All of Us
RESEARCH PROGRAM

An Update on the *All of Us Research Program*


#joinallofus

National Institutes of Health

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Entrepreneurial Patient, Advocate, Caregiver
Director, *All of Us* Research Program

Appreciation to the *All of Us* Research Program Advisory Panel

- *All of Us* Advisory Panel is a working group of the Council of Councils
- Recently included three participant representatives: Miriam Guzman, Ana Carolina Dantas Machado, and Zachary Orlov
- Advisory Panel spearheaded three working groups to gather information and options around critical issues:
  - Genomics – chaired by Lon Cardon
  - Child Enrollment Scientific Vision – chaired by Tina Cheng and Marie Lynn Miranda
  - Tribal Collaboration – chaired by Lynn Malerba and Spero Manson

Advisory Panel Members:

- Teresa Zayas Cabán
- Rob Califf
- Lon Cardon
- Tina Lee Cheng
- Rory Collins
- Jonathan Epstein
- Alejandra Gepp
- Miriam Guzman
- Sachin Kheterpal
- Ana Carolina Dantas Machado
- Terry Magnuson
- Marie Lynn Miranda
- Zachary Orlov
- Bray Patrick-Lake
- Marylyn DeRiggie Ritchie
- Gregory Simon
- Sharon Terry
- David Williams

Appreciate Jonathan Epstein, Terry Magnuson, & Sachin Kheterpal for their AOU service, as well!

Agenda

- **Very brief overview of *All of Us***

- **Quick updates on progress and challenges**
  - Strategy to ramp to 1M
  - Genomics/Return of information
  - Recruiting children
  - Launch of Research Portal

Very quick recap of (or first hearing about) *All of Us*

Mission and Objectives

Our mission

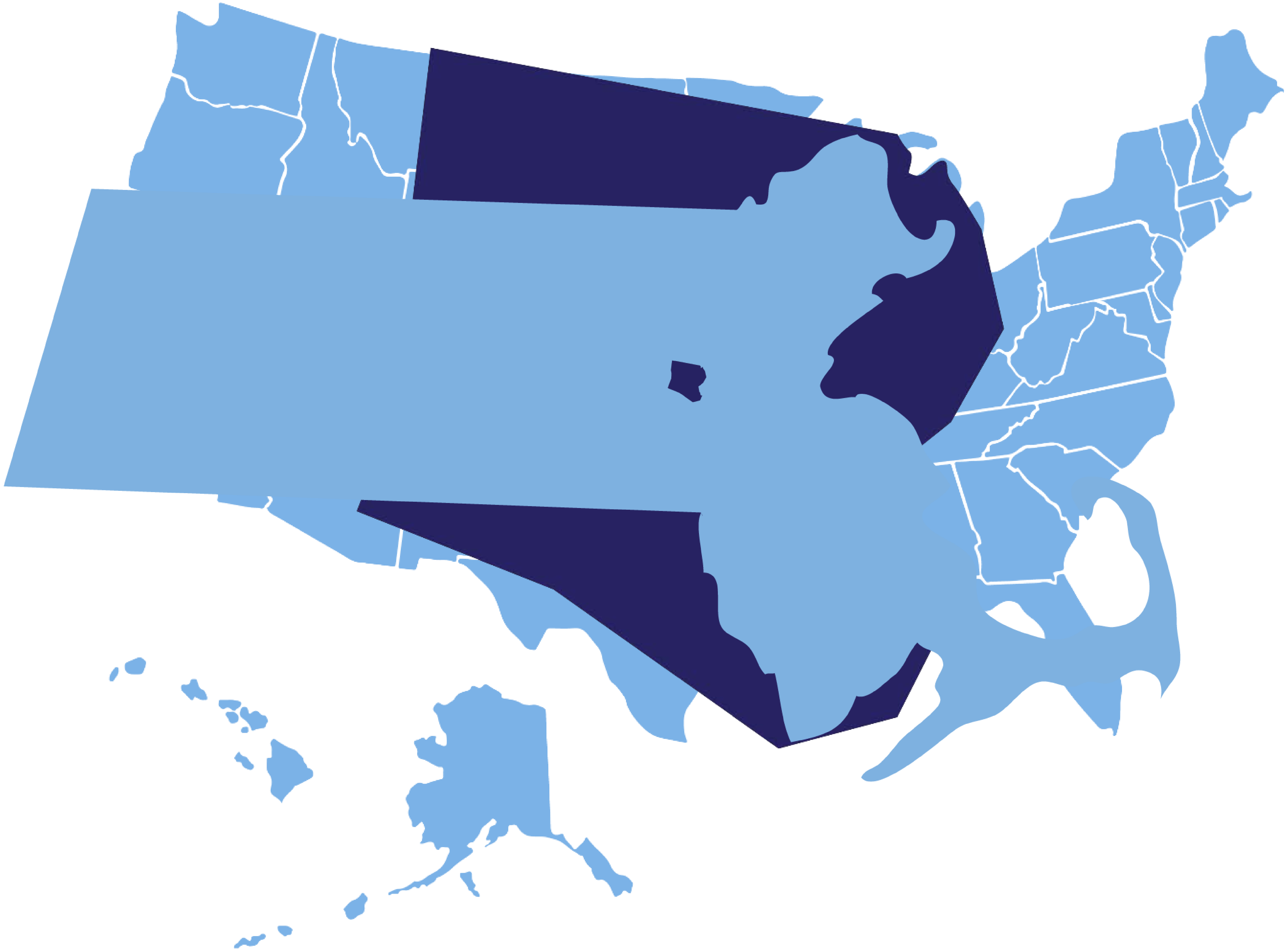
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us

