

NHC's Chief Medical/Scientific Officers Conference

# Accelerating Precision Medicine for All of Us

**All of Us**  
RESEARCH PROGRAM



National Institutes  
of Health

Joni L. Rutter, PhD  
Director of Scientific Programs  
*All of Us* Research Program

# Precision Medicine

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



Prescription Eyeglasses



Blood Transfusions

DRUG	FDA	EMA
aripiprazole	B	Actionable PGx has dosing info
aripiprazole lauroil	B	Actionable PGx has dosing info
atomoxetine	B	Actionable PGx has dosing info
belinostat	B	Actionable PGx has dosing info
brexpiprazole	B	Actionable PGx has dosing info
celecoxib	B	Actionable PGx has dosing info
citalopram	B	Actionable PGx has dosing info
clonazepam	B	Actionable PGx has dosing info
deutetrabenazine	B	Actionable PGx has dosing info
elilustat	B	Testing required has dosing info
loperidone	B	Actionable PGx has dosing info
irinotecan	B	Actionable PGx has dosing info
pimozide	B	Testing required has dosing info
tetrabenazine	B	Testing required has dosing info
voriconazole	B	Actionable PGx has dosing info
warfarin	B	Actionable PGx has dosing info

Pharmacogenetics (PharmGKB Drug Labels)

<https://www.pharmgkb.org/labels>

More research is needed to bring precision medicine to most diseases

*Precision medicine research* → Precision Medicine

# The cost of Imprecise Medicine

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## 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



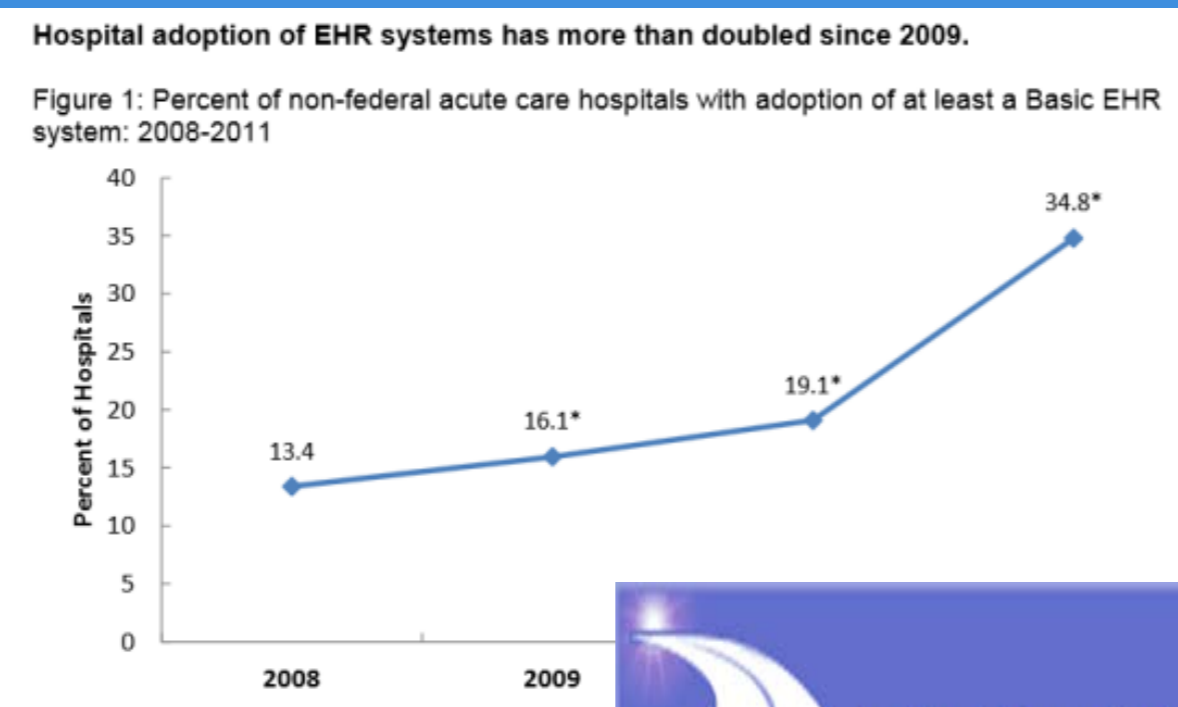
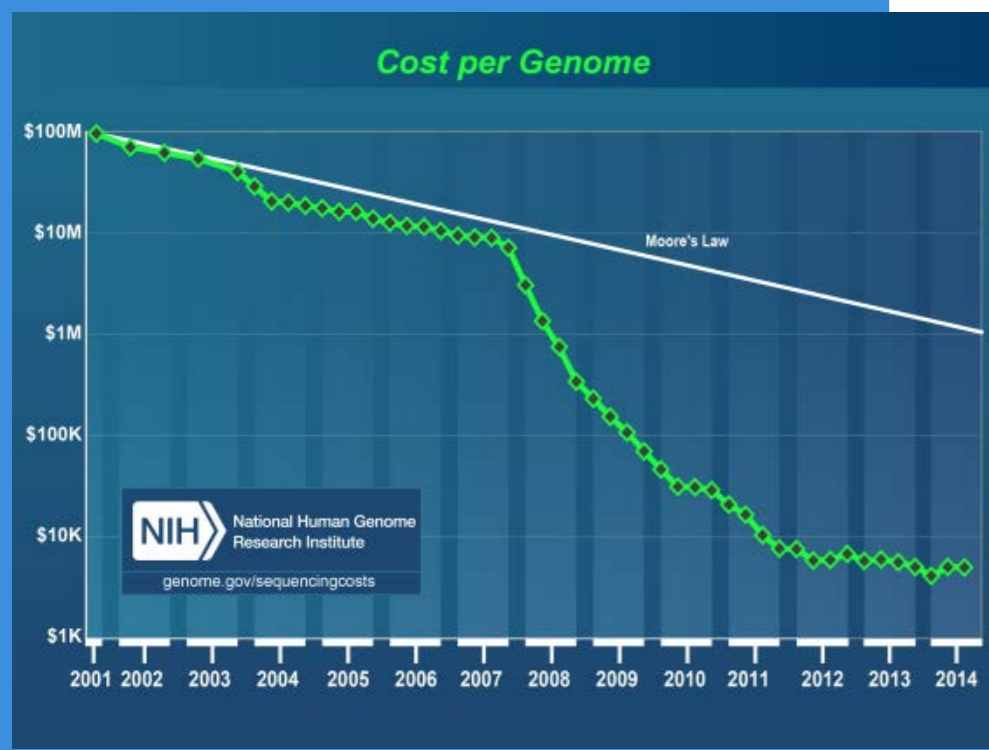
## Providers

