

Pre-Application Technical Assistance Webinar

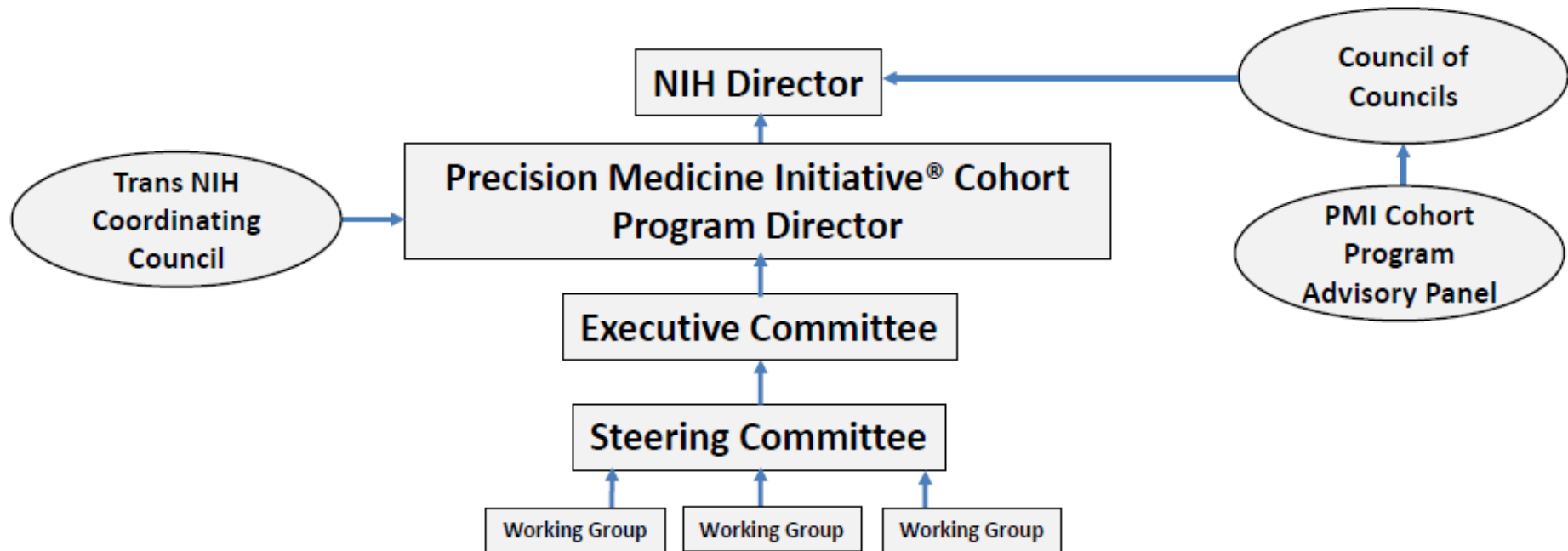
Precision Medicine Initiative[®] Cohort Program

January 14, 2016
12:00-1:30 PM Eastern Time

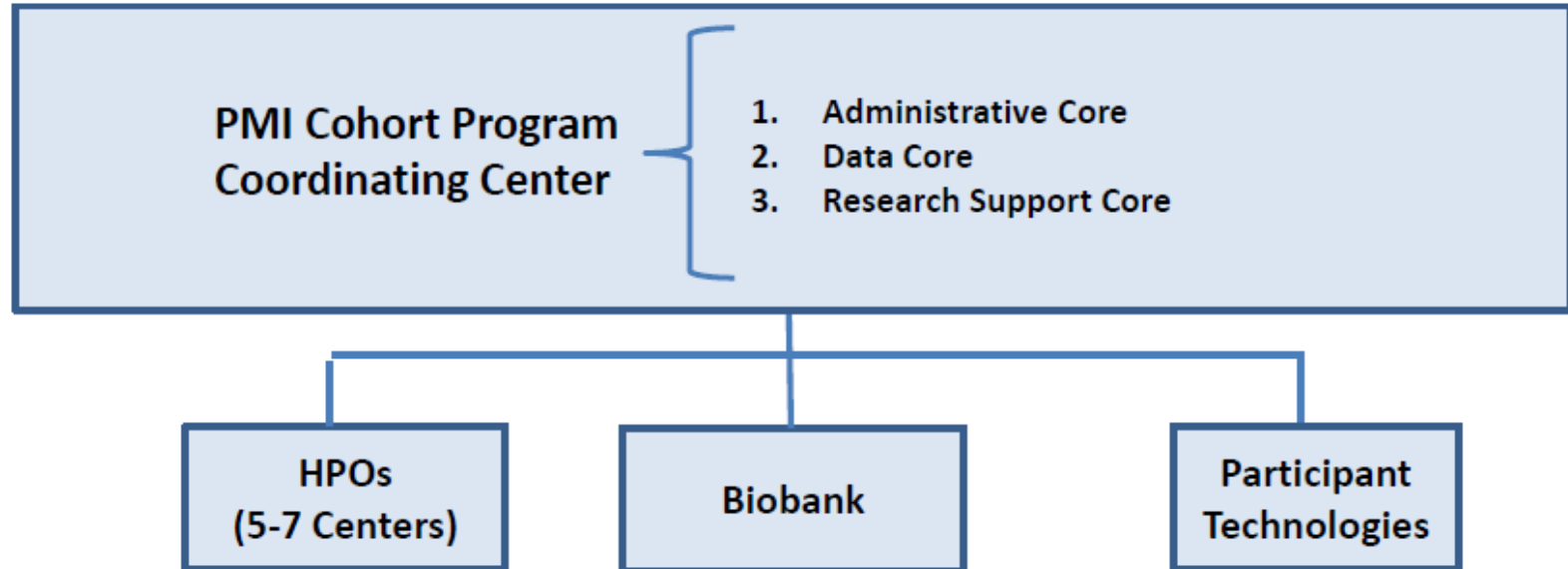
PMI Cohort Program Funding Opportunities

