



## **How PCORnet Can Help Fulfill the Promise of Big Data**

*Sarah M. Greene, MPH, Senior Program Officer, PCORI  
Practice-Based Research Network Conference, June 2014*

Patient-Centered Outcomes Research Institute

# Overview

- About PCORI
- Description of PCORnet and its potential
- Intersection of Big Data Ideals and PCORnet

# About PCORI

- An independent research institute authorized by Congress through the Affordable Care Act.
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process.
- Answers real-world questions about what works best for patients based on their circumstances and concerns.



# Why PCORI?

- Research hasn't answered many questions that patients (and their clinicians) face.
- People want to know which treatment is best for them.
- Patients and their clinicians need information they can understand and use.



# Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from **research guided by patients, caregivers and the broader health care community.**



# We Have a Broad and Complex Mandate

“The purpose of the Institute is to **assist patients, clinicians, purchasers, and policy-makers in making informed health decisions** by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed **through research and evidence synthesis...and the dissemination of research findings** with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services...”

-- from *Patient Protection and Affordable Care Act*



# We are Accountable for Changing Practice

“(g) FINANCIAL AND GOVERNMENTAL OVERSIGHT. ...

(2) REVIEW AND ANNUAL REPORTS. ...

(iv) Not less frequently than every 5 years...  
the overall effectiveness of activities conducted under this  
section...such review shall include an analysis of the  
**extent to which research findings are used by health  
care decision-makers**, the effect of the dissemination of  
such findings on **reducing practice variation and  
disparities** in health care...”

-- from *Patient Protection and Affordable  
Care Act*



# Our National Priorities for Research



**Assessment of  
Prevention, Diagnosis,  
and Treatment Options**



**Improving  
Healthcare Systems**



**Communication &  
Dissemination  
Research**



**Addressing  
Disparities**



**Accelerating PCOR  
and Methodological  
Research**

# Pivotal Investment by PCORI in a National Infrastructure for Comparative Effectiveness Research

- \$100 Million to support 29 research networks and a Coordinating Center
- Complementary and synergistic capabilities in the two types of networks, and national “coverage” from coast to coast
- “Research *infrastructure* done differently,” in support of PCORI’s concept of “research done differently”

# The National Patient-Centered Clinical Research Network (PCORnet)

- Overall Goal: Improve the nation's capacity to conduct clinical research by creating a large, highly representative, national patient-centered network that supports more efficient clinical trials and observational studies.
- Vision: Enable rapid, large-scale, patient-centered research in real-world care delivery systems.





## **11 Clinical Data Research Networks (CDRNs)**

System-based networks, such as integrated delivery systems, academic medical centers, federally qualified health centers,