- 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



**PROMIS** Patient-Reported Outcomes Measurement Information System  
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

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.

# 21<sup>st</sup> Century Cures Act

- ⦿ H.R.34, 21st Century Cures Act, enacted December 13, 2016 (Pub.L. 114-255)
- ⦿ 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

H. R. 34

One Hundred Fourteenth Congress  
of the  
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,  
the fourth day of January, two thousand and sixteen*

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “21st Century Cures Act”.

# All of Us Research Program: Mission and Objectives



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

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## 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

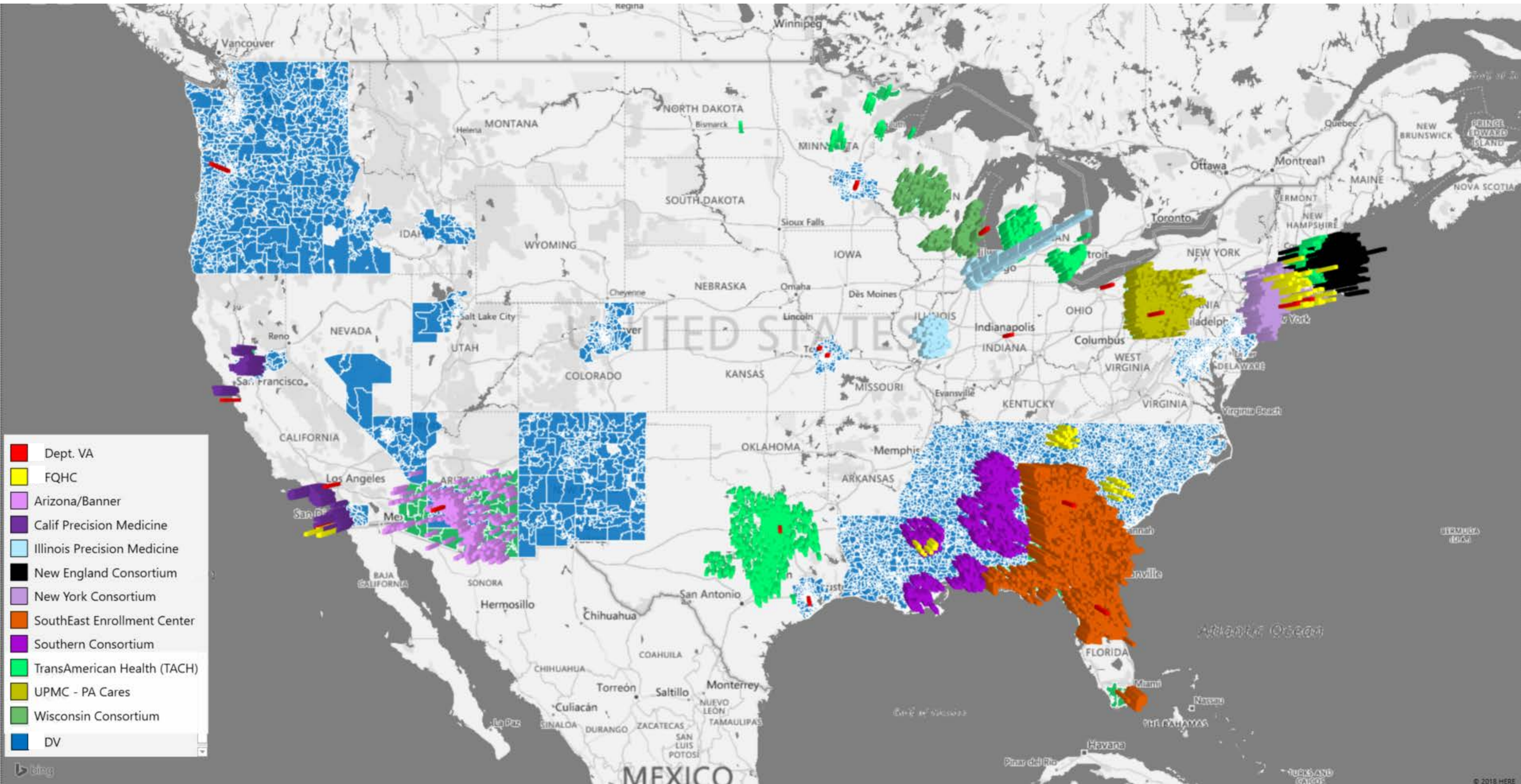
*10 regional medical centers, 6 FQHCs, VA, totaling 165 enrollment sites*

## 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*

# Current Enrollment Centers and Zip-code Catchment





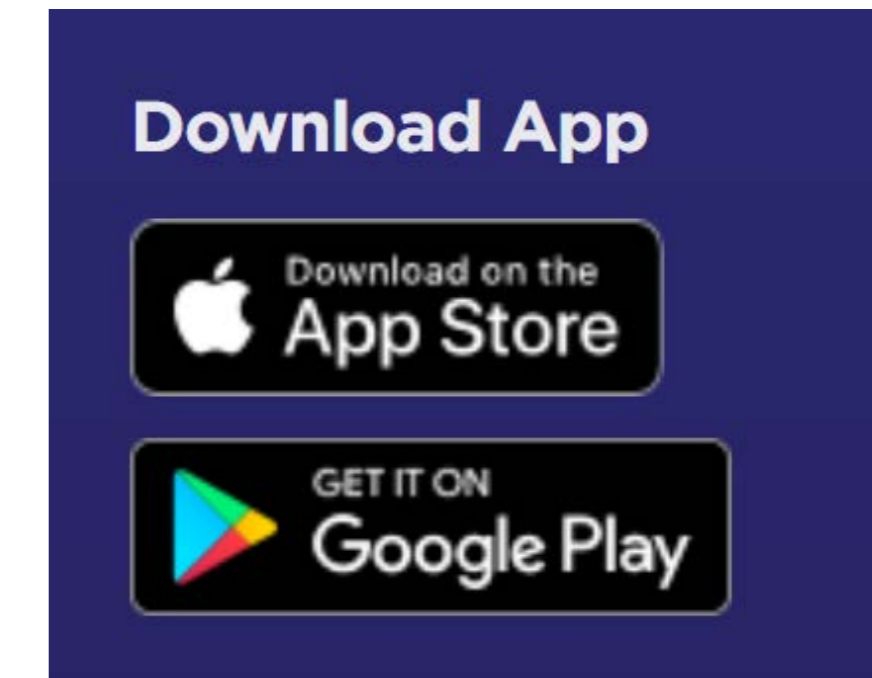
## ○ Potential capacity of the DV Network

