The All of Us Research Program

Accelerating Precision Health for All

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

Eric Dishman
Director, All of Us Research Program
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
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!

- Questions, Problems, & Hypotheses
- Capture, Secure, Clean, & Share Data
- Unleash Science & Diverse Scientists
- Translate Into Action, Practice, & Meaning
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
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**

<table>
<thead>
<tr>
<th>Ready To Go</th>
<th>Determined</th>
<th>Curious But Distracted</th>
<th>Community-Centric</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Altruistic</td>
<td>• Newly diagnosed with chronic disease(s)</td>
<td>• Health-oriented; not likely to have chronic</td>
<td>• Distrusts doctors/medical profession</td>
</tr>
<tr>
<td>• Skews older</td>
<td>• Skews younger</td>
<td>disease(s)</td>
<td>• Sees doctors infrequently</td>
</tr>
<tr>
<td>• Free and/or flexible time</td>
<td>• Committed to beating own disease and being</td>
<td>• Skews younger</td>
<td>• Not likely to have chronic disease(s)</td>
</tr>
<tr>
<td>• Likely volunteers</td>
<td>healthy</td>
<td>• Likely to track health; unlikely to share</td>
<td>• Skeptical that <em>All of Us</em> would be</td>
</tr>
<tr>
<td>• Tends to trust doctors and government</td>
<td>• Tends to trust doctors and government</td>
<td>socially</td>
<td>equitable</td>
</tr>
<tr>
<td>• Could have disease or not have disease</td>
<td>• Likely to track health</td>
<td>• Many things compete for their attention</td>
<td>• Concerned that <em>All of Us</em> won’t address</td>
</tr>
<tr>
<td>• Likely to be early adopter of <em>All of Us</em></td>
<td>• Likely to be early adopter of <em>All of Us</em></td>
<td>• Influenced by others/friends</td>
<td>larger socio-economic issues (<em>&quot;All of Us</em> a</td>
</tr>
<tr>
<td>• Needs little interaction with <em>All of Us</em></td>
<td>• Wants to help self and others struggling with</td>
<td>• Likely to be 2nd wave adopter of <em>All of Us</em></td>
<td>Band-Aid&quot;)</td>
</tr>
<tr>
<td>• May want deeper engagement after joining (e.g.</td>
<td>• Wants to help self and others struggling with</td>
<td>• Likely needs many interactions with *All of</td>
<td>• Needs proof their community</td>
</tr>
<tr>
<td>recruit others)</td>
<td>disease</td>
<td>Us before joining</td>
<td>matters</td>
</tr>
<tr>
<td>• Requires convenience; <em>All of Us</em> must fit in</td>
<td>• May engage more deeply after joining (e.g. citizen</td>
<td>• Requires convenience; <em>All of Us</em> must fit in</td>
<td>• Requires multiple <em>All of Us</em></td>
</tr>
<tr>
<td>with their flow of life</td>
<td>scientist)</td>
<td>with <em>All of Us</em> before joining</td>
<td>“discover” and “inform” touchpoints</td>
</tr>
<tr>
<td>• Requires face-to-face interactions, to build</td>
<td>• Wants <em>All of Us</em> results soon</td>
<td>• Requires face-to-face interactions, to build</td>
<td>• Requires face-to-face interactions, to</td>
</tr>
<tr>
<td>trust, before joining <em>All of Us</em></td>
<td></td>
<td>trust, before joining <em>All of Us</em></td>
<td>build trust, before joining <em>All of Us</em></td>
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<td></td>
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<td></td>
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</tr>
</tbody>
</table>
### All of Us Personas: Key Characteristics