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

Deliver the largest, richest biomedical resource ever,
making it as easy, safe, and free to use as possible

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

Expand Framingham type study to the country and all conditions



1. Diversity of people at scale; 2. Diversity of data; 3. Participant-centeredness; 4. 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

PARTICIPANT CENTER / DV NETWORK

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

Scripps Research Institute (with multiple partners)

HEALTH CARE PROVIDER ORGS NETWORK

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

30+ regional medical centers, FQHCs, VA, and future awards to grow network

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 consortium members (beyond community partners)

DV Network

(Direct Volunteers)

Scripps Translational Science Institute

National Blood Collaborative

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

Cedars-Sinai

Illinois Precision Medicine Consortium

Northwestern University

The University of Chicago

NorthShore University HealthSystem

Rush

The University of Illinois at Chicago

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

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

UAB The University of Alabama at Birmingham

The University of Mississippi Medical Center

UAB Medicine UAB Hospital

Tulane University

Tuskegee University

Cooper Green Mercy Health Services

Huntsville Hospital

University Medical Center

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

Community Health Center, Inc.

Eau Claire Cooperative Health Centers

San Ysidro Health Center

HRHCare Community Health

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

Community Partners Network

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

Fifty Forward

SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

National Alliance for Hispanic Health

American Association on Health and Disability

AAFP

AAHIVM
AMERICAN ACADEMY OF HIV MEDICINE

American Association of Colleges of Nursing

AMA

APHA
AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

ACCESS
assisting. improving. empowering.

APIAHF
SIAN & PACIFIC ISLANDE
MERICAN HEALTH FORU

ANAC
Association of Nurses in AIDS Care

BLACK WOMEN'S
HEALTH IMPERATIVE

W. MONTAGUE Cobb NMA HEALTH Institute

Community Council
Advancing Solutions...Empowering Lives

NRHA
NATIONAL RURAL HEALTH ASSOCIATION

L U L A C

UNIDOSUS
STRONGER COMMUNITIES. STRONGER AMERICA.

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

NAHN
National Association of Hispanic Nurses

NATIONAL BAPTIST CONVENTION, U.S.A. INCORPORATED

National Black Nurses Association, Inc.
NBNA

NCAPIP
National Council of Asian Pacific Islander Physicians

NHCOA
NATIONAL HISPANIC COUNCIL ON AGING

NHMA
National Hispanic Medical Association

NATIONAL Minority Quality Forum

NIH U.S. National Library of Medicine

NATIONAL PAN-HELLENIC COUNCIL

the YMCA

FOUNDED Σ Γ Ρ 1922

What are the potential activities asked of participants in the current protocol?

Enroll, Consent and Authorize EHR

- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data

Answering Surveys

- Five initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History
- Additional surveys will be released on an ongoing basis.

Physical Measurements*

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

**Based on diverse sampling and capacity*

Provide Biosamples*

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank

**Based on diverse sampling and capacity*

Wearables and Digital Apps

- Share data from wearable fitness devices, starting with FitBit
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

Coming soon

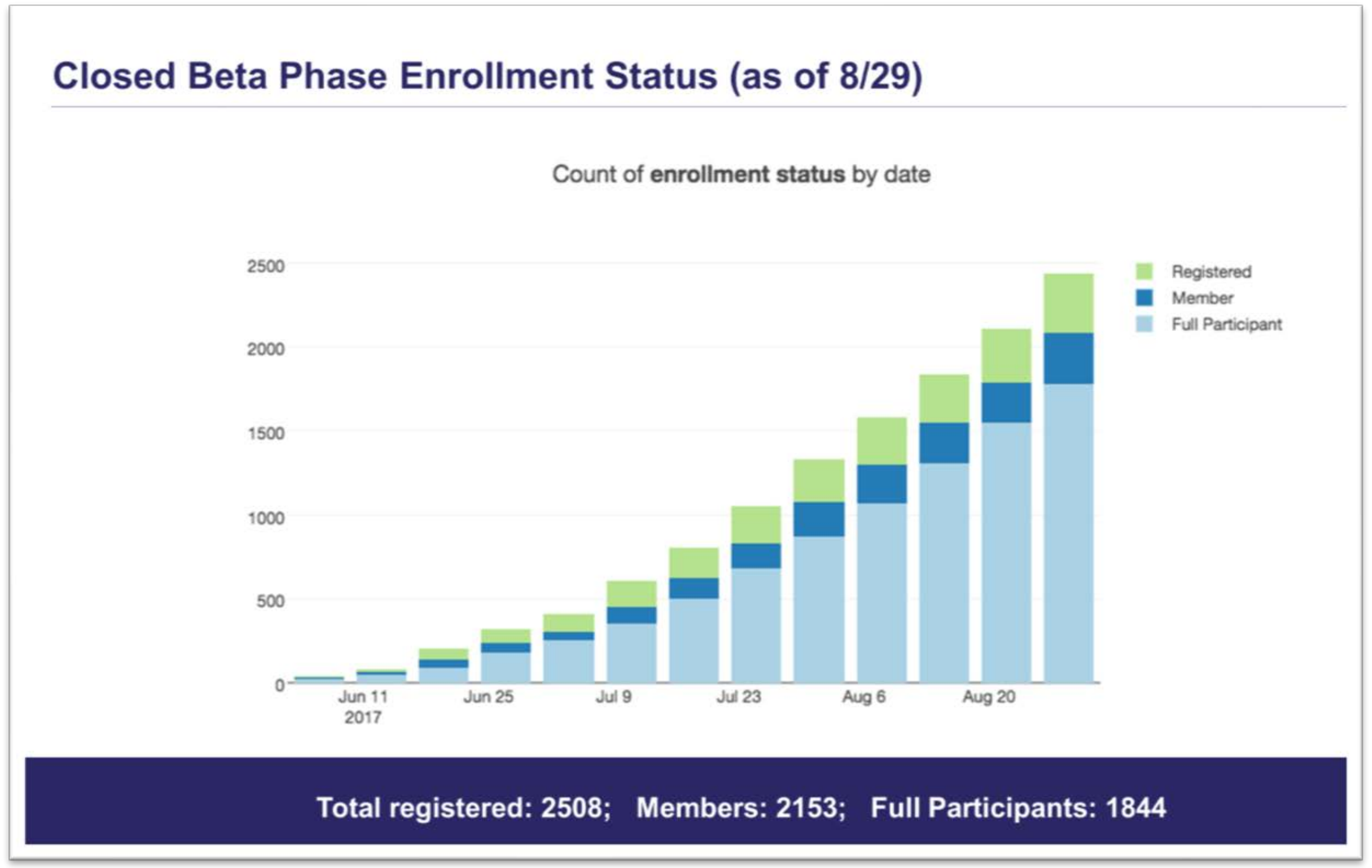
Pilots under development: richer EHR data, health apps, fitness wearables, and return of genetic info

