



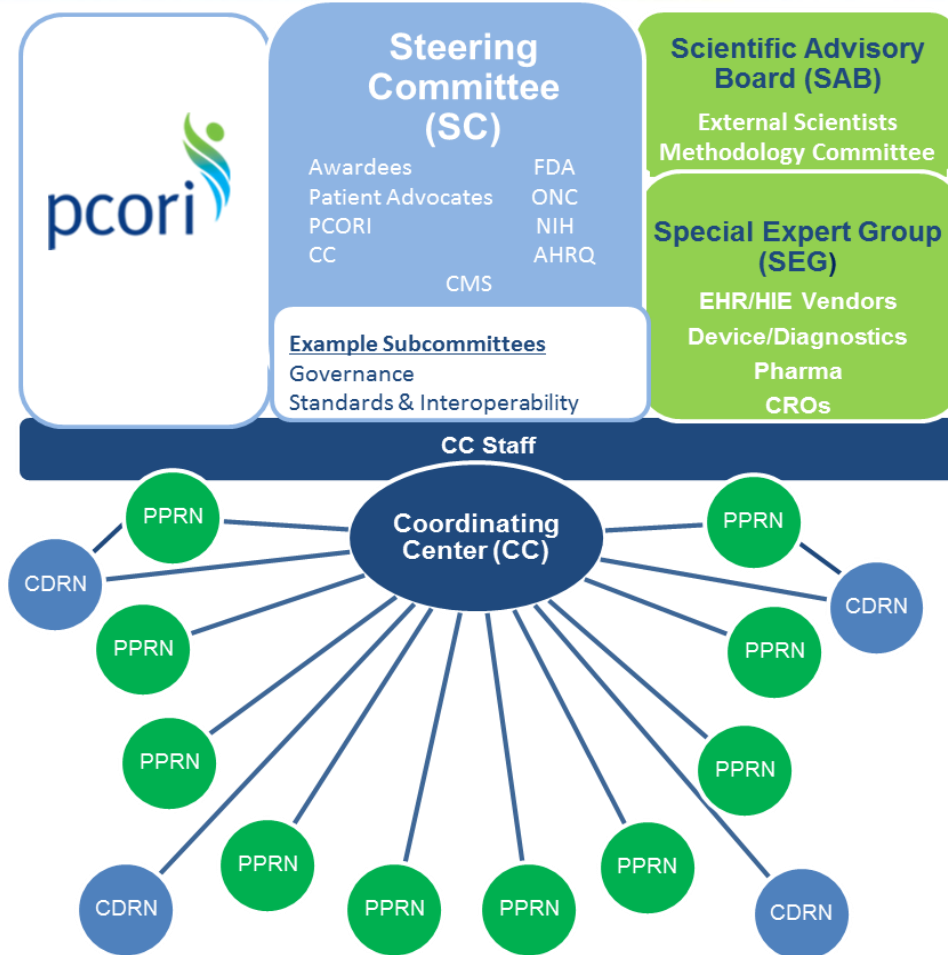
*DATA HARMONIZATION FOR NATIONAL
PATIENT-CENTERED CLINICAL
RESEARCH NETWORK (NCRN)*

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October 31, 2013

Patient-Centered Outcomes Research Institute

Organizational Structure of the NCRN



- Up to 8 **Clinical Data Research Networks (CDRNs)**
- Up to 18 **Patient-Powered Research Networks (PPRNs)**
- A **Coordinating Center** provides:
 - Program management
 - Technical assistance
 - Logistical support
 - Cross-awardee communications and coordination
 - Program evaluation

Requirements and Expectations of Clinical Data Research Networks (CDRN)

- \$56 million to support up to 8 new or existing CDRNs for 18 months

COOPERATIVE AGREEMENT AWARD 18 MONTHS LATER

- At least two health care systems engaged
- Willingness and capacity to work toward data standardization with other awardees
- Willingness to participate in collaborative studies with data sharing as part of a national research infrastructure

- $\geq 1,000,000$ patients enrolled
- Data standardized within network and with other awardee networks
- Patients, system, and clinicians engaged in governance & use
- Capable of implementing clinical trials

Requirements and Expectations of Patient-Powered Research Networks (PPRN)

- \$12 million to support up to 18 new or existing PPRNs for 18 months

COOPERATIVE AGREEMENT AWARD 18 MONTHS LATER

- Patients with a single condition, interested in research participation.
- Ability to increase size and diversity of patient membership
- Willingness to build standardized database of patient-reported data
- Willingness to explore collection of electronic clinical data.

- Target size of 0.5% of U.S population with condition: (≥ 50 patients for rarest diseases; 10,000 for most common)
- Patient-reported data collected for at least 80% of cohort
- Patients involved in governance
- Standardized data suitable for sharing with other infrastructure members

The Vision of a National Research Infrastructure



ONC

- Meaningful Use
- Nationwide Health Information Network
- Federal Health Architecture
- EHR Certification Standards & Interoperability Framework



FDA

- Mini-Sentinel
- OMOP



AHRQ

- DRNs
- PBRNs
- **Registries**
- SPAN
- PROSPECT
- EDM Forum



NIH

- SEER Registries
- CTSA
- Collaboratory
- CRN, CVRN
- ClinicalTrials.gov
- eMERGE Network
- PROMIS/ NIH - Snomed-CT, LOINC



VA

- VistA
- iEHR (2017)



IOM

2011 Report: *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care*

Payers



Specialty Societies



Industry



Innovators and Entrepreneurs



NCRN goals at 18 months

- Data standards and interoperability
- Governance – informatics, data uses, data sharing
- Health System Leadership Involvement / Sustainability
- Readiness to host randomized trials
- Patient and clinician engagement
- Patient-reported outcomes
- Ethical oversight
- Privacy and security
- Biospecimens and biorepositories
- Obesity workgroup
- Rare disease workgroup



CDRN Applicants

- Non-profit **integrated health systems**
 - **Military** health plans, hospitals and providers
 - Networks of **academic medical centers**, hospitals and physician practices with cities
 - **Community clinics** networks
 - **Pediatrics** system networks
 - Networks based on **HIEs**
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- Excellent **geographical** representation
 - **Underserved** populations well represented
 - Range from **1M covered lives to 12M**



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Some examples (from 56) of PPRN disease areas

Common disorders

- Breast Cancer
- 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.



NCRN Metrics of Success

- Ability to conduct high-quality **observational CER**
- **Launch simple interventional trial** embedded within systems in 2014
- Enable participation of external **data partners**
- Enable access to external **researchers**

Keep all CDRNs and PPRNs engaged in the process despite significant diversity in size, experience, data and length of existence.

