

Accelerating Precision Medicine for All of Us

All of Us
RESEARCH PROGRAM



National Institutes
of Health

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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 PCis has dosing info |
| aripiprazole lauroil | B | Actionable PCis has dosing info |
| atomoxetine | B | Actionable PCis has dosing info |
| belinostat | B | Actionable PCis has dosing info |
| brexpiprazole | B | Actionable PCis has dosing info |
| celecoxib | B | Actionable PCis has dosing info |
| citalopram | B | Actionable PCis has dosing info |
| clonazepam | B | Actionable PCis has dosing info |
| deutetrabenazine | B | Actionable PCis has dosing info |
| elilustat | B | Testina required has dosing info |
| loperidone | B | Actionable PCis has dosing info |
| irinotecan | B | Actionable PCis has dosing info |
| pimozide | B | Testina required has dosing info |
| tetrabenazine | B | Testina required has dosing info |
| voriconazole | B | Actionable PCis has dosing info |
| warfarin | B | Actionable PCis 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



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



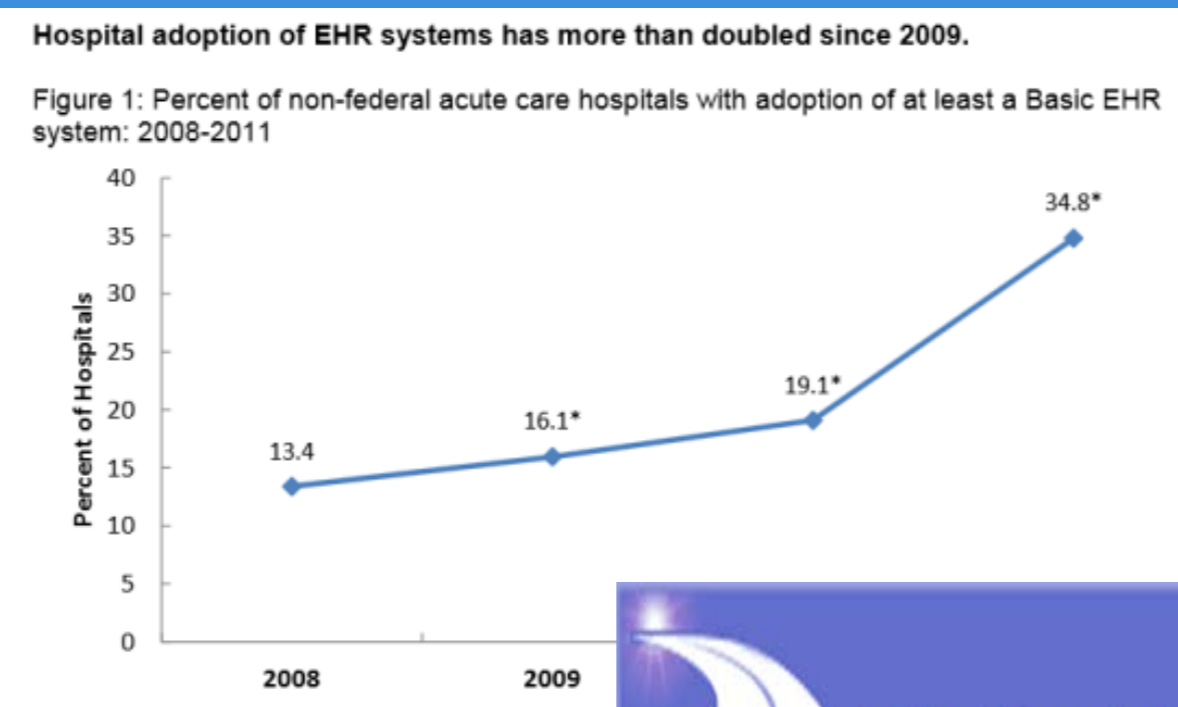
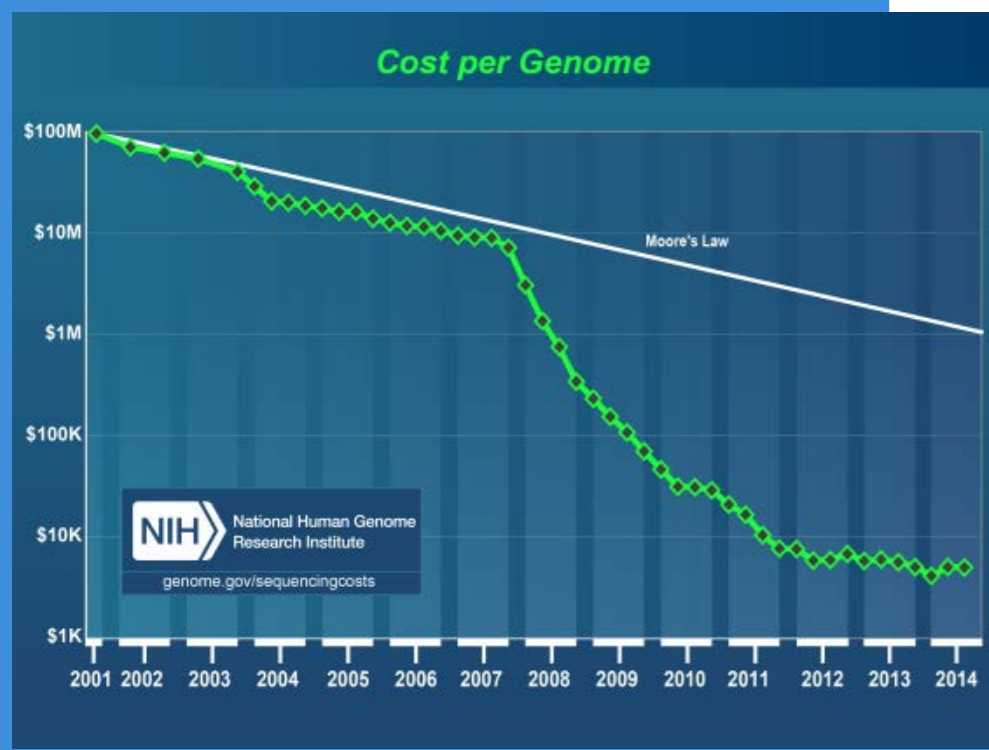
Providers

