

Board of Governors Meeting via Teleconference/Webinar

February 23, 2016
12:00-1:00 p.m. ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00 – 12:05 p.m.	Call to Order, Roll Call, and Welcome Consider for Approval: Minutes of the January 26, 2016 Board meeting
12:05 – 12:30	Consider for Approval: FY2015 Audit Report
12:30 – 12:55	Consider for Approval: Phase II Funding for the PCORnet Coordinating Center
12:55 – 1:00 p.m.	Wrap up and Adjournment



Board Vote

Call for a Motion to:

- **Approve** the minutes of the January 26, 2016 Board of Governors meeting

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



Thank you, Drs. Schneeweiss and Yancy

PCORI thanks the following Methodology Committee members for their significant contributions to PCORI and the healthcare community since they began their service in January 2011.

We wish them well in their future endeavors.



Sebastian Schneeweiss, MD, ScD



Clyde Yancy, MD



Accept FY2015 Independent Auditor's Report

Kerry Barnett, JD

Chair, Governance Committee and Vice Chairperson of the Board

Thomas J. Sneeringer, CPA

Partner, RSM (formerly known as McGladrey)

Regina Yan, MA

Chief Operating Officer



FY 2015 Independent Auditor's Report

PCORI received an unmodified opinion; the financial statements presented fairly, in all material respects, the financial position, the results of operations, and its cash flows

- There are no findings related to deficiencies in internal control over financial reporting
- There are no findings related to compliance or other matters



Statement of Activities

Statement of Activities	FY 2015	FY 2014
Revenue	\$423,066,941	\$425,889,688
Expenses	\$276,958,845	\$161,862,176
Change in Net Assets	\$146,108,096	\$264,027,512



Statement of Financial Position

Statement of Financial Position	FY 2015	FY 2014
Assets	\$835,237,427	\$646,762,631
Liabilities	\$ 87,475,850	\$ 45,109,150
Net Assets	\$747,761,577	\$601,653,481



Board Vote

Call for a Motion to:

- **Accept** the FY2015 Audit Report

Call for the Motion
to Be Seconded:

- **Second** the Motion
- If further discussion, may propose an **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



PCORnet Coordinating Center Phase II Funding

Contract Approvals for Phase II Coordinating Center Activities

Rachael Fleurence, PhD

Program Director, CER Infrastructure

Joe Selby, MD, MPH

Executive Director



PCORnet Successes: Infrastructure Readiness

- Governance framework in place with patient leadership for PCORnet and at the CDRN and PPRN level
- 130 Health Systems involved across the country
- 75 Million patients' data in the Common Data Model with strong privacy protections
- 50 PCORnet DataMarts will launch in the Summer of 2016
- Early linkages between EHR and health claims data underway
- 3 cohorts developed at each CDRN:
 - Weight/Obesity Cohort;
 - Common Conditions (e.g., Coronary heart disease, heart failure, cancer, diabetes)
 - Rare Conditions (e.g., sickle cell disease, Duchenne's muscular dystrophy, congenital heart disease)
- Streamlined contracting and IRB underway across PCORnet institutions
- Common Data Sharing agreement across CDRNs under development
- PCORnet Commons to launch in July 2016



PCORnet Successes: Research Readiness

- PCORnet Front Door to open on April 5, 2016 to formally collect inquiries to use PCORnet
- PCORnet's first pragmatic trial ADAPTABLE will begin recruitment in March 2016
- Two large observational studies using the PCORnet distributed research network have launched:
 - Comparison of different bariatric surgery procedures
 - Comparison of antibiotic regimens in children
- First PCORnet distributed "queries" are underway
- PPRN demonstration projects (to be awarded in March) will build and share common tools and resources across PCORnet



Coordinating Center Context

- In Phase I, PCORnet had two Coordinating Center contracts:
 - Harvard Pilgrim Health Care (HPHC) was awarded **\$13,171,034** total costs (October 2013-March 2016)
 - Genetic Alliance was awarded **\$852,541** in total costs for latter part of Phase I (January 2015-March 2016) for PPRN coordination
- In Phase II, there will be two Coordinating Center contracts:
 - Duke Clinical Research Institute (who was main subcontract to HPHC in Phase I)
 - Genetic Alliance
- The Research Transformation Committee endorses funding for both contracts



Coordinating Center (CC) Budget for Phase I (October 2013-March 2016)

Contract Item	Board Approval Date	Total Cost
Original Phase I CC Contract (October 2013-October 2015)	September 2013	8,999,492
Amendment	December 2014	1,527,142
Amendment	March 2015	654,960
Amendment	November 2015	1,989,439
Total Phase I Budget		\$13,171,033



