

Expanding Patient Reported Outcomes and Patient Generated Health Data across PCORnet®

Current State and Future Opportunities

December 14, 2021

Opening Remarks

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Agenda

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- 06 Opportunities to Capture PGHD

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PCORI is exploring opportunities to enhance PCORnet data infrastructure

- Increasing the availability and accessibility of high value data for research
- Identifying short-term, mid-term, and long-term infrastructure needs
- Topic areas:



**Social
Determinants of
Health**



**Patient Reported
Outcomes (PROs) &
Patient-Generated
Health Data (PGHD)**



**Centers for Medicare
& Medicaid Services
(CMS) data access
and use**

PRO and PGHD Workstream

Informed by Previous Work

- PCORnet PRO Task Force
- PRO Common Measures Work Group

Current Work



PRO & PGHD Webinar Objectives:



Review findings
on the
landscape of PRO
and PGHD
collection across
PCORnet



Discuss
opportunities to
improve
accessibility and
quality of PRO data
within the PCORnet
data infrastructure



Engage
stakeholders on
short-term and
long-term
infrastructure
priorities to expand
PRO and PGHD
availability across
the Network

Webinar Speakers

Opportunities for Leveraging
PRO Data Collected During
Clinical Care



Justin Bachmann
Investigator
STAR



Elizabeth Austin
Research Scientist
University of Washington

Opportunities for Leveraging
PRO Data Collected During
Research



Daniella Meeker
Associate Professor
University of Southern
California



L. Charles Bailey
Director, Data
Coordinating Center
PEDSnet

Opportunities to Capture
PGHD



Mark Pletcher
Professor, in Residence,
Departments of
Epidemiology and
Biostatistics, and
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PCORnet®, The National Patient-Centered Clinical Research Network

Nik Koscielniak, PhD, MPH
Program Officer
Research Infrastructure

- **Funded by PCORI in 2013**
- **Faster, more efficient**
 - Facilitate broad conduct of comparative clinical effectiveness research (CER) of national importance
- **National resource**
 - Accessible via central gateway to researchers within and outside of the Network
- **Harness health data and engage patients and communities**
 - Electronic health records, claims data, patient-reported outcomes, etc.
- **Nationally representative patient populations**
 - Support a wide range of research activities

PCORnet Core Principles

Network is National in scope

Patient is at the center

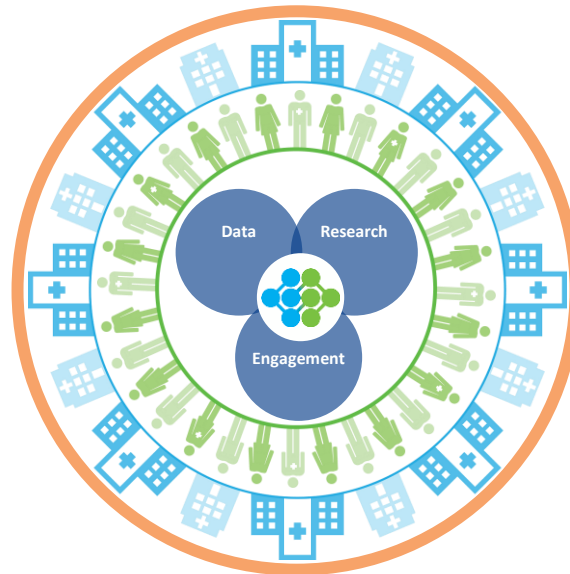
Data can be linked to the patient

- Strengthening the central role of patient and caregiver engagement to produce true partnership in the full research process
- Strengthening the unique ability of PCORnet to generate definitive evidence through studies of national scope, particularly for studies focused on PCORI Strategic Research Priorities and other priorities stemming from PCORI's ongoing strategic planning efforts (e.g., intellectual and developmental disabilities, maternal morbidity and mortality, addressing disparities, and COVID-19)
- Enhancing the unique capabilities of the PCORnet data structures, prioritizing infrastructure capabilities that align with the PCORI Strategic Research Priorities and other priorities stemming from PCORI's ongoing strategic planning efforts
- Strengthening the shared PCORnet governance model, which builds trust among participating networks
- Effective network function capitalizing on the distributed expertise and capabilities of network participants
- Contributing to a learning health care system through effective partnerships with all stakeholders and strengthening the educational resources needed to achieve this goal
- Building and strengthening partnerships with Federal Health Agencies

PCORnet is a “network of networks” that harnesses the power of partnerships

Trust is built. Answers are accelerated. Health improves.

Connecting people and data



to make informed decisions together

**Clinical
Research
Networks
(CRNs)**

+

**Patient
Partners**

+

**Coordinating
Center**

=

**A national
infrastructure for
patient-centered
clinical research**

PCORnet Common Data Model

Data are Research Ready



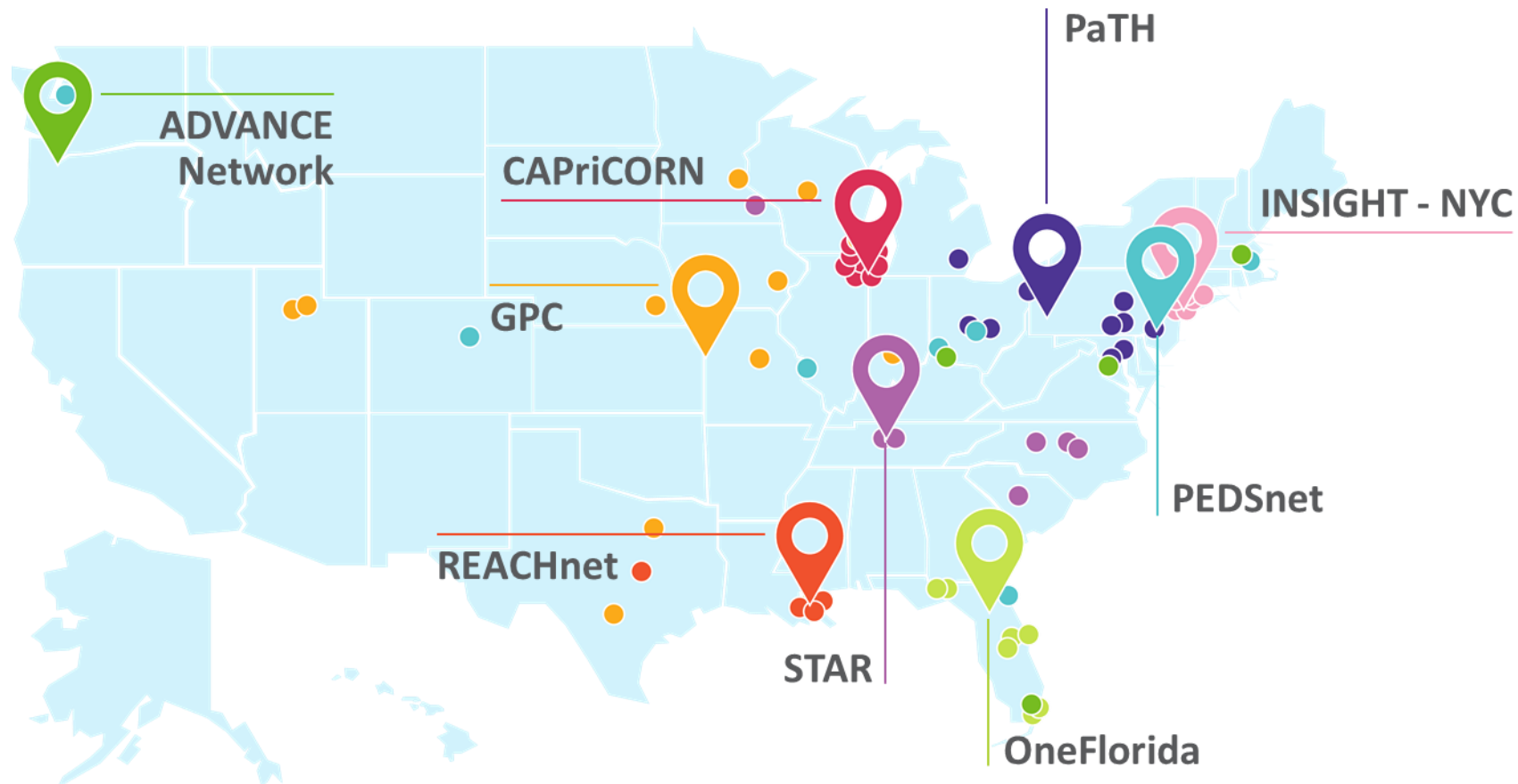
- Lots of data is great, but for it to be useful it has to be standardized across systems. The PCORnet Common Data Model standardizes data into a single language, enabling fast insights, including:

Ready for Research				Available, But Still Evolving			
Death Data	Diagnoses	Medication Orders		Geocodes	Social Determinants of Health	Tumor Registry	Biosamples
Claims	Labs	Demographics	Procedures	Patient-Reported Outcomes	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.

