

All of Us Research Program

National Advisory Child Health and Human Development Council



National Institutes
of Health

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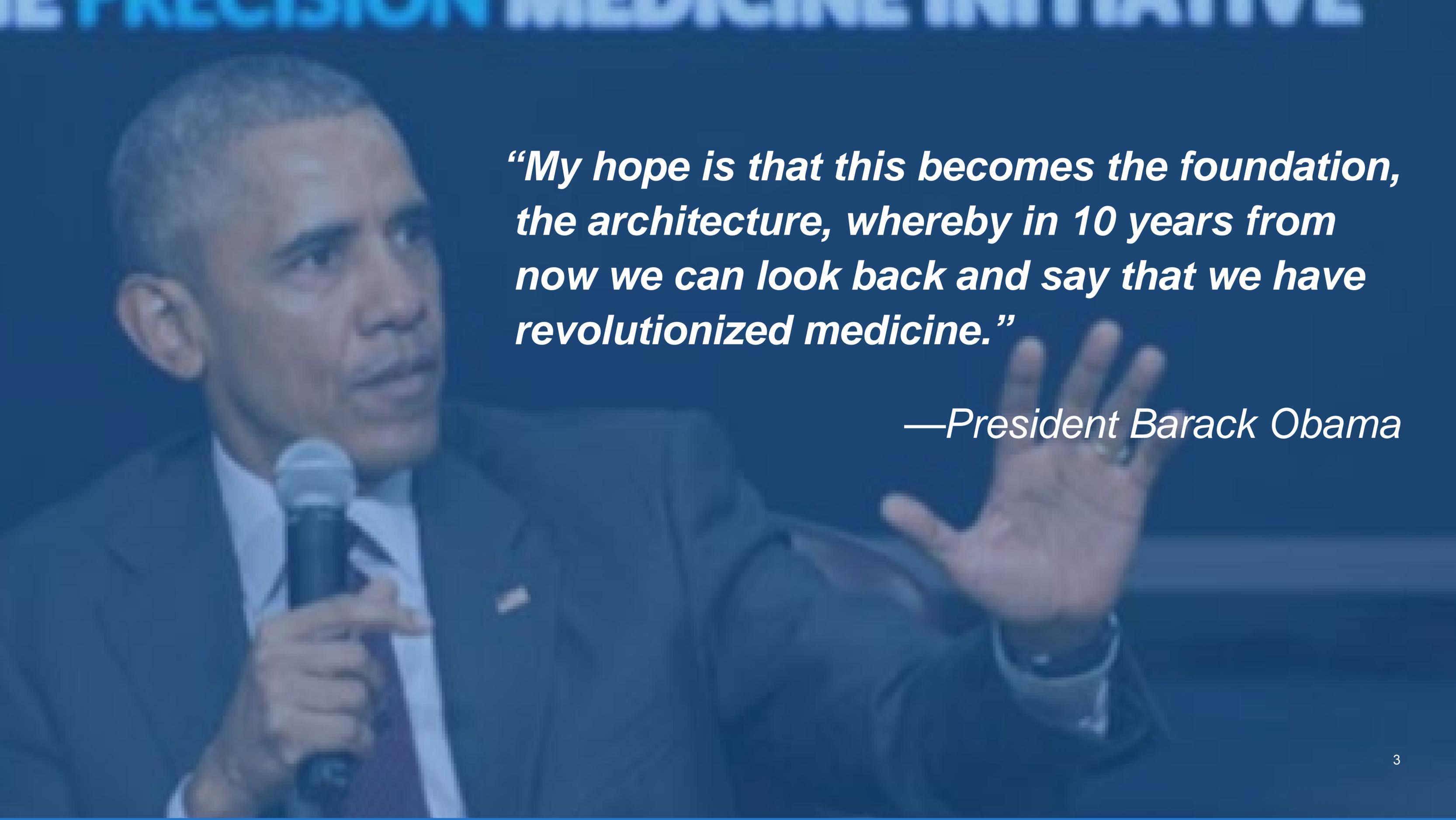
January 31, 2017

The Precision Medicine Initiative (PMI)

Announced by President Barack Obama in his 2015 State of the Union address

MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care





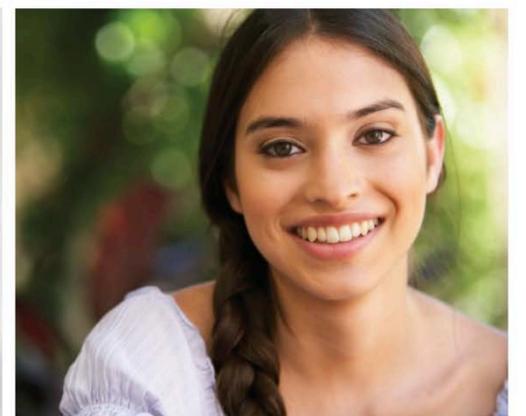
“My hope is that this becomes the foundation, the architecture, whereby in 10 years from now we can look back and say that we have revolutionized medicine.”

