Practical Clinical Trials
Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy

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Decision makers in health care are increasingly interested in high-quality scientific evidence to support clinical and health policy decisions. However, the quality of available scientific evidence is often limited.

Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE trial). A multicenter, prospective, randomized, controlled clinical registry trial based on the Swedish angiography and angioplasty registry (SCAAR) platform. Study design and rationale

Ole Fröbert, MD, PhD, Bo Lagerqvist, MD, PhD, Thorarinn Gudnason, MD, PhD, FESC, Leif Thuesen, MD, PhD, Roger Svensson, MSci, Göran K. Olivecrona, MD, PhD, and Stefan K. James, MD, PhD, Örebro, Uppsala and Lund, Sweden; Reykjavik, Iceland; and Aarhus, Denmark

Tunis SR et al. JAMA 2003;290:1624-32
Frobert O et al. AHJ 2010;160:1042-8
What is PCORnet?
PCORnet’s goal

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.
Overall objectives of PCORnet: Achieving a single functional research network

- **Create** infrastructure, tools, and policies to support rapid, efficient comparative effectiveness research
- **Utilize** multiple electronic health records, insurance claims data, data reported directly by patients, and other data sources
- **Engage** patients, clinicians, and health system leaders throughout
- **Enable** external partners to collaborate with PCORI-funded networks
This map depicts the number of Patient-Centered Research Networks that have coverage in each state. It includes patients and systems in every state. 29 CDRN (11) and PPRN (18) awardees that
Goals for each Clinical Data Research Network (CDRN)

- Create a research-ready dataset of at least 1 million patients that is secure and comprehensive
- Involve patients, clinicians, and health system leaders in all aspects of creating and running the network
- Develop the ability to embed clinical trials into healthcare operations
- Identify 3 cohorts of patients who have a condition in common and who can be characterized and surveyed
Goals for each Patient-Powered Research Network (PPRN)

- Establish patient population with a condition of interest (>50 patients for rare diseases; >50,000 for common conditions)
- Collect patient-reported data for ≥80% of patients
- Involve patients in network governance
- Create standardized research databases
Guiding principle: Make research easier

- 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
Learning Health Care Systems and Pragmatic Trials

- Leverage available medical data from electronic health record (EHR) data to identify eligible patients
- Ascertain endpoints as part of routine healthcare delivery and administrative claims
- Simplify baseline and follow-up data collection through systematic direct patient contact (patient reported outcomes) and multiple data sources
- Large sample sizes embedded within healthcare systems and randomization provide large scale, limit selection biases and provide more generalizable results (by comorbidities, concomitant medication use, and sub-groups)