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PCORI Eugene Washington Engagement Award
AHIP: Evaluating Feasibility & Requirements for
Expanded Health Plan-based Ready Rapid Cycle
Research Capacity (“Rapid”)

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Overview / Background and Need

In 2013, the Patient Centered Outcomes Research Institute (PCORI) funded and established the National Patient Centered Clinical Research Network (PCORnet) with 11 Clinical Data Research Networks (CDRN) and 18 Patient Powered Research Networks (PPRN), supported by a Coordinating Center run jointly by the Harvard Pilgrim Health Care Institute (HPHCI) and the Duke Clinical Research Institute (DCRI), to create a national resource for conducting patient-centered clinical comparative effectiveness research (CER). In 2014, America’s Health Insurance Plans (AHIP) received a Eugene Washington PCORI Engagement Award Evaluating Feasibility & Requirements for Expanded Health Plan-based Ready Rapid Cycle Research Capacity (Contract # 1213-AHIP) to help facilitate the engagement of health plan stakeholders with the PCORnet CDRNs with the goal of ultimately establishing collaborative relationships that involve sharing of data and conducting research that is of interest and benefit to all.

Health plans are key stakeholders in PCORnet and PCORI funded studies. As mandated financial contributors (under Subtitle D of Title VI - Sec. 6301. Patient-Centered Outcomes Research Section 4375 of the 2010 Patient Protection and Affordable Care Act), possible sources of patient data, and potential end-users of PCORI-sponsored research, health plans have a vested interest in PCORI’s efforts. Maintaining engagement and support from the highest levels of stakeholder organizations has been identified as essential for the success and long-term sustainability of PCORI and the new research paradigm it is advancing,¹ as is the commitment by health plan leaders to their organization’s engagement with PCORnet.

This report summarizes the activities conducted under the Engagement Award, key points from the discussions and lessons learned, and offers suggestions for further consideration regarding the engagement of health plans with PCORnet.

The Importance of Health Plans as Partners

As a distributed research network, PCORnet was established with many similarities to other networks, including the FDA Sentinel and the Health Care Systems Research Network (HCSRN formerly HMORN) virtual data warehouse (VDW). PCORnet has a common data model (CDM) based on that developed and refined by the Sentinel. Unlike these other systems, which are either based on health care claims data or the combined electronic health records and claims within integrated systems of care, PCORnet starts with electronic health records and other patient data, including patient-generated and reported data that are readily accessible to these networks. From the beginning, it was expected that PCORnet networks would need access to a significant quantity of health

care claims data in order to supplement electronic health record data and other patient data to create a more complete picture of the diagnoses and care received.

Health plans are seen as important partners in PCORnet: as sources of research questions, end users of research findings, and sources of essential data for answering a wide range of questions. The desirability, feasibility, and challenges of bringing together health plan claims data and the PCORnet networks were acknowledged in the Sentinel-PCORnet joint working group’s November 2015 white paper:

“The ideal setting for the conduct of CER and medical product safety surveillance is administrative claims data combined with EHR and clinic-based and/or patient-based registry data (e.g. from a PPRN). This ideal setting would create a persistent linked dataset with controlled access through a trusted third party. The multiuse dataset would allow for rapid medical product safety surveillance activities and CER study feasibility assessment. There is considerable precedent for the sort of linked dataset that could fulfill this ideal setting in the Accountable Care Organization data models in which payers routinely provide complete claims data for the purposes of clinical care coordination, however institutional guidelines for sharing personal health information vary considerably, and may be more restrictive for purposes other than treatment, payment, or operations. Addressing the governance challenges to facilitate a similar shared data model for research would appeal to both the medical product safety surveillance activities of Sentinel and the PCOR activities of PCORnet.”

PCORnet’s Progress

In late 2014, PCORnet was preparing to complete the objectives of its first 18-month phase of development. In order to fully understand the dynamic landscape surrounding this project, it is important to note the parallel progress of PCORnet coupled with its expansion in its second phase.

PCORnet entered its second phase in October 2015, which included an expansion of the number of networks to 13 CDRNs and 20 PPRNs. In 2016, PCORI issued a funding announcement for health plans to join PCORnet as partners to work initially with the CDRNs. As a result, research divisions of two large national health plans, Anthem (Healthcore) and Humana, were added to PCORnet for an initial period of one year. An evaluation of their work after one year will determine next steps for optional second and third years.