—President Barack Obama

Overview of the *All of Us* Research Program

The *All of Us* Research Program

- One million or more volunteers, reflecting the broad diversity of the U.S.
- Opportunities for volunteers to provide data on an ongoing basis
- Opportunities for researchers from citizen scientists to university researchers to access one of the world's largest biomedical databases to accelerate breakthroughs
- Not a study on any one disease, but a data resource to inform many research studies on a wide variety of health conditions



Why Now?

- Too many diseases lack effective prevention & treatment strategies
 - One size fits all approach is leaving many with poor options
 - Advances in data science, bioinformatics, lab technologies
 - Omic data are getting easier and cheaper to generate
 - Availability of new types of data – microbiome, diagnostics, and sensor data
- Wide spread adoption of EHRs
 - Advent of social media and smart phones – Americans are more connected than ever
 - People want to engage in research
 - Patients and the people who love them are inpatient
- ❖ To do this, we're going to tap into the full potential of big data, technology, talented workforce.
 - ❖ This is an “all of government” effort, with HHS, VA, DOD, DOE involved

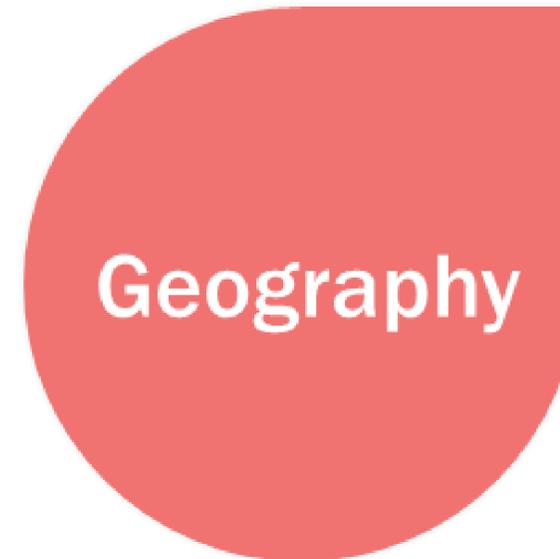
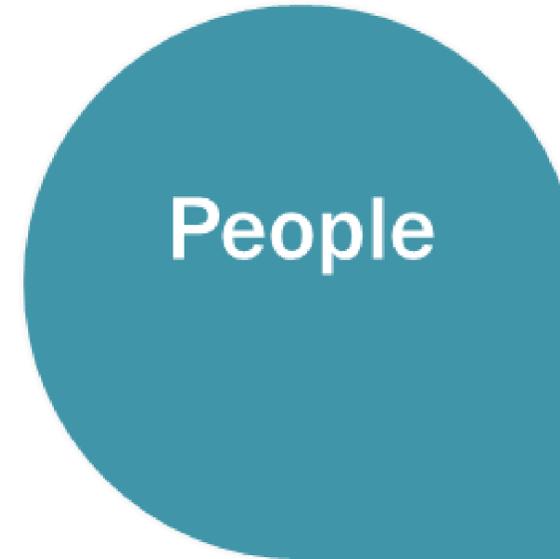
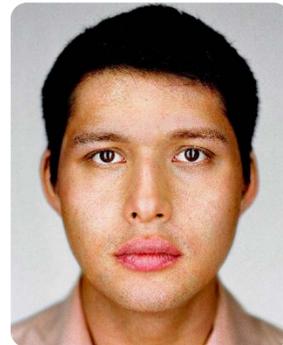


Core Values

- Participation in the *All of Us* Research Program will be **open** to interested individuals.
- The Program will reflect the rich **diversity** of America.
- Participants will be **partners** in the Program.
- Trust will be earned through robust **engagement** and full **transparency**.
- Participants will have **access** to information and data about themselves.
- Data from the Program will be broadly **accessible** to **empower research**.
- The Program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.
- The Program will be a catalyst for **innovative research** programs and policies.

A Transformational Approach to Diversity

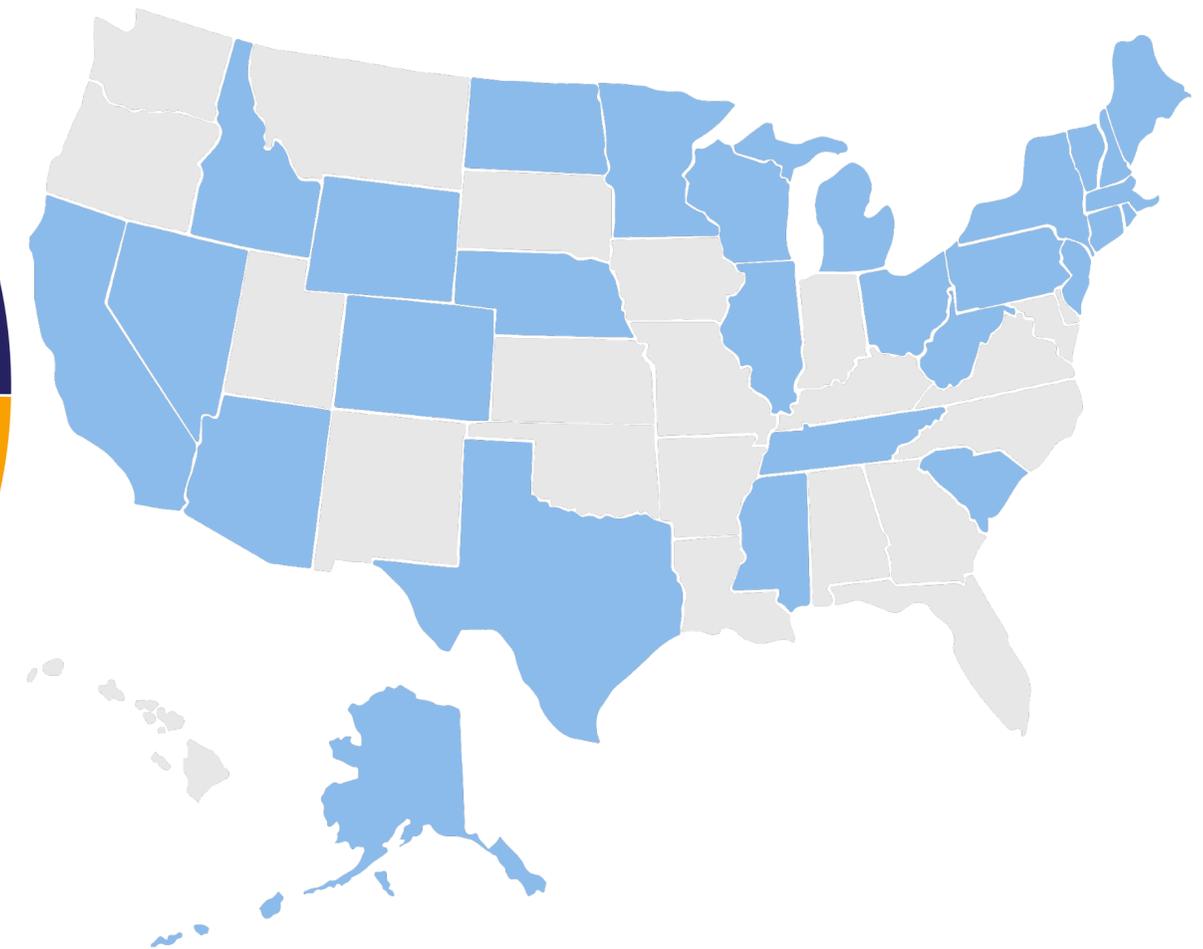
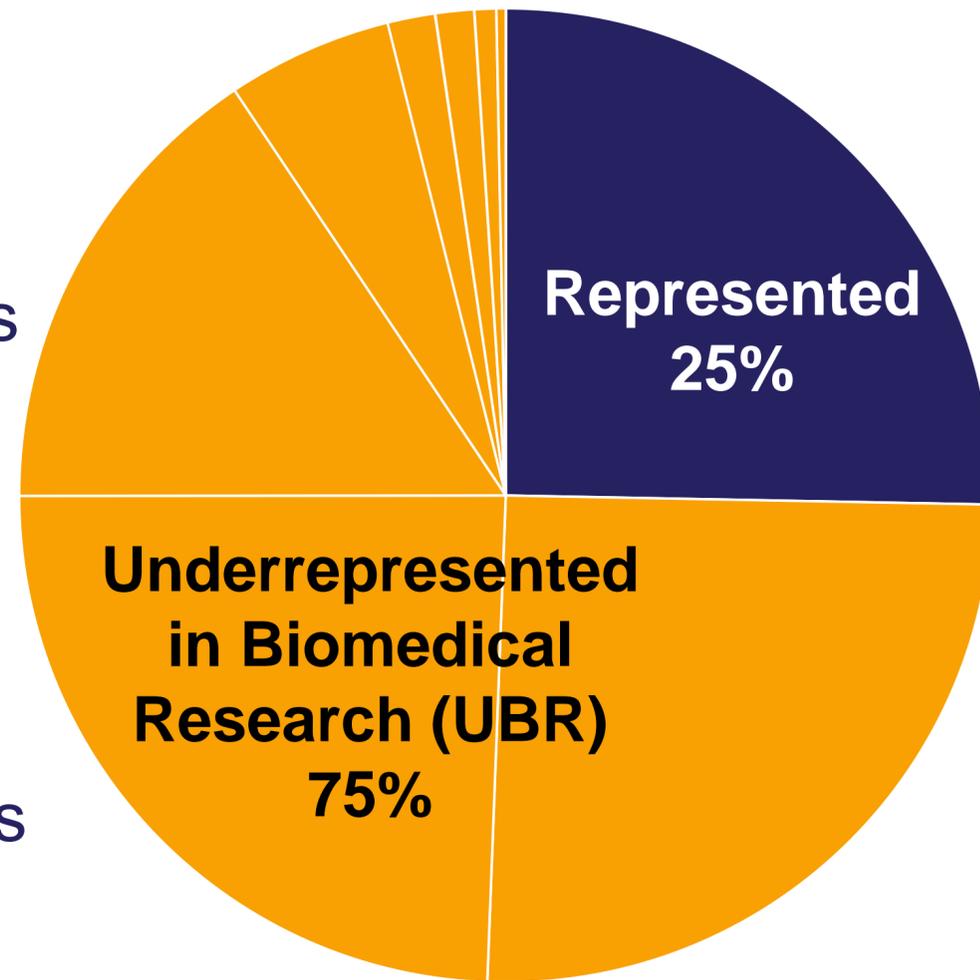
Reflecting the country's rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research



Estimate of target demographics & geography at launch

Underrepresented in Biomedical Research (UBR):

- Women
- Racial and ethnic groups
- Sexual and gender minorities
- Disadvantaged backgrounds
 - Low Socioeconomic Status (SES) (Income, Education, and Occupation)
- Physical or mental disabilities
- Geographically or culturally isolated environment
 - Rural



A Transformational Approach to Participation

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

Involved in every step of program development

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



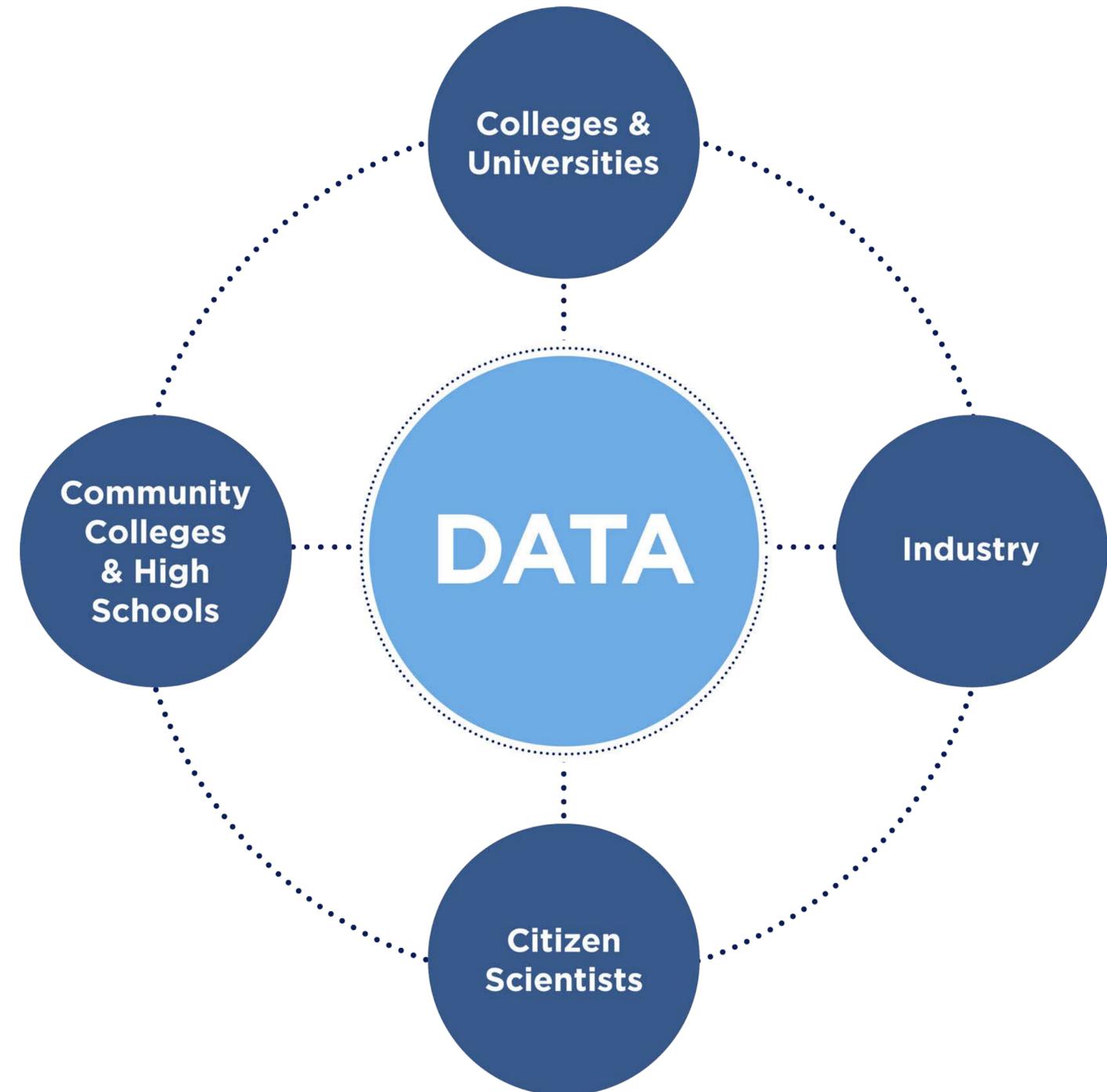
The Value of Participating in *All of Us*

