PCORnet Obesity Observational Research Initiative

Evaluation Plan

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March 31, 2016

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1 INTRODUCTION

The PCORnet Obesity Observational Research Initiative was developed and funded by PCORI to investigate two special interest topics: (1) Short- and Long-Term Outcomes related to Bariatric Surgery (Bariatric Study), and (2) Long-Term Effects of Antibiotics on Childhood Growth (Antibiotics Study). The objectives of these PCORnet demonstration projects include the following:

1) Support research on important unanswered clinical questions faced by patients and their clinicians using PCORnet's Distributed Data Research Network (DRN) and associated processes and programs;
2) Formally test and evaluate the capacity of PCORnet's data infrastructure and the functionalities of the PCORnet Distributed Research Network, and report on the readiness of PCORnet's data infrastructure for observational research;
3) Provide an early opportunity for Clinical Data Research Network (CDRN) and Patient-Powered Research Network (PPRN) investigators, patients, and stakeholders to organize and collaborate in a multisite study and develop an efficient, collaborative processes for doing so.

Dr. John Holmes (University of Pennsylvania) and team at Harvard Pilgrim Health Care Institute (Brie Purcell, MPH, and Beth Syat, MPH) will lead the evaluation of demonstration project activities, report on the solutions implemented to resolve technical issues, and lead the evaluation of the functionality of the network. The evaluation will be conducted in three phases:

1) The **Introductory Phase** will include refinement and initiation of the program evaluation plan and performance indicators (described in the following sections). The CDRN and PPRN PIs will be engaged during this period to review and refine the proposed evaluation plan and indicators. The PIs are key stakeholders as well as the leaders of the activities under evaluation; therefore, their contribution and buy-in is critical to the success of the process.
2) The **Evaluation Phase** will include formative, summative, and validation components:
   a) The formative component of the evaluation phase will consist of surveys and follow-up interviews of key informants, including PCORnet Coordinating Center leadership, study team leadership, participating CDRN leadership, participating CDRN lead site leadership, stakeholder group leadership, IRB WG leadership, data/technical representatives from participating CDRNs, system and database administrators, and data security specialists; observations of calls; and analysis of documents provided by the CC and study teams. Once identified, the informants will continue to participate in the evaluation throughout the length of the study for purposes of internal consistency and validity.
   b) The summative component of the evaluation phase will include an overall assessment of performance, including technical and operational achievements, challenges and suggested corrective actions.
   c) The validation component of the evaluation phase will include dissemination of the results of the formative and summative components after each interview for comment and confirmation by the participating key informants and study team leadership.
3) During the **Dissemination Phase**, the evaluation team will distribute reports on the validated formative and summative evaluation findings. The Evaluation Team will disseminate evaluation findings to the scientific study teams and study stakeholders at months 4, 8, 12, 16, 20, and 24 (May 2016, September 2016, January 2017, May 2017, September 2017, and January 2018). These four-month reports will be posted on iMeet Central.

A logic model was developed to provide a high-level conceptual framework for the evaluation; it is attached in the Appendix. Using the logic model, the evaluation for the Obesity Observational Research Initiative will focus on assessment of the effectiveness and efficiency of PCORnet and the Network's ability to support observational research. The evaluation will prioritize assessment of the following areas of PCORnet infrastructure:

1) Operational processes
2) Involvement of stakeholders in network oversight and use
3) Contracting, IRB, and DSA processes
4) CDM v3.0: data standards and query functionality
5) Utility and efficiency of the DRN and the capacity of PCORnet CDRN DataMarts to conduct secure unmodified queries
6) Overall PCORnet research readiness

During each phase and for each evaluation priority area described below, a process evaluation will assess the development and dissemination of protocols and relevant information by the CC and the study team. An outcome evaluation will assess the effectiveness of the selected approaches.

2 EVALUATION PLAN

The technical and operational priority areas listed below include associated outcomes and indicators that will be used to evaluate the capacity of PCORnet's infrastructure to support the Obesity Observational Research Initiative. The evaluation team will analyze the data collected to report on the readiness of this infrastructure to support future observational research.

