - A **diverse cohort of participants**, including people both healthy and sick, from all walks of life and all parts of the country.
 - Both raw data and data that is already **cleaned and curated**.
 - **Robust computing and analytic tools** to support complex data analyses in a **secure data environment**.
 - A group of **engaged participants** who may be eager to participate in ancillary studies.
- ② The ability to easily **share workspaces** with research partners and reviewers.
- ③ The chance to learn from the program's pilots and experiments and **leverage innovations** for other studies and cohorts.



As with most studies, we are collecting, evaluating and curating initial datasets; availability in 2019.

What is the Promise for Providers?

- ◎ Over time, **increased scientific evidence and improved guidelines** to enable precision medicine opportunities for more people and conditions:
 - Better understanding of the **impact of environment and lifestyle factors** on health.
 - Increased knowledge of differences in risk factors and responses to treatments among **diverse populations**.
 - More information on the development of conditions that will allow for **earlier detection**.
 - Deeper understanding of different conditions that may allow for **better stratification**.
- ◎ Innovations that may make it easier to **share electronic health records (EHRs)** with other providers and patients.
- ◎ New knowledge to help address **health disparities**, increase **patient engagement** and understand the usefulness of **consumer health devices and apps**.



Help accelerate medical breakthroughs by sharing information about *All of Us* with your patients!



Where Are We Now? Where Are We Headed?

Present

- **> 160,000** people registered to begin the participant journey
- **> 94,000** participants have completed all elements of the core protocol
- **~ 75%** of current participants self-identify as belonging to one or more populations that have been historically underrepresented in biomedical research
- **~50%** are from racial and ethnic minority groups

Future

- **Broadening inclusion** to additional demographics
- Expanding **linguistic support** for non-English or Spanish speakers

All of Us
RESEARCH PROGRAM

The
Future of
Health Begins
With You

Join Us!

help@joinallofus.org

joinallofus.org/together | @AllofUsResearch | #JoinAllofUs

Precision Medicine Initiative, PMI, 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.