

The *All of Us* Research Program

Accelerating Precision Health for All

Advisory Committee on Research on Women's Health
April 4, 2017



National Institutes
of Health

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Why do we need the *All of Us* Research Program?



People/ 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



23 years as a cancer patient;
30 years as a patient advocate



Professional Providers

- Not enough research to draw on for clinical evidence
- Medical records scattered in different places
- Not enough time for analysis one patient at a time



Two decades of fieldwork
with families and providers



Biomedical Researchers

- Enormous time/cost spent building IT systems vs. doing research
- Silo'd data resources and funding opportunities
- Challenges acquiring large and diverse sample sizes



Three decades of fieldwork,
understanding researchers

Program Overview

Our New Name: *All of Us* Research Program

All of Us

The
Precision
Medicine
Initiative

On October 13th, 2016 we unveiled our new name: *All of Us* Research Program.

Name is based in part on feedback we heard from ICs, potential participants, and others.

It represents our commitment to building a national resource for diverse participants, providers, and researchers – in other words, *All of Us*!

Mission is to Accelerate Knowledge Turns & Breakthroughs!



Overview: *All of Us* Research Program

- **Mission:** To **accelerate** health research and medical breakthroughs, enabling **individualized prevention, treatment, and care** for all of us.
- **How:** 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!)
- **Priority:** Reflect the **broad diversity** of the U.S.—all ages, races/ ethnicities, gender, SES, geo, & health status—by over-recruiting those **underrepresented in biomedical research**
- **Priority:** Build the **tools & capabilities** that make it easy for researchers from citizen scientists to premier university labs to make discoveries using the **data & biosamples** and through **ancillary studies** w/ the cohort



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.

All of Us Personas: Key Characteristics



Ready To Go	Determined	Curious But Distracted	Community-Centric
<ul style="list-style-type: none"> • Altruistic • Skews older • Free and/or flexible time • Likely volunteers • Tends to trust doctors and government • Could have disease or not have disease • Likely to be early adopter of <i>All of Us</i> • Needs little interaction with <i>All of Us</i> • May want deeper engagement after joining (e.g. recruit others) 	<ul style="list-style-type: none"> • Newly diagnosed with chronic disease(s) • Skews younger • Committed to beating own disease and being healthy • Tends to trust doctors and government • Likely to track health • Likely to be early adopter of <i>All of Us</i> • Wants to help self and others struggling with disease • May engage more deeply after joining (e.g. citizen scientist) • Wants <i>All of Us</i> results soon 	<ul style="list-style-type: none"> • Health-oriented; not likely to have chronic disease(s) • Skews younger • Likely to track health; unlikely to share socially • Many things compete for their attention • Influenced by others/friends • Likely to be 2nd wave adopter of <i>All of Us</i> • Likely needs many interactions with <i>All of Us</i> before joining • Requires convenience; <i>All of Us</i> must fit in with flow of life • Wants to use <i>All of Us</i> results in daily life 	<ul style="list-style-type: none"> • Distrusts doctors/medical profession • Sees doctors infrequently • Not likely to have chronic disease(s) • Skeptical that <i>All of Us</i> would be equitable • Concerned that <i>All of Us</i> won't address larger socio-economic issues ("<i>All of Us</i> a Band-Aid") • Needs proof their community matters • Requires multiple <i>All of Us</i> "discover" and "inform" touchpoints • Requires face-to-face interactions, to build trust, before joining <i>All of Us</i>

All of Us Personas: Key Characteristics



Security-Afraid	Suspicious But Positive	No Time	Too Much Government
<ul style="list-style-type: none"> • Has lived with chronic disease(s) many years • Fears losing health insurance/coverage • If participates in <i>All of Us</i>, 2nd or 3rd wave adopter • Needs multiple “inform” touchpoints • Requires “guarantee” that <i>All of Us</i> data is secure • Wants to control access to their <i>All of Us</i> data • May only participate with their doctor’s involvement • Requires <i>All of Us</i> have concrete plan • Prefers fast results, but knows research takes time 	<ul style="list-style-type: none"> • Sees doctors as little as possible; uses free clinics or ER for general care • Likely does not have chronic disease(s) • Distrusts government • Tends toward conspiracy theories • If participates in <i>All of Us</i>, 2nd or 3rd wave adopter • Unlikely to donate DNA • Concerned <i>All of Us</i> could harm people • Wants to protect self/family/others • Wants to help humanity in substantive ways 	<ul style="list-style-type: none"> • Works multiple jobs and/or has little free time • Likely does not have chronic disease(s) • Wants to improve diet/exercise but has little time/motivation • Skews female (may be caretaker of children and/or parents) • Equates time with money • Unlikely to participate in <i>All of Us</i> without monetary incentive • Likely to be put off if <i>All of Us</i> has too many steps/ requirements • If joins, will only do minimum participation 	<ul style="list-style-type: none"> • Very health minded/proactive • Values/respects medical research and new tech • Tends to be well-read/up-to-date • Tends to trust doctors/medical profession • Unlikely to participate in <i>All of Us</i> without demonstrated results • Distrusts government • Prioritizes privacy • Requires “guarantee” of anonymity • Needs high levels of transparency and detail