## **18 Patient-Powered Research Networks (PPRNs)**

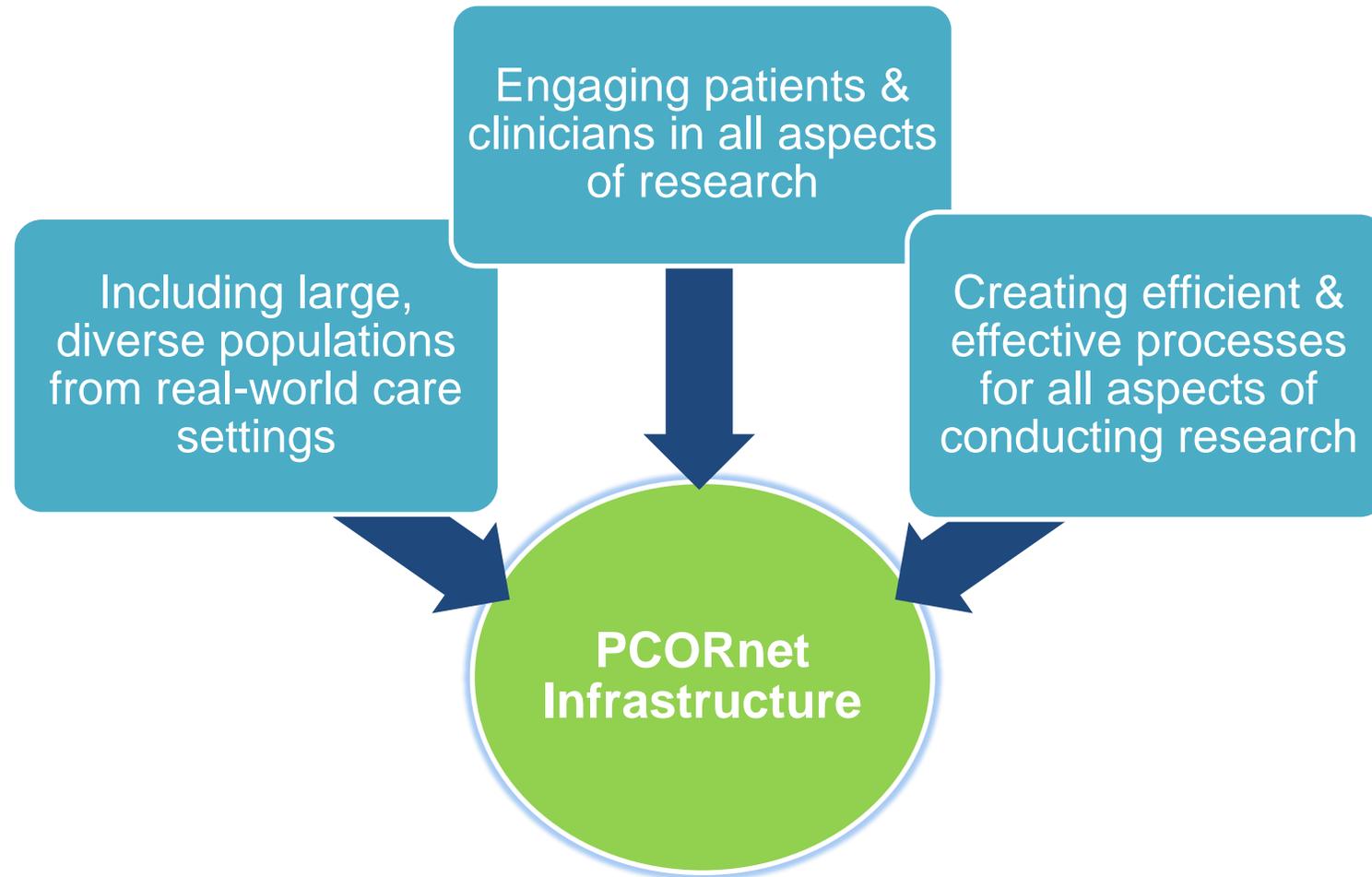
Patients with a condition in common form a research network, often in collaboration with academic researchers



