**All of Us**
**RESEARCH PROGRAM**

# The future of health begins with you

National Institutes of Health

*April 17, 2018*

# Together, we will generate a conversation about:

- The basics of the *All of Us* Research Program
- Our current status
- Ways in which organizations can help support the program at launch and beyond

# Today’s Speakers

**Eric Dishman**
**Director**

**Dara Richardson-Heron, MD**
**Chief Engagement Officer**

*A special update & conversation with advocacy groups:*

# Advocating & Accelerating Precision Health for All of Us

*All of Us* Research Program
April 17, 2018
**allofus.nih.gov** or **joinallofus.org**

---

Eric Dishman
Director, *All of Us* Research Program
Patient, Family Caregiver, Patient Advocate
eric.dishman@nih.gov

NIH
National Institutes of Health

#joinallofus

My  first week of chemo, Summer 1989, Chapel Hill, NC:

“You won’t survive a year, unfortunately.”

**Yes, Whole Genome Sequencing & my complete Electronic Health Record saved my life *recently*.**
**Long before that, specific patient advocates & advocacy organizations saved my life *many times over*!**

# In all my roles, advocacy has been a key part of my life…

American Cancer Society®

National Kidney Foundation®

alz.org® | alzheimer's association®

DONATE LIFE America

**Important to leverage and support both advocacy “in the small” and “in the large.”**

# For today…

- **A reminder of (or first exposure to) the basics of AOU**
  - Mission, objectives, values, building blocks, protocol…

- **Update on accomplishments and status of the program**
  - Beta phase
  - Upcoming launch
  - Plans for data access

- **Catalyze a conversation that goes well beyond today's call**
  - Vision of stitching together cohorts, registries, biobanks, etc.
  - Key areas of collaboration with advocacy community
    - Help shape the science, and thus, the breakthroughs
    - Help communicate, recruit, and manage expectations
    - Help build robust ecosystem of funders to leverage the national resource

**Invitations went out primarily to patient/research advocacy orgs—but apparently spread well beyond! Cool, all are welcome, but am focusing especially on those organizations. And harder to be interactive.**

# The “basics”: overview of the *All of Us* Research Program

# *All of Us Research Program* Mission and Objectives

**Nurture relationships**
with one 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 the robust ecosystem**
of researchers and funders hungry to use and support it

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

# *All of Us Research Program* Mission and Objectives ARE LARGER THAN US!

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

How do we all promote understanding of precision medicine, research participation?

What are the evidence-based methods for reaching & building trust with diverse & especially vulnerable populations?

How can AOU build relationships and recruitment with your community of patients & family members?

## Our mission

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

**Deliver one of the largest, richest biomedical datasets ever**
that is as easy, safe, and free to access

How do we solve common challenges of EHR access, genetic return of info, reliability of mobile devices, etc.?

What can we do to improve security & privacy practices?

And help researchers get storage/compute support?

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

Shared advocacy efforts for more research support?

How to build common roadmaps of key focus areas, methods, & data types needed for your domain across funders?

How to make sure "if we build it, they—your ecosystem of researchers—will come!"?

# *All of Us Research Program* Core Values

- Participation in the *All of Us* Research Program will be **open** to interested individuals.
- The Program will reflect the rich **diversity** of America.
- Participants will be **partners** in the Program.
- Trust will be earned through robust **engagement** and full **transparency**.
- Participants will have **access** to information and data about themselves.
- Data from the Program will be broadly **accessible** to **empower research**.
- The Program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.
- The Program will be a catalyst for **innovative research** programs and policies.

# Summary of our approach & protocol

**<u>Deliver Rich, Longitudinal Resource</u>:**
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!)

**<u>With a Diversity of Participants</u>:**
Reflect the **broad diversity** of the U.S.—all ages, races/ ethnicities, gender, SES, geographies, & health status—by over-recruiting those **underrepresented in biomedical research**

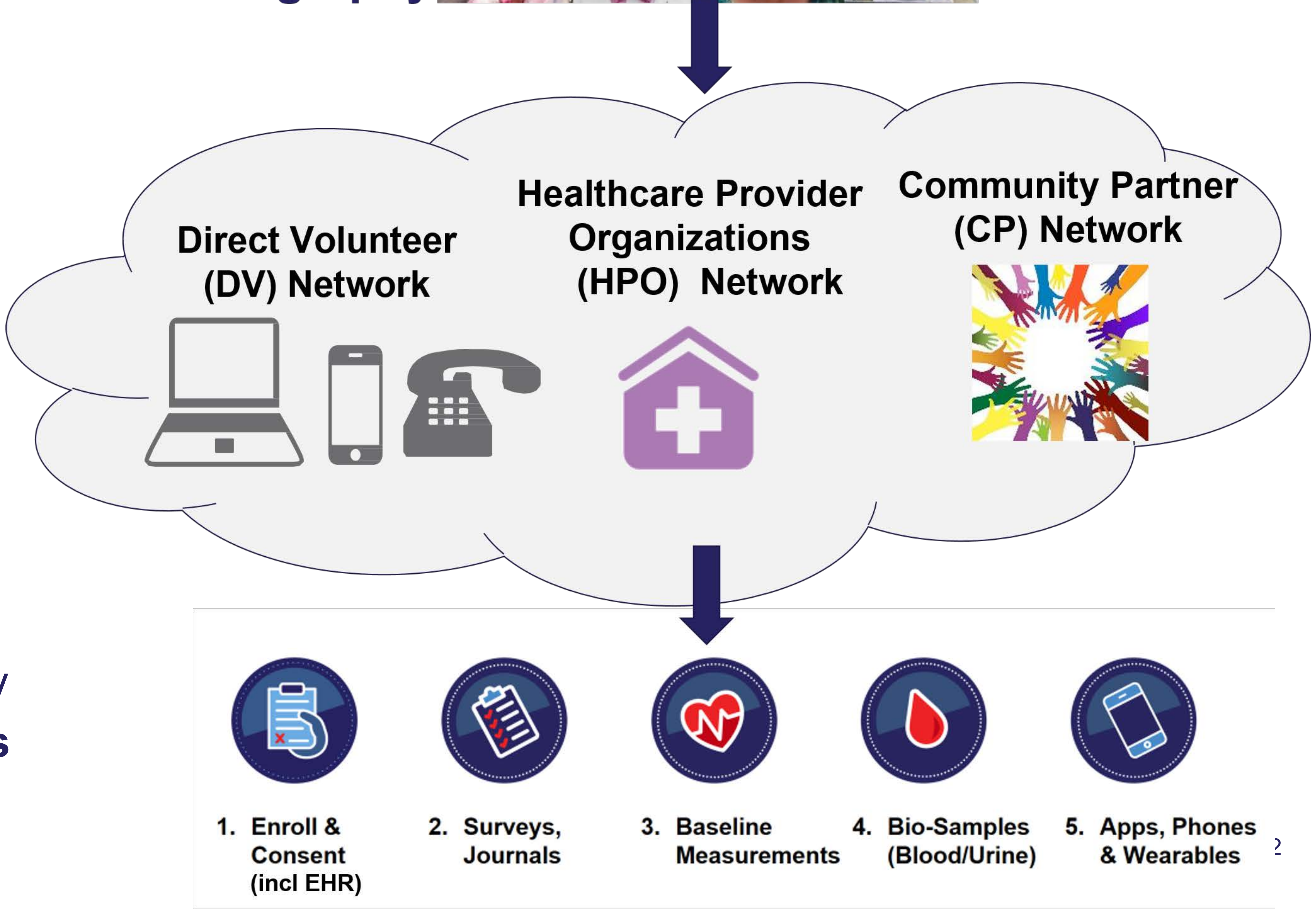
**<u>For a Diversity of Researchers</u>:**
Build the **tools & capabilities** that make it easy for researchers from citizen scientists to premier university labs to make discoveries using the **data & biosamples** and through **ancillary studies** w/ the cohort

**Demographics**

**Health status**

**Geography**

**Environments**



1. Enroll & Consent (incl EHR)
2. Surveys, Journals
3. Baseline Measurements
4. Bio-Samples (Blood/Urine)
5. Apps, Phones & Wearables

# 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, & sharing biosamples (35+M vials)

*Mayo Clinic*

**PARTICIPANT TECHNOLOGY SYSTEMS CENTER**

Web & phone-based platforms for participants

*Vibrent Health*

**PARTICIPANT CENTER / DV NETWORK**

Direct volunteer participant enrollment, digital engagement innovation, & consumer health technologies

*Scripps Research Institute (with multiple partners)*

**HEALTHCARE PROVIDER ORGS NETWORK**

HPOs with clinical & scientific expertise, enrollment & retention of participants

*30+ regional med centers, FQHCs, VA, future awards to grow network*

**COMMUNICATIONS & COMMUNITY NETWORK**

Comms, marketing, & design expertise; Engagement coordination & community partners network

*Wondros, HCM, 25 community partner orgs, future awards to grow network*

# Current Consortium Members: DV & HPO networks, Comms & Engagement

**DV Network**

(Direct Volunteers)

Scripps Translational Science Institute
National Blood Collaborative — Blood Solutions | Trusted Source
QTC — A Leidos Company
Walgreens
BlueCross BlueShield
DXC.technology
Quest Diagnostics
EMSI Health
patientslikeme
WebMD

**Biobank**

Mayo Clinic

**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
- UC Health
- UCSF University of California San Francisco
- San Diego Blood Bank — Saving lives today. Improving life tomorrow.
- Cedars-Sinai

Illinois Precision Medicine Consortium
- Northwestern University
- The University of Chicago
- NorthShore University HealthSystem
- Rush
- The University of Illinois at Chicago — UIC

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 Center — Exceptional Care. Without Exception.
- UMass University of Massachusetts Medical School

Trans-American Consortium for the Health Care Systems Research Network
- Henry Ford Health System
- Essentia Health
- Baylor Scott & White Health
- Spectrum Health

New York City Precision Medicine Consortium
- Columbia University Medical Center
- NYC Health + Hospitals
- NewYork-Presbyterian
- Weill Cornell Medicine

Southern *All of Us* Network
- UAB School of Medicine — Knowledge that will change your world
- UAB The University of Alabama at Birmingham — Knowledge that will change your world
- The University of Mississippi Medical Center
- UAB Medicine — UAB Hospital
- Tulane University
- Tuskegee University
- Cooper Green Mercy Health Services
- Huntsville Hospital
- University Medical Center
- USA University of South Alabama Health System
- LSU Health New Orleans

SouthEast Enrollment Center
- UHealth University of Miami Health System
- University of Miami Miller School of Medicine
- Emory University
- Morehouse School of Medicine
- OneFlorida Clinical Research Consortium

*All of Us*, Wisconsin
- Marshfield Clinic
- Clement J. Zablocki VA Medical Center
- University of Wisconsin School of Medicine and Public Health
- Medical College of Wisconsin
- BloodCenter of Wisconsin — Part of Versiti

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
- San Ysidro Health Center
- HRHCare Community Health
- Community Health Center, Inc.
- Eau Claire Cooperative Health Centers — People in Care of People

**VA Medical Centers**
- VA U.S. Department of Veterans Affairs

**Communication & Engagement**
- Wondros
- HCM Strategists

**Platform Development**
- Scripps Translational Science Institute
- Sage Bionetworks
- Vanderbilt University
- Wondros
- vibrent
- Broad Institute
- verily

# Current Consortium Members: Community Partners Network

American Association of Colleges of Nursing

AAFP

AAHIVM
American Academy of HIV Medicine

ACCESS
assisting. improving. empowering.