- 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.

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

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

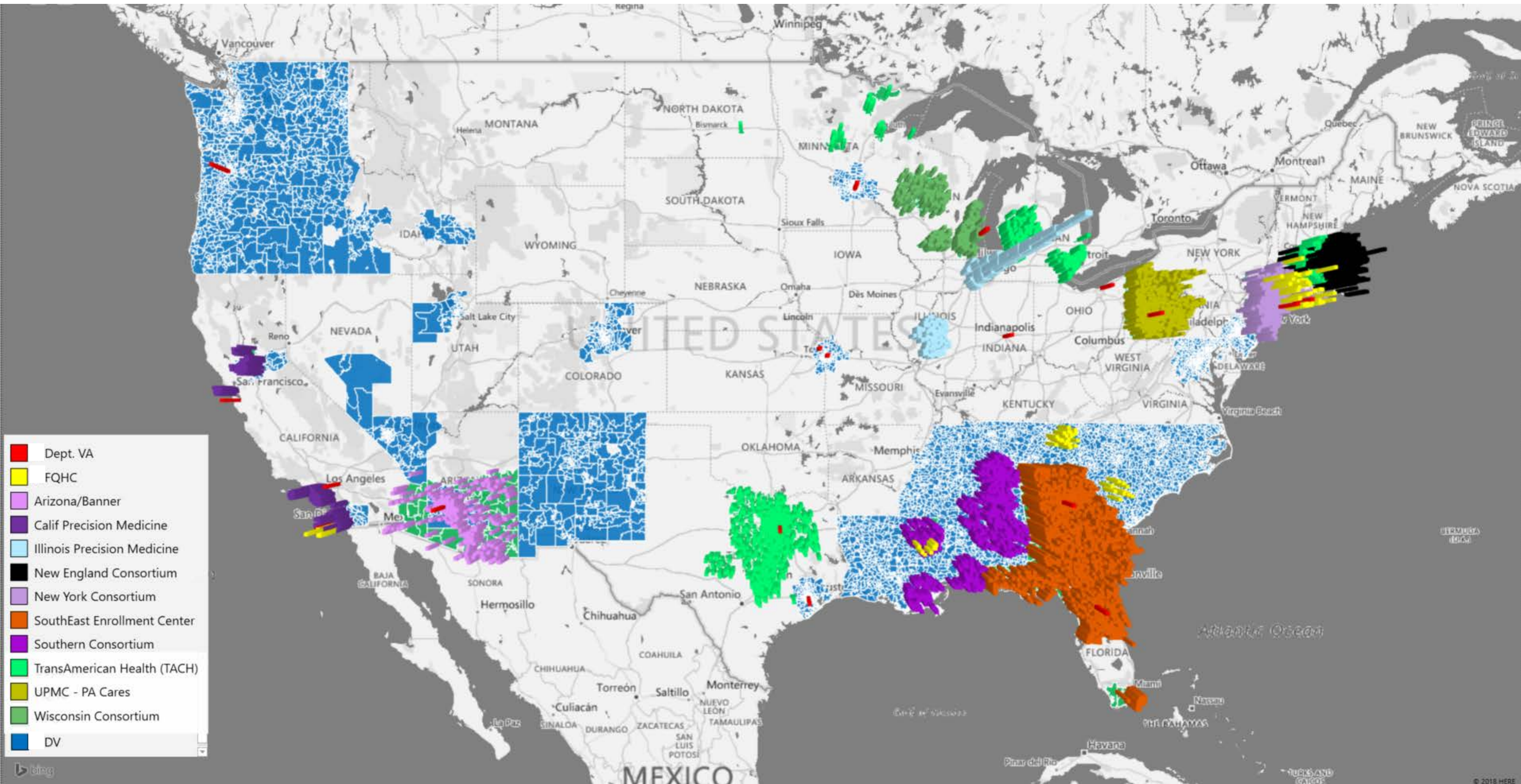
10 regional medical centers, 6 FQHCs, VA, totaling 165 enrollment sites

