

# Disruptive Thoughts

## 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. However, the quality of available scientific evidence is often

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**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**

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# What is PCORnet?

# PCORnet's goal



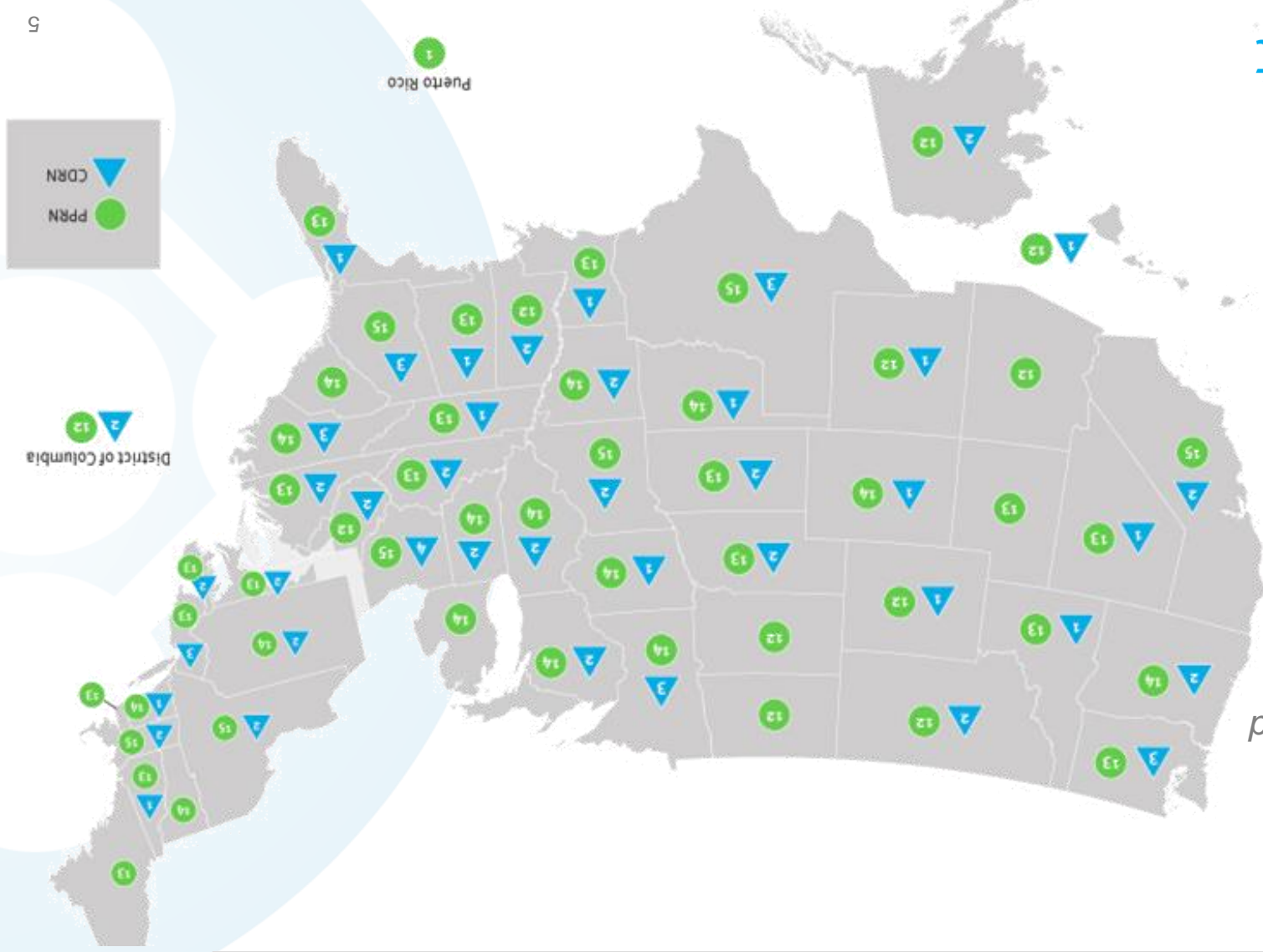
PCORnet seeks to improve the nation's capacity to conduct **clinical research** by creating a large, highly representative, national patient-centered network that supports more efficient clinical trials and observational studies.

# 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

# 29 CDRN (11) and PPRN (18) awardees that include patients and systems in every state

*This map depicts the number of PCORI-funded or Clinical Data Research Networks that have coverage in each state.*



# 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  $\geq 80\%$  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)