

# Precision Medicine Initiative (PMI) Cohort Program

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# THE PRECISION MEDICINE INITIATIVE® (PMI)

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Announced by President Barack Obama in his 2015 State of the Union address

**MISSION:** To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care



# THE VISION OF PRESIDENT OBAMA

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*“My hope is that this becomes the foundation, the architecture, whereby in 10 years from now we can look back and say that we have revolutionized medicine.”*

**- PRESIDENT BARACK OBAMA**

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# The NEW ENGLAND JOURNAL *of* MEDICINE

January 30, 2015

## Perspective

### **A New Initiative on Precision Medicine**

Francis S. Collins, M.D., Ph.D., and Harold Varmus, M.D.

“Tonight, I’m launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes — and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

— President Barack Obama, State of the Union Address, January 20, 2015

The proposed initiative has two main components: a near-term focus on cancers and a longer-term aim to generate knowledge applicable to the whole range of health and disease. Both components are now within our reach because of advances in basic research, including molecular biology, genomics, and bioinformatics. Furthermore, the initiative

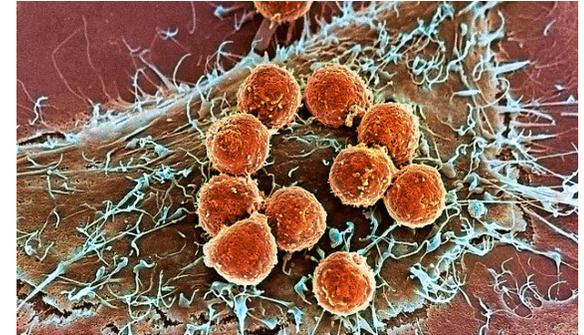
[www.nih.gov/precisionmedicine](http://www.nih.gov/precisionmedicine)

# PMI RESEARCH PROGRAMS AT NIH

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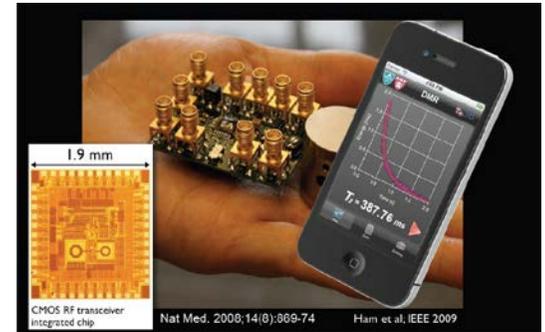
**PMI for Oncology:** Apply precision medicine to cancer

- Use NCI clinical trials as models
- Identify new cancer subtypes, targets
- Test precision therapies, with private sector partners



**PMI Cohort Program:**

- Generate knowledge base to move precision medicine into the full range of health and disease
- Large longitudinal cohort donating data from self-report, physicals, biospecimens, medical records, technological and geographic sources



## National Meeting on Precision Medicine and Cancer in

## AMERICAN INDIAN & ALASKA NATIVE COMMUNITIES

SAVE  
THE  
DATE

NOV 10  
2016

Samis Education Center  
OU Health Sciences Center  
Oklahoma City, Oklahoma

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# PMI COHORT PROGRAM

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## Will comprise:

- 1 million or more U.S. volunteers
- Healthcare Provider Organizations (HPOs)
- Direct Volunteers

## Participants will:

- Be centrally involved in design, implementation
- Be able to donate biological samples, healthcare records, longitudinal self-report and sensor data
- Receive regular feedback on the data they donate

## Will forge new model for scientific research that emphasizes:

- Engaged participants
- Open, responsible data sharing with privacy protections



# A TRANSFORMATIONAL APPROACH TO PARTICIPATION

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Participants in the PMI Cohort Program will be true partners—  
not patients, not subjects—in the research process

