The Precision Medicine Initiative®
Cohort Program:
Update to the Council of Councils

Josie Briggs, MD
Interim Director, PMI Cohort Program
Director, NCCIH

Council of Councils - May 20, 2016

The Precision Medicine Initiative® Cohort Program

Where are we now?

- PMI Cohort Program Director Announced
- Timeline
- OT Awardees
- RFAs
- Data Sprint & Sync for Science (S4S)
- PMI Cohort Program Advisory Panel
- Implementation Papers

PMI Cohort Program Director Announced April 11: *Eric Dishman*

President Obama
Last year, I launched the Precision Medicine Initiative to bring us closer to a new era of medicine—one that takes into account an individual's health history, genes, environment, and lifestyle, so that we can deliver the right treatment at the right time to the right person. And today, I'm proud to announce that we've found the right person to lead one of the most critical aspects of this effort—a massive research study of more than a million volunteers.

U.S.News NEWS

Meet Eric Dishman, the New Face of the Precision Medicine Initiative

The health technology veteran discusses data, accessibility and the future of health research.

Kathy Hudson @KathyHudsonNIH · 1h
.@NIHDirector helping just-named-#pminetwork director @ericdishman with Hope @ NIH lapel pin. Pretty adorable.

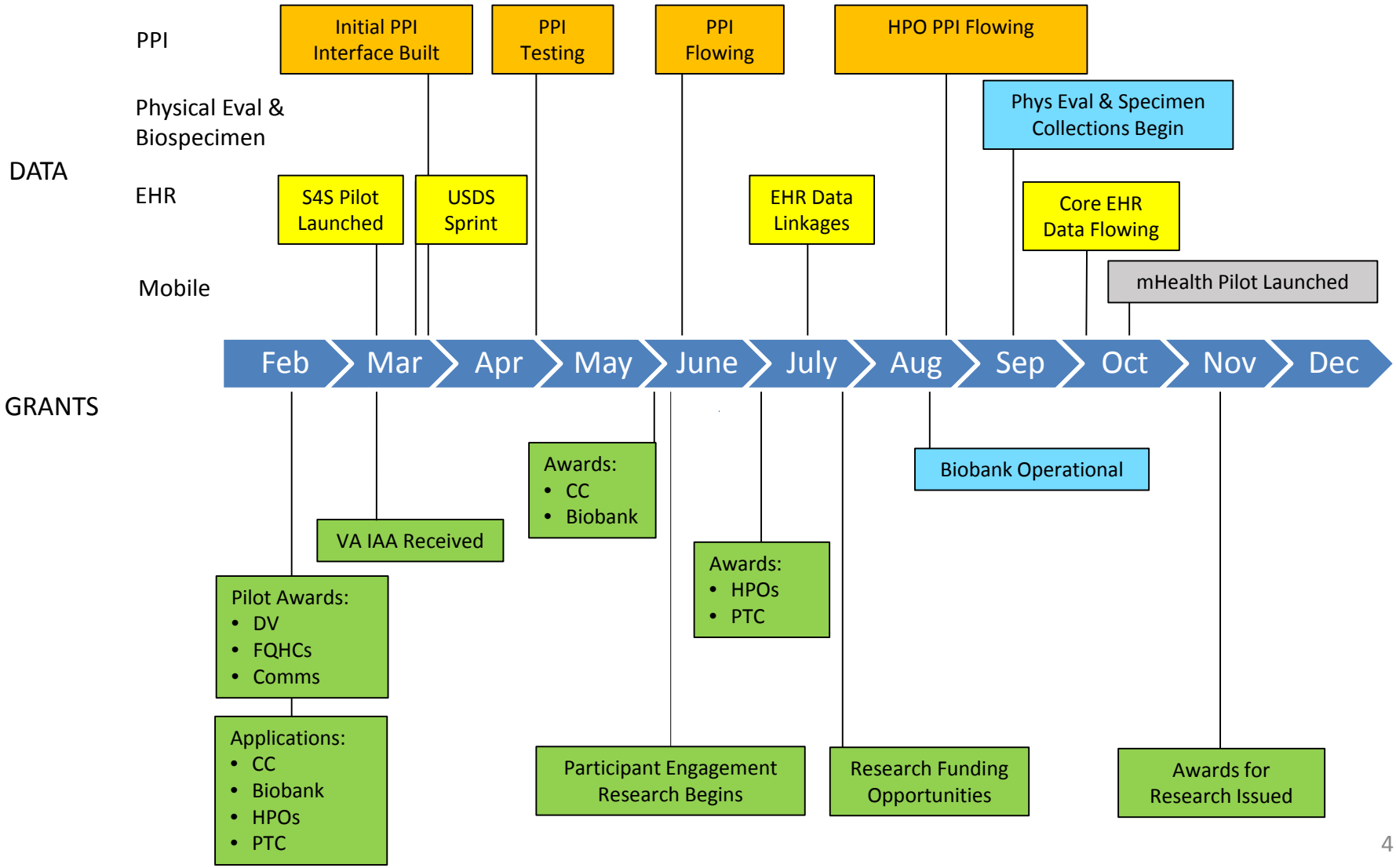
FORTUNE

This Intel Healthcare Guru Is About to Head a Major Government Project

STAT|

Precision medicine helped him beat cancer. Now he's leading Obama's initiative

Preliminary Timeline - 2016



OT Awardees Update

- **Direct Volunteer (DV) Pilot:**
  - Vanderbilt University - Verily advisors (12 month award)
    - ~3 month milestone - February 24 – May 31, 2016
    - Initial Award - $1.3M (3 month milestone)

- **Communication Support:**
  - HCM Strategists (12 month award)
