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PURPOSE STATEMENT:

This document provides a comprehensive guide for consideration at the start of PCORnet studies for use by investigators and PCORnet leadership. It is intended to serve as a tool to stimulate discussion and provide guidance for planning and decision-making during PCORnet study development.

The content of this document is based on the experiences and lessons learned during the PCORnet Obesity Observational Research Initiative, including the PCORnet Antibiotics and Childhood Growth Study (ABX) and Bariatric Study (PBS). Future PCORnet investigators are encouraged to use this document to leverage these experiences and lessons learned to conduct efficient, rigorous research in the PCORnet environment.

This is a living document which will be updated to reflect changes to PCORnet infrastructure and processes for use by future PCORnet investigators.

HOW THIS GUIDE WAS DEVELOPED

This guide was developed by the Obesity Demonstration Projects Evaluation Team in consultation with PCORI leadership, the PCORnet Executive Committee, the PCORnet Coordinating Center (CC), Clinical Data Research Networks (CDRNs), and the ABX and PBS study teams. These groups provided specific insight during the draft and review stages of document development.

EXECUTIVE SUMMARY

This document covers four categories of study implementation: response to funding applications, post award study planning, study activities, and study closeout. Investigator teams are encouraged to reference this document prior to and during the development of study proposals as well as during the execution of study activities to ensure they are following processes best suited for the PCORnet environment. Investigator teams are encouraged to reach out to the PCORnet Coordinating Center as early as possible during study development for assistance in setting timelines and budgeting guidelines. This guide provides a roadmap for investigators of PCORnet’s priorities, strengths, processes, and resources based upon the experience of the ABX and PBS studies. The final section of the guide includes a checklist of high-level activities for investigators as they prepare for and execute PCORnet studies.
1 RESPONSE TO REQUESTS FOR FUNDING APPLICATIONS

The first step for a study using the PCORnet infrastructure is to review the information and resources available on the PCORnet website and the PCORnet Commons. These websites will provide you with a general overview of the PCORnet network, research, and resources for development of your application.

1.1 CONSIDERATION OF STUDY PRIORITIES

During the PCORnet demonstration projects, the following topics were identified as priorities for PCORnet research and querying activities. Investigator teams should identify which key priorities align with their study prior to response to a request for application (RFA), an ongoing program announcement, or development of an industry-sponsored study.

- Scientific aims and contributions to health research and practice
- Network participation
  - Broad network participation (i.e., high volume of Network Partners involved in research activities) versus selective network participation (i.e., selection of Network Partners based on data availability, funds available, and appropriateness to research question(s))
- Patient, provider, and community stakeholder engagement
  - Commitment of diverse stakeholders to study engagement
  - Maintenance of stakeholder engagement through all research activities
- Dissemination of study processes and findings
  - Dissemination to the PCORnet community
  - Dissemination to external audiences, beyond PCORnet (i.e., patient advocacy groups, clinical and professional associations, industry leadership)
- Network data infrastructure development and data quality
  - Alterations or updates to the PCORnet Common Data Model
  - Improvements to network data availability and standardization
- Necessary data agreements for study queries
- Study speed and efficiency

1.2 INITIAL CONSULTATION WITH THE PCORNET COORDINATING CENTER

The PCORnet Coordinating Center (CC) leads the data and engagement activities for the Network, connects with outside research partners, and supports the PCORnet infrastructure. Responsibilities of the CC include: coordinating PCORnet’s operational activities; designing, enhancing, and maintaining the PCORnet data infrastructure; identifying research opportunities and implementing PCORnet-wide research; supporting PCORnet pre-research inquiries including queries, observational studies, and interventional multi-site research studies; developing new products and services, and implementing engagement and network-building services; managing the PCORnet Commons and collaborative sharing; and communicating with CDRN and PPRN partner networks on an individual and group basis to generate collaboration, co-production, and efficiency.
Investigators are encouraged to reach out to the CC early in the development of an application for a PCORnet study through the PCORnet Front Door (see below). This will allow investigators to understand engagement processes, current network infrastructure capabilities, and PCORnet study requirements and determine the feasibility of their proposed activities in the PCORnet environment.

1.2.1 PCORnet Front Door

The first point of contact with the CC for investigators interested in a study using PCORnet is the PCORnet Front Door. The PCORnet Front Door allows potential requestors to submit a request for use of the Network and its partners (e.g., study feasibility review, data network queries, network collaborators, and/or PCORnet study designation). The Front Door team reviews all requests to determine if activities are suited for PCORnet resources and infrastructure and how the CC and Network can support the requested activities. If the Front Door team determines that the proposed activities are feasible for the Network, it will work with investigators to complete the request. Figure 2 depicts investigator interaction with the Front Door and CC. Additional details regarding CC support of potential new investigators are described in subsequent sections of this document.
1.2.2 Distributed Research Network Operations Center (DRN OC)

The DRN OC is responsible for the development and maintenance of PCORnet data infrastructure (i.e., the PCORnet Distributed Research Network (DRN), Common Data Model (CDM), and network querying). During development of applications for PCORnet studies, investigators should reference the following DRN OC resources and consult with the DRN OC team to understand PCORnet data capabilities and the feasibility of their proposed activities:

1.2.2.1 PCORnet Common Data Model (CDM)

The PCORnet CDM is a way of organizing data into a standard structure. The approach PCORnet is using for its CDM is similar to other large national research consortia. Each PCORnet Network Partner maps data to the same consistent format (i.e., with the same variable name, attributes, and other metadata). The current version of the PCORnet CDM is available on the public PCORnet website. Potential investigators should consult this documentation to understand what specific tables and variables are available for their proposed study queries.

The PCORnet CDM implementation guidance is intended to help reduce the variability in how partners populate their CDM-compliant data contributing sites (Network Partners). It provides recommendations and describes preferred approaches when there are multiple interpretations of the CDM specifications or if there is unexpected complexity in a partner’s source data. The current version of the PCORnet CDM Implementation Guidance document is available on the public PCORnet website.

Although the CDM and CDM Implementation Guidance documents aim to standardize the structure of PCORnet data across Network Partners, there is significant heterogeneity in data availability and quality across the Network. Variables listed as "optional" in the CDM may be inconsistently available across sites. Because PCORnet is a new network, investigators are advised to consult with the DRN OC team during study planning to ensure that data heterogeneity is accounted for in study planning, queries, and resource allocation. Some investigators may consider factors related to CDM implementation in their selection of Network Partners for possible study participation.

1.2.2.2 DRN OC Data Curation Documentation

DRN OC data curation is the network’s centralized data checking activity to characterize Network Partner data in the current version of the PCORnet CDM. DRN OC data curation packages are distributed to all Network Partners throughout the year, and results are reviewed by the DRN OC Data Curation team to ensure a foundational level of data quality at all Network Partners. The DRN OC may use results of from these data curation activities to provide initial feasibility estimates for prep-to-research queries, inform study planning activities, and create data quality reports.
As of December 2017, PCORnet has implemented CDM v3.1, and Network Partners have run Data Curation Query Package v3.12. CDM v4.0 will be curated in July 2018.

Each data curation query package includes several “required” checks that all Network Partners must pass for their data to be approved. Required data checks include examination of data availability, conformance to the PCORnet CDM, missing values, and replication errors. In addition, each data curation query package includes several “investigative” checks that Network Partners do not need to pass to be approved. However, they do need to provide information as to why they have exceptions to those checks and if they may be remediable in the future. The investigative checks include preliminary examinations of values and distributions of specific tables and variables. Additional details about the specific data checks are available on the PCORnet website.

Because of heterogeneity in Network Partner implementation of the CDM across the network, Study-Specific Data Characterizations (SSDCs) are recommended for all studies prior to development of study scientific aims queries to assess data completeness and quality of specific study variables. Study teams will be responsible for the development, distribution, and review of results of these SSDC queries in consultation with the DRN OC. If significant data availability or quality issues are discovered for Network Partners participating in a study, the study team may work with the DRN OC and applicable CDRNs to determine plans for data remediation or removal of the Network Partner from study participation. Study teams should factor in time for SSDC queries and any necessary data remediation and should complete preparatory-to-research (PTR) queries prior to applications for funding to determine study feasibility and Network Partner participants’ abilities to contribute to studies, based on data quality and availability.

1.2.2.3 PCORnet Query Fulfillment Process

PCORnet Query Fulfillment is a multi-step process involving receipt of a request, clear definition of specifications, or use of an existing program or tool capability. Once a program package is assembled in consultation with the DRN OC’s Query Fulfillment (QF) team, the QF team facilitates robust testing, program distribution, and production of an analytic report for the requestor. Query fulfillment is a complex, iterative process requiring knowledge of PCORnet Network Partner data, the PCORnet Common Data Model (CDM), existing PCORnet SAS programs and tools, and requests for SAS program development. Thus, investigator collaboration with the QF team is essential for query success, and study teams should work closely with the QF team to develop plans for study querying. The description below includes examples from the experience of the two PCORnet Obesity Demonstration Projects.