2.1 EVALUATION OF OPERATIONAL PROCESSES

2.1.1 Outcomes for Evaluation of Operational Processes

The following outcomes will be assessed:
- The CC supports coordination and productivity among obesity experts, programmers, CDRNs, PPRNs, and the PCORnet Coordinating Center Team.
- The CC facilitates, manages logistics, and provides the necessary administrative support required by study participants (scientific leadership teams, CDRN networks, CDRN participating institutions, Methods Core, and stakeholder advisory groups).
- Study milestones are completed in accordance with the proposed timeline.
- PCORnet governance policies support study aims and activities.
- Participating CDRNs' governance policies support study aims and activities.

2.1.2 Indicators for Evaluation of Operational Processes

The evaluation team will assess the outcomes through the following indicators:
- Evaluation of CC structure, communications, and support of study activities:
  - The evaluation team will describe the CC organizational structure, particularly in relation to its involvement in and support of the studies
  - The evaluation team will describe the personnel and effort required by the CC to support study operations and coordination of study activities
  - The evaluation team will describe the communication tools utilized by the CC and assess the effectiveness of these communication tools.
- Evaluation of study team structure and communications:
  - The evaluation team will describe the study team organizational structures.
  - The evaluation team will describe the personnel and effort required by the study team to support study operations and coordination. Study team members include the scientific team leadership, CDRN leadership, CDRN study team leadership, stakeholder group leadership, and analytic teams.
  - The evaluation team will describe the communication tools utilized by the study teams and assess the effectiveness of these communication tools.
- Evaluation of milestone completion:
  - The evaluation team will assess the timely completion of the study milestones by comparing the study timelines with the study milestone completion tracking documents. The evaluation team will calculate percentages of milestones completed on time and milestones completed after the approved deadlines.
- The evaluation team will review the PCORnet policies and identify policies that support study aims and activities.
- The evaluation team will review the participating CDRNs' governance policies and identify policies that support study aims and activities.

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- The evaluation team will assess whether participating CDRNs and participating CDRN sites would participate in future research activities coordinated and conducted within PCORnet.

2.1.3 Methods for Evaluation of Operational Processes

The evaluation indicators will be assessed using the following methods:
- Surveys of PCORnet Coordinating Center leadership, study scientific team leadership, participating CDRN leadership, participating CDRN lead site leadership, and study stakeholder leadership (Executive Antibiotics Stakeholder Advisory Group (EASAG) and Executive Bariatric Stakeholder Advisory Group (EBSAG))
- Follow-up interviews administered to surveyed individuals, as necessary
- Review Coordinating Center and study organizational charts
- Review of CC communication tools, including utilization of iMeet Central, in-person meetings, conference calls, and email communications
- Review of study team communication plans and tools, including utilization of iMeet Central, in-person meetings, conference calls, and email communications
- Review of the study timelines and milestone completion tracking documentation, as provided by the study scientific team leadership
- Review of query receipt, response, and fulfillment tracking documentation, as provided by the Coordinating Center data analysts (as routinely captured by the DRN OC)
- Review of PCORnet policies, as provided by the PCORnet Coordinating Center, in conjunction with the study scientific team leadership

2.2 EVALUATION OF INVOLVEMENT OF STAKEHOLDERS IN NETWORK OVERSIGHT AND USE

The evaluation team will assess the stakeholder engagement strategy and describe the roles and activities of the various stakeholders throughout the project. In particular, they will focus on the roles and activities of the following stakeholder groups:

- **Patients and Caregivers:**
  - *For the pediatric antibiotic study:* These stakeholders are parents and caregivers of young children who were prescribed and/or took broad-spectrum antibiotics during infancy.
  - *For the bariatric surgery study:* These stakeholders are bariatric patients, those who have severe obesity and are considering bariatric surgery, and their caregivers.
- **Healthcare Providers:**
  - *For the pediatric antibiotic study:* These stakeholders are community and other practicing healthcare professionals important to the proposed study (physicians, nurses, physician assistants) as well as those involved in the care and prescription of antibiotics to infants and young children.
  - *For the bariatric surgery study:* These stakeholders are community and other practicing bariatric surgeons as well as other providers who care for patients with severe obesity.
- **Healthcare System or Organizational Leaders:**
  - *For the pediatric antibiotic study:* These stakeholders are authorities on childhood obesity prevention/management and/or antibiotic use and organizational leadership

who make decisions regarding treatment, coverage, quality reporting, and/or clinical practice guidelines development and education.

