# The ADAPTABLE Aspirin Study

## A PCORnet DEMONSTRATION PROJECT

The Patient-Centered Outcomes Research Institute (PCORI) awarded $14 million to support a clinical trial on aspirin therapy in people with heart disease. Called ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness), it is the first demonstration project to be conducted through PCORnet, the National Patient-Centered Clinical Research Network.

### PURPOSE FOR FUNDING THE STUDY

- Although aspirin has been used for more than 40 years to prevent heart attacks and strokes in people living with heart disease, the best dose has yet to be determined.
- Research has not yet definitively determined how best to use aspirin to reduce the risk of heart attacks and strokes in patients living with heart disease, and physicians' and patients' understanding of aspirin therapy varies widely.
- An estimated 15.4 million Americans have heart disease, and most take either a daily regular-strength aspirin (325 mg) or low-dose aspirin (81 mg) as recommended by their clinicians.
- Regular-strength doses have been associated with a greater risk of bleeding in the gastrointestinal tract. There is insufficient evidence to clearly state whether low-dose aspirin is both safer and as effective for patients with heart disease.
- It's estimated that identifying the dosage of aspirin that works best for these patients could prevent as many as 88,800 deaths worldwide each year.

### PURPOSE OF THIS STUDY

- This patient-centered clinical trial will compare the effectiveness of two daily doses of aspirin now widely used to help prevent heart attacks and strokes in patients who have been diagnosed with heart disease.
- The study is designed to provide patients and providers with detailed information about aspirin therapy given patients' personal characteristics, conditions, and preferences. Researchers will also compare the effects of aspirin in certain patient populations based on gender, age, and racial- and ethnic-minority affiliation and in patients with and without diabetes or chronic kidney disease.
- This study is not designed to look at aspirin use to prevent heart attacks or strokes in patients who aren't known to have heart disease, an approach called "primary prevention." Rather, it will focus on preventing heart attacks and strokes in patients already living with heart disease.

### EXPECTED RESULTS

- The results of this trial will help patients living with heart disease and their caregivers answer questions about aspirin therapy such as:
    - o How much aspirin should I take each day to reduce my risk for a heart attack or stroke?
    - o Do the benefits of taking aspirin every day differ based on the dose?
    - o Do the risks differ based on the dose?
    - o Based on my health, age, and other circumstances, what's the best dose to protect my health?

### HOW THE STUDY WILL BE CONDUCTED

- A total of 20,000 high-risk patients who have had a heart attack or have significant blockage of their coronary arteries will be randomly assigned to take a daily aspirin dose of either 81 mg or 325 mg. Patients will be enrolled over 24 months, with a maximum follow-up of 30 months.
- This will be a three-year study.
- Researchers will compare the effectiveness of the two daily doses in reducing death and hospitalization for heart attacks and strokes in these individuals. The trial will also assess such side effects as bleeding in the stomach and intestines.
- Researchers will also compare the effects of aspirin in certain selected patient groups including:
    - o Women and men
    - o Older and younger patients
    - o Patients from diverse racial and ethnic backgrounds

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  - o Patients with and without diabetes
  - o Patients with and without chronic kidney disease
  - o Patients who use the Internet and those who do not

- Patients are part of the research team for this trial, and they will help design and develop the study procedures to ensure that the trial is patient-centered.

- The aspirin study will collect and securely store data in ways that protect patients' privacy. The study will use existing electronic health records from consenting patients in accordance with privacy and security measures, as well as web-based patient portals and data gathered during patients' visits with their clinicians.

## PCORnet's ROLE

- The ADAPTABLE study is supported by $14 million in total funding from the Patient-Centered Outcomes Research Institute (PCORI).

- This study will be the first to test the capabilities of PCORnet, a national patient-centered clinical research network being developed by PCORI.

- By harnessing the power of clinical data gathered in real-world settings, this national network of 29 individual research networks is designed to allow a range of clinical research studies to be conducted more efficiently and less expensively than traditional research.

- PCORnet's 29 partner organizations include 11 Clinical Data Research Networks (CDRNs), which are health care systems-based, and 18 Patient-Powered Research Networks (PPRNs), which are operated by patient-led groups.

- Patients have a central role in deciding the rules under which PCORnet operates, including developing principles and processes for safeguarding data privacy and security, as well as deciding what research questions to study.

- This study will help to develop and refine the infrastructure for PCORnet to conduct multiple comparative clinical effectiveness and other types of studies in the future.