

Board of Governors Meeting via Teleconference/Webinar

June 20, 2017

12:00 pm - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Gray Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:10	Consider for Approval: Consent Agenda • Minutes of the May 8, 2017 Board Meeting • CTAP and RDAP Charter Revisions
12:10-12:40	Consider for Approval: PCORnet Research PFA
12:40-1:10	Open Science Update
1:10	Wrap up and Adjournment

Welcome to PCORI's Newest Board Member

- We are honored to welcome a new Board member
 - Gopal Khanna, MBA,
Director, Agency for
Healthcare Research and
Quality



Consent Agenda Items

Gray Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director



Motion for Consent Agenda Items

That the Board approve:

- Minutes from May 8, 2017 Board meeting
- Proposed amended Charters for the following PCORI Advisory Panels:
 - Advisory Panel on Clinical Trials (CTAP)
 - Advisory Panel on Rare Disease (RDAP)



Board Vote

Call for a Motion to:

- **Approve** each of the Motions on the Consent Agenda

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Voice Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



Developing Collaborative Research Funding Opportunities within PCORnet

Proposal for a PCORI Funding Announcement (PFA) Targeted to PCORnet and Funding Partners

Joe Selby, MD, MPH
Executive Director



FY17 Budget – for Research in PCORnet

Budget Line	Total FY17 Approved	Committed	Request	Remaining
Research	up to \$37.0 M	\$7.0 M	\$21.0 M	\$9.0 M
Infrastructure (capacity building)	up to \$34.2 M	\$34.2 M	\$0.0 M	\$0.0 M



Emphases on Collaboration and Linkage through Research

- The purpose of this research funding announcement is to answer important patient and stakeholder-driven clinical effectiveness research (CER) questions that remain unanswered due to insufficient or inconclusive evidence
- This research funding announcement emphasizes the necessity of funder collaborations and data linkage for PCORnet sustainability
- This is the next step in PCORI's strategy to achieve the Board's vision of a sustainable national research infrastructure that attracts a diverse set of public and private research funders



Scope of this Funding Announcement

- Limited-Competition Funding Announcement
 - PCORI will invite only Patient-Powered Research Networks (PPRNs) to submit Letters of Intent (LOIs)
- Applicants will be required to secure **partner funding (may include in-kind)** from **industry and/or organization** collaborators prior to submitting full application
 - Preference will be given to applicants who secure at least 20% of total research project costs from partner funding
- Applications must address stakeholder-driven topics within our national priority areas with a CER question related to a rare or common condition



Scope of this Funding Announcement (Cont.)

- Requirements
 - Strong, convincing letters of support from collaborating funders
 - Linkages between patient data and EHR/clinical data (CDRNs) or with data from a disease-specific registry
- PCORI will fund up to 5 individual research projects over 3 years
 - Direct costs (per research project): up to \$5 million
 - Direct costs (for the initiative): up to \$15 million
 - Total costs (for the initiative): up to \$21 million



Tentative Timeline

- ✓ May: RTC endorsement (May 9, 2017)
- ✓ June: SOC endorsement (June 9, 2017)
- June: Limited PFA presented to the PCORI Board of Governors for consideration
- June: Pre-announcement posted
- July: Limited PFA released
- September: LOIs due
- December: Applications due
- January 2018: Merit Review
- February/March: Selection Committee
- March: Present proposed slate of research projects to the Board of Governors for consideration
- May: Earliest research project start date



Board Vote

Call for a Motion to:

- **Approve** the development of a limited PFA for collaborative research within PCORnet, not to exceed \$21 million in total costs

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose **Amendment** to the Motion or an **Alternative Motion**

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Open Science Update

Parag Aggarwal, PhD

Senior Program Officer

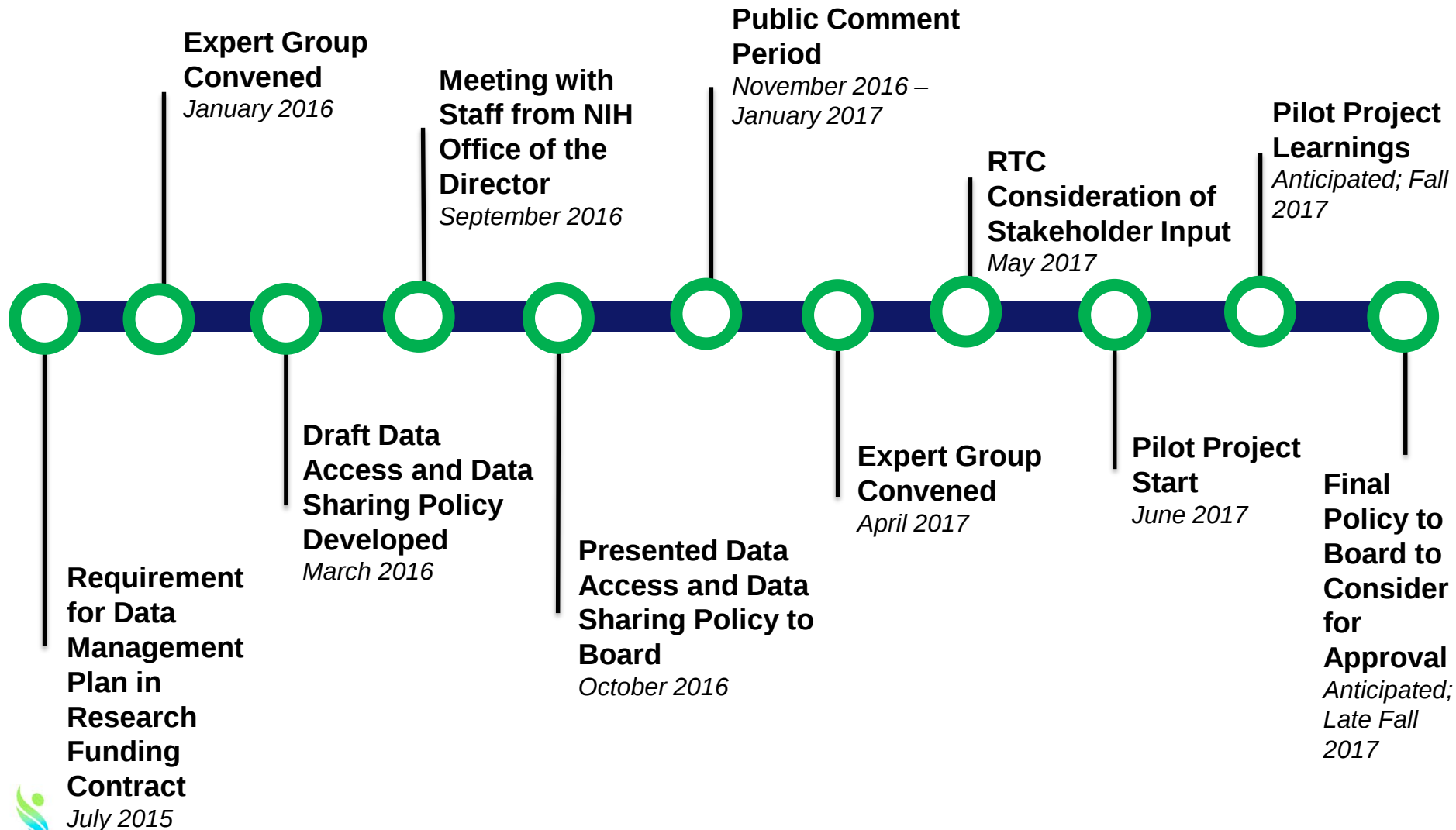


PCORI's Open Science Initiative

- **Process for Peer Review of Primary Research and Public Release of Research Findings**
(Approved by the Board February 2015)
- **Public Access to Journal Articles Presenting Findings from PCORI-Funded Research Policy**
(Approved by the Board April 2016)
- **Policy for Data Access and Data Sharing**
(Draft first presented to the Board October 2016)



