PCORnet Data Committee Charter

I. PURPOSE

The PCORnet Data Committee (PDC) is charged by the PCORnet Council is to oversee PCORnet's data network, which is managed by the PCORnet Coordinating Center. The PDC will provide strategic guidance that ensures the data network is aligned with PCORI's overall goals and that the data network provides the semantic and syntactic interoperability to support PCORnet studies and sustainability. The PDC is also charged with stimulating informatics and research data innovations that advance the goals of PCORnet. (Section 1.1.6 PCORnet Governance Policy).

II. GUIDING PRINCIPLES: EFFICIENCY, TRANSPARENCY, INTER-OPERABILITY, INCLUSIVE, AND SECURITY

PCORnet's goal is to improve our nation's capacity to efficiently conduct patient-centered, comparative effectiveness research and clinical studies by creating a highly representative network to conduct clinical outcomes research. The PDC will focus on defining the processes and governance needed to ensure the quantity (e.g. content, structure, and domains represented) and quality of the data (e.g., reliability, validity, reproducibility) held by the network partners is sufficient to meet the needs of the PCORnet studies, and that it follows the principles of efficiency (e.g. network and infrastructure capacity to use data resources), interoperability (e.g., ability to exchange data easily), transparency, reproducibility (open-source and publicly available source code and results), security (respect patient data and privacy, protection of data from inappropriate use), and inclusivity of stakeholders (e.g. patients, family, clinicians, healthcare systems, researchers, industry) in fulfilling its mission.

III. AIMS

1-Year Aim (Efficiency): By the end of 2016, PCORnet will have established easily accessible, high quality, and legally compliant data system(s) for developing and conducting new PCORnet studies. These studies will benefit in their start-up, data collection, and analysis phases from the PCORnet data network. (Strategic Goal 1: Research throughput)

3-Year Aim (Impact): By the end of 2018, PCORnet research will have demonstrated its value to patients, clinicians, health system leaders, and sponsors. Studies done using PCORnet will be of high value due in part to the PCORnet data infrastructure. (Strategic Goals 2&3: Sustainability and Transformative Research Model)

IV. APPOINTMENT, COMPENSATION, AND TERM OF COMMITTEE MEMBERS

This Committee of the PCORnet Council will be composed of a Chair and up to 10 members drawn from the voting members of the PCORnet Council or their designees. Two members must be participants/patients/caregivers. Committee members will be appointed to a 3-year term and can be re-elected for one additional term. In establishing the first committee slate, the individuals will be assigned staggered term limits (3 years and 2 years) as shown in the table below. Term length (2 or 3 year terms) for committee members appointed in 1/2016 will be determined voluntarily by each committee member; or alternatively by random assignment.

Positions (# individuals)	Term	Current term
Chair (1)	2 years	12/2015-11/2017
Committee Members (3) (eligible for 2 year renewal)	2 years	1/2016-12/2017 (1/2018-12/2019)
Committee Members (3) (eligible for 3 year renewal)	2 years	1/2016-12/2017 (1/2018-12/2020)
Committee Members (4)	3 years	1/2016-12/2018 (1/2019-12/2021)

IV.A Appointment of Chair

The Chair will be elected per the process described in the PCORnet Governance Policy. These are elected for a two-year term per the PCORnet Governance Policy.

IV.B Compensation

The committee members, including the chair, will be compensated for their service. The exact compensation will be determined each year.

Inaugural membership:

Russ Waitman (chair, CDRN: GPC)

Ravi Bhosale (CDRN: OneFlorida)

Bowen Chung (PPRN: Community and Patient-Partnered Centers of Excellence)

Rachel Hess (CDRN: PaTH)

Approved by Executive Committee: [04/08/2016]

Michael Kahn (CDRN: PORTAL, PEDSnet)

Abel Kho (CDRN: CAPriCORN)

Keith Marsolo (PPRN: ICN)

Michael Matheny (CDRN: pSCANNER, MidSouth)

Daniella Meeker (CDRN: pSCANNER)

Shawn Murphy (CDRN: SCILHS)

Heather Siefers (PPRN: MS-PPRN)

Non voting:

Lesley Curtis (Coordinating Center representative)

Administrative Coordination: Primary: Grace Kelso, PCORI, Secondary: Rachel Rath, PCORI (with transition to Coordinating Center planned)

Project Leader: Shelley Rusincovitch (Coordinating Center)

Workgroups members. Workgroups will be created as required to accomplish PCORnet objectives and attendance and communication expanded to include additional members from PCORnet.

Overtime, we anticipate inviting other non-voting liaisons to participate in committee or workgroup activities. (eg. Office of the National Coordinator for Health Information Technology: ONC)

V. MEETING SCHEDULE AND FREQUENCY

The PCORnet Data Committee will meet every other week to every month by webinar with additional subcommittees meetings as needed for specific work products.

The committee will have 2 in-person meetings per year. Ideally these meetings will overlap with those of the other PCORnet Committees and / or the PCORnet annual meeting and be located to minimize travel burden.

