Module 8: Case Study: PCORnet

Category 7: Data Networks as Research-Facilitating Structures

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Data Network Methodology Standards Mapping With Content

- DN-1 (requirements for the design and features of data networks) is discussed in Modules 3, 4, 5, 6, and 7
  A. Data Integration Strategy—Module 4
  B. Risk Assessment Strategy—Module 6
  C. Identity Management and Authentication of Individual Researchers—Module 6
  D. Intellectual Property Policies—Module 7
  E. Standardized Terminology Encoding of Data Content—Module 4
  F. Metadata Annotation of Data Content—Module 4
  G. Common Data Model—Module 5

- DN-2 (selection and use of data networks) is discussed in Modules 8 and 9
Patient-Centered Outcomes Research network (PCORnet; http://www.pcornet.org)

PCORnet is PCORI’s flagship initiative to build an efficient and patient-centered platform for observational and interventional research

Need for a reusable national infrastructure for clinical research

- Clinical trial coordinating centers, large research networks are often established for one purpose or one funding cycle
  - New trial or new condition often begets construction of new infrastructure
- Persistent inefficiencies in the current research process, from regulatory and operational to recruitment and data collection, hinder the research enterprise
- Most research doesn’t harness the full potential of electronic health record (EHR) data
A data platform is needed to support PCORnet, but we also need the data to have utility in real-world health care.

Through PCORnet, we will have ongoing input from patients, clinicians, health system leaders, payers, and other stakeholders on priority research topics.

Engagement 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.

“PCORI is about research done differently” versus “PCORnet is about research infrastructure done differently”
What will PCORnet do for research?
- PCORnet seeks to 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.

What is PRORnet’s vision?
- PCORnet will support widespread capability for the U.S. healthcare system to learn from research, meaning that large-scale research can be conducted with greater speed and accuracy within real-world care delivery systems.
  - Enable rapid, large-scale, patient-centered clinical research in our healthcare systems and communities.
Overall objective of PCORnet:

- Achieving a single functional research network by:
  - Creating a secure national research resource that will enable teams of health researchers, patients, and their partners to work together on researching questions of shared interest
  - Utilizing multiple rich data sources to support research, such as electronic health records, insurance claims data, and data reported directly by patients
  - Engaging patients, clinicians, and health system leaders throughout the research cycle from idea generation to implementation
  - Supporting observational and interventional research studies that compare how well different treatment options work for different people
  - Enabling external partners to collaborate with PCORI-funded networks
  - Sustaining PCORnet resources for a range of research activities supported by PCORI and other sponsors
29 networks + coordinating center

11 Clinical data research networks (CDRNs)
- System-based networks, such as integrated delivery systems, academic medical centers, and federally qualified health centers

18 Patient-powered research networks (PPRNs)
- Participants/patients working together to discover, propose, and answer relevant research questions (9 rare diseases and 9 non-rare)

155 involved organizations across the United States

3000+ collaborators/contributors

Millions of patients receive care in the participating systems

Phase I = March 1, 2014, through September 30, 2015

Phase II = October 1, 2015, through September 30, 2018

PCORI investment in infrastructure and initial projects ≈$275M
Industry faces expensive and inefficient trials with low recruitment:
- Large, cost-effective interventional trials leveraging electronic health data and utilizing streamlined contracting and institutional review board (IRB) processes

Industry needs access to increasingly large samples of real-world data
- Rapid observational studies leveraging a distributed research network and a common data model

Industry needs to respond to emerging regulatory requirements of patient preferences and patient engagement in general
- 18 PPRNs governed by patients
- 11 CDRNs with patient governance
- Patient Council involved in launching PCORnet
Organizational Structure

PCORnet embodies a “community of research” by uniting systems, patients, and clinicians.
Diverse Data Sources

- Electronic health records
- Patient-powered registries
- Clinical and translational science awardees
- Federally qualified health centers
- Health information exchanges
- Integrated delivery systems

- Academic health centers
- Disease advocacy groups
- Pharmacy data vendors
- Data from payers (e.g., Centers for Medicare & Medicaid Services)
- mHealth / patient-generated data
- Biospecimen data
PCORnet Common Data Model (CDM) builds on prior data models, such as HMORN Virtual Data Warehouse and FDA Sentinel.