Quick updates

Since I presented last fall…

- Last update was 9/1/17: had 2,508 participants across ~12 sites back then!
- Now we’ve completed beta testing and **launched nationally**!
- Total #s of participants in process: **>100K**, of which **>50K have completed full protocol** (all 50 states!)
- Doing very well on Underrepresented in Biomedical Research (UBR): **76% of participants UBR, 48% racial/ethnic diversit**y
- **~200 sites up in 20 states**
- Launched **program in Spanish**, including website, call center & materials
- Established partnerships with **30 new community, provider, advocacy orgs & NLM** to help educate and engage diverse populations
- Initial **EHR data evaluations underway** now
- **Mobile health partnerships** in development with Fitbit and Apple; Mood app in testing
- Improving Direct Volunteer capabilities, with partners like **Walgreens & Quest opening sites**
- Hosted a **Research Priorities Workshop** to allow researchers to share >1,300 use cases that will inform future protocol iterations

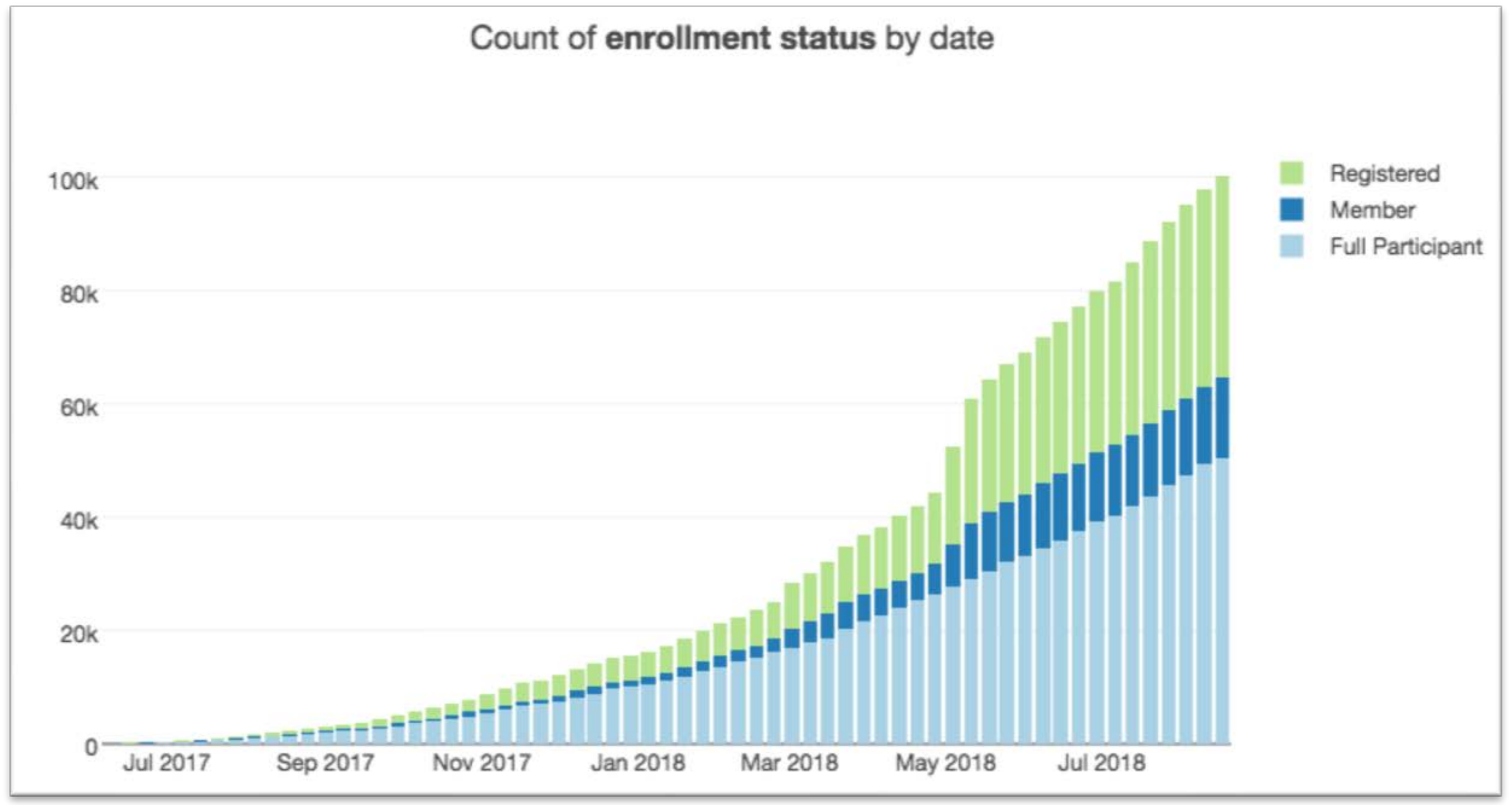
A time capsule from one year ago…



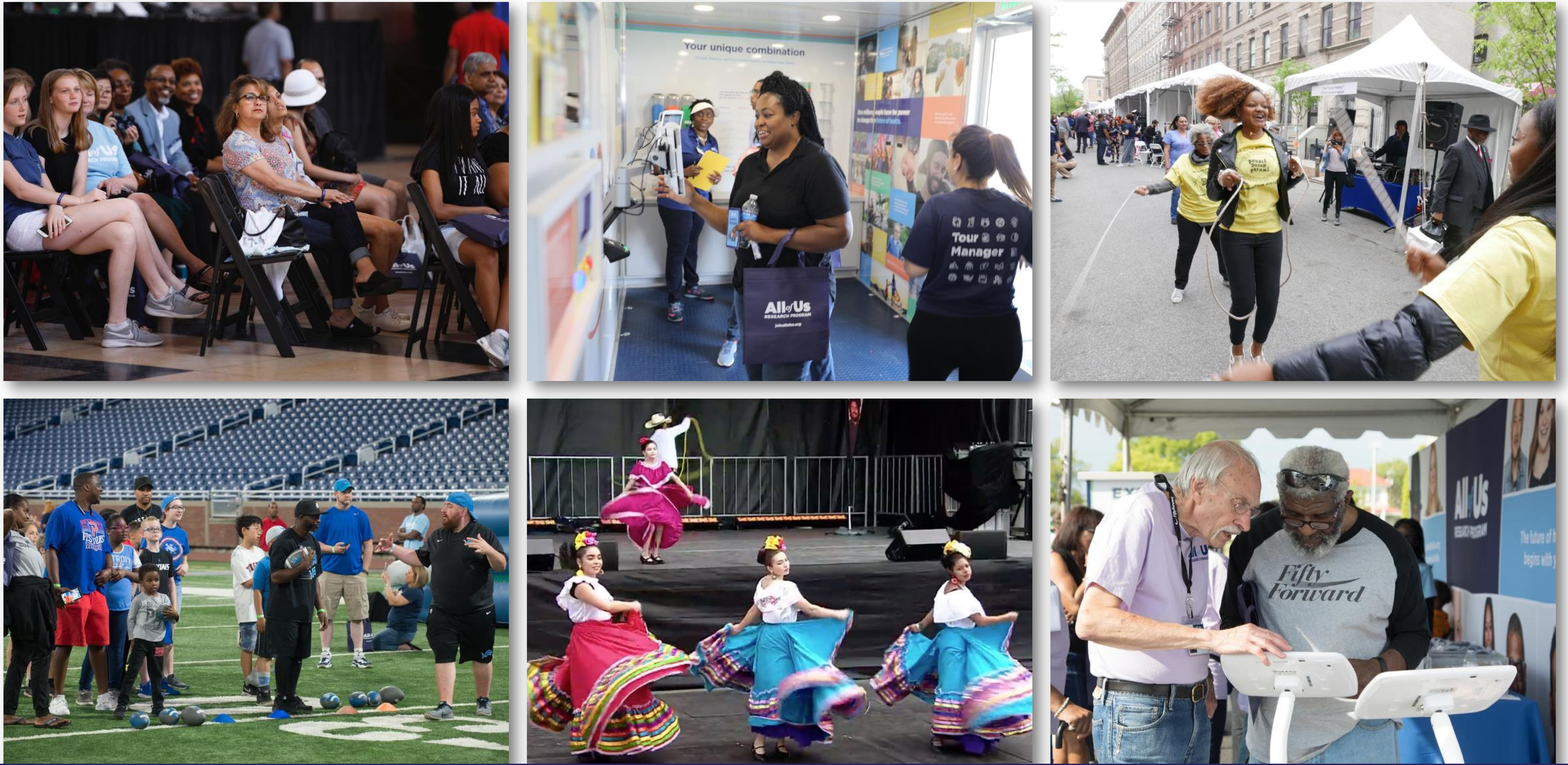
Closed Beta Phase Enrollment Status (as of 8/29)