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PCORnet continued to progress towards its stated goals. These have included developing a common data model, putting in place a governance structure, streamlining operations, creating functional datasets with quality-checked, research-ready data, establishing links to registry data, establishing CDRN-specific links to other data including that of health plans, the initiation of demonstration studies, and piloting linkages to other networks.

The CDRNs have gradually established relationships and linkages with payer data. Some notable early examples include Reachnet with Blue Cross and Blue Shield of Louisiana, Pedsnet with Independence Blue Cross, MidSouth with TennCare, NYCDRN with its existing network of payers in New York, and Greater Plains Collaborative’s initiation of linkages with CMS. Other CDRNs have made progress with linking to claims data from other health plans. With the inclusion of two large national plans in PCORnet, this process will continue on a larger scale.

PCORnet was declared “open for business” at the PCORI Annual Meeting in November 2016 with data ready for use among network members. It is expected that PCORnet will be prepared to work with external users through its “front door” portal for queries beginning in the first half of 2017.

From its inception as a network for conducting CER, PCORnet has been viewed as the potential core of a national evidence generation network or “network of networks” that includes government and private entities such as manufacturers, health systems, and insurers. The following graphic from the 2016 PCORI Annual Meeting shows how PCORnet can link with other networks and support the needs of a variety of partners and stakeholders with bi-directional data to help answer their questions.

(slide #8 from J.V. Selby presentation PCORnet in Action: Journey Towards People-Driven Research Transformation at PCORI Annual Meeting on 11/19/2016)
Among the PCORnet linkages that are being actively pursued are those with the FDA Sentinel and with the CDC. The PCORnet Sentinel Genesis pilot projects have been initiated to address the need for surveillance capacity to assess critical public health concerns like antimicrobial resistance and rare conditions such as congenital Zika syndrome. These pilot projects leverage the combined resources of the PCORnet and Sentinel data to identify populations, conduct surveillance, and monitor outcomes. This is consistent with both PCORnet’s and Sentinel’s objectives to use and reuse systems to address additional questions enabling economies of scale that enhance the return on investment (ROI). As other linkages occur, such as those with health plans and health systems to assess quality of care, they will enhance the ROI for all partners.

**AHIP Engagement Award Project**

As the central component of the Engagement Award project, AHIP convened two in-person meetings with leaders of health plans and of health systems engaged in PCORnet. The ultimate intended purpose of these meetings was: (1) to facilitate the engagement of health plan stakeholders with PCORnet; and (2) to help identify common areas of interest as well as potential research topics for the health plans and PCORnet health systems to pursue collaboratively.

The first meeting was held on May 20, 2015. Participants included representatives from seven health plans along with leaders from PCORI and the PCORnet Coordinating Center. The focus of this meeting was to introduce the health plans to PCORnet and the need for claims data to answer questions posed in the CER being conducted by the networks. Discussion included identifying questions of common interest for the networks and health plans and how methods being used for the PCORnet demonstration studies might also be used to answer other questions of relevance for the health plans.

The second meeting was held on April 14, 2016, with participants from six health plans and eight CDRNs, along with leaders from PCORI and the PCORnet Coordinating Center. AHIP legal staff also provided subject matter expertise regarding concerns about data privacy and sharing of data with health plans. This meeting was informed by the joint Sentinel-PCORnet working group’s November 2015 white paper. Six of the authors of the white paper participated in the meeting. The discussion focused on how to connect PCORnet’s CDRNs and insurers, including how to protect the privacy of the information exchanged, and the value of bringing together CDRN and health plan information to inform CER and, ultimately, to improve care and outcomes.

In addition to the two in-person meetings, two follow-up conference calls were held to further discuss key issues. These calls were held on September 29, 2015, and October 6, 2016. A number of one-on-one discussions by phone and in-person also took place with meeting participants over the duration of the project and helped to inform the broader discussion. In addition, while not a formal part of this project, the conference calls of the

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joint Sentinel-PCORnet working group and development of its 2015 white paper overlapped with and informed the discussions.

**Key Summary Points from the Meetings**

There were several assumptions that served as the basis for the meetings and discussions:

- PCORI has, from the start, seen health plans as partners in PCORnet.
- PCORI believes that there are efficient ways to merge claims and clinical data.
- PCORI has always anticipated bi-directional relationships between the plans and CDRNs will ultimately occur and will be part of sustaining collaboration.
- CDRNs need to partner with health plans for data in order to have more complete information on patients.
- Success requires defining the business case for each stakeholder, including patients, clinicians, health systems, payers, researchers, and research funders.