    - ~3 month milestone - March 3 – May 31, 2016
    - Initial Award - $383,000 (3 month milestone)
  - Hungry Heart Media, Inc. (Wondros) (24 month award)
    - ~3 month milestone - March 4 – June 15, 2016
    - Initial Award $511,000

Update on RFAs

- Applications for Cooperative Agreements received February 2016

- Change to Council approach:
  - CC (U2C) and Biobank (U24):
    - Today's COC meeting
  - HPOs (UG3/UH3) and PTC (U24):
    - June 15 meeting of NHLBI Council

Data Sprint & Sync for Science (S4S)

- Data Sprint
  - NIH and US Digital Service (USDS): examine the ability for HPO-enrolled PMI Cohort participants to share EHR data
    - Facilitate planning and gather information before award
    - Facilitate development of a unified approach to collecting high-quality electronic health information

- Sync for Science (S4S)
  - Develop methods to facilitate individually-controlled clinical data donations to the PMI Cohort
  - Accelerate and guide the national ecosystem for patient-mediated data access through APIs

PMI Cohort Program Advisory Panel

Lon Cardon, Ph.D. (2019)
GlaxoSmithKline

Tony Coles, M.D., M.P.H. (2018)
Yumanity Therapeutics

Rory Collins, F.Med.Sci. (2018)
University of Oxford

Jonathan Epstein, M.D. (2019) **New**
University of Pennsylvania

Alejandra Gepp, M.A. (2019)
National Council of La Raza

Sachin Kheterpal, M.D., M.B.A. (2018)
University of Michigan Medical School

Terry Magnuson, Ph.D. (2020) **New**
UNC School of Medicine

Marie Lynn Miranda, Ph.D. (2020)
Rice University

Dara Richardson-Heron, M.D. (2020)
YWCA USA

Gregory Simon, M.D., M.P.H. (2020)
Group Health Research Institute

Sharon Terry, M.A. (2020)
Genetic Alliance

David Williams, Ph.D., M.P.H. (2019)
Harvard University

Implementation Papers

Precision Medicine Initiative® Cohort Program key recommendations on:

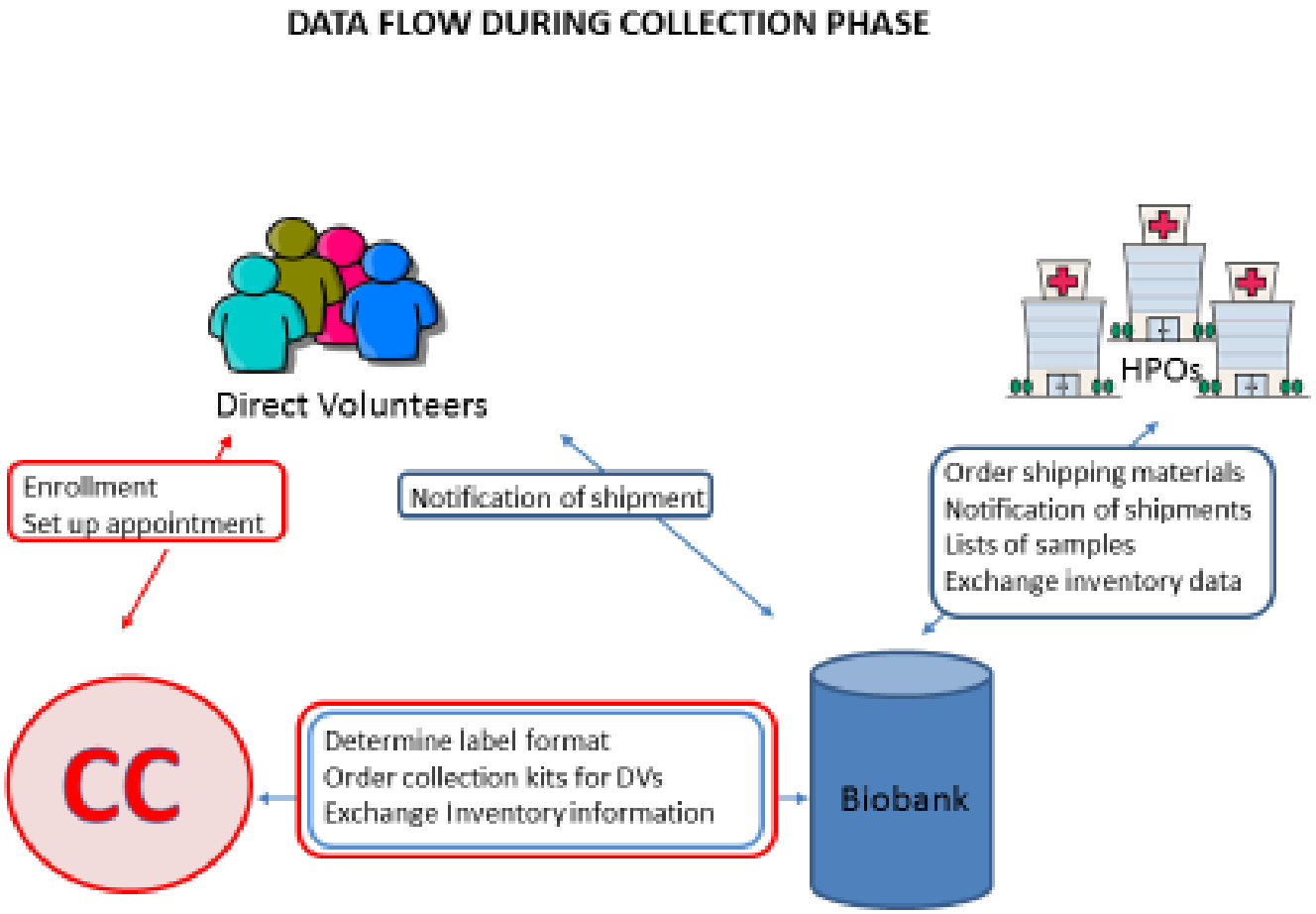
1. Biobank
2. Electronic Health Record
3. Family Engagement
4. Participant Provided Information
5. Physical and Social Environment
6. Physical Evaluation

Biobank

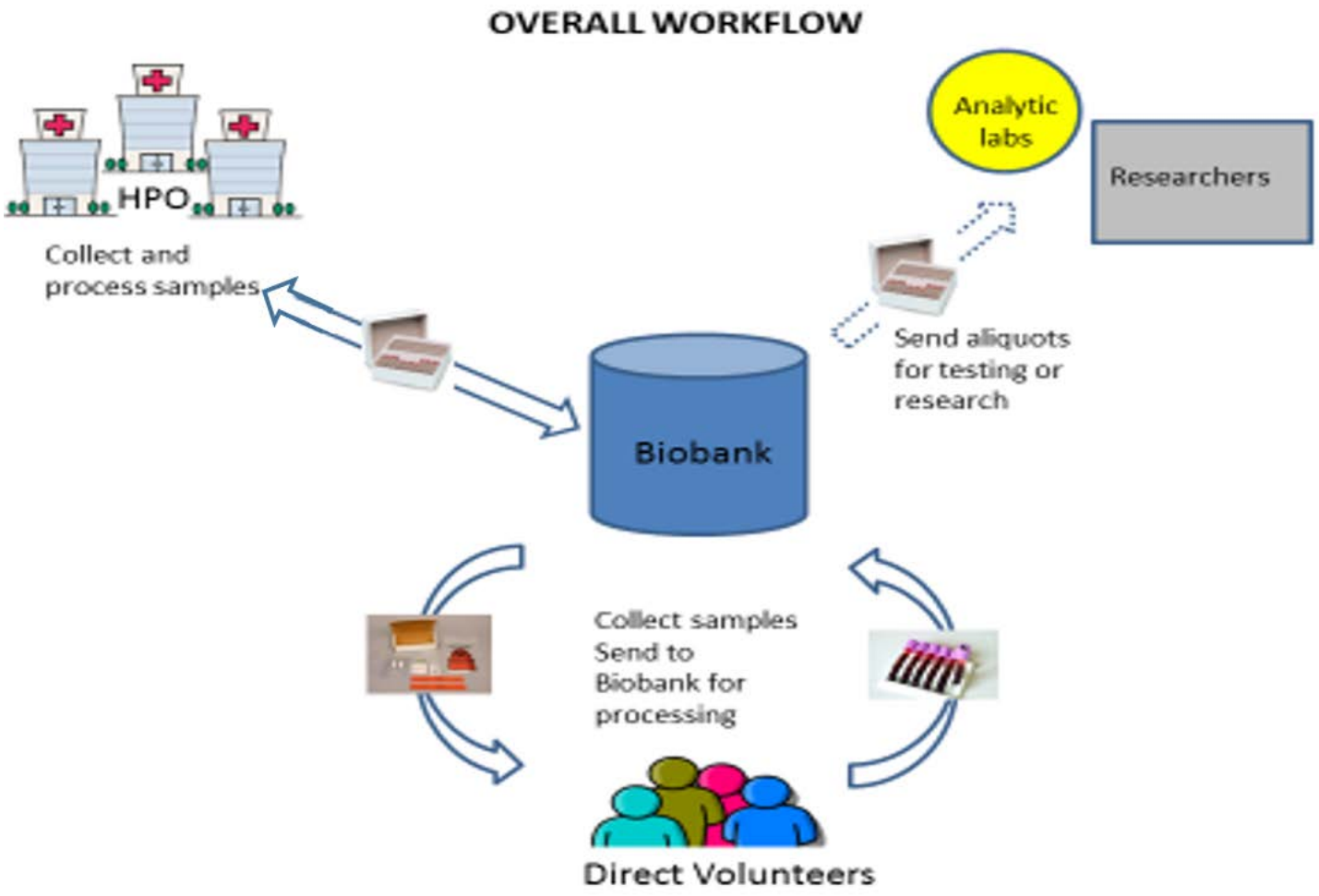
- The HPOs will perform minimal processing prior to shipping the samples on the day of collection to the Biobank for processing and aliquoting within 24 hours.
- DVs will travel to designated community-based facilities for specimen collection and initial processing.
- All samples will be sent by these designated collection sites to the Biobank for further processing and storage.
- The Biobank will be responsible for supplying collection kits, packaging, and monitoring equipment to ensure maintenance of the cold chain throughout the shipping process.