- 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



# Three Ways You Can Participate-- #1: Participants

[Joinallofus.org](http://Joinallofus.org)





**Direct Volunteers  
(DV)**



**Health Care Provider  
Organizations (HPO)**



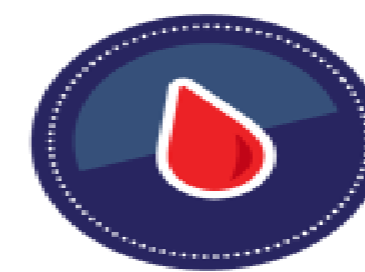


**1. Enroll & Consent**  
(incl EHR)

**2. Surveys, Journals**



**3. Baseline Measurements**



**4. Bio-Samples (Blood/Urine)**



**5. Apps, Phones & Wearables**

Digital only

# Three Ways You Can Participate: #2 Providers



- Community Partner Gateway Initiative (CPGI)

- Hold events to raise awareness for:

- nurses
- physicians
- educators

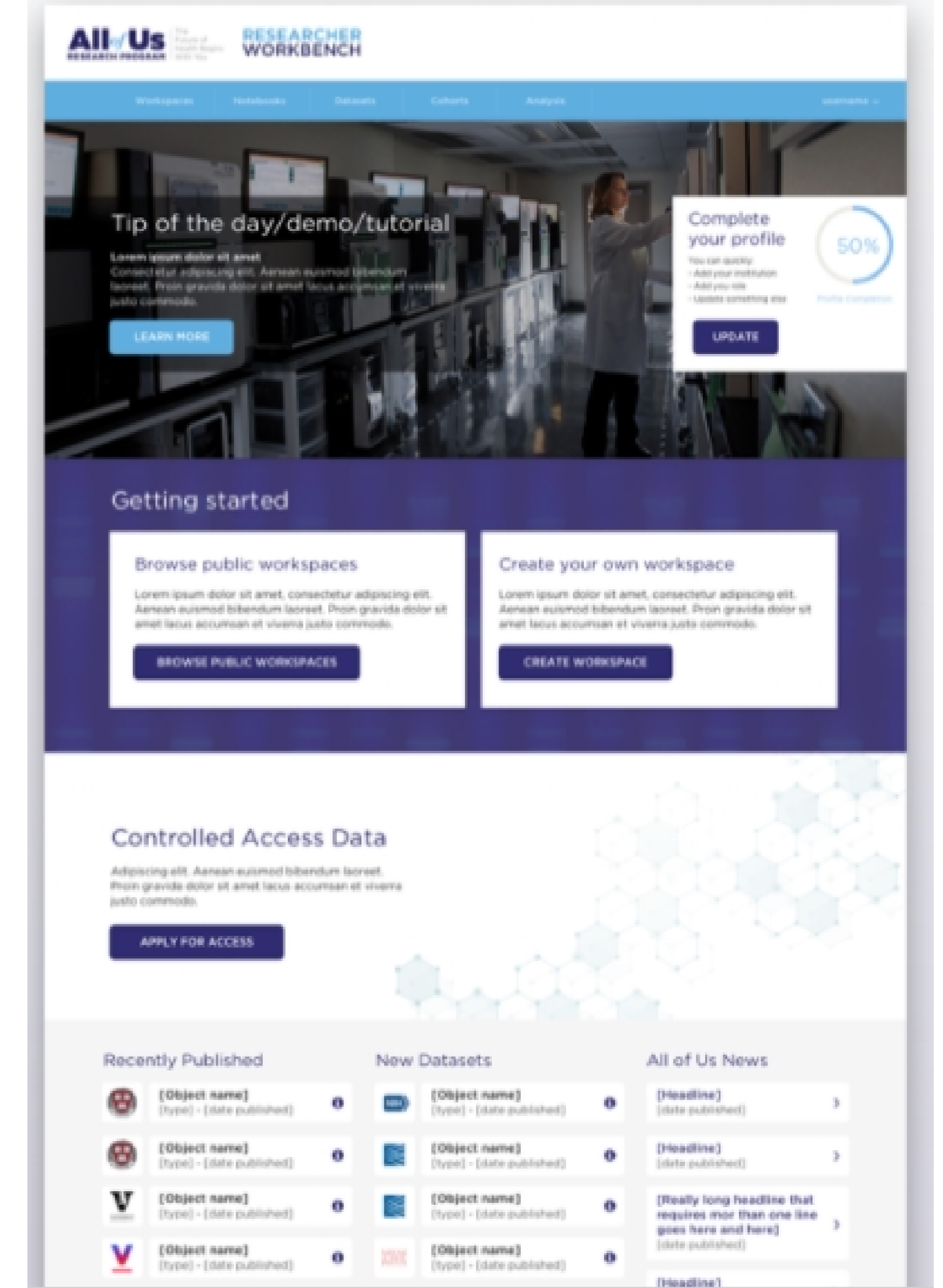
Contact: Ronnie Tepp– HCM Strategists



**It takes a village to create a resource for the nation!**

# Three Ways You Can Participate -- #3: Researchers

- 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*

Initial Data Types	Expanded Data Types (May Include)
<ul style="list-style-type: none"><li>• Demographics</li><li>• Visits</li><li>• Diagnoses</li><li>• Procedures</li><li>• Medications</li><li>• Laboratory Visits</li><li>• Vital Signs</li></ul>	<ul style="list-style-type: none"><li>• Physician Notes</li><li>• Mental Health Data</li><li>• HIV Status</li><li>• Substance Abuse &amp; Alcohol use/misuse</li><li>• Genomic Information</li><li>• Images</li><li>• Dental Records</li></ul>