When considering timelines and resources for development and execution of PCORnet queries, it is important to understand the following steps in the PCORnet querying process (see Figure 3):

1. The Requestor brings a question to the PCORnet CC.
2. The CC works with the requestor to understand what information is required to answer the question.
3. The CC converts the question into a query that is executable in the PCORnet environment.
4. The CC completes Alpha and Beta testing and query refinement.
5. The CC securely sends the code to the PCORnet Network Partners.
6. PCORnet Network Partners review the query and provide a response, which is sent back to the CC. All querying is performed locally at PCORnet partners.

More information about the PCORnet query fulfillment process is available on the PCORnet Query Fulfillment and Analytics public wiki.
1.2.2.4 **PCORnet Reusable Query Tools**

The DRN OC has developed several reusable querying tools to allow for efficient development, distribution, and response to queries. These tools have been developed and distributed for previous PCORnet querying activities, so their functionality has been proven in the PCORnet environment. Existing PCORnet tools are described on the PCORnet Query Fulfillment and Analytics wiki. New investigator teams should consult with the DRN OC to further understand the capabilities and potential application of these tools for their proposed study activities.

In addition to the PCORnet reusable query tools, other query programs, such as identifying and characterizing cohorts of patients, are often developed to be reusable. Thus, new investigators should consult with the DRN OC team during the study planning process to determine whether any query templates used for previous PCORnet studies may be reused for proposed new queries. It is recommended that sites are selected based on data availability that may be assessed via a prep-to-research query.

### 1.3 BUDGET CONSIDERATIONS

When developing study budgets, investigators should consider the following items:

#### 1.3.1 Study Team Time and Effort

Investigator teams should include and consider effort required for investigators and study staff including potential stakeholder engagement staff and stakeholder co-investigators.

When budgeting for these personnel, investigators should consider the time and effort required for the following potential study activities specific to PCORnet:

- Query development, execution, and results review
- Engagement of study stakeholders and relevant community, professional, and industry groups
• Issue troubleshooting, including potential data and administrative issues; effort for subject-matter experts (e.g., clinicians, pharmacists) should be included for review of SSDC results and individual-level query results and any subsequent issue troubleshooting
• Dissemination, including manuscript development, publication fees, meeting/conference presentations, and internal dissemination of study activities and results for the PCORnet community

1.3.2 Coordinating Center Time and Effort

Investigator teams should include time and effort for the CC team to support study activities, particularly for support of querying activities. Studies will require the support of the CC’s DRN OC. Investigators should consult with the PCORnet Front Door team to obtain budget figures based upon specific study needs and requirements. In large, multi-site studies, teams may also consider including time and effort for a CC team “liaison” to serve as the CC point of contact for the study. This individual will have significant knowledge of the network and CC activities, and he or she will be able to direct study team questions or concerns to the appropriate CC team member.

1.3.3 Cost Per Network Partner

In consultation with the CC, investigators should determine the scope of Network Partner participation in the study and utilize this scope to determine appropriate costs or cost structures for Network Partner completion of study activities. Network Partner scopes may include the following activities:

• Completion of administrative requirements (i.e., contract, IRB, DSA)
• Execution and return of results for SSDC queries; of note, some of this data characterization can be done as prep-to-research queries
• Potential data remediation activities linked to findings of SSDC if a study team is interested in funding this activity. If participating sites may be excluded due to data quality issues, the study team should include a clear plan for removal of sites in Network Partner scopes.
• Execution and results return for scientific queries
• Scientific contribution to study analyses, including feedback on results
• Completion of any linkage activities required for study scientific aims
• Development and/or review of study reports and manuscripts
• If applicable, travel to in-person study meetings and conferences for investigators and stakeholders

The above list of Network Partner activities is not exhaustive, and investigators may need to develop more individualized scopes for Network Partners based on the level of participation in study activities (e.g., some partners may contribute data to a study, some partners may provide scientific oversight only).

Network Partner costs may be calculated based on the type and complexity of each query. Investigators should consult with the CC to determine if this type of budgeting is appropriate for their study and discuss associated costs. As of the development of this guide, the CC is developing cost estimates for query support and Network Partner costs.

1.3.4 Study Priority Setting

Investigators should revisit study priorities, as described in Section 1.1 of this document, to ensure that allocation of resources aligns with study priorities.

1.3.5 PCORnet Current Infrastructure

As described in previous sections of this document, investigators should develop study planning documents, including budgets, in consideration of the current PCORnet infrastructure. Investigators should consult with the CC to determine the current infrastructure capabilities of the network and develop budgets accordingly. Investigators should specifically consider the availability and quality of data elements required for study queries. If required data elements have not yet been explored through PCORnet queries, budget funds will be required to support Network Partner identification and troubleshooting of data issues.
1.3.6 Face-to-Face Meetings

Face-to-face kickoff and closeout meetings have proved useful for prior PCORnet studies as a mechanism to build collaboration in the study team and allow for opportunities to discuss scientific plans, stakeholder engagement, and lessons learned. Investigators may consider including funds for these meetings as well as funds to attend conferences for dissemination of study activities and findings. Investigator teams may also consider inclusion of a mid-study meeting or additional stakeholder meetings, based on study needs and resource availability. Possible face-to-face meeting costs include meeting size, meeting space (at participating institution location or external venue), hotel accommodations (additional night(s) required for attendees traveling from far distances), travel, meals and coffee breaks, audio/visual, and printing.

1.3.7 Stakeholder Compensation and Costs

As described in subsequent sections of this document, investigators should develop engagement plans as part of their proposals, including concrete scopes and expectations for stakeholder engagement in study activities. Using their previous experience with PCORnet studies, the CC can provide guidance for stakeholder compensation using these proposed stakeholder scopes and expectations.

It is important to note that stakeholders do not necessarily have institutional support for their engagement in study activities, unlike other members of a study team. Thus, all costs related to stakeholder engagement in study activities need to be included in study budgets. Specifically, if investigators anticipate or expect stakeholder attendance at conferences, travel costs should be included in study budgets, as these costs cannot be covered by other institutional funding mechanisms.

1.3.8 Communication Resources

As PCORnet is a distributed research network, with partners working at institutions across the country, investigators should include funds to cover all necessary communication resources, including conference lines and webinar applications.

Investigator teams may want to consider including funds in the budget to cover publication costs, including manuscript submission and open-access fees.

1.4 DATA AND ADMINISTRATIVE ELIGIBILITY PERIOD

Investigators may consider inclusion of a feasibility period in their timelines and resource allocation. A study feasibility period can be used to assess whether Network Partners that are considered for inclusion in a study can participate in study queries and additional activities. Feasibility periods may include the following study initiation activities:

- Execution of project contracts and subcontracts
- Execution of Data Sharing Agreements or amendments to the PCORnet DSA
- IRB determinations
- Assessment of data availability and quality, examining required study variables as specifically as possible
  - As described in previous sections of this document, there is significant data heterogeneity across the network, so study-specific data characterization activity is necessary to establish feasibility for the study. In most cases, some of this assessment should be done as prep-to-research prior to grant applications.
- Updates to study protocol or analysis plan based on results of study-specific data characterizations

Network Partners’ abilities to complete study initiation activities on a timeline designated by project leadership may determine partner selection for and participation in subsequent study activities.
1.5 ENGAGEMENT

During development of applications for PCORnet studies, investigator teams should consider the following to plan for robust and valuable stakeholder engagement in study activities. For the purpose of this document and PCORnet studies, stakeholders are defined as individuals who represent various interest groups of a study. Thus, stakeholders may include, but are not limited to, patients, parents/caregivers, providers, and representatives from industry and community groups.

