From Design to Dissemination: An Opportunity for Women’s Health

All of Us™ Research Program

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Director of UI Cancer Center
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Overview of the *All of Us* Research Program
"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
“As someone who has personally benefited from precision medicine, I am excited for this study to intersect with other fundamental changes in medicine and research to empower people to live healthier lives.”

Eric Dishman
All of Us Research Program Director
All Of Us Research Program : DJ TIMBUCK2
The *All of Us* Research Program

- The cornerstone of the larger PMI – led by the NIH

- One million or more volunteers, reflecting the broad diversity of the U.S.

- Opportunities for volunteers to provide data on an ongoing basis

- Data shared freely and rapidly to inform a variety of research studies
Traditional Way: Bring data to researchers

<table>
<thead>
<tr>
<th>Problems</th>
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<tbody>
<tr>
<td>Security (data handoffs)</td>
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<tr>
<td>Data sharing = data copying</td>
</tr>
<tr>
<td>Huge infrastructure needed</td>
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<tr>
<td>Fixed amount of compute</td>
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PMI Way: Bring researchers to the data

<table>
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<tr>
<th>Advantages</th>
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<tr>
<td>Threat detection and auditing</td>
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<tr>
<td>Cost</td>
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<tr>
<td>Increased Accessibility</td>
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<td>Elastic compute</td>
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A Transformational Approach to Diversity

Reflecting the country’s rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research
A Transformational Approach to Data Access

- Data sharing will be a priority to both researchers and participants
- Participants will have access to study information and data about themselves
- 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 play
Two Methods of Engagement

HEALTH CARE PROVIDER ORGANIZATIONS

Vs.

DIRECT VOLUNTEERS
The Program will start by collecting a limited set of standardized data from sources that will include:

- Participant questionnaires
- Electronic health records
- A baseline physical evaluation
- Biospecimens (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

Data types will grow and evolve with science, technology, and trust.
The Value of Participating in *All of Us*

- **A chance to learn** some of your own health indicators and get your own data
- An opportunity to **fight disease** and improve the health of future generations
- An opportunity to **ensure that your community is included** in the studies that lead to new understanding and new treatments
- The chance to **be part of a movement**, to make our healthcare more precise, more personal, and more effective
Program Status
Established Program Infrastructure

**DATA AND RESEARCH 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

**HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)**
Regional Medical Centers, Health Centers (including Federally Qualified Health Center pilots), VA Medical Centers
Data and Research Support Center (DRSC)

- Led by Vanderbilt, Verily, and Broad
- **Collaborators**: Columbia, Northwestern, University of Michigan, University of Texas Health Science Center at Houston
- To acquire, organize, and provide secure access to the PMI Cohort Program datasets
- To provide research support for the scientific data and analysis tools for the program, helping to build a vibrant community of researchers who can propose studies using this information
Biobank

- Led by Mayo Clinic

- To support the collection, analyses, storage, and distribution of biospecimens for research use
Participant Technologies Center (PTC)/Direct Volunteer Operations

- Led by Scripps Research Institute and Vibrent Health
  
  *Collaborators:* PatientsLikeMe, Sage Bionetworks, Walgreens

- Coordinate all direct volunteer enrollment and engagement activities

- Develop mobile applications and other technologies to collect data from and communicate with participants
Illinois Precision Medicine Consortium: IPMC

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Abel Kho, MD
Robert A. Winn, MD
Martha Diviglius, MD, PhD
Denise Hynes, PhD
Habibul Ahsan, MD
Karen Kim, MD
Illinois Precision Medicine Consortium

- Northwestern University
- University of Illinois at Chicago
- University of Chicago
- University of Illinois at Chicago, Peoria
- Cook County Health and Hospitals
- NorthShore University HealthSystem
- OSF Saint Francis Medical Center
- Rush University Medical Center
- Sinai Health System
- SIU Healthcare; Memorial Medical Center; Blessing Health System; Sarah Bush Lincoln
HPOs: Federally Qualified Health Centers (FQHCs)

- Develop and pilot community health center approaches for enrolling underserved populations, especially those historically underrepresented in biomedical research

- A collaboration with the Health Resources and Services Administration (HRSA) and the MITRE Corporation
Collaboration with Department of Veterans Affairs

- Strategic partners to learn from/with

- VA medical centers to help enroll veterans

- Million Veteran Program:

