Update from PCORI

Claudia Grossmann, PhD and Julianna Paris, MPH

Research Infrastructure and Innovation
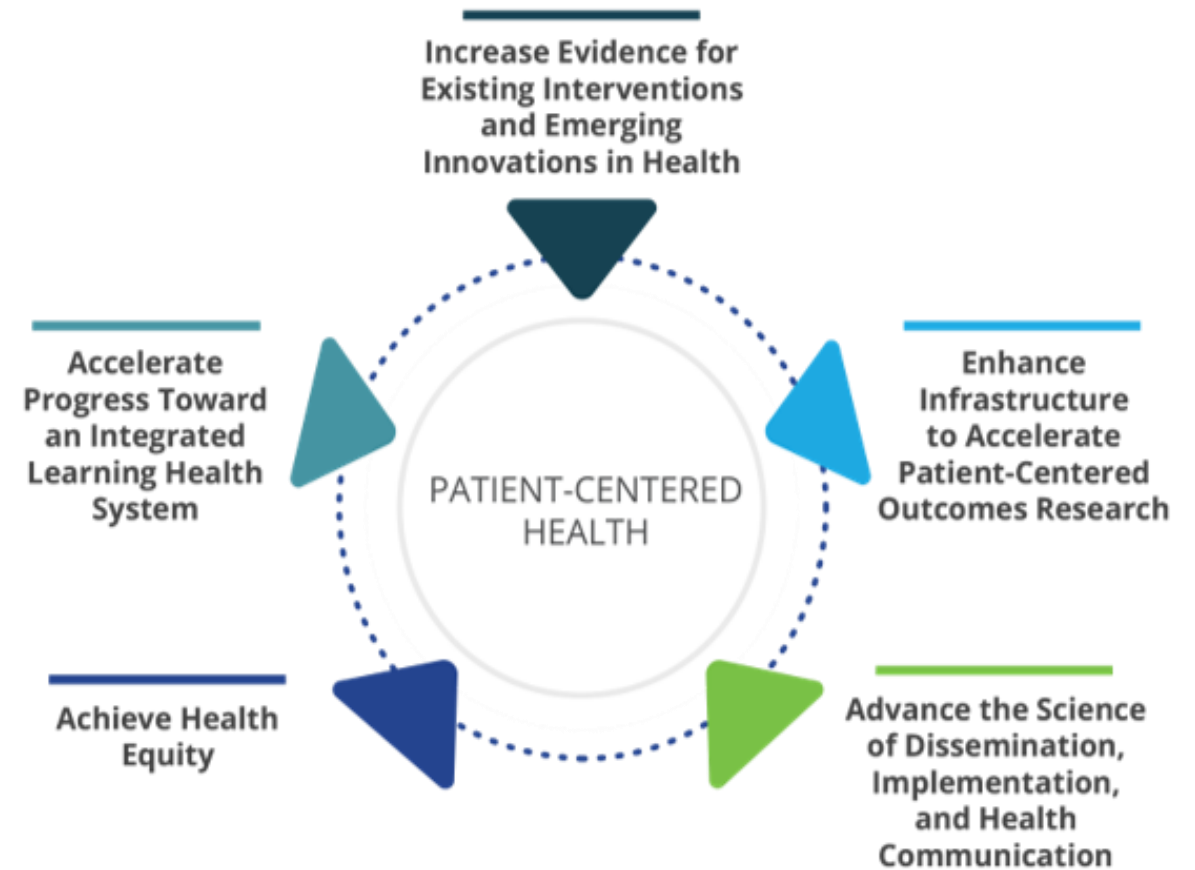
PCORI

