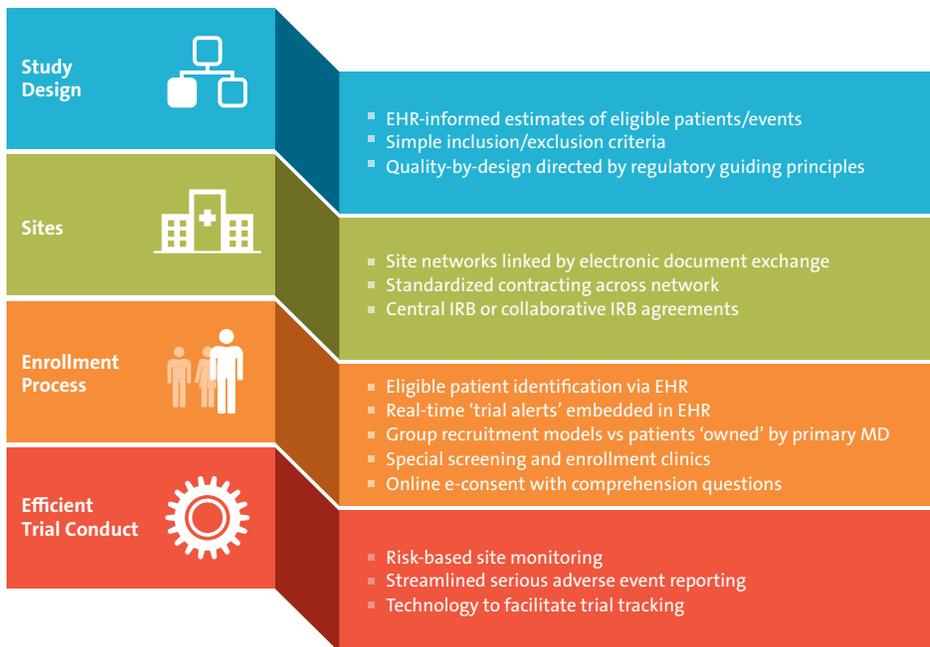


DCRI PRAGMATIC CLINICAL TRIALS

Research Fit-for-Purpose

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
Executive Director, DCRI*

DCRI PRAGMATIC CLINICAL TRIALS

Find out more about DCRI Pragmatic Clinical Trials.

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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.

The infographic is titled "The ADAPTABLE Aspirin Study" and features the PCORnet logo. It is divided into several sections: "THE QUESTION" (yellow background) stating that clinicians often prescribe aspirin but research is needed to determine the best dose; "THE PROBLEM" (blue background) with three statistics: heart disease is the No. 1 killer in the U.S. (611,000 deaths in 2013), cardiovascular disease is the most common form of heart disease (heart disease strikes someone every 43 seconds), and aspirin is widely prescribed (60% of patients take 325 mg daily while 36% take 81 mg); "THE STUDY" (blue background) stating the trial will compare two dosages (325 mg and 81 mg), involve 20,000 patients, and use PCORnet for data collection; "ANSWERS FOR BETTER CARE" (green background) listing three research questions and stating that 88,800 deaths could be prevented worldwide. The PCORI logo is at the bottom left.

The ADAPTABLE Aspirin Study

THE QUESTION

Clinicians often prescribe aspirin to prevent strokes and heart attacks in people living with heart disease. Research has yet to determine the best dose to use, since aspirin can cause serious side effects — like bleeding — in some people.

THE PROBLEM

- Heart disease is the No. 1 killer in the U.S. **611,000** people in 2013, one death in 4; accounting for 1 in every 6 healthcare dollars.
- Cardiovascular disease (heart attack and stroke) is the most common form of heart disease. Heart disease strikes someone in the U.S. about once every **43 seconds**.
- Aspirin is widely prescribed to prevent heart attacks and strokes in people living with heart disease. **60%** of patients with heart disease take a 325 milligram dose each day while 36% take 81 milligrams (or baby aspirin).

THE STUDY

- The ADAPTABLE trial will compare two common aspirin dosages: 325 mg and 81 mg.
- The study will be large and will involve patients across the U.S. **20,000** patients living with heart disease will use a daily aspirin dose of either 81 mg or 325 mg.
- ADAPTABLE will use PCORnet to conduct the study and disseminate results. Patients will be partners at every stage of the trial, which will collect data using tools with state-of-the-art security.

ANSWERS FOR BETTER CARE

Results of this study will help patients and their caregivers answer questions like:

- How much aspirin should I take each day to reduce my risk of another heart attack or stroke?
- Do the benefits of taking aspirin every day differ based on the dose?
- Do the risks differ based on the dose?
- Based on my health, age, and other circumstances, what's the best dose to protect my health?

This study will use the power of PCORnet to seek answers to these questions and improve patient care and outcomes.

DATA **KNOWLEDGE** **CARE**

Identifying the aspirin dose that works best could prevent as many as **88,800** deaths per year worldwide.

pcori PCORnet is an initiative of the Patient-Centered Outcomes Research Institute.



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE