



Heartflow Initiates DECIDE Registry to Evaluate Utility of Heartflow AI-Enabled Plaque Analysis for Patients with Suspected Coronary Artery Disease

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The largest prospective registry of its kind will build upon clinical data supporting the use of plaque insights to empower clinical decision making for patients with suspected coronary artery disease

MOUNTAIN VIEW, Calif. – March 26, 2024 — Heartflow, Inc., the leader in AI-driven healthcare technology, today announced the launch of the DECIDE Registry, the largest prospective registry of its kind, with the first site initiated, Cone Health Care. The registry will collect multi-site, real-world information on how the Plaque Analysis product provides enhanced patient insights, empowering physicians and helping to inform their medical management decisions for patients with suspected coronary artery disease (CAD). Heartflow Plaque Analysis is the only FDA cleared AI-enabled plaque quantification tool validated in a prospective international trial against the gold standard of invasive imaging (IVUS), with a reported 95% agreement.¹

The DECIDE Registry will evaluate changes in treatment management decisions made by clinicians using Heartflow Plaque Analysis derived from coronary computed tomography angiography (CCTA) in comparison to decisions made with CCTA alone. The registry, which is a real-world, prospective registry, aims to further the work highlighted in the retrospective DECODE study, published today in *The Journal of the Society for Cardiovascular Angiography & Interventions*. The DECODE study showed that clinicians using the Heartflow Plaque Analysis changed their management decisions for 66% of patients compared to CCTA alone across various patient presentations and disease stages. Furthermore, nearly 50% of patients with a calcium score of zero were reclassified following clinician review of the Heartflow Plaque Analysis, highlighting the importance of quantifying total plaque beyond just calcium score.²

"Data from the DECODE study shows the value of using Plaque Analysis. We are continuing to invest and build upon that data to gain a better understanding of the impact of our technology," said John Farquhar, chief executive officer at Heartflow. "We believe real-world prospective data from the new DECIDE Registry will empower clinicians with enhanced patient insights leveraging Heartflow Plaque Analysis to improve patient outcomes. The DECIDE Registry underscores the rigor of Heartflow's clinical portfolio, with an intentional study design to offer meaningful insights."

The DECIDE Registry, which aims to include 20,000 patients from approximately 40 sites across the U.S., represents Heartflow's clinical evidence investment at the forefront of cardiovascular therapy. The primary endpoint for this registry will highlight change in medical management after Heartflow Plaque Analysis compared to after CCTA alone. Observed outcomes and biomarkers are secondary endpoints. Safety endpoints include MACE (Major Adverse Cardiovascular Events) – death, MI, and urgent hospitalization leading to revascularization. The lead principal investigators of the DECIDE Registry are Dr. Leslee Shaw, Director of the Blavatnik Family Women's Health Research Institute at the Icahn School of Medicine at Mount Sinai, and Dr. Sarah Rinehart, Medical Director of CV Imaging, CT and Nuclear at Charleston Area Medical Center.

"Coronary artery disease remains one of the leading causes of death in the United States. While treatment options for the disease have improved over time, the complexity of the disease still leaves opportunity to enhance diagnostic and treatment protocols," Dr. Leslee Shaw, Mount Sinai and co-lead investigator of the DECIDE Registry. "The DECIDE Registry has the potential to improve how coronary artery disease is diagnosed and set a new standard of care in cardiovascular care driving positive change in population health overall."

[Heartflow Plaque Analysis](#), which has been studied in over 16,000 patients, offers physicians comprehensive and actionable data with plaque characteristics and volume in major coronary arteries.³ This critical information is delivered seamlessly to physicians in the Heartflow platform, and when paired alongside anatomy and physiology of the patient, enhances clinical decision-making for the clinician.

"When treating patients with coronary artery disease, the more information we have at our fingertips the better. Use of Plaque Analysis provides more complete data on the type and amount of coronary plaque present," said Dr. Thomas Stuckey, medical director and co-founder of the LeBauer-Brodie Center for Cardiovascular Research and Education at Cone Health, a DECIDE Registry site. "We are excited to continue our partnership with Heartflow as the first initiated site in the DECIDE Registry and to build a collection of real-world data that could revolutionize decision-making in cardiology."

About Heartflow, Inc.

Heartflow is transforming precision coronary care with the only AI-powered non-invasive integrated heart care solution across the CCTA pathway. As the pioneer of FFR_{CT}, which is now supported by the ACC/AHA Chest Pain Guideline, Heartflow continues to

advance the diagnosis and management of CAD. Heartflow's suite of non-invasive technologies includes its [FFR_{CT} Analysis](#), [Roadmap™ Analysis](#) and [Plaque Analysis](#). To date, more than 500 peer-reviewed publications have validated our approach and, more importantly, our technologies have helped clinicians diagnose and manage over 250,000 patients. For more information, visit www.Heartflow.com

Media Contact

Linly Ku
Heartflow
media@Heartflow.com

¹ Narula et al. Prospective Deep Learning-based Quantitative Assessment of Coronary Plaque by CT Angiography Compared with Intravascular Ultrasound EHJ 2024

² Rinehart et al. JSCAI 2024

³ Tzimas et al. JACC 2023