1.5.1 Stakeholder Engagement Plans

Successful stakeholder engagement in PCORnet studies will require a thoughtful plan for how to identify, invite, and incorporate stakeholder leaders in all aspects of the research process. Investigators should consider how stakeholders will best contribute to a study, based on study goals and deliverables. Investigators should work with stakeholders to agree on these goals and deliverables and ensure that all expectations are clear. When possible, investigator teams should identify stakeholder leaders prior to project funding and develop engagement plans that address the following key components of stakeholder engagement:

- Identification of stakeholder groups and individual stakeholders prior to study funding to participate in the development of study aims
- Diversity of stakeholders, including consideration of the following:
  - Stakeholder demographics
  - Stakeholder expertise, skills, and interests
  - CDRN and PPRN involvement and diversity
- Initial communication with and recruitment of stakeholders, including consideration of how to leverage existing PCORnet stakeholder communities
- Stakeholder education and training to ensure their understanding of key concepts for effective contribution to study activities and deliverables
  - PCORnet infrastructure and processes
  - Scientific and technical aspects of study aims and query and analytic activities
- Investigator education and training on key concepts for effective collaboration with stakeholder partners (if necessary)
  - Understanding of core principles and methods for engagement
  - Understanding of methods for incorporating stakeholder feedback in each phase of study
- Expectations for stakeholder engagement in study activities
  - Specific study activities that require stakeholder input
  - Plans for communication with stakeholders, including type(s) and frequency of communications
- Maintenance of stakeholder engagement
  - Inclusion of interim assessments of stakeholder interests and satisfaction with study engagement
  - Plans to address stakeholder dissatisfaction and updates to stakeholder roles in study activities
  - Recruitment of new stakeholders as needed

Investigators can consider the inclusion of specific stakeholder study aims for stakeholders to lead and implement. If such aims are included, engagement plans should detail the specific activities involved with completing these aims and associated deliverables. Engagement plans should also describe who will lead all activities and how additional stakeholders will be engaged.

Study investigators should consider and plan for appropriate compensation for stakeholders to support their ongoing commitment to and participation in study activities. Investigators should consult the Coordinating Center (CC) to determine appropriate compensation. The current version of the PCORnet Engagement Assessment Tool is available here: [http://pcornetcommons.org/wp-content/uploads/2017/02/PCORnet-Engagement-Assessment-Tool_FINAL_Jan-2017.pdf](http://pcornetcommons.org/wp-content/uploads/2017/02/PCORnet-Engagement-Assessment-Tool_FINAL_Jan-2017.pdf). Stakeholder engagement tools are also included in the appendix of this guide in section 6.2.
1.5.2 Expectations for Stakeholder Engagement in PCORnet Studies

Investigators should define stakeholder roles and expectations for stakeholder engagement in study activities through early consultation with individual stakeholders and stakeholder groups. Expectations and roles should be activity- and stakeholder-specific (i.e., clinicians may have greater involvement in study cohort definition development; parents may have greater involvement in participant recruitment or research question development). Stakeholder roles may change during the study based on stakeholder interests; investigators should consider structures and procedures to assess whether changes in stakeholder involvement are necessary and accommodate these potential changes. It is helpful to clearly state these expectations in a Memorandum of Understanding-style document.

Investigators may want to consider inclusion of a stakeholder co-investigator as part of the study team, to help manage and lead the team of stakeholders and to serve as a liaison with the study team. The stakeholder co-investigator will bring expertise to the study team. Inclusion of a “Patient PI” was a requirement for the ABX and PBS studies, with this individual representing the perspectives of a patient or caregiver for the leadership team. The stakeholder co-PI for both studies worked collaboratively with the scientific investigators and supported study engagement leadership to facilitate consistent stakeholder engagement in all study activities.

Investigator teams should develop and provide resources, guidance, and training to ensure that stakeholders can meaningfully engage in study activities as their roles and expectations describe. Resources to allow for stakeholder engagement may include information about PCORnet infrastructure and processes, lay guides describing the study aims and activities, and lay descriptions of analyses. Investigators should consider inclusion of face-to-face stakeholder training early in study timelines (e.g., during study kickoff meetings) to introduce PCORnet and study concepts. Additional training will be required periodically to support stakeholder understanding of specific information and processes (e.g., results of analytic queries, manuscript development) and allow for effective stakeholder feedback and contribution when requested.

1.6 RECRUITING AND SELECTION OF NETWORK PARTNERS

Investigators should reach out to the PCORnet Front Door, via the public PCORnet website, to request collaboration with or use of PCORnet for research and/or querying activities. Through the Front Door, investigators can submit a study feasibility review, data network request, network collaborator request, or PCORnet study designation request (after a study is funded). Front Door requests are triaged by the CC, which has the most up-to-date information about network infrastructure functionality and data availability. Thus, the Front Door should be investigators’ first step in understanding of the feasibility of conducting research in the PCORnet context and determining which Network Partners may participate in their proposed study activities.

1.6.1 Recruitment of Network Partners

Recruitment of Network Partners for participation in new study activities should be directed through the PCORnet Front Door, if not done separately. New investigators should submit a Front Door network collaborator request, and the CC will work with investigators to help identify potential partners for participation in study activities. Even if investigators have had previous contact with PCORnet and/or Network Partners through previous work or institutional affiliations, they are encouraged to direct all requests for network collaboration through the Front Door.

1.6.2 Selection of Network Partners for Participation in PCORnet Projects

When selecting Network Partners for participation in PCORnet projects, investigators should define criteria for participation in their study based on the proposed study activities. Criteria for Network Partner selection may include:

- Appropriate population of interest (e.g., children, elderly)
- Sufficient cohort size and follow-up, based on prep-to-research queries
- Experience with development of prior PCORnet queries
- Adherence to the PCORnet CDM
• Data availability and quality
• PCORnet DSA execution (and possible additional data use agreements, as necessary)
• Participation in PCORnet IRB structure
• Time required for subcontract execution
• Co-investigator and staff experience and expertise
• Ability to engage stakeholders needed for the study
• Budget

These criteria are not exhaustive, and other criteria may need to be developed based on the specific plans for each study. Information related to data availability and quality can be obtained via a prep-to-research query through PCORnet’s Front Door. Investigators should develop project-specific criteria and work with the CC to select Network Partners for participation based on their defined criteria.

1.7 STUDY TIMELINE CONSIDERATIONS

When developing study timelines for inclusion in PCORnet study applications, new investigators should consider the following:

1.7.1 Current PCORnet Infrastructure Capabilities

Investigators should consult with the CC to determine the current infrastructure capabilities of the network, including processes and resources for network governance, contracting, data agreements, IRB, data availability, and querying tools and processes. Investigators will need to include some flexibility in timelines if they plan to utilize new PCORnet processes, resources, or data elements, as Network Partners may need to complete relevant updates to their infrastructure. Specific considerations for PCORnet infrastructure capabilities are described in additional detail in the subsections below.

1.7.2 Study-Specific Data Characterizations (SSDCs)

SSDC activity is required for all PCORnet studies to ensure the availability and quality of data elements required for study queries and analyses. If SSDC queries examine PCORnet CDM variables that have not been utilized or explored through previous PCORnet characterization or query activity, additional time will be required for the investigator team and lead analysts to carefully examine SSDC results for each participating Network Partner and troubleshoot any data issues identified. Investigators should consult with the CC to estimate the time required for SSDC based on the specific data elements that will be examined. In most cases, the assessment of data availability and quality should begin in the prep-to-research phase, allowing for study teams to determine feasibility and Network Partners prior to applying for funding.

1.7.3 Query Development, Execution, and Results Review

Querying processes for PCORnet follow the workflow described and depicted in Section 1.2.2.3 of this document. Query development timelines may be affected by the following factors: use of existing versus development of new PCORnet tools, investigator experience and expertise in query development within a distributed research network environment, study team experience with PCORnet and/or other distributed research networks, investigator understanding of the limitations of PCORnet data, and exploration/utilization of study variables in previous PCORnet research activities.

• If both individual- and aggregate-level queries are required for study scientific analyses, it is best if the development, distribution, and results review for the individual-level queries precede the development of the aggregate-level queries so that investigators may troubleshoot any data issues and leverage lessons learned from the individual-level queries for the aggregate-level queries. If a study includes both individual- and aggregate-level queries, study timelines should be developed with this consideration.
To avoid delays in query testing and ensure that query timelines move forward as planned, it may be helpful for investigator teams to share query results with the DRN OC QF team for data review (data sharing and use agreements may be required).

1.7.4 Study Initiation Activities

Study initiation activities include contract and subcontract execution, IRB determination, and DSA execution (if necessary). Timelines for study initiation depend on the number of Network Partners participating in a study. More participating Network Partners may require more time for completion of initiation activities. Investigators must also consider updates to or implementation of centralized PCORnet resources, including the PCORnet contracting template, centralized or reliance IRB structures, and the PCORnet DSA. Use of new or updated resources or processes will increase the time required for Network Partner completion as partners become accustomed to the new or updated infrastructure and materials. Investigators should consult with the CC to determine the availability of resources and timing for their implementation to create appropriate timelines for study initiation activities.

1.7.5 DRN OC Activities

Investigators should consult with the CC, particularly the DRN OC team, to ensure that study timelines consider centralized PCORnet data activities which require time and effort of the Network Partners as well as the DRN OC teams. These centralized data activities may include implementation of a new version of the PCORnet CDM and distribution of a new DRN OC data curation package.