AMA

ANAC
Association of Nurses in AIDS Care

APIAHF
ASIAN & PACIFIC ISLANDER AMERICAN HEALTH FORUM

BLACK WOMEN'S
HEALTH IMPERATIVE

W. MONTAGUE Cobb NMA HEALTH Institute

DELTA
RESEARCH AND EDUCATIONAL FOUNDATION
CREATING POSSIBILITIES ... IMPROVING LIVES

Fifty Forward

LULAC

National Alliance for Hispanic Health

NATIONAL BAPTIST CONVENTION, U.S.A. INCORPORATED

NHMA
National Hispanic Medical Association

NIH U.S. National Library of Medicine

NATIONAL Minority Quality Forum

SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

UNIDOSUS
STRONGER COMMUNITIES. STRONGER AMERICA.

the Y YMCA

NATIONAL PAN-HELLENIC COUNCIL

Community Council
*Advancing Solutions...Empowering Lives*

# Summary: Version 1 of Protocol Currently Underway

## Enroll, Consent & EHR

- Recruit 18+ years old initially; plan to include children in next iteration
- eConsent or paper long-form
- Participants complete additional authorization to share EHR data

## Surveys

- Three initial participant provided information modules: The Basics, Overall Health, & Lifestyle

## Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

## Biosamples

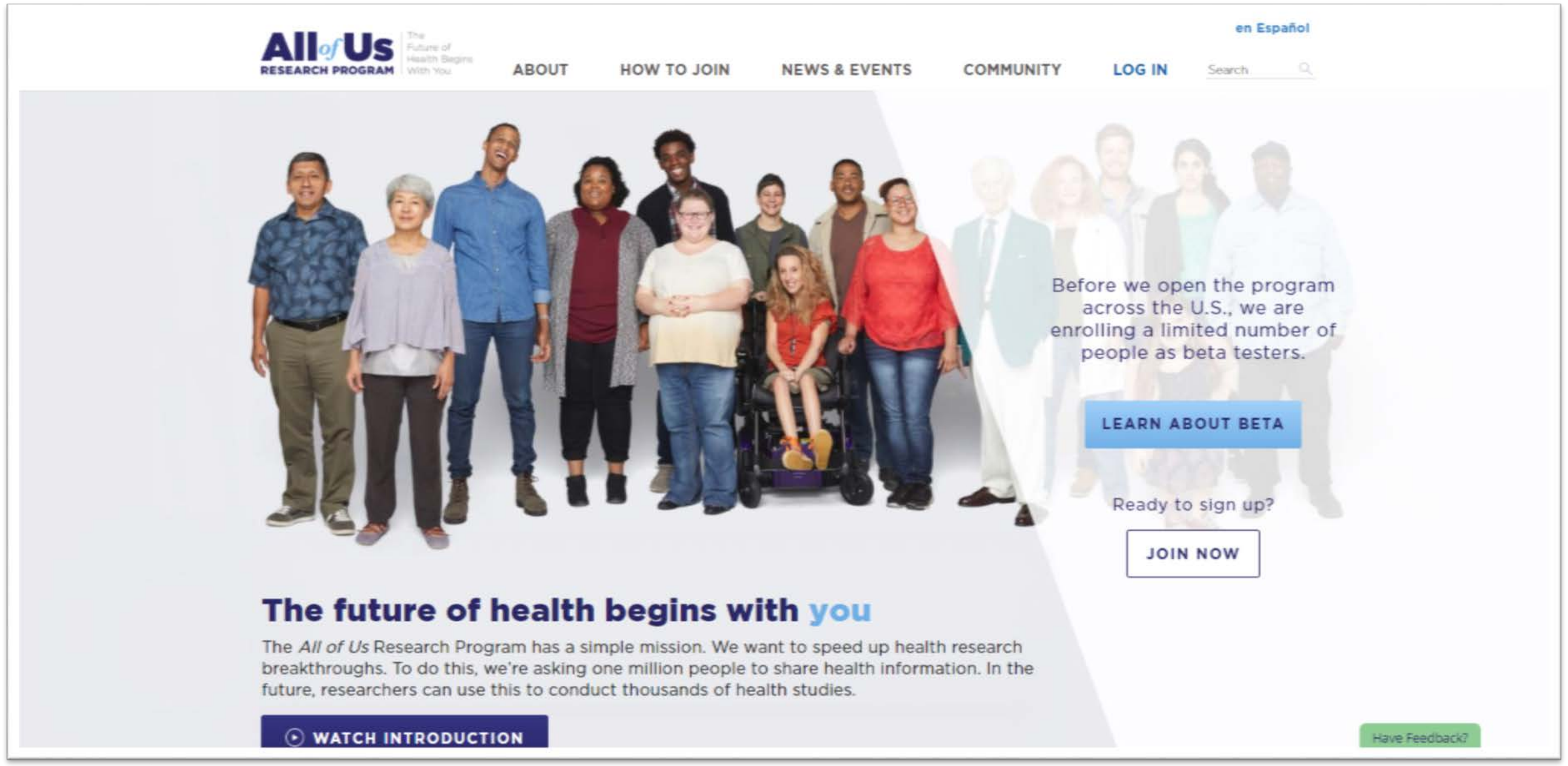
- Blood (or saliva, if blood draw is unsuccessful)
- Urine
- 28 aliquots of blood and 6 of urine stored in Biobank

**Full protocol at allofus.nih.gov. Updates to v1.0 regularly, major new versions every 2 – 5 years!**

# Updates on accomplishments & current status

# We are wrapping up a beta phase right now—about to launch nationally

- Initial goal of beta: enroll 10-15,000 participants who can give feedback on all aspects before national launch
- Ramp over 100 locations around the country slowly, carefully week by week
- Test & iterate the initial protocol, call center, online tools & interfaces, language of consent & questionnaires, workflow for staff at each location, biobank shipments, etc.



Before we open the program across the U.S., we are enrolling a limited number of people as beta testers.

Ready to sign up?

**The future of health begins with you**

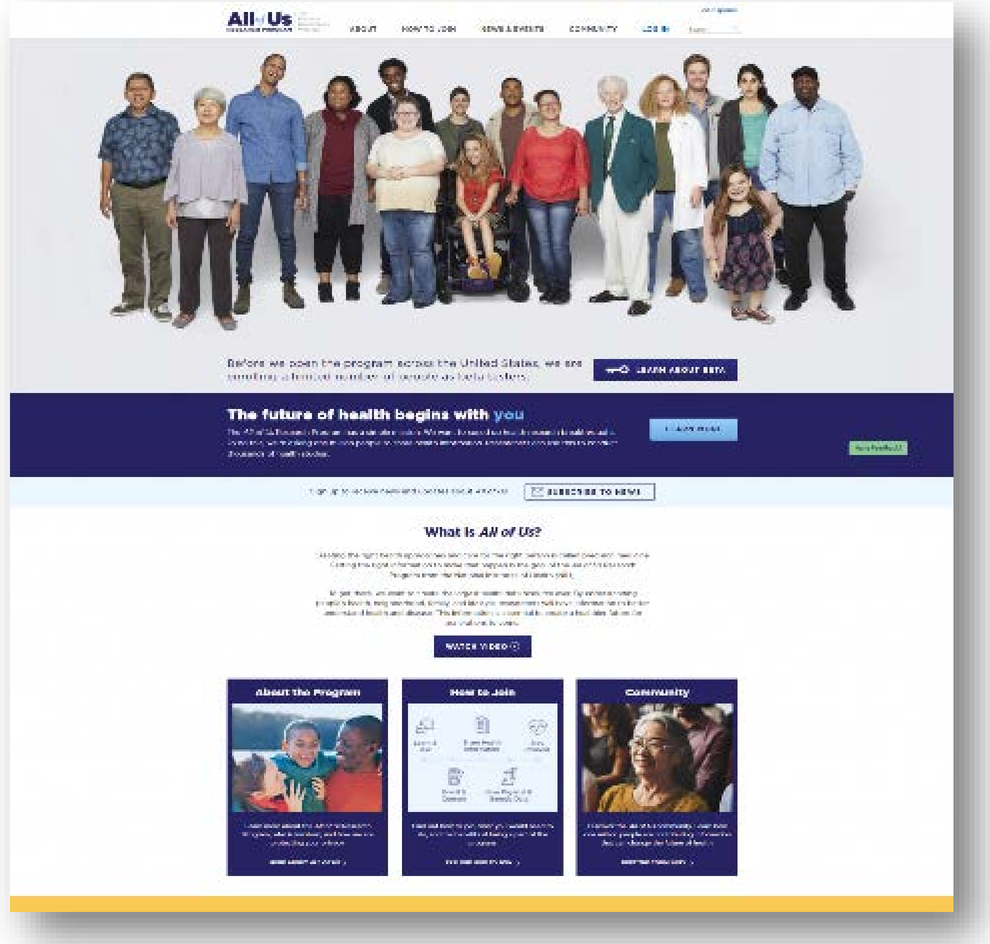
The *All of Us* Research Program has a simple mission. We want to speed up health research breakthroughs. To do this, we're asking one million people to share health information. In the future, researchers can use this to conduct thousands of health studies.

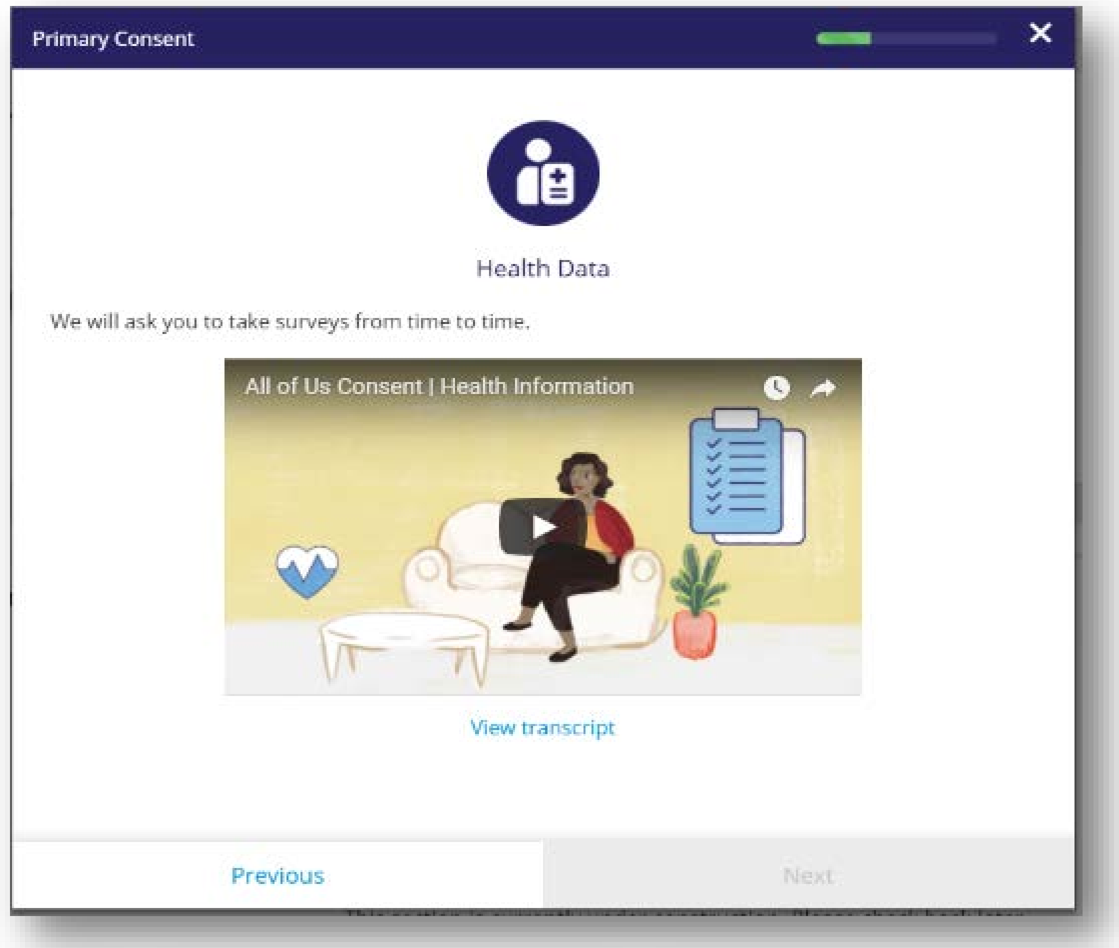
**https://www.joinallofus.org/**

**We have >40,600 participants at some stage of the process, of whom >24,000 have completed the full protocol. After national launch, we will only report # of participants who have completed all available protocol modules.**