PCORnet CDM is complementary to and compatible with both OMOP and i2b2.

Most networks have harmonized local data to CDM Version 1.0.

Version 3.0 of PCORnet CDM.

Readying data to be “interrogated” for various research questions.

PopMedNet will be used as the secure querying engine.

10 of 11 CDRNs and 8 of 18 PPRNs established on PopMedNet.
Common Data Model

- Demographics
- Enrollment
- Dispensing
- Death
- Vitals
- Conditions
- Encounters
- Diagnosis
- Procedures
- Lab results
- Prescribing

Informatics Principles

- Analysis-ready data
  - Standard format
  - Harmonized definitions
  - Quality-checked in advance

- Reusable analysis tools

- Efficient clinical trial enrollment and follow-up mechanisms

- Simple, pragmatic studies integrated into routine care

- Administrative simplicity (e.g., streamlined contracting)

- Initial PCORnet demonstration projects will help assess end-to-end functionality: design, implementation, analysis, and reporting
Rather than bringing the data to the question, PCORnet is designed to bring the question to the data.

1. User creates and submits query (a computer program)
2. Individual CDRNs/PPRNs retrieve query
3. CDRNs/PPRNs review and run query against their local data
4. CDRNs/PPRNs review results
5. CDRNs/PPRNs return results via secure network
6. Results are aggregated
Distributed Research Network (DRN)
Distributed Research Network (DRN)
Operational Model (DRN and Privacy Protection)
Sharing Infrastructure With Other Networks

Mini-Sentinel

PCORNet

NIH Distributed Research Network

CTSA Clinical and Translational Science Awards

Health Plan 1
Health Plan 2
Health Plan 3
Health Plan 4
Health Plan 5
Health Plan 6
Health Plan 7
Health Plan 8
Health Plan 9
Hospital 1
Hospital 2
Hospital 3
Hospital 4
Hospital 5
Hospital 6
Outpatient Clinic 1
Patient Network 1
Outpatient Clinic 2
Patient Network 2
Outpatient Clinic 3
Patient Network 3
This map depicts the number of PCORI-funded patient-powered research networks (PPRNs) or clinical data research networks (CDRNs) that have coverage in each state (total 29)
CDRN Goals

- Create a research-ready dataset of at least 1 million patients that is:
  - Secure and does not identify individual patients
  - Comprehensive, using data from EHRs to describe patients’ care experience over time and in different care settings

- Involve patients, clinicians, and health system leaders in all aspects of creating and running the network

- Develop the ability to run a clinical trial in the participating systems that fits seamlessly into healthcare operations