Type of sample and collection tube	Volume Collected (mls)	Transport T°C	Fraction created	Aliquots (0.5 ml) -80°C	Aliquots Liquid N2 (-150°C)
EDTA	9	4	DNA	TBD	TBD
EDTA	9	4	Plasma	6	2
Clot activator (SST)	8	4	Serum	6	2
Acid citrate dextrose	6	18	Whole Blood (cryopreserved)	6	2
Urine	9	4	Urine	4 (1.4 ml aliquots)	2 (1.4 ml aliquots)
EDTA*	4	4	Clinical testing	-	-

Biobank Data Flow



Biobank Overall Workflow



Physical Evaluation

Measure	Method Utilized	Add'l Training Needed	Participant Burden
Blood Pressure	Digital BP monitor, 2 reading 1 minute apart	No	3 mins
BMI	Kg/m2 autocalculated from height and weight	No	NA
Heart Rate	Via BP monitor	No	NA
Height	Standing height without shoes	No	< 1 min
Hip Circumference	Non-stretchable sprung tape measure	Minimal	1 min plus removal of some clothing
Heart Rhythm	AliveCor 1 lead (12 lead in subset for validation)	No	< 5 min
Waist Circumference	Non-stretchable sprung tape measure	Minimal	1 min plus removal of some clothing
Weight	Digital, remove shoes and outer clothing layers	No	< 1 min

Additional Considerations for Special Populations:

- Age 65 and older: Motor skill (4m walk), grip strength, portion of NIH Toolbox cognition battery
- Newborn to age 2: Replace BMI with weight and length, add head circumference
- Age 2 to 18: Same as adults, Add age appropriate portion of NIH toolbox cognition battery

Participant Provided Information

- Initial Eligibility and Sociodemographics (gender, education, race/ethnicity)
- Socioeconomic Status (employment, occupation, financial)
- Substance Use (tobacco, alcohol, other substances)
- Anthropometry (height, weight, weight history)
- Personal Medical History (diagnoses, procedures)
- Medications (prescribed, OTC, supplements)
- Healthcare Access/Utilization (visits, hospitalizations, coverage)
- Diet (24 hr. recall)
- Physical Activity (leisure time physical activity, work physical activity)
- Sleep (sleep schedule, quality)
- Health Status (health rating, health-related quality of life)
- Family Health History (Illnesses in family, causes of death of parents and relatives)
- Psychosocial/mental health status (depression, fatigue, emotional or social limitations
- Oral Health
- Pain (intensity and interference)