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



A Transformational Approach to Data Access

- ⦿ Data sharing will be a priority to both researchers and participants
- ⦿ Participants will have access to study information and data about themselves
- ⦿ Data collection will start small and will grow over time
- ⦿ Privacy and security will adhere to the highest standards
- ⦿ Will invest to level the playing field so diverse researchers can play



Two Methods of Engagement



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**

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...

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A Data and Technology Framework to Accelerate Precision Medicine Research

Success will require that health data is portable, and can be easily shared between providers, researchers, patients, and research participants.

- Enabling patients to access their EHR data easily, including to contribute it for research
 - OCR guidances clarifying HIPAA right of access:
 - Form and format
 - Fees, timeliness
 - Right to share with research
 - ONC collaboration around pilots of standards that support health IT interoperability for research
 - Sync-4-Science: collaboration with the largest EHR vendors

Leading national EHR vendors, including Allscripts, Athenahealth, Cerner, drchrono, Epic, and McKesson, have pledged to pilot the use of open, standardized application programming interfaces (APIs) to give individuals the ability to access and contribute their health data to All of Us.

Program Status

Established Program Infrastructure

DATA AND RESEARCH CENTER (DRC)

Vanderbilt University Medical Center
with the Broad Institute and Verily

BIOBANK

Mayo Clinic

PARTICIPANT TECHNOLOGIES CENTER (PTC)

Scripps Research Institute
with Vibrent Health

HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)

Regional Medical Centers, Health Centers
(including Federally Qualified Health Center pilots),
VA Medical Centers

National Network of Partners for Launch

**Building
Block
Partners**

RMCs
regional med centers

FQHCs



Right Now: Preparing for V1 launch

- Built **awardee network** (50+); refining governance
- Finalizing **protocol**, including consent language and initial set of questionnaires
- Releasing a **funding opportunity** for community engagement (*coming soon*)
- Delivered & tested **new name, content, & brand**
- Development almost complete of **enrollment website, 1-800#, smartphone apps, data center**
- Testing **IT interfaces** for data/sample transfer and testing/documenting **security systems** for ATO
- Building out of **biobank capacity** (35M+ vials)
- Launching **expert Trans-NIH** group for scientific planning (*coming soon*)



Protocol (*DRAFT*)

Consent / e-Consent

- Recruit 18+ years old initially; kids plan in Q1
- eConsent or paper long-form
- 6th grade reading level; English & Spanish initially
- eConsent process includes modules on:
 - Participant Provided Info (PPI) + Linkage + Re-contact
 - Physical Measurements (PM) + Biospecimen
 - Sensors or wearable devices
 - EHR
 - Genetic information
- Separate opt-in & signature for some modules, including EHR and genetics (state laws)