<table>
<thead>
<tr>
<th>Security-Afraid</th>
<th>Suspicious But Positive</th>
<th>No Time</th>
<th>Too Much Government</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Has lived with chronic disease(s) many years</td>
<td>• Sees doctors as little as possible; uses free clinics or ER for general care</td>
<td>• Works multiple jobs and/or has little free time</td>
<td>• Very health minded/proactive</td>
</tr>
<tr>
<td>• Fears losing health insurance/coverage</td>
<td>• Likely does not have chronic disease(s)</td>
<td>• Likely does not have chronic disease(s)</td>
<td>• Values/respects medical research and new tech</td>
</tr>
<tr>
<td>• If participates in <em>All of Us</em>, 2nd or 3rd wave adopter</td>
<td>• Distrusts government</td>
<td>• Wants to improve diet/exercise but has little time/motivation</td>
<td>• Tends to be well-read/up-to-date</td>
</tr>
<tr>
<td>• Needs multiple “inform” touchpoints</td>
<td>• Tends toward conspiracy theories</td>
<td>• Skews female (may be caretaker of children and/or parents)</td>
<td>• Tends to trust doctors/medical profession</td>
</tr>
<tr>
<td>• Requires “guarantee” that <em>All of Us</em> data is secure</td>
<td>• If participates in <em>All of Us</em>, 2nd or 3rd wave adopter</td>
<td>• Equates time with money</td>
<td>• Unlikely to participate in <em>All of Us</em> without demonstrated results</td>
</tr>
<tr>
<td>• Wants to control access to their <em>All of Us</em> data</td>
<td>• Unlikely to donate DNA</td>
<td>• Unlikely to participate in <em>All of Us</em> without monetary incentive</td>
<td>• Distrusts government</td>
</tr>
<tr>
<td>• May only participate with their doctor’s involvement</td>
<td>• Concerned <em>All of Us</em> could harm people</td>
<td>• Likely to be put off if <em>All of Us</em> has too many steps/requirements</td>
<td>• Prioritizes privacy</td>
</tr>
<tr>
<td>• Requires <em>All of Us</em> have concrete plan</td>
<td>• Wants to protect self/family/others</td>
<td>• If joins, will only do minimum participation</td>
<td>• Requires “guarantee” of anonymity</td>
</tr>
<tr>
<td>• Prefers fast results, but knows research takes time</td>
<td>• Wants to help humanity in substantive ways</td>
<td></td>
<td>• Needs high levels of transparency and detail</td>
</tr>
</tbody>
</table>

- Security-Afraid: Individual has lived with chronic disease(s) for many years, fears losing health insurance/coverage, and is likely a 2nd or 3rd wave adopter. They require multiple “inform” touchpoints, need a guarantee that their data is secure, want control over their data, may only participate with their doctor’s involvement, and require *All of Us* to have a concrete plan. They prefer fast results but know research takes time.
- Suspicious But Positive: Individual sees doctors as little as possible, uses free clinics or ER for general care, is likely to not have chronic disease(s), distracts government, tends toward conspiracy theories, is likely a 2nd or 3rd wave adopter, and requires *All of Us* data to be secure. They are concerned *All of Us* could harm people, want to protect self/family/others, and want to help humanity in substantive ways.
- No Time: Individual works multiple jobs and/or has little free time, is likely to not have chronic disease(s), 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, may only participate with their doctor’s involvement, and seeks concrete plan. They are likely to be put off if *All of Us* has too many steps/requirements and wants to help humanity in substantive ways.
- Too Much Government: Individual is 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, is unlikely to participate in *All of Us* without demonstrated results, distrusts government, prioritizes privacy, requires “guarantee” of anonymity, and needs high levels of transparency and detail.
## Major Building Blocks of the Research Program

