Accelerating Precision Medicine for All of Us

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All of Us Research Program

 NIH
National Institutes of Health

NHC’s Chief Medical/Scientific Officers Conference
Precision Medicine

Right treatment. Right person. Right time. Right dose.

Prescription Eyeglasses

Blood Transfusions

More research is needed to bring precision medicine to most diseases

Pharmacogenetics (PharmGKB Drug Labels)
https://www.pharmgkb.org/labels

Precision medicine research → Precision Medicine
The cost of Imprecise Medicine

**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

**Providers**
- Not enough research to draw on for clinical evidence, especially in diverse populations
- Medical records scattered in different places
- Not enough time for analysis one patient at a time

**Researchers**
- Enormous time and cost spent building IT systems vs. doing research
- Siloed data resources and funding opportunities
- Challenges acquiring large sample sizes
- Slow translation of data into knowledge
Now is the time for precision medicine research – a revolutionary approach for disease prevention and treatment that takes into account individual differences in lifestyle, environment, and biology.
21st Century Cures Act

- Broad bi-partisan support
- Provisions relevant to All of Us:
  - Provides the Precision Medicine Initiative with $1.455 billion over 10 years
  - Provides flexible funding mechanism, Other Transaction Authority
  - Language on diversity, whole genome sequencing, data sharing, privacy
  - Provides important privacy protections critical for engendering trust
All of Us Research Program: Mission and Objectives

**Nurture relationships with 1 Million or more participant partners, from all walks of life, for decades**

**Our mission**
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us

**Catalyze a robust ecosystem of researchers and funders hungry to use and support it**

**Deliver the largest, richest biomedical dataset ever that is easy, safe, and free to access**

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1. Diversity of people at scale with participants at the center;
2. Diversity of data;
3. Open resource for all
Major building blocks of the *All of Us* Research Program consortium

**DATA AND RESEARCH CENTER**
Big data capture, cleaning, curation, & sharing in secure environment

*Vanderbilt, Verily, Broad Institute*

**BIOBANK**
Repository for processing, storing, and sharing biosamples (35+M vials)

*Mayo Clinic*

**PARTICIPANT TECHNOLOGY SYSTEMS CENTER**
Web and phone-based platforms for participants

*Vibrent Health*

**THE PARTICIPANT CENTER / DIRECT VOLUNTEER**
Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies

*Scripps Research Institute (with multiple partners)*

**HEALTHCARE PROVIDER ORGS NETWORK**
HPOs with clinical & scientific expertise, enrollment & retention of participants

10 regional medical centers, 6 FQHCs, VA, totaling 165 enrollment sites

**COMMUNICATIONS & COMMUNITY NETWORK**
Communications, marketing, and design expertise; engagement coordination and community partners network

*Wondros, HCM, 34 community partner orgs, and future awards to grow network*
Invent Network of Direct Volunteer Partners

Potential capacity of the DV Network

- Reach 90% where all people live, within 20 – 45 minutes
  - Not all at once--Cycle up or down locations depending on need (~50 at time)
- Convenient locations
- In-Home enrollment (EMSI)
- AoU on wheels – Journey Bus

Once proven, this capability—“to go where the people are”—may prove valuable for future research
Three Ways You Can Participate-- #1: Participants

Digital only

Joinallosfus.org
Three Ways You Can Participate: #2 Providers

- Community Partner Gateway Initiative (CPGI)
- Hold events to raise awareness for:
  - nurses
  - physicians
  - educators

Contact: Ronnie Tepp—HCM Strategists

It takes a village to create a resource for the nation!
The opportunity to **save time and resources** and **accelerate your research breakthroughs** by leveraging:

- A **rich resource of data**, including biospecimens and increasingly robust electronic health records.
- A **longitudinal dataset** that will follow participants as they move, age, develop relationships, get sick, and try treatments.
- A **diverse cohort of participants**, including people both healthy and sick, from all walks of life and all parts of the country.
- Both raw data and data that is already **cleaned and curated**.
- **Robust computing and analytic tools** to support complex data analyses in a **secure data environment**.
- A group of **engaged participants** who may be eager to participate in ancillary studies.