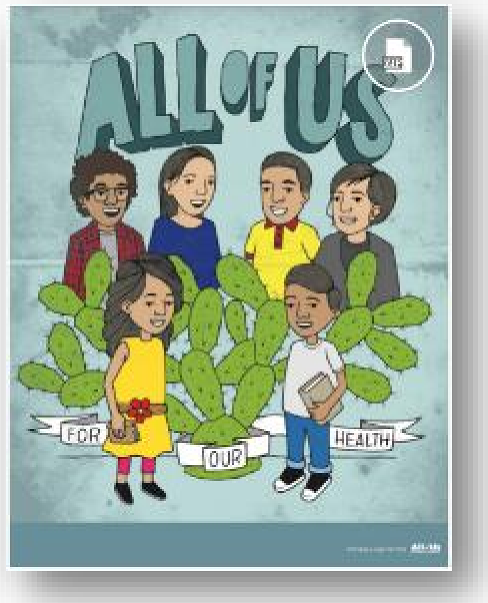
# Consortium accomplishments since May 2016 kickoff…

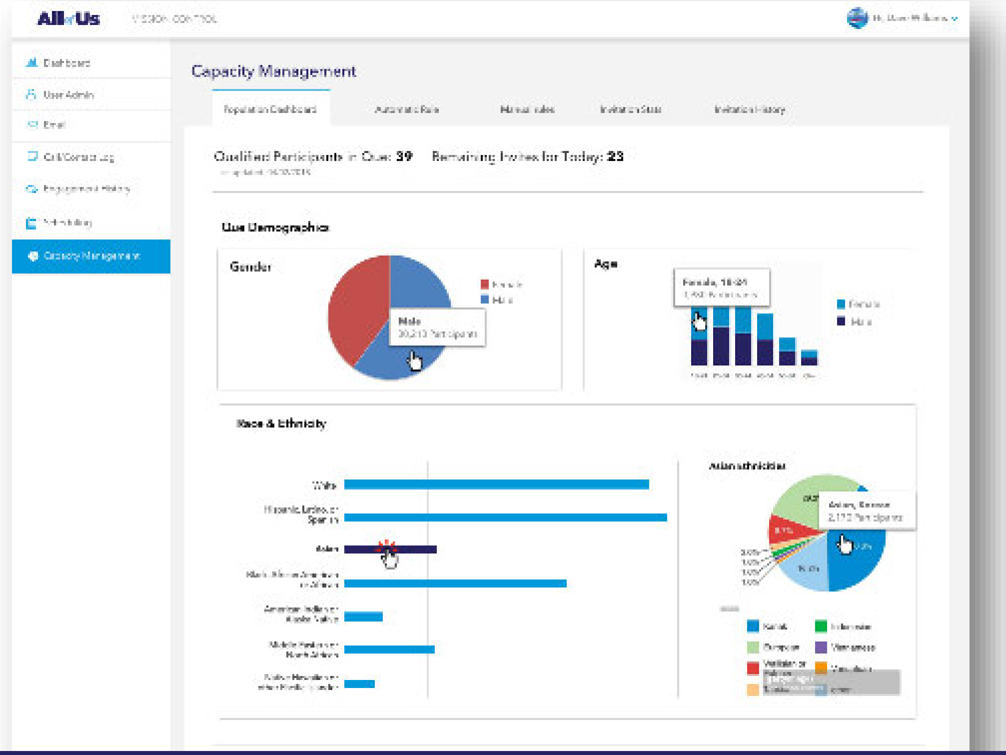
- **Successful beta phase (real people, protocol, tools, data)**
    - 115+ HPO & DV sites now enrolling in 18 states
      >40k participants in process now, >25k completed V1 protocol
    - ~73% are under-represented in biomedical research
- **Participant-facing tools are tested & well-honed**
    - Completed final usability, security, bug bashing, and surge testing of JoinAllofUs.org & Participant Portal
    - Support Center ready: 600 contacts/day, English/Spanish
    - 1,800+ pieces of collateral developed & IRB approved – including materials to engage diverse communities
- **Staff-facing infrastructure** tested & improved during beta
- **Databank** in public cloud receiving EHR + survey data
- **Biobank** already >710k tubes, process ~10k new tubes/day
- Working early prototype for **Research Portal** exists now
- **25+ Community & provider partners** ready for outreach

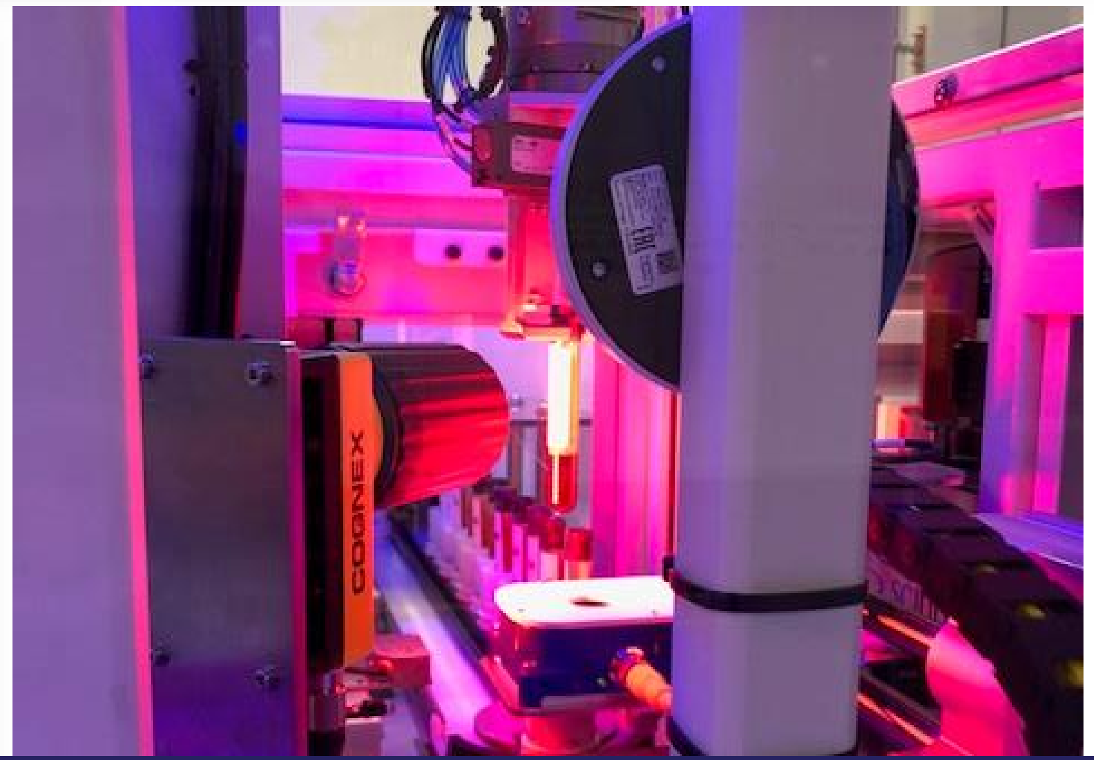




We will ask you to take surveys from time to time.







**On track national launch coming on Sunday, May 6th! (Press telebriefing on May 1st—contact AllofUsPress@mail.nih.gov)**

# Major parts of national launch to create “grass roots” awareness of PM & AOU

**Seven sites host half-day, simulcasted events that include:**

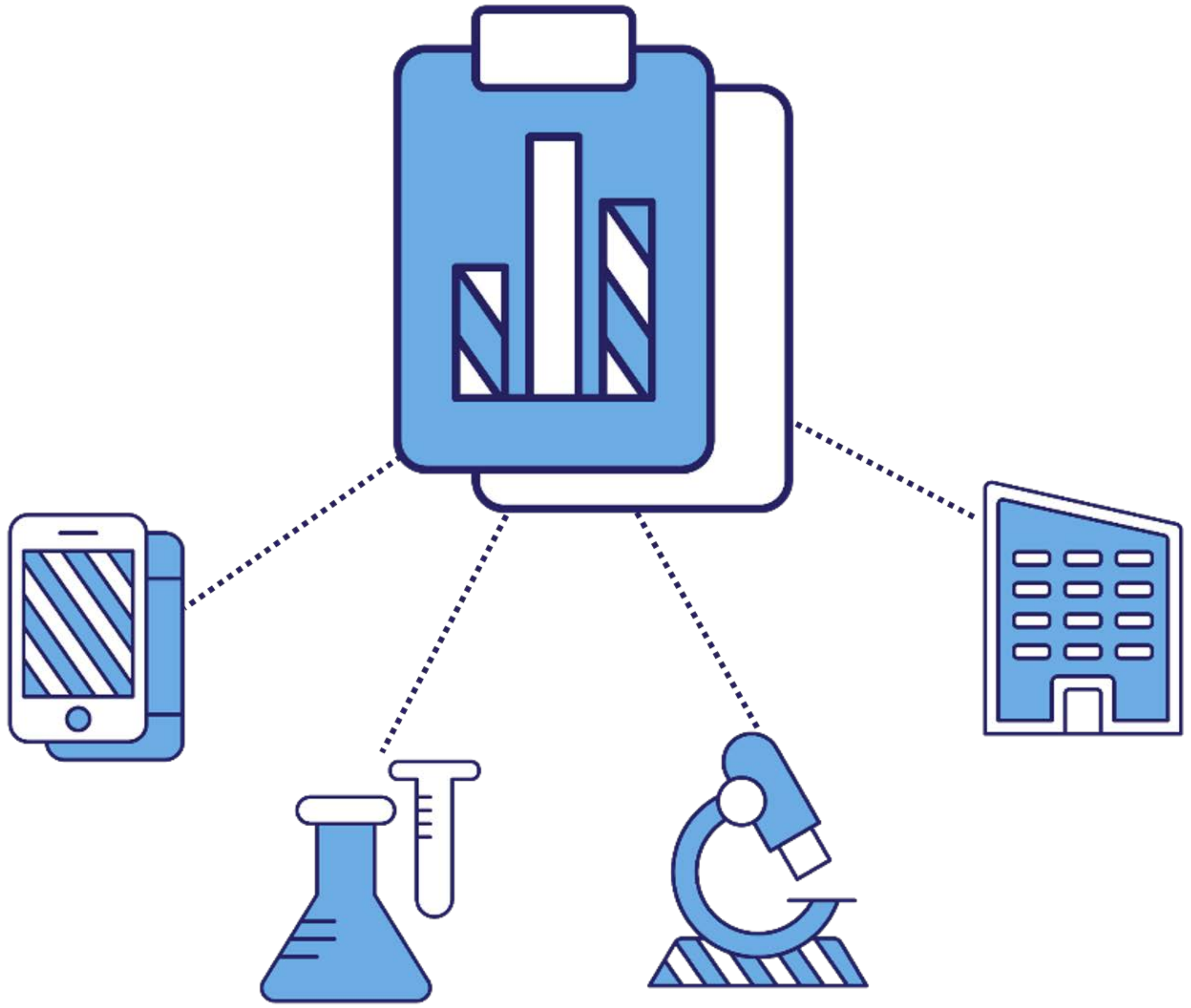
- **Speakers program:**
  - One-hour livestreamed program at all sites
  - Representative of local community – participants, cultural performances, luminaries
  - Dr. Francis Collins, Eric Dishman, Dr. Dara Richardson-Heron at two sites, remarks simulcasted live
- **Community educational fair:**
  - Interactive *AOU* booth - engage with program staff, begin digital enrollment, branded giveaways
  - Local vendors: farmer’s market, cooking demonstration, health screenings
- **Art activation**:
  - One local artist at each site creates interactive, collaborative community portrait