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DATA AND RESEARCH CENTER (DRC)</strong></td>
<td>Big data capture, cleaning, curation, &amp; sharing in secure environment</td>
<td>Vanderbilt, Verily, Broad Institute</td>
</tr>
<tr>
<td><strong>BIOBANK</strong></td>
<td>Repository for processing, storing, &amp; sharing biosamples (35+M vials)</td>
<td>Mayo Clinic</td>
</tr>
<tr>
<td><strong>PARTICIPANT CENTER</strong></td>
<td>Direct volunteer participant enrollment, digital engagement innovation, &amp; mobile/wearable/consumer health technologies</td>
<td>Scripps Research Institute</td>
</tr>
<tr>
<td><strong>PARTICIPANT TECHNOLOGY SYSTEMS CENTER</strong></td>
<td>Web &amp; phone-based platforms for participants</td>
<td>Vibrent Health</td>
</tr>
<tr>
<td><strong>HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)</strong></td>
<td>Clinical &amp; scientific expertise network, enrollment &amp; retention of participants</td>
<td>20+ regional med centers, FQHCs, VA</td>
</tr>
<tr>
<td><strong>COMMUNITY &amp; ENGAGEMENT PARTNERS</strong></td>
<td>Local, regional, national orgs to educate, enroll, &amp; retain participants</td>
<td>Awards under review now</td>
</tr>
</tbody>
</table>
Main Awardees So Far

Anticipate new “community partner” awards begin mid ‘17
Current Consortium Members & Their Roles

- **Direct Volunteers**
  - WONDROS
  - WebMD
  - Walgreens

- **Health Care Provider Organizations**
  - Scripps Translational Science Institute
  - National Blood Collaborative
  - Quest Diagnostics
  - Quest Health
  - Emsi Health
  - Walgreens
  - WebMD

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### Roles

- **Branding & Content**
- **Education & Awareness**
- **Outreach & Recruitment**
- **Enrollment: Informed Consent, PPI, EHR**
- **Baseline Evaluation & Biospecimen Collection**
- **Sustained Engagement**

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### Health Care Provider Organizations

- California Precision Medicine Consortium
- Geisinger Health System
- Trans-American Consortium for the Health Care Systems Research Network
- New England Precision Medicine Consortium
- HHSC
- Community Health Initiative
- University of Arizona
- Northwestern University
- The University of Pittsburgh
- University of Miami
- University of Miami Miller School of Medicine
- Kaiser Permanente
- Kaiser Permanente Northern California
- Kaiser Permanente Southern California
- Kaiser Permanente Hawaii
- Kaiser Permanente Washington
- Geisinger Health System
- Trans-American Consortium for the Health Care Systems Research Network
- New England Precision Medicine Consortium
- University of Miami
- University of Miami Miller School of Medicine
- Kaiser Permanente
- Kaiser Permanente Northern California
- Kaiser Permanente Southern California
- Kaiser Permanente Hawaii
- Kaiser Permanente Washington
- Geisinger Health System
- Trans-American Consortium for the Health Care Systems Research Network
- New England Precision Medicine Consortium
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 Biomedical Research (UBR):
- Women
- Racial and ethnic groups
  - Asian
  - Black/African American
  - Some Other Race
  - Hawaiian/Pacific Islander
- Sexual and gender minorities
- Disadvantaged backgrounds
  - Low Socioeconomic Status (SES) (Income, Education, and Occupation)
- Physical or mental disabilities
- Geographically or culturally isolated environment
  - Rural

Underrepresented in Biomedical Research (UBR) 75%
Represented 25%
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

Surveys came from NIH resources & external researcher input; leveraging trusted, known instruments
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
Future PPI/Survey Modules (*DRAFT*)

1. Physical activity
2. Anthropometry (height, weight, weight history)
3. Diet
4. Environmental exposures
5. Oral health
6. Pain
7. Sexual/reproductive health
8. Socioeconomic status (employment, occupation, financial)
9. Substance use

Opportunity for ORWH to help develop & prioritize these and to pilot future modules
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!
Selected Scientific Opportunities

- Develop quantitative **estimates of risk** for a range of diseases by integrating environmental exposures and genetic factors.
- Identify the causes of individual variation in response to commonly used therapeutics = **pharmacogenomics**.
- Discover **biological markers** that signal increased or decreased risk of developing common diseases.
- Develop **solutions to health disparities**.
- Use **mobile health technologies** to correlate activity, physiological measures, and environmental exposures with health outcomes.
- **Empower study participants** with data and information to improve their own health.
- 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
Please back by 10:45.