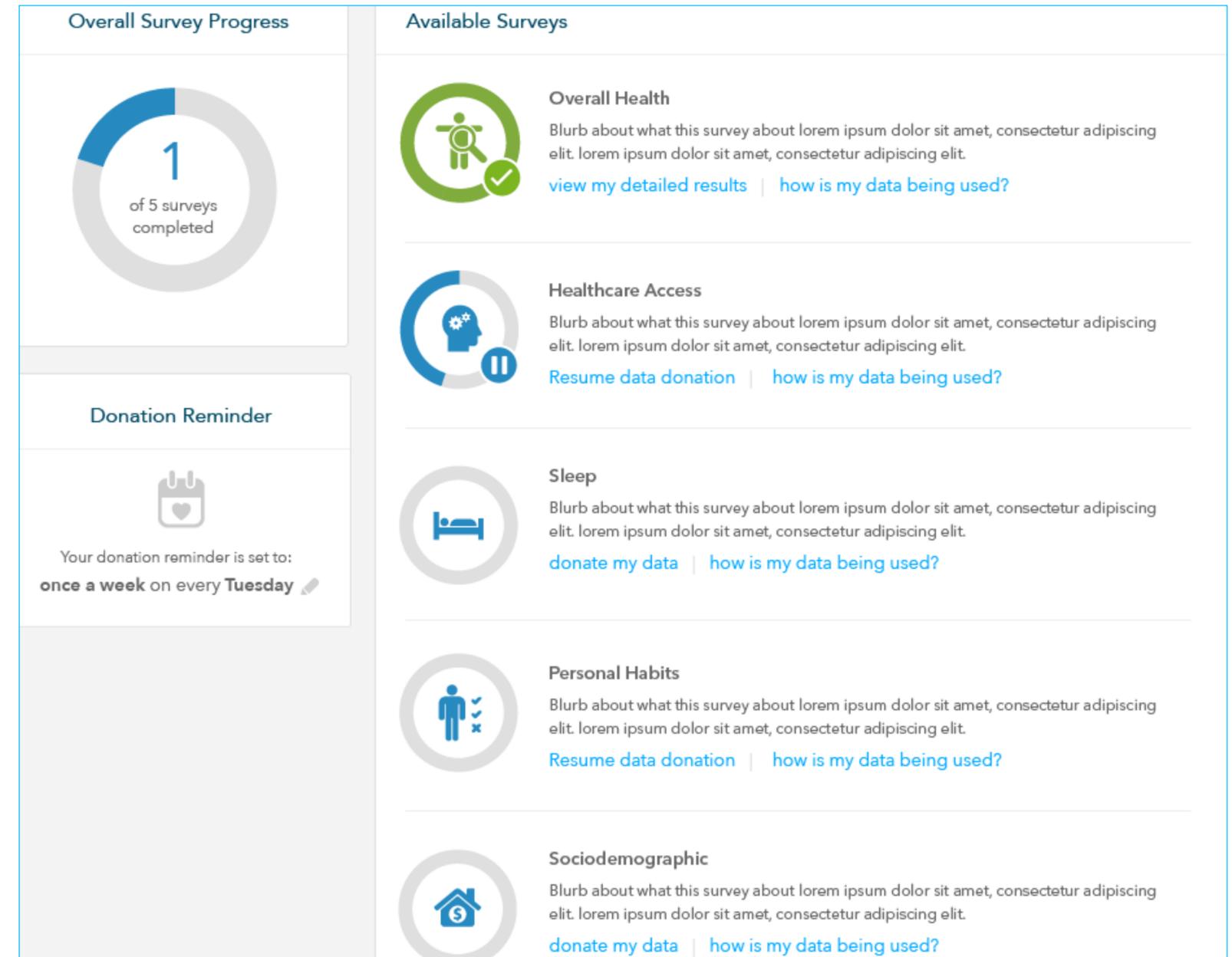
Video script:

To get information about your past health, we may ask for access to your electronic medical record. There will be a separate place for you to sign if you decide to give us access. We would see information about your health problems, test results, medical procedures, images (such as X-rays), and medicines you take. Medical records can contain sensitive information. For example, they may tell us about your mental health, or use of alcohol or drugs. They may contain sexual or infection information, including HIV status.