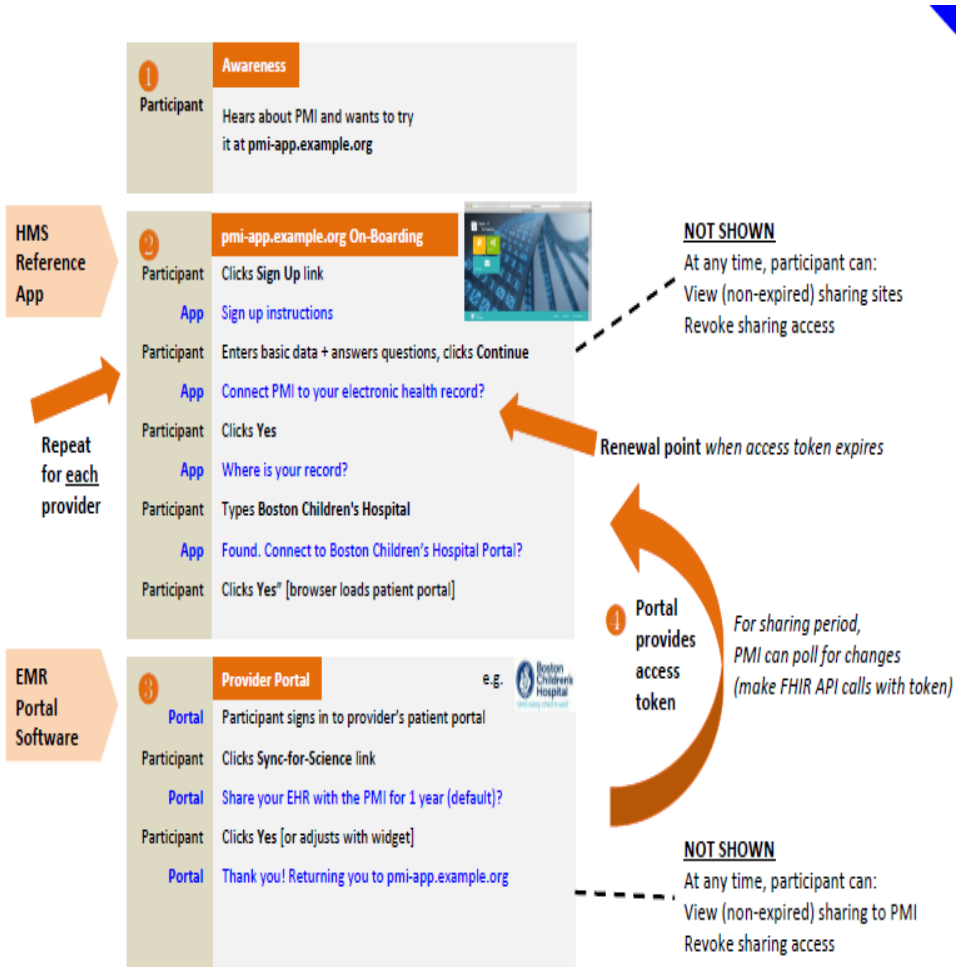
Physical and Social Environment

- **Location, Location, Location**
  - Physical address (work and home)
  - Past addresses (report or database)
  - Smartphone GPS detailed location
- **GIS database linkages**
  - Pollution, neighborhood characteristics
  - Value to participants as a return of results to foster engagement
- **Self-report of personal and home based exposures (lead, pesticides)**

- **Sensors/Devices**
  - Sensors resident on smartphones
    - Location
    - Movement
    - Audio/Video capture
  - Bring your own device
    - FDA approved (e.g., wireless glucometers)
    - Personal commercial (e.g., activity and hr monitors – require validation)
  - Sensors provided to specific subgroups (e.g. secondhand smoke sensors for identified smokers)

Electronic Health Record

- **Initial Data Types:**
  - Demographics
  - Diagnosis
  - Prescribing
  - Encounter and Procedure
  - Vital
  - Lab Results
- **Expand to include additional structured data** and unstructured data as capacities improve
- **HPOs:**
  - Learn from HPO Data Sprint
  - Transmission from HPO to CC in specified format
  - Make available to participants
- **DVs:**
  - Sync for Science (S4S)
  - Develop a FHIR-based API
    - Single "S4S" indication from DV
    - Indicate EHR home
    - Permission and authentication
    - Secure transmission
    - Make available to participants



Proposed Flow for S4S Pilot at Harvard Center for Bioinformatics

PMI Cohort Program
Institutional Review Board (IRB)

Carrie D. Wolinetz, PhD
Associate Director for Science Policy, and
Director of the Office of Science Policy
National Institutes of Health

PMI Cohort Program
IRB Roster

- Nancy Kass, Professor of Bioethics and Public Health, Johns Hopkins (***Chair)***
- Anita Allan, Vice Provost for Faculty Professor of Law and Philosophy, University of Pennsylvania
- Arlene Chung, Assistant Professor of Medicine, Pediatrics, Bioinformatics Core, University of North Carolina
- Ysabel Duron, Founder, Latinas Contra Cancer
- James Jackson, Distinguished Professor, Psychology Director, Institute for Social Research, University of Michigan
- Loretta Jones, Founder and CEO, Healthy African American Families
- David Magnus, Professor of Medicine and Biomedical Ethics, Stanford University
- David Murray, Associate Director for Prevention, NIH
- Jay Shendure, Associate Professor of Genomic Science, University of Washington
- John Wilbanks, Chief Commons Officer, Sage Bionetworks










IRB of Record

- The PMI Cohort Program IRB will serve as the IRB of record, charged with:
  - Risks to participants are minimized
  - Risks to participants do not outweigh anticipated benefits
  - Selection of participants is equitable
  - Informed consent meets regulatory requirements
  - Data monitoring for safety of participants
  - Appropriate provisions to protect participant privacy
  - Protections for vulnerable populations
- PMI Cohort Program participant enrollment and research will occur at many sites
- The IRB will review initial protocols for establishing the Cohort Program
- The role of this IRB in review of future proposed research uses of the cohort data and specimens is TBD.

Thank you!