1.7.6 Timeline Dependencies

Some study activities will be dependent on the completion of other study activities (e.g., execution of DSAs prior to Network Partner response to queries). Investigators should incorporate potential dependencies into their study timelines. Investigators should consult with the CC to determine dependencies related to centralized network development which may affect study activities.

1.7.7 Study Team Schedules

Investigators should consider study team members’ schedules, including stakeholders’ schedules, when developing study timelines. Caregivers, parents, teachers, etc. may have specific scheduling that need to be taken into account when planning study meetings and deliverable deadlines.

1.8 PCORNET COMMONS

The PCORnet Commons is an online community maintained by the CC, to facilitate collaboration, and sharing of materials, processes, and lessons learned across the Network. The site includes a repository of PCORnet tools and resources, as well as groups and forums for members to collaborate on material development. Investigators are encouraged to explore resources available on the Commons as they develop applications for PCORnet projects. Study teams may also contribute project materials and lessons learned. As of April 2018, the Commons is located at https://pcornetcommons.org/.

1.9 PROJECT MANAGEMENT OFFICE (PMO)

The PCORnet Project Management Office (PMO) is an entity of the CC, and it provides central coordination for the network and oversees PCORnet operational activities and implementation of PCORnet research. Specific activities of the PMO include coordination of internal and external communication platforms; PCORnet leadership support, including PCORnet committee support and coordination; PCORnet infrastructure support, including efforts related to single IRB and quality improvement reporting; proposal and project support; meeting planning and logistics; and technical assistance for the partner networks, including cross-network support and learning.
Investigators may reach out to the PMO at pmo@pcornet.org with general questions about PCORnet infrastructure and management and proposal development.

Investigators may also consider use of PMO-developed communications for sharing information with the network. Such communications include weekly newsletters and email updates as well as meetings with PCORnet leadership and project management teams. Investigators should contact the PMO for more information on these resources.

2  POST-AWARD STUDY PLANNING

2.1  REVISIT TIMELINE

Once funding has been awarded for a PCORnet study, investigators should revisit study timelines to ensure alignment of study plans with centralized network timelines. Post-award, timeline planning should involve the following discussions:

- Discussions with the DRN OC
  - Centralized data curation timelines for distribution to Network Partners and Network Partner response
  - Study-specific data characterization timeline. (As mentioned in previous sections of this document, data elements that have not been previous examined will require more extensive data checking and additional time to troubleshoot data issues.)
  - Study scientific query timelines, including tool use versus ad hoc programming
  - Identification of study team key point of contact for the DRN OC. This individual should lead communications related to study requirements and timeline. This role is often filled by the study PM.

- Discussions with participating Network Partners
  - Study timelines for administrative deliverables and querying activity, including feasibility period timeline if applicable and consequences for not meeting these timelines
  - Timeline flexibility versus strict deadlines, based on current centralized and distributed infrastructure capabilities
  - Centralized network timelines (e.g., DRN OC data curation timelines) versus study timelines and how timelines and outcomes of centralized data checking activity will affect study timelines and Network Partner activities

- Discussions with the CC, including expectations for timing of dissemination of study activities and findings to internal PCORnet teams

2.2  REVISIT BUDGET ALLOCATION

Once funding has been awarded for a PCORnet study, investigators should revisit study budgets to ensure appropriate resource allocation based on all study plans detailed in the application as well as current PCORnet infrastructure capabilities. If there were any changes to network or Network Partner capabilities, investigators should update budgets accordingly.

2.3  CONTRACTING

Investigator teams should consider using the PCORnet contracting template for all contracts and subcontracts. The PCORnet templates will help to expedite the contracting process, as the language included in the templates has been reviewed and agreed upon by all PCORnet Network Partners. Investigators can reach out to the CC to procure the current version of the contracting template once a study has been funded.

All subcontracts for Network Partners should include detailed study deliverable timelines and due dates. Investigators should determine whether the deliverable due dates are flexible or strict based on study needs and timelines. If studies do not include a feasibility period to complete study initiation activities and initial study-specific data characterization queries and results review, investigators should include language in the Network Partner subcontracts to identify any
deliverables that, if not completed on the determined timeline, will result in specific consequences (e.g., Network Partner removal from study participation or participation in specific study queries). Such deliverables may include contract execution, IRB determination, DSA execution, and confirmation of data availability and quality for all variables required for study analyses (through SSDC queries).

Requirements for the contracting approach may be included in the funding announcement. If this information is available in the funding announcement, investigator teams should defer to those requirements.

2.4 IRB

Investigators should consult with the CC regarding the current PCORnet IRB approach and the availability of centralized IRB infrastructure. As of the time of the development of this document (February – April 2018), PCORnet Network Partners are in the process of SMART IRB onboarding. Investigators should determine if the PCORnet IRB infrastructure is appropriate for their study and create a IRB plan accordingly. If a centralized or reliance PCORnet IRB structure is available for a study’s use, but an investigator team decides not to use it, investigators should consult with the CC to determine the timeline and resources required for getting IRB determinations at all participating Network Partners. Investigators should also consult with the participating Network Partners to determine their IRB approach and the timing associated with IRB approval. It may be helpful to host a conference call with IRB representatives from participating institutions to describe the study and discuss and resolve any questions.

Requirements for the IRB approach may be included in the funding announcement. If this information is available in the funding announcement, investigator teams should defer to those requirements.

2.5 DSA

Investigators should consult with the CC to determine the status of DSA execution among the Network Partners that are participating in a study. The current version of the DSA as of April 2018 is version 2.0.

Based on the specific data use and sharing needs for a study, amendments to the PCORnet DSA or a separate Data Use Agreement (DUA) may be required. If additional amendments are required, investigators should work with Network Partners to ensure that appropriate personnel are available at each participating site to review relevant documentation immediately following contract execution.

2.6 REVISIT APPROACH TO STUDY COMMUNICATIONS

Once funding has been awarded for a PCORnet study, investigator teams should revisit the proposed approaches to study communications. Specifically, investigator teams should consider the following:

- Communications with the PCORnet Network
  - Type and frequency of communications with the larger Network, based on contract and CC expectations
  - Presentations of study activities and progress via regular Network calls (e.g., Executive Committee, PCORnet Council, etc.)
- External communications
  - Work with the PCORnet Communications Team to consider methods for promoting and sharing the study with the research and participant communities using social media, press releases, and emails to key partners with strong ties to the patient/stakeholder community. Investigators should reach out to the PMO to connect with the PCORnet Communications Team.

2.7 STUDY KICKOFF MEETING AND STAKEHOLDER ORIENTATION

Investigators may consider holding study kickoff meetings following the study start date. Study stakeholders should be included in kickoff meetings, and these meetings may serve as a time for stakeholder training and orientation as previously described.
Given stakeholder inclusion in these meetings, meeting planning teams should carefully consider the audience for all presentations and meeting materials to ensure that all attendees can understand and potentially contribute to presentations and discussions. For materials related to stakeholder training in PCORnet infrastructure and processes, investigators should reach out to the CC to see how they may leverage existing training materials. Study-specific training materials (i.e., lay guides about study scientific aims) will need to be developed by study teams. Time should be allotted for stakeholders to meet independently as well as integrated throughout scientific sessions.

2.8 PERSONNEL EXPECTATIONS

Once funding has been awarded, investigator teams should revisit personnel expectations and responsibilities. Specifically, investigator teams should discuss PI rights and responsibilities regarding removal of Network Partners that are not able to fulfill study participation requirements as well as stakeholder roles and expectations. Investigator teams should reach out to stakeholders to confirm their specific skills and interests related to study activity and define their roles accordingly.

3 STUDY ACTIVITIES

3.1 STUDY QUERYING

3.1.1 Study-Specific Data Characterizations

As described in Section 1.7.2 of this document, SSDC queries should be as specific as possible to allow for investigator understanding of the strengths and limitations of required data elements and for troubleshooting any data issues that arise through review of results to these SSDC queries.

Study teams should work closely with the CC, including the DRN OC, in the development, testing, distribution, and results review of the SSDC queries. The CC can leverage its knowledge of Network Partner data based on previous data checking activities and study queries to support new SSDC activities. New studies are encouraged to utilize existing PCORnet querying tools to efficiently facilitate the SSDC activities. Investigators should discuss these tools with the DRN OC team to identify the appropriate approach to the SSDC queries.

As noted in previous sections of this document, SSDC queries that quality check all data elements in the manner necessary for study analyses will require specific time and effort to troubleshoot issues discovered in these data elements. SSDC queries should examine the required study variables at each of the participating Network Partners using the code necessary for study analyses. Study teams should ensure that they have the appropriate expertise on their team to assess data quality and support issue troubleshooting. Much of this assessment should be completed prior to submitting a funding proposal, through a prep-to-research query submitted through the Front Door.