**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****

# AoU Genomics Platform

## 1. AoU Genome Centers (GCs)

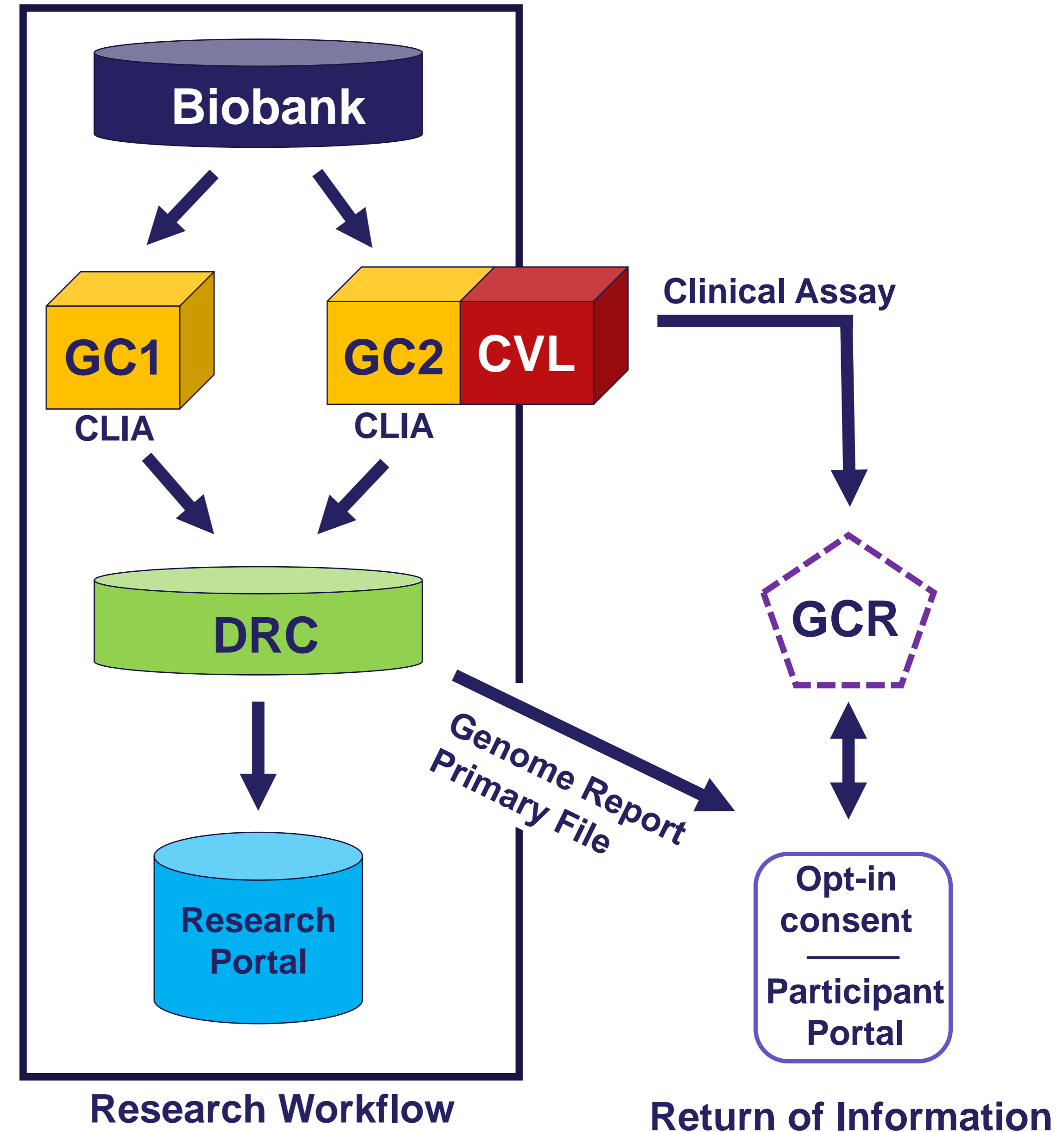
- Genotyping and WGS platforms
- Analysis pipeline includes variant calling and clinical interpretation (in program-defined regions)

## 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



# Data Access | Principles and Framework

## Breaking down data silos:

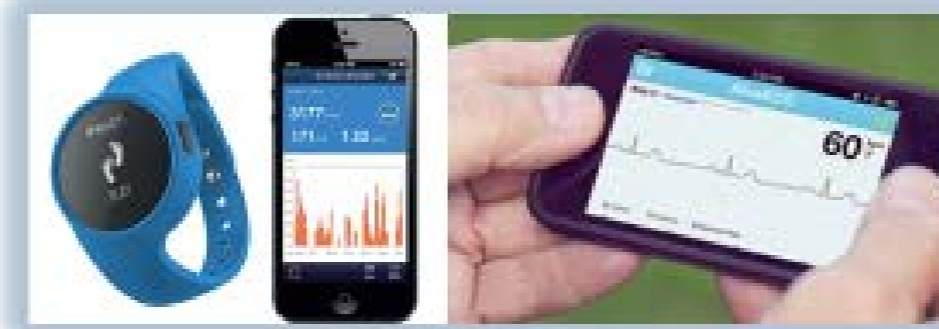
- ⦿ Data available to **all types of users**
- ⦿ Employ a secured, **cloud-based, analysis platform (no data removal)**,
- ⦿ Access will be **tiered**
- ⦿ Users will be granted **data passports**
- ⦿ Project information will be made **public and auditable**