- Identify at least three cohorts of patients who have a condition in common and who can be characterized and surveyed
- Networks of academic health centers, hospitals, and clinical practices
- Networks of nonprofit integrated health systems
- Networks of federally qualified health centers (FQHCs) serving low-income communities
- Networks leveraging NIH and AHRQ investments (CTSAs)
- Inclusion of health information exchanges
- Wide geographic spread
- Inclusion of underserved populations
- Range from 1M covered lives to 28M
<table>
<thead>
<tr>
<th>CDRN name</th>
<th>Lead organization</th>
<th>Principal investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVANCE</td>
<td>Oregon Community Health Information Network</td>
<td>Jennifer DeVoe</td>
</tr>
<tr>
<td>CAPriCORN</td>
<td>The Chicago Community Trust</td>
<td>Terry Mazany</td>
</tr>
<tr>
<td>Great Plains Collaborative</td>
<td>University of Kansas Medical Center</td>
<td>Lemuel Waitman</td>
</tr>
<tr>
<td>Louisiana Clinical Data Research Network</td>
<td>Louisiana Public Health Institute</td>
<td>Anjum Khurshid</td>
</tr>
<tr>
<td>Mid-South CDRN</td>
<td>Vanderbilt University</td>
<td>Russell Rothman</td>
</tr>
<tr>
<td>NYC-CDRN</td>
<td>Weill Medical College of Cornell University</td>
<td>Rainu Kaushal</td>
</tr>
<tr>
<td>PEDSNet</td>
<td>The Children’s Hospital of Philadelphia</td>
<td>Christopher Forrest</td>
</tr>
<tr>
<td>PORTAL</td>
<td>Kaiser Foundation Research Institute</td>
<td>Elizabeth McGlynn</td>
</tr>
<tr>
<td>pSCANNER</td>
<td>University of California, San Diego</td>
<td>Lucila Ohno-Machado</td>
</tr>
<tr>
<td>P2ATH</td>
<td>University of Pittsburgh</td>
<td>Rachel Hess</td>
</tr>
<tr>
<td>SCIHLS</td>
<td>Harvard University</td>
<td>Kenneth Mandl</td>
</tr>
<tr>
<td>CDRN name</td>
<td>Common cohort</td>
<td>Rare cohort</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ADVANCE</td>
<td>Diabetes</td>
<td>Co-infection with HIV and hepatitis C virus</td>
</tr>
<tr>
<td>CAPriCORN</td>
<td>Anemia; asthma</td>
<td>Sickle cell disease (SCD); recurrent <em>C. difficile</em> colitis</td>
</tr>
<tr>
<td>Great Plains Collaborative</td>
<td>Breast cancer</td>
<td>Amyotrophic lateral sclerosis (ALS)</td>
</tr>
<tr>
<td>Louisiana Clinical Data Research Network</td>
<td>Diabetes</td>
<td>Sickle cell disease (SCD), rare cancers</td>
</tr>
<tr>
<td>Mid-South CDRN</td>
<td>Diabetes</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>NYC-CDRN</td>
<td>Coronary heart disease (CHD)</td>
<td>Sickle cell disease (SCD)</td>
</tr>
<tr>
<td>PEDSNet</td>
<td>Inflammatory bowel disease</td>
<td>Hypoplastic left heart syndrome</td>
</tr>
<tr>
<td>PORTAL</td>
<td>Colorectal cancer</td>
<td>Severe congenital heart disease</td>
</tr>
<tr>
<td>pSCANNER</td>
<td>Congestive heart failure</td>
<td>Kawasaki disease</td>
</tr>
<tr>
<td>P2ATH</td>
<td>Atrial fibrillation</td>
<td>Idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td>SCIHLS</td>
<td>Osteoarthritis</td>
<td>Pulmonary arterial hypertension</td>
</tr>
</tbody>
</table>
Each CDRN Network will have 1 to 10 DataMarts

Total anticipated DataMarts = 75

Annotated data dictionaries received = 62

Software installation completed = 30

Nine of 11 CDRNs have transformed data for at least one million individuals
PPRN Goals

- Target size of 0.5% of U.S. population
- Establish an activated patient population with a condition of interest (size >50 patients for rare diseases; >50,000 for common conditions)
- Collect patient-reported data for ≥80% of patients in the network
- Involve patients in network governance
- Create standardized database suitable for sharing with other network members that can be used to respond to “queries” (ideas for possible research studies)
Participating organizations and leadership teams include patients, advocacy groups, clinicians, academic centers, and practice-based research networks.

