The *All of Us* Research Program & eMERGE: Points of Synergy

October 30, 2017

National Institutes of Health

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National Institutes of Health

All of Us RESEARCH PROGRAM

The
Precision
Medicine
Initiative

Rich, Longitudinal Resource: Deliver a national resource of deep clinical, environmental, lifestyle, & genetic data from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)

Diversity of Participants: Reflect the broad diversity of the U.S.; all ages, races/ ethnicities, gender, SES, geographies, & health status

Diversity of Researchers: Build the tools & capabilities that make it easy for researchers from citizen scientists to premier university labs

All of Us & eMERGE

Many similarities and differences that provide opportunities for shared learning, validation of findings/methods, leveraging tools

- Expanding the data set for:
  - PGx genotypes and drug response
  - Actionable genes/variants
  - Genomic medicine implementation studies
  - ELSI, policy research
- Innovative methods for integration of different types of health data for research
- Engagement & Retention: Participant feedback; FQHC lessons learned; consent testing; usability
- Return of results (ACMG, PGx to start)
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  - Patient education
- Electronic phenotyping (building and validating)
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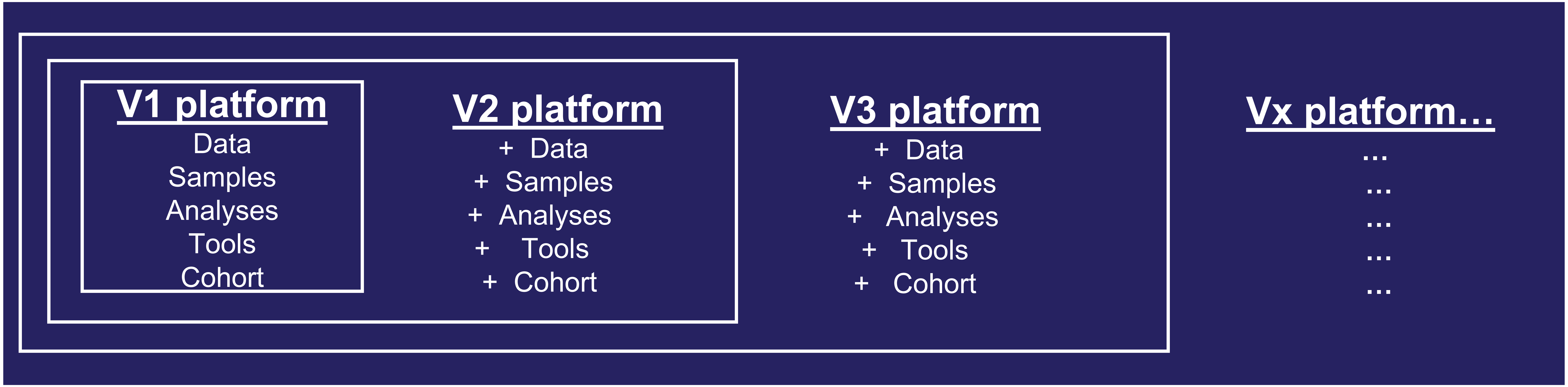
All of Us Research Program Data

The Program will start by collecting a limited set of standardized data from sources that will include:

- Participant questionnaires
- Electronic health records
- A baseline physical evaluation
- Biospecimens (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

Data types will grow and evolve with science, technology, and trust.



V1 platform
Data
Samples
Analyses
Tools
Cohort

V2 platform
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

V3 platform
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

Vx platform…
…
…
…
…
…

Two Methods of Engagement

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS

National Network of Inaugural Partners

National Partners

Regional Medical Centers

FQHCs

Community Partners

San Francisco General Hospital Foundation

Wondros

Scripps Translational Science Institute (Participant Center)

California Precision Medicine Consortium

San Ysidro Health Center

University of Arizona (w/Banner Health)

Mayo Clinic (Biobank)

All of Us, Wisconsin

Illinois Precision Medicine Consortium

Vanderbilt Univ. Medical Center, with Broad & Verily (Data and Research Center)

Southern *All of Us* Network

Jackson-Hinds Comprehensive Health Center

Trans-American Precision Medicine Consortium

University of Pittsburgh

Cherokee Health Systems

FiftyForward

SouthEast Enrollment Center

Hudson River Health Care

Eau Claire Cooperative Health Center

Community Health Center, Inc.

New England Precision Medicine Consortium

New York City Precision Medicine Consortium

Federal Partners: White House, HHS, NIH, ONC, HRSA, VA, USDS

HCM

Vibrent (Participant Technology Systems Center)

National Alliance for Hispanic Health

Delta Research and Educational Foundation

Developing the Genomics Plan for *All of Us*

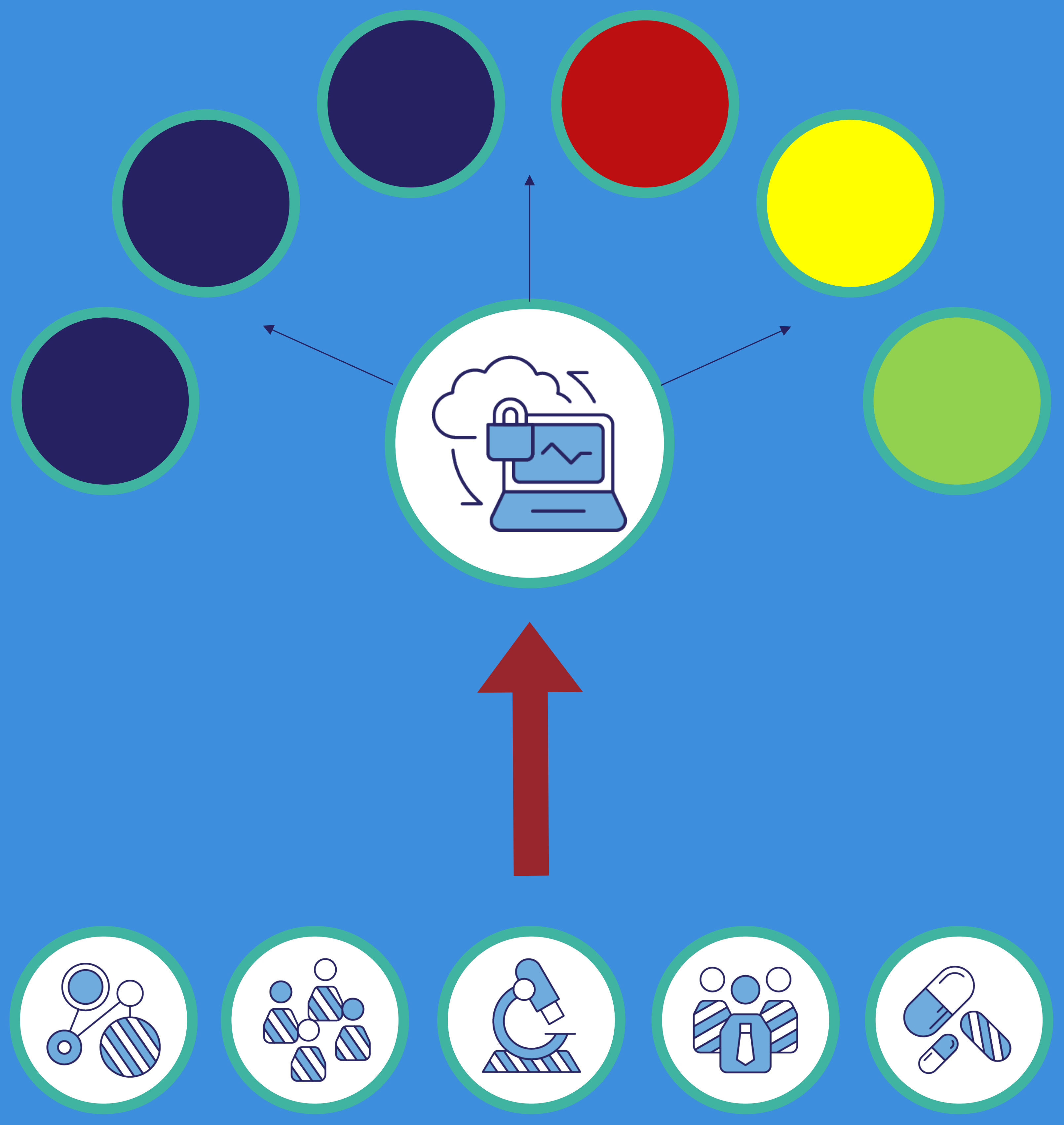
- **Recommendations from the ACD Working Group**:
  - "…very large investments such as whole genome sequencing for large numbers of individuals need to be keyed to specific scientific use cases that are compellingly cost-effective at the current time…"
  - "…establish a mechanism to obtain ongoing expert advice on when the costs and capabilities of laboratory methods have achieved a "tipping point" where scientific value justifies whole-cohort sequencing, proteomic, or other omic assessments…"
- **We have started the process of determining AOU's genomic plans**:
  - Gathered feedback from potential participants in different communities on their concerns/hopes
  - Held Return of Genetic Results Workshop with internal and external experts (March 2017)
  - Kicked off Genomics Working Group of the Advisory Panel, in partnership with NHGRI
  - Report expected this week

Data Access

Researcher Based Access

Work Stations

Public Posting:
researchers
project description
data used
publications



- No data removal
- Tiered access approval
- Data passport model
- Broad access, researchers from all sectors, citizen scientists, etc