The discussions during the meetings and in follow-up telephone conversations identified opportunities, challenges, elements essential to sustainability, and some key lessons from other data collaborations. These are summarized below.

**Key Opportunities, Challenges, and Lessons Learned**

**Opportunities and Motivating Factors for Data Sharing**

The opportunities and motivating factors discussed included the potential benefits from working together to find answers to shared questions as well as access to information otherwise not readily available to a collaborator. Additional factors are highlighted below.

**Health plans may be interested in using PCORnet to address research questions in which they have a stake.** In addition, health plans may find value in identifying a patient population and asking the research networks questions about that population.

**Health plans are concerned with the value of care.** Health systems may be interested in looking at issues such as readmission rates or healthcare acquired infections (HAIs) that are driven by CMS requirements but that may not be a top priority for some health plans. Health plans generally have an interest in real issues of high-cost and high-frequency procedures and to what extent they reflect best practices or provide high-value care. PCORI and PCORnet offer the potential for true randomization of patients into comparative clinical effectiveness (CE) trials. Cardiac care and back pain are examples of areas where studies of CE for surgical intervention or other procedures versus medical management of the condition hold significant interest for health plans. High-cost care interventions need to be better understood to know which are resulting in high value care/outcomes. High-cost specialty pharmaceuticals are also an area for study.
A key motivating factor for sharing data in the framework of PCORnet is public interest. Several people specifically cited that there is a shared interest in getting to better research outcomes as well as better health outcomes for both individuals and the population as a whole. One person pointed out that a lot of health plans are increasingly driven by the triple aim of improving patient experience, improving the health of populations, and lowering the cost of care. To achieve this, plans need data to support all three components; collaborating with PCORnet might be a way to achieve this objective.

Health plans are interested in data sharing in order to access clinical data to address a wide range of research questions. CDRNs noted that having claims data along with their clinical data and other sources helps to complete the picture of health care provided to the patient. This is especially the case in large, fragmented health care markets such as major metropolitan areas. The need for bi-directional data sharing is important. The data sharing must flow both ways, with the PCORnet networks having access to health plans’ claims data and the plans having access to the clinical data in the networks. Bi-directionality also needs to extend to having research questions originating in the networks and from the health plans.

Organizations will clearly be more motivated to share data when it is worth their while to participate, such as when an organization has an interest in the answer to a specific research question. It was noted that there is a need for any partnership to be designed as a “win-win” to benefit both parties to achieve their objectives, including understanding what care works best for patients, health systems, and payers. It was also noted that organizations share data all the time with both for-profit and nonprofit partners when there is a clear reason for doing so.

Potential Benefits of Collaborating

The number one benefit cited for a collaboration between health plans and PCORnet is to support research studies that answer questions to make informed medical policy decisions. Health plans need research that can drive quality and affordability and having a more complete understanding of outcomes is essential. Closing gaps is a motivating factor and as one person put it: “We want to close gaps in data that are necessary to close gaps in evidence in order to close gaps in care.” Others mentioned additional benefits of collaboration that are highlighted below.

Completeness of data is an objective that supports collaboration. From the clinical research side, it’s about longitudinal data and access to full clinical records from multiple sources. For health plans, it’s about getting access to data from electronic health records, such as lab tests and more detailed data on diagnoses, and outcomes. It’s about bi-directional data sharing that expands the data available to the collaborators to obtain more complete answers to questions. Having more complete data makes the research all that much more valuable. For example, having claims data along with clinical data can help to understand what happens after a patient is discharged from the hospital. Another potential benefit of collaborating is the opportunity to understanding the impact of large-scale policy changes (e.g., Medicaid expansion). Similarly, for researchers, having
commercial data along with Medicare and Medicaid data enables them to have a more robust picture of the population.

Working together can help identify the key clinical questions and system delivery questions that are of greatest interest to payers, researchers, and patients/consumers.

Establishing and strengthening relationships between payers, providers and patients is another benefit of collaboration. One person pointed out that, while there hasn’t been a use case yet to test it, there might be a benefit in collaborating with providers on projects around engaging patients, streamlining how patients work with their payers, or what patients want.

Another reason given for collaborating was the opportunity to understand mutual priorities and lessen the misconception by some that health plans don’t invest in research. As a corollary to this, a collaboration with PCORI enables plans to showcase their commitment to working with others including federal agencies and foundations.