Title / Type	Year 1 \$	Number of awards	Project Period	Application	Award
Direct Volunteers Pilot Studies (OT)	TBD	1	1 yr	December 22, 2015	February 2016
Communication Support for the Precision Medicine Initiative Research Programs (OT)	TBD	1	2 yrs	December 22, 2015	February 2016
PMI Cohort Program Biobank (U24)	\$15 M	1	5 yrs	February 4, 2016	June 2016
PMI Cohort Program Coordinating Center (U2C)	\$21 M	1	5 yrs	February 17, 2016	July 2016
PMI Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3)	\$28 M	≤7	5 yrs	February 17, 2016	July 2016
PMI Cohort Program Participant Technologies Center (U24)	\$8 M	1	5 yrs	February 17, 2016	July 2016

Precision Medicine Initiative[®] Cohort Program Governance



Coordinating Center (U2C)



Coordinating Center: Administrative Core

- **Scientific & Administrative Leadership**
 - Ensure effective transition from pilot phase
 - Coordinate consortia-wide process for development of the baseline protocol and subsequent core protocol additions
 - Coordinate and monitor baseline protocol implementation
 - Provide consortium-wide logistical support
 - Co-chair Steering and Executive Committees
 - Monitor enrollment, retention, and tracking of data submissions from both DV and HPO participants
 - **Monitor diversity across the Cohort**
- **Direct Volunteer Operations**
 - Point-of-contact for direct volunteers
 - Schedule & track biospecimens and physical evaluations
- **Healthcare Provider Organization (HPO)-related Operations**
 - Ensure effective protocol implementation and consistent patient engagement strategies

Coordinating Center: Data Core

■ General Functions

- Develop & maintain all shared scientific and management data resources for the cohort
- Develop and oversee implementation of a common data model
- Establish standards and implement processes for federated data resources, such as legacy HPO health care data
- Establish and implement standards for RUID, consent preferences, self-report, clinical & biospecimen data, return of results
- Oversee all aspects of data security
- Oversee all steps necessary to protect the privacy of participant data

■ Health IT Specific Operations

- Provide effective interfaces that facilitate integration of data from health IT records both from HPOs and from DV (Blue Button) records

Coordinating Center: Research Support Core

- Establish and oversee secure computing environment
- Define analytical capabilities for data core
- Develop software tools & algorithms for datasets
- Provide all needed researcher-focused services
- PoC for all users at all levels of sophistication to design and implement studies using the PMI Cohort Program datasets and technical issues
- Provide interface to future –omics lab services
- Oversee the development, analysis and quality assessment of cohort-wide lab analysis

Healthcare Provider Organization Enrollment Centers (UG3/UH3)

- Establish structures to enroll participants, meeting diversity targets
- Establish effective local participant engagement, monitor participant enrollment and retention
 - UG3: >10K expected enrollees
 - UH3: >35K expected enrollees/yr
- Conduct baseline physical evaluation on all enrolled participants
- Collect baseline biospecimens on all enrolled participants. Legacy biospecimens will not be used.
- Establish methods to capture complete health care information of all enrolled participants, both ongoing and when possible legacy data.
- Develop methods to transmit health care information to CC in standardized format, meeting interoperability standards across the consortium
 - Standards for EHR capture and representation of family health history
 - SNOMED CT and HL7 Version 3

Federally Qualified Health Center (FQHC)