A national, voluntary research program studying how genes affect health; participants to be invited to enroll in the PMI Cohort Program as well
Why Person Based Precise Medicine Matters

- Ambien (zolpidem)
- Women eliminated Ambien more slowly than men (metabolized in liver)
- Associated with women potentially having increased driving accidents
- The U.S. Federal Drug Agency strongly recommended halving the dose of Ambien in women
- Treatment with lower dose Ambien (5mg) had the same benefit for women as the standard higher doses (10mg) for men
GEOGRAPHY
Geography Matters (Zip code vs. Genetic code): The Tale of Two Sisters

• Two sisters
• Raised together in the same town
• The same home
• Under the same circumstances
• Subsequently grow up and move apart
The city of **Chicago**; e.g. Gold Coast

- Is very affluent (higher income)
- It has access to the lake front, gyms, parks
- Many farmers markets and fresh food markets
- Top universities, hospitals, etc.

The city of **Moline**

- High poverty rate (lower income)
- High incidence rate and mortality of Breast Cancer
- Lack of access to fresh foods
- Lack of access to top universities, hospitals, etc.
Geography Matters (Zip code vs. Genetic code): The Tale of Two Sisters

- They both develop breast cancer
- Will the treatment be the same for both sisters
- How does what they eat affect their treatment (e.g. microbiome)
- How will the everyday stresses they have to live with affect their treatments (e.g. epigenetics)
SOCIAL DETERMINANTS OF HEALTH

• HEALTH CARE
• HOUSING
• EDUCATION
• FOOD
• BUILT ENVIRONMENT
• POLLUTION
• COMMUNITY AND DOMESTIC VIOLENCE
• CRIMINAL JUSTICE
• EMPLOYMENT
• GOVERNANCE
FOOD DISPARITIES IN CHICAGO

**FOOD DESERTS IN CHICAGO**

Distance to grocers by tract with community boundaries

The map shows distance to all types of grocery stores in Chicago. Black-colored areas are the farthest distance from grocers. These areas form three key food deserts on Chicago’s West and South sides.

Food deserts are nearly exclusively African-American

The map shows only tracts that are in the farthest distance to grocers and shades them by race.

- **CLOSEST DISTANCE**
- **AVERAGE DISTANCE**
- **FARDEST DISTANCE**

**SOURCE:** Examining the Impact of Food Deserts on Public Health in Chicago
Food Disparities and BMI in Chicago

This map by Zip Code indicates BMI and Food Balance Scores. Brown dots indicate areas that are the most out-of-balance; they have no or distant grocers but nearby fast food.
From “Big Data” to “Precise Data”

“Old” Model

- Based on “BIG DATA”
  - Little to no “community input”

Develop Cancer Screening Program

- Model depends on patients coming “TO” clinics
- Programs done “TO” patients and not “FOR” patients

Implement Cancer Screening Program

- Patients in mostly underserved communities diagnosed at “LATE STAGE”
- Late Stage Diagnosis MORE COSTLY than early stage diagnosis

Outcomes: Late Stage Cancer Diagnosis

“Precise” Data Driven Model

- Based on data at “relevant level”
  - Ongoing input from political, community, clinical and academic partners

Develop Cancer Screening Program

- Model supports screening WITHIN the community clinics
  - Screening done “FOR” patients and not “TO” patients

Implement Cancer Screening Program

- Early Stage Diagnosis
  - Cost savings for Early Stage Diagnosis

Outcomes: Early Stage Cancer Diagnosis
Empowering Women from All Communities to Be a Part of the Conversation

• Health Determinants of our Zip codes vs our Genetic Code.
• If we aren’t at the table we end up on the menu.
• Clinical Trials
  • Non participation widens the gap of health disparity.
  • Participation ensures miracle drugs are created with ____ in mind.
  • Creation of drugs that will benefit future generations.
• To move from having things done “to” us as opposed to “for” us, we have to begin doing things “with” them.
thank you!
HOPE for All of Us
An Introduction to the

All of Us℠
Research Program

NIH
National Institutes of Health
THE PUBLIC HEALTH CRISIS

- September 2015
  - Dr. Mona Hanna-Attisha warns Flint to stop using Flint River
  - Dr. Marc Edwards reports on lead leaching into water supply