Finally, there is a shared value in disseminating local innovations. One person pointed out that innovation in health care typically happens at the local level and then gradually moves nationally. It was suggested that PCORnet offers the opportunity to leverage the innovations that are happening at the nodes and then help to disseminate those that work best to others across the broader network.

Challenges to Making Collaboration Work

Data and its use, as well as the justification for sharing, are at the core of the challenges mentioned. The challenges to making collaboration work can be split into several categories:

- technical issues
- governance issues
- resources / time
- disparate systems / fragmented marketplace
- the business case / ROI

Health plans are concerned with federal rules, potential secondary use of data, and the consumer perspective. Their clients/customers need to be assured that their data is protected. Health plans are reluctant to release data due to the risk of a breach. Trust is essential. One big concern expressed by plans is the need to ensure that the data shared is not disseminated in a way that it could be misused in a way that harms competition. Governance and permitted uses of data must be specified and agreed to up front. It may be possible to build trust through a stepped approach. For example, participating organizations may be offered an opportunity to opt-in to share data based on topics of high priority to them. With this type of approach, trust can develop over time; this may, in particular, help plans with more limited research and information-sharing experience than is needed for this type of work.
Health plans need to guard their data; if it is shared, they need to know who will guard it and how. From their perspective, sharing must have a specific purpose and, when that is defined, it can be easier to document in an agreement. Health plans do not customarily share information from administrative services only (ASO) or self-insured employer accounts because the data are considered to belong to the employer. Both PCORnet networks and health plans consider their data to be essential to their operations; as a result, they will be cautious in exposing themselves to any risk that comes with data sharing.

Access to data for the broader population poses challenges based on different scenarios for who owns or controls the data. While the data belongs to the health plan on the commercial side, it belongs to the employer on the self-funded/ASO side. Medicaid data belongs to the state (and is therefore governed by data release rules on a state-by-state basis). One participant said that in order for the organization to provide data, they would need an independent (legal) entity to have responsibility for data oversight and analysis that is not itself a data contributor; that entity would need to establish a contractual relationship with the plan that would define roles and responsibilities. It was suggested that the entity could be PCORI, AHIP, Duke University, or another organization that could take on the role and meet the necessary criteria.

Health plan legal staff play an important role in the decision process regarding data-sharing. Legal departments would need answers about specifics for a given situation, such as the level of security, standards used, and other technical details. A further challenge to collaboration is that the specifics will likely vary by organization and/or the individual circumstances of the data sharing. For example, any use of identifiable data would result in greater scrutiny and require that more detail about the process be provided.

Participants expressed a preference for an independent data repository that doesn’t have restrictions on what can be researched and where researchers can conduct studies without being beholden to external funders or limited by political constraints. The group recognized the need for the protection of specificity on data use, to get an agreement in place, as well as the need for flexibility to achieve the scalability needed for research. It was also noted that the CDRNs are complex organizations comprising academic and provider institutions. Therefore, it may be difficult for the health plans to understand which individual institution they may be sharing information with and who is responsible for protecting that information.

Ensuring that consumers have affordable access to evidence-based care is a priority for health plans. The limitations on PCORI-sponsored research to address cost is a challenge for health plan engagement. The legislation establishing PCORI prohibits funding for studies that conduct formal cost-effectiveness analysis or directly compare the costs of care between two or more alternatives. However, studies may measure and report utilization of services as well as evaluate reducing waste and improving health
system efficiency. As secondary aims, studies may look at the effects of costs on patients such as direct out-of-pocket costs, hardships, lost opportunities, or barriers to care.

**Key technical challenges revolve around how to establish data linkage and in what form to make data available to one another.** There is also the question of getting informed consent and the associated challenges to that process. Regarding data linkage, it was pointed out that the challenge is two-fold: (1) getting individual patient consent; and (2) privacy concerns, including HIPAA and IRB review. While obtaining consent is consistently challenging, the privacy concerns have only heightened in recent years as identified data moves across entities (e.g., CDRN-to-CDRN, CDRN-to-health-plan, and so forth) or is “hashed” to minimize risk of loss of confidentiality. Possible solutions were seen in following the lead of Sentinel, which has a CDM with siloes of data linked internally to identifiable data. Another suggestion was the use of a blockchain, where only the patient controls his or her data. What overlays much of this discussion is the importance of getting the infrastructure component right. It was also suggested that one demonstrated solution to get more data in the CDM is through a VDW that would standardize and link health plans to the CDM to streamline the process.