Total registered: 2508; Members: 2153; Full Participants: 1844

Where we are today (as of 8/16/18)…



Launch day across the country



If you are 18 or older, you can sign up at JoinAllofUs.org. I hope you will give it careful consideration!

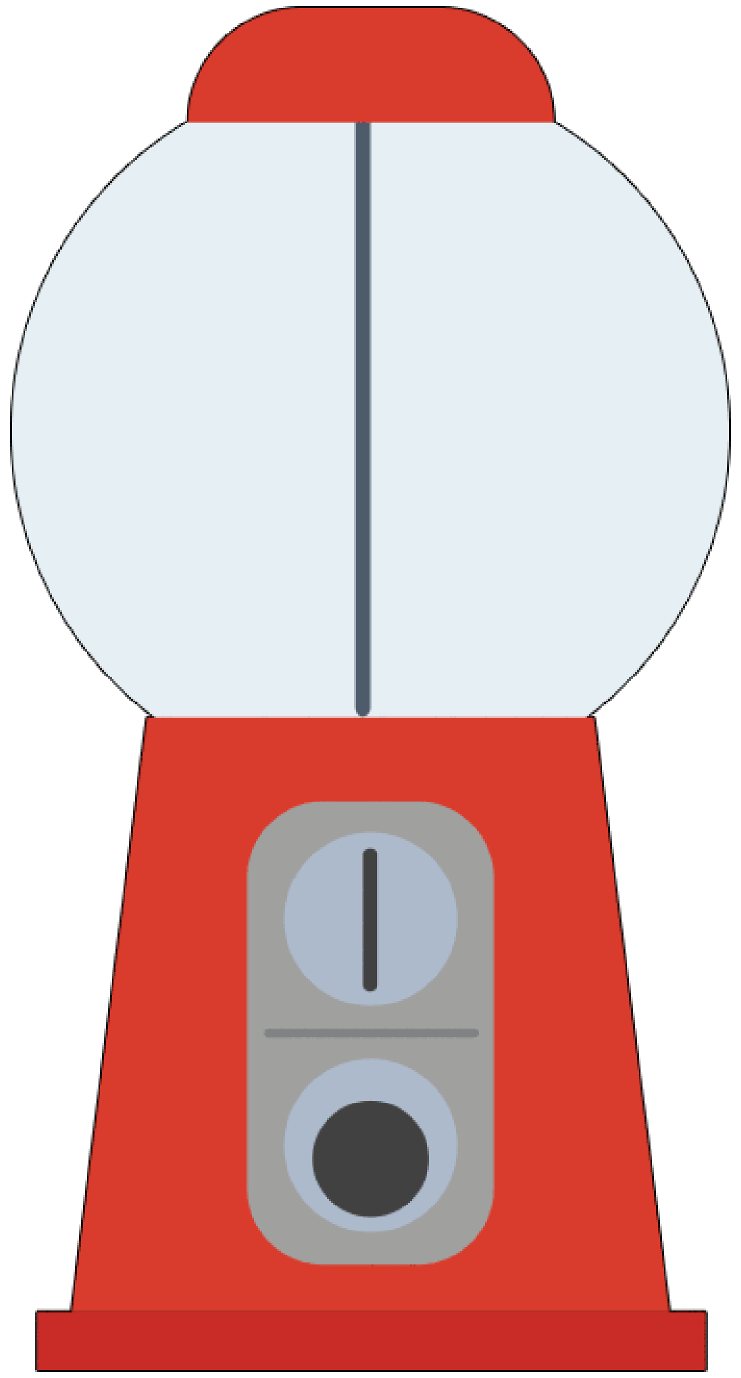
Scaling up to 1 Million: 4 strategies to get us there