PPI/Survey Modules for our Launch (*DRAFT*)

1. Contact/Sociodemographics (10:29)
2. Overall Health/Mental Health (2:48)
3. Personal Habits (2:47)
4. Personal Health History
5. Medications
6. Family History
7. Health Care Access and Utilization (3:22)
8. Sleep (4:10)

Participant dashboard on their progress



Surveys came from IC (thank you!) & external researcher input; leverage trusted, known instruments

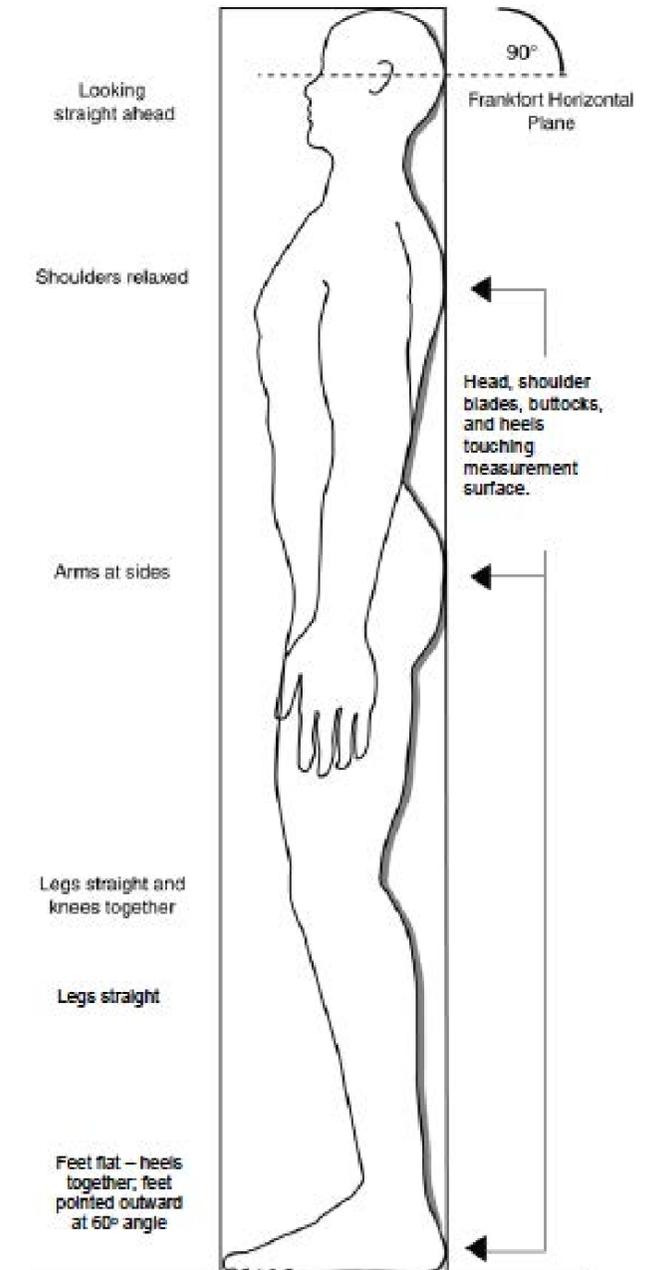
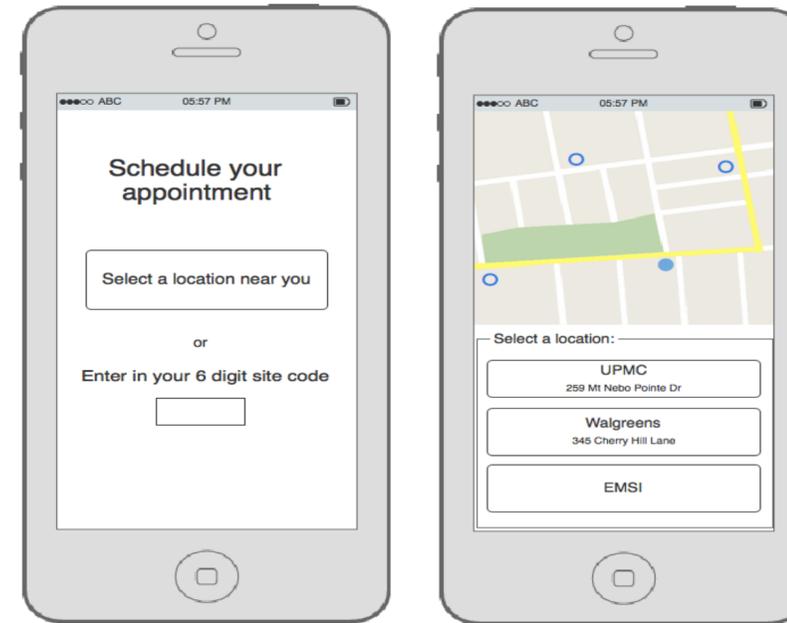
Version 1 Physical Measurements & Biospecimen Collection (*DRAFT*)