3.1.2 Scientific (Study Aim) Queries

Study teams should work closely with the DRN OC for all study querying activities. The DRN OC may provide specific guidance and support with query development (technical specification development, programming, testing, distribution, and preliminary results review). Study teams will be responsible for careful scientific examination of query results.

As for the SSDC activity, investigator teams should ensure close communication with the CC during the development of study queries to leverage lessons learned from previous PCORnet querying activity. If study teams, rather than the DRN OC, will lead programming work for study queries, study teams should utilize the PCORnet Programming Guidance documentation, which is a compilation of rules for programming in the PCORnet DRN.
3.1.2.1 Considerations for Query Development

Aggregate queries can mask problems with data. Thus, studies should include time and effort, when possible, to develop and test any study cohort and regression queries in at least one site providing individual-level data to ensure the quality of included data. If a study includes both individual-level and aggregate queries, it is recommended that investigators develop, distribute, and review results from individual-level queries prior to developing aggregate queries.

3.1.2.2 Development of Code Lists

Prior to developing procedure, diagnosis, or medication code lists, investigator teams should consult with the CC to determine whether previous network activities have required development of similar code lists that new investigators may leverage or update to serve the needs of their specific study.

It is important for investigators to understand which coding terminologies are in use at the participating sites, and they should include time and effort to develop code lists for each terminology. Code list development is an iterative process, and stakeholder input is valuable to the creation of comprehensive code lists (i.e., code lists should undergo review by clinicians and/or clinical experts before they are finalized).

3.1.3 Network Partner Issue Troubleshooting

Examples of potential Network Partner data issues that affect data usability based on the experiences of the ABX and PBS studies include, but are not limited to the following:

- Limited availability of specific variables of interest
- Lower prevalence of diseases or conditions and low rates of prescribing
- Variables not PCORnet CDM-compliant
- Network Partner inability to share patient-level information
- SAS-related issues (e.g., older SAS versions or insufficient SAS software packages)
- Unexpected small cohort size among Network Partner population

Investigators should note that the CC has not done a standardized assessment of data quality for all medications and labs within the Prescribing, Dispensing, and Labs tables of the PCORnet CDM. Thus, investigators are likely to discover issues among these variables that will require time and effort to troubleshoot, especially if specific medications and labs have not been assessed in prior studies. For example, the obesity demonstration projects did a thorough assessment of antibiotics, anti-reflux medications, steroids, diabetes medications, and hemoglobin A1c; other medications and labs may not be as well curated. In addition, investigators should be aware that some tables and variables in the PCORnet CDM are that are listed as “optional,” meaning they are not required to be populated at all. Data availability and quality for these tables and variables is more limited across the network, and will require more careful data checking and issue troubleshooting.

Issue troubleshooting should be completed as a collaborative effort between the study team, CC, and Network Partners. Resolution to Network Partner issues may involve simply re-running a query at a Network Partner and resubmitting results. Or with more complex issues, it may include updates to Network Partner implementation of the CDM; changes to the Network Partner extract, transform, and load (ETL) process; central re-characterization of Network Partner data by the DRN OC; and re-running of study queries. Network Partners may also need to consult their institutions’ clinicians to learn about local coding practices and how those affect data. Thus, close communication should be maintained between the study team, CC, and Network Partners to ensure that all relevant parties are appropriately informed of identified issues as well as plans and activities for troubleshooting. In some cases, issues may result in Network Partner removal from participation in specific study activities or overall study participation. Study PIs should maintain responsibility for decision-making regarding Network Partner participation.
3.2 **LINKAGE**

PCORnet does not yet have standardized processes for linkage to non-PCORnet data sources (as of April 2018). Thus, all linkage activity is currently conducted on an as-needed basis by investigator teams. If a study requires linkage to external sources, such as US Census data, insurance claims, or pharmacy dispensing, investigators should consult with the CC to see if there is an opportunity to leverage lessons learned from linkage activities completed for previous PCORnet studies. Both obesity demonstration projects completed linkages, with ABX study linking maternal and child records and the PBS study linking to claims data.

3.3 **STAKEHOLDER ENGAGEMENT**

### 3.3.1 Lay Guides for Stakeholders

As described in previous sections of this document, study leadership should develop lay guides to educate stakeholders on the research and manuscript development processes as well as study scientific aims and analyses. These lay guides will allow stakeholders to understand technical language on study calls, effectively engage in study activities, and provide substantive feedback when requested from investigators. Examples of lay guides for stakeholders are available on the PCORnet Commons.

### 3.3.2 Stakeholder Activities

Stakeholder activities may include, but are not limited to, input on deliverables, leadership and contribution to stakeholder-specific study aims, participation in workgroups and manuscript development, and attendance of project meetings. Investigators and engagement leadership should prioritize communications with stakeholders to ensure their understanding of study plans and science and maintain stakeholder engagement in all study activities.

As not all investigators have experience in engagement of stakeholders in research, investigators are encouraged to consult the CC regarding effective engagement of stakeholders in PCORnet research. The CC can provide guidance and suggestions for investigator leadership of stakeholder activities based on lessons learned from previous PCORnet activities.

Investigator teams should ensure that stakeholder compensation is appropriately invoiced and distributed during studies. It is important for stakeholders to be compensated for their time, effort, and contributions like all other study team members. A decision should be made early on if stakeholders will be reimbursed for their time by the lead study site or the Network Partner which they represent.

### 3.3.3 Monitoring Stakeholder Experience

Study engagement leadership should lead regular assessments of the stakeholder experience to monitor overall stakeholder satisfaction and address any challenges related to their engagement in study activities. These assessments may be conducted via survey. A survey template for assessment of the stakeholder experience within the context of PCORnet studies is available on the PCORnet Commons. Study engagement leadership is also encouraged to hold one-on-one phone conversations with stakeholders to provide stakeholders with additional opportunities to reflect on their engagement in study activities and discuss any questions or concerns. Based on these assessments of the stakeholder experiences, engagement leadership can expand or alter specific stakeholder roles and provide additional support to stakeholders so that they may fulfill expectations for their engagement.

3.4 **DISSEMINATION**

### 3.4.1 Dissemination to the PCORnet Community

Investigator teams should implement plans for dissemination to the PCORnet community based on plans developed during the application phase and confirmed following notice of award. As described in previous sections of this document, these dissemination activities should be aligned with PCORnet expectations for dissemination and may
include study updates for the PCORnet weekly announcement, attendance and presentation on PCORnet leadership calls, and sharing study materials and resources for the PCORnet Commons.

Investigators are encouraged to share study resources and materials with the PCORnet Commons to continue to build this repository of lessons learned for future study teams, improve study efficiency, and further network growth. Investigator teams should work with the CC to determine what types of materials are helpful to share via the PCORnet Commons.

3.4.2 External Dissemination

External dissemination plans and activities should comply with requirements for publication and presentation, as determined by the funder and PCORnet governance. Policies for PCORnet studies can be found in Section 5.1 of the PCORnet governance document.

3.4.2.1 Publications and Manuscript Development

Manuscript topics should be developed early in the study period as a collaborative effort between study leadership, study team members, participating network partners, and stakeholders. Based on the structure and roles of team members and Network Partners, investigators can determine the appropriate method to seek input from all participating personnel. Study teams should consider the inclusion of a stakeholder-led publication, with topic determination and writing led by study stakeholders.

The structure of manuscript writing and authorship should be clearly defined and communicated at the start of a study. Investigator teams should determine and document the manuscript writing process as well as roles and expectations for study personnel and share this planning with all team members and participating Network Partners. Manuscript authorship planning should be based on the PCORnet Publication Guidance Document, which is available on the PCORnet Commons.

One option for this publication development structure is inclusion of two entities: 1) a writing group which is responsible for developing the manuscript and shepherding it through the review process; and 2) a larger, “corporate” or “collaborative,” authorship group which is composed of additional study team members, stakeholders, and representatives from data contributing sites and is responsible for reviewing and approving the manuscript. If this structure or a similar structure is selected, it will be necessary to develop and document clear expectations of the activities required for members of the corporate authorship group; also this group must meet authorship criteria outlined by journal (typically described by the Internal Committee of Medical Journal Editors – ICMJE). While requiring substantial time and effort, this approach ensures that all team members and institutions have the opportunity to be part of study publications.

3.4.2.2 Conferences

As mentioned in previous sections of this document, study budget planning activity should include consideration of potential conferences for presentation of study activities and findings. Study budgets may include costs to support study team member attendance of and presentation at conferences of interest.

Investigator teams may consider an inclusive, corporate authorship structure for poster presentations that allows for wide study team participation and contribution to poster development.

3.4.2.3 Study Website

Study investigator teams may consider development of a study website for dissemination of study activities and findings. Prior to development of a study website, investigators should consult with the CC to determine if there are resources or templates that may support the development of study websites.
3.4.3 Stakeholder Involvement in Dissemination Activities

Investigator teams will need to provide clear guidance regarding expectations for stakeholder engagement in dissemination activities. If participation in corporate authorship groups is part of stakeholder roles, expectations for stakeholder review of manuscripts and/or posters will need to be clearly documented and communicated with stakeholders. Additional efforts to help stakeholders with manuscript reviews, such as scheduling a phone call to present and discuss the results and manuscript, should be considered.

A key component to stakeholder contribution to dissemination of study activities and findings is stakeholder education and training. Investigator teams will need to ensure that, prior to requesting stakeholder review of dissemination materials, stakeholders have had the opportunity to review lay language summary documentation and/or discuss relevant content with investigator team members to ensure that they can provide substantive feedback.

Stakeholders should also be consulted when planning for implementation of dissemination plans, as they may be able to provide specific suggestions regarding how to communicate study results with relevant patient, processional, and community groups that may benefit from study findings.

4 STUDY CLOSEOUT

4.1 CLOSEOUT MEETING

Study teams are encouraged to host a study closeout meeting to summarize and discuss dissemination of study findings. When possible, stakeholders should be invited to attend and participate in study closeout meetings. This meeting may be an opportunity for study teams to discuss future research.

4.2 SHARING LESSONS LEARNED

As described in previous sections of this document, investigator teams are encouraged to share lessons learned from the conduct of their studies with the Network. Sharing lessons learned will allow the Network to continue to grow, mature, and increase efficiency. Investigators may communicate lessons learned with the CC and PCORnet leadership.

Lessons learned can be incorporated into this document to ensure that this toolkit is relevant for future PCORnet research and investigator teams.
5 CHECKLIST

The following is a checklist summary of the key PCORnet study activities described in the previous sections. Investigators may use this list as a starting point in preparing for PCORnet studies.

☐ Review key study definitions to become familiar with PCORnet terminology
☐ Prepare a proposal for a PCORnet study
  ☐ Determine study priorities
  ☐ Reference available CC resources
  ☐ Consult with the PCORnet CC on current PCORnet infrastructure capabilities and resources, including data availability and quality, IRB processes, DSA, and query development
  ☐ Develop stakeholder engagement plan, with specific consideration for stakeholder recruitment, initiation and maintenance of stakeholder engagement, and expectations for engaged stakeholders
  ☐ Select Network Partners based on investigator team-defined criteria for study participation and consultation with the CC
  ☐ Develop timeline for study activities, with specific consideration for current PCORnet infrastructure and querying capabilities, heterogeneity of the PCORnet network, and additional CC and network activities
  ☐ Develop study budget, with specific consideration for study team, CC, and participating site time and effort to support study activities; current PCORnet infrastructure and querying capabilities; stakeholder engagement; and communications

☐ Post-award study planning
  ☐ Revisit timeline
  ☐ Revisit budget
  ☐ Execute contracts with all participating institutions, utilizing current PCORnet contracting resources
  ☐ Ensure all participating institutions have the appropriate IRB approval, leveraging available PCORnet IRB structures and processes when appropriate
  ☐ Ensure appropriate data sharing and data use agreement(s) are in place at all data-contributing sites
  ☐ Revisit expectations for study personnel and communications

☐ Conduct the study
  ☐ Develop and distribute study-specific data characterization queries to carefully assess all data elements in the manner required for study analyses. Troubleshoot any data issues that arise due to this characterization activity.
  ☐ Prepare and distribute study queries. Investigator teams will be required to lead or support code list development for study queries.
  ☐ Engage stakeholders in study activities as outlined in the proposed stakeholder engagement plan. Develop materials (i.e., “lay guides”) to ensure that stakeholders can effectively contribute to study activities.
  ☐ Conduct all internal (i.e., with the PCORnet network) and external communication and dissemination activities

☐ Study closeout
6  APPENDIX

6.1  GLOSSARY OF TERMS FOR NEW INVESTIGATORS

**Alpha and Beta Testing**: Data queries in PCORnet are regularly tested in the Network prior to formal release. This type of testing before release is called beta testing. Sites selected for beta testing queries may maintain different types of data environments to allow for testing of the query in multiple data environments. Many studies also designate one site as a query alpha tester. This site would be the first Network Partner to execute complete study queries.

**Clinical Data Research Networks (CDRNs)**: PCORnet Partner Networks that are based in healthcare systems such as hospitals, integrated delivery systems, and federally qualified health centers.

**Coordinating Center (CC)**: The Coordinating Center leads the Network’s data and engagement activities, connects with outside research partners, and supports the PCORnet infrastructure. Responsibilities of the CC include: coordinating PCORnet’s operational activities; designing, enhancing, and maintaining the PCORnet data infrastructure; identifying research opportunities and implementing PCORnet-wide research; supporting PCORnet pre-research, observational studies, and interventional multi-site research studies; developing new products and services, and implementing engagement and network-building services; and communicating with CDRN, PPRN, and HPRN partner networks on an individual and group basis to generate collaboration, co-production, and efficiency.

**Data Committee**: The Data Committee’s purpose is to oversee PCORnet’s data network, which is managed by the Coordinating Center. It will also be charged to stimulate informatics and research data innovations that advance the goals of PCORnet.

**DataMart**: A DataMart refers to a collection of data that will be queried and will return output via the PCORnet DRN Query Tool. Each PCORnet Network may have multiple data sources. Several PCORnet Network Partners organize multiple data sources into one centralized DataMart while others organize their data sources in separate DataMarts. PCORnet DataMarts are Network Partners which adhere to the PCORnet CDM. In network documentation, the terms “Network Partner,” “Network Partner,” and “Site” are often used interchangeably to refer to the data-contributing entities of PCORnet.

**Distributed Research Network Operations Center (DRN OC)**: The DRN OC, within the CC, operates, enhances, and maintains the PCORnet Distributed Research Network, which oversees data transformation into the PCORnet Common Data Model (CDM), data quality assessment and remediation, query fulfillment, data science, and facilitation of multi-site patient-centered research across the CDRNs, PPRNs, and other interested contributors. The distributed research network enables the conduct of observational research and clinical trials while allowing each participating organization to maintain physical and operational control over its data.

**Engagement Committee**: The Engagement Committee’s purpose is to design, continuously improve, and oversee PCORnet’s system of engagement of patients, clinicians, researchers, health system leaders, industry, regulators, and other stakeholders. The Engagement Committee reviews and make recommendations to the PCORnet Council for approval of Network engagement policies and standard operating procedures.

**Executive Committee**: The Executive Committee develops PCORnet’s strategic plan under the PCORnet Council’s oversight, develops operational plans for executing the PCORnet Council’s agenda for PCORnet, soliciting input by those affected by PCORnet policies, and ensuring the network’s performance is optimized for quality and efficiency.

**Health Plan Research Networks (HPRNs)**: PCORnet Partner Networks that are operated by health plans.

**Patient Powered Research Networks (PPRNs)**: PCORnet Partner Networks that are operated and governed by groups of patients and their partners.
**PCORnet**: Funded by the Patient Centered Outcomes Research Institute (PCORI), PCORnet: The National Patient-Centered Clinical Research Network, is a large, highly representative, national “network of networks” that collects data routinely gathered in a variety of healthcare settings, including hospitals, doctors’ offices, and community clinics. PCORnet engages a variety of stakeholders, including patients, families, providers, and researchers, to empower individuals and organizations to use this data to answer practical questions that help patients, clinicians, and other stakeholders to make informed healthcare decisions.

**PCORnet Common Data Model (CDM)**: The PCORnet CDM is a way of organizing data into a standard structure. Each PCORnet partner network maps data to the same consistent format (i.e., with the same variable name, attributes, and other metadata). This process creates a platform that enables more rapid responses to research questions. The PCORnet CDM is based on the FDA Sentinel Initiative Common Data Model and has been informed by other distributed initiatives such as the Health Care Systems Research Network, the Vaccine Safety Datalink, various AHRQ Distributed Research Network projects, and the ONC Standards & Interoperability Framework Query Health Initiative. The PCORnet CDM leverages standard terminologies and coding systems for healthcare (including ICD, SNOMED, CPT, HCPSC, and LOINC) to enable interoperability with and responsiveness to evolving data standards.

**PCORnet Council**: The PCORnet Council is the main governing body of PCORnet. The PCORnet Council is responsible for the oversight of PCORnet’s research agenda, for commissioning and approving PCORnet’s strategic plan, and for achieving its strategic goals as a premier national clinical and patient-centered outcomes research network.

**PCORnet Commons**: The PCORnet Commons is a public website fostering connection, communication, engagement and learning among people involved in clinical research. The site was created collaboratively with insight and feedback from across the PCORnet community and provides opportunities to increase collaboration, efficiency, and people-centeredness in clinical research. On the PCORnet Commons, you can share and access resources, engage in dialogue, and connect with colleagues and friends.