**The simulcasted events will be supported by:**

- **Facebook Live speakers program**: produced like broadcast television, to occur before streaming of simulcasted sites
- **Community events**: organized by many NIH champions, *AOU* consortium members, advocates, etc. using *AOU’s* “event-in-a-box toolkit”
- **National & local print, broadcast, and social media strategy**

# Good progress on principles, policies, infra for Research Portal launch in ‘19

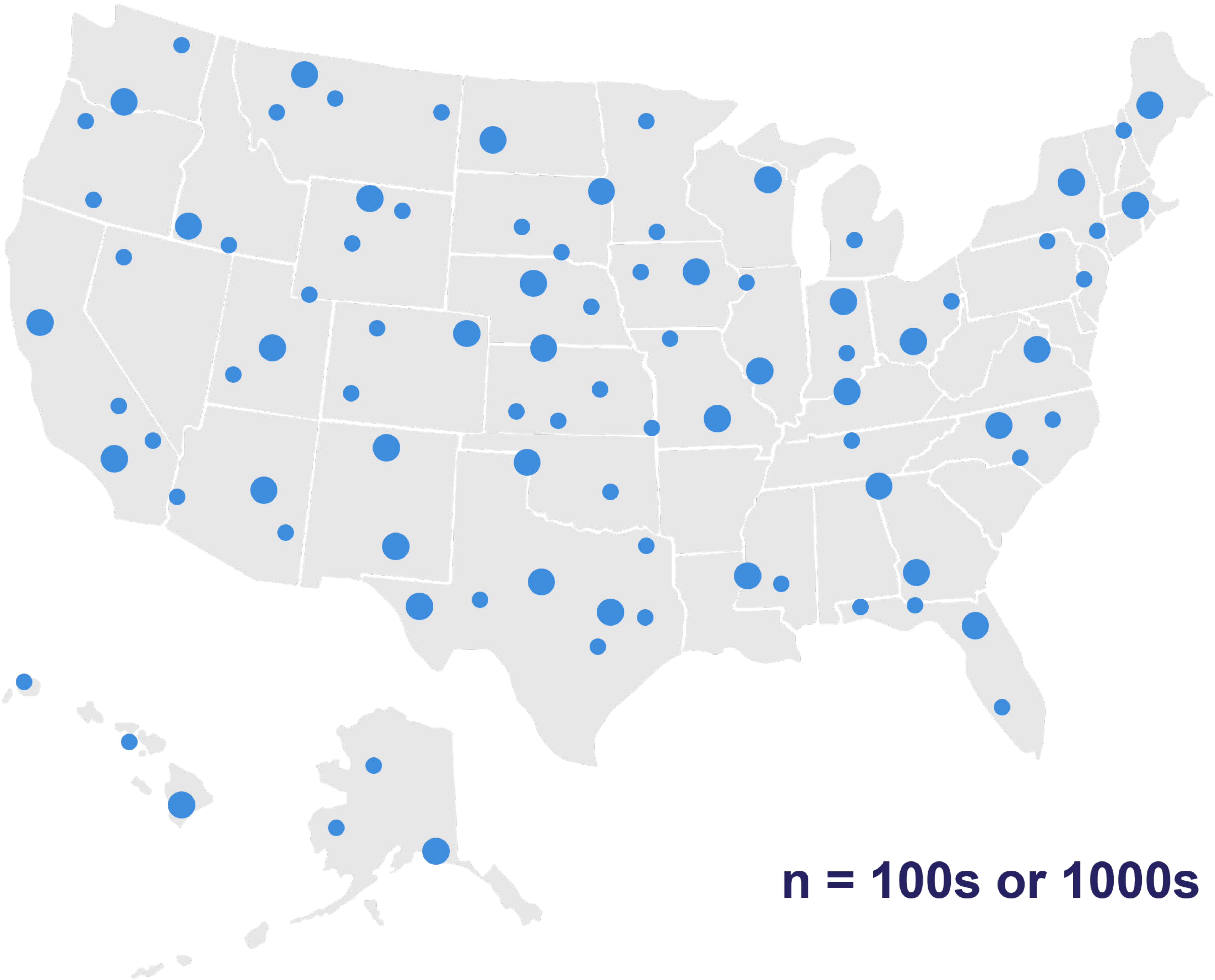
- **Broad access**: researchers from all sectors, open up to community colleges, citizen scientists, etc.
- **Data passport**: researcher based (not project based)
- **Access** will be granted by data tiers
- **Data use** will be audited and reported publicly
- **Data stored and used in secure enclave** in cloud, cannot be downloaded, researchers go to the data
- Potentially **stigmatizing re**search cannot be pre-defined or prevented, but should be addressed by:
  - Transparency on data uses
  - Regular assessment
- Consortium researchers have **no special or early access** to the full dataset



**Like most studies, must take time to collect, validate, clean, & curate data—testing on all of this already underway**

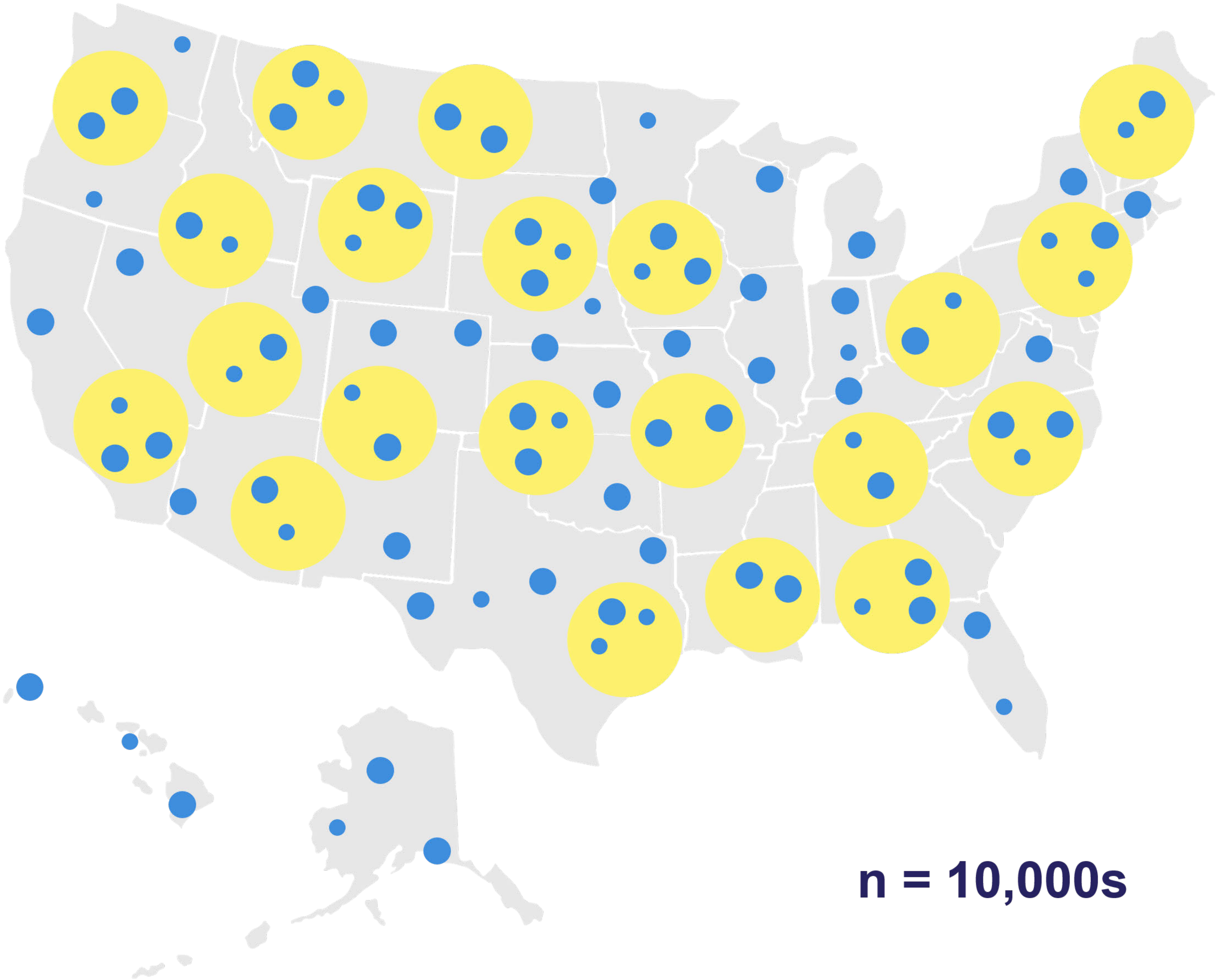
# Vision: Towards the end of cohorts as we know them?

