



# Sustaining a National Infrastructure for Patient- Centered Clinical Research

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Patient-Centered Outcomes Research Institute

# A National Data Infrastructure for Research – Among the Visionaries



## 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



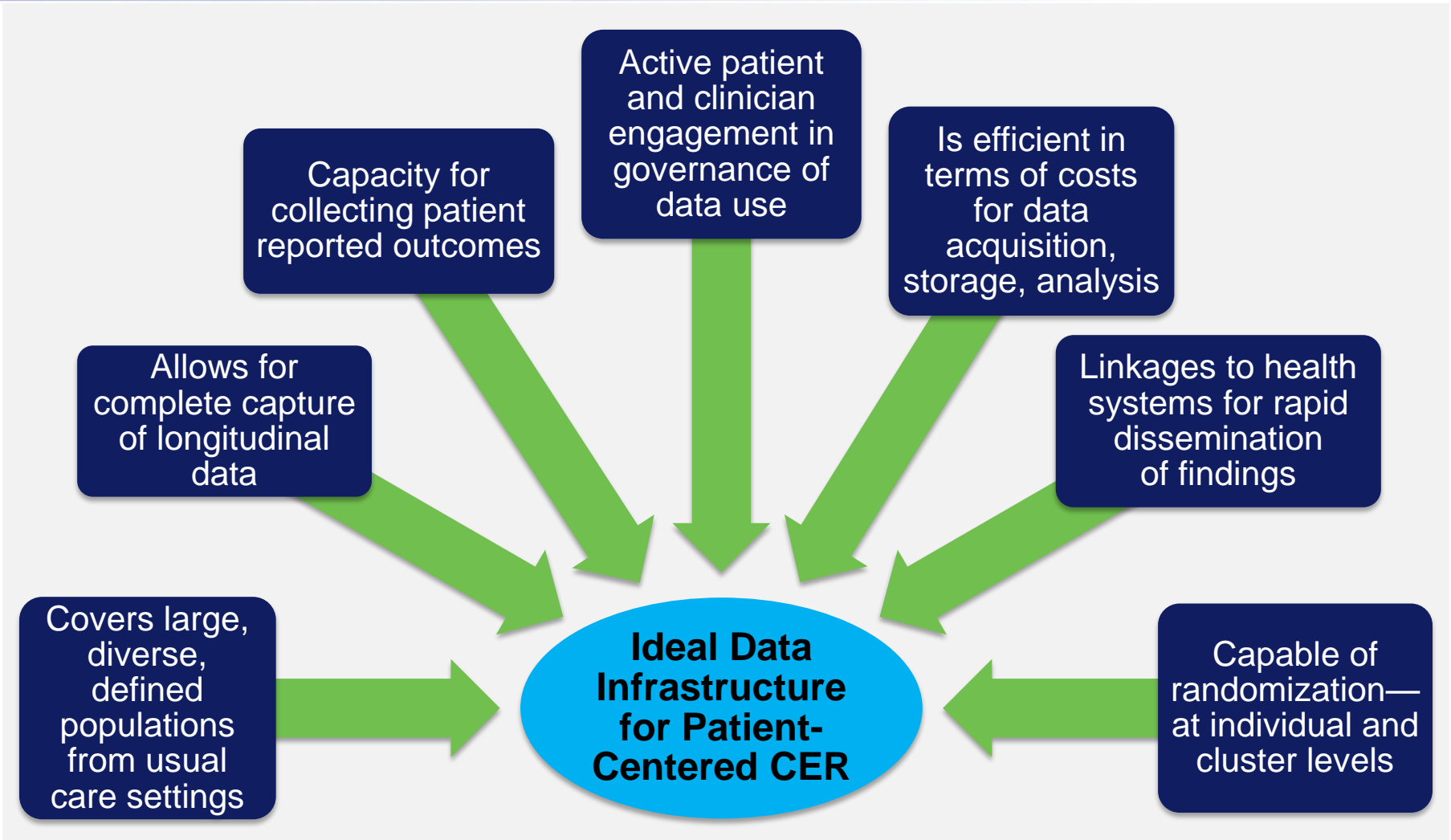
## Industry



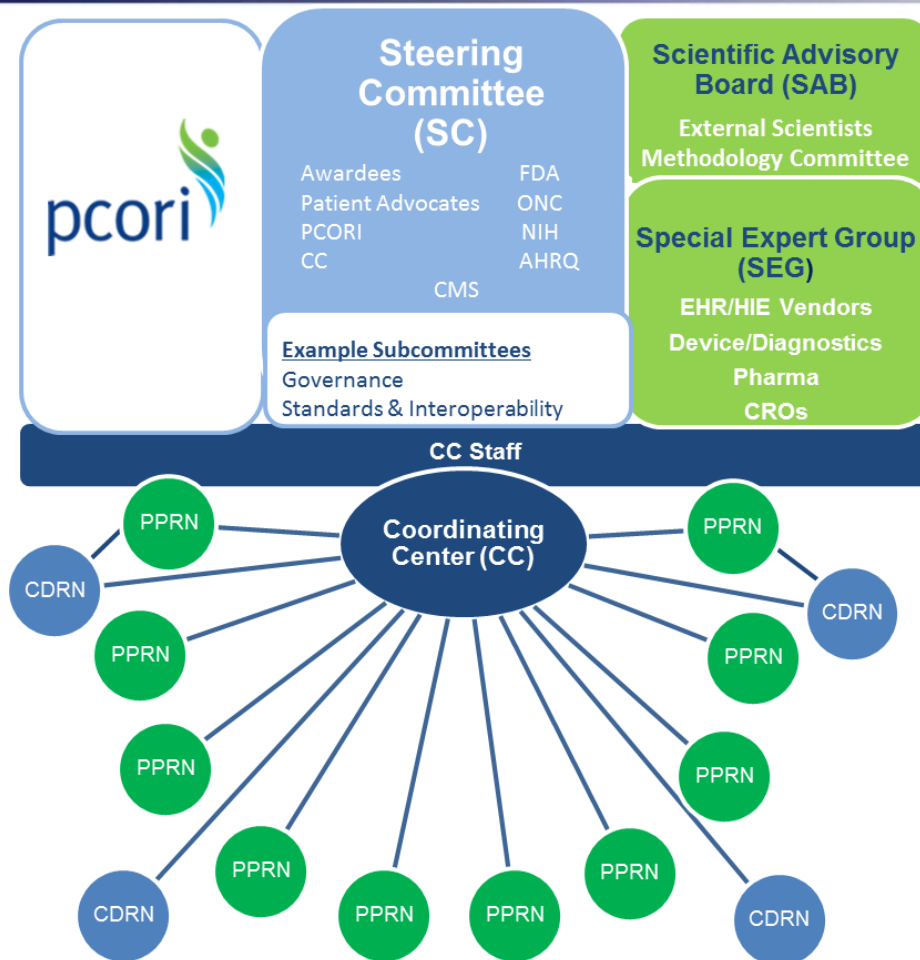
## Innovators and Entrepreneurs



# Requirements of the NCRN



# Making the Vision Real - National Patient-Centered Clinical Research Network (NCCRN)



- 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: ( $\geq 50$  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

# Announcing the NCRN's Coordinating Center

- Endorse **Harvard Pilgrim Health Care** as choice for the NCRN Coordinating Center
  - PI: **Richard Platt, MD, MSc** (Harvard Pilgrim, Harvard Medical School)
  - Co-PI: **Robert Califf, MD** (Duke Clinical Research Institute, Duke University)
  - **Other participating organizations:** AcademyHealth, America's Health Insurance Plans (AHIP), Brookings Institution, Center for Democracy & Technology, Center for Medical Technology Policy, Group Health Research Institute, The Johns Hopkins University, RAND

# Features of the NCRN Intended to Enhance Sustainability

- More comprehensive, longitudinal standardized EHR, claims and self-reported data – designed for multiple uses and users
- 18+ activated patient cohorts, increasingly linked with the 8 large systems
- Involvement of health systems, clinicians and patients in governance and use of the resource
- Strong commitment to development of capacity to conduct large, simple trials within the network
- Commitment to improving human subjects oversight, especially for low risk CER studies, including waiving/streamlining of informed consent as appropriate, use of cluster RCTs.
- Inclusion of potential end-users of the resource on the Steering Committee, Scientific Advisory Board and the Special Expert Group