- **Deliver value to participants ASAP**
  - Accelerate capabilities to do return of information
  - Figure out best way to deliver on their desire for community

- **Finish build out of clinic and recruitment capacity**
  - 135 remaining clinic sites planned for
  - Remove barriers to scaling Direct Volunteer mechanism to 25 more markets
  - Comparative analysis of home visit vs. HPO vs. drugstores

- **Deploy and test multiple marketing approaches**
  - Improved websites & participant portal
  - Finish precision digital marketing approvals & infrastructure

- **Shift more of protocol to lower touch paradigms**
  - Salivary pilot, pilot of home blood kit
  - Explore how to make “physical measures” a DIY kit
  - Distribute other tests in patient’s normal workflow (time of their physical, coming in for another purpose)



Challenges: very few best practices or evidence; embracing precision marketing

Genomics progress

- **Consent for use of DNA** released before national launch
  - Working on re-consent plan for earlier beta participants

- **Frequent FDA discussions** (on omics committee) about IDE

- Funding opportunity for **Genome Centers closed on July 12th**
  - Review meeting: mid-August
  - Awards expected: late September
  - 1-2 genomic centers, using OT mechanism

- **Genetic Counseling Resource** funding opportunity – expect to release fall 2018; award in 2019

- **Pilot of Genetic ROI and consent** w/ 20k diverse participants
  - Compare approaches (from preference engine to messaging)
  - Scope: 1) Pathogenic/Likely pathogenic ACMG variants; 2) Report of no pathogenic ACMG variant observed; 3) PGx report; 4) Access to data file

- On track for **starting genomic data collection by end of 2018**; responsible ROI pilot trending later ‘19

Challenges: aggressive pace for pipeline development; total costs per participant; predicting timelines

Child Enrollment progress

- **Our aims**
  - Generate protocols for children that are “parallel” to adult protocol
  - Expect ~10-18% of cohort of 1 million will be <18 years old
  - Phased enrollment by age: birth to 6 years; 7 to 12, 13 to 17