Nine PCORnet CRNs can help researchers conduct research more efficiently. Researchers can access data from everyday medical encounters from more than 60 million people across the United States.



PCORnet Front Door

- Access point for investigators, patient groups, healthcare organizations, clinicians, government, industry, sponsors, and all stakeholders seeking to leverage the PCORnet infrastructure and collaborate on patient-centered research

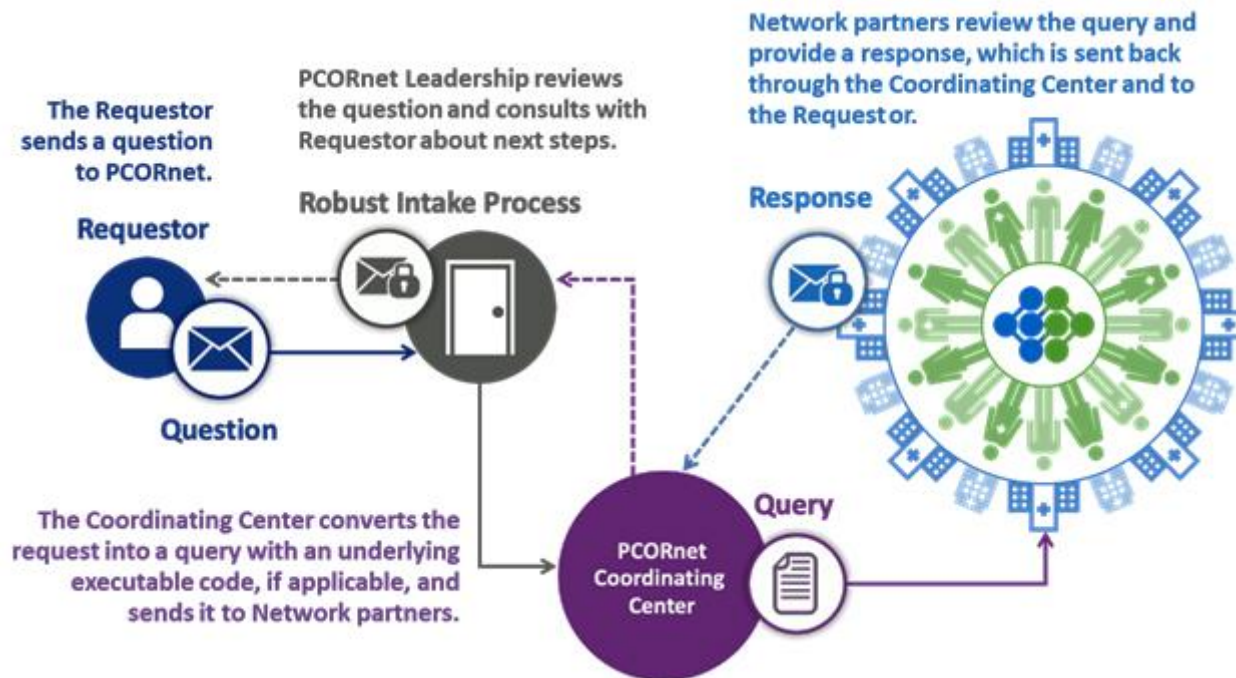
- **Data Network Requests**
- **Network Collaborator Requests**
- **Study Feasibility Review**



PCORnet

Coordinating Center Front Door

- Data curation processes to ensure data are research ready
- Query process is performed locally at the network site
- The data remains at the network site behind institutional firewalls, maintaining security
- Quarterly data refreshes



PCORI's Prioritizing Principles for PCORnet Infrastructure



Patient-Centered

- I. Strengthen the central role of patient and caregiver engagement to produce true partnership in the full research process
- II. Attend to and strengthen the diversity of the patient populations served and the inclusion of care sites that serve underserved populations

National Scope

- III. Recognize and strengthen the unique ability of PCORnet to generate definitive evidence through studies of national scope; prioritize investments that strengthen that capability particularly for studies focused on PCORI *Strategic Research Priorities*
- IV. Build on the unique capabilities of the PCORnet data structures, prioritizing investments that will align with the PCORI *Strategic Research Priorities*