- o *For the bariatric surgery study:* These stakeholders are authorities on bariatric surgical care or obesity management. In addition, the study is engaging organizational leadership who make decisions regarding treatment, coverage, quality reporting, and/or clinical practice guidelines development and education.

- **Community and Advocacy Groups:**
    - o *For the pediatric antibiotic study:* These stakeholders are organizations outside of the participating institutional healthcare systems that are authorities concerning community and public perspectives on treatments in early childhood and its implications for family community ecosystems.
    - o *For the bariatric surgery study:* These stakeholders are organizations outside of the participating institutional healthcare systems that are authorities concerning community and public perspective on bariatric surgical care and its implications for family community ecosystems.

2.2.1 Outcomes for Evaluation of Involvement of Stakeholders in Network Oversight and Use

The following outcomes will be assessed:
- The study meets the needs of a truly representative population in their communities, including:
    - o Diverse racial, ethnic, and socioeconomic audiences
    - o Engagement with the four stakeholder groups (described above) in study activities, including study oversight and leadership
- Engagement with the well-established broad patient and provider networks as represented by the participating CDRN communities
- Strategic dissemination of study findings to patient, family/caregiver, clinician, and other relevant stakeholder populations throughout the project timeline.

2.2.2 Indicators for Evaluation of Involvement of Stakeholders in Network Oversight and Use

The evaluation team will assess the outcomes through the following indicators:
- The evaluation team will describe the racial, ethnic, and socioeconomic distribution of the study population.
- The evaluation team will describe how stakeholder groups (described above) are engaged in and contribute to study oversight and leadership.
- The evaluation team will describe study approaches to engagement of patient and provider networks of the CDRNs in PCORnet, focusing on barriers and facilitators to engagement.
- The evaluation team will describe the strategies and activities for dissemination of study findings among patients, families/caregivers, clinicians and other relevant stakeholder populations.

2.2.3 Methods for Evaluation of Involvement of Stakeholders in Network Oversight and Use

The evaluation indicators will be assessed using the following methods:
- Surveys of study team leadership, the EASAG, and the EBSAG
- Follow-up interviews of surveyed individuals, as necessary
- Review of demographic data, provided through study population characterization queries
- Review of CDRN engaged patient and provider networks, as collected by the EASAG and EBSAG
- Review of study engagement plans

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- Review of study communication plans
- Review of study communication materials

2.3 EVALUATING CONTRACTING, IRB, AND DSA PROCESSES

The evaluation team will assess the efficiency of the contracting process between PCORI and the prime study sites (Harvard Pilgrim Health Care Institute and Group Health Research Institute), the subcontracting process between the prime sites and lead CDRN sites, and the subcontracting process between the lead CDRN sites and additional participating CDRN sites and subcontractors. The evaluation team will also assess the efficiency of the IRB approach used for the studies and the efficiency of execution of the PCORnet data sharing agreement (DSA).