- October 2015
  - Flint city officials urge residents to stop drinking water
  - MDEQ Reports inappropriate use of corrosion control

- January 2016
  - President Obama and Governor Snyder declare emergency
  - Blizzard of 2016 - The Congressional Response Effort Begins
RED-LINING

Home Owner’s Loan Corporation (1933-1935)

- 4 - Tiered assessment
- Measured sale and rental demand, % ownership, social status of population, utilities, schools, churches, business, transportation

- GRADES
  - A – Green “hot spots”
  - B – Blue “developed”
  - C – Yellow “aged”
  - D – Red “undesirable population”
PMI Cohort Program Major Components

- Data and Research Support Center (DRSC)
- Biobank
- Participant Technologies Center (PTC)
  - Regional Medical Centers
  - Community Health Centers (Federally Qualified Health Centers)
  - VA Medical Centers
- Healthcare Provider Organizations (HPOs)
Data and Research Support Center

- Develop questionnaires for participant-provided information
- Finalize all IT interfaces with biobank, PTC, and HPOs
- Prepare and test transfer of electronic health records (EHRs) from HPOs
- Conduct security testing and gain authority to operate
Questions?

Sign up for updates:

https://www.nih.gov/allofus-research-program
Biobank

- Finalize blood and urine collection protocols for HPOs and direct volunteers
- Finalize collection kits
- Develop the capacity for an orderable test to be implemented at all sites
- Pilot test receiving samples from all sites
Participant Technologies Center &
Direct Volunteer Operations

- In collaboration with the direct volunteer pilot, get IRB approval on program protocol
- Conduct security testing and gain authority to operate
- Develop website and apps for direct volunteer enrollment
- Finalize processes for direct volunteer enrollment
- Stand up call center
### Proposed Participant Enrollment

<table>
<thead>
<tr>
<th>Year</th>
<th>SHS</th>
<th>IPMC Overall</th>
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<tbody>
<tr>
<td>Year 1</td>
<td>174</td>
<td>10,000</td>
</tr>
<tr>
<td>Year 2</td>
<td>624</td>
<td>35,000</td>
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<tr>
<td>Year 3</td>
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<tr>
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<tr>
<td>Year 5</td>
<td>624</td>
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<tr>
<td></td>
<td>2,670</td>
<td>150,000</td>
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Deciphering Protein Molecular Signatures in Cancer Tissues to Aid in Diagnosis, Prognosis, and Therapy

Richard M. Caprioli

Department of Biochemistry and the Vanderbilt-Ingram Cancer Center, Vanderbilt University, Nashville, Tennessee

**Figure 1.** Process for discovery on molecular signatures consists of the integration of three basic components: (top, left) physician/patient interaction encompassing patient history and other clinical information, acquisition of the appropriate tissue sample and pathology; (right) analytic component involving tissue preparation, MS data acquisition, raw data normalization, and validation; (bottom, left) biocomputational processing to identify protein signatures at high confidence levels and with appropriate validation relevant to the clinical question at hand.
UI Health is now One of 8 Regional Medical Centers Awarded

- Able to enroll diverse patient populations
- Strong electronic health record capacity
- Geographic spread
- Capacity to enroll 35,000 a year

Illinois Precision Medicine Consortium
Northwestern, U of C, and UIC
Chicago, IL

Henry Ford Health System
Public Health Sciences
Detroit, MI

Geisinger Health System
Genomic Medicine Institute
Danville, PA

University of California San Diego
Department of Biomedical Informatics
La Jolla, CA

University of Pittsburgh
Clinical and Translational Science Institute
Pittsburgh, PA

University of Arizona
College of Medicine & Public Health
Tucson, AZ

Massachusetts General Hospital
Genetics & Genomics Unit
Boston, MA

Columbia University
Institute for Genomic Medicine
New York, NY

All of Us℠ | The Precision Medicine Initiative®
HPOs: FQHC Pilot Sites

Initial sites selected July 2016
More to come
https://wdrv.it/782dcafcd

[Not for public release]
Why Person Based Precise Medicine Matters

- Lipitor (atorvastatin)
- Cytochrome p450 (a drug metabolizing enzyme)
- Too much of a good thing lead to toxicity in asian populations
- Treatment with **low dose** statin has the same cardiovascular benefit of reducing heart disease (i.e. coronary artery disease) in Asians as the standard higher doses in Caucasians