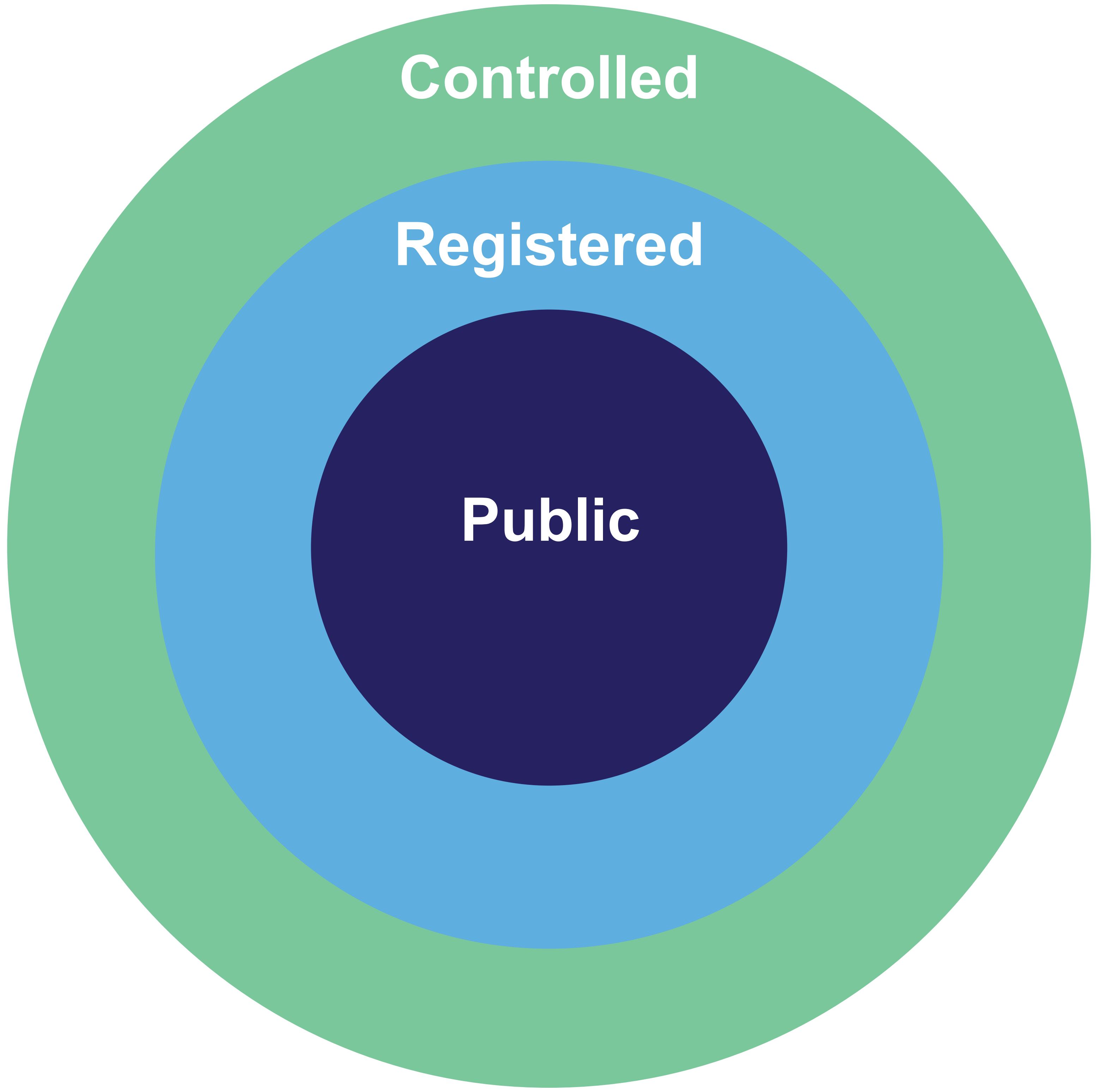
Data Passport:
All of Us data is consented for general research use; no specific data use restrictions.

Access to All of Us data resources will be researcher-based, not project-based, manner.

Researchers will be granted “data passports” to access Registered- and/or Controlled-access datasets.

21st Century Cures Act
“...on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.”

Data Tiers



Public - Data that poses minimal risks to the privacy of research participants. Fully open without login.

anyone, anywhere, anytime

Registered- Data that has some risk of identifying research participants and therefore poses some privacy risk to participants.

requires data use agreement, identity verification, ethics training, approval

Controlled - Data that poses more risk to the privacy of research participants.

requirements for registered access + institutional signing official

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Technology to Support Integration of Health Data

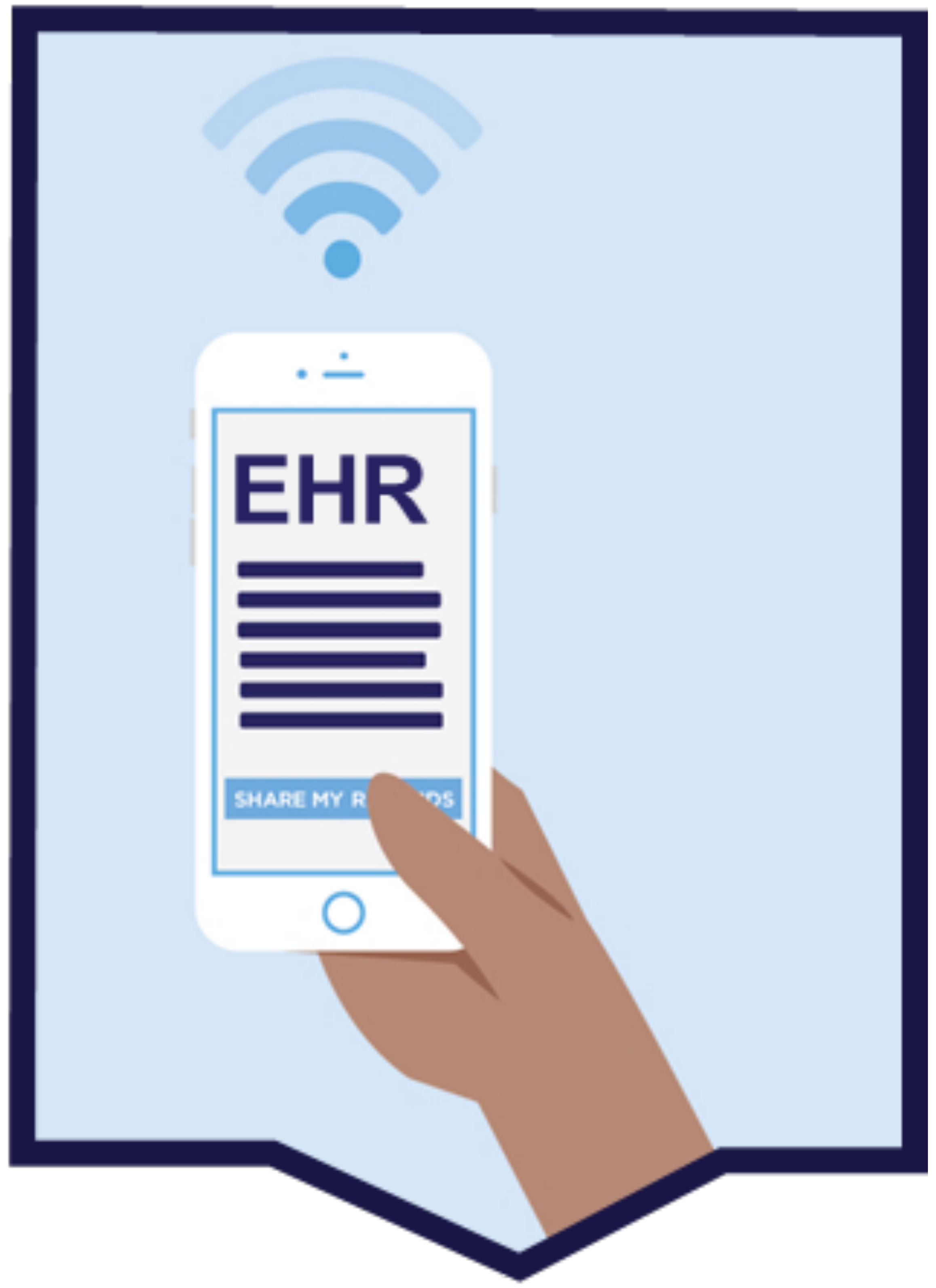
Building capacity for the entire research community:

- EHR data from disparate sources: Sync 4 Science, data aggregators
- Claims data: CMS-NIH collaboration (PCORTF): Medicare Beneficiary Claims Data to Research Studies
- Medications: directly from pharmacies
- Genetic testing reports: Sync 4 Genes, **Sync for Genes** has been created to leverage HL7 FHIR infrastructure for communicating information from clinical genomic labs in a format for universal use across medicine.

Electronic Health Records

- Participants will be asked to authorize linkage of their EHR information.