Major Building Blocks of the Research Program

DATA AND RESEARCH CENTER (DRC)

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 CENTER

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

Scripps Research Institute

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web & phone-based platforms for participants

Vibrent Health

HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)

Clinical & scientific expertise network, enrollment & retention of participants

20+ regional med centers, FQHCs, VA

COMMUNITY & ENGAGEMENT PARTNERS

Local, regional, national orgs to educate, enroll, & retain participants

Awards under review now

Main Awardees So Far

**Building
Block
Partners**

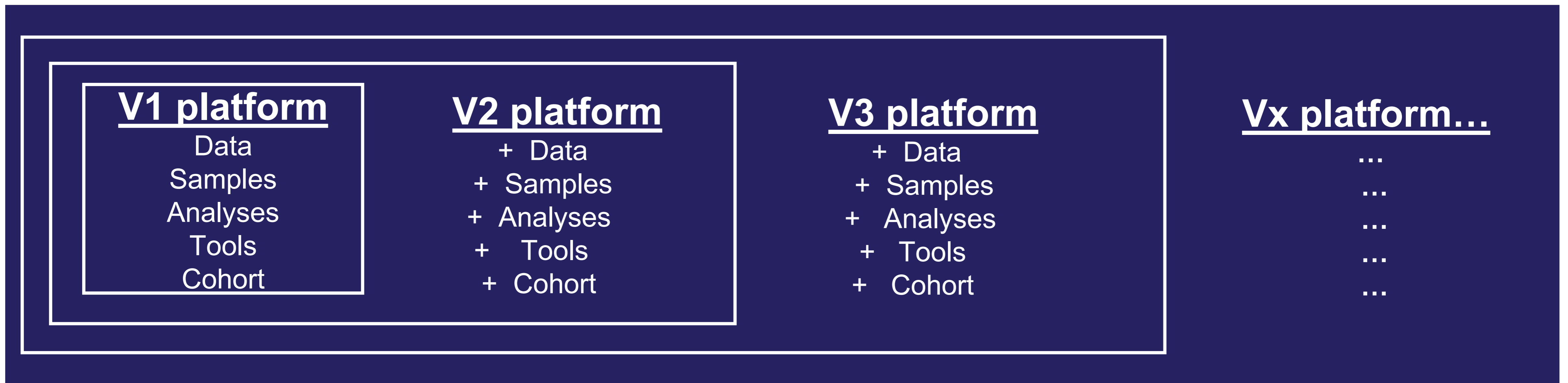
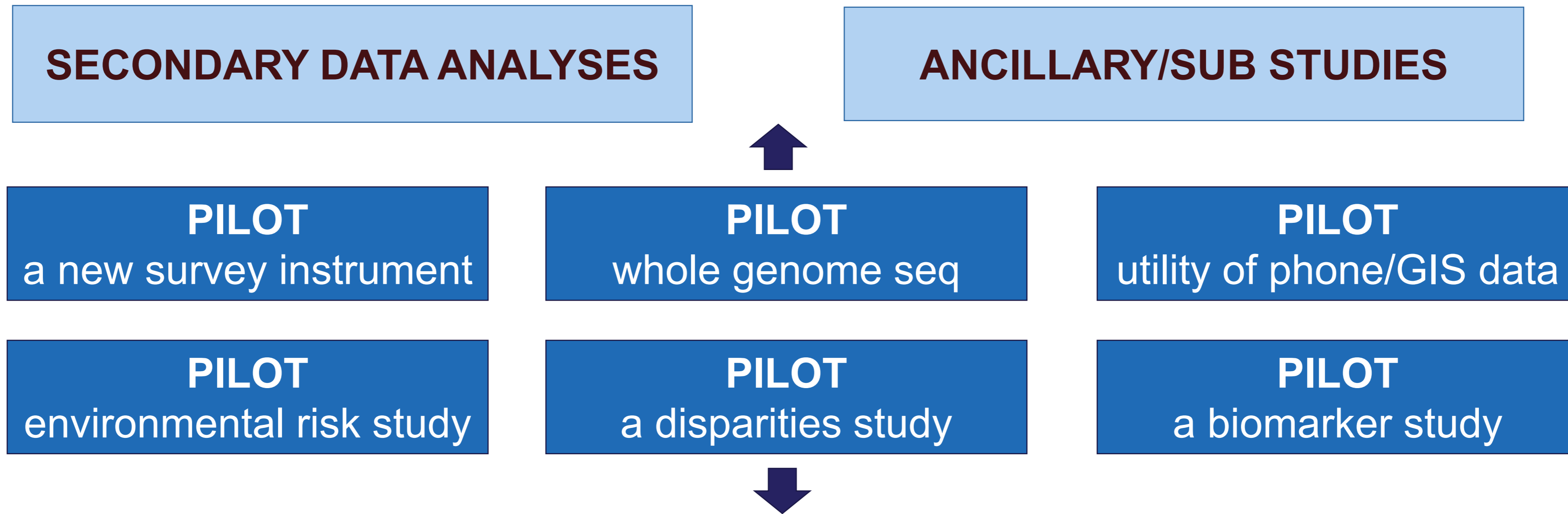
RMCs
regional med centers

FQHCs



Anticipate new “community partner” awards begin mid ‘17

We are building a Foundation for others (e.g., you) to drive your science



Status Update

Current Status of *All of Us*

- Built robust network of 50+ academic, provider, technology, & community partners
- Have plans/methods to recruit 75% of 1M as underrepresented in biomed research
- Pilot test completed on language, concepts, interfaces
- Version 1 protocol submitted to IRB (consent, EHR authorization, 5 initial surveys, blood & urine collection, physical measures)
- Biobank capacity ready for alpha/beta launch, on schedule for national launch (35M+ vials)
- Enrollment website, 1-800#, smartphone apps, and data center developed with early testing & training begun
- Final end-to-end security testing, user testing, workflow testing, & training starts this month

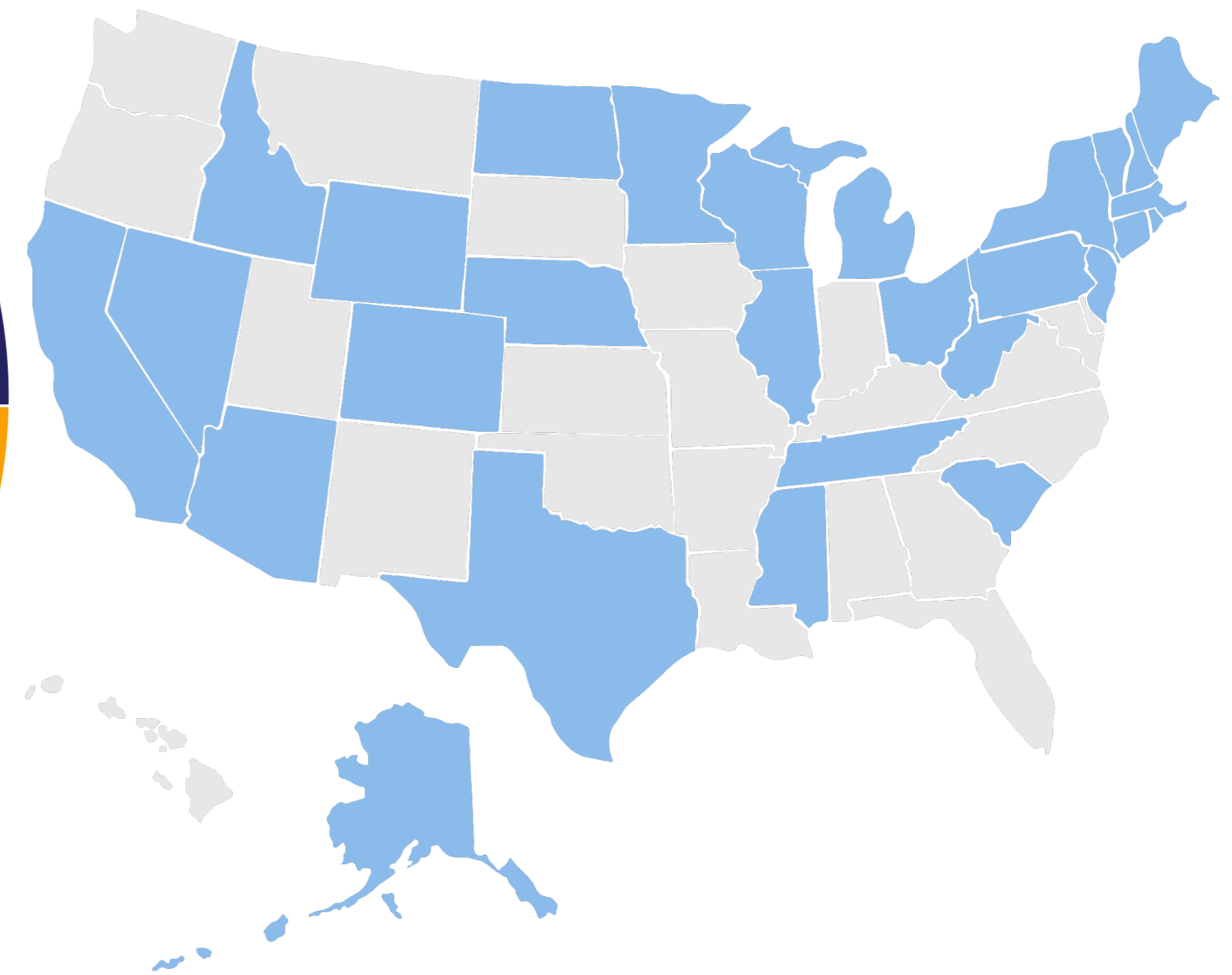
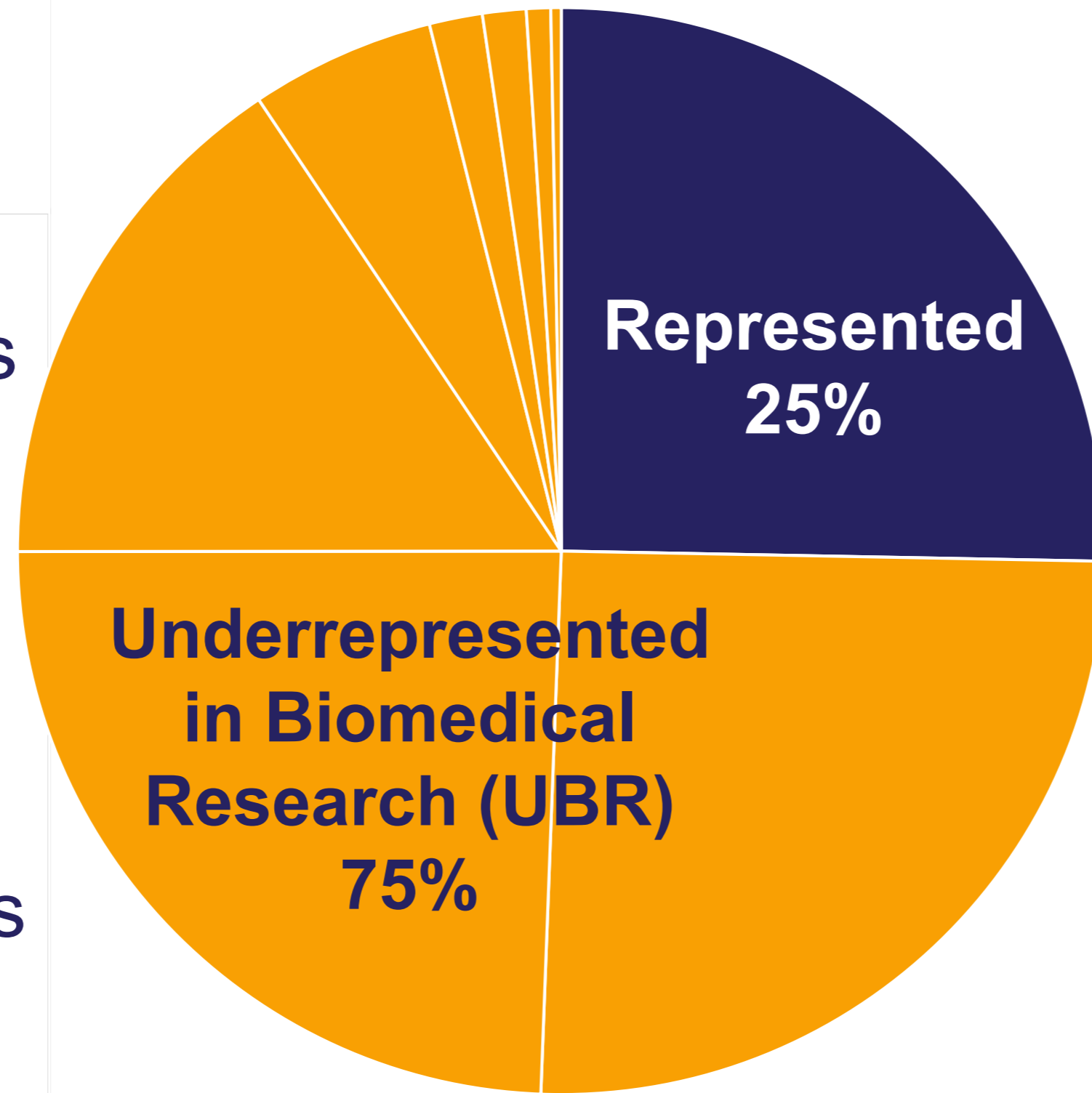


