The PCORnet® Common Data Model & Patient-Reported Outcomes

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**The PCORnet Story**

Our nation’s clinical research system needs improvement.

It doesn’t answer all the questions that matter most to people, is too expensive, and too slow.

PCORI created PCORnet to help us improve it.

PCORnet is a large, highly representative patient-centered clinical research network.

PCORnet enables more efficient, trustworthy clinical research to help people:

- Make better-informed health decisions,
- Achieve significant cost savings, and receive faster clinical insights

PCORnet’s research community unites people, clinicians, and health systems with patient data from multiple sources: electronic health records, insurance claims data, data reported directly by people, and other data.

**Clinical Data Research Networks**

CDRNs originate in healthcare systems, such as hospitals, health plans, or practice-based networks.

**Patient-Powered Research Networks**

PPRNPs are operated and governed by groups of patients and their partners.

PCORnet is a national infrastructure for people-centered clinical research.

PCORnet represents:

- ~90 Million patients who have had a medical encounter in the past 5 years
- Some individuals may have visited more than one Network Partner and would be counted more than once

(as of July 15, 2016)

PCORnet represents a national infrastructure for people-centered clinical research.

- Underpinned by a Common Data Model,
- To advance clinical research using PCORnet.

- Answer pre-research questions faster.
- Collaborate with our network partners.
- Benefit from PCORnet study designation.

Think of all the different ways researchers can leverage PCORnet.

- Pre-research
- Observational studies
- Interventional studies

[pcornet logo]
PCORnet Data Strategy

- Standardize data into a common data model
- Focus on data quality: data curation
- Operate a secure distributed query infrastructure
  - Develop re-usable tools to query the data
  - Send questions to the data and only return required information
- Learn by doing and repeat
Why a Common Data Model?

Same information is represented differently at different institutions (e.g., Race)

In order to be able to trust results of an analysis, we need to have consistent representations.
PCORnet Common Data Model v3.1

**Fundamental basis**
- DEMOGRAPHIC

**Associations with PCORnet clinical trials**
- PCORNET TRIAL

**Process-related data**
- HARVEST

**Data captured from processes associated with healthcare delivery**
- ENROLLMENT
- DISPENSING
- DEATH
- DEATH CAUSE

**Data captured within multiple contexts: healthcare delivery, registry activities, or directly from patients**
- VITAL
- CONDITION
- PATIENT-REPORTED OUTCOMES (COMMON MEASURES)

**Data captured from healthcare delivery, direct encounter basis**
- ENCOUNTERT
- DIAGNOSIS
- PROCEDURES
- PRESCRIBING
- LABORATORY RESULTS (COMMON MEASURES)

- 800+ discrete comments from stakeholders
- Multiple stakeholder sessions to review feedback
- Available at www.pcornet.org/pcornet-common-data-model/
Data within a distributed research network

- People interpret the CDM specification differently, resulting in variability in how CDM is populated.
- Network composed of different health systems, with different EHRs, implemented at different times.
- Clinical workflows differ across institutions & impact availability of data.
- Understanding of EHR / claims data sources differs across institutions – may impact what gets loaded from source systems.
- Important to assess data quality before running a query.
Data Curation assesses and improves global data quality

- Characterize the contents of the PCORnet CDM
- Evaluate global data quality and fitness-for-use across a broad research portfolio

**Data curation**

**Step 1**
Network partner plans DataMart refresh

**Step 2**
Network partner responds to the data characterization query package

**Step 3**
Coordinating Center approves the DataMart

**Step 4**
Coordinating Center analyzes results and solicits more information as needed

**Step 5**
Coordinating Center holds Data Characterization and Implementation Forums and updates Implementation Guidance

**Data Curation**
- **Step 1**: Network partner plans DataMart refresh
- **Step 2**: Network partner responds to the data characterization query package
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**Table 1: Missing or Unknown Values**

<table>
<thead>
<tr>
<th>Table Name</th>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCORnet Implementation Guidance</td>
<td>v.0.0 for CDM v.3.0</td>
<td>Defines the rules for identifying missing or unknown values in the PCORnet CDM.</td>
</tr>
</tbody>
</table>

- **PCORnet Implementation Guidance** v.0.0 for CDM v.3.0
- Defines the rules for identifying missing or unknown values in the PCORnet CDM.
PROs in the PCORnet CDM v3.1 (PRO_CM)

- Focused on the PCORnet PRO Common Measures
- Measures established by PCORnet PRO Task Force
  - Charge: develop recommendations for brief set (5-10 items) of common “core” questions, allowing comparisons across PCORnet
  - Resulted in 21 standardized measures (primarily PROMIS)
- Table populated by about 10% of DataMarts (as of Feb. 2017)
PROs in future versions of the PCORnet CDM

Currently developing draft specifications for a new version of CDM

Considering expansion of PRO_CM table to include non-common measures

Interested in comments on potential modifications
  - Support inclusion of domain scores
  - Allow for PROs from terminologies besides LOINC
  - Learn from existing models?

Also preparing guidance/best practices for groups that wish to supplement the CDM with additional data domains (e.g., device data)
Questions?

Send any thoughts/feedback on CDM modifications to keith.marsolo@cchmc.org