Timeline of Data Sharing Initiative



Pilot Data Sharing Initiative

Objective: To assess operational challenges of implementing a data sharing requirement and generate learnings to further inform refinement and finalization of the Policy

PCORI Awardees:

- Six awardees have been selected: Three completed studies from the Broad PFAs and three ongoing pragmatic clinical studies
- Awardees were selected to represent a diversity of therapeutic areas, study designs (both observational and RCTs) and data sources (EHR, claims data, imaging data)

Data Repositories:

- Multi-Regional Clinical Trials (MRCT) Center, Brigham and Women's Hospital
- Inter-university Consortium for Political and Social Research (ICPSR) at the University of Michigan



Policy for Data Access and Data Sharing: Public Comment Period

- Public comment period: Obtained input from various stakeholders about strengths and limitations of initial draft Policy
 - 32 responses from November 1, 2016 – January 23, 2017
 - Additional input from NIH Office of the Director staff members
- Reconvened expert advisory group to discuss comments
- Areas of consensus:
 - Enthusiasm for PCORI to support data sharing (both deposit and maintenance of data and data documentation)
 - Universal support for prohibition on re-identification of data
 - Broad consensus that requests for data must include clear scientific purpose; data will be used to create or enhance generalizable scientific knowledge



Summary of Key Issues

- **Issue 1:** Restrictions on data use
- **Issue 2:** Requestor qualifications and Required documentation
- **Issue 3:** Informed consent
- **Issue 4:** Applicability to studies using EHR and other health systems data



Issue 1: Restrictions on Data Use

Public Comments/ Workgroup Comments

- PCORI should evaluate potential types of data uses
 - There are challenges with being overly prescriptive regarding permitted uses in the Policy

RTC Recommendations

- Explicitly prohibit re-identification of data in the Policy
- Adhering to principle of transparency is paramount regardless of purpose for which data is used



Issue 2a: Requestor Qualifications

Public Comments/ Workgroup Comments

- Determine whether Policy should specify certain education level or scientific expertise requirements
- There are challenges with imposing team qualifications rather than specific individual credentials

RTC Recommendations

- Include general qualifications for teams
- Indicate technical assistance will not be provided by PCORI or by primary study investigators



Issue 2b: Required Documentation

Public Comments/ Workgroup Comments

Policy should consider minimum documentation requirements for data requestors including:

- Scientific purpose
- Assurance that data requested will be used to enhance scientific knowledge
- Assurance that proposed research can be addressed using requested data

RTC Recommendations

- Concur with minimum requirements gathered from stakeholder input.

Additionally,

- Provide assurance data will not be re-distributed
- Ensure all findings and associated data will be shared with PCORI



Issue 3: Informed Consent

Draft Policy requires:

“Appropriate documentation of patient consent that permits data collected as part of the study to be de-identified, used for future research purposes and shared broadly with researchers not affiliated with the institution conducting the study.” (Section IV.B.1.d)

Public Comments/ Workgroup Comments

- There are challenges with data sharing if primary study:
 - Had insufficiently broad informed consent; or
 - Was conducted based on waiver of informed consent

RTC Recommendations

- Studies that do not satisfy the general consent requirement may require additional review
- Specify that the Policy pertains to data that have been de-identified in accordance with HIPAA



Issue 4: Applicability to studies using EHR and other health systems data

Public Comments/ Workgroup Comments

- There may be strict prohibitions on data sharing due to contractual and legal obligations that attach to health system data (e.g., EHR and claims data)
- There is potential value in sharing the research queries used to generate study datasets even when data cannot be shared

RTC Recommendations

- Require query codes and parameters to be made available when underlying data cannot be shared
- Studies that involve health system data may require additional review
- For future projects, consider availability of data for secondary uses at the funding stage



Wrap Up and Adjournment

Gray Norquist, MD, MSPH

Chairperson, Board of Directors