Pending testing results & IRB approval, aiming for Alpha/Beta launch in May & National launch in Oct

Estimate of target demographics & geography at launch

Underrepresented in Overall Research (UBR):

- Women
- Racial and ethnic groups
 - 50.6% White
 - 24.7% Hispanic/Latino
 - 15.6% Black/African American
 - 5.5% Asian
 - 1.6% Some Other Race
 - 1.3% AIAN
 - 0.7% 2+ Races
 - 0.3% NHPI
- Sexual and gender minorities
- Disadvantaged backgrounds
 - Low Socioeconomic Status (SES) (Income, Education, and Occupation)
 - Physical or mental disabilities
 - Geographically or culturally isolated environment
 - Rural



Protocol

Consent / e-Consent

- Recruit 18+ years old initially; kids plan next version
- 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**)

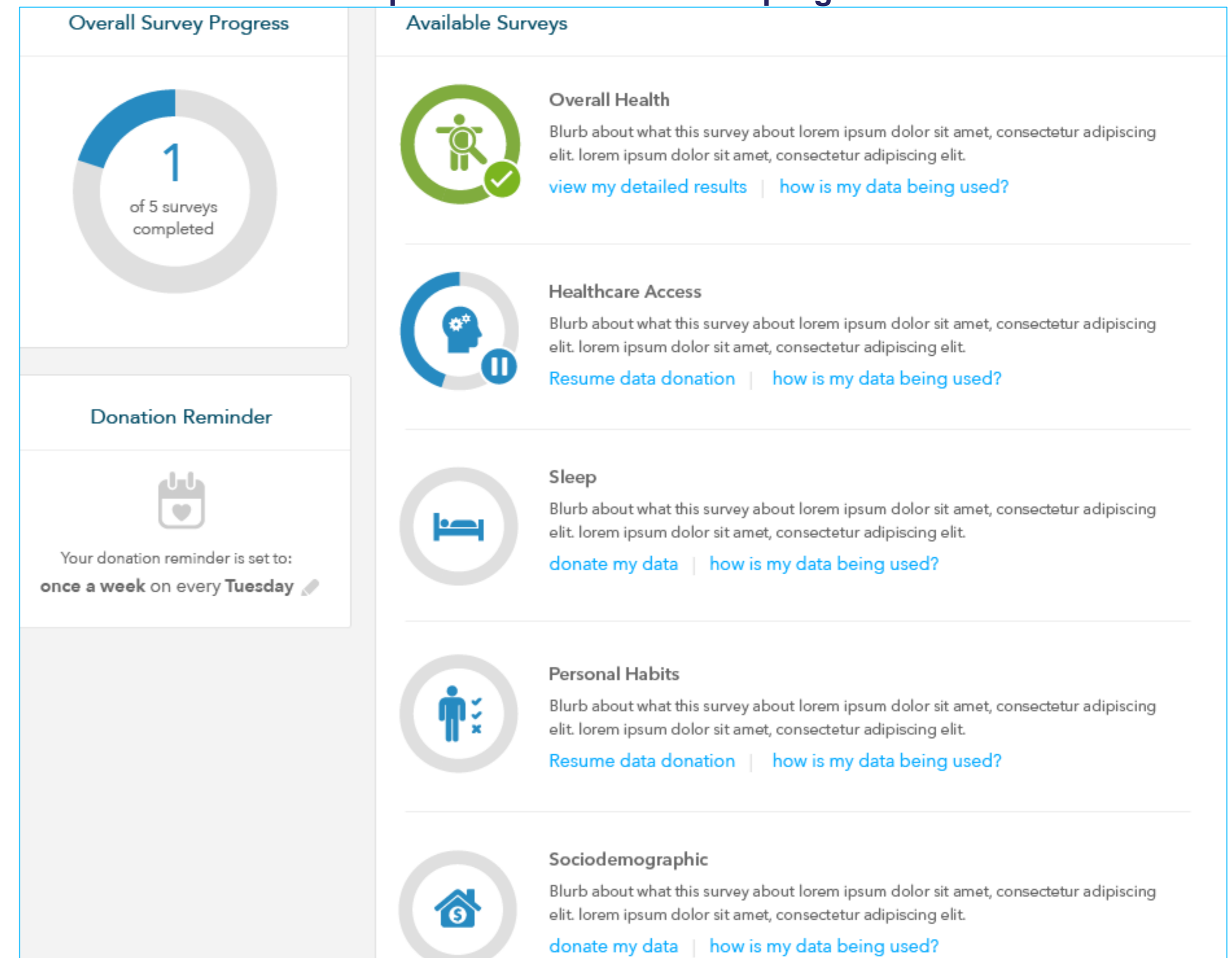
Proposed Enrollment Surveys

1. Contact/Sociodemographics
2. Overall Health/Mental Health
3. Personal Habits (includes substance use)

In Development

4. Personal Health History
5. Medications
6. Family History
7. Health Care Access and Utilization
8. Sleep

Participant dashboard on their progress



Surveys came from NIH resources & external researcher input; leveraging trusted, known instruments