Initial Data Types	Expanded Data Types (May Include)
• Demographics • Visits • Diagnoses • Procedures • Medications • Laboratory Visits • Vital Signs	• Clinical Notes • Radiology, cardiology, and other reports • Mental Health Reports • Substance Abuse, Alcohol use, and Tobacco use • More laboratory results, potentially including genomics



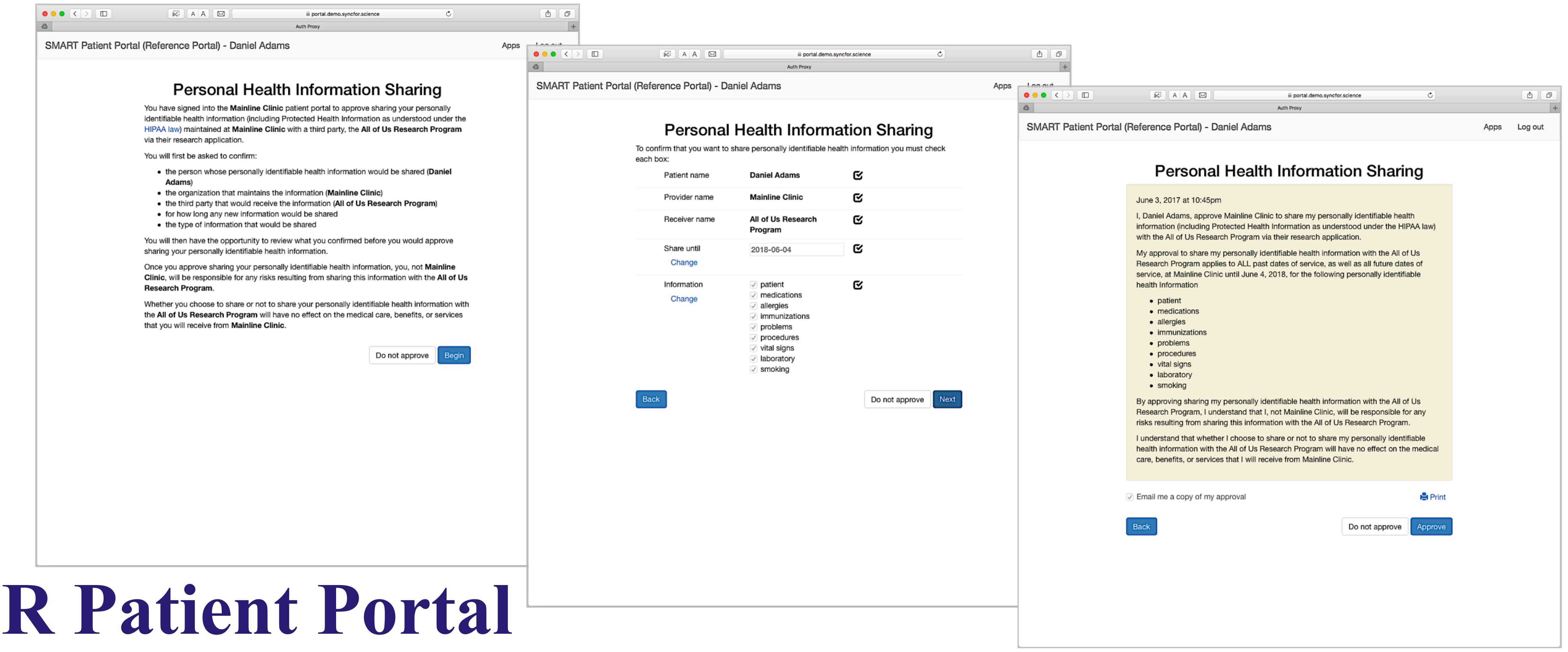
SYNC FOR SCIENCE

Sync 4 Science User Experience

Research App

With a few clicks, research participants can share their EHR data

Patient
Portal
Login



Personal Health Information Sharing

You have signed into the **Mainline Clinic** patient portal to approve sharing your personally identifiable health information (including Protected Health Information as understood under the HIPAA law) maintained at **Mainline Clinic** with a third party, the **All of Us Research Program** via their research application.

You will first be asked to confirm:

- the person whose personally identifiable health information would be shared (**Daniel Adams**)
- the organization that maintains the information (**Mainline Clinic**)
- the third party that would receive the information (**All of Us Research Program**)
- for how long any new information would be shared
- the type of information that would be shared

You will then have the opportunity to review what you confirmed before you would approve sharing your personally identifiable health information.

Once you approve sharing your personally identifiable health information, you, not **Mainline Clinic**, will be responsible for any risks resulting from sharing this information with the **All of Us Research Program**.

Whether you choose to share or not to share your personally identifiable health information with the **All of Us Research Program** will have no effect on the medical care, benefits, or services that you will receive from **Mainline Clinic**.

Do not approve | Begin

Personal Health Information Sharing

To confirm that you want to share personally identifiable health information you must check each box:

Patient name	**Daniel Adams**	☑
Provider name	**Mainline Clinic**	☑
Receiver name	**All of Us Research Program**	☑
Share until Change	2018-06-04	☑
Information Change	☑ patient ☑ medications ☑ allergies ☑ immunizations ☑ problems ☑ procedures ☑ vital signs ☑ laboratory ☑ smoking	☑

Back | Do not approve | Next

Personal Health Information Sharing

June 3, 2017 at 10:45pm

I, Daniel Adams, approve Mainline Clinic to share my personally identifiable health information (including Protected Health Information as understood under the HIPAA law) with the All of Us Research Program via their research application.

My approval to share my personally identifiable health information with the All of Us Research Program applies to ALL past dates of service, as well as all future dates of service, at Mainline Clinic until June 4, 2018, for the following personally identifiable health Information

- patient
- medications
- allergies
- immunizations
- problems
- procedures
- vital signs
- laboratory
- smoking

By approving sharing my personally identifiable health information with the All of Us Research Program, I understand that I, not Mainline Clinic, will be responsible for any risks resulting from sharing this information with the All of Us Research Program.

I understand that whether I choose to share or not to share my personally identifiable health information with the All of Us Research Program will have no effect on the medical care, benefits, or services that I will receive from Mainline Clinic.

☑ Email me a copy of my approval | Print

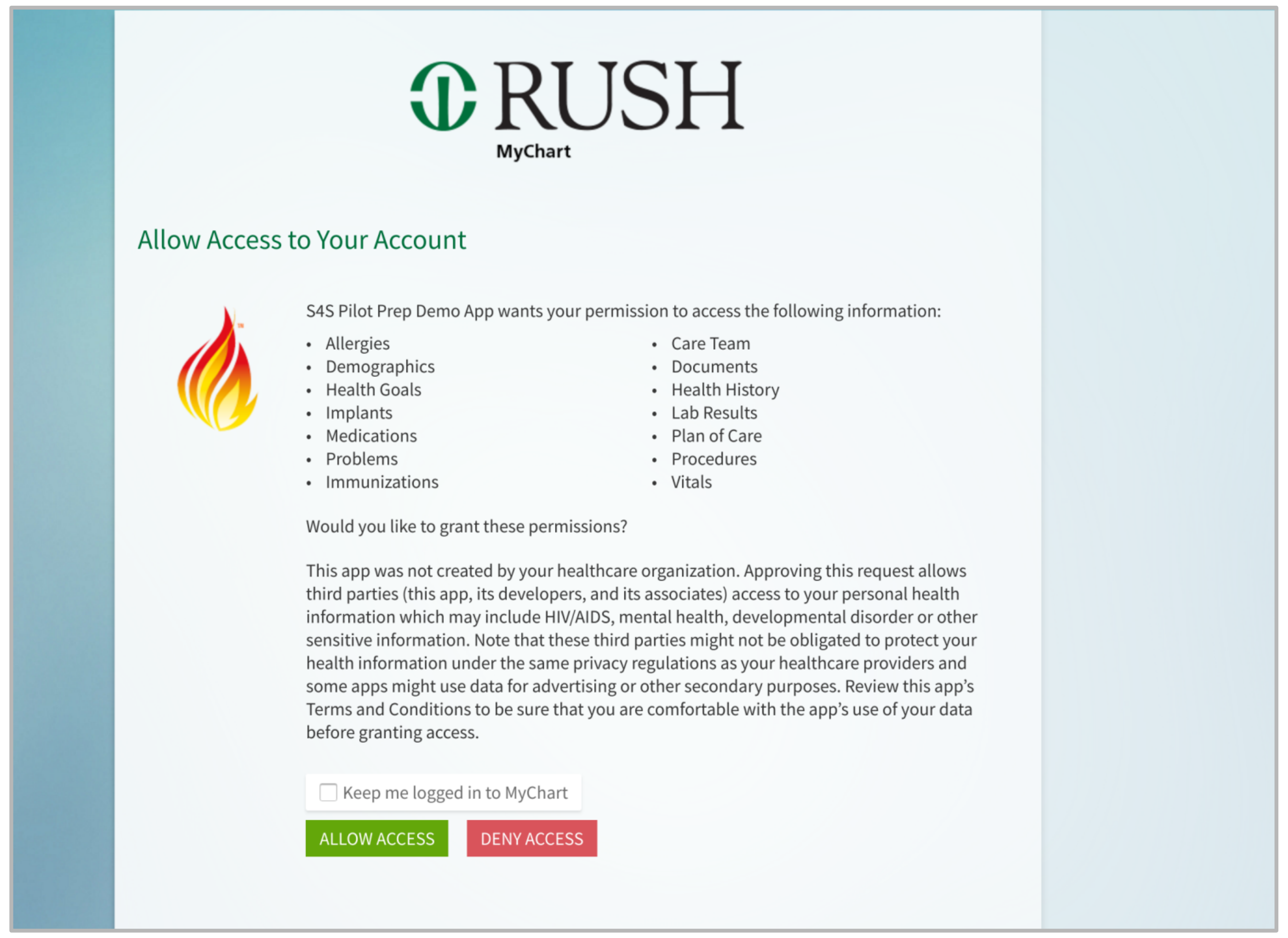
Back | Do not approve | Approve

EHR Patient Portal

Approve
Sharing
EHR Data

Sync 4 Science Vendor Partners

Epic



RUSH
MyChart

Allow Access to Your Account

S4S Pilot Prep Demo App wants your permission to access the following information:

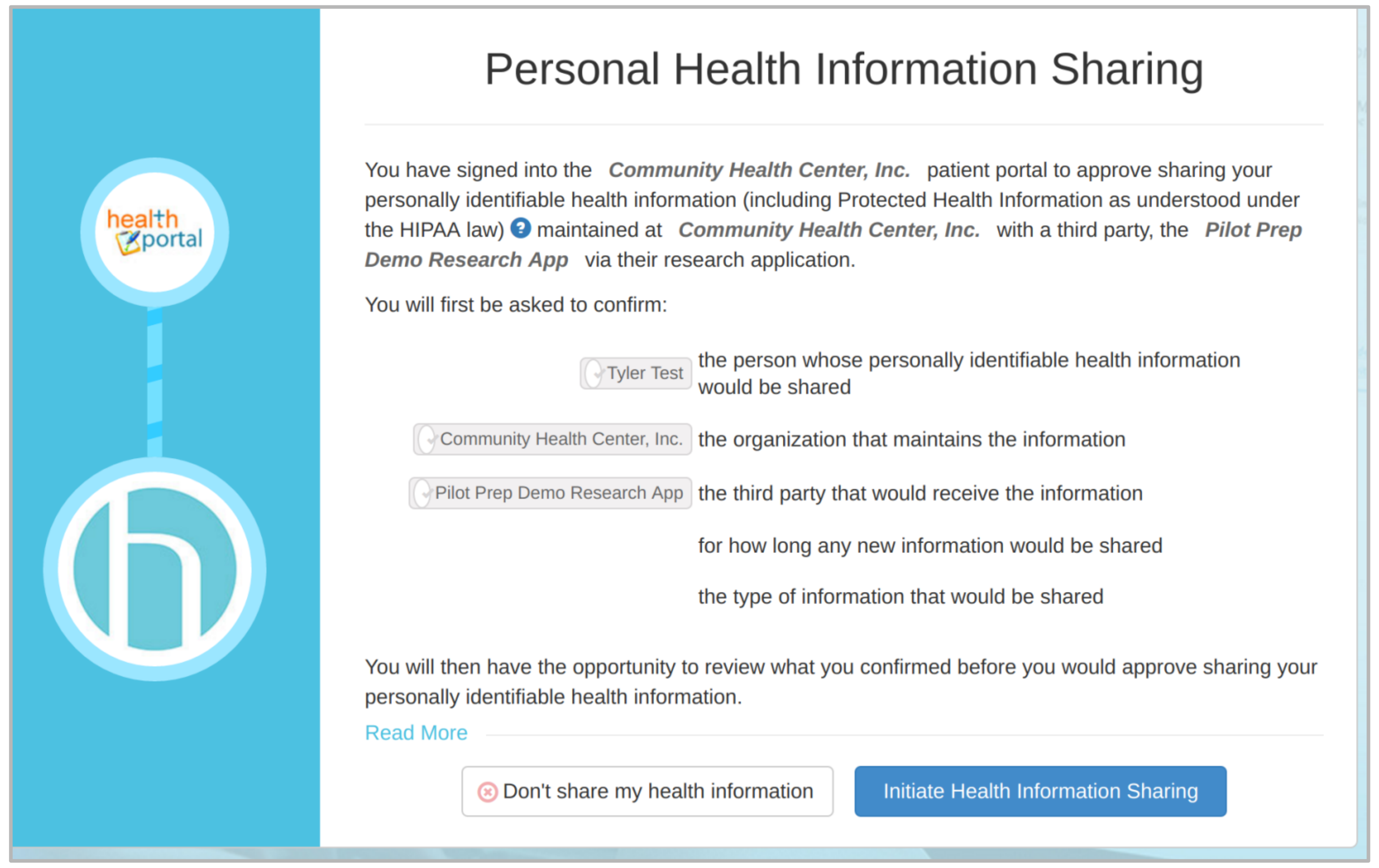
- Allergies
- Demographics
- Health Goals
- Implants
- Medications
- Problems
- Immunizations
- Care Team
- Documents
- Health History
- Lab Results
- Plan of Care
- Procedures
- Vitals

Would you like to grant these permissions?

This app was not created by your healthcare organization. Approving this request allows third parties (this app, its developers, and its associates) access to your personal health information which may include HIV/AIDS, mental health, developmental disorder or other sensitive information. Note that these third parties might not be obligated to protect your health information under the same privacy regulations as your healthcare providers and some apps might use data for advertising or other secondary purposes. Review this app's Terms and Conditions to be sure that you are comfortable with the app's use of your data before granting access.

☐ Keep me logged in to MyChart

eClinicalWorks



Personal Health Information Sharing

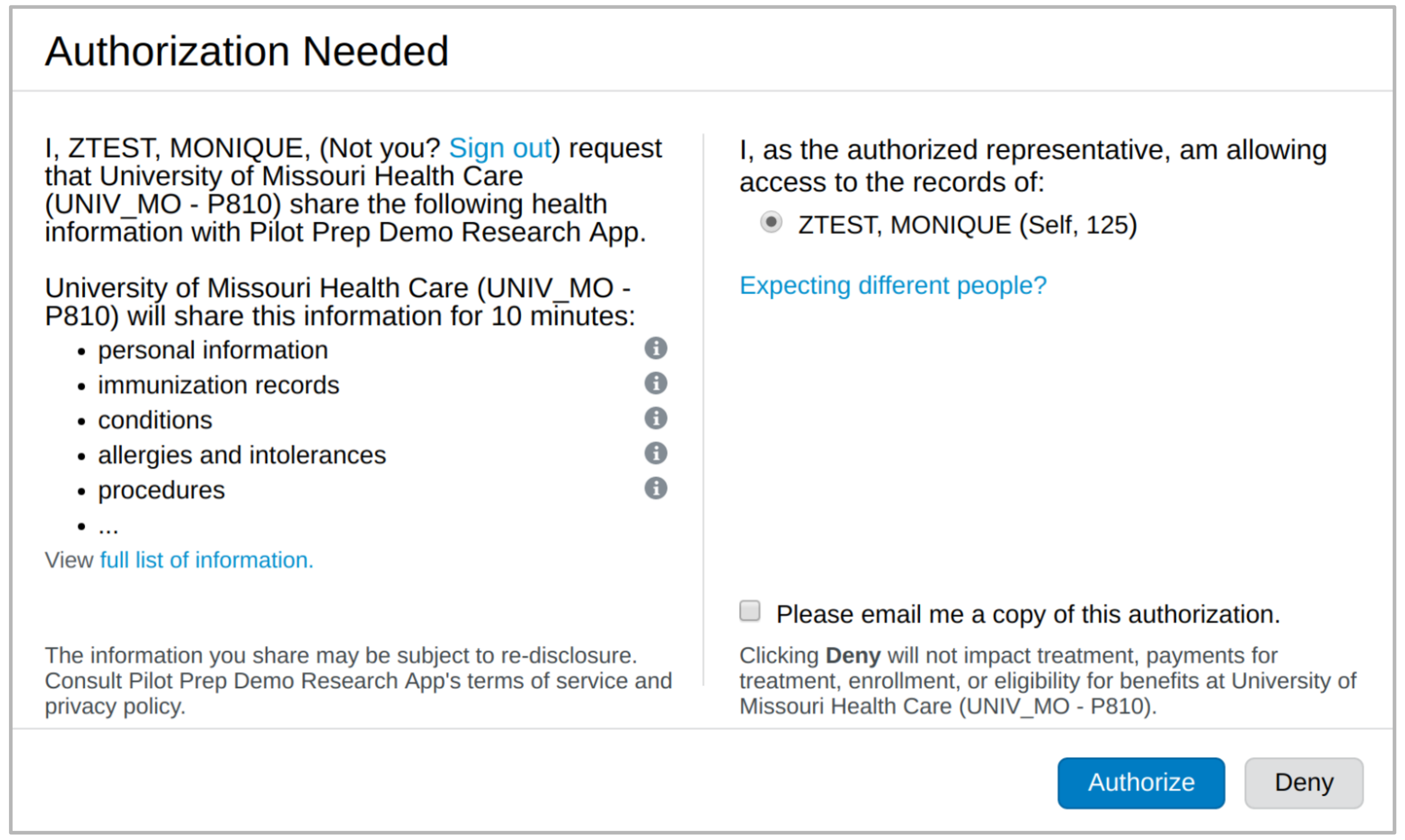
You have signed into the ***Community Health Center, Inc.*** patient portal to approve sharing your personally identifiable health information (including Protected Health Information as understood under the HIPAA law) maintained at ***Community Health Center, Inc.*** with a third party, the ***Pilot Prep Demo Research App*** via their research application.

You will first be asked to confirm:

Tyler Test	the person whose personally identifiable health information would be shared
Community Health Center, Inc.	the organization that maintains the information
Pilot Prep Demo Research App	the third party that would receive the information
	for how long any new information would be shared
	the type of information that would be shared

You will then have the opportunity to review what you confirmed before you would approve sharing your personally identifiable health information.

Cerner



Authorization Needed

I, ZTEST, MONIQUE, (Not you? Sign out) request that University of Missouri Health Care (UNIV_MO - P810) share the following health information with Pilot Prep Demo Research App.

University of Missouri Health Care (UNIV_MO - P810) will share this information for 10 minutes:

- personal information
- immunization records
- conditions
- allergies and intolerances
- procedures
- ...

View full list of information.

The information you share may be subject to re-disclosure. Consult Pilot Prep Demo Research App's terms of service and privacy policy.