August 2024

pcori

PCORI Strategic Plan: https://www.pcori.org/strategicplan

PCORI Topic Themes
12 themes that will inform focused funding opportunities

pcori

Populations

- Improving outcomes for people with intellectual and developmental disabilities
- Promoting health for older adults
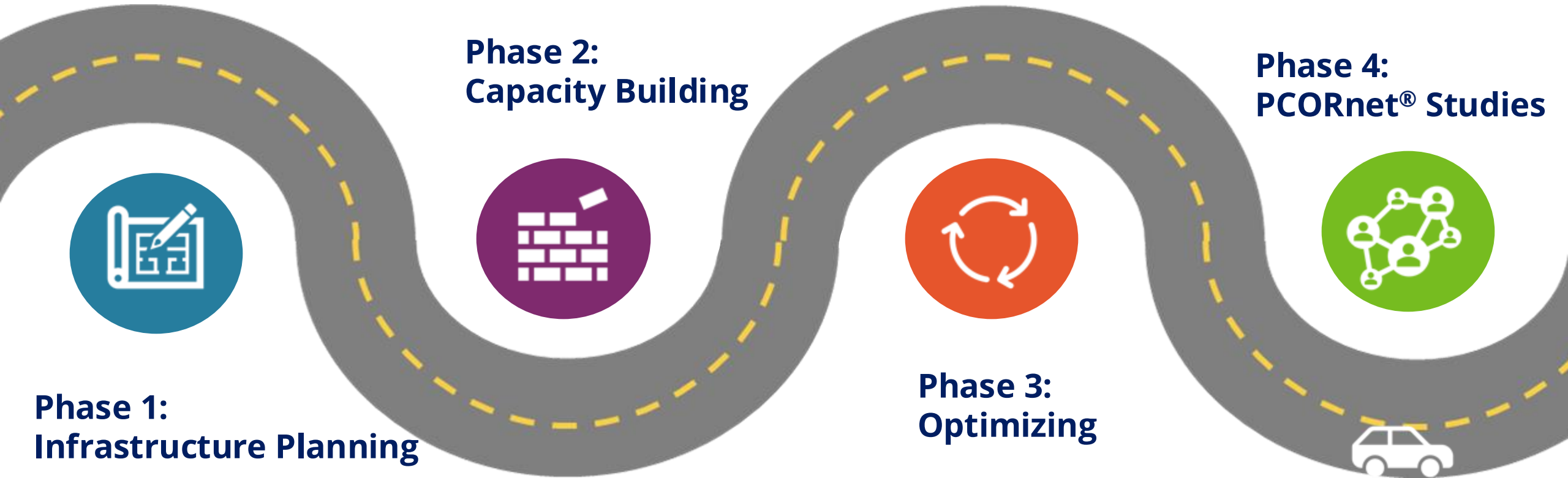- Promoting healthy children and youth

Health Behaviors

- Addressing substance use
- Addressing violence and trauma

Health Conditions

- Addressing COVID-19
- Addressing rare diseases
- Improving cardiovascular health
- Improving mental and behavioral health
- Managing pain
- Preventing maternal morbidity and mortality
- Promoting sleep health

PCORnet® Phases 1-4

Phase 2:
Capacity Building

Phase 4:
PCORnet® Studies

Phase 1:
Infrastructure Planning

Phase 3:
Optimizing

Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance

- In 2021, the Board developed and approved the [Prioritizing Principles for Infrastructure Funding Relating to PCORnet]