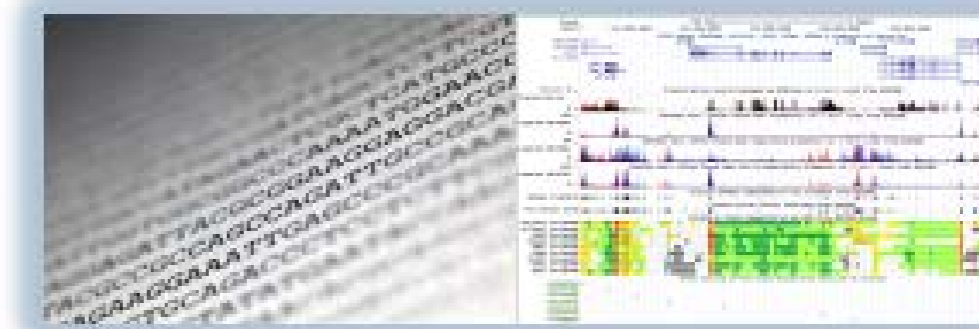
Participant Partnerships



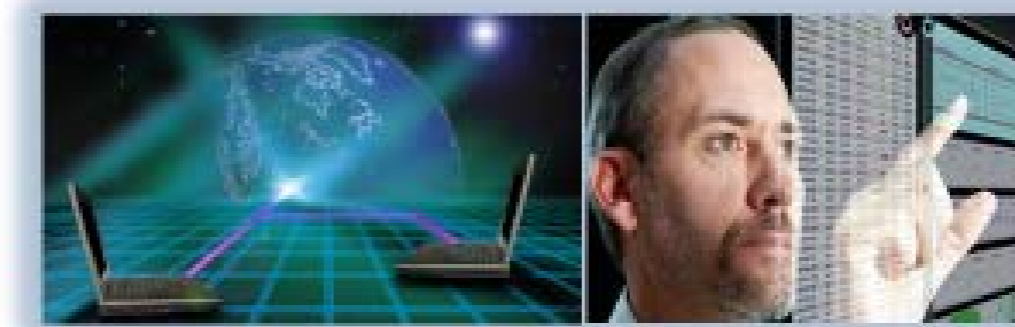
EHRs



Technologies



Genomics



Data Science



<https://www.researchallofus.org/>

# 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...

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- ◎ **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

