PCORnet®: An Introduction

An Overview for Industry Stakeholders, Academic Audiences, and Health Services Researchers
A bold vision

- In 2013, the Patient-Centered Outcomes Research Institute (PCORI), decided to do **SOMETHING BOLD**.

- Looking at the inefficiencies that can limit traditional clinical research, they said:
  - Let’s chart a **new path**
  - Let’s make research **easier, less expensive, faster, and more meaningful**
  - And let’s make sure **patients are our North Star**
The result of that bold vision is **PCORnet, the National Patient-Centered Clinical Research Network**, a network of networks with access to secure, curated data from millions of patients across the largest health systems in the United States.

With **66 million** patients accessible for observational studies and **30 million** accessible for clinical trials, PCORnet offers:

- Access to electronic health record (EHR) data
- Exceptional research teams
- Expertise in integrating research with clinical care
- Streamlined administrative processes
- Partnered with patients
What is PCORnet? Many things at once...

- **National Resource**: A national, sustainable resource for conducting research in a way that is faster and easier than traditional randomized trials.

- **Network of Networks**: A network of networks committed to bringing trustworthy, meaningful insights to patients.

- **Bellwether for a New Era**: A bellwether for a new era of research in which patients are partners in the design and conduct of trials.
PCORnet: The big picture

Three things to know about PCORnet:

- **Patient-Partnered**: Patients, and those who love and care for them, are integral to ALL PHASES OF PCORNET-ENABLED RESEARCH.

- **Data-Driven**: Data accessible via PCORnet draws from millions of EHRs with growing links to patient-reported and payor data, all consolidated using a common data model.

- **Broadly Connected**: PCORnet connects you to thousands of clinicians and researchers who are committed to answering important questions that will improve patient lives.
PCORnet is a “network of networks” that harnesses the power of partnerships

Clinical Research Networks (CRNs) + Health Plan Research Networks (HPRNs) + Patient Partners + Coordinating Center = A national infrastructure for people-centered clinical research
Why a network of networks works

Patients, providers, data, and systems. In the traditional research environment, each operates in a silo. In PCORnet, they unite to form a coalition.

PCORnet works because it’s the only research network that allows researchers to unite insights to build better trials.
It starts with data

The PCORnet solution starts with real-world data. PCORnet-partnered CRNs and HPRNs can help users conduct research more efficiently. Users can access data from everyday medical encounters from more than 66 million people across the United States.
Next, the data must be usable

Lots of data is great, but for it to be useful it has to be standardized across systems. The PCORnet Common Data Model standardizes data into a single language, enabling fast insights, including:

### Ready for Research
- Death Data
- Diagnoses
- Medication Orders
- Procedures

### Available, But Still Evolving
- Social Determinants of Health
- Tumor Registry
- Biosamples
- Genomic Results
- Natural Language Processing Derived Concepts
- Patient-Generated Data

Data available from several Clinical Research Networks, in the PCORnet Common Data Model and ready for use in research.

Data available at some Clinical Research Networks, may or may not be in the PCORnet Common Data Model and require additional work for use in research.
The Common Data Model

The Common Data Model, developed by PCORnet, is a key component of the Network’s infrastructure and central to its work. PCORnet’s Common Data Model standardizes millions of data points from a variety of clinical information systems into an innovative common format that can be used for specified research projects.

**CHALLENGE**

Health systems collect data specific to each system, resulting in large data challenges.

**PCORNET SOLUTION**

Sourced from differing health systems, the process of querying the data in PCORnet’s Research networks allows it to be analyzed as if it were a single, actionable data set.

**IMPACT**

Data from PCORnet resources can be used alone or easily linked to other types of data (payer) to accelerate research.
A secure infrastructure to make real-world data accessible

PCORnet was developed with a secure and streamlined infrastructure that offers researchers a simple process for querying the accessible data and deriving efficient insights.

The Requestor sends a question to PCORnet.

PCORnet Leadership reviews the question and consults with Requestor about next steps.

The Coordinating Center converts the request into a query with an underlying executable code, if applicable, and sends it to Network partners.

Network partners review the query and provide a response, which is sent back through the Coordinating Center and to the Requestor.

Robust Intake Process

Question

Response

Query

PCORnet Coordinating Center
With patients as the North Star

Benefits for Patient Partners

**SETTING THE RESEARCH AGENDA**
Patient advocates are active in prioritizing research questions and setting the research agenda.

**COLLABORATING IN ALL PHASES OF RESEARCH**
Patients contribute to study designs, making clinical research less burdensome and identify outcomes that matter to them.

**PARTICIPATING IN CLINICAL RESEARCH**
Study participants report positive experiences in contributing to research that leads to improved clinical answers.

**ACTING ON RESEARCH FINDINGS**
Patients drive adoption of actionable findings and changes in clinical care.
How can PCORnet help you?

PCORnet enables answers to questions like...

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<tr>
<th>Site Selection and Cohort Identification</th>
<th>Descriptive Analytics</th>
<th>Data Characterization and Quality Assessments</th>
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<td>Are patients who switched to a new heart failure medication achieving better symptom outcomes than their former treatment?</td>
<td>How do three popular bariatric procedures fare in an assessment of long-term comparative effectiveness?</td>
<td>Which aspirin dose offers the right balance of effectiveness and minimal risk of bleeding?</td>
<td>How do health systems compare across three well-established measures of quality in pediatric populations?</td>
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Comparing drugs: A pragmatic trial

The Question
Would patients who switched to a new heart failure (HF) medication achieve better outcomes from a symptom perspective than their current treatment?

