TCT 2026: CT-guided PCI Matches IVUS Outcomes in Randomized P4 Trial; Heartflow PCI Navigator Changes PCI Plans in Approximately 70% of Patients

November 1, 2026

Late-Breaking P4 study, simultaneously published in NEJM, shows CT guidance delivers matched one-year clinical outcomes with shorter procedures, demonstrating pre-procedural CCTA can guide key PCI planning decisions

NAVIGATE-PCI shows Heartflow PCI Navigator drove modifications to stent length and lesion prep compared to angiography alone

SAN FRANCISCO, Nov. 01, 2026 (GLOBE NEWSWIRE) -- Heartflow, Inc. (Heartflow) (Nasdaq: HTFL), the leader in AI technology for diagnosing and managing coronary artery disease (CAD), today announced new landmark randomized clinical data presented at Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, demonstrating computed tomography (CT)-guided percutaneous coronary intervention (PCI) matches gold-standard imaging outcomes with greater efficiency. These data are supported by registry insights on the procedural impact of Heartflow PCI Navigator.

In a late-breaking presentation simultaneously published in the *New England Journal of Medicine (NEJM)*, the 1,105-patient P4 randomized clinical trial met its primary endpoint, demonstrating that CT-guided PCI planning was non-inferior to gold-standard intravascular ultrasound (IVUS) for one-year clinical outcomes. In the largest randomized trial of its kind, CT guidance achieved these matched results compared to IVUS while significantly improving procedural efficiency, delivering faster procedure times and utilizing lower contrast volume. Data from the NAVIGATE-PCI registry showed that interventional cardiologists altered their procedural strategy in approximately 70% of cases after incorporating 3D anatomic, plaque, and physiologic insights from Heartflow PCI Navigator compared to standard invasive coronary angiography alone.

“CT has already become routine for planning structural procedures like TAVR. The data presented at TCT show coronary intervention is ready to follow the same path with advanced pre-procedural imaging and Heartflow’s AI-powered analysis to deliver precision and efficiency,” said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer at Heartflow. “What we learned planning P4 cases across six separate tools shaped Heartflow PCI Navigator, which brings anatomy, plaque and physiology together in the first and only PCI planning tool backed by prospectively validated accuracy and randomized clinical trial data. Together, P4 and NAVIGATE-PCI support a paradigm shift in coronary intervention, bringing non-invasive CT-guided PCI planning into routine cath lab practice.”

P4 Trial: Validating CT-guided PCI Against IVUS with Greater Efficiency
Main Arena 4, November 1

The Heartflow-supported, investigator-initiated P4 trial directly evaluated the clinical efficacy of non-invasive CT-guided PCI planning against invasive IVUS guidance.

Enrolling 1,105 patients across 23 centers in the U.S., Europe, and Japan, P4 randomized stable CAD patients to either CT-guided PCI planning, including Heartflow FFR_{CT} Analysis and Heartflow Planner (an earlier version of Heartflow PCI Navigator), or intra-procedural IVUS guidance.

Key P4 trial one-year findings showed CT-guided PCI matched IVUS on outcomes while enabling a faster procedure and lower contrast use, including:

- CT-guided PCI matched IVUS for the primary endpoint of 12-month target-vessel failure (4.1% vs. 4.6%).
- CT-guided PCI had a 17-minute shorter median procedure time than IVUS (46 minutes vs. 63 minutes, a 27% reduction).
- Contrast volume was reduced by approximately 12% in the CT-guided arm (median 150 mL vs. 170 mL).
- CT-guided PCI more than doubled the use of advanced calcium modification (9.2% vs. 3.8%).

“Intravascular ultrasound is an established benchmark, but performing assessments inside the cath lab adds procedural time and requires expertise,” said Carlos Collet, M.D., Ph.D., principal investigator of the P4 trial and Director of Cardiovascular Imaging, Physiology and Translational Therapeutics at the Cardiovascular Research Foundation in New York. “P4 shows that non-invasive CT-guided PCI planning achieves comparable clinical outcomes with shorter procedure times and less contrast, enabling interventionalists to anticipate challenges, tailor their strategy, and enter the cath lab better prepared.”

NAVIGATE-PCI Registry: Optimizing Strategy Before Entering the Cath Lab
TCT AI Lab 3, November 1

NAVIGATE-PCI is a prospective, multi-center registry evaluating the real-world utility of Heartflow PCI Navigator, the first and only integrated, AI-driven PCI planning tool that gives interventional cardiologists a patient-specific 3D model detailing anatomy, plaque composition, and lesion-specific physiology, all aligned to streamline procedures with increased efficiency and clinical confidence. In the 203-patient cohort presented at TCT, investigators evaluated how access to integrated pre-procedural insights altered treatment strategies established immediately after invasive angiography.

Key NAVIGATE-PCI findings include:

- Treatment plans were modified in approximately 70% of patients after physicians reviewed Heartflow PCI Navigator prior to intervention, compared to angiography alone. The most frequent changes included stent length (41%) and lesion preparation technique (12%).
- Physicians rated their PCI Navigator plans with higher confidence than their angiography-based plans.

“Angiography only shows a two-dimensional silhouette, leaving critical blind spots around plaque burden, calcium and true vessel size,” said Ziad A. Ali, M.D., D.Phil., principal investigator of the NAVIGATE-PCI registry and Director of the DeMatteis Cardiovascular Institute at St. Francis Heart Center in New York. “Heartflow PCI Navigator fundamentally changes our approach, providing the comprehensive 3D and physiologic clarity needed to tailor treatment plans with greater confidence before entering the cath lab.”

