

MEDIA RELEASE

Contact: Rae Holliday, Communications Specialist, Rae.Holliday@duke.edu

Investigators from Multiple U.S. Organizations Collaborate on First Embedded Pragmatic Clinical Trial Using National Health Plans' Data

IMPACT-AFib trial used health plans' administrative and claims data to conduct an 80,000+ person pragmatic randomized trial; sets the stage for future trials embedded into health plans

Durham, N.C.—September 1, 2020— Today, at the [ESC Congress 2020 – The Digital Experience](#), a group of U.S. investigators from several organizations announced their collaborative findings from the Implementation of a randomized controlled trial to improve treatment with oral **AntiCoagulanTs** in patients with **Atrial Fibrillation** (IMPACT-AFib), the first trial to use the U.S. Food and Drug Administration's (FDA) FDA-Catalyst System network of electronic health data from a diverse group of national health plan data partners. The 80,000-patient randomized clinical trial tested the effect of mailed provider and patient outreach to increase the use of oral anticoagulants (OACs) among patients with atrial fibrillation (AF) who were at high risk of stroke and not on treatment.

Aetna, the Clinical Trials Transformation Initiative (CTTI), Duke Clinical Research Institute, the Harvard Pilgrim Health Care Institute's Department of Population Medicine, Harvard Pilgrim Health Care, HealthCore Anthem, Humana, Optum, and the FDA, as well as a patient representative, collaborated to plan and conduct the IMPACT-AFib study.

“Our workgroup’s approach was ambitious – be the first to combine well-curated electronic data from multiple national health plans to conduct a large pragmatic randomized trial,” said Richard Platt, co-principal investigator at Harvard Pilgrim Health Care Institute's Department of Population Medicine. “It had never been done before, but a novel method is required when trying to tackle a critical public health issue.”

AF affects more than five million Americans, and this number is increasing as the U.S. population ages. AF can result in stroke, and AF-related strokes are more disabling and deadly than other strokes.

“It is imperative to identify all patients with AF who are at risk of stroke, especially because strokes can be prevented with OAC,” said Sean Pokorney, co-principal investigator at Duke Clinical Research Institute. “The underuse of OAC is a significant public health priority, and also a priority of health plans like those participating in this study, which is why we were so eager to collaborate on IMPACT-AFib.”

The study tested the effect of mailing educational information to both AF patients and their providers, theorizing that patients would become agent of change to initiate OAC prescribing discussions with their providers. Administrative health plan data and

pharmacy dispensing data from the Sentinel System were used to identify eligible patients, to randomize them to an early or delayed intervention, and to assess clinical outcomes. Educational information was mailed to patients and their providers in the early intervention arm around the time of randomization, and mailings were sent to providers of patients in the delayed intervention arm approximately 12 months later. The primary analysis compares the early intervention arm to the delayed intervention arm, prior to the delayed intervention being conducted (i.e., compares intervention to non-intervention).

“The evidence generated from the trial showed that a single educational mailing about the recommended treatment, as compared to a control group, wasn’t effective in this context,” said Christopher Granger, co-principal investigator at Duke Clinical Research Institute. “And while the intervention did not increase the proportion of patients with at least one OAC dispensed, the study itself is a tremendous success. We conducted an extensive collaboration to conduct the first-ever trial using a decentralized database of claims data – that, in and of itself, sets a foundation for future clinical trials in AF and other diseases.”

“Among many goals, we established FDA-Catalyst to serve as a platform to advance the science of real-world evidence,” added Jacqueline Corrigan-Curay, director of the Office of Medical Policy within the Center for Drug Evaluation and Research at FDA. “The IMPACT-AFib study is an impressive example of how the system can be used to conduct trials in new and resourceful manners – approaches that hopefully will bring us to clinical answers faster than before.”

“CTTI played a key role in the pre-work for this trial, proving the viability of running a large-scale trial using the FDA-Catalyst platform,” added Pamela Tenaerts, executive director at CTTI. “The study is a successful proof of concept of embedding a randomized clinical trial into a claims system, while confirming in a large scale experiment that the use of educational interventional approaches in medicine might be limited. We believe that all future clinical trials should maximally leverage available clinical and nonclinical data to minimize collection of necessary trial specific data, and the IMPACT-AFib trial is a fantastic example of that; it serves as a strong model for future research.”

###

About the Clinical Trials Transformation Initiative (CTTI)

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-

based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI's more than 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at www.ctti-clinicaltrials.org.

About the Duke Clinical Research Institute

The DCRI, part of the Duke University School of Medicine, is the largest academic clinical research organization in the world. Its mission is to develop and share knowledge that improves the care of patients through innovative research. The institute conducts groundbreaking multinational clinical trials, manages major national patient registries, and performs landmark outcomes research. DCRI research spans multiple disciplines, from pediatrics to geriatrics, primary care to subspecialty medicine, and genomics to proteomics. The DCRI also is home to the Duke Databank for Cardiovascular Diseases, the largest and oldest institutional cardiovascular database in the world, which continues to inform clinical decision-making 40 years after its founding.

About The Harvard Pilgrim Health Care Institute's Department of Population Medicine

The Harvard Pilgrim Health Care Institute's Department of Population Medicine is a unique collaboration between Harvard Pilgrim Health Care and Harvard Medical School. Created in 1992, it is the first medical school department in the United States based in a health plan. The Institute focuses on improving health care delivery and population health through research and education, in partnership with health plans, delivery systems, and public health agencies. Learn more at www.populationmedicine.org and follow us at twitter.com/deptpopmed.

About Optum

Optum is a leading information and technology-enabled health services business dedicated to helping make the health system work better for everyone. With more than 180,000 people worldwide, Optum delivers intelligent, integrated solutions that help to modernize the health system and improve overall population health. Optum is part of UnitedHealth Group (NYSE: UNH). For more information, visit www.optum.com.