- In 2022, building upon the Principles, the Board approved the [Strategies to Leverage PCORnet to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance]
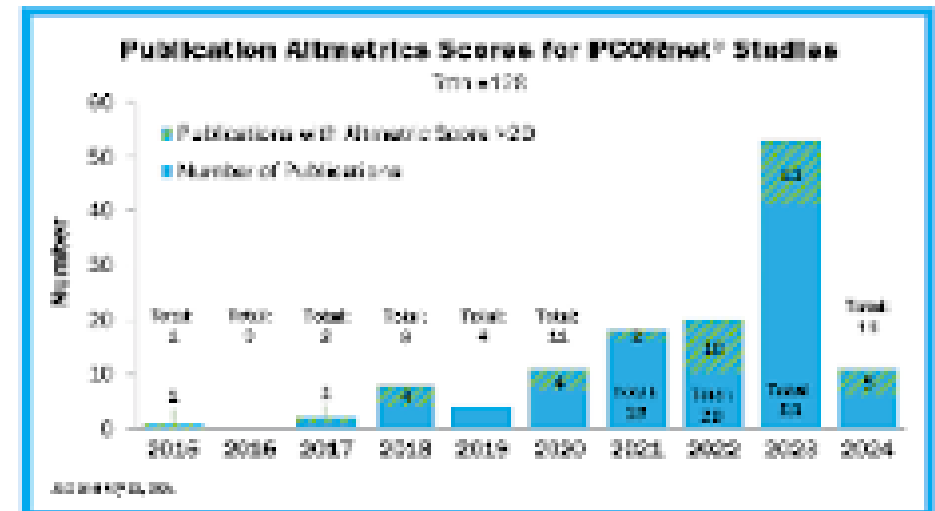