Behind the ADAPTABLE Study, the Largest Decentralized Clinical Trial to Date.

About the Study

For over half a century, millions of Americans living with heart disease have relied on a daily dose of aspirin to help prevent a heart attack or stroke. The most commonly prescribed dosages are 81 mg and 325 mg. The goal of the ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness) study is to determine the dosage that most effectively maximizes results while minimizing harmful side effects such as internal bleeding. The study is led by researchers at the Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization and a part of the Duke School of Medicine.

The Solution

The ADAPTABLE study team has compiled multiple partners and platforms to support the study. One partner is Mytrus and its Engage service, an electronic virtual trial platform based on high-profile work with other global pharmaceutical and biopharmaceutical companies. When Mytrus was acquired by Medidata in 2017, Engage became the core technology behind Rave Virtual Trials, an intuitive, web-based application that serves as the patient-facing interface for 100 percent virtual trials and hybrid studies. Rave Virtual Trials provided the platform needed to remotely manage the informed consent process, enrollment, and randomization of ADAPTABLE participants while allowing them to easily report their health outcomes throughout the study from the comfort of their homes.

To enable clinical research sites to invite eligible patients to join the ADAPTABLE study, a series of "golden tickets" were generated by Medidata for each participating site. The tickets were then assigned by the site to eligible patients who met the study's criteria. Golden tickets provided a unique, one-time-use alphanumeric access code to protect the identities of qualified patients and allow them to register for the study. The golden tickets enabled sites to track eligible patients from identification, recruitment, and enrollment all the way through to follow-up. This functionality is critical in large-scale studies, as sites need to be able to accurately and efficiently manage patient follow-up.

THE VALUE OF RAVE VIRTUAL TRIALS

- Single source of data
- Improves engagement and compliance
- Trial Dial™ – Enabling fully virtual, hybrid and traditional clinical trials

"Rave Virtual Trials allows us to reach patients who wouldn't normally participate in a clinical trial because of location or convenience."

Dr. Holly Robertson
Project Leader at DCRI

"Rave Virtual Trials allows us to reach patients who wouldn't normally participate in a clinical trial because of location or convenience," says Holly Robertson, PhD, Project Leader at the DCRI. "ADAPTABLE is designed to support more representative inclusion of patients, enhance engagement while reducing the burden on patients to participate in a clinical trial, and reduce many of the burdens and costs associated with traditional site-based studies."

Over 650,000 patients were identified as matching the inclusion criteria for the study, and 450,000 of these were issued a golden ticket and invited to review the ADAPTABLE materials. More than 30,000 people used their unique access codes to enter the patient-friendly Medidata portal via a browser on their desktop, laptop, smartphone, or tablet. The golden ticket ensured that the correct informed consent and site information was presented to the right patient.

When a virtual visit was coming due, the Rave Virtual Trials system automatically notified patients with a text or email reminder to visit the study portal. Patients were able to complete the scheduled electronic patient reported outcomes, case report forms and update their health status online. The system provided additional reminders if a patient did not complete the virtual visit and would also alert the study's call center staff in cases of patient noncompliance. Call center staff were able to follow up directly to these patients by calling them and even recording updates for patients without Internet access or who were otherwise unable to complete the forms themselves.

Over half of the 30,000 patients who used their golden tickets enrolled in ADAPTABLE, making it the largest 100 percent virtual pragmatic clinical trial conducted to date.

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Dr. Schuyler Jones
Associate Professor of Medicine
Duke University Medical Center

The ADAPTABLE study is funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (Contract Number: ASP-1502-27079). ADAPTABLE is the first demonstration project to be conducted through PCORnet®, the National Patient-Centered Clinical Research Network.

The Results

As a holistic patient engagement platform, Rave Virtual Trials is a research team's centralized eClinical data source. The convenience of the platform makes it easier for patients to remain compliant to protocol objectives and provide updates to the clinical team for key study data, such as hospitalizations, without having to conduct an in-person study visit. It also meets regulatory and compliance requirements for clinical research.

"When compared with traditional cardiovascular trials that engage hundreds or thousands of sites, this technology allowed us to enroll 15,000 participants from 40 centers. We think this infrastructure and approach will facilitate studies that can be direct-to-patient, easier for patients and investigators, and faster to completion," says Dr. Schuyler Jones, Associate Professor of Medicine Duke University Medical Center and co-principal investigator of the ADAPTABLE study.

What's Next

Building upon the success of the Rave Virtual Trials Platform, myMedidata is the Next Generation Patient Portal that is a single destination for patients to complete clinical trial activities. Enhancements will include patient education, alerts/notifications, the ability for patient study data to be integrated into EHRs, between visit adverse events monitoring and providing access to the patient's clinical trial results. The portal is a solution built by patients for patients, with the goal of minimizing patient burden and improving the experience of study participants.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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