I, as the authorized representative, am allowing access to the records of:

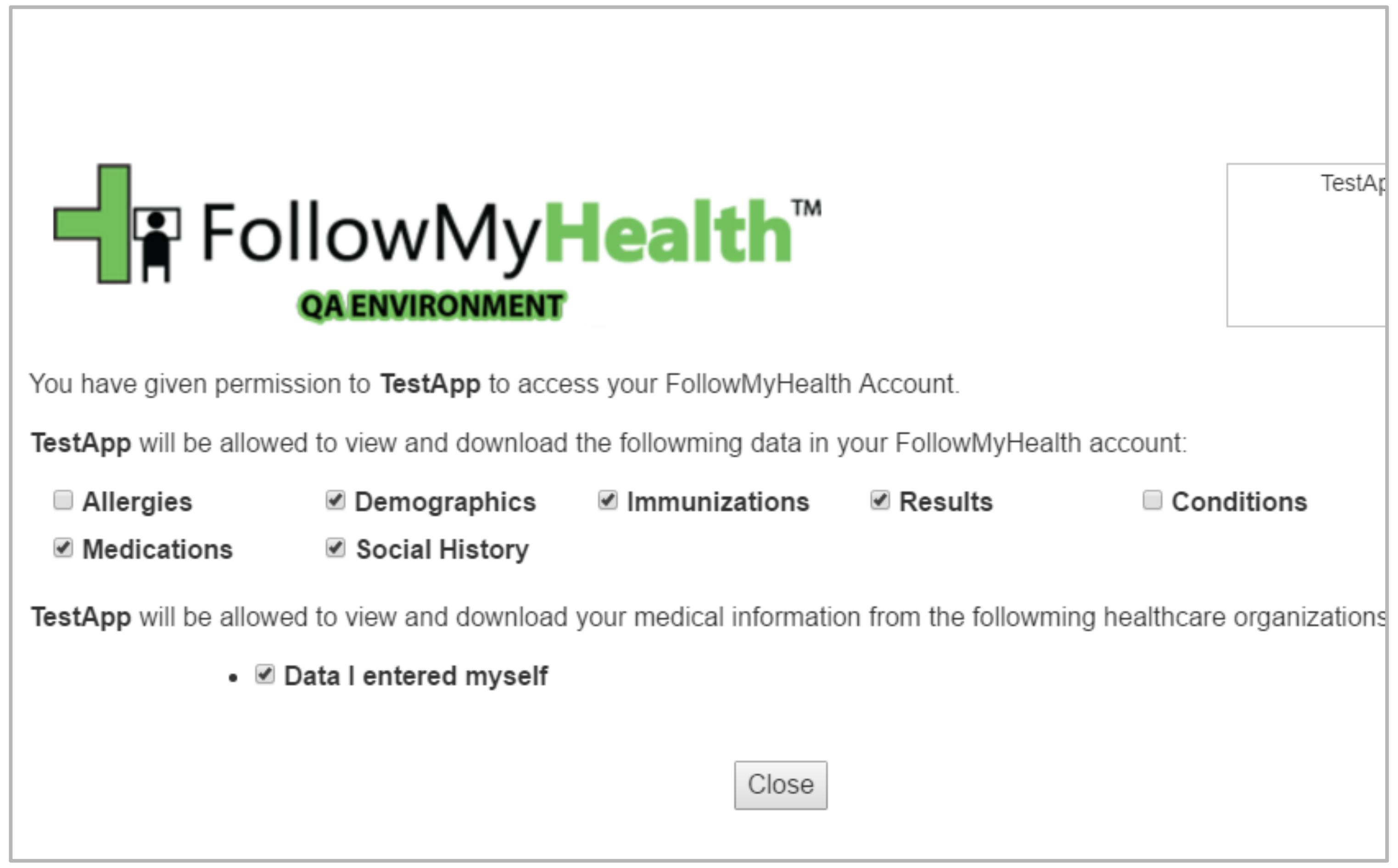
● ZTEST, MONIQUE (Self, 125)

Expecting different people?

☐ Please email me a copy of this authorization.

Clicking **Deny** will not impact treatment, payments for treatment, enrollment, or eligibility for benefits at University of Missouri Health Care (UNIV_MO - P810).

Allscripts™



FollowMyHealth™
QA ENVIRONMENT

You have given permission to **TestApp** to access your FollowMyHealth Account.

TestApp will be allowed to view and download the followming data in your FollowMyHealth account:

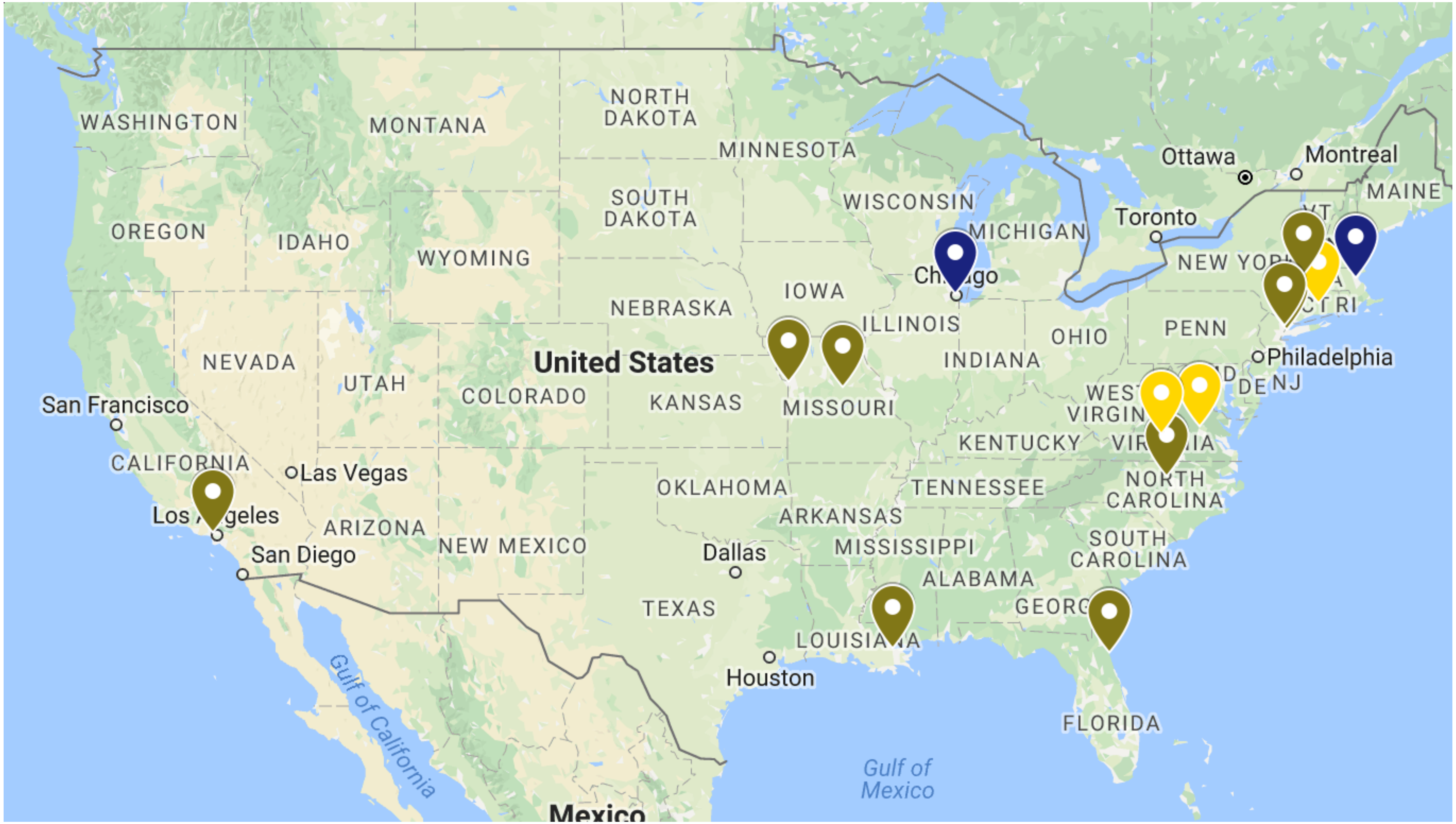
☐ Allergies ☑ Demographics ☑ Immunizations ☑ Results ☐ Conditions
☑ Medications ☑ Social History

TestApp will be allowed to view and download your medical information from the followming healthcare organizations

- ☑ Data I entered myself

SYNC FOR SCIENCE

Sync-4-Science Pilot Sites



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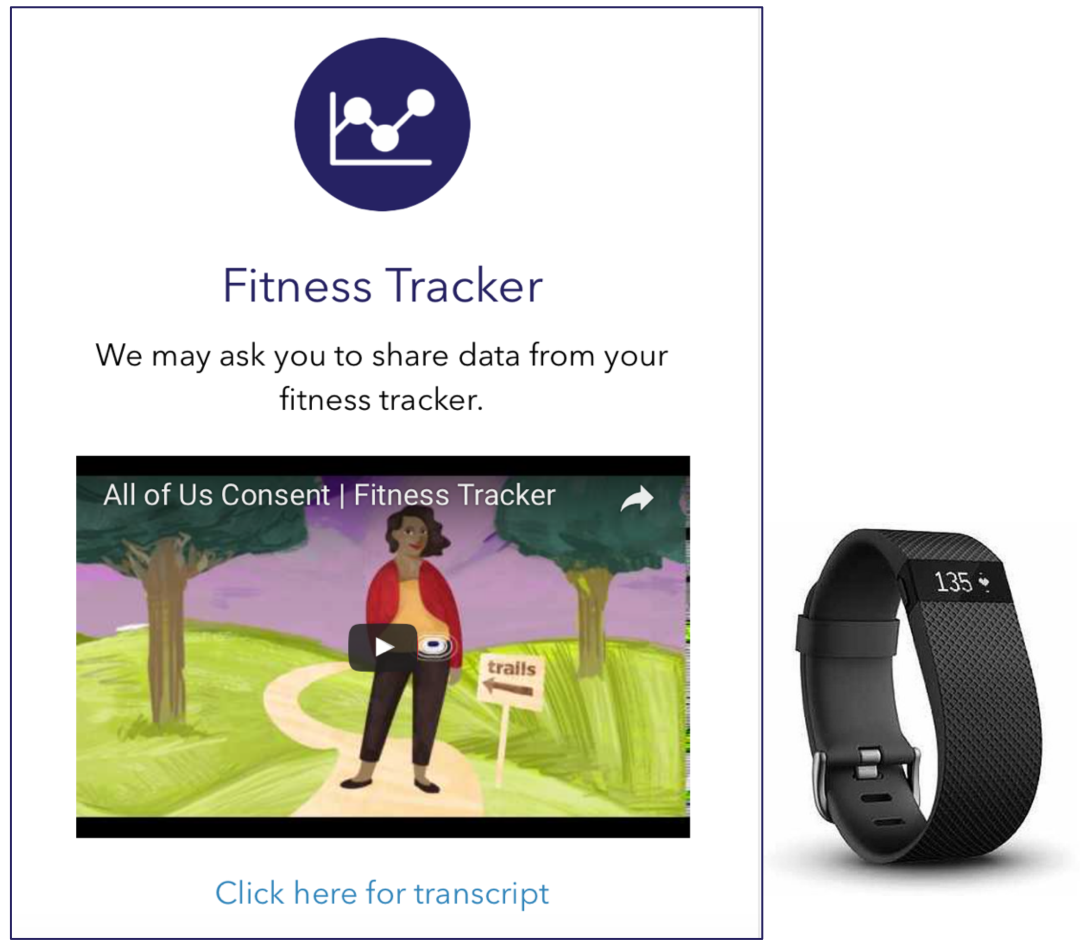
Digital Engagement (items under consideration)