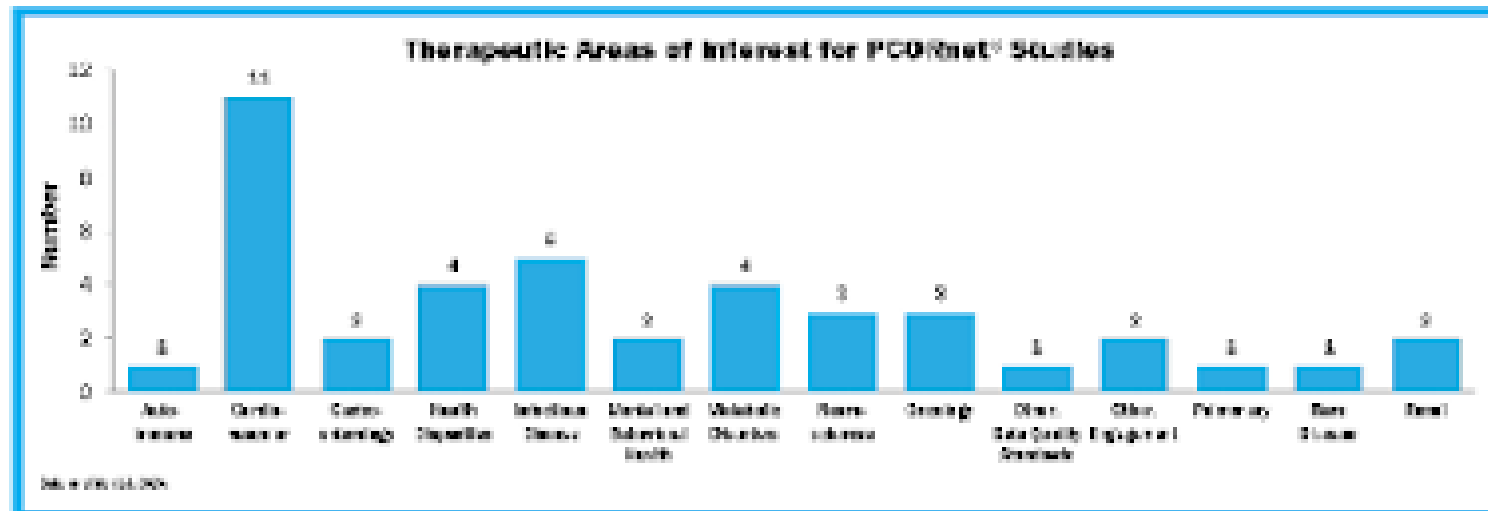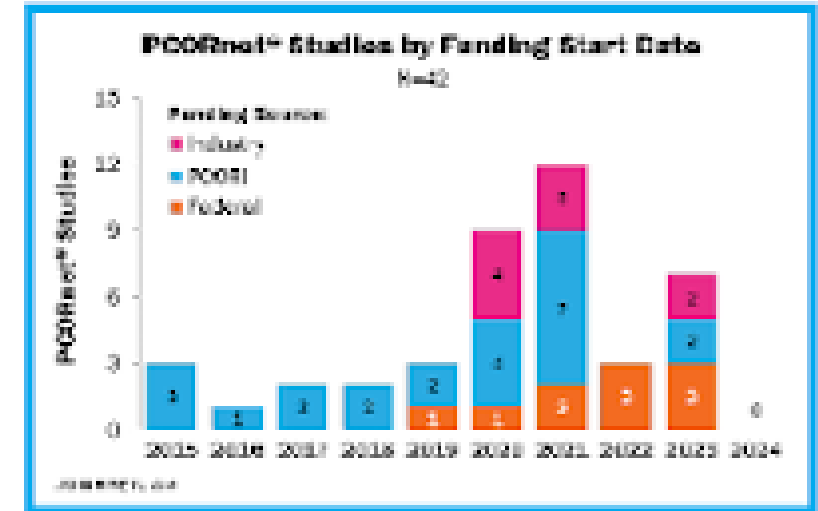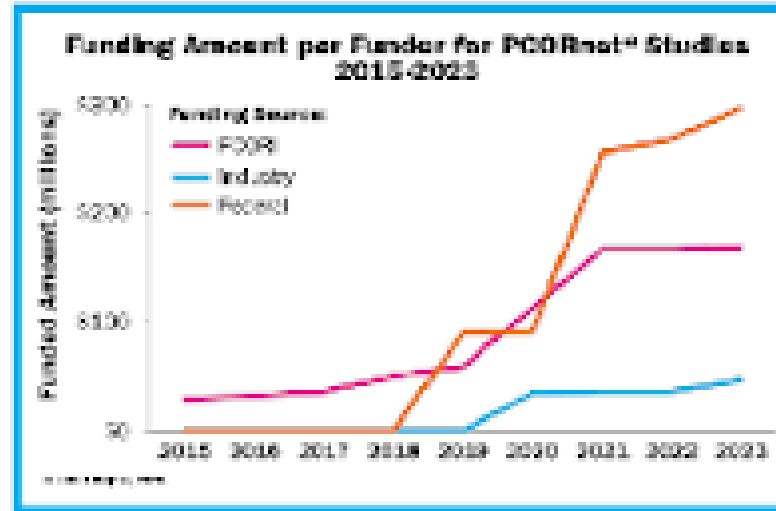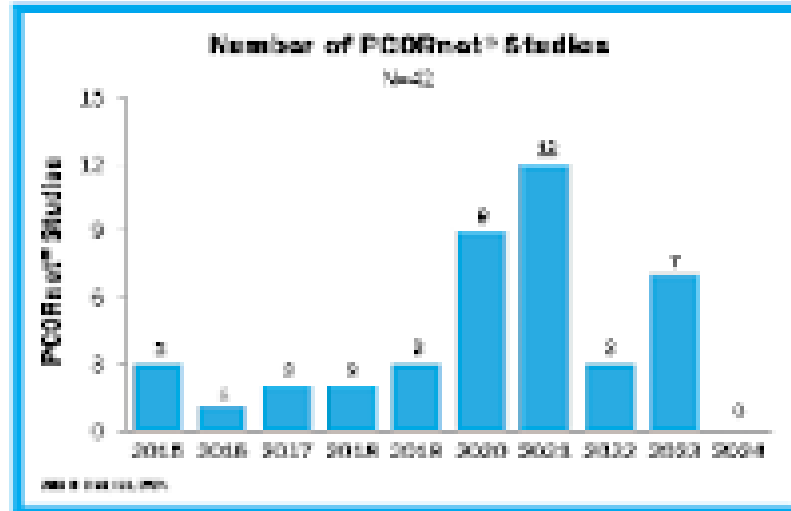
Priorities to Make Progress on Board Strategies