We are collecting, evaluating, and curating initial datasets; **availability in 2019**
Two pathways for EHR data sharing

FOR HPOs
- Using OMOP v5 Common Data Model
- Starts with limited EHR fields
  - Labs, Dx, medications, etc.
- Focus on quality improvement and mapping to standards
- Will grow over time to include expanded data types

FOR DIRECT VOLUNTEERS
- Start with pilot of Sync for Science program with top EHR vendors with the goal to “donate your EHR at touch of a button”
  - patient-initiated using an industry-adopted, standard API technology to read data from a Patient Portal
- Exploring partnership opportunities with aggregators to bring in more data – Need to be tested

<table>
<thead>
<tr>
<th>Initial Data Types</th>
<th>Expanded Data Types (May Include)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Demographics</td>
<td>• Physician Notes</td>
</tr>
<tr>
<td>• Visits</td>
<td>• Mental Health Data</td>
</tr>
<tr>
<td>• Diagnoses</td>
<td>• HIV Status</td>
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<tr>
<td>• Procedures</td>
<td>• Substance Abuse &amp; Alcohol use/misuse</td>
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<tr>
<td>• Medications</td>
<td>• Genomic Information</td>
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<tr>
<td>• Laboratory Visits</td>
<td>• Images</td>
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<tr>
<td>• Vital Signs</td>
<td>• Dental Records</td>
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HITECH and CURES Acts: making progress on provider access and use of health information, with individuals at the center of their care, and S4S enabling patient’s sharing EHR with researchers
1. **AoU Genome Centers (GCs)**
   - Genotyping and WGS platforms
   - Analysis pipeline includes variant calling and clinical interpretation (in program-defined regions)

2. **Clinical Validation Laboratory (CVL)**
   - CLIA/CAP validation assay w/ sign-off

3. **Genetic Counseling Resource (GCR)**
   - Responsible return of actionable results
   - Case work approach
Breaking down data silos:

- Data available to all types of users
- Employ a secured, cloud-based, analysis platform (no data removal),
- Access will be tiered
- Users will be granted data passports
- Project information will be made public and auditable
There are thousands of research questions. Let’s find some answers.

The All of Us Research Program is building one of the largest biomedical resources of its kind to explore how lifestyle, environment, and biological makeup affect health and disease. When it’s available, researchers will be able to use the diverse data here to explore a wide range of biomedical and scientific hypotheses.

Learn more about the All of Us Research Program protocol >

Sign up to get updates on the All of Us Research Hub. GET EMAIL UPDATES
Grand Challenges & Opportunities for all of us…

- **Risk Populations** – Need prevalent, incident, and pre-onset age groups (precursors, EHR, medications, lifestyles, demographics, etc);
  - Participants from existing cohorts can -- and are-- invited to participate

- **Access to data** -- and translating the findings to knowledge that can be tested

- **EHR - Syntactic harmonization** – driving towards the use of the same schema to represent the same values (e.g. cognitive tests, brain scans).
  - We're leaning heavily on existing standards and vocabularies; with some heterogeneity

- **EHR - Semantic harmonization** -- ability to compare values across sources (e.g. reference ranges, medication names, prescribing and coding habits).
  - This will be a long and ongoing challenge, need lots of data in place and ready for analysis
  - Use what we learn to feed back into the system

**Grand Opportunity:** moving from observing outcomes, to predicting them and then *changing* them
TO DATE...

**National launch:** Sunday May 6, 2018

>124,000 Participants; >69,000 core participants

78% are under-represented in biomedical research

190+ sites now enrolling in 20 states

Biobank > 1M tubes (capacity for 35M)

Developed data warehouse to collect, clean, curate, de-identify the data

COMING SOON:

**Research Portal** to be open with initial public dataset in 2019

Begin enrolling **children** once plans and protocol approved

**Genomics** to begin in late 2018/early 2019
Participants are our Partners

- **Steering and Executive Committees and Advisory Panel**
  - Provide participant perspectives to oversight and governance
  - Help set strategic direction

- **Participant Ambassadors**
  - Co-create and provide input on ongoing work and AoURP program implementation
  - Serve on select Working Groups and Task Forces

- **Director’s Think Tank**
  - Small group of mid-level professionals/community members from DMV area to provide feedback to AoURP leadership
  - Help shape and co-create new approaches
The future of health begins with you
THANK YOU!

- **NIH website:** [https://allofus.nih.gov](https://allofus.nih.gov)

- **Enrollment site:** [JoinAllofUs.org](https://JoinAllofUs.org)

- **Follow us on social media:** @AllofUsResearch, @JoniRutter, #JoinAllofUs