Pragmatic Clinical Trials (PCTs) offer considerable promise to support a new system of clinical research. Today, the DCRI is applying pragmatic methodologies to catalyze change for a clinical research system that is in need of transformation.

A Pragmatic Approach to Clinical Research — At-a-Glance

**PCTs and Electronic Health Records**

With the growing availability of clinical EHRs, PCTs have access to data gathered in real-world treatment settings without needing to invest in the tremendous overhead costs associated with other data-capture systems. EHRs are being rapidly adopted in both ambulatory and hospital settings, thereby providing researchers with the potential to screen, identify, enroll, and follow large numbers of patients. Linked systems of EHR-facilitated research will make a new era of pragmatic clinical trials possible. Efficient patient enrollment and lower costs will allow studies to be done in larger, more diverse, and more representative populations. This, in turn, can potentially increase the validity and generalizability of study findings, while also improving access to research participation for under-served or under-represented groups.

**Why Pragmatic Clinical Trials?**

Pragmatic Clinical Trials seek to yield more “actionable” information for practitioners and patients at a faster rate and lower cost than conventional randomized controlled trials. With PCTs, researchers can:

- Examine “real-world” outcomes that are important to patients and clinicians
- Conduct trials in settings and patient populations where the treatment will actually be used
- Streamline trials operations for efficient conduct and data acquisition

“A thoughtful approach to harnessing EHRs for clinical research could unleash a genuine transformation across the clinical research enterprise—one that will eventually result in improved patient outcomes and better population health.”

Eric D. Peterson, MD, MPH
Faculty, DCRI
A Pragmatic Approach to Study Design: PCORnet’s ADAPTABLE Study

Aspirin has been used for more than 40 years to prevent heart attacks and strokes in people with heart disease but, surprisingly, research has yet to determine the best dose to prescribe. For the millions of Americans with heart disease, doctors typically recommend either a regular-strength (325 mg) or a low-dose (81 mg) aspirin. But we still don’t know which dose is best for balancing aspirin’s benefits against its risks, such as bleeding in the gastrointestinal tract in some patients.

The ADAPTABLE Study is the first demonstration project to be conducted through PCORnet, the National Patient-Centered Clinical Research Network. The study, called ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness), will compare the benefits and harms of a low- and regular-strength daily dose of aspirin in patients diagnosed with heart disease. ADAPTABLE represents a transformative approach to developing a new, efficient, and interactive clinical trial model.

For more information about ADAPTABLE and PCORnet, visit www.pcornet.org.