- **Research using PCORnet®:** Develop and execute PCORnet® Studies; define and implement research metrics that demonstrate the value of PCORnet

- **PCORnet Awareness and Use:** Increase awareness and use of PCORnet by diverse investigators; develop new partnerships to use PCORnet for range of research types

- **PCORnet Maintenance and Innovation:** Enhance availability of new data types (e.g., social determinants of health, patient reported outcomes) in the PCORnet ® Common Data Model; increase diversity of populations and care settings

- **Use PCORnet for PCORI priorities:** Use PCORnet to inform PCORI's research agenda
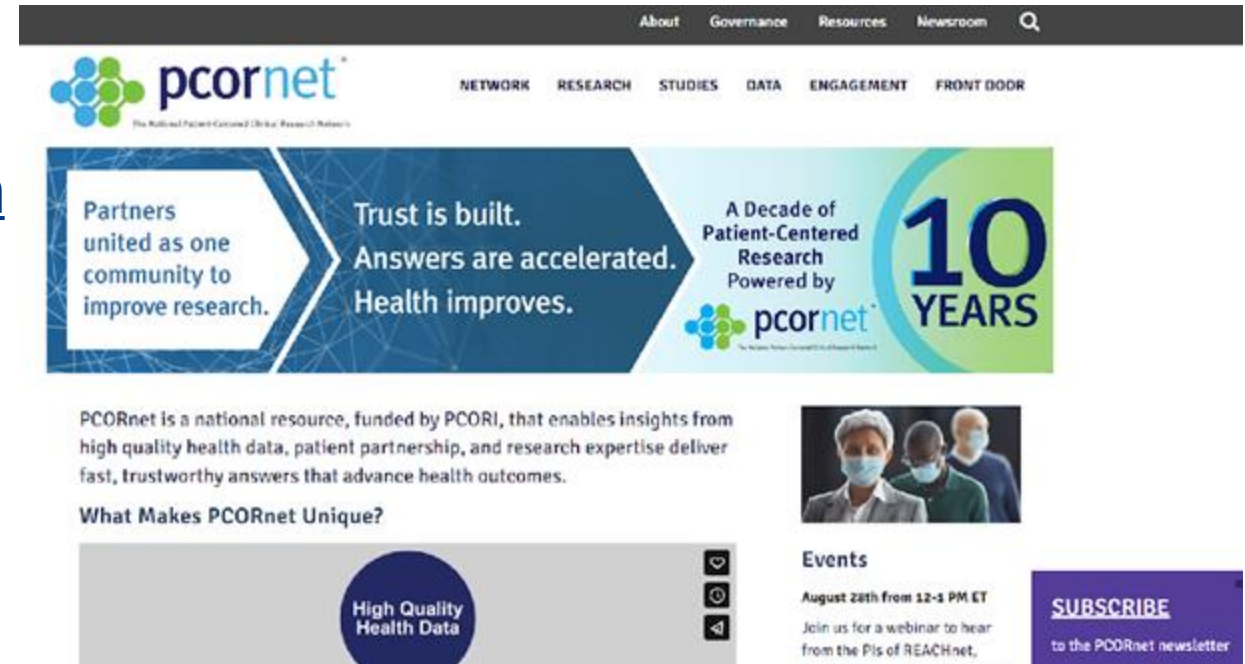
PCORnet® Studies

PCORnet® Studies on the PCORnet Website

PCORnet® Awareness and Use

- Videos:
  - [What Makes PCORnet Unique?](#)
  - [Knock on the Front Door to Begin Collaborating with PCORnet](#)
- New "Studies" tab
- PCORnet Newsletter
- PCORnet Workshops at scientific meetings
- **Coming Soon: PCORnet® Playbook**

PCORnet® Maintenance and Innovation: Overview of PCORnet Phase 3 Enhancement Funding pcori

Activity	Category of Board-authorized Enhancement Funding	Associated Funds	Details
Site Expansion	Supporting PCORnet coverage comparable to the US population	$3.55M	• All funding was committed in FY23.
Targeted PCORnet® Common Data Model (CDM) Enhancements	• Enhancements to promote efficiency in CER/PCOR and research partnerships and • Enhancing Data Capacity for Patient Reported Outcomes • Build capacity to support PCORI's National Priorities for Health	Up to $4.25M	• Responsive to NORC report, IDD/MMM workgroups, Innovation Work Group (IWG) recommendations • Focus on four targeted areas: (1) SDOH data; (2) patient-reported medications; (3) data related to IDD and MMM; and (4) patient-reported outcomes/patient-generated health data • *PMO formalizing process now*
Technology Enhancements in Support of Increased Volume of PCORnet® Studies	Enhancements to promote efficiency in CER/PCOR and research partnerships	Up to $4.5M	• Responsive to infrastructure mapping findings, IWG recommendations • Focus on 1) improving local query run times and 2) demonstrating ability for sites to run multiple queries simultaneously • *Application Deadline: July 15, 2024*
PCORnet® Playbook		Up to $450K	• Responsive to infrastructure mapping findings, IWG recommendations • Living collection of user guides, toolkits, best practices, and specific considerations for use of the PCORnet for PCORnet® Studies • *To be managed by the PMO*
Digital Toolkit to Facilitate Patient Engagement in PCORnet® Studies	• Enhancing Data Capacity for Patient Reported Outcomes • Enhancements to promote efficiency in CER/PCOR and research partnerships • Build capacity to support PCORI's National Priorities for Health	Up to $1.3M	• Responsive to infrastructure mapping findings, IWG recommendations • Focus of this presentation