- Strong understanding of patient engagement
- Significant range of conditions and diseases
- Variety in populations represented (including pediatrics and underserved populations)
- 50% are focused on rare diseases
- Varying capabilities with regard to developing research data
- Several PPRNs have capacity to work with biospecimens
<table>
<thead>
<tr>
<th>Organization</th>
<th>Principal investigator</th>
<th>Condition</th>
<th>Population size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated Cure Project for Multiple Sclerosis</td>
<td>Robert McBurney</td>
<td>Multiple sclerosis</td>
<td>20,000</td>
</tr>
<tr>
<td>American Sleep Apnea Association</td>
<td>Susan Redline</td>
<td>Sleep apnea</td>
<td>50,000</td>
</tr>
<tr>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>Peter Margolis</td>
<td>Pediatric Crohn's disease and ulcerative colitis</td>
<td>15,000</td>
</tr>
<tr>
<td>COPD Foundation</td>
<td>Richard Mularski</td>
<td>Chronic obstructive pulmonary disease</td>
<td>50,000</td>
</tr>
<tr>
<td>Crohn's and Colitis Foundation of America</td>
<td>R. Balfour Sartor</td>
<td>Inflammatory bowel disease</td>
<td>30,000</td>
</tr>
<tr>
<td>Global Healthy Living Foundation</td>
<td>Seth Ginsberg</td>
<td>Arthritis, musculoskeletal disorders, and inflammatory conditions</td>
<td>50,000</td>
</tr>
<tr>
<td>Massachusetts General Hospital</td>
<td>Andrew Nierenberg</td>
<td>Major depressive disorder (MDD) and Bipolar disorder (BP)</td>
<td>50,000</td>
</tr>
<tr>
<td>University of California San Francisco</td>
<td>Mark Pletcher</td>
<td>Cardiovascular health</td>
<td>100,000</td>
</tr>
<tr>
<td>University of South Florida</td>
<td>Rebecca Sutphen</td>
<td>Hereditary breast and ovarian cancer (HBOC)</td>
<td>17,000</td>
</tr>
<tr>
<td>Organization</td>
<td>Principal investigator</td>
<td>Condition</td>
<td>Population size</td>
</tr>
<tr>
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<td>---------------------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>ALD Connect, Inc.</td>
<td>Florian Eichler</td>
<td>Adrenoleukodystrophy</td>
<td>3,000</td>
</tr>
<tr>
<td>Arbor Research Collaborative for Health</td>
<td>Bruce Robinson</td>
<td>Primary nephrotic syndrome</td>
<td>1,250</td>
</tr>
<tr>
<td>Duke University</td>
<td>Laura Schanberg</td>
<td>Juvenile rheumatic disease</td>
<td>9,000</td>
</tr>
<tr>
<td>Epilepsy Foundation</td>
<td>Janice Beulow</td>
<td>Aicardi syndrome, Lennox-Gastaut syndrome, Phelan-McDermid syndrome, etc.</td>
<td>1,500</td>
</tr>
<tr>
<td>Genetic Alliance, Inc.</td>
<td>Sharon Terry</td>
<td>Alström syndrome, Dyskeratosis congenital, Gaucher disease, hepatitis, inflammatory breast cancer, Joubert syndrome, etc.</td>
<td>50-50,000</td>
</tr>
<tr>
<td>Immune Deficiency Foundation</td>
<td>Kathleen Sullivan</td>
<td>Primary immunodeficiency diseases</td>
<td>1,250</td>
</tr>
<tr>
<td>Parent Project Muscular Dystrophy</td>
<td>Holly Peay</td>
<td>Duchenne and Becker muscular dystrophy</td>
<td>4,000</td>
</tr>
<tr>
<td>Phelan-McDermid Syndrome Foundation</td>
<td>Megan O’Boyle</td>
<td>Phelan-McDermid syndrome</td>
<td>737</td>
</tr>
<tr>
<td>University of Pennsylvania</td>
<td>Peter Merkel</td>
<td>Vasculitis</td>
<td>500</td>
</tr>
</tbody>
</table>
Why engage patients in infrastructure development and research?

- Greater likelihood of trust and participation in research networks when patients are involved in the development and governance of research network
- Greater likelihood of uptake of research findings when patients are involved as partners in the design, conduct, and dissemination of the research

Governance

- Patients engaged at coordinating center level and on Executive Steering Committee
- Patients engaged in PCORnet task forces and policy development
- PCORnet Patient Council, a national deliberative body of patient leaders, provides feedback and recommendations on key PCORnet policies to ensure full consideration of both the highest patient engagement standards and issues related to protection of patient privacy, consent, and autonomy
  - Patients choose the research studies in which they will participate
## Patient Engagement Categories

<table>
<thead>
<tr>
<th>Governance</th>
<th>Enrollment &amp; Diversity</th>
<th>Data Collection</th>
<th>Privacy &amp; Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Development of network governance structure, roles, and responsibilities</td>
<td>- Increasing size of the network</td>
<td>- The development of data collection tools</td>
<td>- The development of data collection tools</td>
</tr>
<tr>
<td>- Development of procedures, bylaws, and policies for the network</td>
<td>- Increasing the diversity of the network</td>
<td>- Identification of patient-reported outcomes (PROs) for inclusion in database</td>
<td>- Identification of patient-reported outcomes (PROs) for inclusion in database</td>
</tr>
<tr>
<td>- Patient are partners in decision making about research priorities</td>
<td>- Retention of network members</td>
<td>- Registry development</td>
<td>- Registry development</td>
</tr>
</tbody>
</table>

- **Enrollment & Diversity**
  - Increasing size of the network
  - Increasing the diversity of the network
  - Retention of network members

