State University System of Florida BOG 6th Annual CW Bill Young Federal R&D Agency Workshop

Accelerating Precision Medicine for A of Us



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

of **RESEARCH PROGRAM**















Precision Medicine

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



Prescription Eyeglasses



More research is needed to bring precision medicine to most diseases

Precision medicine research \rightarrow **Precision Medicine**

Transfusions

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



The cost of Imprecise Medicine



- Health care is often targeted to the average patient, not the individual
- Health problems can take years to unravel, with significant trial and error



- 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

Providers



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

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of EHR systems has more than doubled since 2009



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.





The Precision Medicine Initiative



21st Century Cures Act

- H.R.34, 21st Century Cures Act, enacted December 13, 2016 (Pub.L. 114-255)
- Broad bi-partisan support \bigcirc
- 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

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



1. Diversity of people at scale with participants at the center; 2. Diversity of data; **3. Open resource for all**





Deliver the largest, richest biomedical dataset ever

that is easy, safe, and free to access

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

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

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, totaling165 enrollment sites

BIOBANK

Mayo Clinic

PARTICIPANT **TECHNOLOGY** SYSTEMS CENTER

Web and phone-based platforms for participants

Vibrent Health

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



Invent Network of Direct Volunteer Partners

Potential capacity of the DV Network \bigcirc

- 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







Walgreens















Once proven, this capability— "to go where the people are"—may prove valuable for future research





Three Ways FL Can Participate-- #1: Participants

Joinallofus.org









 Direct Volunteer is for anyone who wants to join, even if you don't have a clinic location nearby at the time of enrollment—STAY TUNED!

SEEC (SouthEast Enrollment Center) HPO:

- University of Florida
 - Clinical Research Center
 - Jacksonville (ASCENT)
 - Springhill
 - Heart & Vascular Clinic
- University of Miami
 - Biomedical Research Bldg
 - Professional Arts Center



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Three Ways FL Can Participate: #2 Providers



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

Community Partner Gateway Initiative (CPGI)

- Hold events to raise awareness for:
 - nurses
 - physicians
 - educators

Contact: Ronnie Tepp– HCM Strategists

Three Ways FL 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 \bigcirc standards
- Will grow over time to include expanded data types

Initial Data Types

- Demographics
- Visits
- Diagnoses
- Procedures
- Medications
- Laboratory Visits
- Vital Signs

FOR DIRECT VOLUNTEERS

- Start with pilot of Sync for Science program with top EHR \bigcirc 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 \bigcirc bring in more data – Need to be tested

Expanded Data Types (May Include)

- Physician Notes
- Mental Health Data
- **HIV Status**
- Substance Abuse & Alcohol use/misuse
- Genomic Information
- Images
- **Dental Records**

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 programdefined 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** \bigcirc
- Employ a secured, **cloud-based**, \bigcirc analysis platform (no data removal),
- Access will be **tiered**
- Users will be granted **data passports** \bigcirc
- Project information will be made **public** \bigcirc and auditable



Participant Partnerships



EHRs



Technologies



Genomics



Data Science

controlled data individual-level health data and genomics

registered data low-risk individuallevel data

public data summary statistics and aggregate data



No Specific Disease Focus, but All Disease Interest





NOAA pulls data from these buoys to predict the trajectory of a hurricane.

Buoys might represent individuals, biobanks, registries, etc—want to learn how to work together



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.

Sign up to get updates on the *All of Us* Research Hub.



GET EMAIL UPDATES

Grand Challenges & Opportunities for all of us...

- **<u>Risk Populations</u>** Need prevalent, incident, and pre-onset age groups (precursors, \bigcirc 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 \bigcirc
- **<u>EHR Syntactic harmonization</u>** 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

\bigcirc

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

EHR - Semantic harmonization -- ability to compare values across sources (e.g.



TO DATE...

National launch: Sunday May 6, 2018 >110,000 (FL: 2779) Participants; >60,000 (FL: 1452) core participants 76% are under-represented in biomedical research 150+ sites now enrolling in 19 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 in 2019 Genomics to begin in late 2018/early 2019



The future of health begins with you













National Institutes of Health

THANK YOU!

NIH website: <u>https://allofus.nih.gov</u>

• Enrollment site: JoinAllofUs.org

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

RMCs HPO Network Trans-American Illinois New England (Health Care Provider Consortium for the Precision Precision New York City Organizations) Medicine Health Care Systems Precision Medicine California Precision Medicine Southern Research Network All of Us Network Medicine Consortium Consortium Consortium Consortium COLUMBIA UNIVERSITY Northwestern University HenryFord HEALTH SYSTEM UC San Diego Health PARTNERS SCHOOL OF MEDICINE MEDICAL CENTER nowledge that will change MASSACHUSETTS GENERAL HOSPITAL CHICAGO UCDAVIS Keck Medical NYC HEALTH+ 隊 Essentia Health HEALTH THE UNIVERSITY OF MISSISSEPTI MEDICAL CENTER Center of USC BRIGHAM HEALTH BRIGHAM AND WOMEN'S HOSPITAL HOSPITALS +NorthShore (III) UC Irvine Health BaylorScott&White Tulane 💆 University TUSKEGEE BU Retor University School of Medic NewYork-Presbyterian RUSH SPECTRUM HEALTH UCSF **UC HEALTH** BOSTON THE Weill Cornell Medicine UNIVERSITY OF University of Californi San Francisco HUNTSVILLI HOSPITAL ILLINOIS CEPTIONAL CARE WITHOUT IS AT C(S CHICAGO University of Massachusetts Blood Bank UIC HEALTH SYSTEM CEDARS-SINAL FQHCs (Federally Qualified Health Centers) All of Us, Wisconsin University of Arizona University of Pittsburgh Dittsburgh THE UNIVERSITY OF ARIZONA Cherokee TACKSON-HINDS 🇌 Marshfield Clinic MEDICAL University of Wisconsin SCHOOL OF MEDICINE AND PUBLIC HEALTH Danner Health Communt ty Health Center, Inc. Eau Claire BLOODCENTER -PART OF VERSITI V Platform Communication Scripps Translational WONDROS WONDROS VANDERBILT Development & Engagement UNIVERSITY

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Approach to Privacy and Security

- Data warehouse built with the most advanced security available
- Continuous rigorous security testing \bigcirc
- Data is encrypted and de-identified \bigcirc
- Committed to transparency in the event of a data breach
- Researchers must go through identity proofing, ethics training, agree to a code of conduct
- Protected by a Certificate of Confidentiality \bigcirc





Kinds of Questions this Resource May Help Answer

How can we prevent the chronic pain that affects more than 100 million people across the U.S. each year?

Or develop better pain medicines that aren't addictive?

Or develop better treatments for diabetes, which affects almost 10% of Americans-or prevent diabetes altogether?

Or drive local disparities interventions that work sustainably?

Or slow or even stop different kinds of dementia?

Or develop more cancer cures that will work the first time, so we can skip painful trial-and-error chemotherapy?