**A clear set of governance policies that are generalizable is essential rather than addressing governance on a project-by-project basis.** For example, who sends data to whom? What are the controls on who holds the data and who can use it? It was noted that setting up registries raises additional governance questions. One person pointed to Sentinel, noting that Step 1 there was to tackle the issue of governance. Once that was in place, the path forward was easier. He added that the notion of having something classified as a public health surveillance interpretation by the HHS Office of Human Research Protections (OHRP), had helped the conversation that researchers needed to have with the attorneys within their organizations.

**There was also discussion about ongoing health plan collaborations with CMS.** One person noted that establishing that first relationship helps to build credibility — and facilitates new relationships with other federal agencies. The person suggested that PCORI bring in CMS (i.e., a trusted broker) to kick-start the process at a totally different level and as a broader and less isolated approach.

**Regarding disparate systems, different markets have different health plans and the relationships between payers and providers varies.** As a result, figuring out how collaboration works will vary by location and CDRN. The lack of a national data exchange means that large insurers likely would have to deploy multiple solutions — which would be a managerial nightmare and not sustainable.

**Identifying the value proposition or making the business case is a major challenge to beginning and sustaining collaboration.** Aligning the incentives at the level of the data infrastructure is essential. The parties participating in data sharing must have incentives to participate or the system will break down. There also needs to be sufficient volume for the system to make it sustainable.
Although there is some motivation to share data with PCORnet, there are also corporate concerns. The primary concern is resources. One person specifically noted that it is complicated and expensive to scrub the data to make sure any shared data set contains no protected health information. Another concern cited was the need to ensure that the data sharing/dissemination does not disclose competitively sensitive information.

Getting data ready to use is a big lift for health plans and another challenge to making collaboration work. A lot of money, time, and resources are involved. The biggest question regarding the cost of collaboration is how costs will be distributed and borne by the partners. One solution mentioned to make this work is investing in building infrastructure for data sharing, with a clear value proposition, that it can be reused continuously for additional studies.

Ensuring Patient Privacy / The Role of Data Linkage and Anonymity

There was a general consensus that information technology and legal departments, two key groups that are committed to protecting patient privacy within many organizations, need to be fully engaged in the process and confident in the security of the system to mitigate risk, including making sure data sharing is done in accordance with all legal and regulatory obligations. Additional factors cited for ensuring privacy in moving forward with data sharing are highlighted below.

Data-use and data-sharing agreements are necessary. It was noted that data already moves in identifiable ways for treatment and payment purposes, but that new provisions are needed to afford opportunities to use data that are already protected for research. At the same time, there are business operations concerns with having individual-level clinical data moving from one organization to another.

Moving forward requires having very clear controls over the decisions about how to use shared data and who has the right to use the data. While organizations may already share a lot of their information with each other, they generally do so in ways that give them complete control over what happens with the data. It is essential to have very clear controls in order to limit the flow of protected health information as data are moved and used. The FDA Sentinel may offer a way forward as the Sentinel isn’t just about trust — the data resides with individual partners so that each is less worried about data breaches and confidentiality issues.

In addition to Sentinel, several other examples of health data sharing were cited as options for PCORnet to learn from their experience such as the Utah Health Information Network (UHIN) and Surescripts. UHIN gathers claims data from the various health plans and makes it available to participants. The value of participation is that it gives each plan a more comprehensive information about the health care that its members receive. Surescripts was created to improve the safety and efficiency of the prescribing process by enabling payers/pharmacy benefit managers to deliver benefits information, formulary, and medication history to prescribers at the point of care and enable the bi-directional exchange of medication information with pharmacies. The
Surescripts infrastructure can be reused for other purposes including research. Two additional examples mentioned from within the health care sector were Optum Healthcare’s exchange of data with the Mayo Clinic, and IBM Watson.

**One person suggested the need for a legislative approach** to encourage data sharing in the health care sector while protecting individual organizations from liability concerns. One approach could involve creating “safe harbor” provisions for the organizations involved. More expansive approaches could include establishing an entity to coordinate data sharing or providing some form of direct incentives whether as a “carrot” or “stick”.

