Medtronic News

Medtronic Launches App-Based Study to Better Understand Relationship Between Atrial Fibrillation Disease Burden and Impact on Patient Outcomes

DEFINE AFib Study Will Leverage Data from Medtronic Insertable Cardiac Monitors and Medtronic Discovery App™ with the Goal of Informing Atrial Fibrillation (AF) Management Strategies

DUBLIN, June 29, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the initiation of the DEFINE AFib study, the company's first app-based research study. Using data collected from the LINQ family of insertable cardiac monitors (ICMs), the study aims to address unanswered questions around atrial fibrillation (AF) burden and its impact on patient outcomes, quality of life, and healthcare utilization. The first patients in the study were enrolled at Duke University Medical Center in Durham, N.C., by Jonathan Paul Piccini, M.D., MHS, FHRS, director of Cardiac Electrophysiology and associate professor of medicine at Duke University School of Medicine, and at Florida Electrophysiology Associates in Atlantis, Fla., by Robert S. Fishel, M.D., founder of the practice and director of Electrophysiology at JFK Medical Center.

DEFINE AFib will be conducted remotely through the new Medtronic Discovery App™ in coordination with U.S. sites that collectively will enroll approximately 5,000 patients. Study participants will include patients age 22 or older who have a history of AF, an iPhone device (iOS version 13 or higher), and one of the LINQ family of ICMs, among other criteria. The study will incorporate both device data and patient-reported data derived from scheduled patient surveys and the HealthKit — coupled with electronic health record information about medications and previous cardiac procedures — to provide comprehensive, actionable insights. Through a machine learning approach, aggregated study data will be leveraged to enable improved AF management in the future.

"When it comes to managing atrial fibrillation, there is not a 'one-size-fits-all' approach, and the hope is that DEFINE AFib may give us the tools to help personalize AF management based on a patient's individual health profile and physiology," said Dr. Piccini, who is also chair of the DEFINE AFib Steering Committee. "DEFINE AFib will harness the power of digital health to make fundamental discoveries about how we can manage atrial fibrillation better in each and every one of our patients."

Medtronic developed the app using the ResearchKit framework, given Apple's commitment to privacy and user-friendly experience. The app design leveraged insights from more than 100 hours of patient interviews to simplify and customize patient enrollment, data collection, and communication processes. Extensive app functionality will allow researchers to conduct DEFINE AFib and future large, integrated Medtronic studies remotely, with less site implementation burden.

"Traditional, in-person clinical studies are critically important to deepen our understanding of how to manage chronic conditions like AF but can place a lot of demands on the patients and physicians involved," said Julie Brewer, president of the Cardiovascular Diagnostics and Services business, which is part of the Cardiovascular Portfolio at Medtronic. "A fully app-based study design, with sophisticated data aggregation capabilities and remote monitoring using the LINQ family of ICMs, enables us to conduct DEFINE AFib without in-person patient enrollment or follow-up. This first-of-its-kind trial paves the way for future app-based studies at Medtronic."

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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