Use PCORnet® for PCORI Priorities: PCORnet Workgroup Reports Outline Research Uses of the Network and Data Capabilities

pcori

- Two reports demonstrate a community-engaged approach to accelerate patient-centered CER using PCORnet, including:
  - Identifying critical gaps and needs in knowledge, and prioritizing unanswered CER questions
  - Conducting a PCORnet query to identify populations with specific conditions that are eligible for study participation
  - Identifying questions that can be answered with PCORnet now as well as recommendations for infrastructure enhancements

- Mental and Behavioral Health report underway

December 2023

A Roadmap for Accelerating Research to Prevent Maternal Morbidity and Mortality Using PCORnet®

December 2023

A Roadmap for Accelerating Research in Intellectual and Developmental Disabilities Using PCORnet®

Use PCORnet® for PCORI Priorities: Telehealth Query

- Query supports the following PCORI operational and strategic priorities:

  - Understanding utilization of telehealth to manage one or more chronic conditions in underserved populations,

  - Informing PCORI's continued development of its Telehealth portfolio; and

  - Understanding how PCORnet can be used for PCOR studies on telehealth.

- Telehealth services were utilized by ~9.2 million unique patients across PCORnet® Network Partners over the 3-year period

- Of the more than 20 chronic conditions included in the query, patients with cardiovascular-related health conditions were highest utilizers of telehealth

  - Hypertension (29%), hyperlipidemia (27%), arthritis (17%), diabetes (13%)

pcornet®
The National Patient-Centered Clinical Research Network

NETWORK   RESEARCH   DATA   ENGAGEMENT   FRONT DOOR

November 8, 2023

Telehealth Visits Provide Opportunity For PCORnet® Data Resources

The COVID-19 pandemic prompted a shift to the use of telehealth visits, opening a new frontier in healthcare delivery and an opportunity for PCORnet® data resources to assist researchers in studying the effectiveness of this rapidly evolving method of healthcare delivery.

Figure 2. Counts of Patients with Ambulatory or Telehealth Encounters by Month (2019-2022).
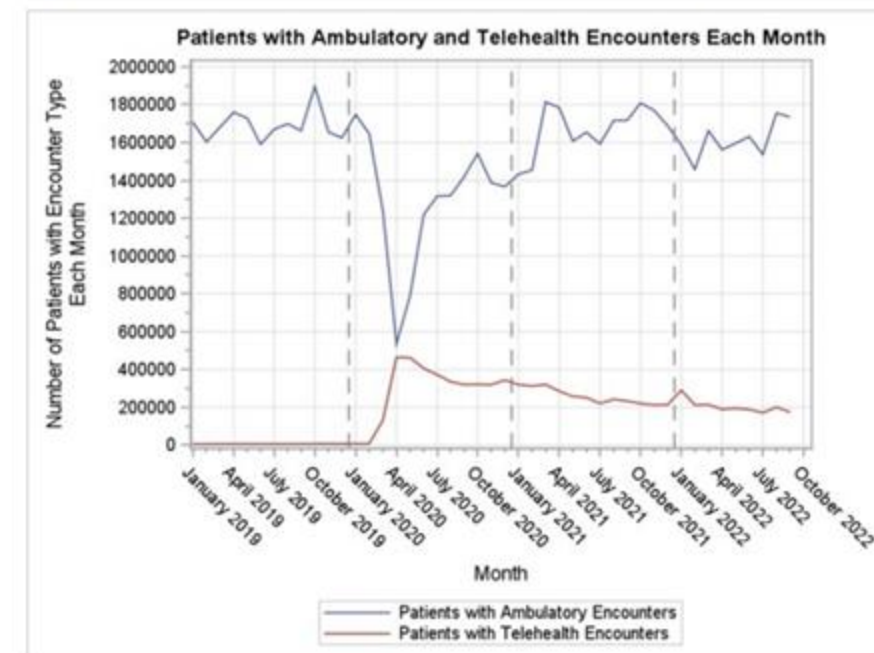
Evaluating PCORnet®: Maturity Model

PCORI's Maturity Model for PCORnet®

PCORI's vision is that patients and the public have information they can use to make decisions that reflect their desired health outcomes.