## Participant Partners on Steering Committee, Executive Committee, and Advisory Panel



**Michael Castro**  
Bronx, New York



**Katherine Chang**  
Los Angeles, California



**Miriam Guzman**  
Chicago, Illinois



**Ana Carolina Dantas Machado**  
Los Angeles, California



**Richard Hochfelder**  
Longwood, Florida

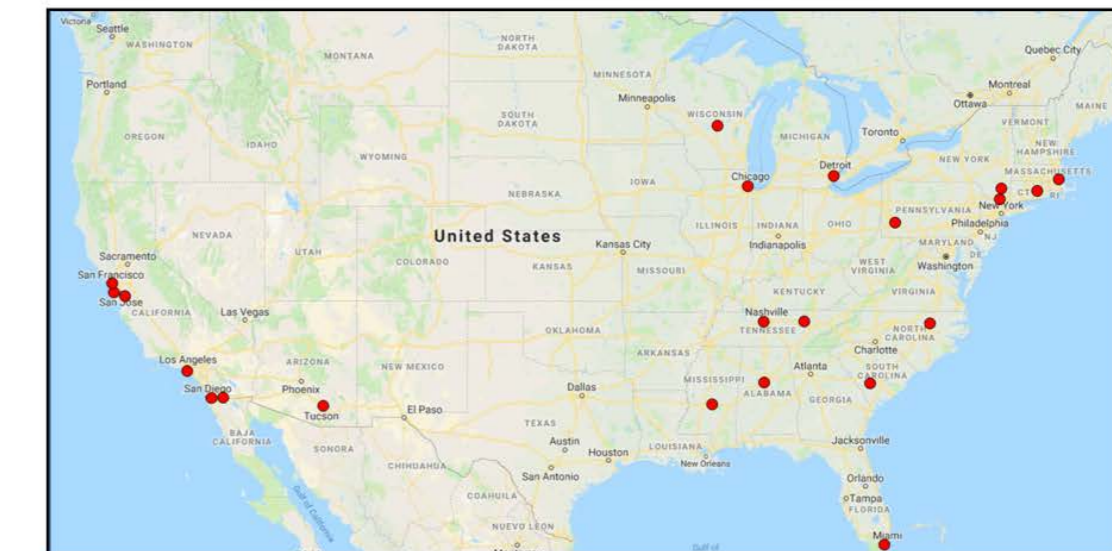


**Michelle McNeely**  
Dallas, Texas



**Zachary Orlov**  
Boston, Massachusetts

## Participant Ambassadors



## Director's Think Tank



**Marianne Chung**  
Asian and Pacific Islander  
American Health Forum



**Kelton Ellerbe**  
Retired, DC Firefighter



**Alberto Figueroa**  
American Psychological  
Association



**Ileana Herrell**  
Retired, National Institutes of Health



**Dylan Hedtler-Gaudette**  
National Federation of the Blind



**Kimberly Varner**  
Consultant



**Davey Yarborough**  
Musician  
Duke Ellington School of Arts



**Carrie Wade**  
American Association of  
People with Disabilities

- ◎ **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>
- **Enrollment site:** [JoinAllofUs.org](https://JoinAllofUs.org)
- **Follow us on social media:** @AllofUsResearch, @JoniRutter, #JoinAllofUs

## HPO Network (Health Care Provider Organizations)

### RMCs

California Precision Medicine Consortium

UC San Diego Health

UC DAVIS HEALTH Keck Medical Center of USC

UC Irvine Health

UCHEALTH UCSF

San Diego Blood Bank CEDARS-SINAI

All of Us, Wisconsin

Marshfield Clinic BLOODCENTER of WISCONSIN PART OF VERITY

Illinois Precision Medicine Consortium

Northwestern University

THE UNIVERSITY OF CHICAGO

NorthShore University HealthSystem

RUSH

THE UNIVERSITY OF ILLINOIS AT CHICAGO

UC

New England Precision Medicine Consortium

PARTNERS HEALTHCARE

MASSACHUSETTS GENERAL HOSPITAL

BRIGHAM HEALTH BRIGHAM AND WOMEN'S HOSPITAL

BU Boston University School of Medicine

BOSTON MEDICAL CENTRAL

UMASS Medical School

University of Arizona

THE UNIVERSITY OF ARIZONA

Banner Health

Trans-American Consortium for the Health Care Systems Research Network

Henry Ford HEALTH SYSTEM

Essentia Health

Baylor Scott & White HEALTH

SPECTRUM HEALTH

University of Pittsburgh

University of Pittsburgh

New York City Precision Medicine Consortium

COLUMBIA UNIVERSITY MEDICAL CENTER

NYC HEALTH+HOSPITALS

New York Presbyterian

Weill Cornell Medicine

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEM

Community Health Center, Inc.

JACKSON-HINDS COMPREHENSIVE HEALTH CENTER

Eau Claire

HRHCare

Southern All of Us Network

UAB SCHOOL OF MEDICINE

THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

Tulane University

HUNTSVILLE HOSPITAL

UNIVERSITY OF SOUTH ALABAMA HEALTH SYSTEM

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

UAB MEDICINE UAB HOSPITAL

TUSKEGEE UNIVERSITY

University Medical Center

LSU Health NEW ORLEANS

SouthEast Enrollment Center

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE

EMORY UNIVERSITY

MOREHOUSE SCHOOL OF MEDICINE

OneFlorida Clinical Research Consortium

VA Medical Center

VA U.S. Dept. of Veterans Affairs

DV Network (Direct Volunteers)

Scripps Translational Science Institute

DXC technology

NATIONAL BLOOD COLLABORATIVE

Quest Diagnostics

QTC A Leidos Company

EMSI HEALTH

Walgreens patientslikeme

BlueCross BlueShield

WebMD

### Community Partners

American Association of Colleges of Nursing

AAFP

AAHIVM

ACCESS

AMA

ANAC

APIAHF

BLACK WOMEN'S HEALTH IMPERATIVE

W.MONTAGUE Cobb Institute

DELTA RESEARCH AND EDUCATIONAL FOUNDATION

Fifty Forward

U.S. Dept. of Veterans Affairs

National Alliance for Hispanic Health

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

NHMA

Minority Quality Forum

SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

UNIDUS

## Communication & Engagement

WONDROS

HCM

## Platform Development

Scripps Translational Science Institute

Sage

VANDERBILT UNIVERSITY

WONDROS

vibrent