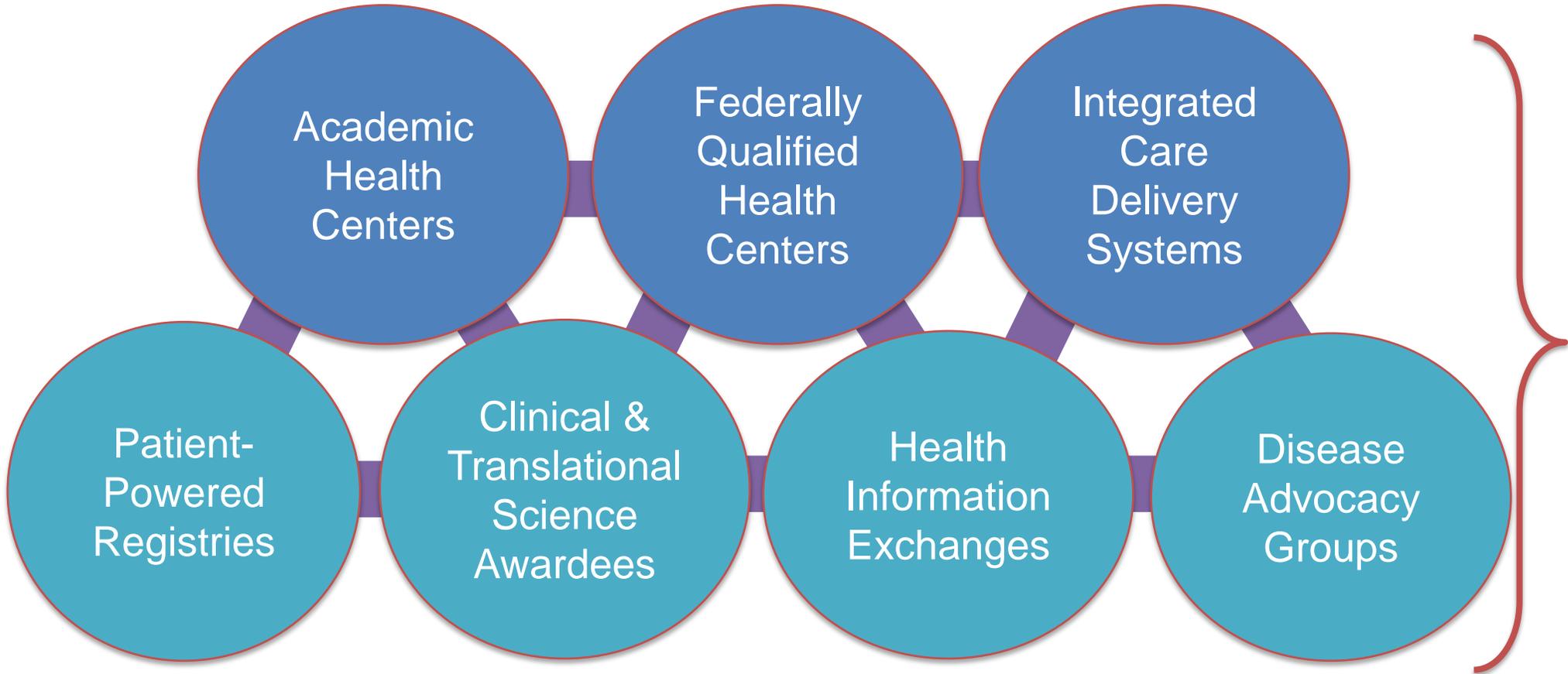
## **Coordinating Center**

Provides technical and logistical assistance under the direction of a steering committee and PCORI staff