# Stage 1: Era of Individual Study Silos



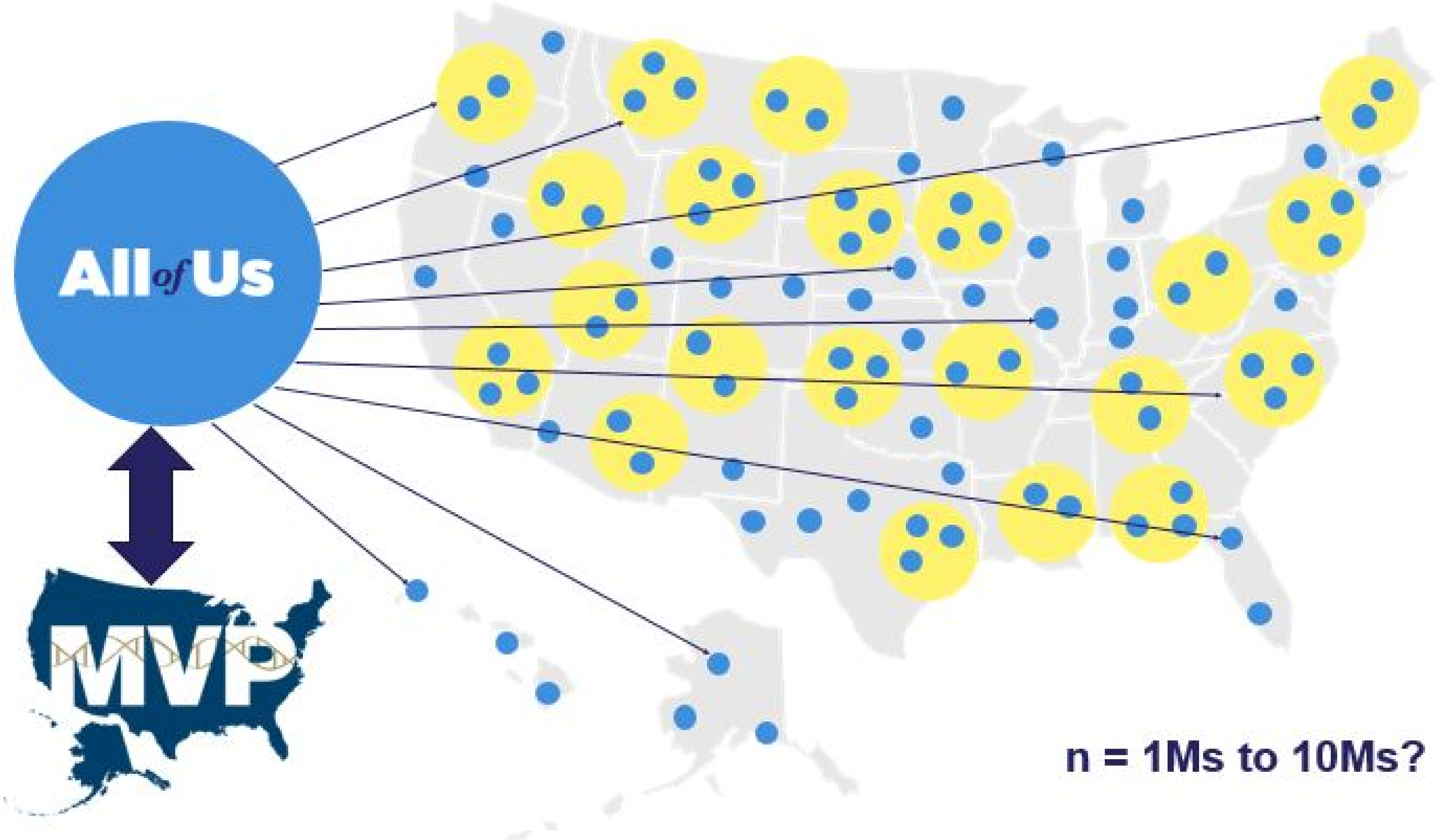
**n = 100s or 1000s**

# Stage 2: Era of Competitive Consortia (larger silos?)



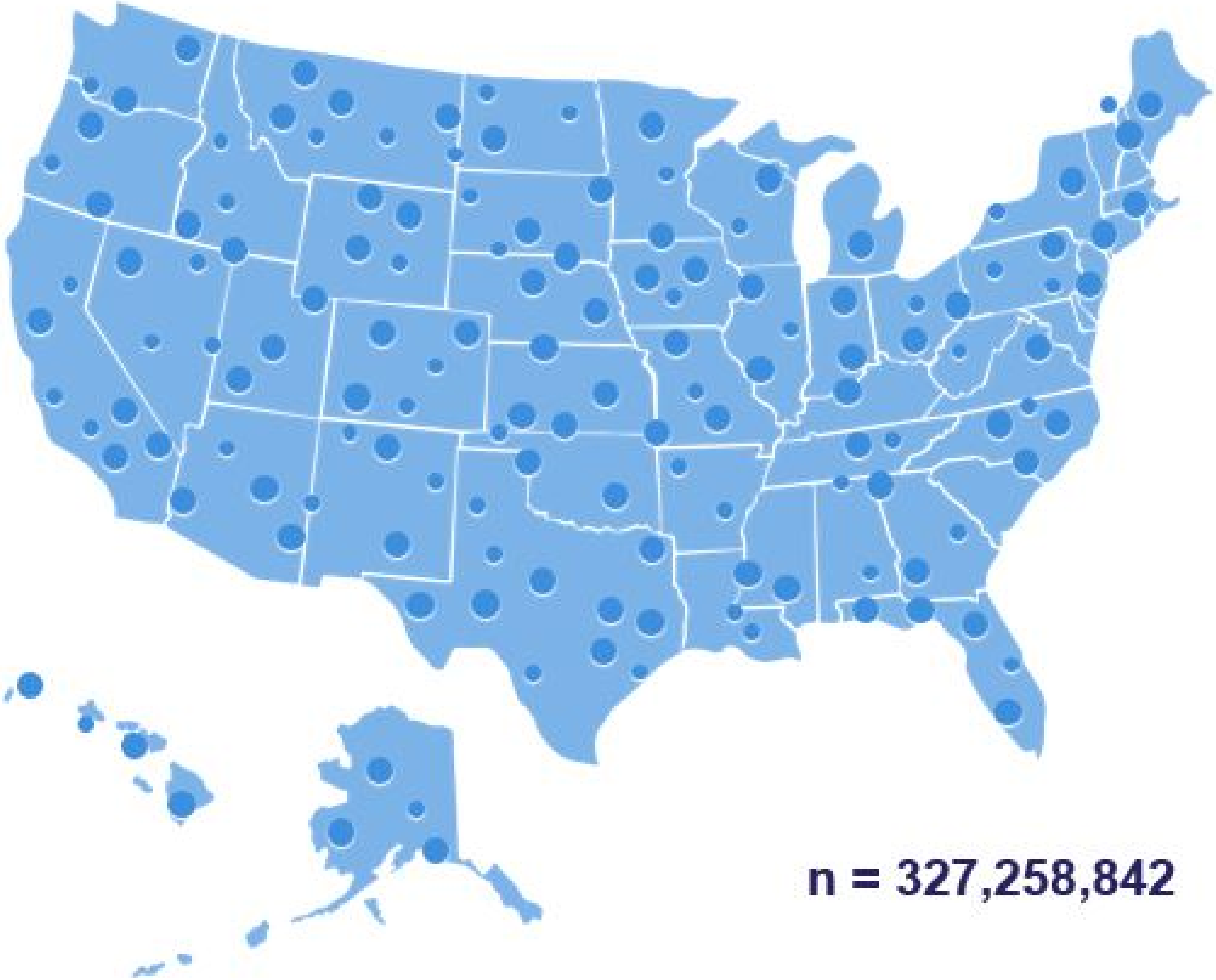
**n = 10,000s**

# Stage 3: Era of Large Cohorts? (some as silos, some as national resource?)



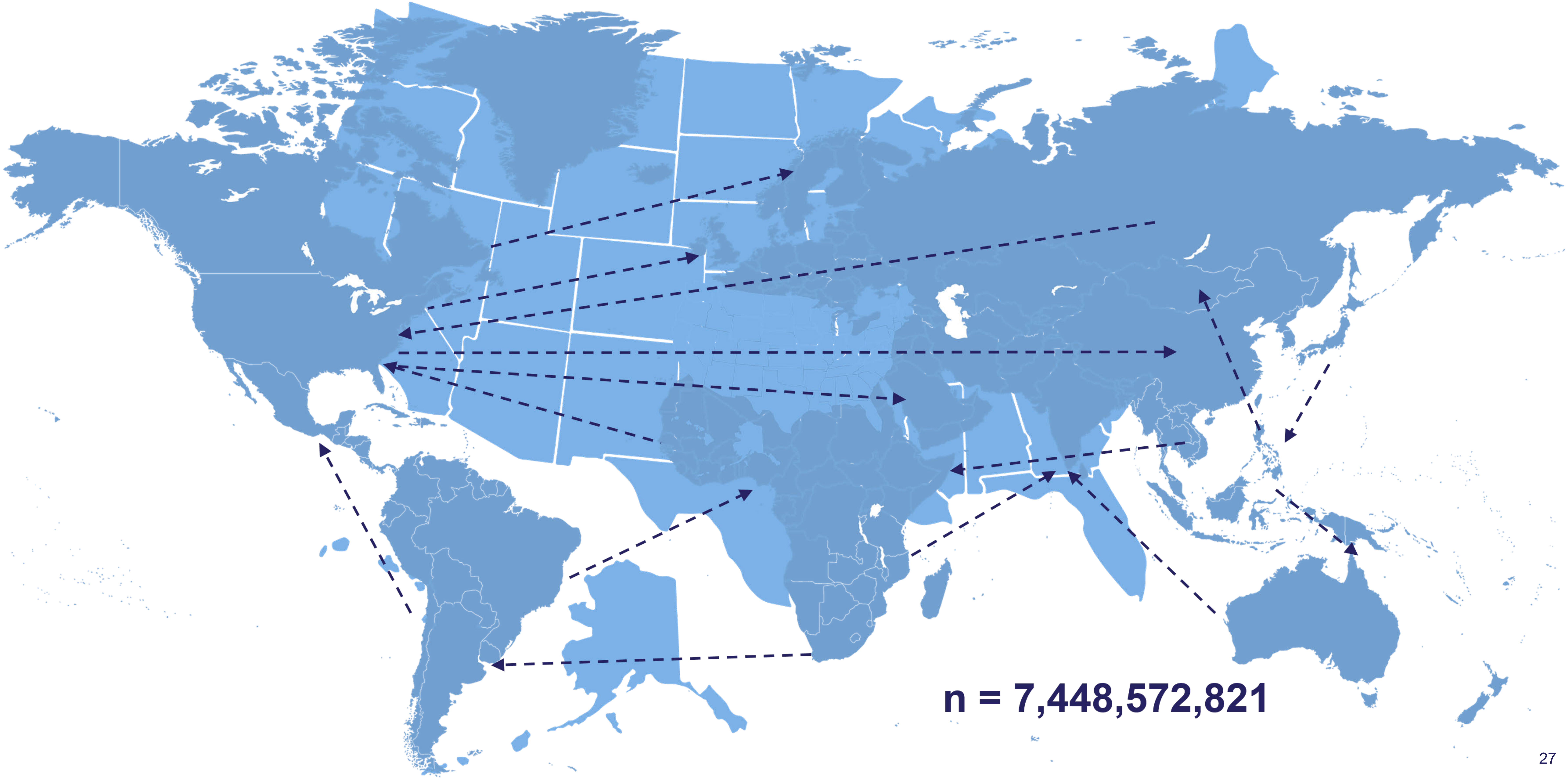
n = 1Ms to 10Ms?