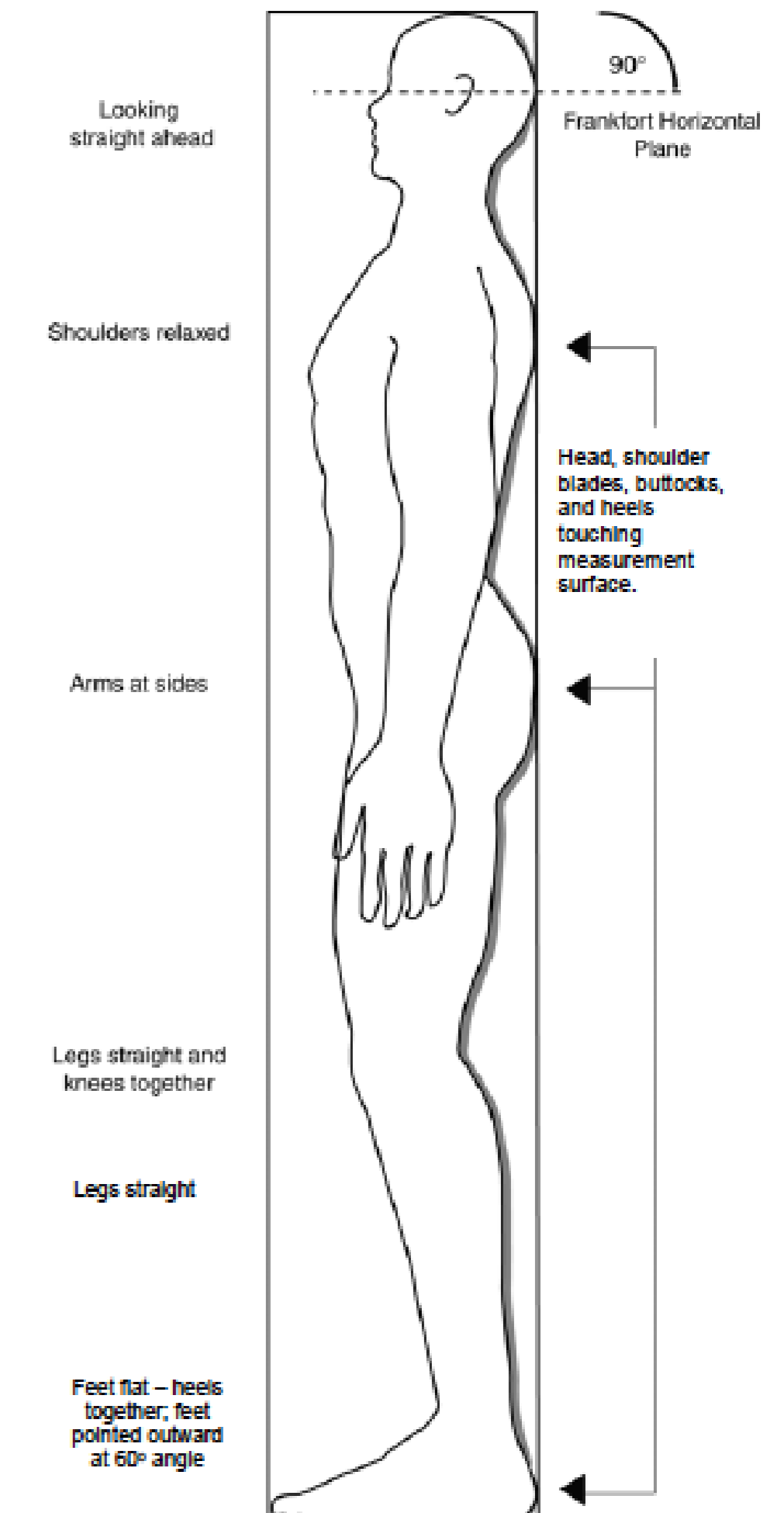
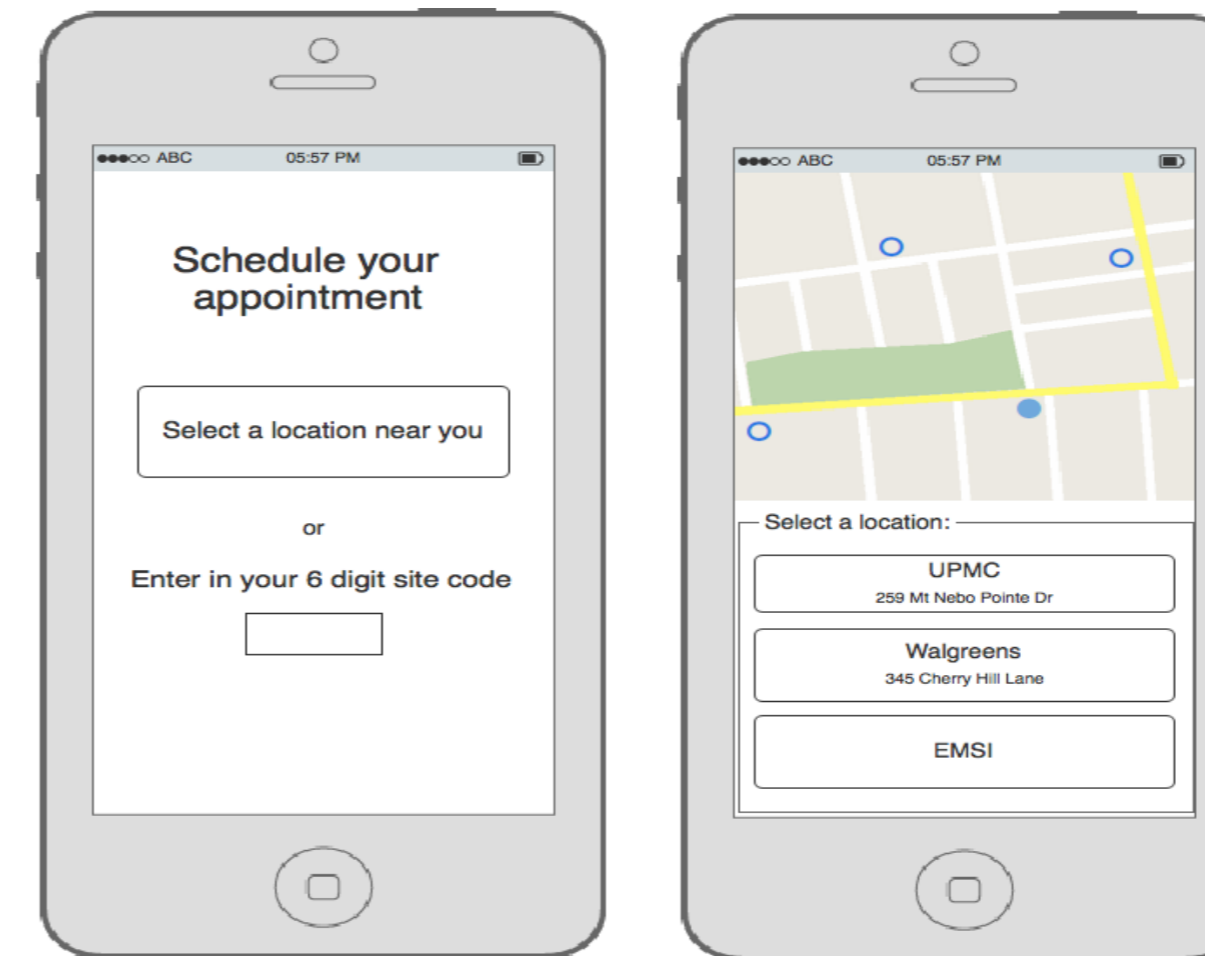
Version 1 Physical Measurements & Biospecimen Collection (**DRAFT**)