Physical Measurements

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

Biospecimen Collection

- 44 ml blood (spit as backup)
- Urine
- 35 aliquots stored in Biobank
- 24 hour courier nationwide
- Nights & weekend collections

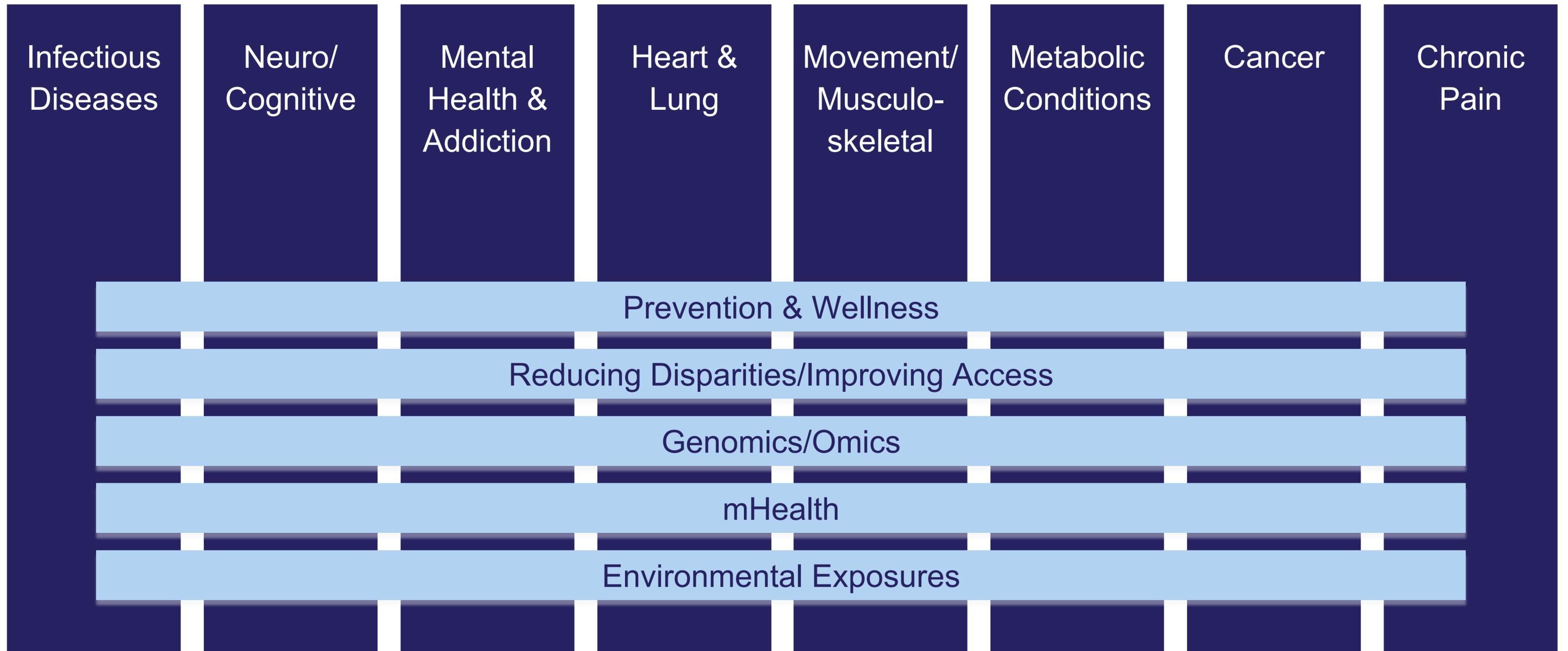


Looking ahead

Plans for Launch and Beyond

- We're working like a technology platform company, centered on the user experience
- Will launch when ready and right
- Phased implementation as we pilot, iterate, and scale
- Anticipate 3–4 years to reach one million
- Over time, anticipate new technologies, protocols, and assays
- Will provide transparency and open access to our protocols to enhance interoperability with other cohorts

Building a Framework for Research Questions & Requirements



These are just a few examples of scientific bodies of knowledge.

Key Opportunities for Working Together

- **Programs we are planning as our staff grows**
 - IC Liaisons
 - IC Strategy Syncs
 - Informal kitchen cabinets on key topics
 - Helping to define/execute the ***All of Us Research Roadmap*** for the next decade, starting with forthcoming Research Priority Roadmap Workshops
 - **Educating** researchers about *All of Us* and data they can use as it becomes available
 - Exploring **recruitment** potential for *All of Us* participants from the community/cohorts
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Questions?

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