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

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Deputy Director, All of Us Research Program
National Institutes of Health
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
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)
  - Electronic clinical decision support
  - Patient education

- Electronic phenotyping (building and validating)

- Integration of genomic findings into EMRs for clinical research and care
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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.

<table>
<thead>
<tr>
<th>V1 platform</th>
<th>V2 platform</th>
<th>V3 platform</th>
<th>Vx platform...</th>
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</thead>
<tbody>
<tr>
<td>Data</td>
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<td>+ Data</td>
<td>...</td>
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<tr>
<td>Samples</td>
<td>+ Samples</td>
<td>+ Samples</td>
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<tr>
<td>Analyses</td>
<td>+ Analyses</td>
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<tr>
<td>Tools</td>
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<tr>
<td>Cohort</td>
<td>+ Cohort</td>
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Two Methods of Engagement

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
National Network of Inaugural Partners

National Partners
- Mayo Clinic (Biobank)
- Hudson River Health Care
- 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
- Vibrent (Participant Technology Systems Center)
- National Alliance for Hispanic Health
- Delta Research and Educational Foundation

Regional Medical Centers
- San Francisco General Hospital Foundation
- Scripps Translational Science Institute (Participant Center)
- California Precision Medicine Consortium
- San Ysidro Health Center
- University of Arizona (w/Banner Health)
- Southern All of Us Network
- Jackson-Hinds Comprehensive Health Center
- FiftyFourward
- SouthEast Enrollment Center
- Vibrent (Participant Technology Systems Center)
- National Alliance for Hispanic Health
- Delta Research and Educational Foundation

FQHCs
- Wondros

Community Partners
- All of Us, Wisconsin
- Illinois Precision Medicine Consortium
- University of Pittsburgh
- Hudson River Health Care
- 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
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National Network of Inaugural Partners
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**

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

<table>
<thead>
<tr>
<th>Initial Data Types</th>
<th>Expanded Data Types (May Include)</th>
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<tbody>
<tr>
<td>Demographics</td>
<td>Clinical Notes</td>
</tr>
<tr>
<td>Visits</td>
<td>Radiology, cardiology, and other reports</td>
</tr>
<tr>
<td>Diagnoses</td>
<td>Mental Health Reports</td>
</tr>
<tr>
<td>Procedures</td>
<td>Substance Abuse, Alcohol use, and Tobacco use</td>
</tr>
<tr>
<td>Medications</td>
<td>More laboratory results, potentially including genomics</td>
</tr>
<tr>
<td>Laboratory Visits</td>
<td></td>
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<tr>
<td>Vital Signs</td>
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Sync 4 Science User Experience

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

Research App

EHR Patient Portal

Patient Portal Login

Approve Sharing EHR Data
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Digital Engagement (items under consideration)

- Mood App
- Fitbit Data Share
- CardioRespiratory Fitness App
- Headache App
- Snapshot Surveys
**All of Us & eMERGE**

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

Workshop
March 6-7, 2017

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.
All of Us & eMERGE

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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.

### 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?
Health Conditions

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?

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

*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.*
## All of Us Consortium Members

### DV Network
(Direct Volunteers)

- Scripps Translational Science Institute
- National Blood Collaborative
- QTC
- Walgreens
- DXC.technology
- WebMD
- EMSI Health
- patientslikeme
- BlueCross BlueShield
- WONDROS

### 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

#### All of Us, Wisconsin

- University of Wisconsin
- University of Chicago
- Northwestern University
- UCSD
- UC Irvine Health
- UC Heath
- Cedars Sinai
- Rush University Medical Center
- University of California Davis
- Kaiser Permanente
- University of Illinois at Chicago
- Mayo Clinic
- Advocate Health Care
- Northwestern Medicine

#### University of Arizona

- University of Arizona
- Banner Health

#### University of Pittsburgh

- University of Pittsburgh
- University of Kansas Medical Center
- Johns Hopkins University
- Michigan State University
- University of Michigan
- University of Minnesota
- University of North Carolina
- University of Pennsylvania
- University of Texas Health Science Center
- University of Wisconsin Madison

#### VA Medical Centers

- VA Medical Centers
- Leveraging Health & Learning
- University of Miami
- Emory University
- Morehouse School of Medicine
- University of Florida
- University of Minnesota Medical Center
- The University of Mississippi Medical Center
- University of Alabama at Birmingham
- Tufts University
- University of Pennsylvania
- University of Michigan
- University of Washington
- University of Southern California
- University of Wisconsin Medical Foundation
- University of California San Francisco

#### FQHCs (Federally Qualified Health Centers)

- Cherokee Community Health Center
- Community Health Center Inc
- East Central Area Health
- Henry Ford Health System
- Idaho Health Care District
- Iowa Health and Wellness
- Iowa Hospital Association
- Kentucky Health Services Network
- Knoxville Area Health Services
- Lehigh Valley Health Network
- MedStar Health
- University of Utah

#### Community Partners

- Delta
- National Alliance for Hispanic Health
- Fifty Forward
- San Francisco General Hospital Foundation

#### Communication & Engagement

- WONDROS
- HCM INTEGERS

#### Platform Development

- Scripps Translational Science Institute
- Sage
- Vanderbilt University
- WONDROS
- vibrent