COMMUNICATIONS & COMMUNITY NETWORK

Communications, marketing, and design expertise; engagement coordination and community partners network

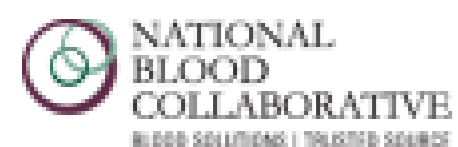
Wondros, HCM, 34 community partner orgs, and future awards to grow network

Current Enrollment Centers and Zip-code Catchment



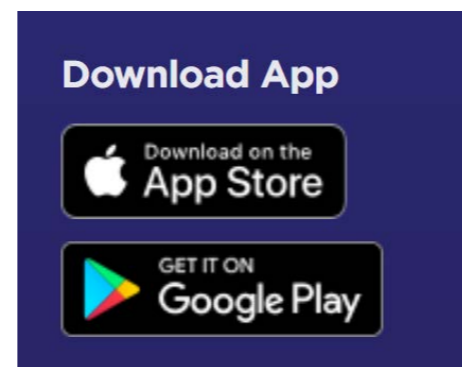
○ Potential capacity of the DV Network

- 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 WV Can Participate-- #1: Participants

Joinallofus.org



“all of us”

**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



- 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!**
- Discussion between *All of Us* Pennsylvania and WVU