Involved in every step of program development

- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned



# A TRANSFORMATIONAL APPROACH TO DIVERSITY

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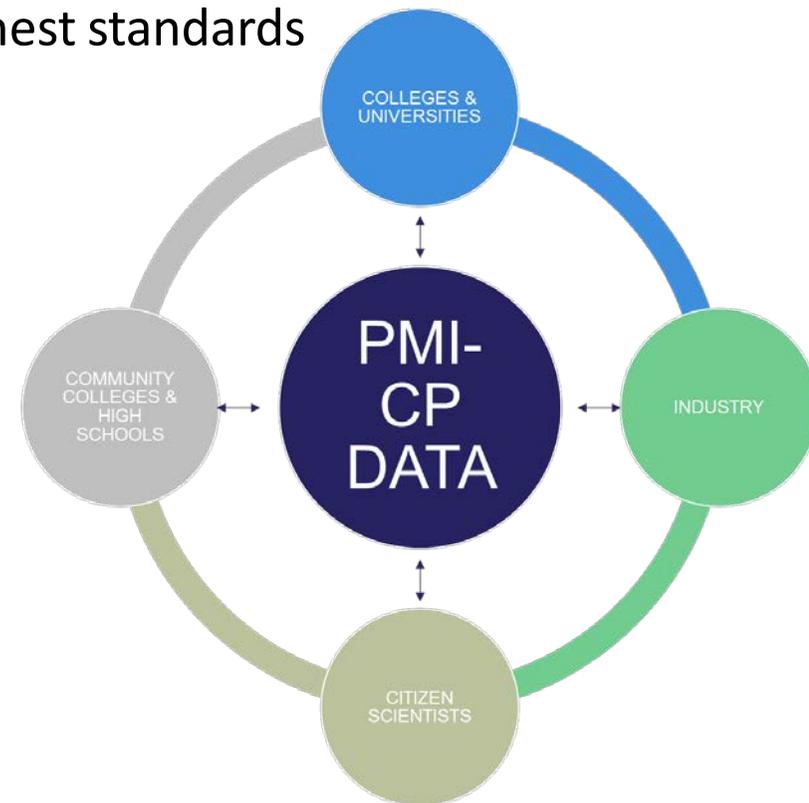
The cohort will reflect the rich diversity of America to produce meaningful health outcomes for subpopulations traditionally underrepresented in health research (across race/ethnicities, across socioeconomic status, across geographic areas).



# A TRANSFORMATIONAL APPROACH TO DATA ACCESS

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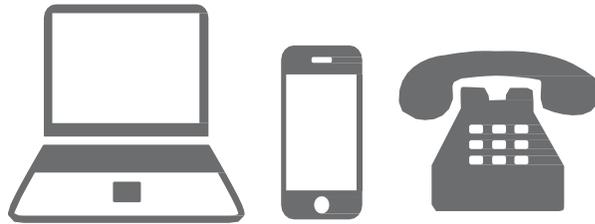
- Data sharing will be swift to both researchers and participants
- Data collection will start small and will grow over time
- Privacy and security will adhere to the highest standards
- Will invest to level the playing field so diverse researchers can benefit



# TWO METHODS OF ENGAGEMENT

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## Direct Volunteers

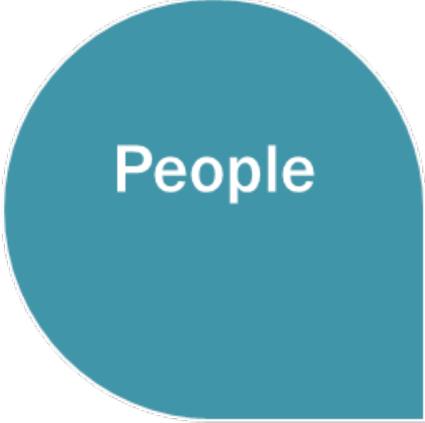


## Healthcare Provider Organizations



# AIMING FOR DIVERSITY ACROSS . .

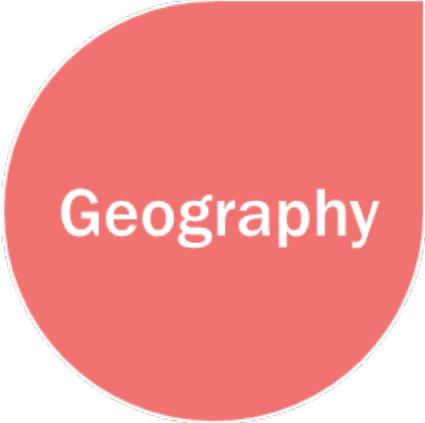
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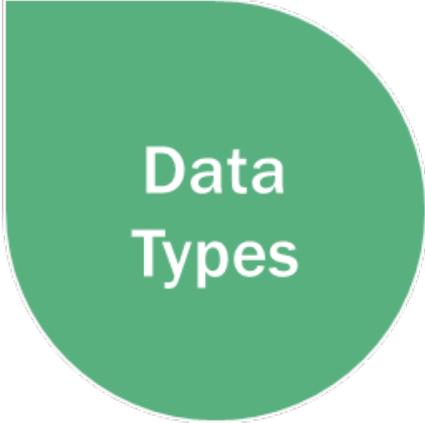
People