Committee members and project management staff will conduct correspondence via email and archive email correspondence via a listserv mailing list (currently data.pcornet@listserv.kumc.edu) To promote transparency and relevance the listserv will be publically available for review (http://listserv.kumc.edu/pipermail/data.pcornet/).

VI. SCOPE

This section describes the scope for PDC in 2016. At the end of this period, the Committee will reevaluate its scope and develop new objectives, as necessary, for its work. The time frame was chosen to evaluate progress against the initial objectives and as the interaction of the PDC with the Distributed Research Network Operations Center (DRN OC) is evolving.

The principle function of the PDC will be to recommend to the EC and to the PCORnet Council the strategy going forward that will be most productive for PCORI to achieve its overall data goals. The PDC may suggest strategic corrections that should be made so that the widest possible set of PCORI goals can be achieved. Consistent with the PCORnet governance policy, all PCORnet policies are subject to approval by PCORI.

VI.A. *Charter*
A PDC Charter will be a living charter to be reviewed and revised at a minimum annually.

Deliverable:
- Final Charter Draft
- Approved by PCORnet Executive Committee
- Vote by PCORnet Council

VI.B. *Assess Current Data Strategy Implementation Approach.*
The PCORnet Executive Committee Chair has tasked a subset of the PCORnet Executive Committee and PDC to assess the current progress on the implementation of the PCORnet data strategy implementation approach (i.e. capability of data resources and infrastructure). This group will assess the strategy and timeliness, and recommend mitigation strategies, if necessary.

Deliverable: February through March 2016
Summary report on current PCORnet data strategy:
1. Evaluation of research readiness (readiness of data marts, support of prep-to-research, descriptive statistics, support of demonstration projects)
2. Evaluation of operational structure and data governance
3. Evaluation of affordability and scalability
4. Risk mitigation strategies

Data committee will provide preliminary feedback and participate in additional work activities organized by PCORnet such as the design day in Spring 2016.

VI.C. Support efficient use of the PCORnet data network

In collaboration with the PCORnet Coordinating Center (and its Distributed Research Network Operations Center) and the Research Committee Front Door Working Group, a PDC working group will 1) specify, review, and oversee processes for requesting access to the Distributed Research Network (DRN) query tool; and 2) monitor and assess the PopMedNet (PMN) Query tool usage.

Metric / Deliverable:

Deliverable: work collaboratively with the Coordinating Center to define process and standard operating procedures for requesting access to DRN query tool and metrics (with definitions).

Procedural Metrics:

- Number of requests
- Number of approved requests/number of rejections
- Time to approval/rejection
- Number of queries distributed through PMN
- Number of responses received
- Average response time

Strategic Metrics:

The Data Committee will work collaboratively with the Research Committee and Coordinating Center to develop processes that allow PCORnet to evaluate the strategic impact of the DRN by tying procedural metrics to impactful scientific translations (publications, grants/contracts, other dissemination methods).

VI.D PCORnet IRB System Implementation

The PDC will select a single member to serve as its liaison to the IRB implementation working group. The PDC IRB representative will communicate strategic guidance from the PDC and present options for and feasibility of activities such as data processing / obfuscation / de-identification given legal restrictions on data use and institutional data requirements.

VI.E PCORnet Data Sharing Agreement

The PDC will launch a working group to develop a reciprocal data sharing agreement for PCORnet's institutional partners to achieve PCORnet objectives, maximize sustainability by matching customer expectations, and advance comparative effectiveness research while respecting institutional constraints and allowing trust to develop over time.

Deliverable:

- Initial PCORnet Institutional Data Sharing Agreement supporting non-commercial use that supports feasibility analyses, distributed analyses, and transmission of de-identified and limited datasets by June 2016 for current PCORnet institutions.
- A method for institutions to transparently share their institutional data sharing profile/constraints with collaborators by August 2016.
- Timing of later modifications to support external partners, commercial use, and data exchange in collaboration with the Health Plan Payor linkage contracts to be determined.

Metrics:

- Institutions signing the agreement and specifying their data sharing profile allowing them to operate within their institutional boundaries
- Data requests, approvals, and timeliness of fulfillment analogous to VI.C.

VI.F Data Infrastructure Software Development Environment (DISDE)

A PDC work group will determine how best to

- place data infrastructure assets like programming code and agreements and data structure / domains so they are publicly available, and serve the needs of PCORnet.
- Specify open source licenses appropriate for generating PCORnet work products
- Provide an environment and establish processes for software development and issues tracking across the networks and the coordinating center

Deliverable:

- Recommendations for the DISDE by April 2016
- Established DISDE by May 2016

Metrics:

- Projects hosted in or linked to the DISDE
- Issues logged
- Software commits and downloads

VI.G: Monitor Data Quality of the Distributed Research Network (DRN)

A data quality working group will be created to define the processes and governance necessary to monitor the quality of the data in the network. This may include approval of proposed data quality metrics proposed by the Coordinating Center, recommendations for new or modified metrics, and/or a proposal for the Data Community to propose new metrics and approaches to assessing data quality (eg. general and analysis-specific; pragmatic frameworks for EHRs).

Deliverable:

Process and governance for proposing, defining, approving, monitoring data quality metrics by August 2016.