# Stage 4: Era of "America as a Cohort?"



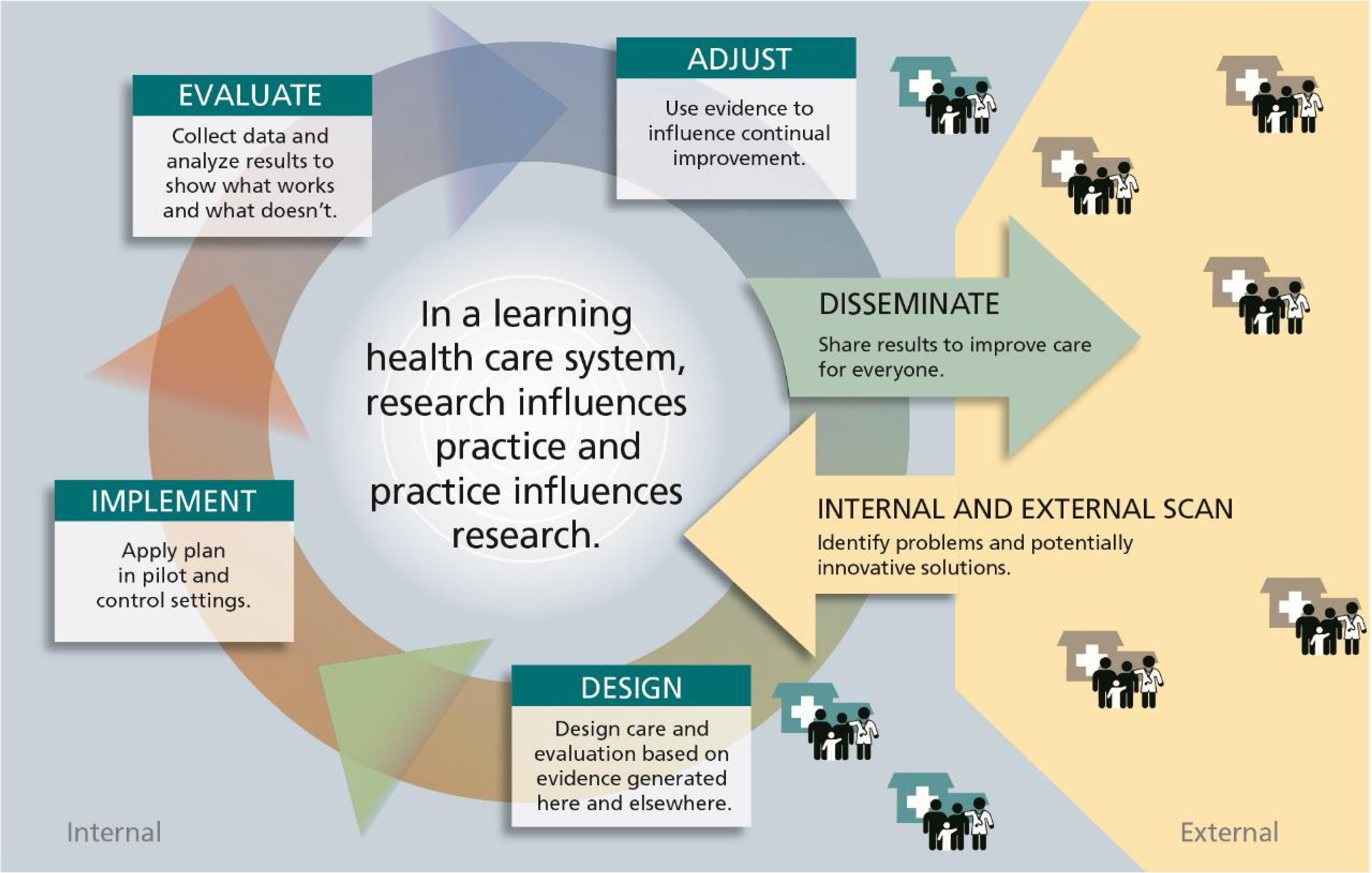
n = 327,258,842

# Stage 5: Era of a “Universal Cohort” (no silos? no cohorts?)



n = 7,448,572,821

# End State: what many people call a "learning healthcare system"



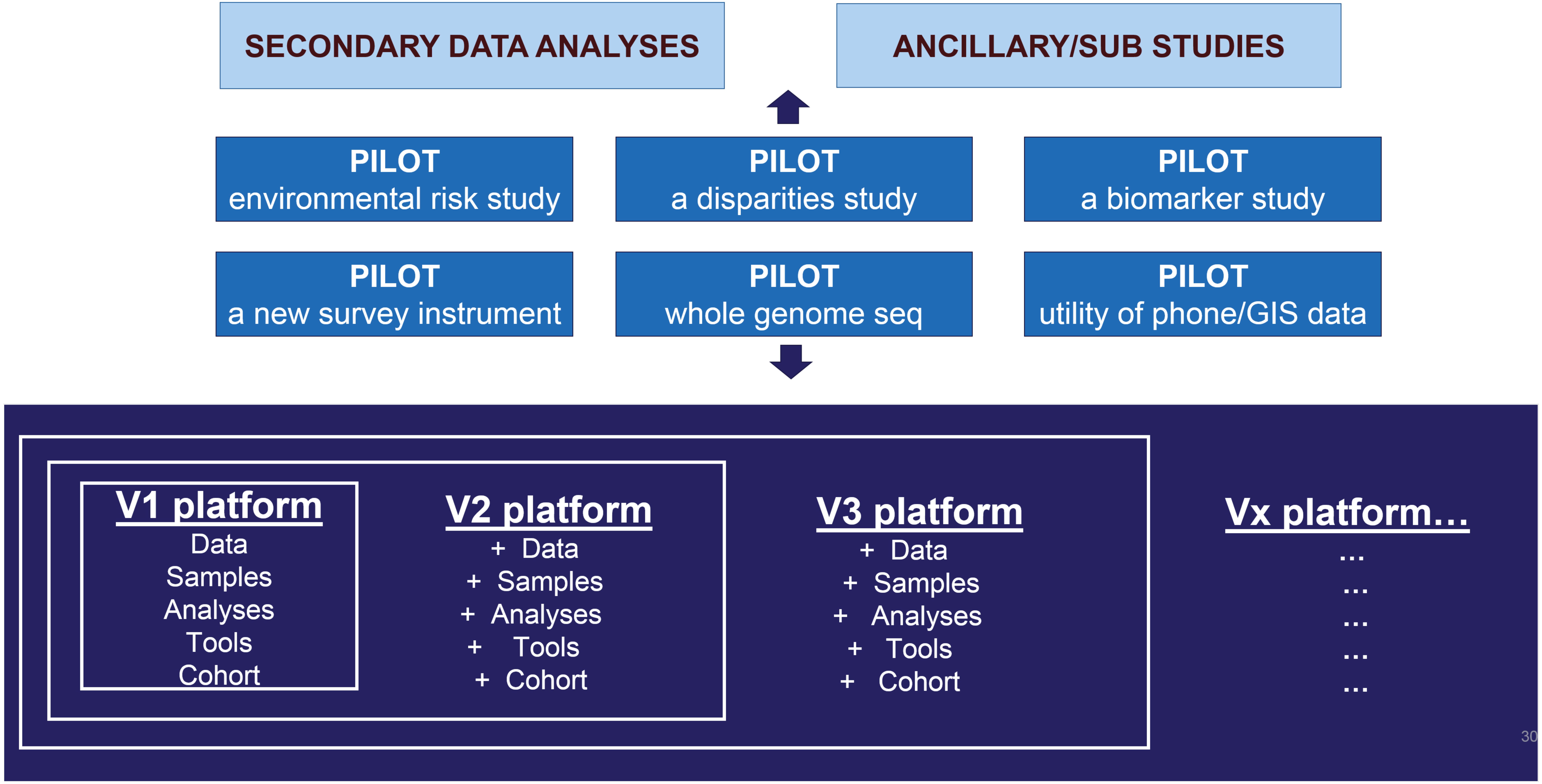
Source: Green SM, et. al., Ann Intern Med, 2012

All *of* Us RESEARCH PROGRAM | The Future of Health Begins With You

***All of Us* is an early prototype to learn about the scale of diverse recruitment & retention, open data sharing, responsible return of information, affordable collection & cleaning of new data types…**

# How do we begin to achieve that kind of vision?

# First, Build an Evolving Public Resource that Grows/Generates Lots of Studies



**SECONDARY DATA ANALYSES**

**ANCILLARY/SUB STUDIES**

**PILOT**
environmental risk study

**PILOT**
a disparities study

**PILOT**
a biomarker study

**PILOT**
a new survey instrument

**PILOT**
whole genome seq

**PILOT**
utility of phone/GIS data

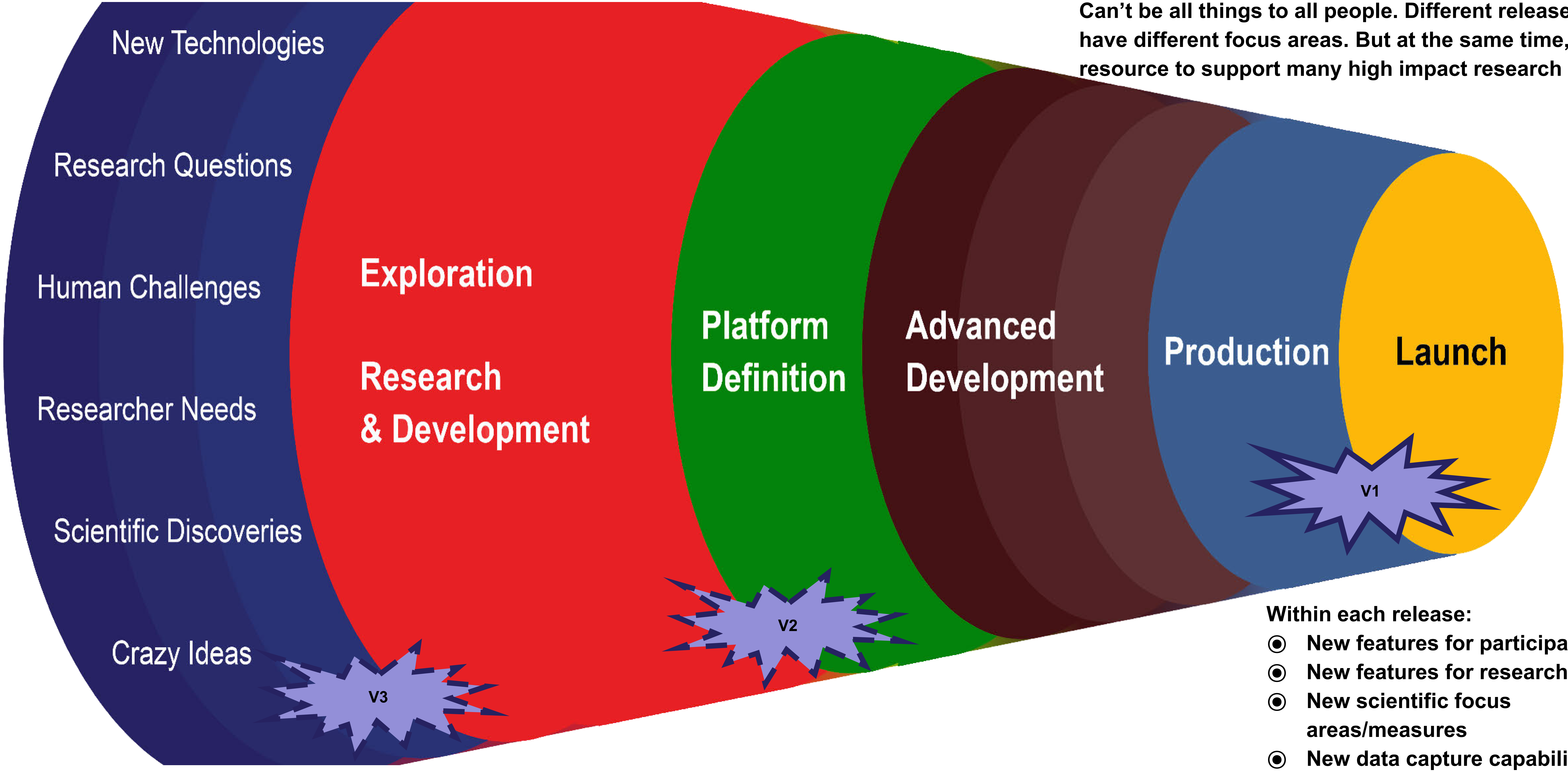
**V1 platform**
Data
Samples
Analyses
Tools
Cohort

**V2 platform**
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

**V3 platform**
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

**Vx platform…**
…
…
…
…
…

# Second, Develop an Iterative Process with Others to Work on Shared Roadmaps



Can’t be all things to all people. Different releases will have different focus areas. But at the same time, want the resource to support many high impact research areas.