Health  
Status



Geography



Data  
Types

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# PMI COHORT PROGRAM DATA

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- The Program will start by collecting a limited set of standardized data from sources that will include:
    - Participant provided information
    - Electronic health records
    - Physical evaluation
    - Biospecimens (blood and urine samples)
    - Mobile/wearable technologies
    - Geospatial/environmental data
  - Data types will grow and evolve with the science, technology, and participant trust.
  - Tiered approach (not all data from all participants)
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# PROGRAM INFRASTRUCTURE

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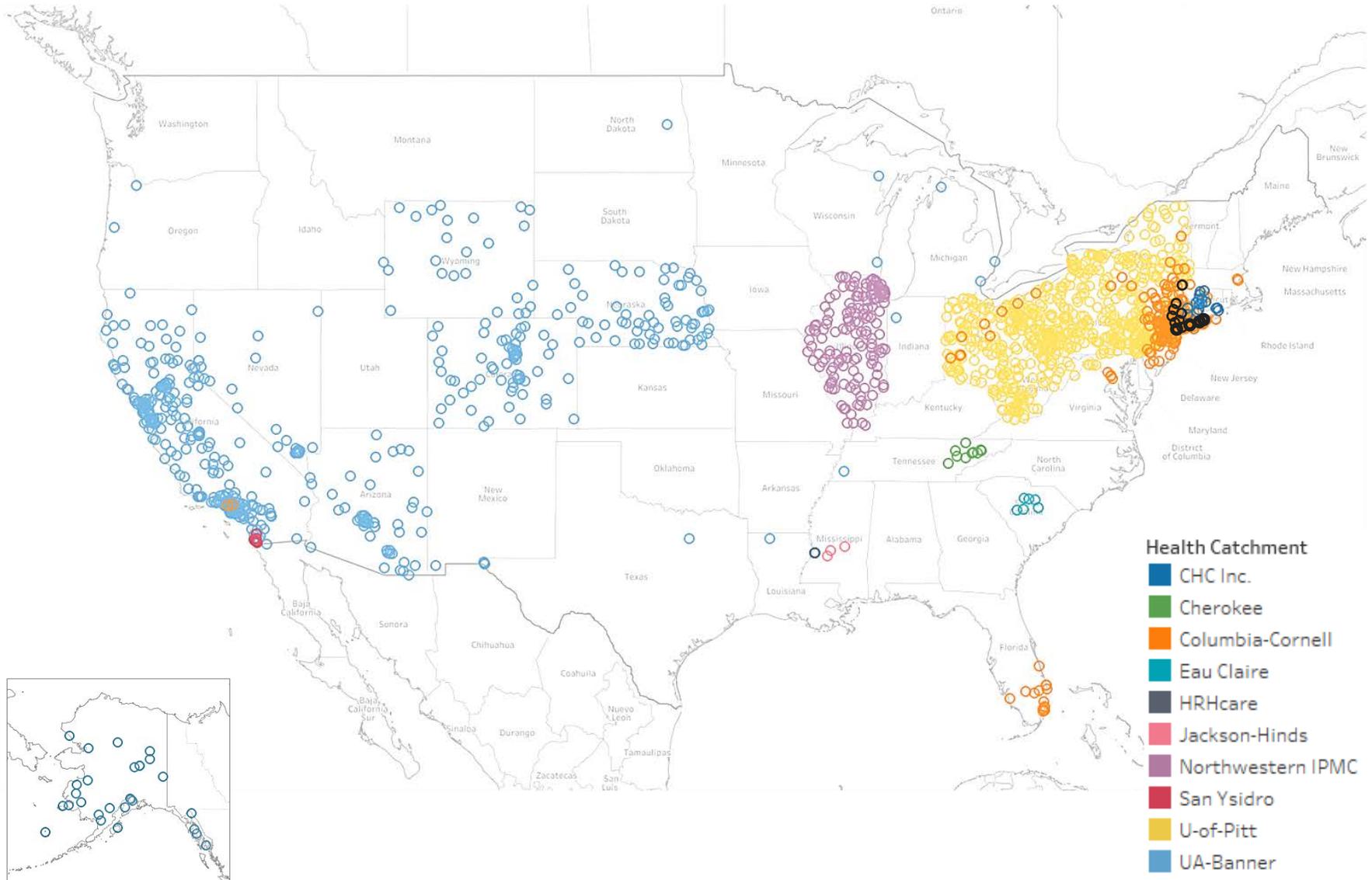
- Data and Research Support Center (DRC) –  
Vanderbilt University Medical Center, with the Broad Institute and Verily
- Biobank – Mayo Clinic
- Participant Technologies Center (PTC) –  
Scripps Research Institute, with Vibrent Health
- Healthcare Provider Organizations (HPOs)
  - Regional Medical Centers
  - Community Health Centers (e.g., Federally Qualified Health Centers)
  - VA Medical Centers