2.3.1 Outcomes for Evaluation of Contracting, IRB, and DSA Processes

The following outcomes will be assessed:
- PCORI and GHRI/HPHCI (prime sites) contracting process:
  - Timeliness associated with executing the contract, from contract initiation to contract execution
  - Dates of contract revision requests made by both parties
- HPHCI, GHRI, and the lead CDRN sites subcontracting process:
  - Timeliness associated with executing each of the subcontracts, from contract initiation to contract execution
  - Dates of contract revision requests made by all parties (documented for each CDRN)
  - Whether and how a lead contracting CDRN site that is not serving as the lead in PCORnet Phase II affects the above measures (based on timeliness of subcontract execution and revision requests)
- Lead CDRN sites and other participating CDRN sites/subcontractors subcontracting process:
  - Timeliness associated with execution of subcontracts between the lead CDRN sites and additional participating CDRN sites and subcontractors (if relevant), from contract initiation to contract execution
- The feasibility of the IRBRely approach based on the study protocol and system readiness and alternative solutions if IRBRely does not meet the needs of the study (including whether the research is "not human subjects research").
- Following the assessment of the feasibility of the IRBRely approach for the studies, implementation of an IRB approach that is appropriate for the study design and addresses ethical and regulatory aspects of the research.
- Obtain approval from the participating institutions' local IRBs to adopt the selected approach and assess the timeliness of that process.
- Timely execution of the PCORnet data sharing agreement between prime sites (Harvard Pilgrim Health Care and Group Health Research Institute) and the participating CDRN sites.

2.3.2 Indicators for Evaluation of Contracting, IRB, and DSA Processes

The evaluation team will assess the outcomes through the following indicators:
- The evaluation team will describe the contracting approach between PCORI and the prime sites, including use of PCORnet Contracting Workgroup deliverables.
- The evaluation team will characterize the resources required for the contracting process between PCORI and the prime sites, noting successes and challenges of this process.

- The evaluation team will describe the subcontracting approach between the prime sites and the lead CDRN sites, including use of PCORnet Contracting Workgroup deliverables.
- The evaluation team will characterize the resources required for the subcontracting process between the prime sites and the lead CDRN sites, noting successes and challenges of this process.
- The evaluation team will characterize the resources required for the subcontracting process between the lead CDRN sites and the additional participating CDRN sites and subcontractors (if relevant), noting successes and challenges of this process.
- The evaluation team will describe the IRB approach selected for the studies, including the options considered, the decision-making process, dependencies, and the final approach selected.
- The evaluation team will characterize the resources required for IRB approval by the participating CDRN sites.
- If applicable, the evaluation team will describe the process and characterize the resources required for modification of the approved IRB at the participating CDRN sites.
- The evaluation team will characterize the resources required for execution of the PCORnet data sharing agreement by the participating CDRN sites.

2.3.3 Methods for Evaluation of Contracting, IRB, and DSA Processes

The evaluation indicators will be assessed using the following methods:
- Surveys of PCORnet Coordinating Center leadership, study scientific team leadership, participating CDRN leadership, participating CDRN lead site leadership, study stakeholder leadership (EASAG and EBSAG), and PCORnet IRB workgroup leadership
- Follow-up interviews of surveyed individuals, as necessary
- Review of contracting process tracking documents for contracting between PCORI and prime institutions, as provided by the study scientific team leadership
- Review of the subcontracting process tracking documents between prime institutions and lead CDRN sites, as provided by the study scientific team leadership
- Review of subcontracting process tracking documents between lead CDRN sites and additional participating CDRN sites and subcontractors (if relevant), as collected by lead CDRN sites
- Review of IRB tracking documentation, as provided by the study scientific team leadership
- Review of CDRN reliance model SOPs, work plans, and lessons learned
- Review of PCORnet DSA execution tracking documents, as provided by the study scientific leadership

2.4 EVALUATING CDM V3.0 – DATA STANDARDS AND QUERY FUNCTIONALITY

The evaluation team will prepare a report on the readiness of participating sites' data sets as stored in Common Data Model Version 3.0 (CDM V3.0) and data characterization activities. The team will also report on the readiness of the data sets at the participating sites and list issues encountered at participating sites, solutions deployed, and time to resolution by assessing the following outcomes:

2.4.1 Outcomes for Evaluation of CDM v3.0 – Data Standards and Query Functionality

The following outcomes will be assessed:
- Participating CDRNs have their data organized in accordance with PCORnet CDM v3.0.
- PCORnet CDM v3.0 provides the necessary data elements for the study.

- Participating institutions' data affects the study team's decisions, including whether participating institutions are able to provide data that are critical to the study aims.
- The quality and completeness CDM v3.0 metadata meets the requirements of the study.