**PCORnet Data Sharing Agreement (DSA)**: The PCORnet DSA is a document which defines standard terms to which the Coordinating Center (CC) and PCORnet CDRNs, PPRNs, and HPRNs have agreed regarding what data can be shared within the PCORnet Network and how the data can be used for PCORnet projects. Based on the needs of new studies, amendments to the PCORnet DSA or additional data agreements may be necessary prior to study queries to ensure that all anticipated study activities are appropriately covered. The PCORnet DSA was developed by PCORnet leadership and reviewed by all PCORnet networks before it was finalized. As of the development of this document, all networks are required to have executed PCORnet DSA v2.0 in order to participate in PCORnet studies.

**PCORnet Front Door**: The PCORnet Front Door allows potential requestors (e.g., investigators, patient groups, healthcare organizations, clinicians and clinician groups, government, industry scientists, and sponsors) to submit a request for study feasibility review, data network queries, network collaborators, and/or PCORnet study designation. This is a requestor’s first point of contact for a new PCORnet project. Following submission, the Coordinating Center (CC) reviews all requests to determine if activities are suited for PCORnet resources and infrastructure and how the CC and network can support the requested activities.

**PCORnet Program Management Office (PMO)**: The PMO, within the CC, provides central coordination for PCORnet, oversees all PCORnet operational activities, and oversees implementation of PCORnet research. The following activities are supported by the PMO: coordination of internal and external communication platforms; PCORnet leadership support, including PCORnet committee support and coordination; PCORnet infrastructure support, including efforts related to single IRB and quality improvement reporting; proposal and project support; meeting planning and logistics; and technical assistance for the partner networks, including cross-network support of learning.
People-Centered Research Foundation (PCRF): The PCRF was established to sustain and expand a national network for clinical research that originated with funding from the Patient-Centered Outcomes Research Institute (PCORI) and studies conducted by The National Patient-Centered Clinical Research Network (PCORnet).

Query Fulfillment (QF) Team: The QF team is a part of the DRN OC. Query fulfillment in PCORnet is a multi-step process involving receipt of a request; clear definition of specifications in collaboration with the Requester to inform SAS code development, if necessary; or use of an existing PCORnet program or tool capability (e.g. PMP1, MDQ). Once the program package is assembled, the QF Team facilitates robust internal and beta testing, program distribution, and compilation of output to produce an analytic report for the requester.

Research Committee: The Committee’s purpose is to design, continuously improve, and oversee PCORnet’s research activities, which includes such topics as generating and prioritizing research concepts, ensuring research quality, developing research partnerships, and assigning PCORnet study designation to individual projects when principal investigators request such designation.

Stakeholders: For the purposes of this document, stakeholders are defined as individuals who represent the various interest groups of a study. Stakeholders may include, but are not limited to: patients, parents/caregivers, clinicians, representatives from industry, and representatives from community groups.

Study Leadership/Investigator Teams: Throughout this document, study leadership and investigator teams are terms that are used interchangeably to refer to the study principal investigators, project managers, and additional co-investigators that lead the scientific, administrative, and engagement study activities.

Study-Specific Data Characterization (SSDC): Study-Specific Data Characterization (SSDC) queries aim to assess data quality and availability prior to the start of a study. These are similar to a prep-to-research query where study populations are assessed.
6.2 STAKEHOLDER ENGAGEMENT TOOLS FOR STUDIES

Study participants and other stakeholders are often the intended end users of research results. In stakeholder-engaged research, they can provide integral feedback to help shape the formation, dissemination, and utilization of research results and increase enrollment and retention in clinical trials. It is important that the stakeholder engagement process be implemented equitably and with open space for both technical team members and stakeholders to share thoughts and feedback. This can be challenging, and communication barriers will vary based on the audiences relevant to each study question.

This toolkit serves as a guide for study teams to execute stakeholder engagement in their project. The sample tools model some of the activities and principles that facilitate meaningful participation and decision-making of stakeholders in large, multisite studies. The tools included below were developed using lessons learned and stakeholder feedback from the PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth.

There are three resources in this toolkit:
- A sample Memorandum of Understanding between stakeholders and lead study investigators
- A checklist guide for stakeholder engagement activities
- A sample of a survey used to assess quality and improve stakeholder activities

See the PCORnet Engagement Glossary for definitions of engagement terms used throughout this toolkit.
6.2.1 Template: Memorandum of Understanding for Stakeholder Partnerships

Memorandums of Understanding can be used as agreements between study teams and stakeholders to describe the scope of work that will be completed. Both formal and informal forms of these agreements have been used to set expectations for stakeholder participation and ensure that roles and responsibilities are clear for all involved. While the below template outlines several sections typically included in a Memorandum of Understanding, the study team should include any legal language that may be required by their host institution and consult their contracts department prior to executing agreements.

**Memorandum of Understanding**

[Name of the Project/Study]

[Time Period for Agreement]

This Memorandum of Understanding (MOU) between the [Insert Name of Principal Investigator/host institution] and [Insert Name of Stakeholder] is agreed as of this __ day of Month, __Year__.

**Background**

Describe the background for the question being investigated in this project. Include any relevant information on the study team and/or institutions involved and how the project was developed.

**Project Overview**

Give a detailed description of the project, its aims, and how stakeholders will be involved, written at a basic literacy level so the information is clear, concise, and easily understood by a variety of stakeholders.

**Roles and Responsibilities**

In a bulleted or numbered list, categorize and describe the duties and expectations for each person signing this agreement (i.e. the Principal Investigator and the Stakeholder). Roles and responsibilities could vary depending on the type of stakeholder (i.e. clinician, patient, caregiver, community member, etc.).

**Principal Investigator**

In support of the stakeholders involved in this project, the Principal Investigator (on behalf of the study team) agrees to do the following:

[Insert specific roles and responsibilities. Examples included below.]

- Provide updates on the study during regular meetings and calls
- Identify and ensure opportunities for stakeholder involvement and decision making
- Incorporate stakeholder feedback in study protocols, documents, and dissemination plans

**Stakeholder**

As a stakeholder participating in this project, [insert name] agrees to do the following:

[Insert specific roles and responsibilities. Examples included below.]

- Serve on the Stakeholder Advisory Group
- Attend regular meetings and calls (include frequency)
- Assist in selecting the study question
- Provide feedback on study protocols, documents, and dissemination plans

**Stakeholder Deliverables**

List any deliverables that are expected for the stakeholder and give a short description of each.
Communication Plan
Describe how the study team (represented by the Principal Investigator) and the stakeholder will be expected to communicate. Include information about regular meetings or calls if necessary. Describe planned communication methods: e.g. email, in-person meetings, conference calls, etc.

Timeline of Activities
Describe the project period and include an anticipated number of hours per week/month required to fulfill the roles and responsibilities outlined. A table is a helpful way to illustrate the expected timeline of the deliverables and activities over the duration of the project.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ex. Signed MOU due</td>
<td>7/30/2018</td>
</tr>
<tr>
<td>Ex. Kick-off Meeting</td>
<td>8/20/2018</td>
</tr>
<tr>
<td>Ex. Monthly Calls</td>
<td>The first Monday of each month beginning 10/2018</td>
</tr>
<tr>
<td>Ex. Final Report</td>
<td>8/31/2019</td>
</tr>
</tbody>
</table>

Funding
Describe monetary and any other compensation that will be provided in this role. If any expenses will be reimbursed, describe along with the process for requesting reimbursement.

Signature of Stakeholder: ___________________________    Date: _________
Signature of Principal Investigator: _______________________   Date: _________
6.2.2 Engaging Stakeholders in a Research Project: A Planning Checklist

This checklist is designed to help investigators and study teams meaningfully involve stakeholders throughout all phases of the research process, including:

- Identification of research priorities
- Research planning
- Research design and identification of meaningful outcomes that matter
- Execution of research
- Data analysis
- Dissemination of research results

Lessons learned and examples of engagement activities from the PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth informed the development of this tool. For further tactics and examples, reference the PCORnet Engagement Assessment Tool and other engagement resources and case studies on the PCORnet Commons.

Research Question Generation and Prioritization

- ✓ Involve stakeholders (i.e. patients, caregivers, clinicians, and communities) in research question identification and prioritization prior to securing funding (i.e. using online platforms, including registries, community forums, or social media to crowdsourc ideas; in-person meetings, conferences, etc.).
- ✓ Develop a research question that matters to patients, families, and communities.
  - o For examples of tools, resources, and processes that PCORnet networks have used to involve stakeholders in research question generation and prioritization, see this guide.
- ✓ Identify specific individuals who are interested in working with you on a proposal to identify funding opportunities and move identified research questions forward.

