



# Real World Data for Clinical Research: A PCORnet Workshop with the Device and Diagnostics Industry Meeting Summary

## Overview

On March 31, 2015, members of the PCORnet Executive Steering Committee and PCORI leadership joined participants from the device and diagnostics industry for a one-day workshop on The National Patient-Centered Clinical Research Network (PCORnet). Participants included over 25 industry representatives. The agenda was designed to elicit discussions about how to drive the development of PCORnet as a resource for device and diagnostics industry research. PCORI and PCORnet leaders presented network progress, and the planned demonstration projects were used to illustrate PCORnet's anticipated capabilities.

The discussions throughout the day emphasized:

- The need to **collaborate and not duplicate efforts** from other networks
- Critical importance of **data standards and data quality**
- The essential need for device/diagnostic research to **follow patients longitudinally across time and care settings**
- Exploration of strategies to **use and integrate existing registries** as a complement to other PCORnet data resources
- The opportunity that would be afforded by **integrating Universal Device Identifiers** into the PCORnet Common Data Model (CDM) to enable post-market device surveillance and outcomes research
- Desire for **pilot studies to demonstrate the network's abilities**
- Interest in **post-market studies** as an opportunity for early PCORnet studies
- Interest in PCORnet for **observational research** and **research on rare diseases**

The workshop raised many key questions and indicated an overall need for more publicly available guidance materials, particularly regarding PCORnet processes and operations. Several key questions that arose from the workshop were:

- How will researchers access PCORnet?
- What are the components and quality of data available in the Common Data Model (CDM)?
- How will data quality be monitored?
- How will data elements in the DM expand/progress?
- Which networks already have registries in practice?
- What efficiencies exist for using PCORnet at the individual network level and the overall PCORnet level?
- What will different types of research cost during Phase II?

Some of the questions and requests for information raised during the workshop can be answered now, and that information will be made available on [www.pcornet.org](http://www.pcornet.org). Other questions will inform the development of PCORnet and stimulate areas of network collaboration.

Moving forward, PCORI plans to convene interested attendees from PCORnet and industry workshops to identify concrete pilot studies and other tangible steps. PCORI intends to reconvene the device and diagnostic industry workshop participants in about six months.