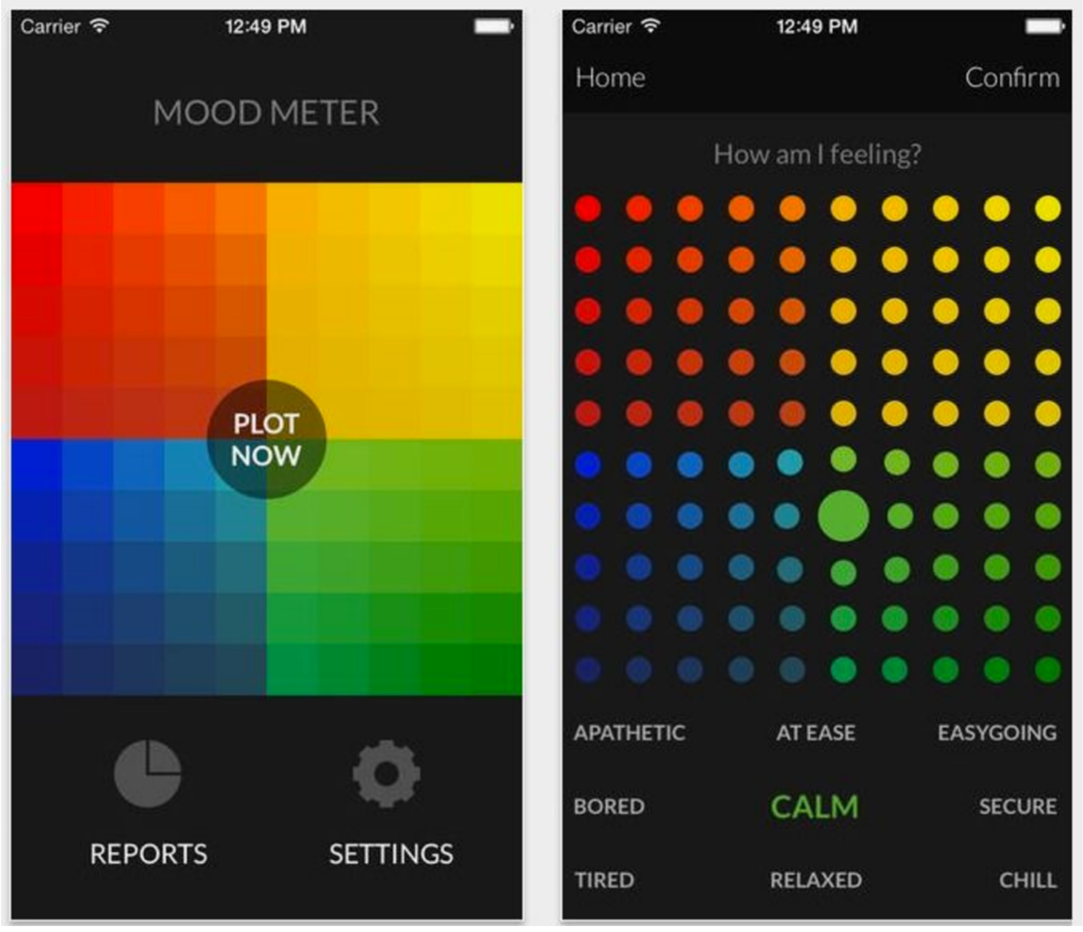


Fitness Tracker

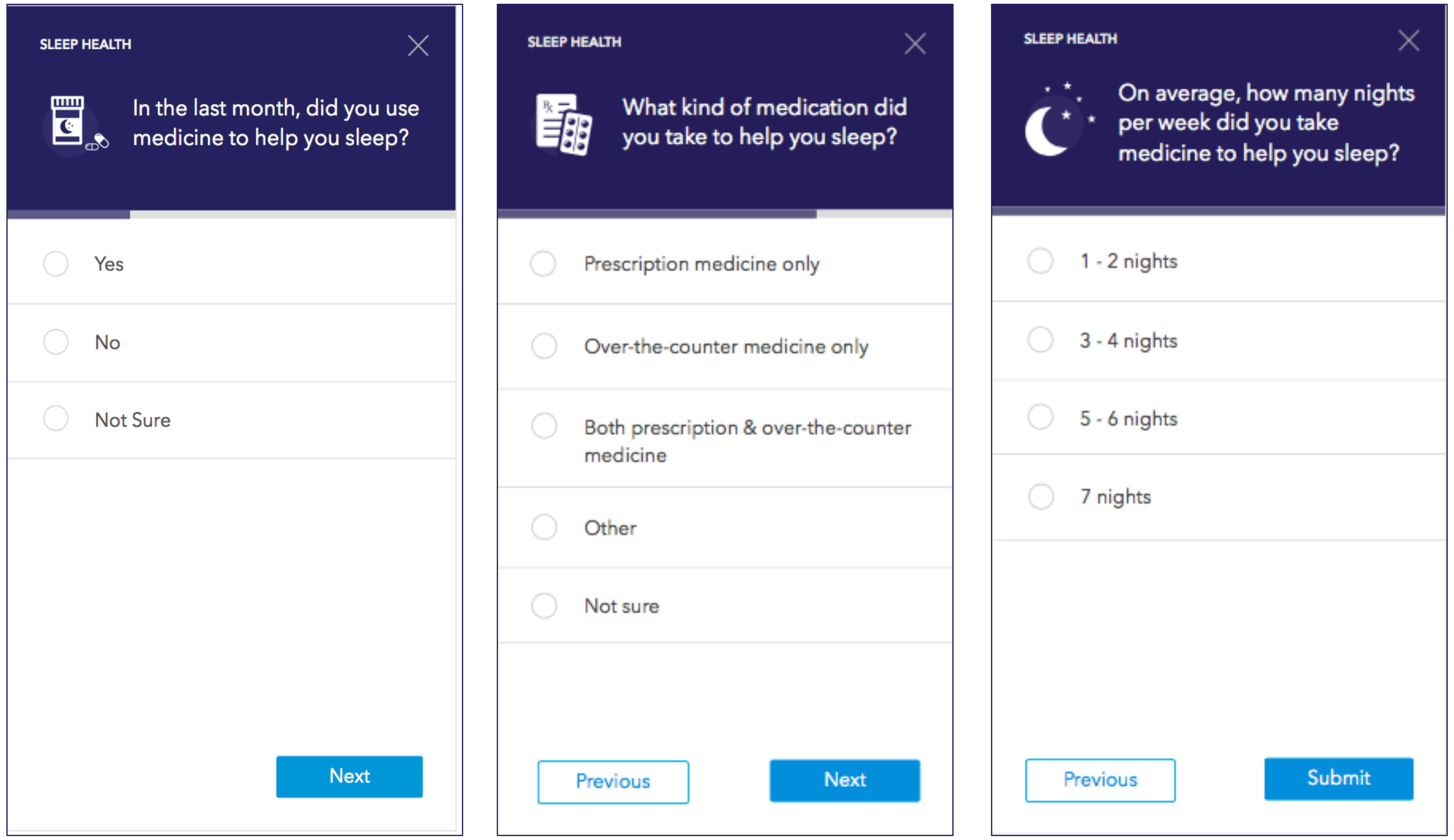
We may ask you to share data from your fitness tracker.

Click here for transcript

Fitbit Data Share



Mood App



In the last month, did you use medicine to help you sleep?

○ Yes

○ No

○ Not Sure

Next

What kind of medication did you take to help you sleep?

○ Prescription medicine only

○ Over-the-counter medicine only

○ Both prescription & over-the-counter medicine

○ Other

○ Not sure

Previous Next

On average, how many nights per week did you take medicine to help you sleep?

○ 1 - 2 nights

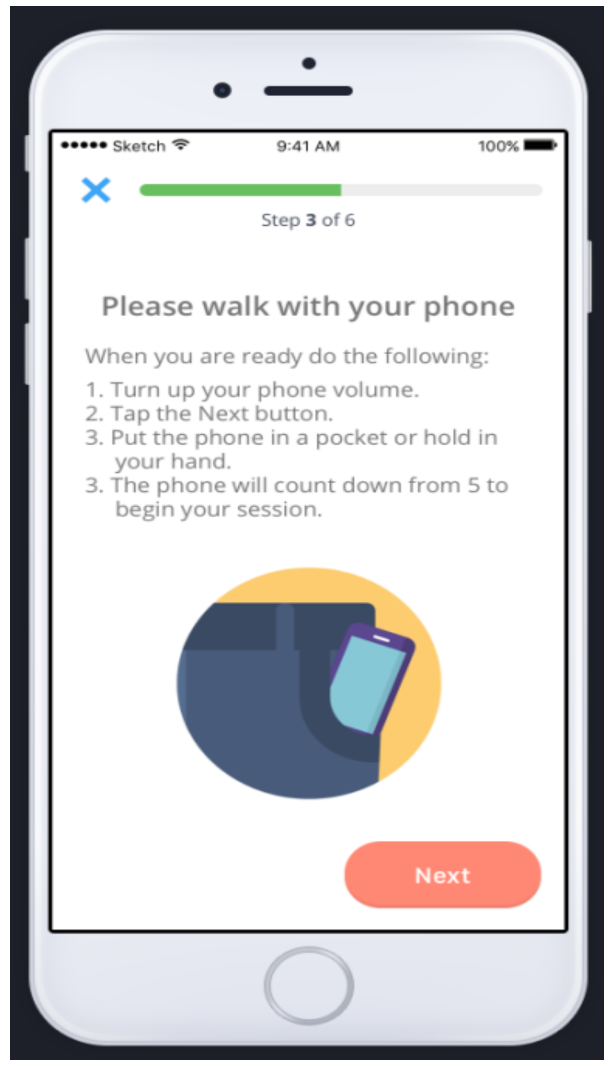
○ 3 - 4 nights

○ 5 - 6 nights

○ 7 nights

Previous Submit

Snapshot Surveys



Please walk with your phone

When you are ready do the following:

1. Turn up your phone volume.
2. Tap the Next button.
3. Put the phone in a pocket or hold in your hand.
3. The phone will count down from 5 to begin your session.