Developing Your Study Proposal

- ✓ Consider the inclusion of a stakeholder Co-Principal Investigator or Co-Investigator as part of the lead investigator team for the proposed study.
- ✓ Plan for engagement activities to occur from the beginning of the study and create opportunities for stakeholders to contribute to the development of research and engagement plans.
- ✓ Avoid tokenism by finding opportunities for stakeholder involvement and contributions to add value to the project.
  - o Have a process to ensure that you have the time and ability to meaningfully incorporate stakeholders’ input.
- ✓ Develop specific aims for which stakeholders can either lead or significantly contribute.
- ✓ Establish core principles to guide your project’s engagement efforts throughout the entire research process.
  - o The PCORnet Engagement Assessment Tool provides recommendations for key principles for partnership.
- ✓ Allocate sufficient budget and staff full-time equivalence (FTE) hours towards engagement activities, as well as monitoring and improving these activities over time.

Launching the Study

- ✓ Inform stakeholders involved in the proposal phase that the project was awarded and assess how you can actively involve them across the phases of the study.
- ✓ Identify and provide all involved stakeholders with a memorandum of understanding or contract to outline the roles and responsibilities, timeline, and compensation expectations at the outset of the project.
- ✓ Compensate stakeholders fairly according to their contributions to the project.
- ✓ Give all stakeholders an opportunity to be involved in identifying needs and priorities for the project, including topics to cover at a study kick-off meeting.
✓ Host a kick-off meeting with all project stakeholders to define roles and responsibilities, align on project goals and objectives, and confirm timeline and deliverables.
✓ Have investigator teams develop and provide resources, guidance, and training to ensure that stakeholders can meaningfully engage in study activities as outlined by their respective roles and expectations.
✓ Formally train all investigators on stakeholder engagement.
✓ When finalizing project timeline and deliverable schedules, build in sufficient time for stakeholders to review and provide input on all study materials throughout the project.

Study Implementation and Analysis
✓ Convene stakeholders frequently (e.g. monthly) to ensure members receive ongoing study updates, review and provide feedback on study documents and plans, and identify opportunities for future engagement activities.
✓ Have a mechanism in place to capture stakeholder feedback, including a plan for how to implement changes accordingly.
✓ Develop materials that include lay language to ensure all stakeholders have the ability to understand the project aims, goals, and other details.
  o Reference this Plain Language Principles guide to help develop these materials.
✓ Select individual members of each stakeholder group (i.e. patients/participants, caregivers, clinicians, etc.) to serve in a more involved capacity, such as an advisory committee or workgroup.
✓ Create metrics or measures for engagement that allow you to track progress towards engagement goals and objectives.
✓ Continue to monitor staff time and budget to ensure you have accounted for engagement activities throughout the entire project duration.
✓ Work with stakeholders to find activities and roles that best leverage their strengths and expertise (i.e. participants may have greater involvement in participant requirement or research questions development; clinicians may have greater involvement in study cohort development).
✓ Identify opportunities for stakeholders to inform analysis activities.

Dissemination
✓ Integrate stakeholders into publication and dissemination planning activities.
✓ Include stakeholders as authors on publications. It may be helpful to hold conference calls to review manuscripts with stakeholders before they have the opportunity to provide feedback on study manuscripts.
✓ Work with stakeholders to identify non-traditional channels for disseminating research findings (outside of publication).
6.2.3 Monitoring Stakeholder Engagement in a Study: A Sample Survey

The PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth was one of the first demonstration projects in PCORnet, the National Patient-Centered Clinical Research Network. As part of this project, stakeholder engagement was built into multiple layers of the project; most notably through the formation of the Executive Antibiotics Stakeholder Advisory Group (EASAG). The EASAG was a governance committee comprised of parents, health systems leaders, pediatricians, pharmacists, and organization leaders. EASAG members became integral working parts of the team, connecting frequently with the investigators; providing feedback on study plans including protocols, analysis approaches, and dissemination planning; and reflecting on the value of the project and their role.

As the project was underway, the engagement leadership team worked with the stakeholders to develop a survey to collect EASAG members’ feedback on their involvement in the project. Goals of the survey included:

- Determining stakeholder satisfaction
- Informing the study’s engagement process and opportunities for improvement
- Documenting lessons learned to benefit future studies

Note: This survey was not intended to be a formal evaluation or measurement of engagement in the study. It was a quality improvement effort designed to understand stakeholders’ satisfaction with their involvement and to identify successes and challenges that could inform changes to engagement processes for the remainder of the study. The questions were developed in collaboration with the stakeholders and were specific to their role and experiences in this study. Other PCORnet engagement resources, including the PCORnet Engagement Assessment Tool, were also referenced in the development of this survey.

Investigators interested in adapting this survey for their own research projects should consider the context of stakeholder engagement in their study and work with their stakeholders to hone these questions to be relevant to their study. Future efforts should also leverage existing engagement tools and resources available on the PCORnet Commons.

ABX Stakeholder Survey Content

Introduction: This survey is designed to help us understand your experience as a stakeholder in the PCORnet Antibiotics Study (ABX). The survey is meant to provide feedback on your participation and will be used to improve stakeholder involvement for the remainder of the project. We may present aggregate findings from the survey to the various groups including the executive stakeholders, the principal investigators and project managers, and others involved in PCORnet. This information will also be summarized for the overall PCORnet evaluation team to use for their reports to PCORI and may be presented in summary form in future manuscripts describing the PCORnet Antibiotics Study and its stakeholder engagement strategy.

1. What stakeholder role do you play in the ABX study? (you can choose more than one)
   a. Investigator/Researcher
   b. Community Organizational Leader
   c. Advocacy Group Leader
   d. Parent/Caregiver
   e. Healthcare Provider
   f. Healthcare System/Organization Leader
   g. I am not sure
   h. Other (please specify)
2. In which of the following study groups have you participated?
   a. Executive Antibiotics Stakeholder Advisory Group (EASAG)
   b. Secondary Aim Focus Group Site
   c. Dissemination Workgroup
   d. Publications Workgroup
   e. Maternal-Child Linkage Workgroup
   f. PCORnet Antibiotics Scientific Core

The following questions will ask you how much you agree with statements about the activities (in-person or phone meetings, and any other work that you did as part of these groups) of being a stakeholder in this study. If you are not sure how you feel about the statement, please use the response “Neither agree nor disagree.”

3. Individuals whose lives are most impacted by children's antibiotics use or pediatric obesity are well-represented.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

4. The study values the differences of contributing stakeholders.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

5. I have decision-making authority and believe I contribute meaningfully to relevant outcomes and objectives for the study.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

6. I feel the study team has a clear understanding of stakeholders' expertise, strengths, and roles.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:
7. I feel that I have been compensated appropriately for my time and expertise as a stakeholder.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

8. ABX study stakeholders engage in open communication and demonstrate a willingness to listen to others.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

9. My fellow stakeholder participants respect what I have to say, even when they do not agree with me.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

10. I have enough information about the general topic area of antibiotics and pediatric obesity to participate effectively.
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree
    f. Open text space for additional comments:

11. Study information and materials are always shared and presented in ways that I can understand.
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree
    f. Open text space for additional comments:
    g. Strongly agree

12. Participating in these activities has helped me better understand research on antibiotics and obesity in early childhood.
    a. Agree
    b. Neither agree nor disagree
    c. Disagree
    d. Strongly disagree
    e. Open text space for additional comments:
13. I have learned a lot from participating in these activities.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

14. I feel I could explain the ABX study to others.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Open text space for additional comments:

15. We would like to know if 1. you expected to participate in each study activity when you first became a stakeholder, and 2. if you later had the opportunity to participate. Please also rate your satisfaction with your participation. If you were not satisfied, we ask that you provide further feedback using question 19.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Did you expect to participate?</th>
<th>Were you able to participate?</th>
<th>How would you rate your participation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning the research aims</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Planning stakeholder engagement</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Planning data analysis/interpretations</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Interpreting results</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Planning the Secondary Aim</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Planning for dissemination</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Participating in conferences and presentations to research audiences</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Participating in publication development</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
<tr>
<td>Participating in engagement of partners and other groups</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>High, moderate, low</td>
</tr>
</tbody>
</table>

16. How much time per month on average do you spend on work related to the study (minutes or hours)

17. Do you consider this amount of time:
   a. Not enough, I could do more
   b. Just right
   c. Too much
   d. Not sure
18. Overall, how satisfied have you been so far with your role as a stakeholder in the study?
   a. Extremely satisfied
   b. Satisfied
   c. Somewhat satisfied
   d. Somewhat dissatisfied
   e. Extremely dissatisfied
   f. Not sure
   g. Additional comments:

19. What could be changed to improve your stakeholder experience?