# How is PCORnet different from other research networks?



# Diverse Contributors + Rich Data = High Potential

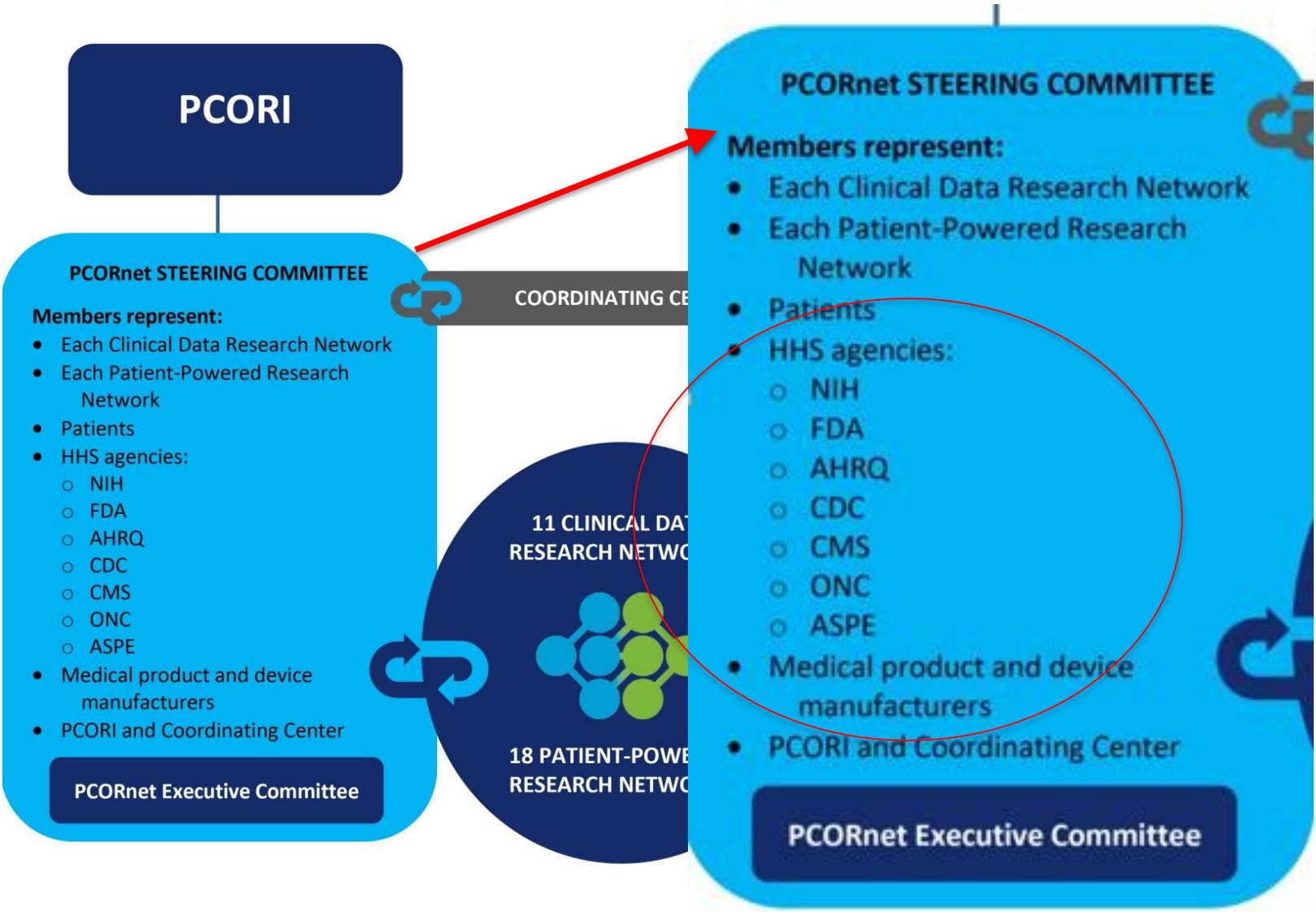


Ultimately, PCORnet will have wide range of data sources including:

- EHRs
- Social Media
- Biospecimens
- Insurance Claims
- Patient-Generated Information



# PCORnet Organizational Chart supports broad collaboration



# Three (Quick) Examples of PCORnet's Potential

- 🌐 National Conversations on Key Research Issues
- 🌐 Large Pragmatic Trial
- 🌐 Big Data

# PCORnet can drive public dialogue about key clinical research issues

- What is the right balance between patients' concerns about how their individual health information is used in research and the imperative to improve medical care through research that utilizes a wide spectrum of patient data?
- In the context of a pragmatic clinical trial comparing nighttime vs. morning dosing for HBP medication, does the act of randomizing patients to one of the study arms create “more than minimal risk?”
- Can we work within the current regulatory framework while building a more contemporary ethics & regulatory system to support comparative effectiveness research?
- Does the concept of participation in biomedical research as a societal good warrant a public interest campaign?

# PCORI will use PCORnet for a pragmatic trial

- The trial will be characterized by **operational simplicity and clinical relevance**
- Will make extensive use of electronic health records to identify patients and report outcomes
- Can be completed in  $\leq 18$  months with total cost of \$10 million
- PCORI solicited topics from the CDRNs and PPRNs and narrowed to six viable topics from the network for prioritization
- Anticipate submitting trial topics for PCORI Board of Governors in Fall 2014

# Big Data attributes: relevance to research

## Characterized by the 3 V's:

- *Volume*: so much data, so little time
- *Velocity*: accumulating at incredibly fast rate
- *Variety*: different from source to source

## Some other “V” words emerging:

- *Veracity & Validity*: Are the data correct and true, can we draw reliable conclusions?
- *Value*: do the data produce something I want and need?

Most data sources will require cleaning and preparation to be usable for research

# PCORnet as a Big Data Resource

- If it succeeds, PCORnet will be able to leverage:
  - Health system information (diagnoses, procedures, EHR)
  - Mobile health data (FitBit, Ginger.io, symptom trackers)
  - Biologic data from stored blood, saliva, tissue
  - Online patient communities & social media
- Not turn-key or automatic!
  - Determining the veracity and validity, AND transforming them into research-ready form
- Privacy and security controls are paramount
  - Partnering with patients to devise data sharing practices