CardioRespiratory Fitness App

Headache App

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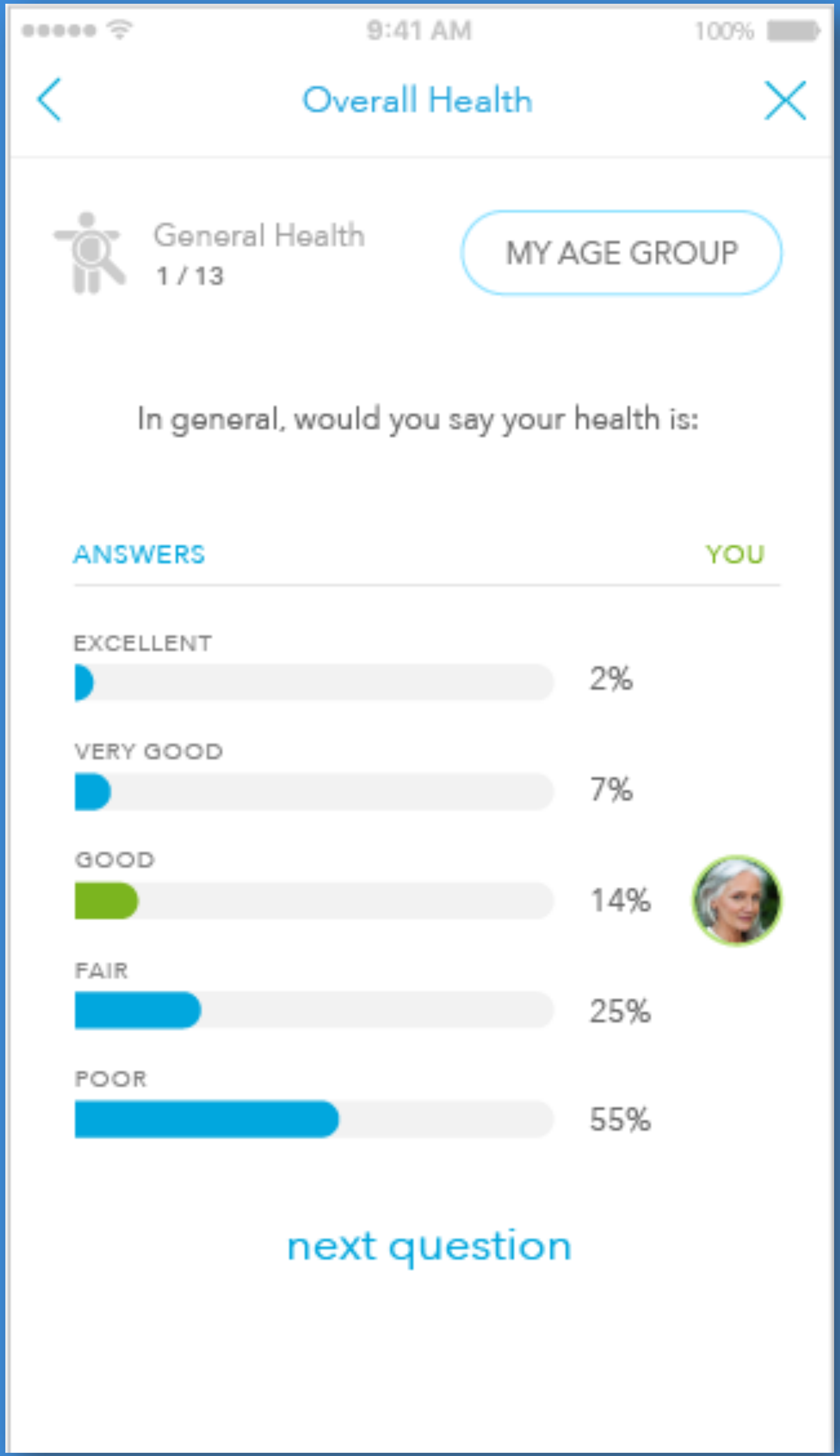
Return of Information

Participants may receive, depending on their preferences:

- Individual health information
- Survey data (comparative)
- EHR data, claims data
- Research results
- Ongoing study updates
- Aggregated results
- Scientific findings
- Opportunities to be contacted for other research opportunities



In general, would you say your health is:

ANSWERS		YOU
EXCELLENT	2%	
VERY GOOD	7%	
GOOD	14%	●
FAIR	25%	
POOR	55%	

NIH
National Institutes of Health

Return of Genetic Results in the *All of Us* Research Program

Workshop
March 6-7, 2017

All of Us
RESEARCH PROGRAM

WORKSHOP GOALS:

- Assess the state-of-the-field for the return of genomic information.
- Establish guidelines for return of genetic results considering the distinctive features and core principles of the *All of Us* Research Program.

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Setting Priorities

The *All of Us* Research Priorities Workshop

- **Date and Location:** March 21-23, 2018, in Bethesda, MD
- **Purpose**: Identify key research priorities that will capitalize on the *All of Us* Research Program's one million or more participants to help ensure optimal value for advancing precision medicine.
- **Planning Committee:** Senior leaders across NIH's Institutes and Centers.
- **Workshop Participants:** A broad array of stakeholders (e.g., researchers, participants, professional societies, advocacy groups); by invitation
- **Outreach Plans:** Obtain substantial input on research questions and requirements prior to the workshop.

All of Us RESEARCH PROGRAM
The Precision Medicine Initiative

Three Big Questions for the workshop

1. **Near Term**

   What are low-hanging fruit questions/measures for which the scale of *All of Us* could help accelerate knowledge & breakthroughs in precision medicine?

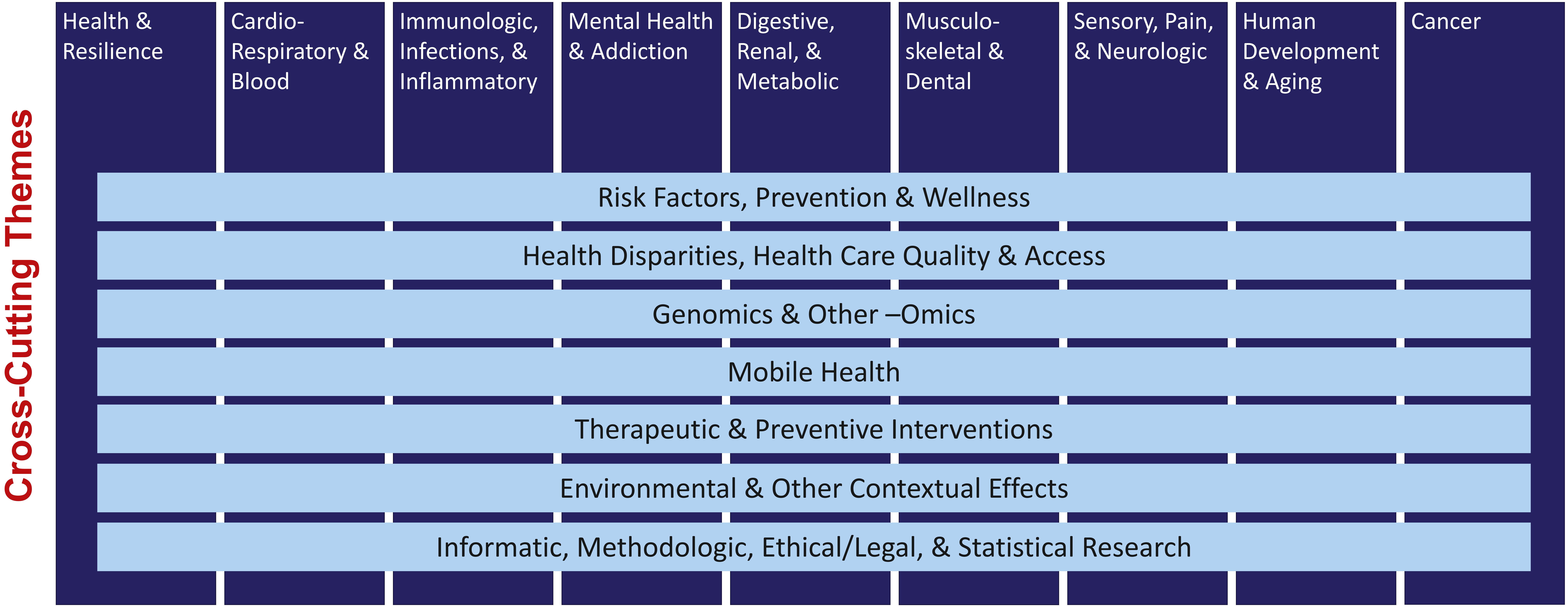
2. **Mid-Term**

   What kinds of questions might this Program answer where additional work selecting among measures/instruments is needed?