- **Data Collection**
  - The development of data collection tools
  - Identification of patient-reported outcomes (PROs) for inclusion in database
  - Registry development

- **Privacy & Consent**
  - The development of data collection tools
  - Identification of patient-reported outcomes (PROs) for inclusion in database
  - Registry development
Patient Engagement Elements

- Planning the study
  - Identifying the topic and developing the research question to be studied
  - Identifying the intervention or comparators to be studied
  - Defining the characteristics of study participants

- Conducting the study
  - Participating in and monitoring the conduct of the project
  - Assisting with the recruitment of study participants
  - Assisting with data analysis

- Disseminating the study results
  - Identifying partner organizations for dissemination
  - Planning dissemination efforts
  - Participating in dissemination efforts, such as the authoring of manuscripts and the presentation of study findings

Key governance topics include (adapted from the Governance task force):

- Stakeholder/patient engagement
- Leadership
- Human subjects policies (regulatory and ethical oversight)
- Data use (includes data use agreements [DUAs], business associate agreements [BAAs], data sharing, data security, and data safety and monitoring boards)
- Conflict of Interest
- Intellectual property
- Privacy of personal information
- Reproducibility of research
Until now, we have been unable to answer many of the most important questions affecting health and health care.

By combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patients’ priorities and speed the creation of new knowledge to guide treatment on a national scale.
Each CDRN

Each PPRN

U.S. Department of Health and Human Services agencies:
  ▶ National Institutes of Health
  ▶ Food and Drug Administration
  ▶ Agency for Healthcare Research and Quality
  ▶ Centers for Medicare & Medicaid Services
  ▶ Office of the National Coordinator for Health Information Technology
  ▶ Assistant Secretary for Planning and Evaluation

Medical product and device manufacturers

PCORI and Coordinating Center
Governance and Collaboration Task Force:
  - Develop policies that support trust and collaboration

Data Standards, Security, and Network Infrastructure Task Force:
  - Create the PCORnet Distributed Research Network that facilitates multisite research across the CDRNs, PPRNs, and others

Data Privacy Task Force:
  - Identify privacy issues raising particular challenges, highlight promising or best practices for addressing them, and develop privacy policies to govern data sharing

Patient and Consumer Engagement Task Force:
  - Ensure engagement of patients and consumers in all components of PCORnet and serve as technical resource, with PCORI staff
Health Systems Interactions Task Force:
- Help the CDRNs create a supportive environment for clinical research with their clinicians and clinical leadership

Ethics and Regulatory Task Force:
- Address ethical and regulatory issues related to research that arise in PCORnet’s work

Patient-Reported Outcomes Task Force:
- Focus on measurement, collection, and analysis of patient-generated information

Clinical Trials Task Force:
- Adopt methods, standards, and quality by design principles for clinical trials; develop pathways for trials; oversee trial conduct, feedback learnings
Task Forces

- Rare Diseases Task Force:
  - Support identification of populations and research priorities for studies of rare diseases
  - Create an information source for rare disease research
  - Create a discussion and advocacy forum to identify and advocate for needs specific to rare disease research

- Biorepositories Task Force:
  - Support a regulatory-compliant, comprehensive, and sustainable Network-wide biorepository to serve PCORnet research

- Obesity Task Force:
  - Facilitate construction of the obesity cohort at each CDRN, and identify potential research uses
Demonstration Goals

- **Address** questions important to patients and clinicians that require multisite evaluation
- **Assess** PCORnet’s ability to perform large-scale interventional and observational research
- **Facilitate** collaboration between networks
- **Guide** further development of policies, procedures, and infrastructure
- **Road-test** data and networking capabilities
- **Ensure** PCORnet’s privacy-protecting data infrastructure and analysis capabilities are sound
- **Develop** efficient methods for identifying, enrolling, and following potential clinical trial participants
Demonstration Goals

PCORnet goal
Capacities in place to support all three types of research

Interventional trials

Observational studies

Rapid cycle research on healthcare delivery
Use Cases / Demonstration Projects

- Demonstration projects will move PCORnet from concept to action
- Aspirin Clinical Trial (ADAPTABLE)
- Obesity Observational Studies
  - Bariatric Surgery Outcomes
  - Antibiotics and Weight Gain in Children
- PPRN Research Demonstration Projects
- Health Systems Demonstration Project
- NEXT-D Initiative with CDC
- Discussing topics of interest to health plans
Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE) Trial