Governance and Partnerships

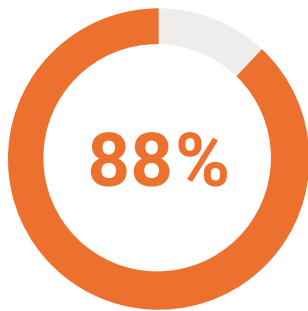
- V. Continue to develop the shared governance model which builds trust among participating networks and is coupled with close milestone-based monitoring of PCORI's infrastructure funds. As appropriate, encourage the development of mechanisms for cost recovery for infrastructure use related to projects supported by other funders
- VI. Recognize the importance of optimum distribution of core coordinating functions, with the dual goals of optimizing effective network function and capitalizing on the distributed expertise and capabilities of this complex network
- VII. Recognize, enable and promote the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders. Strengthen the educational resources needed to achieve this goal
- VIII. Recognize, enable and optimize the value of PCORnet for building partnerships with Federal Health Agencies

Current Landscape of PROs and PGHD Collection and Use Within PCORnet

Priyanka Desai

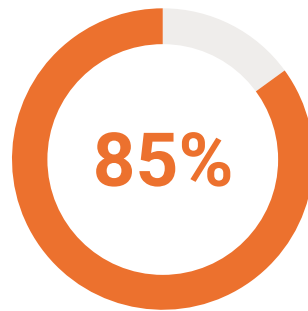
Health systems are collecting PROs as part of clinical care (n=41)

Health-related quality of life



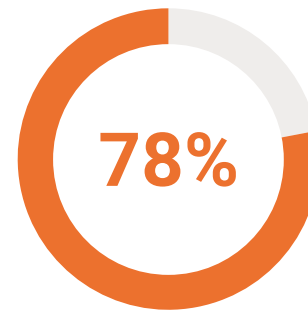
36 health systems collect PRO data on health-related quality of life

Symptoms and symptom burden



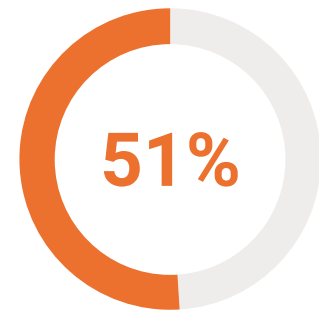
35 health systems collect PRO data on symptoms and symptom burden

Health behaviors



32 health systems collect PRO data on health behaviors

Experience with care



21 health systems collect PRO data on experience with care

PRO data collection across health systems

78%

**Most health systems
collecting PRO data use
PROMIS**

(32 of 41 health systems)

48%

**About half of health
systems collecting PRO
data report full EHR
integration**

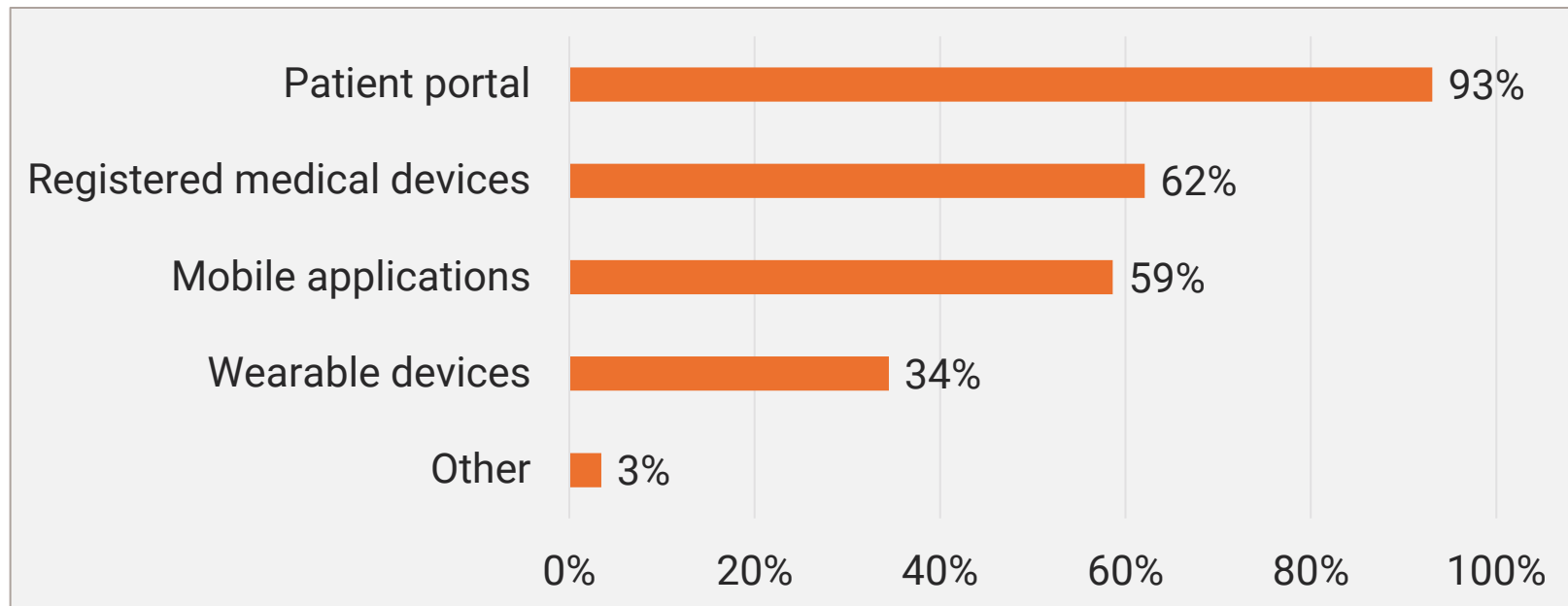
(22 of 46 health systems)