Three Ways WV Can Participate: #2 Providers

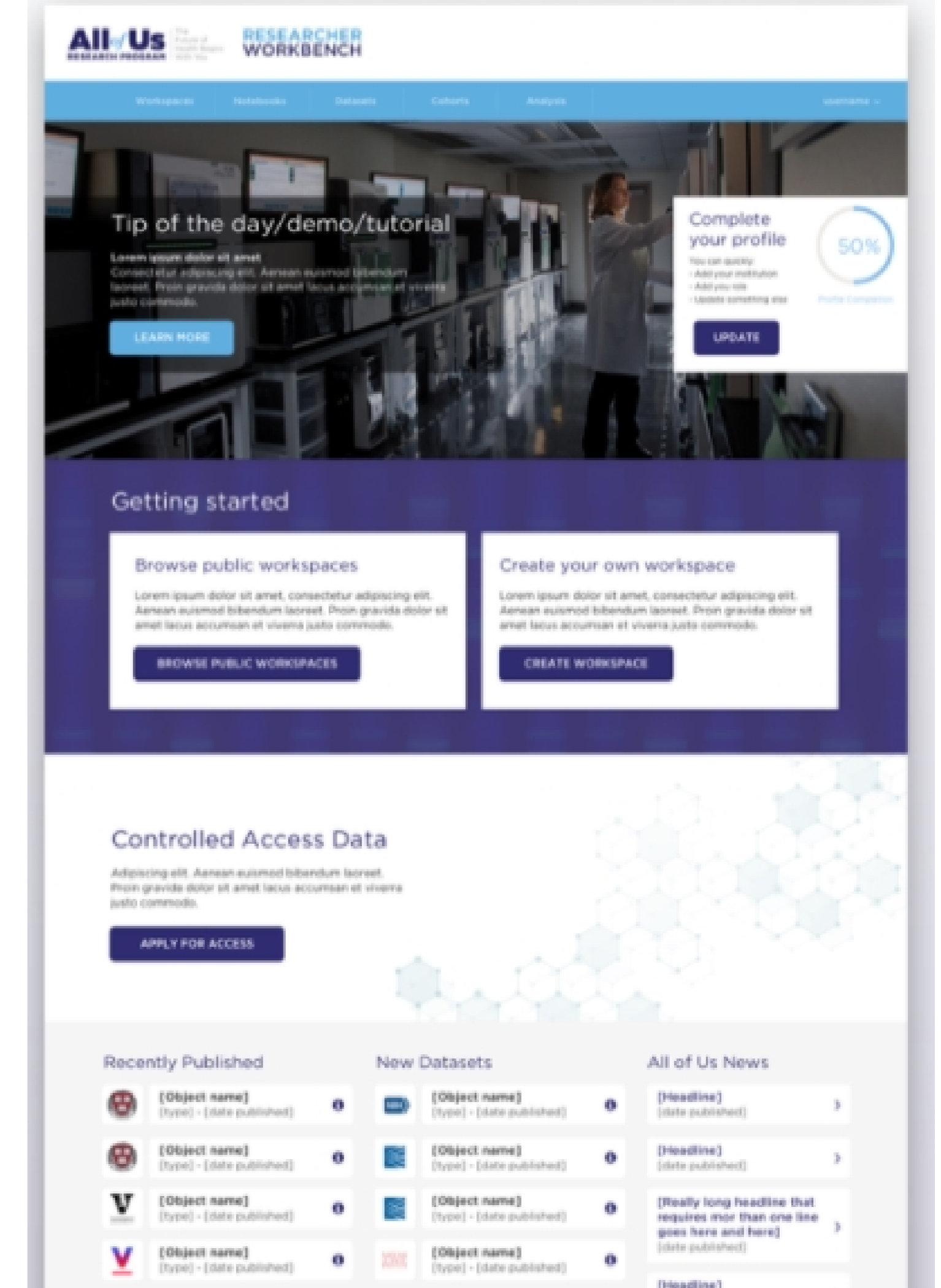


- Community Partner Gateway Initiative (CPGI)
 - American Association of Clinical Care Nurses made a sub award to **Bluefield State College** to host an *All of Us* informational session
- The event was led by Betty Nash from the School of Nursing and Allied Health
 - attended by 150 people
 - nurses
 - physicians
 - educators
 - fitness instructors
 - seniors

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

Three Ways WV 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**

Data Access | Principles and Framework

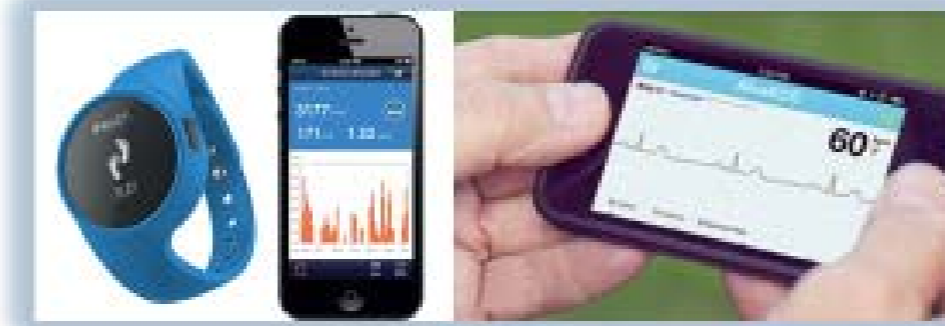
- ⦿ Data available to **all types of users**
- ⦿ Employ a secured, **cloud-based, analysis platform (no data removal)**,
- ⦿ Access will be **tiered**
- ⦿ Users will be granted **data passports**
- ⦿ Project information will be made **public and auditable**



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

TO DATE...

National launch: Sunday May 6, 2018

>110,000 (WV: 69) Participants registered; **>60,000 (WV:12)** 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

All of Us
RESEARCH PROGRAM

**The future
of health
begins
with **



THANK YOU!

- **NIH website:** <https://allofus.nih.gov>
- **Enrollment site:** 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 VERITEC

University of Wisconsin SCHOOLS OF MEDICINE AND PUBLIC HEALTH

MEDICAL COLLEGE OF WISCONSIN

University of Arizona

THE UNIVERSITY OF ARIZONA

Banner Health

University of Pittsburgh

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEMS

JACKSON-HINDS COMPREHENSIVE HEALTH CENTER

Community Health Center, Inc.