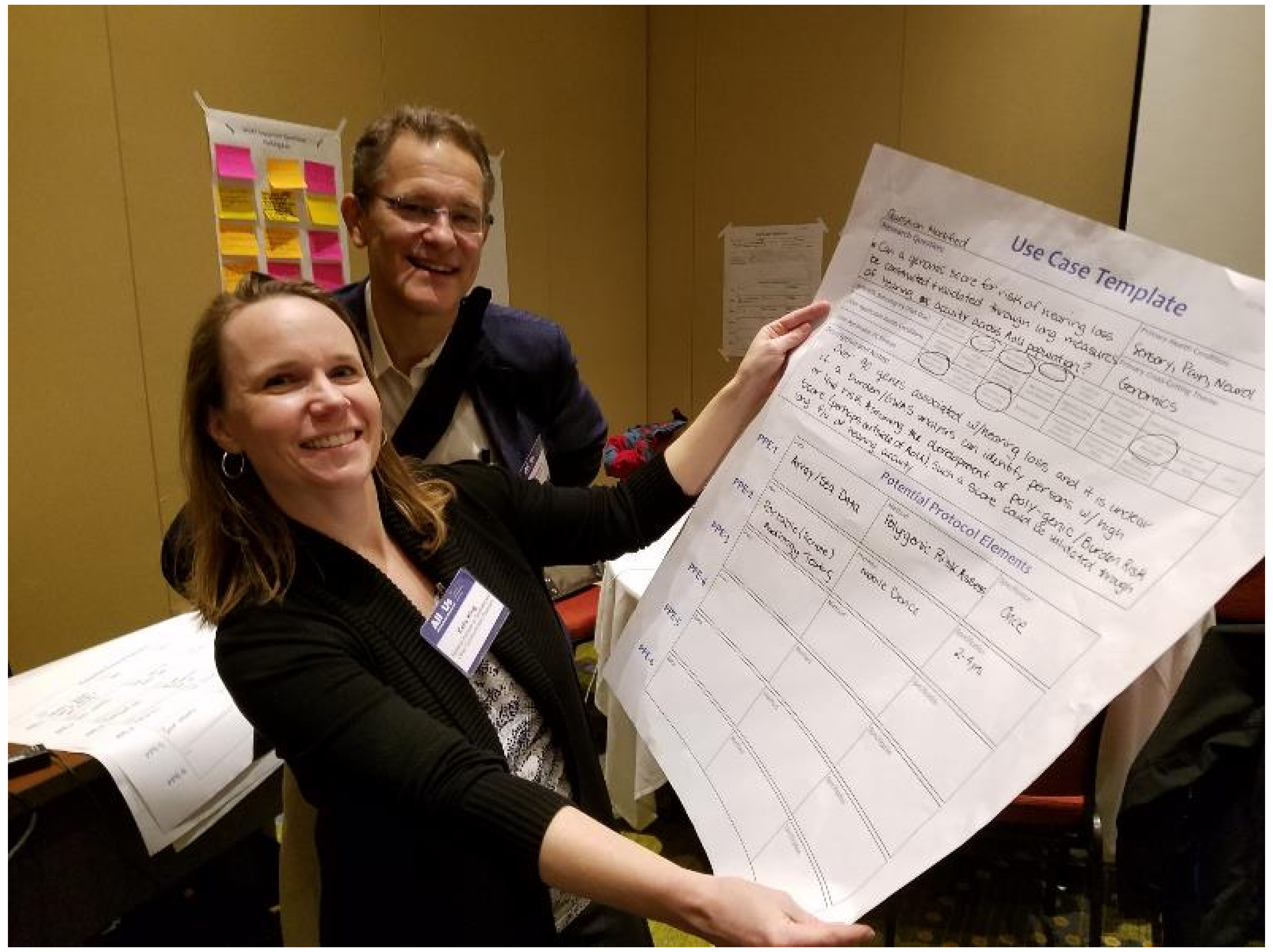
Within each release:

- ◉ New features for participants
- ◉ New features for researchers
- ◉ New scientific focus areas/measures
- ◉ New data capture capabilities

**Can’t be “AOU’s roadmap” in isolation—but invented & developed with NIH & research partners!**

# Third, Be Requirements Driven (e.g., recent Research Priorities Workshop)

- Invited a broad array of stakeholders, including researchers, participants, professional societies, & advocacy groups to the Workshop in Bethesda, MD on March 21-23, 2018
- 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
- Collected use cases & requirements
  - 800+ in advance from the stakeholder community through IdeaScale crowdsourcing platform
  - 500+ at the workshop
- *All of Us* team is currently reviewing & synthesizing the data we gathered
- Will have additional opportunities to submit use cases & requirements

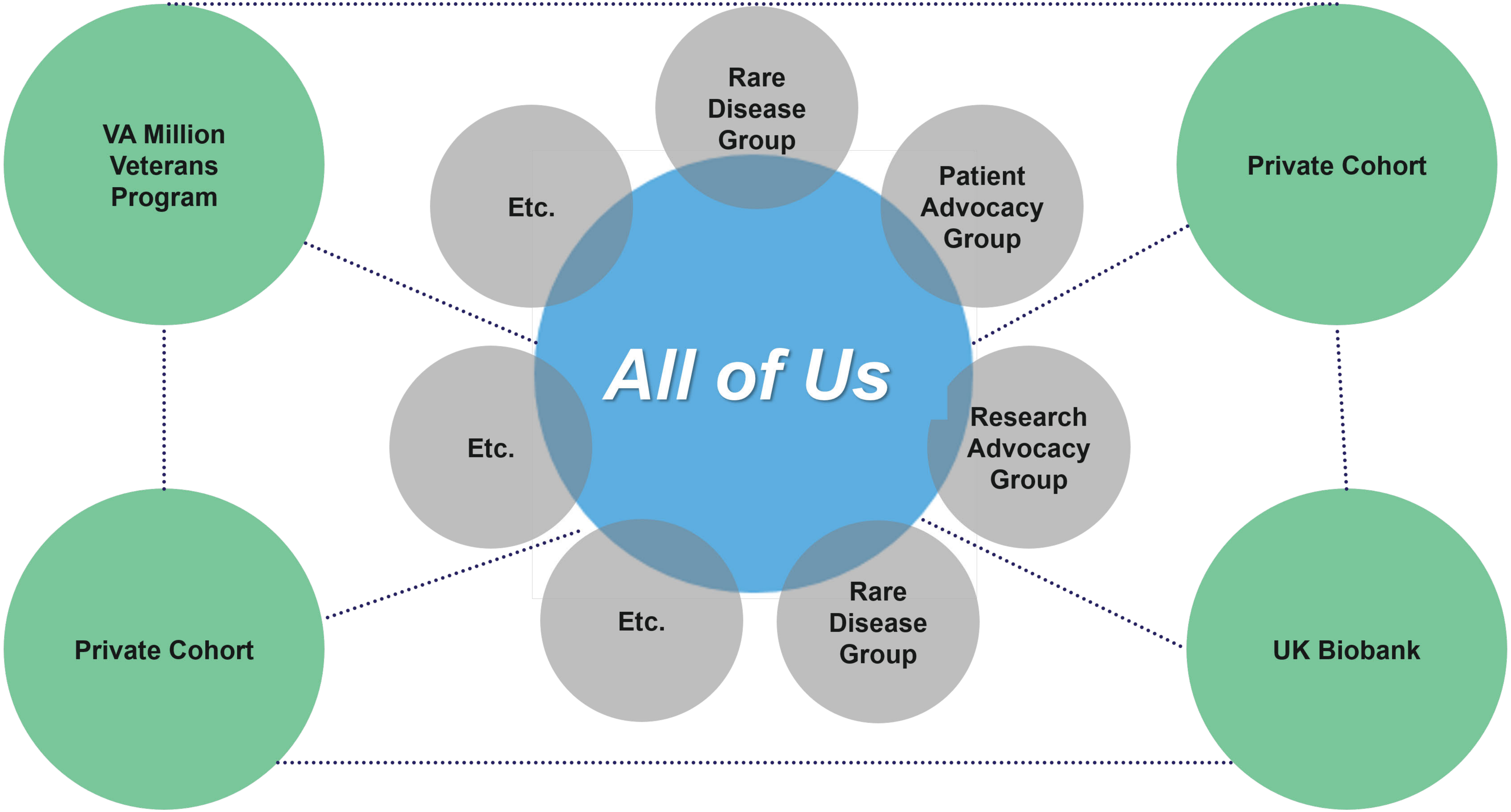


# (Thank you to the many advocacy organizations who provided requirements!)

- Adenoid Cystic Carcinoma Research Foundation
- Alliance for Aging Research
- Alzheimer's Association
- American Association on Health and Disability
- American Cancer Society
- American Cancer Society
- American College of Cardiology
- American Heart Association
- American Medical Association
- American Physical Therapy Association
- American Psychiatric Association
- Autism Speaks
- Biotechnology Innovation Organization
- City of Hope
- COPD Foundation
- Epilepsy Foundation
- Infectious Diseases Society of America
- International Alliance for Pediatric Stroke
- JDRF
- March of Dimes
- Michael J. Fox Foundation for Parkinson's Research
- Muscular Dystrophy Association
- National Jewish Health
- National Organization for Rare Disorders
- National Psoriasis Foundation
- Sjögren's Syndrome Foundation
- Society for Maternal-Fetal Medicine
- Spinal Muscular Atrophy Foundation
- The LAM Foundation

**These just represent attendees' primary affiliations. Many Workshop attendees wore multiple hats.**

# Fourth, figure out how to drive "franchising" and cross-cohort collaborations!



**How do we support disease-specific efforts? Especially rare diseases? And drive a cohort of cohorts?**

# Key areas of collaboration with the advocacy community

# Am *starting* to be able to look beyond national launch to key collaborations

- Shaping the **science** – continue to identify use cases and gather requirements
- Growing the **cohort** – getting the word out, recruitment, & expectations management
- Wooing the **ecosystem** – bring together funders & researchers to leverage the resource in your domain

***All of Us* Research Program Mission and Objectives ARE LARGER THAN US!**

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

How do we all promote understanding of precision medicine, research participation?

What are the evidence-based methods for reaching & building trust with diverse & especially vulnerable populations?

How can AOU build relationships and recruitment with your community of patients & family members?

Shared advocacy efforts for more research support?

How to build common roadmaps of key focus areas, methods, & data types needed for your domain across funders?

How to make sure "if we build it, they—your ecosystem of researchers—will come!"?

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

**Deliver one of the largest, richest biomedical datasets ever** that is as easy, safe, and free to access

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

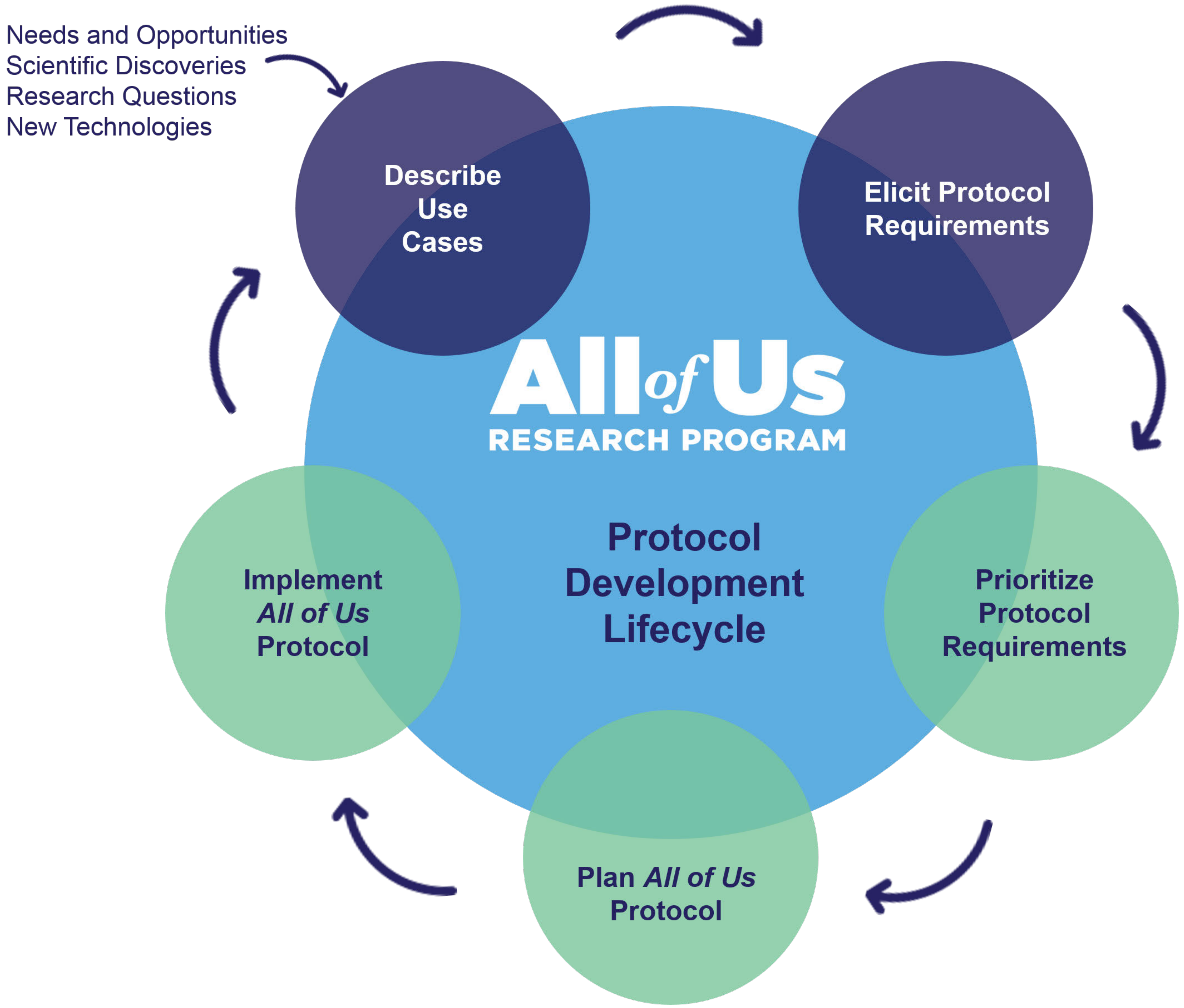
How do we solve common challenges of EHR access, genetic return of info, reliability of mobile devices, etc.?