500

**~500 distinct PRO
measures collected
with limited overlap in
measures across health
systems**

Over half of health systems indicated that they are currently collecting PGHD (n=29)

Health Systems' Sources of PGHD for those Currently Collecting PGHD



Key opportunities for PRO and PGHD capture

Leveraging PRO Data Collected During Clinical Care	<ul style="list-style-type: none">• Conduct additional surveillance to identify commonly used PRO questionnaires and measures• Standardize a subset of commonly used instruments across PCORnet CRNs• Identify use cases to develop processes and workflows for standardizing PRO measures within the CDM• Enhance PCORnet data curation processes to ensure that existing PRO data are “research ready”
Leveraging PRO Data Collected During Research	<ul style="list-style-type: none">• Develop a repository of PRO questionnaires for sites to use• Identify data infrastructure supports both locally (i.e., for participating health systems) and centrally (i.e., across the Network) for PRO data collection for PCORnet studies
Capturing PGHD	<ul style="list-style-type: none">• Near-term, identify data infrastructure supports and platforms for PGHD collection for PCORnet studies• Longer-term, modify the PCORnet CDM to capture certain types of PGHD

Opportunities for Leveraging PRO Data Collected During Clinical Care

Justin Bachmann & Elizabeth Austin

Standardizing PRO data from the EHR in the PCORnet CDM



- Most health systems collecting PROs use commonly measured PRO domains (e.g., PROMIS measures, PHQ-9)
- There is considerable variability in the questionnaires used for the same measures (e.g., different versions of the same instrument)
- EHR capability to support collection of PRO measures is improving (e.g., EPIC PROMIS instruments), but challenges persist

Standardizing PRO data from the EHR in the PCORnet CDM

Opportunities

- Conduct additional surveillance to identify commonly used PRO questionnaires and measures
- Standardize a subset of commonly used instruments across PCORnet CRNs
- Identify use cases to develop processes and workflows for standardizing PRO measures within the CDM



Questions for Discussants

1. Which clinical areas (e.g., oncology, orthopedics, and behavioral health) are most primed in terms of widespread collection of PROs as part of clinical care?
2. What technical considerations should inform PCORI's planning as it looks to expand the capture of PRO data from EHRs across the Network?
3. What opportunities are there to leverage PRO data collected from other sources such as patient portals for research?



Questions for Audience

1. What PRO measurement instruments should PCORI consider prioritizing for standardized data capture across PCORnet CRNs?
2. What additional opportunities do you see for leveraging PRO data from the EHR across the Network?

Ensuring that PRO data are research ready



Landscape

- Research readiness of PRO data available in DataMarts is unclear until a query is submitted
 - There are differences in the latency of data
 - There are inconsistencies in whether sites provide item-level scores or summary scores
 - Sites can put the same PRO data elements in different fields of the CDM



Opportunity

- Enhance PCORnet data curation processes to ensure that existing PRO data are “research ready”



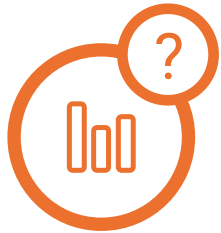
Questions for Discussants

1. What are the near-term opportunities to enhance PRO data curation processes (e.g., using test queries)?
2. What are existing best practices or guidance regarding the use of item-level versus summary scores for PRO measures?
3. What, if any, modifications to the CDM should be considered to support consistent standardization of PRO data?