- Pilot enrollment through FQHCs
- Enhances a focus on underserved populations
 - FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act (PHS)
 - FQHCs must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors
 - Certain tribal organizations and FQHC Look-Alikes (an organization that meets PHS Section 330 eligibility requirements, but does not receive grant funding) also may receive special Medicare and Medicaid reimbursement

Participant Technologies Center (U24)

- Develop, upgrade mobile applications developed in pilot phase for DV enrollment, supporting their use for entire cohort
- Provide parallel platforms for non-smartphone users (e.g., feature phones, web site)
- Provide scientific leadership and technical expertise for use of mHEALTH technologies across the cohort
 - Develop, pilot and implement use across the cohort of data acquisition from a wide array of potential participant technologies,
 - Devices should include participants own devices, novel sensors and wearable devices
- Test emerging technologies for study deployment, validate, and co-calibrate emerging technologies with existing technologies to ensure continuity of trend data over time

Biobank (U24)

- Provide biospecimen collection kits and mailers
- Receive, process, store, and distribute:
 - Phase 1: receive saliva or blood
 - Phase 2: plasma, serum, RBCs, buffy coats, urine, DNA
- Establish automation of specimen aliquoting, DNA extraction initially; Transition to automated specimen retrieval systems, when it is cost effective
- Set up information systems for sample tracking, coordinating RUIDs with CC as well as other PMI Cohort Program sites
- Establish robust QA and QC, CLIA processes

Other Transaction Authority

Pilot Phase
Systems & Services

Communications & Public
Relations

Direct Volunteers Pilot Studies (OT)

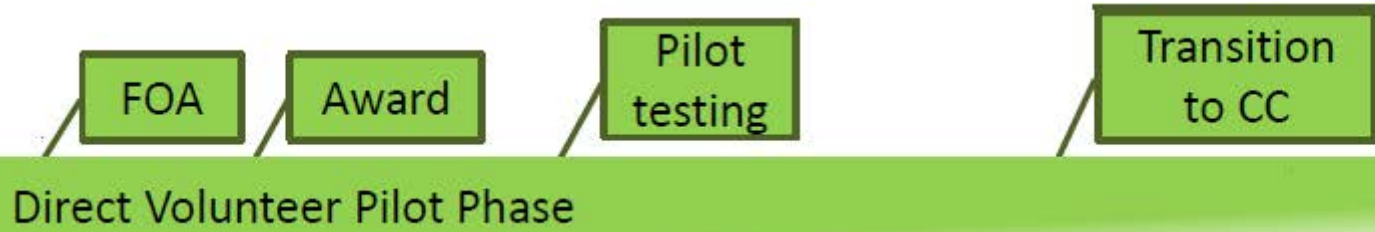
- Develop and test innovative methods and technologies for data collection and management, and participant engagement.
 - Website to engage potential volunteers
 - Participant interface optimized to keep participants engaged and return information
 - Data structures ensure the secure collection and sharing
 - Approaches for biospecimen collection

Communication Support (OT)

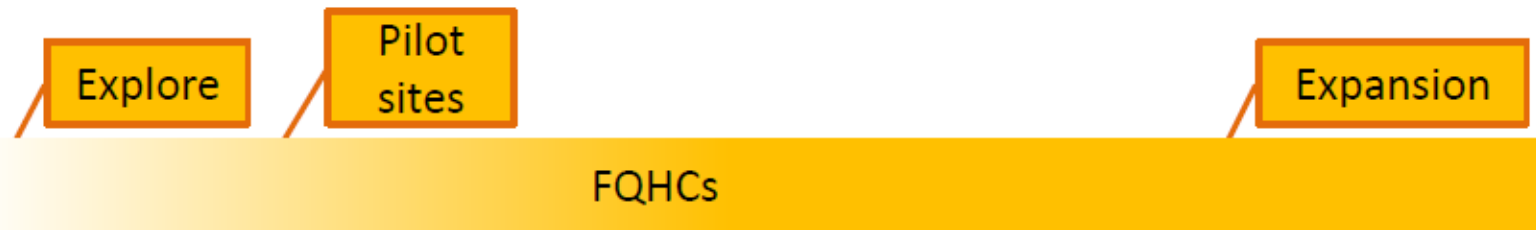
- Support communication efforts for the PMI research programs at NIH, with particular emphasis on the PMI Cohort Program:
 - Communications planning, message and visual identity development
 - Collection and analysis of evaluation metrics.
 - Outreach through a variety of strategies and platforms

Timeline

2016



HPOs, Biobank, Participant Technologies



PMI Cohort Program Information

Email address for questions related to PMI Cohort Program FOAs:

PMICPFOAInquiries@mail.nih.gov

Link to FAQs on the PMI Cohort Program Website:

<https://allofus.nih.gov/other-transaction-awards-faq>