# Late Breaking Data from Independent Government-Funded Trial at ESC Shows Heartflow FFRCT Analysis Reduces Unnecessary Invasive Heart Procedures by Nearly Half

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## FUSION trial presented at ESC and published in Journal of the American College of Cardiology demonstrates adding non-invasive lesion-specific physiology resolves critical diagnostic uncertainty, supporting Appropriate Use Criteria for cath lab referrals

SAN FRANCISCO, Aug. 28, 2026 (GLOBE NEWSWIRE) -- Heartflow, Inc. (Heartflow) (Nasdaq: HTFL), the leader in AI technology for diagnosing and managing coronary artery disease (CAD), today announced late-breaking one-year results from an independent randomized clinical trial proving the Heartflow $FFR_{CT}$ Analysis safely and significantly reduced unnecessary invasive heart procedures by 44% ($p < 0.001$).

Presented as Late-Breaking Science at the European Society of Cardiology (ESC) Congress 2026, FUSION trial, funded by the Dutch National Health Care Institute, demonstrates that standard coronary computed tomography angiography (CCTA) alone drives overutilization of invasive catheterizations.[1] By adding Heartflow $FFR_{CT}$ Analysis to standard CCTA scans, clinicians dramatically reduced diagnostic catheter lab procedures. The FUSION study has been published simultaneously in the Journal of the American College of Cardiology (JACC).

CCTA is the primary first-line test recommended by both European (ESC) and U.S. (ACC/AHA) guidelines for evaluating patients with suspected CAD. However, visual assessment of CCTAs is limited to assessing anatomy and whether plaque is present; it cannot determine lesion-specific physiology or whether a blockage significantly restricts blood flow to the heart. This diagnostic uncertainty frequently leads physicians to refer patients for invasive coronary angiography (ICA), a hospital procedure where a catheter is threaded through an artery, normally in the groin or arm, to get into the heart to assess blocked or narrowed blood vessels.[1,2,3,4]

These findings show Heartflow $FFR_{CT}$ - the only AI platform prospectively validated against invasive gold standard - bridges this critical diagnostic gap. By applying advanced AI and computational fluid dynamics to standard CT scans with documented narrowings, Heartflow creates a personalized 3D model that quantifies blood flow within the coronary arteries.[5]

“CCTA is established as the optimal first-line diagnostic test for coronary artery disease as it is noninvasive, but when anatomical scans show intermediate stenosis, determining whether that blockage is clinically significant remains a critical challenge,” said Alexander Hirsch, M.D., principal investigator of the FUSION trial and associate professor of cardiology at Erasmus MC in Rotterdam, Netherlands. “The FUSION trial shows that adding Heartflow lesion-specific physiology makes CCTA even more powerful and improves diagnostic efficiency. It gives clinicians the clarity to know which patients require further invasive testing, safely avoiding unnecessary invasive catheterizations while maintaining excellent patient outcomes.”

**One-Year FUSION Results**

Enrolling 528 patients with stable chest pain across twelve hospitals in the Netherlands, FUSION is an independent randomized controlled trial funded through the Dutch government’s Zorginstituut Nederland ‘Potentially Promising Care’ program. The study evaluated Heartflow $FFR_{CT}$ Analysis across diverse scanner vendors in both academic and community hospital settings, with blinded, independent clinical event adjudication.

Key 1-year findings include:

- A sustained 44% relative reduction in unnecessary ICA was demonstrated at one year in the Heartflow pathway compared to the CCTA-only group (22% [57/263] Heartflow vs. 39% [103/265] CCTA alone; $p < 0.001$), consistent with the 90-day primary endpoint results (18% [48/263] vs. 33% [87/265] CCTA alone; $p < 0.001$).
- Overall rates of ICA were significantly lower at one year in the Heartflow pathway compared to the CCTA-only group (43% [114/263] Heartflow vs. 61% [161/265] CCTA alone; $p < 0.001$).
- Rates of coronary revascularization remained identical across groups (20% [52/263] vs. 20% [53/265]; $p = 0.948$), proving that safely reducing diagnostic cath lab procedures did not prevent patients from receiving necessary intervention.
- There were no significant differences in safety endpoints between pathways, including major adverse cardiac events (MACE), ICA complications, or stroke.

**Validating Heartflow $FFR_{CT}$ at Critical Clinical Decision Points**

While previous randomized controlled trials, such as FORECAST and PRECISE, evaluated the pathway of CCTA and Heartflow $FFR_{CT}$ in broader patient populations early in the diagnostic pathway, FUSION is the first randomized trial to test Heartflow $FFR_{CT}$ Analysis at a pivotal clinical junction: immediately following a CCTA scan that identifies anatomically obstructive stenosis, a decision point recently affirmed in the 2026 SCCT/SCAI expert consensus statement and endorsed by the ACC.[6,7] As an independent, government-funded study with no industry involvement in trial design or analysis, FUSION delivers robust, unbiased evidence supporting the routine integration of Heartflow $FFR_{CT}$ Analysis into everyday clinical practice. The landmark findings build on more than 15 years of rigorous clinical research across major trials, further establishing Heartflow $FFR_{CT}$ as the leading and most extensively validated CT-FFR technology in cardiology.[5,6,7,8]

"One of the persistent challenges in cardiology has been accurately identifying, prior to catheterization, which patients have disease severe enough to warrant an invasive procedure," said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer at Heartflow. "The FUSION data demonstrate that our technology can meaningfully address this challenge, providing physicians with more precise insight into a patient's disease burden after CCTA has documented stenosis over 50%. This allows care teams to direct invasive procedures to the patients most likely to benefit, while sparing others the risk and burden of a catheterization they may not require."

**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.[2] 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.[9,10,11,12] 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, 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.

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[2] 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.

[3] Vrints C, et al. 2024 ESC Guidelines for the Management of Chronic Coronary Syndromes. Eur Heart J 2024; 00:1–105.

[4] Tonino PA, et al. Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME). N Engl J Med 2009; 360:213-224.

[5] Taylor CA, et al. Computational Fluid Dynamics Applied to Coronary Computed Tomography Angiography. J Am Coll Cardiol 2013; 61(22):2233-2241.

[6] Curzen N, et al. Fractional Flow Reserve Derived From Computed Tomography in Suspected Stable Angina: The FORECAST Trial. Eur Heart J 2021; 42(37):3807-3818.

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[8] 15-Year Evidence Base includes DISCOVER-FLOW (JACC 2011), DeFACTO (JAMA 2012), NXT (JACC 2014), PLATFORM (Eur Heart J 2015), and ADVANCE Registry (Eur Heart J 2019).

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

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

[11] 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).

[12] 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).