The National Patient-Centered Clinical Research Network: 
Building a National Data Infrastructure to Advance Patient-Centered Comparative Effectiveness Research (CER) 

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WISH 
November 16th, 2013
PCORI’s Mission and Vision

- The Patient-Centered Outcomes Research Institute (PCORI) is an independent, non-profit health research organization authorized by the Patient Protection and Affordable Care Act of 2010.

- PCORI funds patient-centered research to assist patients, caregivers, and other stakeholders in making informed health decisions.

**Mission**

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

**Vision**

Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
Our Focus

Comparative Clinical Effectiveness Research

- Patient-centered: answering questions that matter to patients and other clinical decision makers
- Comparisons of outcomes that matter to patients
PCORI’s Three Strategic Goals

- **Increase the quantity, quality, and timeliness of evidence** available to support health decisions.
- **Influence** research funded by others to be more patient-centered.
- **Speed the implementation of** research
We Use Engagement as a Path to Rigorous Research

Advising Us on What PCORI Should Study

Review Proposals and Partner in Research

Tell Us How We’re Doing

Help Us Share the Findings
PCORI’S National Priorities for Research

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication & Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research
Our Growing Research Portfolio

Total number of research projects awarded to date: 197
Total funds committed to date: $273.5 million
Number of states where we are funding research: 36 states (including the District of Columbia)
Minimum research commitment in 2013: $400 million
National Patient-Centered Clinical Research Network
The **goal** of PCORI’s National Patient-Centered Clinical Research Network Program is to **improve the nation’s capacity to conduct CER efficiently, by creating a large, highly representative, national patient-centered clinical research network.**

The **vision** is to support a **learning US healthcare system**, which would allow for **large-scale research** to be conducted with **enhanced accuracy and efficiency.**
National Patient-Centered Clinical Research Network

The **core components** of this network will be:

- Clinical Data Research Networks (CDRNs), which are **system-based networks** that have the potential to become an ideal electronic network.

- **Patient-Powered Research Networks (PPRNs),** which are **groups of patients** interested in forming a research network and in participating in research.

- A **Coordinating Center** which will provide **technical and logistical assistance** under the direction of the Steering Committee and PCORI Staff.
CDRN Characteristics
CDRN Requirements at entry

- Multiple health systems working on data standardization and interoperability
- Health system leadership involved in governance
- Ability to conduct observational and interventional research
- Willingness to participate in research studies as part of the national network
CDRN Goals at 18 months

- >1,000,000 patients enrolled
- Engagement with patients for purposes of research
- Data standardized within network and with other awardee networks
- Patients, system, and clinicians engaged in governance & use
- Capable of implementing clinical trials
- Obesity and rare disease cohorts characterized for the purposes of research
PPRN Characteristics
PPRN Requirements

- Activated patients willing to generate questions and share (de-identified) data for the purposes of research
- Increase activated patient community to at least 50,000 patients (less for patients with rare disorders).
- Explore new approaches for patient members to contribute their electronic clinical data to the PPRN
- Is willing to explore new approaches for patient members to collect self-reported data.
PPRNs Will Concentrate on the Following Activities During the 18 months Initiative

- **Patient recruitment** to their network.
- Patients involved in the governance of the network
- Establishment of **standards-based** data infrastructure and policies to support these efforts.
- **Characterization of the network membership** in terms of demographic and clinical characteristics.
- Refining the process for **identifying research needs** of greatest interest to patients.
- Collection of **patient generated information**, including patient reported outcomes information for 80% of their members.
NCRN Coordinating Center Task Forces
National Patient-Centered Clinical Research Network: Key Areas of Focus

- Data Standards and Interoperability
- Governance / Collaboration
- Health System Leadership Involvement / Sustainability
- Patient Engagement
- Patient Reported Outcomes
- Ethical Oversight
- Privacy and Security
- Biospecimens and biorepositories
- Obesity workgroup
- Rare disease workgroup
NCRN Metrics of Success

- **Launch simple intervention trial** embedded within systems in 2014
- **Ability to conduct high quality** observational CER
- **Enable participation of external data partners**
- **Enable access to external researchers**
CDRN and PPRN Applicants
Among applicant CDRNs

- Non-profit integrated health systems
- Major commercial health plans
- Networks of academic medical centers, hospitals and physician practices
- Networks of low income clinics
- Networks leveraging AHRQ investments
- CTSA (NIH investments)
- Network based on HIEs
- Geographical representation
- Underserved populations
- Range from 1M covered lives to 12M
Among applicant PPRNs

- Variety of **stakeholders** in participating organizations and in leadership team: patients, advocacy groups, physician organizations, academic centers, PBRNs etc.
- Strong understanding of **patient engagement**
- Significant range of **conditions and diseases**
- Variety in **populations** represented (including pediatrics, underserved populations etc.)
- Close to 50% **rare diseases**
- Significant range in the **maturity** of the group (some with little data and some with significant data collected from registries or databases),
- **Biospecimens**
Some examples of PPRN disease areas
These do not reflect merit review scores and are just illustrative

Common disorders
- Breast Cancer
- BRCA Carriers
- COPD
- Crohn’s
- End of Life
- Fertility
- Lung Cancer
- Mood
- Multiple Sclerosis
- Parkinson’s
- Pediatric IBD
- Preeclampsia
- Prostate Cancer
Etc.

Rare Diseases
- Adrenoleukodystrophy
- Chromosome 15q Duplication Syndrome
- Fragile X
- Hypoplastic heart syndrome
- Multiple endocrine neoplasia
- Pediatric rheumatic diseases
- Phelan McDermid Syndrome
- Rare epilepsies
- Rare lung disease network
- Sickle Cell
- Vasculitis
Etc.
After the first phase of infrastructure building June 2015

- Potentially more infrastructure investments for new and existing entrants
- Research funding available for studies conducted through the NCRN
Find Us Online

www.pcori.org
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