PCORI funds PCORnet, the National Patient-Centered Clinical Research Network, to facilitate definitive studies that are national in scope, with high-quality health data, patient partnership and research expertise that can deliver fast, trustworthy answers that advance health outcomes.

PCORI will use the Maturity Model for PCORnet to support PCORI's Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance.

- The Maturity Model for PCORnet articulates what the Network overall will look like at each stage of maturity to achieve PCORI's vision for PCORnet.

- PCORI's organizational learning and evaluation agenda and framework will include the key questions to be answered about progress and success for PCORnet at each stage of maturity, and the measurement strategy.

The menu to the right lists the domains through which PCORI expects PCORnet to mature (e.g., Research, Data and Technology, etc.).

Maturity Model Domains

- Research
- Data & Tech
- Governance
- Operations
- Engagement
- Diversity, Equity and Inclusion
- Partnership & Public Awareness

Download the Maturity Model

https://www.pcori.org/funding-opportunities/what-who-we-fund/pcornetr-national-patient-centered-clinical-research-network/pcoris-maturity-model-pcornetr

2024 Research Award Funding Opportunities

pcori

1. Up to $5M 2. $5–12M	**Broad Pragmatic Studies (BPS)** Investigator-initiated awards in alignment with the National Priorities for Health Three funding categories, including PCORnet® Studies
Up to $750K	**Methods** Improve use of AI and ML, improve study design, support data research networks, Ethical and human subject protections in CER
1. Up to $500K 2. Up to $1.5M	**Science of Engagement** Two funding categories: Development and validation of measures Development and testing of engagement techniques
Variable	**Topical/Targeted** Stakeholder-driven topics, issues, and questions of national significance *Upcoming topicals: (1) Managing Pain and (2) Promoting Healthy Children and Youth (each up to $12 million in direct costs)*
Up to $22M for feasibility and full-scale study phases	**Phased Large Awards for Comparative Effectiveness Research (PLACER)** Large, meritorious, and innovative studies with some risks

Cycle 3 2024 LOI Deadline for Standing PCORI Funding Announcements (PFAs): Sept. 4, 2024

LOI Deadlines for Upcoming Topical PFAs:

Oct. 1, 2024 (Promoting Healthy Children and Youth)

Jan. 14, 2025 (Managing Pain)

*All funds and timeline noted above are subject to change

14

Broad Pragmatic Studies PCORI Funding Announcement: Category 3 for PCORnet® Studies

pcori

- **Broad Pragmatic Studies PFA: Category 3 to support PCORnet Studies** that advance PCORI's National Priorities for Health
  - Will repeat each funding cycle
  - Upcoming opportunity: Cycle 3 2024 BPS PFA
- **Studies must:**
  - Address National Priorities for Health
  - Include 2 or more Clinical Research Networks
  - Share study progress, performance metrics monthly (e.g., days to IRB, number of days to first patient enrolled)
  - Share best practices at least annually with the Network (e.g., PCORnet Steering Committee), as outlined in additional PCORnet Study milestones
  - Use PCORnet resources to improve the efficiency of the patient-centered research conducted (e.g., PCORnet Common Data Model, single IRB, engagement resources)
- *Up to $12 million direct costs*
  - Studies requesting direct costs greater than $5 million will be required to meet additional requirements

Category 3 Requirements

- Applicants to Category 3 must contact the PCORnet® Front Door before preparing their applications.

- In the full application, applicants must submit Letters of Support from at least two CRN sites that have agreed to participate.

- Category 3 PCORnet Studies will include additional milestones that specify:
  - Share study progress and best practices regularly with the network, such as through annual presentations to the PCORnet Steering Committee,
  - Report performance on study site metrics (e.g., time to IRB, enrollment rates) monthly to the Coordinating Center for PCORnet to promote continuous learning and improvement.

Cycle 3 2024 BPS PFA Dates

September 4, 2024	**Funding Announcement Opens**
October 1, 2024; 5:00 pm ET	**Letter of Intent Deadline**
October 29, 2024	**Letter of Intent Status Notification**
January 14, 2025; 5:00 pm ET	**Application Deadline**

pcori

Questions?

cgrossmann@pcori.org

jparis@pcori.org