3. **Long Term**

   What kinds of questions are ripe for a program of this size but for which we need fundamental science & tech to develop the instruments and methods?

Scientific Framework for the *All of Us* March 2018 Workshop



Health Conditions

Health & Resilience

Cardio-Respiratory & Blood

Immunologic, Infections, & Inflammatory

Mental Health & Addiction

Digestive, Renal, & Metabolic

Musculo-skeletal & Dental

Sensory, Pain, & Neurologic

Human Development & Aging

Cancer

Cross-Cutting Themes

Risk Factors, Prevention & Wellness

Health Disparities, Health Care Quality & Access

Genomics & Other –Omics

Mobile Health

Therapeutic & Preventive Interventions

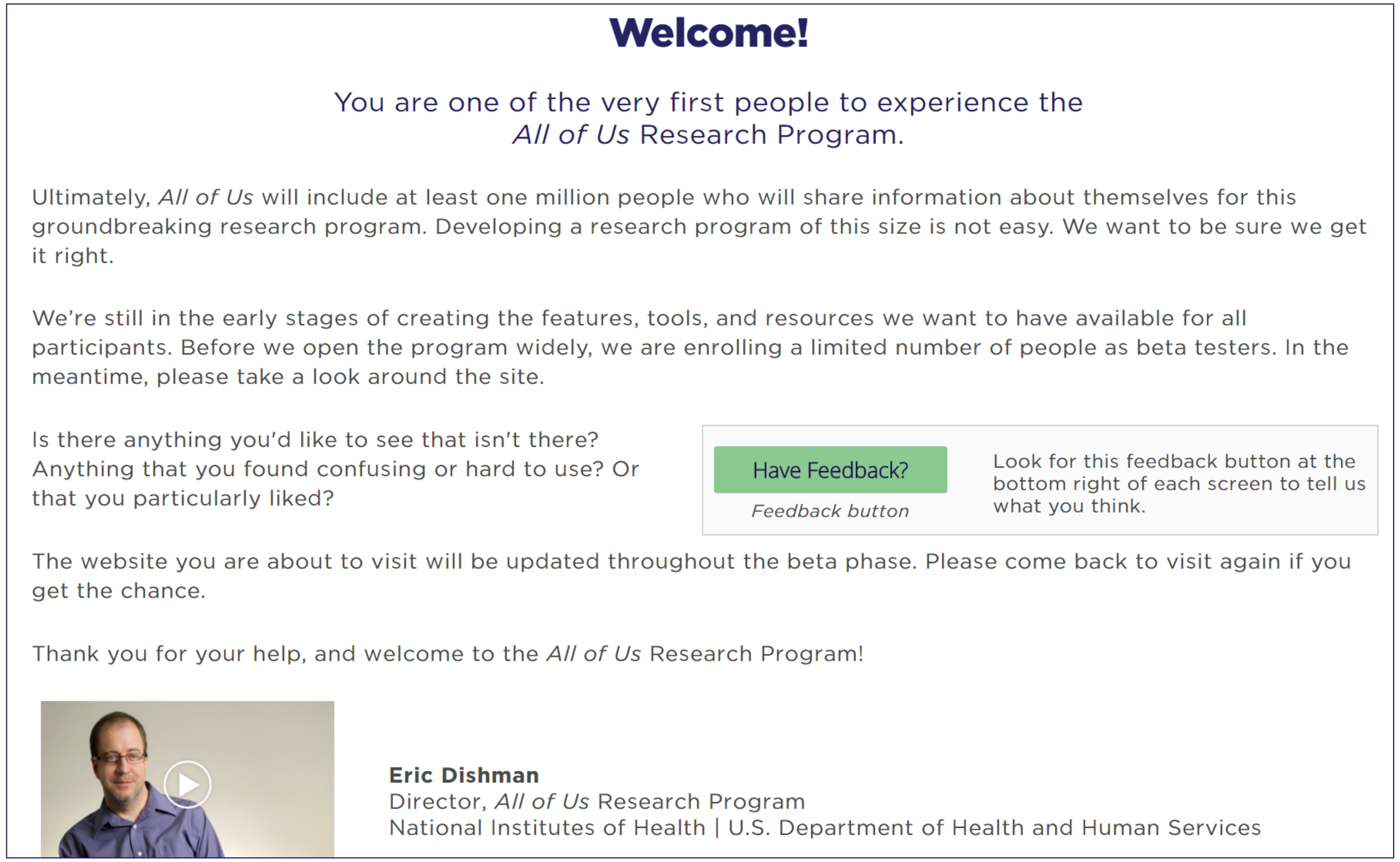
Environmental & Other Contextual Effects

Informatic, Methodologic, Ethical/Legal, & Statistical Research

Where are we now?

Beta Phase, Leading to National Launch Spring 2018

- Currently we have >4600 participants enrolled at >60 sites
- Through the fall and winter, will enroll 10-15,000 participants
- Ramp over 100 locations around the country slowly, carefully week by week
- Test the initial protocol, call center, online tools & interfaces, language of consent & questionnaires, workflow for staff at each location, biobank shipments, etc.



Welcome!

You are one of the very first people to experience the *All of Us* Research Program.

Ultimately, *All of Us* will include at least one million people who will share information about themselves for this groundbreaking research program. Developing a research program of this size is not easy. We want to be sure we get it right.

We're still in the early stages of creating the features, tools, and resources we want to have available for all participants. Before we open the program widely, we are enrolling a limited number of people as beta testers. In the meantime, please take a look around the site.

Is there anything you'd like to see that isn't there? Anything that you found confusing or hard to use? Or that you particularly liked?

Feedback button

Look for this feedback button at the bottom right of each screen to tell us what you think.

The website you are about to visit will be updated throughout the beta phase. Please come back to visit again if you get the chance.

Thank you for your help, and welcome to the *All of Us* Research Program!

Eric Dishman
Director, *All of Us* Research Program
National Institutes of Health | U.S. Department of Health and Human Services

Click "We're in beta" at top of https://www.joinallofus.org/

Questions?

Sign up for updates: joinallofus.org

@AllofUsResearch #JoinAllofUs

All of Us Consortium Members

DV Network

(Direct Volunteers)

- Scripps Translational Science Institute
- NATIONAL BLOOD COLLABORATIVE — BLOOD SOLUTIONS | TRUSTED SOURCE
- QTC — A Leidos Company
- Walgreens
- BlueCross BlueShield
- WONDROS
- DXC.technology
- EMSI HEALTH
- patientslikeme
- WebMD
- HCM STRATEGISTS

HPO Network

(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium
- UC San Diego Health
- UC DAVIS HEALTH
- Keck Medical Center of USC
- UC Irvine Health
- UC HEALTH
- UCSF — University of California San Francisco
- San Diego Blood Bank — Saving lives today. Improving life tomorrow.
- CEDARS-SINAI

Illinois Precision Medicine Consortium
- Northwestern University
- THE UNIVERSITY OF CHICAGO
- NorthShore University HealthSystem
- RUSH
- THE UNIVERSITY OF ILLINOIS AT CHICAGO — UIC

New England Precision Medicine Consortium
- PARTNERS HEALTHCARE
- MASSACHUSETTS GENERAL HOSPITAL
- BRIGHAM HEALTH — BRIGHAM AND WOMEN'S HOSPITAL
- BU Boston University School of Medicine
- BOSTON MEDICAL CENTER — EXCEPTIONAL CARE. WITHOUT EXCEPTION.
- UMASS University of Massachusetts Medical School

Trans-American Consortium for the Health Care Systems Research Network
- Henry Ford HEALTH SYSTEM
- Essentia Health
- BaylorScott&White HEALTH
- SPECTRUM HEALTH

New York City Precision Medicine Consortium
- COLUMBIA UNIVERSITY MEDICAL CENTER
- NYC HEALTH+ HOSPITALS
- NewYork-Presbyterian
- Weill Cornell Medicine

Southern *All of Us* Network
- Morehouse School of Medicine
- LSUHealth
- TUSKEGEE UNIVERSITY
- THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
- Tulane University
- Cooper Green Mercy HEALTH SERVICES
- HUNTSVILLE HOSPITAL
- University Medical Center
- USA UNIVERSITY OF SOUTH ALABAMA HEALTH SYSTEM

SouthEast Enrollment Center
- UNIVERSITY OF MIAMI
- EMORY UNIVERSITY
- MOREHOUSE SCHOOL OF MEDICINE
- UF UNIVERSITY of FLORIDA

***All of Us*, Wisconsin**
- Marshfield Clinic
- CLEMENT J. ZABLOCKI VA MEDICAL CENTER
- THE UNIVERSITY WISCONSIN MADISON
- MEDICAL COLLEGE OF WISCONSIN
- BLOODCENTER of WISCONSIN — PART OF VERSITI

University of Arizona
- THE UNIVERSITY OF ARIZONA
- Banner Health

University of Pittsburgh
- University of Pittsburgh

FQHCs (Federally Qualified Health Centers)
- Cherokee HEALTH SYSTEMS
- JACKSON-HINDS COMPREHENSIVE HEALTH CENTER
- SAN YSIDRO HEALTH CENTER
- HRHCare COMMUNITY HEALTH
- Community Health Center, Inc.
- Eau Claire Cooperative Health Center — People in Care do better

VA Medical Centers
- VA U.S. Department of Veterans Affairs

Community Partners
- DELTA RESEARCH AND EDUCATIONAL FOUNDATION — CREATING POSSIBILITIES ... IMPROVING LIVES
- National Alliance for Hispanic Health
- Fifty Forward
- SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

Communication & Engagement
- WONDROS
- HCM STRATEGISTS

Platform Development
- Scripps Translational Science Institute
- Sage BIONETWORKS
- VANDERBILT UNIVERSITY
- WONDROS
- vibrent