# PCORnet = Big Data, but Much More

- 🌐 A data platform is needed to support PCORnet, but we also need the data to have utility in real-world healthcare
- 🌐 Through PCORnet, we will have ongoing patient & clinician input about priority research topics
- 🌐 Engagement of patients, clinicians, and health systems is the “special sauce” that will enable PCORnet to provide the answers patients need more quickly and efficiently, and at lower unit cost, than has ever been possible

# As we contemplate the potential & promise of big data...

- Find ways that the data can simultaneously support healthcare research and healthcare improvement
- Leveraging myriad data sources can help us attain greater precision
- Precision/personalized medicine = the holy grail of healthcare — targeting treatment to patient's unique traits

# Big Data, Big Culture Change?

patientslikeme® newsroom

Newsroom Home About PatientsLikeMe What's New Media Kit Social

## PatientsLikeMe Launches "Data for Good" Campaign to Encourage Health Data Sharing to Advance Medicine

*Public Service Announcement-Style Video Calls Patients to "Donate Your Data for You. For Others. For Good"*

Monday, March 10, 2014 8:45 am EDT

### Personal Data for the Public Good

New Opportunities to Enrich Understanding of Individual and Population Health

March 2014 | Publisher: Robert Wood Johnson Foundation  
Author(s): University of California, San Diego

Tweet 17 | G+ 6 | Like 10 | Share 15 | Print | Email



This study examines attitudes toward personal health data (PHD) from the individuals who track PHD, the companies involved in self-tracking devices, apps, or services, and researchers who might use the data.

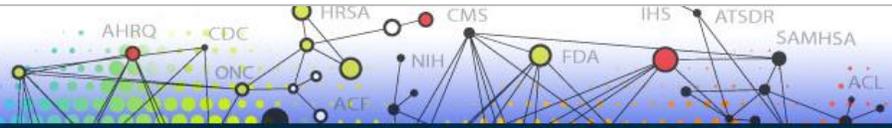
[Read the report \(PDF\) >](#)

Recommended

Topics  
[Health IT >](#)

Individuals were very willing to share their self-tracking data for research. However, the dominant condition (57%) for making their personal health data available for research was an assurance of privacy for their data.

HealthData.gov



Home Data Blog Q & A Ideas Developers

f t Search entire site...

# IOM Learning Health System Activities

**TABLE: Characteristics of a Continuously Learning Health Care System**

## Science and Informatics

- **Real-time access to knowledge**—A learning health care system continuously and reliably captures, curates, and delivers the best available evidence to guide, support, tailor, and improve clinical decision making and care safety and quality.
- **Digital capture of the care experience**—A learning health care system captures the care experience on digital platforms for real-time generation and application of knowledge for care improvement.

## Patient-Clinician Relationships

- **Engaged, empowered patients**—A learning health care system is anchored on patient needs and perspectives and promotes the inclusion of patients, families, and other caregivers as vital members of the continuously learning care team.

## Incentives

- **Incentives aligned for value**—In a learning health care system, incentives are actively aligned to encourage continuous improvement, identify and reduce waste, and reward high-value care.
- **Full transparency**—A learning health care system systematically monitors the safety, quality, processes, prices, costs, and outcomes of care, and makes information available for care improvement and informed choices and decision making by clinicians, patients, and their families.

## Culture

- **Leadership-instilled culture of learning**—A learning health care system is stewarded by leadership committed to a culture of teamwork, collaboration, and adaptability in support of continuous learning as a core aim.
- **Supportive system competencies**—In a learning health care system, complex care operations and processes are constantly refined through ongoing team training and skill building, systems analysis and information development, and creation of the feedback loops for continuous learning and system improvement.

# Endgame: Ideal attributes of learning health system align with attributes of PCORnet research ecosystem

- Involvement of stakeholders and patients in identifying relevant research study topics
- Data systems and data sources enable efficiencies in study operations
- Ability to embed trial operations into routine clinical care
- Pragmatic and realistic trial designs are required to close gap between pace of research and relevance to care delivery decision-makers
- Ensure continuous learning based on accumulating evidence



**Thank you!**

[www.pcori.org](http://www.pcori.org)

[www.pcornet.org](http://www.pcornet.org)

@PCORnetwork

*Sarah Greene*

[Greene.sm@ghc.org](mailto:Greene.sm@ghc.org)

*@researchmatters*

Patient-Centered Outcomes Research Institute