2.4.2 Indicators for Evaluation of CDM v3.0 – Data Standards and Query Functionality

The evaluation team will assess the outcomes through the following indicators:
- The evaluation team will identify which participating CDRNs have data characterized in static PCORnet CDM v3.0 format with appropriate SAS data formats by the appropriate time, as described in the study timelines.
- The evaluation team will describe CDRNs' potential challenges with characterizing their data in static PCORnet CDM v3.0 format with appropriate SAS data formats, based on the requirements identified in the study teams and timelines.
- The evaluation team will describe whether CDM v3.0 data elements meet the needs of study queries.
- The evaluation team will assess the quality and completeness of CDM v3.0 metadata, assessed by domain.

2.4.3 Methods for Evaluation of CDM v3.0 – Data Standards and Query Functionality

The evaluation indicators will be assessed using the following methods:
- Surveys of PCORnet Coordinating Center leadership, study scientific team leadership, participating CDRN leadership, participating CDRN lead site leadership, data/technical representatives from participating CDRNs (as identified by the DRN OC)
- Follow-up interviews of surveyed individuals, as necessary
- Review of PCORnet CDM v3.0
- Review of CDM v3.0 data elements required for completion of study objectives
- Review of tracking documentation on participating CDRN institutions' availability of data characterized in static PCORnet CDM v3.0 format with appropriate SAS data formats
- Review of DRN OC data characterization results
- Review of Antibiotic and Bariatric study-specific data characterization results
  - *For the bariatric surgery study*: demographic data, anthropometric measures, bariatric cases, diagnosis data, procedure data, HbA1c data, death data, diabetes medication data, insurance claim and death linkage, and patient-reported outcomes data
  - *For the pediatric antibiotics study*: demographic data, anthropometric data, maternal-child linkage variables, prescribed and dispensed antibiotic data, and diagnosis data
- Bi-weekly meetings between the evaluation team and the CC data analysts, to be scheduled

2.5 EVALUATING THE UTILITY AND EFFICIENCY OF THE DRN AND THE CAPACITY OF PCORNET CDRN DATAMARTS TO CONDUCT SECURE UNMODIFIED QUERIES

2.5.1 Outcomes for Evaluation of the Utility and Efficiency of the DRN and the Capacity of PCORnet CDRN DataMarts to Conduct Secure Unmodified Queries

The following outcomes will be assessed:
- Participating sites can execute SAS programs without modification against static PCORnet CDM v3.0 formatted data with appropriate SAS data formats.

- Study query initiation, query management, and dissemination of results to the core scientific teams are optimized by the CC.
- The PCORnet DRN is built to serve as a secure infrastructure:
  - Securely share information with one another and with external researchers
  - Allow distributed querying of local data resources to inform study design and conduct analyses while minimizing exchange of PHI
  - Allow efficient reuse of research data sets by new investigators so they can perform analyses on these data
  - The extent to which the DRN reduces the need to exchange PHI through the use of a distributed data model
- Successful data linkage to appropriate data sources.
  - *For the bariatric surgery study:* linkage to state or national death index data or claims data capture post-operative adverse events
  - *For the pediatric antibiotics study*: linkage to maternal data on antibiotic use during pregnancy as well as delivery type (cesarean v. vaginal)

2.5.2 Indicators for Evaluation of the Utility and Efficiency of the DRN and the Capacity of PCORnet CDRN DataMarts to Conduct Secure Unmodified Queries

The evaluation team will assess the outcomes through the following indicators:
- The evaluation team will describe the process of preparing and executing queries for the studies in the PCORnet Distributed Research Network, including how distributed querying affects how the scientific teams approach study questions.
- The evaluation team will describe the resources required for development and execution of each query for the studies.
- The evaluation team will identify which CDRNs/participating DataMarts can execute SAS programs without modification against static PCORnet CDM v3.0 formatted data with appropriate SAS formats.
- The evaluation team will describe challenges or barriers that make it difficult for CC or participating CDRNs to engage in the study querying process and CDRNs'/DataMarts' ability to execute SAS programs without modification against static PCORnet CDM v3.0 formatted data with appropriate SAS formats.
- The evaluation team will describe how the use of the DRN allowed study teams to avoid exchange of PHI in the queries executed for the studies.
- The evaluation team will describe the types of data linkage capabilities of participating CDRNs and which CDRNs/participating DataMarts can successfully link data to relevant data sources.
- The evaluation team will describe challenges or barriers to data linkage for participating CDRNs/DataMarts.