Questions for Audience

1. How can PCORI strengthen the Network's existing PRO data to ensure the data are "research ready"?
2. What tools/resources are needed to facilitate use of the PRO table in the PCORnet CDM?



Poll Question

Which opportunity would you prioritize to enhance capabilities to leverage PRO data collected during clinical care?

- a. Standardizing a subset of PRO questionnaires used in clinical care
- b. Developing processes and workflows for standardizing PRO measures within the CDM for specific use cases
- c. Enhancing data curation processes
- d. Providing additional guidance about use of the CDM for PRO data collection
- e. Other (please specify in the chat)

Opportunities for Leveraging PRO Data Collected During Research

Charles Bailey & Daniella Meeker

Prospective PRO collection using data collection/survey platforms

Landscape

- CRNs serve as venues for prospective collection of PRO data as part of research
- Sites often use third party platforms separate from the EHR for data collection (e.g., REDCap)
- There is heterogeneity in the PRO data collected due to customized instruments and study-specific data dictionaries

Opportunity

- Develop a repository of PRO questionnaires for sites to use



Questions for Discussants

1. How can collection/survey platforms (e.g., REDCap) support the use of common data dictionaries and questionnaires across PCORnet sites?
2. What technical considerations should inform PCORI's planning as it looks to expand the capture of PRO data collected through data collection/survey platforms?
3. What opportunities are there to leverage PRO data captured as part of research studies from other sources such as patient portals?



Question for Audience

What PRO measures should be prioritized for inclusion in a central repository of questionnaires accessible to all CRNs?

Getting PRO data from survey platforms into the PCORnet CDM



Landscape

- PRO data collected as part of research are not put into the PCORnet CDM due to two factors:
 1. Researchers are used to their existing workflows, which are siloed and based on project specific tasks
 2. Developing site-specific extract, transform, and load (ETL) processes are resource intensive



Opportunity

- Identify data infrastructure supports both locally (i.e., for participating health systems) and centrally (i.e., across the Network) for PRO data collection for PCORnet studies



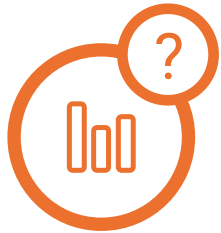
Questions for Discussants

1. What are the near-term opportunities to facilitate PRO data collection locally for PCORnet studies?
2. What opportunities are there to facilitate PRO data collection centrally?
3. What are the benefits of and barriers to using a local infrastructure to capture PRO data for research?
4. What are the benefits of and barriers to using a centralized infrastructure to capture PRO data in research?



Question for Audience

What data infrastructure supports/enhancements are needed to facilitate capture of PRO data in the CDM collected as part of research?



Poll Question

Given the benefits and tradeoffs, do you consider supporting local or central infrastructure as the more promising opportunity for PCORnet?

- a. Local infrastructure
- b. Central infrastructure
- c. Undecided

Opportunities to Capture PGHD

Mark Pletcher

Capturing PGHD in the PCORnet CDM

Landscape

- Many health systems that are part of CRNs are still in early stages of PGHD collection, with limited EHR integration
- Health systems that are collecting PGHD are primarily collecting data through patient portals and medical devices
- Health systems are most commonly collecting biometric data, symptoms, and health history

Opportunities

- Near-term, identify data infrastructure supports and platforms for PGHD collection for PCORnet studies
- Longer-term, modify the PCORnet CDM to capture certain types of PGHD



Questions for Discussant

1. How do third-party platforms (e.g., the Eureka Research Platform) currently facilitate the collection of PGHD as part of research?
2. What technical considerations should inform PCORI's planning as it looks to expand the capture of PGHD through the PCORnet data infrastructure?
3. Would modifications to the PCORnet CDM specification be useful for collecting PGHD?



Questions for Audience

- What types or sources of PGHD are most critical to capture within the CDM?
- What do you see as the most viable options for platforms to capture PGHD? For example, apps integrated into EHRs, patient portals or third-party platforms?

Final Thoughts and Q&A

Prashila Dullabh & Priyanka Desai

Thank you.

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