



Heartflow Announces Completion of Patient Enrollment in the PRECISE Trial

May 11, 2021

2,100 patients enrolled in randomized controlled trial to evaluate a precision-testing pathway for suspected coronary artery disease

REDWOOD CITY, Calif. – May 11, 2021 — Heartflow, Inc., a leader in revolutionizing precision heartcare, today announced the completion of patient enrollment in the Prospective Randomized Trial of the Optimal Evaluation of Cardiac Symptoms and Revascularization (PRECISE) randomized controlled trial. Physicians from more than 50 hospitals around the world successfully enrolled 2,100 patients.

"With the PRECISE trial, we aim to demonstrate that a coronary-CTA led diagnostic pathway tailored to patient risk will offer greater precision in the diagnosis and management of patients with suspected CAD, while reducing the number, risks, and costs of unnecessary tests and procedures," said Pamela Douglas, M.D., MACC, FASE, FAHA, the Ursula Geller Professor for Research in Cardiovascular Disease, Duke University School of Medicine and study chair of the PRECISE trial. "The pace of enrollment in the PRECISE trial was outstanding, despite the global pandemic, reinforcing that coronary artery disease remains one of the most important health issues we face as a society."

The PRECISE trial is designed to compare a "Usual Care" approach of diagnosing and evaluating patients with stable chest pain using a stress test and/or invasive cardiac catheterization to a new "Precision Evaluation Strategy" using risk-based testing and coronary computed tomography angiography (CTA) scans coupled with the Heartflow FFR_{CT} Analysis, when indicated. The PRECISE trial will evaluate whether the new "Precision Evaluation Strategy" can improve the accuracy, outcomes, efficiency, and cost of diagnosing and caring for patients with suspected coronary artery disease (CAD).

Patients enrolled in the PRECISE trial were randomized to either the "Usual Care" or "Precision Evaluation Strategy" arm. Patients in the "Precision Evaluation Strategy" arm were assessed using the PROMISE Minimal Risk Score and placed in either a low/no risk group or the intermediate/high risk group. Patients in the low/no risk group were treated with medications and lifestyle modifications but no immediate planned testing. Patients in the intermediate/high risk group underwent a coronary CTA, and when additional information was needed, a Heartflow FFR_{CT} Analysis was conducted. The primary endpoint of the PRECISE trial is the rate of major adverse cardiac events comprised of death, heart attack (myocardial infarction) or invasive coronary angiography without obstructive disease at 1 year.

"We want to thank all of the patients, physicians, and research teams participating in the PRECISE trial for sharing our vision of advancing the scientific evidence for improving the diagnostic pathway for patients with CAD," said Campbell Rogers, MD, FACC, Chief Medical Officer, Heartflow. "Heartflow is committed to providing the highest quality and most clinically relevant data to providers and patients, and we look forward to the results from the PRECISE trial being presented in the future."

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About the Heartflow FFR_{CT} Analysis

Starting with a standard coronary CTA, the Heartflow Analysis leverages deep learning and highly trained analysts to create a digital, personalized 3D model of the heart. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and provides FFR_{CT} values along the coronary arteries. This information helps physicians evaluate the impact a blockage may be having on blood flow and determine the optimal course of treatment for each patient. A positive FFR_{CT} value (≤ 0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

Data demonstrating the safety, efficacy and cost-effectiveness of the Heartflow Analysis have been published in more than 425 peer-reviewed publications, including long-term data out to five years. The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test.¹ To date, clinicians around the world have used the Heartflow Analysis for more than 75,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a leader in revolutionizing precision heartcare, uniquely combining human ingenuity with advanced technology. Our non-invasive Heartflow FFR_{CT} Analysis leverages artificial intelligence to create a personalized 3D model of the heart. By using this model, clinicians can better evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Our technology is reflective of our Silicon Valley roots and incorporates decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, Canada, Europe

and Japan. For more information, visit www.Heartflow.com.

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1. Driessen, R., et al. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. J Am Coll Cardiol. 2019;73(2),161-73.