ADAPTABLE Study
Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness

Adrian Hernandez, MD, MHS, Co-Principal Investigator, Matthew Roe, MD, MHS, Co-Principal Investigator

Key Objectives

- To compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg) in 20,000 high-risk patients with atherosclerotic cardiovascular disease (ASCVD)
  - **Primary effectiveness endpoint:** all causes of mortality, hospitalization for MI, or hospitalization for stroke
  - **Primary safety endpoint**: Hospitalization for major bleeding
- To compare the effects of aspirin in predefined key subgroups of ASCVD patients
  - Age, diabetes, sex
  - Race, P2Y12 inhibitor use
  - Chronic kidney disease
- To develop and refine the infrastructure for PCORnet to conduct multiple comparative effectiveness trials in the future

Rationale

- Evidence does not exist on the most effective dose of aspirin for people with ASCVD
- Potential to prevent 19,000 deaths from heart attacks Or thousands of bleeds annually in the United States

Adaptable
The Aspirin Study

Website: theaspirnstudy.org

Design

- Electronic, computable phenotype to query electronic health records (EHR) to identify and screen potential participants
  - Golden tickets issued to eligible patients
- Multi-touch approach to reach eligible participants
  - Direct mail, email, EHR alerts, tablet-based recruitment, in-clinic conversations
- E-consent & e-randomization on study portal: theadaptablepatient.com
  - Process for participants without Internet access
- Endpoint Ascertainment
  - Routine queries of the PCORnet Common Data Model
  - Patient-reported data
  - Surveillance of the Centers for Medicare & Medicaid Services, private health plans
  - Death determination via Social Security Administration (Medicare beneficiaries) & National Death Index

Who's Involved

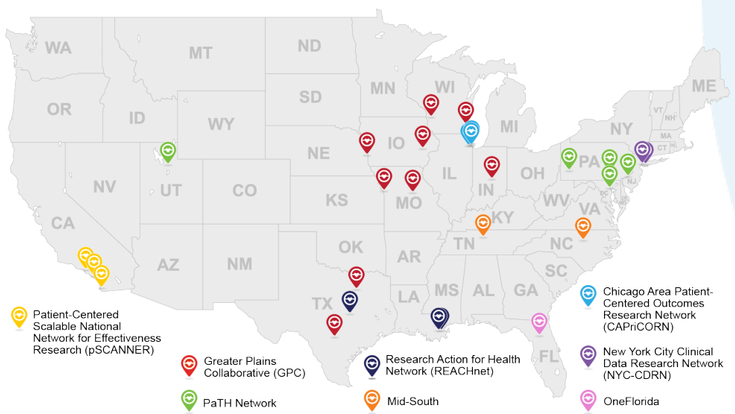
- Researchers from 8 PCORnet CDRNs and 35 Health Systems
- Adaptors Team (8 patients representing each CDRN)
- Health eHeart Aliance PPRN support the Adaptors team

Enrollment Status

CDRN	Site	Golden Tickets Entered	Enrolled	% Enrolled Per Golden Ticket Entered
MidSouth	Vanderbilt	542	259	48%
CAPriCORN	Northwestern	33	22	67%
REACHnet	Tulane	2	2	100%
REACHnet	Baylor Scott and White	9	7	78%
REACHnet	Ochsner	288	106	37%
GPC	Iowa	63	29	46%
PaTH	Temple	8	2	25%
PaTH	Univ. of Utah	5	2	40%
PaTH	UPMC	165	49	30%
PaTH	Penn St.	56	16	29%
OneFlorida	UF Gainesville	20	15	75%
TOTAL		1191	509	43%

*As of 11/9/2016 with six of eight CDRNs enrolling.

Participating CDRNs



Patient Engagement

Adaptors Team at the ADAPTABLE Kick-off Meeting

- Involved in the prioritization of the research topic, protocol design, trial conduct, and plans for trial results dissemination
- Sit on the Steering Committee (one Adaptor from each CDRN)
- Sit on the Executive Committee (two Adaptors
- Sit on the Data Safety & Monitoring Board (two patients with no other role in the study)
- Central to the empirical development of participant-centric consent form & comprehension assessment
- Integral to review and development of study portal, recruitment plans and materials

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CONTACT INFORMATION

Holly Robertson, PhD
holly.robertson@duke.edu

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