Eau Claire

HRHCare

VA Medical Center

VA U.S. Dept. of Veterans Affairs

Community Partners

DV Network (Direct Volunteers)

Scripps Translational Science Institute

NATIONAL BLOOD COLLABORATIVE BLOOD SOLUTIONS | TRANSFUSION SERVICE

QTC A Lexia Company

Walgreens

BlueCross BlueShield

DXC technology

Quest Diagnostics

EMSI HEALTH

patientslikeme

WebMD

American Association of Colleges of Nursing

AAFP

AAHIVM

ACCESS

AMA

ANAC

APIAHF ASIAN & PACIFIC ISLANDER AMERICAN HEALTH FORUM

BLACK WOMEN'S HEALTH IMPERATIVE

W.MONTAGUE COBB NMA HEALTH Institute

DELTA RESEARCH AND EDUCATIONAL FOUNDATION

Fifty Forward

National Alliance for Hispanic Health

NHMA National Hispanic Medical Association

Minority Quality Forum

SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

UNIDDSUS STRONGER COMMUNITIES. STRONGER AMERICA.

Communication & Engagement

WONDROS

HCM STRATEGISTS

Platform Development

Scripps Translational Science Institute

Sage

VANDERBILT UNIVERSITY

WONDROS

vibrent

Approach to Privacy and Security

- ◎ Data warehouse built with the most advanced security available
- ◎ Continuous rigorous security testing
- ◎ Data is encrypted and de-identified
- ◎ 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



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 slow or even stop different kinds of dementia?

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

Or drive local disparities interventions that work sustainably?

21st 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, 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