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In collaboration with community  
and federal partners, provider  
groups, and others

Maps reflect coverage as of August 25, 2016.

# HPO (RMC & FQHC PILOT) CATCHMENT AREA TO-DATE



Each individual dot represents a zip code area where the org has coverage/patients.

# U ARIZONA: HPO RMC INCORPORATING OUTREACH TO AN/AI COMMUNITIES

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- Through U. Arizona's Tribal Consultation Policy, consulting with the InterTribal Council of Arizona (Usha Menon leading this effort) and the Navajo Nation
    - From that consultation, will initiate AI/AN participant representation on PMI Cohort governance and working groups
  - The first of of many consultation and input efforts to address potential issues of concern to broad segments of AI/AN communities, such as:
    - Tribal Nation consent
    - Tiered consent for participants
    - Withdrawal of consent and of donated biospecimens
    - Data sharing and feedback to participants
    - Culturally-appropriate content and materials
    - Research questions pertinent to AI/AN stakeholders
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# **AI/AN COMMUNITIES IN THE PMI COHORT PROGRAM: DEVELOPING A VISION AND STRATEGY**

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Approach: develop a plan for AI/AN engagement, e.g.

- Pilot program specifically for AI/AN communities?
- Collaborate to distribute info on forthcoming funding opportunity for health centers?
- Collaborate to distribute information on launch to Direct?
- Other approaches?
  - UAZ HPO/RMC – example of an HPO integrating AI/AN communities

TCAC:

- Do you recommend a consultation process?

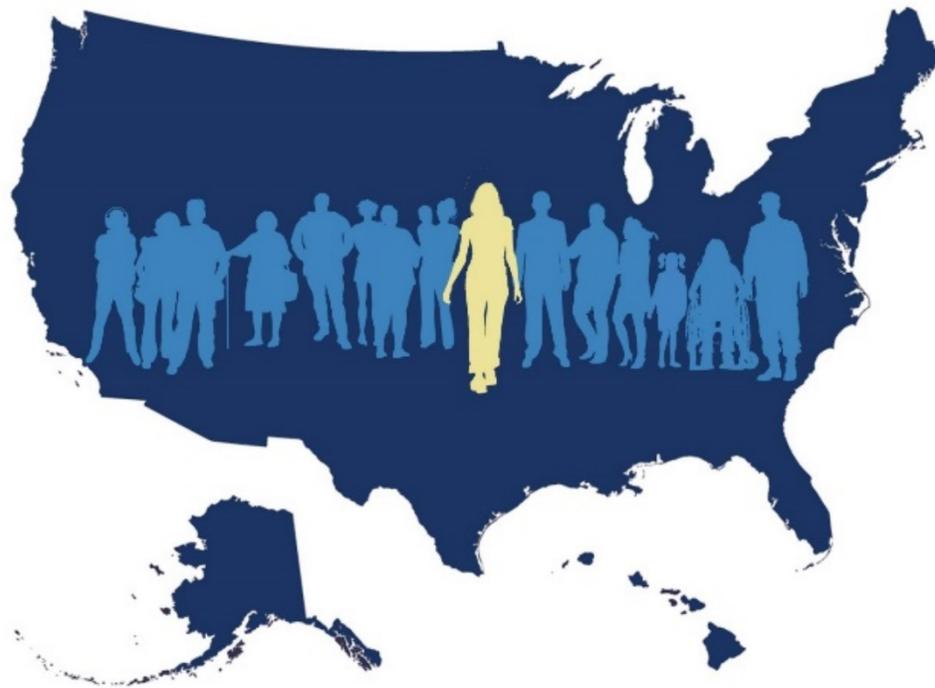
Welcoming staff to steward this effort:

- Daozhong Jin
  - Michael Banyas
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**Thank you for the opportunity to address TCAC!**

Questions and Comments?



**Sign up for updates at:**

<https://www.nih.gov/precisionmedicine>

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