Physical Measurements

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

Biospecimen Collection

- Blood and/or spit
- Urine
- 35 aliquots stored in Biobank
- 24 hour courier nationwide
- Nights & weekend collections



Opportunity for ORWH to shape future physical evaluations & biospecimen collections

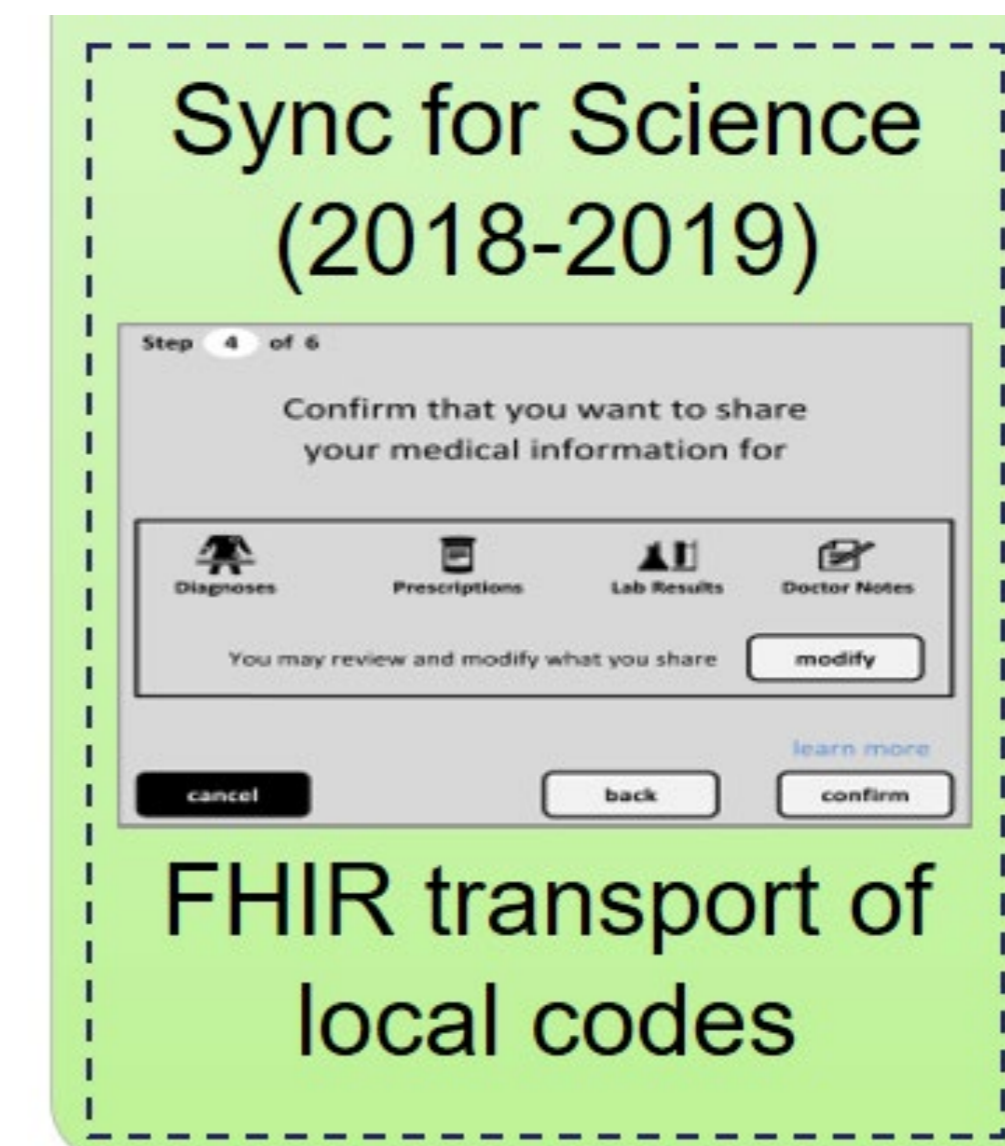
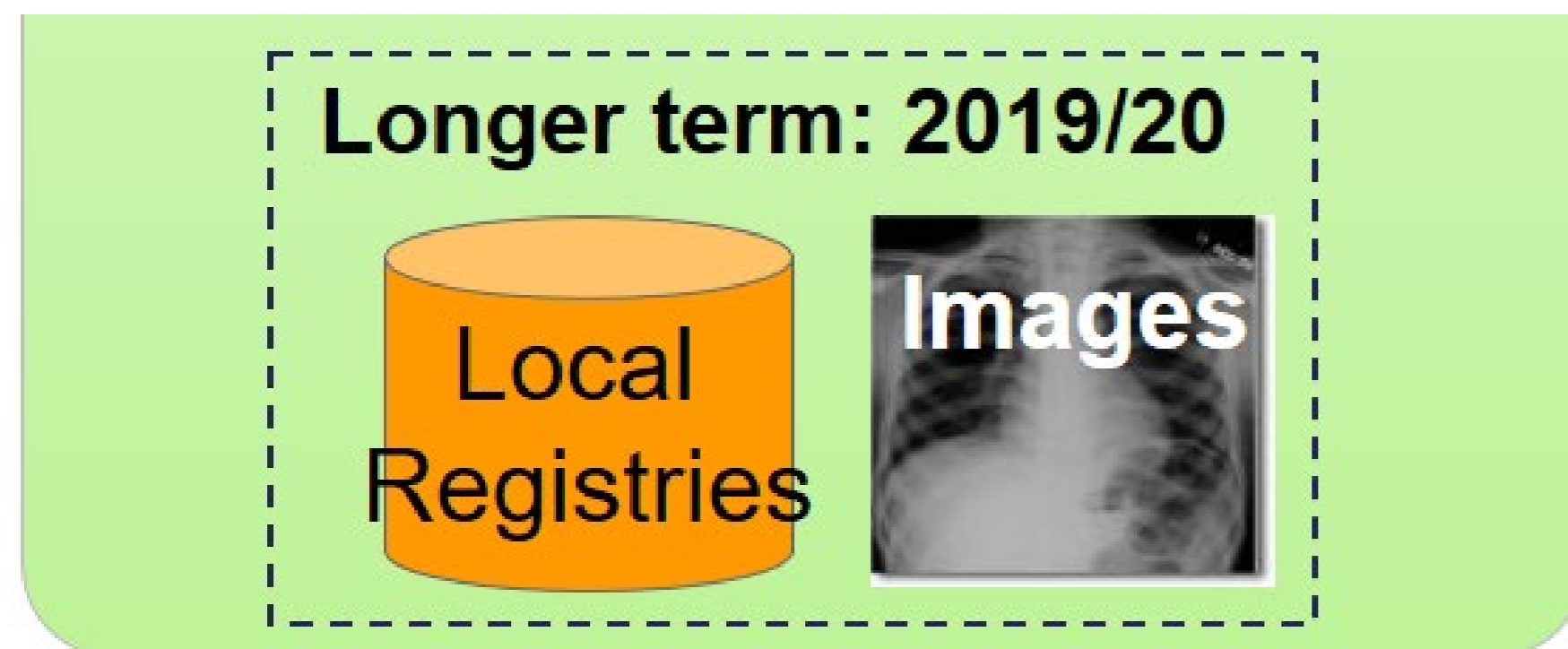
EHR data from both enrollment pathways (*DRAFT*)