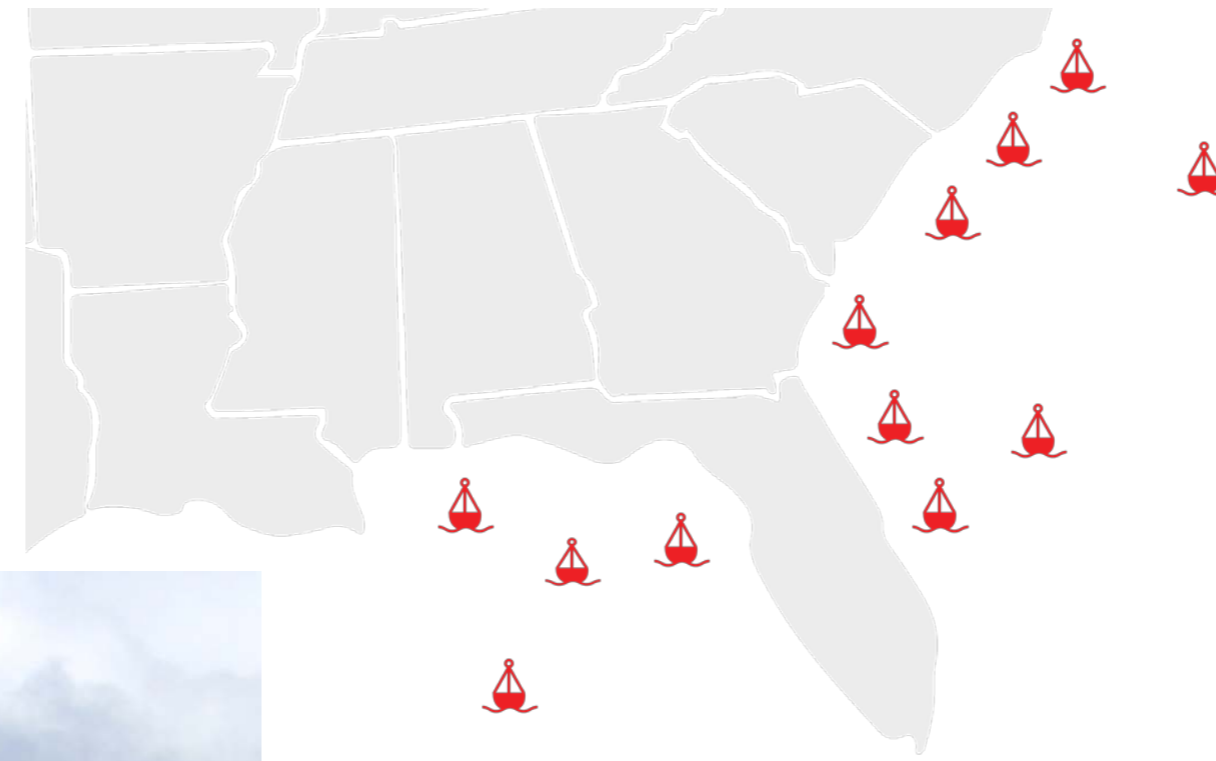
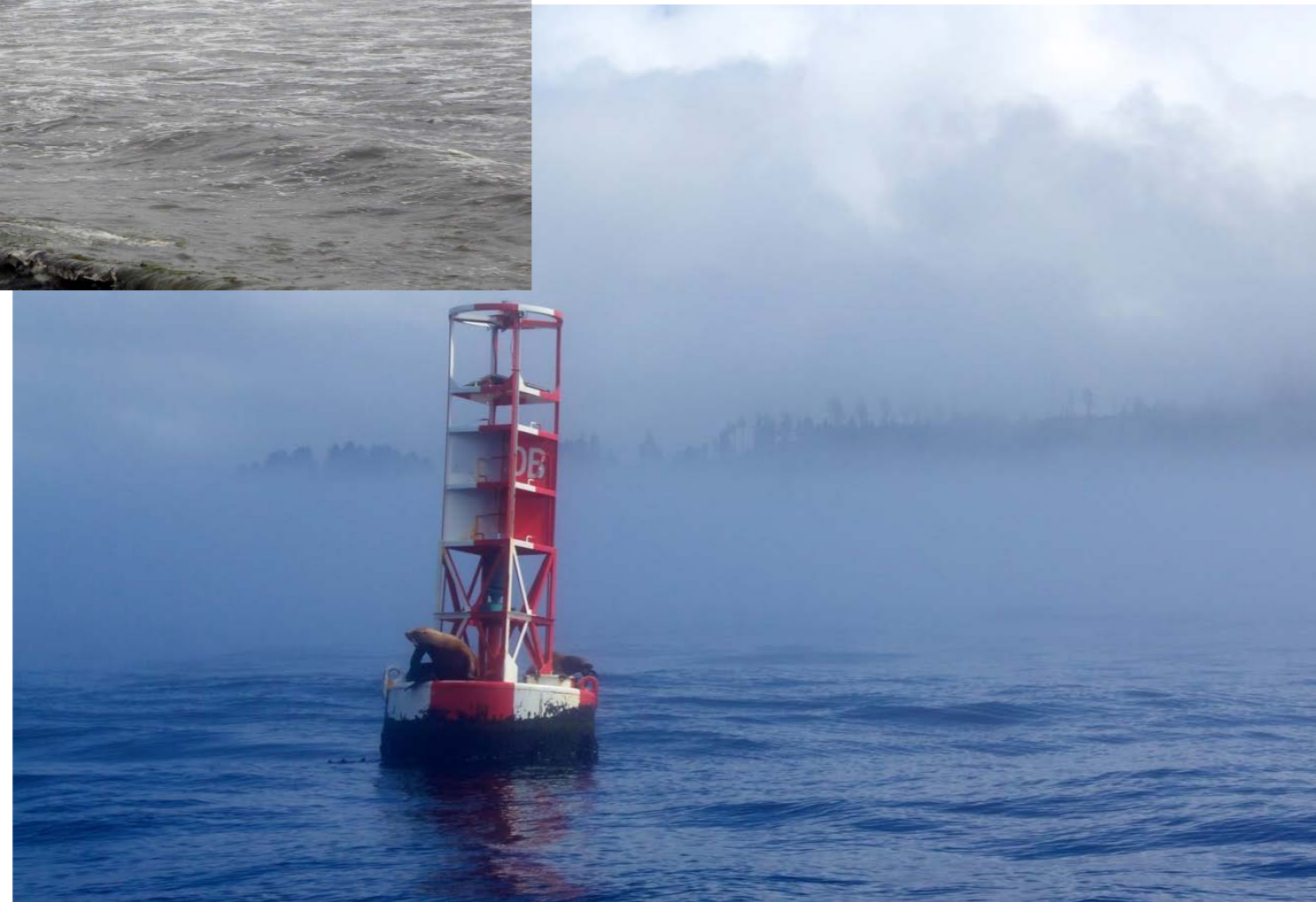
To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

*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”.

Why 1M?



Heart disease:
11.5% of US population

AoU Possibility:
115,000 participants with heart
disease provide data

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