What can we do to improve security & privacy practices?

And help researchers get storage/compute support?

**What are other opportunities you see for partnership between your organization & *All of Us*?**

# Help shape the science by knowing & sharing your requirements



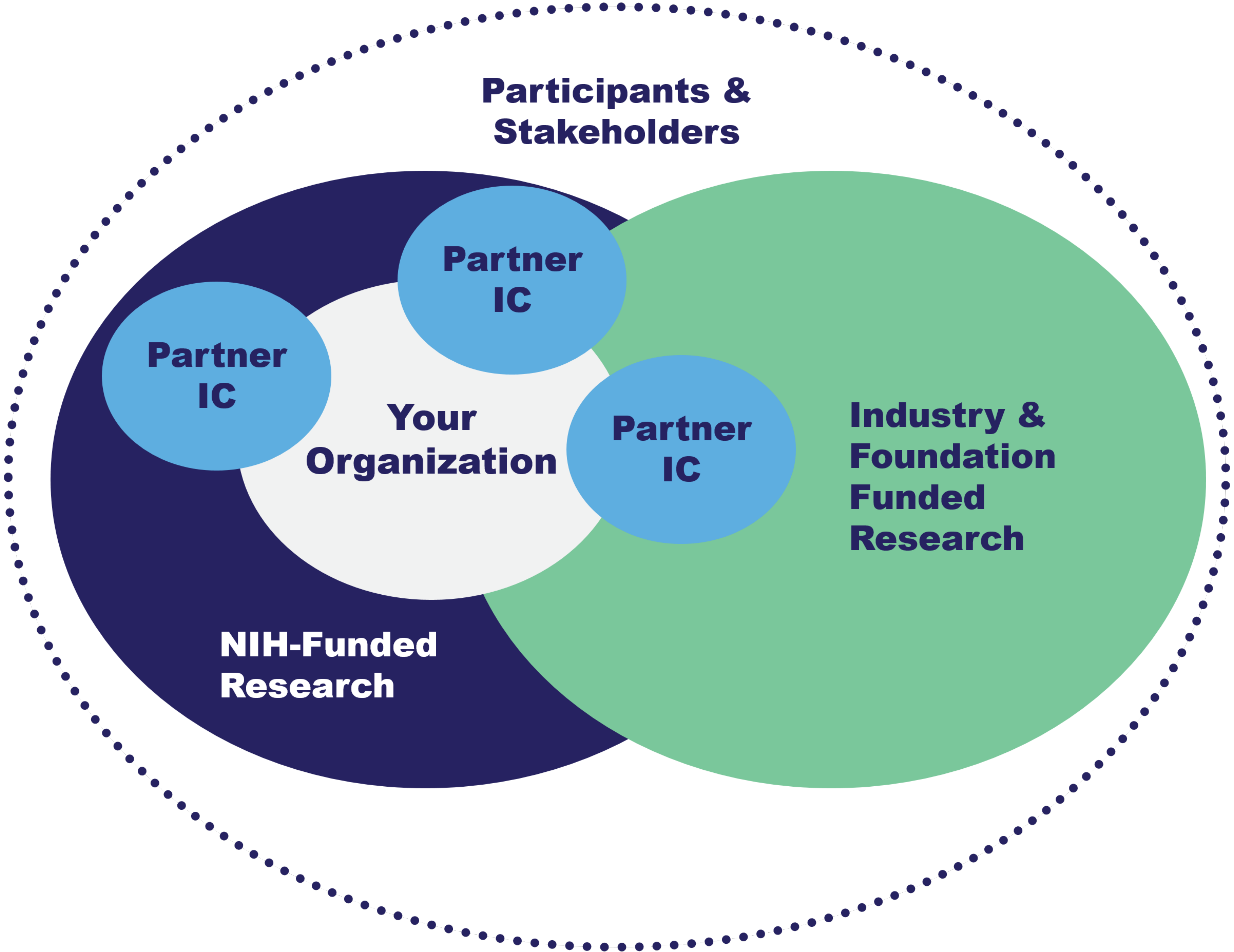
- Where would you get the biggest breakthroughs with use of this resource?
- What kinds of requirements to data types would you need for those?
- Can they practically and economically be collected, stores, for 1M people?
- Which are for subsets/ancillary studies?
- Do you have  a sense of a roadmap over time—near, within a couple of years, 5+ years?
- Is there a coalition/forum of multiple advocacy groups who work in common on these big problems?

# Help grow the cohort by getting word out & helping to manage expectations

1. Understanding what precision medicine is (early days, great promise, no “one size fits all”)
2. “AOU is open for business” (no longer need a special code to enroll in AOU after May 6th)
3. Value of this public resource (no more silos, open access, unprecedented scale)
4. Importance of a diverse cohort scientifically (gaps in scientific record, gaps in cures)
5. The power of collecting diverse data types (behavioral, social, genetic, clinical, environ)
6. Power of longitudinality (understand complex changes & causes over the lifestage)
7. Importance of collaboration and sharing of cohorts (larger sample size, rare disease)
8. Potential value to individuals who decide to volunteer (giving back, access to own info)
9. Challenge & promise of rich electronic health records (still too hard, takes time to get)
10. Challenge & promise of genomics (early days, lots we don’t understand, expensive)

**Do you have advice on how to communicate these messages and to successfully manage the expectations of participants & broader stakeholder community?**

# Help woo an ecosystem to leverage this national resource in your domain



Participants & Stakeholders

Partner IC

Partner IC

Your Organization

Partner IC

Industry & Foundation Funded Research

NIH-Funded Research

# Thank you

# Engaging with *All of Us*

# *All of Us Research Program* Core Values

- Participation in the *All of Us* Research Program will be **open** to interested individuals.
- The Program will reflect the rich **diversity** of America.
- Participants will be **partners** in the Program.
- Trust will be earned through robust **engagement** and full **transparency**.
- Participants will have **access** to information and data about themselves.
- Data from the Program will be broadly **accessible** to **empower research**.
- The Program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.
- The Program will be a catalyst for **innovative research** programs and policies.

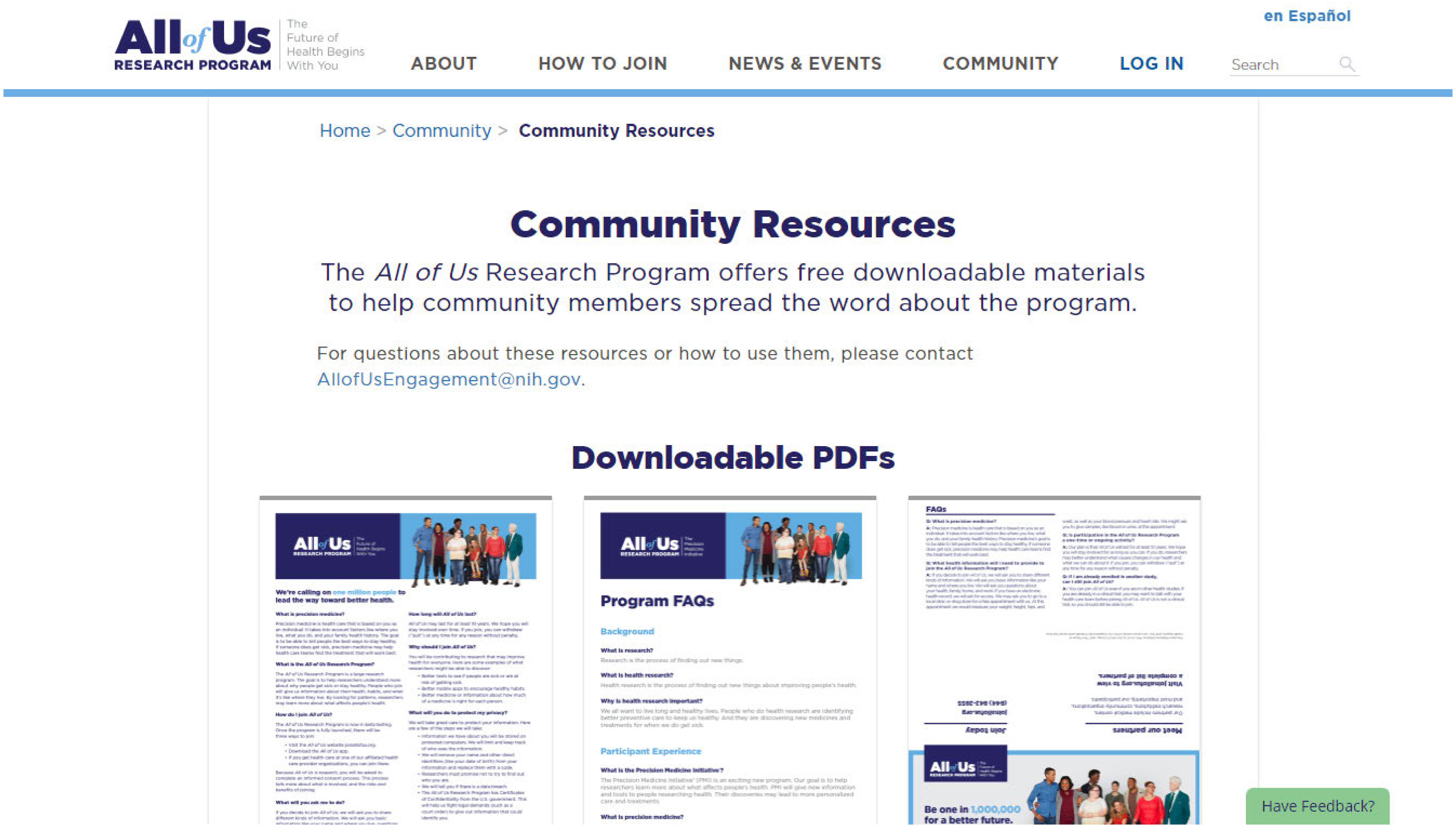
UNDERREPRESENTED IN BIOMEDICAL RESEARCH

# Build Trust, Be Authentic, and Create Value

# Engaging at Launch and Beyond

- Post program information on your organization’s social media channels
- Follow *All of Us* on social media and retweet program content
- Include information about *All of Us* in a weekly or monthly digital newsletter
- Write and post a blog about the importance and value of *All of Us*
- Host an in-person community event or conference call/webinar with network or partners
- Distribute *All of Us* info flyers, posters, etc. at a meeting, conference, or event
- Become a program Champion
- Promote the national launch online experience including the live webcast
- Share a recap about the national launch in digital or print newsletters

# Community Resources (JoinAllofUs.org)



Home > Community > **Community Resources**

## Community Resources

The *All of Us* Research Program offers free downloadable materials to help community members spread the word about the program.

For questions about these resources or how to use them, please contact AllofUsEngagement@nih.gov.

## Downloadable PDFs

We're calling on one million people to lead the way toward better health.

Program FAQs

Background

Participant Experience

FAQs

Be one in 1,000,000 for a better future.

# Questions

Sign-up for updates at joinallofus.org

@AllofUsResearch   #JoinAllofUs

Email: kim_cantor@hcmstrategists.com

---