FOR HPOs

- Starts with limited EHR fields
 - Labs, Dx, medications, etc
- Focus on quality improvement and mapping to standards
- Using OMOP v5 Common Data Model
- Will grow over time
 - Clinical notes
 - Local registries
 - Images

FOR DIRECT VOLUNTEERS (DV)

- Starts with manual transfers
- Long term, pilot Sync 4 Science program with top EHR vendors
- Future goal: “donate your EHR at touch of a button”
 - Sharing will be patient-initiated using a patient-facing app that leverages an industry-adopted, standard API technology to read data from a patient’s healthcare provider’s Patient Portal



Working with ORWH

Preparing to Fund Research Question Workshops

Premise

Imagine *All of Us* exists only to accelerate *your* body of thought and research in a particular domain!

Three Big Questions

1) Near Term

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

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?

Kinds of Attendees

Research experts, co-funders, participant/advocacy orgs, providers, etc.

What We'll Do

Fund & manage the workshops and report writing within certain size/cost limits

Factor analysis of common needs across multiple knowledge domains = our “versions”

Partner with domain stakeholders to grow funding for unique areas = sub-studies

Questions?

Thank you!



National Institutes
of Health

All of Us

THE FUTURE OF HEALTH BEGINS WITH YOU

The
Precision
Medicine
Initiative

Selected Scientific Opportunities

- ① Develop quantitative **estimates of risk** for a range of diseases by integrating environmental exposures and genetic factors.
- ① Identify the causes of individual variation in response to commonly used therapeutics = **pharmacogenomics**.
- ① Discover **biological markers** that signal increased or decreased risk of developing common diseases.
- ① Develop **solutions to health disparities**.
- ① Use **mobile health technologies** to correlate activity, physiological measures, and environmental exposures with health outcomes.
- ① **Empower study participants** with data and information to improve their own health.
- ① Create a platform to enable **trials of targeted therapies**.



The Power of a Million: How *All of Us* Can Lead to Better Health

- Provide breakthrough information that helps researchers and providers to:
 - Determine an individual's risk of developing certain diseases
 - Find biological markers to aid in prevention and diagnosis
 - Find the most effective therapy for the full diversity of people
 - Identify solutions to health disparities that work locally
- Build a community of participants interested in joining clinical trials to help new cures happen faster
- Empower participants with data to improve their own understanding and health; save them from “trial-&-error” treatment we often have today



BREAK

Please back by 10:45.