Coordinating Center Phase I Achievements

- **Developed Infrastructure for PCORnet Research Projects**
 - Initiated three multi-site demonstration projects to demonstrate PCORnet's infrastructure and data capabilities
 - Facilitated the inclusion of PCORnet in external proposals such as the NIH-funded INVESTED trial
- **Data Infrastructure Support**
 - Developed and implemented the PCORnet Common Data Model (CDM)
 - Established a functional and secure distributed network with over 80 unique software installations and over 200 users
 - Developing distributed queries to characterized data quality and availability across the network
 - Developing tools to query across the network
 - Developed and tested a complex analytic SAS query describing the "Weight Cohort"
- **Program Management**
 - Supported PCORnet Committees, Work Groups and Task Forces
 - On-boarded networks and provided ongoing support for a total of 13 CDRNs and 22 PPRNs
 - Managed a collaborative online platform
 - Maintained network resources
 - Managed regular best practice sharing sessions to facilitate network collaboration
 - Distributed PCORnet Weekly Announcement to 1,300+ network members
 - Maintained public PCORnet website (pcornet.org)



Coordinating Center Phase II Contract Structure

- Phase II Coordinating Center contract is structured as a master contract with Task Orders to facilitate flexibility as the network needs emerge and develop
- The budget proposed is a maximum budget – PCORI staff are currently negotiating each budget item with Duke and discussing the timing of each Task Order initiation
- Future Coordinating Center activities will be negotiated on an activity-by-activity basis, using the task order set aside system



Coordinating Center Activities Requested for Phase II through November 2018

Task Order	Amount
Base Coordinating Center Personnel	4,056,640
Network Management and Program Management	3,553,557
IRB Simplification	239,230
Dashboard	1,024,954
Quality Improvement Activities	218,132
Front Door	2,398,540
Sustainability Planning	350,000
Program Office Activities SUBTOTAL	\$11,841,054
Data Operations Center	5,335,767
Data Characterization	3,509,733
Analytic Tool Development	1,206,028
Query Fulfillment	2,648,453
Data Research Network SUBTOTAL	\$ 12,699,981
Coordinating Center Phase II SUBTOTAL	\$ 24,541,034
Future Task Order Set Aside	\$ 4,500,000
TOTAL Coordinating Center Phase II	\$ 29,041,034



Examples of Key Product Deliverables for Phase II

- **Network Operations**

- Support streamlined PCORnet contracting and IRB
- Publish PCORnet Dashboard
- Open PCORnet Front Door
- Develop the infrastructure to support conducting 50 Data queries in Year 1
- Support strategic planning and sustainability planning
- Support PCORnet communications and project management

- **Data Infrastructure Implementation**

- Maintain Common Data Model (CDM)
- Develop the infrastructure to support launching 50 fully characterized DataMarts across PCORnet by June 2016
- Develop query distribution system
- Develop the infrastructure to support 3 large multi-site research studies



Board Vote

Call for a Motion to:

- **Approve** \$29 million in total costs for Phase II PCORnet Coordinating Center Activities for Duke Clinical Research Institute

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **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



PPRN Coordinating Center Context

- As previously mentioned, in December 2014, funding was approved for a PPRN focused CC to help advance the progress of the PPRNs
 - Awarded to Genetic Alliance
- Genetic Alliance has been awarded \$852,541 in total funds for this Phase I contract (January 2015-March 2016)
- In January 2016, the RTC endorsed supplemental funding for Genetic Alliance to assume PCORnet Phase II Coordination activities



Genetic Alliance Coordinating Center Budget for Phase I through October 2018

	Board Approval Date	Total Cost
Original Phase I CC Contract (January 2015-September 2015)		324,469
Amendment		4,108
Amendment	November 2015	523,964
Total Phase I Funding (January 2015-February 2016)		\$852,541



Genetic Alliance: Key Deliverables In Phase I

- Supported collaborations and partnerships between PPRNs and CDRNs in Phase II applications
- PPRN demonstration project development
- Collecting and comparing data dictionaries across the PPRNs
- Development of a Common Data Model lay guide
- PPRN EHR report and progress in EHR extraction
- PPRN computable phenotypes project
- mHealth workgroup
- Whiteboard video workgroup
- Patient incentives workgroup



PPRN Coordinating Center Activities: Budget Request for Phase II

Expense Category	Amount
PPRN Coordination	813,113
Network Operations	404,415
Patient and Stakeholder Engagement Activities	719,269
Commons Development	483,574
PPRN Data Standardization	170,669
Total Cost (Direct and Indirect)	\$ 2,591,040



Examples of Key Product Deliverables in Phase II

- **PPRN Coordination**
 - Daily support and communications
 - Overall project management
 - PPRN Flash Workgroups, Engagement Metrics, and EHR extraction
- **Network Operations**
 - Participate in, support and lead Work Groups
 - Support PCORnet Commons' aim within the PPRN Demonstration Projects
- **Network Engagement**
 - Engagement Committee support
 - Public Trustworthiness meeting leadership
- **Commons Development**
 - Assess, choose, build, and curate the PCORnet Commons
- **PPRN Data Standardization**
 - Data and Technical Support
 - CDM Summary
 - mHealth reports



Board Vote

Call for a Motion to:

- **Approve** \$2.59 million in total costs for Phase II PCORnet Coordinating Center Activities for Genetic Alliance

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **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



Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Directors