2.5.3 Methods for Evaluation of the Utility and Efficiency of the DRN and the Capacity of PCORnet CDRN DataMarts to Conduct Secure Unmodified Queries

The evaluation indicators will be assessed using the following methods:
- Surveys of PCORnet Coordinating Center leadership, study scientific team leadership, participating CDRN leadership, participating CDRN lead site leadership, study stakeholder group leadership (EASAG and EBSAG), system and database administrators, and data security specialists
- Follow-up interviews of surveyed individuals, as necessary
- Review of PCORnet DRN process documents and SOPs

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- Review of tracking documents produced by the DRN OC regarding participating sites' readiness to execute SAS programs without modification against static PCORnet CDM v3.0-formatted data with appropriate SAS data formats
- Review of PCORnet query tracking, execution, process, and management documents
- Review of policies and procedures related to DRN security
- Review of data linkage capabilities
  - *For the bariatric surgery study:* assessment of linkage to state or national death index data or claims data capture post-operative adverse events
  - *For the pediatric antibiotics study*: assessment of linkage to maternal data on antibiotic use during pregnancy as well as delivery type (cesarean v. vaginal)
- Bi-weekly meetings between the evaluation team and the CC data analysts, to be scheduled

2.6   EVALUATING OVERALL PCORNET RESEARCH READINESS

2.6.1   Outcomes for Evaluation of Overall PCORnet Research Readiness

The following outcomes will be assessed:
- PCORnet infrastructure, governance, and participation are indicative of PCORnet research readiness.
- Study teams develop, share, and curate obesity study products shared in the PCORnet Commons.

2.6.2   Indicators for Evaluation of Overall PCORnet Research Readiness:

The evaluation team will assess the outcomes through the following indicators:
- The evaluation team will provide reports to PCORI detailing lessons learned and areas for improvement for the CC and study teams. This information will be shared with the study teams and study stakeholders.
- The evaluation team will describe the reusable infrastructure developed by the CC to support study activities and for future PCORnet observational studies.
- The evaluation team will describe the reusable infrastructure developed by the study teams to support study activities and for future PCORnet observational studies.
- The evaluation team will describe the resources developed by the study teams and shared in the PCORnet Commons.

2.6.3   Methods for Evaluation of Overall PCORnet Research Readiness

The evaluation indicators will be assessed using the following methods:
- Review of all interview transcripts, study documents, and meeting notes detailed in previous sections
- Review of documents provided to the PCORnet Commons, a collection of common tools, practices and resources to provide logistical and technical support to PCORnet and PCORnet studies
- Review the overall infrastructure, governance, and participation challenges experienced by all study participants and the opportunities for improvement of the network's governance procedures. At the end of the project, the evaluation team will report on the functionality of PCORnet and its research readiness, highlighting the accumulated experience and infrastructure built to facilitate more efficient and collaborative PCORnet studies in the future. Lessons learned will provide descriptive guidance about progress toward a network with reusable infrastructure.

- *Logistics:* How to run a study like this. What did and did not work in governance, communication, personnel deployment, etc.?
- *Methodology and science:* We will have developed and used a number of queries. For example, we will have learned a lot about harmonizing medication data. What processes and programs can we leave behind for future users? How does this process affect the questions that can be addressed and the flexibility of the research process?
- *Regulatory:* What did we learn from IRB/human subjects protections, forging data use agreements and contracting that others should emulate?
- *Engagement:* Which engagement strategies worked well and not so well? Are there lessons for dissemination, implementation, and decision making?
- *Distributed Research Network and CDM:* Did the DRN work efficiently? Was it useful to the study? What was the capacity of the PCORnet CDRN node sites to conduct unmodified queries?