Metrics:

- Approved general quality metrics for DRN and data infrastructure as a whole
- Study-specific quality metrics

VI.H: Develop annual updates of the Common Data Model

In collaboration with the Coordinating Center, create the processes and governance that will be used to specify annual updates to information model and domains that are instantiated in the Common Data model, which may include optional modules or new domains. These proposals will be presented to the Council for approval. Included in this process will be the factors used to evaluate whether to include a domain (e.g., effort needed to acquire data, analytic value, ability to standardize, etc.), the updates' cost/sustainability, and methods to gather input and evaluate work from external stakeholders (e.g. NIH/CTSA, FDA, HHS ONC, ODHSI, patients / families, healthcare systems, insurers, medical device, and pharmaceutical companies). The PDC will also be responsible for developing the governance needed to surface and harmonize CDM implementation decisions by individual institutions or networks, with the goal of facilitating high-quality, reproducible research. These efforts will ensure that the structure of the data model continues to serve the purpose of PCORnet and allows the most efficient conduct of research.

Using the criteria developed above, in the first 6-months, the PDC will survey the domains representing in the CDM and, in collaboration with the research committee, identify high value domains for inclusion in the PCORnet CDM. The PDC will also assess the initial adequacy of the PCORnet CDM structure to support the Obesity observational studies and ADAPTABLE study. Based on this assessment, the PDC will make

recommendations to DRNOC and the PCORnet council regarding further development or modification of the PCORnet data infrastructure.

Deliverables:
- Process / governance to develop and process annual updates to CDM
- An overall report of ability of CDM to meet needs of Obesity studies and ADAPTABLE will be provided at the end of 12 months.

VI.I: Foster innovation in the PCORnet Data Community

In accordance with the strategic oversight that the PDC will provide, the innovations of the Data Community of CDRNs and PPRNs will be assessed and possible contributions understood and prioritized. In general, proposed innovations will have been demonstrated on actual data in service of a meritorious research activity. If the contributions from the Data Community are thought to be of adequate merit and contribute to the overall goals of PCORnet, then the PDC may encourage further testing through pilot programs. The funding for these pilot programs may be pursued directly with the PCORnet Council and PCORI. The PDC will develop the processes and governance to solicit, assess and evaluate these contributions.

Deliverables: Processes and governance to solicit, assess and evaluate these contributions with date to be determined.

Metrics (examples):
- Number of submissions from the community
- Number funded by PCORnet
- Number of contributions added to the main model

VI.J Data Security and Privacy

The vision of a national patient-centered clinical research network for conducting CER relies on the support and trust of individual patients, of the clinicians and healthcare systems participating in and providing data to the network, and of the public. To realize this vision a working group will be created to promote practices, with respect to data acquisition, linkage, storage, analysis, and transmission that are directed toward protecting the security and confidentiality of individual-level clinical data.

Deliverables: Processes and standards for preserving patient privacy such as de-identification standards (eg. Safe Harbor), responding a to data breach, privacy

preserving record linkage, and recommendations for information security methods such as penetration testing are shared and disseminated.

Metrics (examples):
- Studies performed that use distributed analysis or de-identified data analysis instead of requiring patient identifiers from the networks and patients
- Queries rejected by data marts due to privacy constraints at their institution. Note; the term data mart refers to the data held at an institution (CDRN, PPRN, or a site within a CDRN/PPRN) that is accessed by PCORnet.
- Number of networks and data marts using shared policies, procedures, and methods
- Number of data marts and infrastructure components utilizing common approaches to data security and privacy

VII. CRITERIA FOR SUCCESS

The primary measure of success for the PDC will be successful achievement of deliverables and metrics provided above. Eventual goals are that the PCORnet data is high quality and relevant; easily, inexpensively, and securely query-able; the data infrastructure is reliable and consistent across network sites; that PCORnet data are relevant and reflective of the needs of stakeholders such as patients, family members, clinicians, insurers, healthcare systems, medical device / pharmaceutical industry.

VIII. VOTING

The PDC will seek consensus. However, at the discretion of the PDC Chair, certain matters or recommendations will be put to a vote. When voting is necessary, it will require the presence of a quorum, which will consist of a majority of voting PDC members and the Chair. Votes of the PDC require a majority vote of the voting members who are present at a meeting where a quorum has been established.

IX. CHARTER UPDATES

Each June, the PDC will produce the subsequent calendar year's charter, which will be reviewed and approved by the Executive Committee and Council.

X. TIMELINE

Date	Milestone	Status
Dec 2015	Present slate of members to EC for review	Done
Dec 2015	Present slate of members to Council for approval.	Done
Jan 2016	Obtain input from Council on the Committee Charter.	Active
Jan 2016	Data Meeting 1601	Done
Jan 2016	Distribute draft Charter for PRC input.	Active
Feb 2016	Executive Committee review and approval of Charter	
Feb 2016	Council review and approval of Charter	
Feb 2016	Data Meeting 1602:	Done
Feb 2016	Summary of Data Strategy Assessment	Done
Feb 2016		
	Additional milestones to be completed once management plans are finalized	