

Pre-Application Technical Assistance Webinar

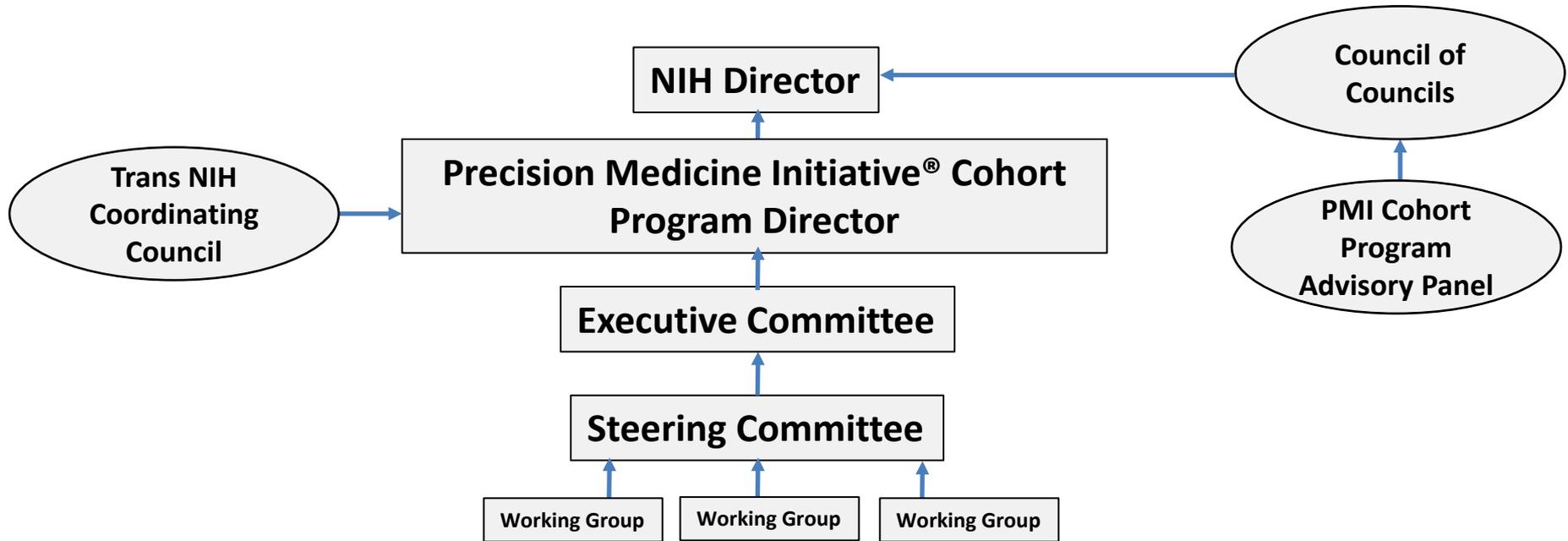
Precision Medicine Initiative[®] Cohort Program

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

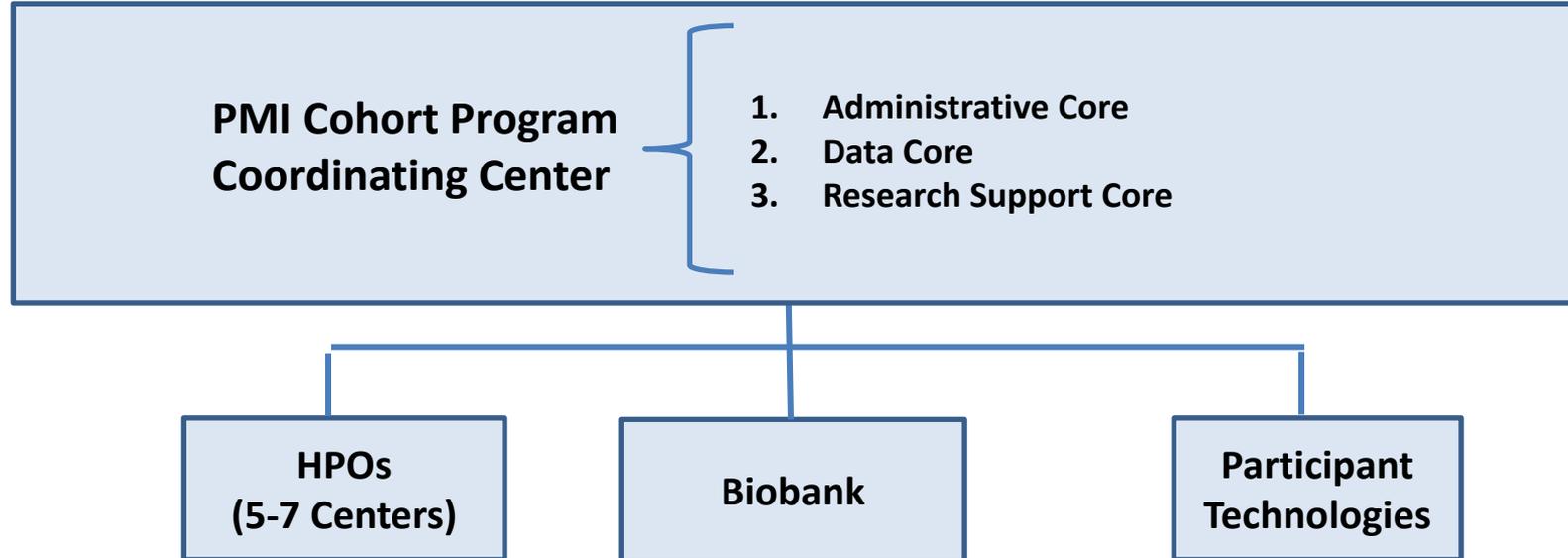
PMI Cohort Program Funding Opportunities

| 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

Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

FOA

Award

Pilot testing

Transition to CC

Direct Volunteer Pilot Phase

FOAs

Applications

Awards

Integrate DV Pilot

Coordinating Center

HPOs, Biobank, Participant Technologies

Explore

Pilot sites

Expansion

FQHCs

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:

[http://www.nih.gov/precision-medicine-initiative-cohort-program/frequently-asked-questions-grants.](http://www.nih.gov/precision-medicine-initiative-cohort-program/frequently-asked-questions-grants)