The BRAVEHEART Registry: Revealing High CAD Burden in Firefighters to Accelerate Prevention
TCT 1488, November 3

Highlighting the impact of Heartflow’s technology across the entire continuum of care, investigators will also present data from the prospective BRAVEHEART registry. The study evaluated the use of AI-powered Heartflow Plaque Analysis and Heartflow FFR_{CT} Analysis to identify hidden coronary risk and encourage earlier preventive therapy in 96 asymptomatic firefighters with at least 10 years of occupational smoke exposure.

Key BRAVEHEART findings include:

- Subclinical coronary plaque was identified in 72% of asymptomatic firefighters (mean age 48.1 years), with 16% presenting with severe total plaque volume (>250 mm^3).
- Willingness to initiate lipid-lowering medical therapy was reported by 68% of participants following review of their CCTA and Heartflow Analysis insights, while 93% committed to lifestyle modifications.

Experience Heartflow PCI Navigator at TCT 2026

TCT 2026 attendees are invited to visit Heartflow at exhibit booth #3819 for live demonstrations of Heartflow PCI Navigator. See the full schedule of other Heartflow programs, including a lunch symposium, hands-on training workshops, and more at event.heartflow.com/tct2026.

About Heartflow PCI Navigator

Heartflow expanded the Heartflow One platform with the addition of Heartflow PCI Navigator to support diagnosing, managing and guiding treatment for patients throughout the spectrum of CAD care. PCI Navigator is the only integrated, AI-driven percutaneous coronary intervention (PCI) planning tool that gives interventional cardiologists a patient-specific 3D model detailing anatomy, plaque composition, and lesion-specific physiology, all aligned to optimize potential stent placement. Heartflow introduced PCI Navigator to close the critical information gaps interventional cardiologists face before entering the cardiac catheterization lab.

About Heartflow Plaque Analysis with Plaque Staging

Heartflow Plaque Analysis is the only FDA-cleared, AI-powered plaque analysis tool with 95% agreement against the gold standard, intravascular ultrasound (IVUS), in a prospective, international trial.[1] Heartflow Plaque Staging builds on this foundation, categorizing plaque burden into clinical risk stages to guide actionable risk stratification.[2,3] The framework is validated in 23,000 patients with up to 16 years of follow-up, offering the reproducibility clinicians need for serial monitoring and individualized preventive care.

About Heartflow’s Technology and Research

Heartflow’s technology is redefining precision diagnostic testing and management for coronary artery disease (CAD) through clinically proven AI and the world’s largest coronary imaging dataset. Heartflow has been adopted by more than 1,800 institutions globally and continues to strengthen its commercial presence to make this cutting-edge solution more widely available to an increasingly diverse patient population. Backed by American College of Cardiology and American Heart Association (ACC/AHA) guidelines and supported by more than 625 peer-reviewed publications, Heartflow has redefined how clinicians manage care for over 750,000 patients worldwide.[4] Key benefits include:

- **Unmatched proprietary data pipeline:** Built from the world’s largest database of more than 200 million annotated CTA images, Heartflow’s data foundation powers advanced AI models that deliver highly accurate, reproducible diagnostic insights across diverse patient populations.

- **Extensive clinical and real-world validation:** Heartflow's AI-driven solutions have been validated through clinical evidence in over 200 studies assessing over 365,000 patients. Heartflow is the only AI platform prospectively validated against invasive gold standards and demonstrated through real-world evidence to improve patient outcomes.[3,5,6,7] Proven in real-world practice with reproducibility and accuracy, Heartflow's coronary CTA image acceptance rates exceed 97%.
- **Seamless clinical integration via upgraded workflow:** Heartflow delivers final quality-reviewed analyses instantly upon order, enabling clinicians to move from diagnosis to decision without delay.
- **Quality system, global security and patient-data integrity compliance:** Heartflow meets or exceeds leading international standards, including HITRUST r2, SOC 2 Type 2, MDSAP, ISO 13485, and ISO 27001.

About Heartflow, Inc.

Heartflow is transforming coronary artery disease from the world's leading cause of death into a condition that can be detected early, diagnosed accurately, and managed for life. The Heartflow One platform uses AI to turn coronary CTA images into personalized 3D models of the heart, providing clinically meaningful, actionable insights into plaque location, volume, and composition and its effect on blood flow — all without invasive procedures. Discover how we're shaping the future of cardiovascular care at heartflow.com.

Media Contact
Elliot Levy
elevy@heartflow.com

Investor Contact
Nick Laudico
nlaudico@heartflow.com

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[1] Ihdayhid A, et al. Radiol Cardiothorac Imaging. 2024. doi: 10.1148/ryct.230312 and internal bridging study with ICC correlation between first generation and second generation Plaque Analysis algorithm.

[2] Rinehart, et al. JACC Imaging. 2025.

[3] Fairbairn et al. Coronary CT Angiography Plaque as a Predictor of Death, Cardiovascular Death and Myocardial Infarction. Presented at AHA 2025. (Real-world study with n=7,899 patients, higher TPV results in increased cardiovascular death and MI)h

[4] Gulati M, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCAI Guideline for the Evaluation and Diagnosis of Chest Pain. Circulation 2021; 144:e368–e454.

[5] Narula, et al. EHJ CVI 2024.

[6] Danad, et al. JAMA Cardiol 2017.

[7] Madsen KT, et al. ADVANCE-DK 7-year. Presented at TCT Scientific Sessions 2024. (n=900 patients determined a 2.5x increase in cardiovascular events or deaths at 7 years).