PCORnet’s Strength
PCORnet offered a “one stop shop” process for capturing three complementary sources of data (patient data, EHR data, and survey data) that would have been cumbersome in more traditional research.

Study Snapshot
○ Prospective cohort study of 400 chronic HF patients
○ Looked at retrospective electronic health record (EHR) data accessible via PCORnet
○ Evaluated baseline and follow-up patient-reported outcomes (PROs) via electronic patient reported outcomes form (ePRO)

https://clinicaltrials.gov/ct2/show/results/NCT03387163?view=results
Comparing drugs: A pragmatic trial

RESULTS

The team reported more timely PRO data when compared to traditional follow-up surveys in an observational study. All while serving as the first PCORnet project to implement SMART IRB.

The Takeaway

PCORnet is an efficient resource for capturing fast insights related to populations with tricky situations, such as those initiating use of a new medication.
Comparing procedures: Real-world evidence

The Question
We don’t know much about the long-term effectiveness of bariatric interventions. Can we use PCORnet to compare weight loss, diabetes risk, and safety among three popular bariatric procedures?

PCORnet’s Strength
The study design required a massive and diverse cohort, and with PCORnet’s broad reach of data partners across the nation, it was well-poised to deliver.

Study Snapshot
- Retrospective observational cohort study of 65,073 participants
- Aged 20 to 79 years with body mass index (BMI) of 35 kg/m² or greater who had bariatric procedures
- Evaluated weight loss, diabetic risk, and safety across three interventions:
  - Roux-en-Y gastric bypass
  - Sleeve gastrectomy
  - Adjustable gastric banding

Comparing procedures: Real-world evidence

RESULTS

- Identified bariatric procedures from
  >100 million patient records in 41 health systems across 11 clinical research networks

- The resulting cohort included more than 900 adolescent bariatric patients:
  the largest adolescent cohort in research to date

Effectively answered a question prior studies have not been large or diverse enough to answer across important subgroups (> 65 years old and racial/ethnic minorities)

The Takeaway

When you need to capture a large, diverse cohort of patients for retrospective analysis of real-world data, PCORnet is a valuable resource.
Aspirin dosing: Engagement in research

The Questions
1) Which aspirin dose offers the right balance of effectiveness and minimal risk of bleeding?
2) Can PCORnet be used to find the answer using a clinical trial model wherein patients are drivers of engagement?

PCORnet’s Strength
Adaptors: Nine patient partners from ADAPTABLE’s clinical research networks.
• Offered study guidance
• Embedded at every study step, from study concept to completion and dissemination

Study Snapshot
○ Pragmatic clinical trial
○ 15,000 patients who are living with heart disease
○ Randomly assigned in a 1:1 ratio
○ Receive an aspirin dose of 81 mg/day vs. 325 mg/day

The Takeaway

PCORnet supports patient partner engagement that can fortify your study’s efforts and contribute to faster enrollment and improved retention.
Quality measures: Health systems research

The Question
A comparative assessment across three well-established measures of quality in pediatric populations. Can PCORnet be used to accurately and thoroughly benchmark healthcare quality?

PCORnet’s Strength
With its broad access to EHR data in sensitive pediatric populations, PCORnet facilitated data use across 13 health systems for evaluation.

Study Snapshot
- Assessed 1,144 eligible children across three measures:
  1) Screening children with sickle cell disease for stroke risk
  2) Appropriate antibiotics for ear infections
  3) Cholesterol and glucose testing for children on antipsychotic medications

Quality measures: Health systems research

RESULTS

The information drawn directly from the EHRs to assess these measures was highly valid, with a positive predictive value of 98%

Promising results compelled over $500,000 cost-matching from 10 health systems in OneFlorida and PEDSnet for a second year of research

Solutions for Patient Safety is now set to use benchmarking approach to change national outcomes

The Takeaway

PCORnet is a resource for assessing quality of care and establishing benchmarking across health systems nationally.
Study Snapshot

- Used EHR data accessible via PCORnet
- Characterized, according to CV risk status
  1) early use of PCSK9 inhibitors
  2) standard lipid-lowering therapies

The Question
Can the EHR data curated in part by PCORnet network partners be used to better understand prescribing patterns for PCSK9 inhibitor according to patients’ cardiovascular (CV) risk status?

PCORnet’s Strength
The study team was able to access EHR data curated by PCORnet network partners across:
- 18 health systems
- With geographic diversity
- 17.5 million adults aggregated via datamarts

**Rx patterns: Population health research**

**RESULTS**

Of 17.5 million adults identified via PCORnet, 3.6 million met study criteria. Confirmed low early prescribing patterns of PSCK9 inhibitors, which cost approximately $14,000 per year at the time.

As a PCORnet Rapid-Cycle Research Project, the analysis was completed in 8 months.

**The Takeaway**

PCORnet can help researchers quickly identify and access specific populations, facilitating fast insights.
How can PCORnet help you?

14 PCORI-funded PCORnet-enabled demonstration studies are answering critical research questions. What questions can PCORnet help answer for you?

While PCORnet is fit for a broad range of research types, research conducted using the Network’s resources has focused on studies like:

- Real-world evidence studies
- Health systems research
- Population health research
- Pragmatic clinical trials
- Studies on how to best engage patients in research
Learn More.

Work with PCORnet.
Visit us at www.pcornet.org
to get the relationship started.