Many people felt strongly that any data linkage with PCORnet has to be **anonymous**. One person said that his organization will not release identified data unless it can clearly identify the health care need. Another said that it is not that the linkages need to be anonymous but that the final data set needs to be de-identified. He added that there are different types of anonymous linkage including probabilistic matching, which can be but isn’t always accurate, and deterministic matching, using a third party to make sure that the ultimate data set is completely de-identified. Another person stressed that while there are alternatives for how you do anonymous linkage he believed that identified linkage is a non-starter.

It was pointed out that the notion of patient consent can negate the need for anonymous linkage. Another person said that anonymous data linkage is not necessary on a case-by-case basis but might be for a master patient locator. If an organization is willing to share direct identifiers, then that’s the best way to go.

There was discussion about the concept of a universal identifier. The concept was mentioned regarding the value of coming up with a model for how a payer would handle data exchange with PCORnet that others could consider. One CDRN investigator noted that if PCORnet would have a network-wide patient identifier for Phase 2, it may help with some of the concerns about identifying/re-identifying patients.

**Essential Elements for Sustainability**

Building a network with health plans engaged as partners in collaboration on multiple research questions over the longer term is essential for sustainability. Additional elements to support sustainability of a multi-stakeholder research network are highlighted below.

**There has to be some clear ROI for an organization to share data** for this collaborative exchange to work over the longer term. The key for establishing a value proposition for health plans is for PCORnet to do studies of interest to the health plans. For health plans, some options for sustaining collaboration include having the data brought together for use in evaluating outcomes for potential use in areas such as individual value-based payment models.
There is a need for bi-directional data in order to make the return on investment possible for all parties. Bi-directionality allows everyone at the table to have a stake and gain value.

It is important to understand the value of integrating clinical and claims data. This was something stressed by both PCORI and health plans. Using data to close gaps in knowledge about factors such as diagnoses, utilization of care, and clinical outcomes offers the opportunity for more complete and reliable research.

There are different perspectives on what types of information are important to which stakeholder. For example, health plan researchers are interested in physiological data; health plans clinical leaders are interested in outcomes data.

Mutually beneficial results are essential to sustainability. Organizations must be able to justify the total financial investment including time, cost, staff resources, and the opportunity cost. One person noted that he has nothing to take to his CEO and CMO to justify continuing to support PCORnet and he stressed that PCORnet must create “wins” that health plans can support. There was also discussion about the need for PCORI to understand the priorities of the various partners in order to ensure their sustained collaboration. As one person said: if you have things of significant value to each party then it will be sustainable.

Financial sustainability is important, including the need for an underlying economic platform to ensure sustainability. One person pointed out that, without adequate dollars and resources, no one will take the time to work on the collaborative effort. There are lessons on financial sustainability to be learned from Sentinel where the infrastructure of the data and modular programs has allowed for reusing the same resources for multiple studies. Doing one-off studies is expensive; it is also expensive to develop and maintain the data for the network. The latter requires a commitment of resources to a steady-state system. It was noted that using and reusing the data regularly spreads out the cost and makes the individual studies much less expensive than a one-off study.

Strong governance is also seen as key to sustainability. There needs to be a clear rationale and an efficient way for organizations to decide to engage in a data-sharing project as well as a cost-effective way to make it happen.

Personal relationships can help build the foundation to achieve sustainability. Possible mechanisms for this may be an annual meeting among PCORnet participants, medical directors, and plan leaders to help build trusting relationships through in-person interactions. The importance of relationships extends to those not just within PCORI but also the multiple relationships that organizations have outside their PCORI activities.

It was noted that in considering opening PCORnet to users beyond the core, it will be important to balance demands from academic researchers, public health, industry, payers, and others. This will require clear governance as well as a pricing model for users.
Conclusion

This Engagement Award facilitated a series of important discussions with health plan stakeholders in PCORI and PCORnet. The process helped to identify key considerations for the health plans and PCORnet CDRNs in building a long-term, sustainable collaboration. This Engagement Award also, in part, supported AHIP’s participation in the joint Sentinel PCORnet working group and the development of a 2015 white paper outlining the potential linkage of the two networks.

PCORI and AHIP have acknowledged the need for continuing dialogue and work to address the issues identified in order to facilitate expanded engagement of the payer community as collaborators in PCORnet. Future discussions will need to focus on better understanding of the value proposition and return on investment for the health plans and strategies for longer term sustainability and success of the network.

Through the meetings and the simultaneous progress and development of PCORnet, a number of issues have emerged that must be addressed to enable the continued development and sustainability of PCORnet. These include creating opportunities for bi-directional exchange of data between health plans and CDRNs to identifying the minimal data necessary to support the agreed-upon purpose of any project.

