Artificial Intelligence-Derived Plaque Quantification: CCTA and AI-QCPA for Determining Effective CAD Management (DECIDE) Registry Study Design

DECIDE Registry. Rinehart, et al., presented at SCCT 2025.

Objective

Understand changes in medical management with insights from Heartflow Plaque Analysis with Plaque Staging*, as well as resulting impact to biomarkers and outcomes.

Methods

- Real-world evidence from ~20,000 patients at over 30 centers across the United States.
- For primary endpoint subset, Plaque Analysis with Plaque Staging* was provided for patients who underwent CCTA 90 days prior to the start of the registry.
  - » Armed with the addition of quantified and characterized plaque insights and Plaque Staging*, treating physicians then determined changes to medical management.
- In addition, Plaque Analysis is being used prospectively and control arms were included for treatment based on CCTA only and stress test only.

Endpoints

- Primary: Change in medical management following Plaque Analysis with Plaque Staging* compared to CCTA alone
- Secondary: Biomarkers and observed outcomes
- Safety: CV death and MI

>50%

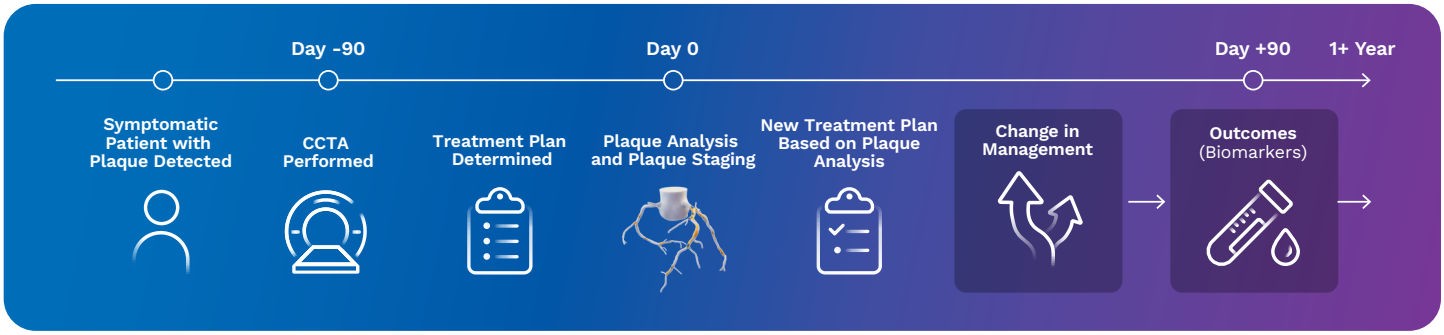
Patients had their medical management changed when Plaque Analysis with Plaque Staging* was added compared to their management based on CCTA alone.

~1/3

Patients with a calcified plaque of 0 had a change in management compared to CCTA alone.

~15%

Suggested decrease in risk of cardiac events based on average LDL-C decrease of 18.7mg/dL for those with change in management.[1]



Heartflow Plaque Staging*

How Insights Transform Into Action

Highly validated Plaque Staging* translates total plaque volume to inform actionable treatment plans, simplifying decision-making and personalizing preventive treatment based on patient risk.[2,3]

Overall considerations: Consider GLP1 treatment if BMI>27 | Lifestyle modifications guidance especially in higher stages.

Stage	Total Plaque Volume	Lipid Biomarkers Thresholds/Goals	Medical Management Under clinical evaluation in the DECIDE Registry
Mild‡	1-100	LDL-C: 100 mg/dL Non-HDL: 130 mg/dL Apo-B: 90 mg/dL	• Statin • ± Aspirin
Moderate‡	>101–250	LDL-C: 70 mg/dL Non-HDL: 100 mg/dL Apo-B: 70 mg/dL	• High intensity statin ± PCSK9I ± Bempedoic Acid ± Ezetimibe • ± Aspirin • If DM: Intensify therapy with GLP1 ± SGLT2I
Severe‡	>251–750	LDL-C: 55 mg/dL Non-HDL: 85 mg/dL Apo-B: 60 mg/dL	• High intensity statin ± PCSK9I ± Bempedoic Acid ± Ezetimibe • Aspirin • Aggressive BP Rx • If DM: Intensify therapy with GLP1 ± SGLT2I • If elevated BMI: weight loss treatment • If elevated CRP & LDL at target: consider anti-inflammatories
Extensive	>750	All as low as can be achieved: LDL-C: <50 mg/dL Non-HDL: <80 mg/dL Apo-B: <50 mg/dL	• Same as severe • ± Colchicine ± Icosapent Ethyl

‡Consider intensifying to next stage if nomogram percentile >50th and/or risk enhancers.[4]

"The new Heartflow Plaque Staging* framework can equip physicians to move beyond plaque quantification to providing personalized care decisions for their patients, with the potential to offer higher quality care leading to better outcomes."

— Leslee Shaw, Ph.D.,
Director of the Blavatnik Family Research Institute at the Icahn School of Medicine at Mount Sinai, Co-lead investigator of the DECIDE Registry

*Heartflow Plaque Analysis is an FDA-cleared device. Heartflow Plaque Staging is an investigational only framework and its safety and effectiveness have not been reviewed by the FDA

1. Collins et al. Lancet 2016. DOI: 10.1016/S0140-6736(16)31357-5
2. Fairbairn, et al. HEART. 2025. doi:10.1136/heartjnl-2025-BSCI.5
3. Rinehart, et al. JACC Imaging. 2025.
4. Tzimas, et al. JACC. 2023. https://doi.org/10.1016/j.jcmg.2023.05.011

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