3 REPORTS

The evaluation team will submit the evaluation plan to PCORI within 60 days of the study kickoff meeting (February 2016), and detailed reports of evaluation methods and indicators every four months thereafter. All reports will be shared with the study leadership teams and study stakeholders on iMeet Central, with an Executive Summary included to provide an overview of the evaluation team's findings and recommendations. The Final Evaluation Report will be submitted during month 24 (January 2018). Throughout the project, the evaluation team will respond promptly to any ad hoc requests required by either PCORI or the study team within the limits of the available budget.

Please see the Evaluation Plan Report Template documents for the Antibiotics and Bariatric studies for more information on how the Evaluation team will report on the results and recommendations for this evaluation of the Obesity Observational Research Initiative.

4 TIMELINE

The timing and frequency associated with each method described above is detailed in the timeline below:

Method	Timing
Surveys of CC leadership, scientific study team leadership, participating CDRN leadership, participating CDRN lead site leadership, stakeholder group leadership (EASAG, EBSAG), IRB WG leadership, system and database administrators, and data security specialists	Every 4 months, prior to submission of interim evaluation reports
Follow-up interviews of key informants, as necessary	Every 4 months, prior to submission of interim evaluation reports
Review of CDM guiding principles and CDM v3.0	Apr 2016
Review of PCORnet policies	Apr 2016
Review of contracting, IRB, and DSA process and tracking documents	Apr-Sep 2016
Review of study timelines, milestone completion tracking documentation, query tracking documentation, data characterization tracking documentation, study engagement plans, DRN process documents and SOPs, DRN security policies and procedures, query process documents, study communication plans, communication materials, documents provided to the PCORnet Commons	Every 4 months, prior to submission of interim evaluation reports
Observation of Obesity Demonstration Leadership Council calls	Bi-weekly (Thursdays, 4:00pm Eastern)
Observation of additional PI, PM, Methods Core, Stakeholder Advisory Group, etc. calls	Review minutes following calls, attend as appropriate
Collection and review of query responses	Collected as necessary
Meetings between evaluation team and CC data analysts	Bi-weekly meetings, to be scheduled

5 APPENDIX

5.1 LOGIC MODEL OF EVALUATION ACTIVITIES

	Inputs	Activities	Outputs	Outcomes
Operational Processes	Surveys, interviews, organizational charts, communication tools, communication plans, query documentation, project reports, PCORnet policies	Qualitative evaluation of milestones, collaborations, communications, and alignment with policies and aims	Report on operational process	Adherence to stated aims and project plans Evidence of collaboration and communication
Stakeholder Engagement	Surveys, interviews, demographic data, engaged stakeholders, engagement plans	Qualitative analysis survey and interview data Quantitative analysis of demographic data on study population	Report on stakeholder engagement	Evidence of a representative study population and meaningful stakeholder engagement across spectrum
Contracting, IRB, and DSA	Surveys, interviews, tracking documents	Qualitative analysis of contracting, IRB, and DSA execution processes	Report on approaches, barriers, facilitators, and achievements of contracting, IRB, and DSA processes	Identification of resources, barriers, and facilitators to contracting, IRB, and DSA execution processes
CDM v3.0 - Data standards and query functionality	Surveys, interviews, CDM v3.0, tracking documents, data characterization results, meetings with CC analysts	Analysis of CDRN data availability and CDM v3.0 support of proposed study activities	Report on availability and use of CDM v.30	Determination of CDRN readiness for querying and use of CDM v3.0 in observational research
Utility and Efficiency of the DRN	Surveys, interviews, process and tracking documents, DRN policies and procedures, data linkage capabilities, meetings with CC analysts	Qualitative and quantitative analysis of the querying process and data linkage	Report on utility and efficiency of the DRN in conducting unmodified queries	Demonstration that the query tool and query approach are feasible and efficient
PCORnet Research Readiness	All evaluation data	Summary and meta-analysis of qualitative and quantitative data	Final report: assessment of PCORnet functionality and resources created for future PCORnet research	Basis for continuation of PCORnet approach

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