Lessons learned, particularly from the FDA Sentinel program may provide guidance for PCORnet as it evolves. One key lesson from the Sentinel program is that while being reimbursed for the costs was somewhat important, the decision to participate was driven not by cost or public interest but by each plan’s individual interests and perception of ROI. This also pointed to the heart of the question about long-term sustainability as stated by one of the participants: “Is it worth enough to each of the organizations to go ahead and collaborate?”
Appendix: Summary of Critical Considerations, and Challenges for Health Plan Collaboration with PCORnet

Health plan engagement with PCORnet is occurring with the two large national plans under contract to PCORI and individual relationships that exist at the local CDRN level. The focus moving forward is on expanding the scale and scope of health plans engaged with PCORnet and sustaining the collaborations over time. This requires attention to the primary factors that motivate health plans to collaborate with PCORnet, the conditions that can help to sustain collaboration, and major factors that can create barriers to collaboration. While diversity of data systems poses some technical challenges, they are generally considered as secondary to the factors below.

Motivating Factors for Health Plan Collaboration

A key motivating factor for sharing data in the framework of PCORnet is public interest. There is a shared interest in better research to achieve better health outcomes for individuals and the population as a whole. Health plans are increasingly driven by the triple aim of improving patient experience, improving the health of populations, and lowering the cost of care.

Health plans are interested in data sharing in order to access clinical data to address a wide range of research questions. The need for bi-directional data sharing is important. The data sharing must flow both ways, with the PCORnet networks having access to health plans’ claims data and the plans having access to the clinical data in the networks. Bi-directionality must include having research questions originate in the networks and the health plans.

Organizations will be more motivated to share data when they have an interest in the answer to a specific research question such as understanding what works best for patients, health systems, and payers.

Health plans may be interested in using PCORnet to address research questions in which they have a stake. In addition, health plans may find value in identifying a patient population and asking the research networks questions about that population.

Health plans are concerned with the value of care. Health plans generally have an interest in real issues of high-cost and high-frequency procedures and to what extent they reflect best practices or provide high-value care. PCORI and PCORnet offer the potential for true randomization of patients into comparative clinical effectiveness (CE) trials.

Priorities for Expanding and Sustaining Engagement

Identifying the value proposition or making the business case is a major challenge to beginning and sustaining collaboration. The parties participating in data sharing must have incentives to participate or the system will break down. Better understanding of the value proposition and ROI for health plans is essential for longer term success.
Mutually beneficial results are essential to sustainability. Organizations must be able to justify the total financial investment including time, cost, staff resources, and the opportunity cost. PCORnet must create “wins” that health plans can support with realization of significant value by each party for it to be sustainable.

Strong governance is a key to sustainability. A clear set of governance policies that are generalizable is essential rather than addressing governance on a project-by-project basis. Trust is essential and plans is the need to ensure that the data shared is not disseminated in a way that it could be misused in a way that harms competition. Governance and permitted uses of data must be specified and agreed to up front.

- The FDA Sentinel may offer a way forward as the Sentinel data resides with individual partners and reduces concerns about data breaches and confidentiality issues.
- A longer term solution may be establishing an independent entity or a data repository to have responsibility for data oversight and analysis with contractual relationships that define roles and responsibilities.

A universal identifier to facilitate how a payer would handle data exchange may be needed. Implementation of a PCORnet network-wide patient identifier may help with concerns about identifying/re-identifying patients.

Factors That May Challenge Collaboration by Health Plans

There has to be some clear ROI for an organization to share data for this collaborative exchange to work over the longer term. The key for establishing a value proposition for health plans is for PCORnet to do studies of interest to the health plans.

Ensuring that consumers have affordable access to evidence-based care is a priority for health plans. The limitations on PCORI-sponsored research to address cost is a challenge for health plan engagement.

Although there is some motivation to share data with PCORnet, there are also corporate concerns. The primary concern is resources, along with the need to ensure that the process does not disclose competitively sensitive information.

Bi-directional data is necessary in order to make the return on investment possible for all parties.

Financial sustainability is important, including the need for an underlying economic platform to ensure sustainability. Adequate dollars and resources are needed to work on the collaborative effort. The Sentinel provides lessons on financial sustainability Sentinel where the data infrastructure and modular programs have allowed reusing the same resources for multiple studies.