- **NICHD and ECHO** members on our committee to drive synergies

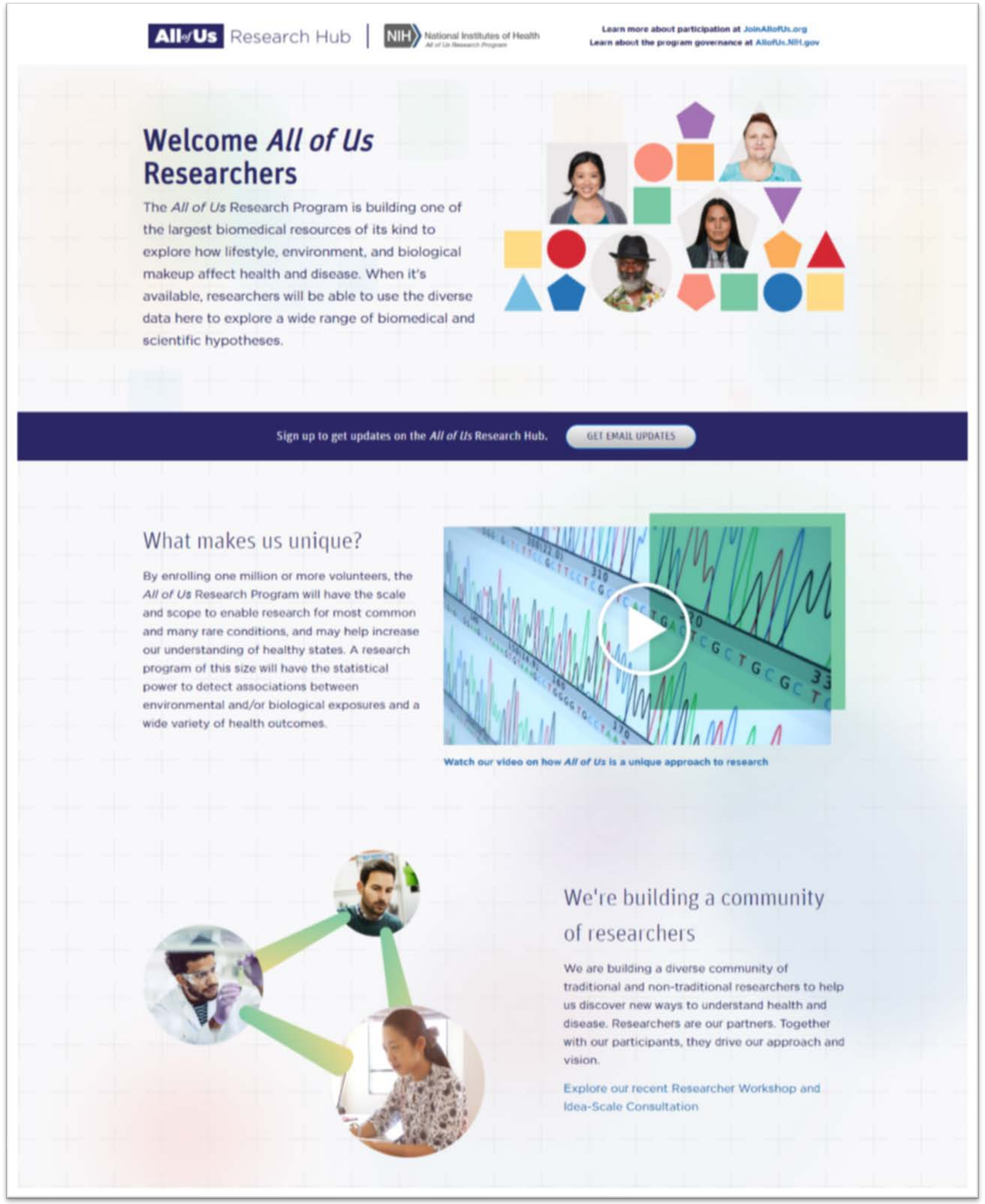
- Aiming for **launch of birth to 6 years old in Spring/Summer 2019**
  - This age range has least complexity of legal/ethical/tech challenges
  - Any child may enroll, even if parent/guardian not enrolled
  - Any child completely enrolled after completion of:
    - Creation of an account by their parent/guardian
    - Parent/guardian consent
    - EHR consent
    - Donation of biospecimen sample and physical measurements
    - Participant (parent/guardian)-Provided Information

- Exploring **family-based enrollment**

Challenges: logistics of scale; own experts finding protocol balance

Researcher Portal Plans & Aspirations

- **Completed needs-finding for researchers**
  - Surveys
  - Segmentation Model / Personas
- **Developed research access policies & committee**
  - Approved 3 tier approach for data (public, registered, controlled)
  - Passport model for individuals wanting access
  - Developing policies on access to samples & cohort
  - Developing procedures for allowing citizen scientist access to controlled tier
- **Basic model of the Research Portal is**
  - Entry page with description of program, policies & procedures, values, data, and tools
  - Public data browser
  - Research workspace, with cohort builder, Jupyter notebooks, & common analytic tools
- **Initial research website** (with research priorities workshop use cases) launched last month
- **Alpha and beta testing** our data cleaning, curation processes as well as Research Portal apps fall ’18
- On track to **launch 1st curated dataset 1st half of ’19**; access to cohort and samples to come later



Learn more about participation at JoinAllofUs.org
Learn about the program governance at AllofUs.NIH.gov

Welcome *All of Us* Researchers

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.

What makes us unique?

By enrolling one million or more volunteers, the *All of Us* Research Program will have the scale and scope to enable research for most common and many rare conditions, and may help increase our understanding of healthy states. A research program of this size will have the statistical power to detect associations between environmental and/or biological exposures and a wide variety of health outcomes.

Watch our video on how *All of Us* is a unique approach to research

We're building a community of researchers

We are building a diverse community of traditional and non-traditional researchers to help us discover new ways to understand health and disease. Researchers are our partners. Together with our participants, they drive our approach and vision.

Explore our recent Researcher Workshop and Idea-Scale Consultation

Challenges: complex security & beta testing; balance of recruit vs. release; managing expectations