- PCORnet’s First Pragmatic Clinical Trial

Illustrating the need for an Aspirin trial:

- Ted had chest pain while working and was taken to the emergency department, where he learned he was having a heart attack. Doctors told him that plaque was building up in his arteries.
- Upon discharge from the hospital, Ted was advised to take 325 mg of aspirin each day (regular strength). Ted compared notes with a friend who said his doctor has him on a baby aspirin because it causes less bleeding and bruising.
- Ted is confused about what dose he should take. He does a lot of work outdoors and carpentry. He is worried about bleeding while working but doesn’t want another heart attack either. And now Ted wonders what he should do.
ADAPTABLE Use Case: Evidence

- Distribution of aspirin dosing at time of hospital discharge has been shown to vary

![Graph showing aspirin dosing distribution]

- 325 mg: 61%
- 81 mg: 36%
- 162 mg: 3%
- Other: 0.01%

Aspirin ...
- Has proven clinical benefit in reducing ischemic vascular events
- Is cost-effective
- Has benefit with combination antiplatelet therapies

But there are issues:
- Emerging evidence for dose modifiers (e.g., aspirin resistance, genetics)
- Equal efficacy across patients?
- Intolerance
- Most effective dose uncertain
  - ADAPTABLE Trial aims to resolve that uncertainty
ADAPTABLE Use Case: Role of PCORnet

Patients with known coronary artery disease (MI, CAD, or Revasc) + >1 enrichment factor

Identified through HER / direct patient consent in CDRN and PPRN clinics/hospitals

Patient contacted electronically with trial information and eConsent + treatment assignment

ASA 81 mg QD

ASA 325 mg QD

Electronic follow-up at 4 months; supplemented with EHR/CDM/claims data

Duration: enrollment over 24 months; maximum follow-up of 30 months

Primary endpoint: composite of all-cause mortality, nonfatal MI, nonfatal stroke
Primary safety endpoint: major bleeding complications

Enrichment factors

- Age >65 yrs
- Creatinine >1.5
- Diabetes
- Known 3-vessel CAD
- Current CVD and/or PAD
- Known ejection fraction <50%
- Current smoker
ADAPTABLE Use Case: CDRN

Use EHR data to create “computable phenotype” that can identify patient at participating CDRNs

History of CAD
- Past MI, or
- Past cath. showing significant CAD, or
- Revascularization (PCI/CABG)

At least one:
- Age >65 yrs
- Creatinine >1.5
- Diabetes
- Known 3-vessel CAD
- Current CVD and/or PAD
- Known ejection fraction <50%
- Current smoker

Obtain consent, electronically when possible
This is a novel clinical trial using novel methods

Large group of pioneering networks and people, working together to leverage different experiences, skills, expertise (patients = co-creators)

ADAPTABLE needs to be adaptable!

If successful, ADAPTABLE will:
► Help solve the challenge and demonstrate the value of a reusable infrastructure
► Launch a new era for pragmatic clinical trials and observational research to answer questions with high impact on population health

Annually, in the United States alone, getting the dose of aspirin right could save up to tens of thousands of lives and/or prevent heart attacks (and prevent thousands of major bleeding episodes)
Near-Term Goals

- Able to conduct large observational studies affordably using a common data model, distributed querying, and sharing of data when needed
- Able to conduct clinical trials affordably through streamlined contracting; IRB coordination; engagement of clinicians and sites; and rapid identification, recruitment, consenting, and follow-up of subjects
- Openness to data linkage with other databases (e.g., registries, CMS) for funded studies
- Launch additional PCORnet studies already in the pipeline
- Expand the number of PPRNs and CDRNs
- Identify and initiate studies that are attractive to and/or proposed by other entities
- Fine-tune infrastructure on the basis of demonstration projects
- Determine business model and business plan that lead to a durable and sustainable research infrastructure
PCORnet will:

- Establish priorities that clinicians, clinical leaders, patients, and investigators share
- Facilitate trust leading to collaboration between networks
- Embed research into practice settings without disrupting clinical operations
- Create a distributed data network that protects patients’ confidential information
- Develop oversight procedures that protect patients while minimizing redundancy
- Engage individuals and organizations beyond the initial awardees