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Prospective **L**ongitudin**A**l **T**rial of **F**FFR_{CT} **O**utcome and **R**esource I**M**pacts

Clinical outcomes of FFR_{CT}-guided diagnostic strategies versus usual care in patients with suspected coronary artery disease

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On behalf of the PLATFORM Investigators

Supported by HeartFlow Inc, Redwood, CA, USA

Duke Clinical Research Institute

HeartFlow

DECLARATION OF INTEREST

- Research contracts

Background and Aim

- The optimal evaluation of new onset stable chest pain is uncertain. Ideally, testing will clarify the diagnosis and direct subsequent care while maximizing efficiency and safety.
- The recent PROMISE and SCOT-HEART trials compared anatomic and functional strategies, finding that CTA improved processes of care. However, CTA also increased rates of invasive catheterization and revascularization with no significant reduction in events.
- Fractional Flow Reserve derived from CTA (FFR_{CT}) may address these limitations by providing both functional and anatomic data.
- **STUDY AIM:** To determine whether use of a CTA/FFR_{CT} guided strategy, as compared to standard practice, will reduce the rate of invasive angiograms that show no obstructive CAD, without increasing the occurrence of major cardiac events.

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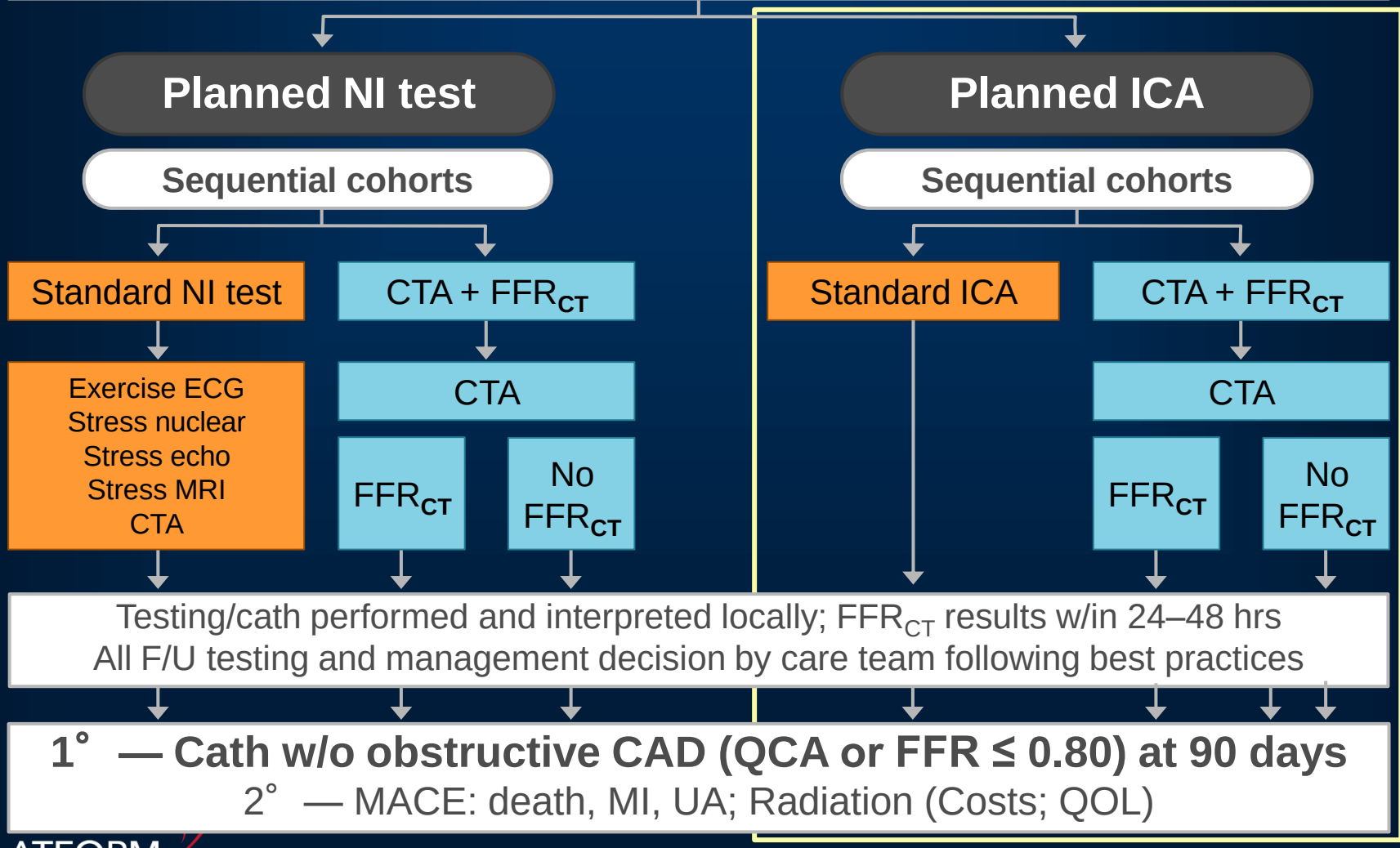
PLATFORM Trial Design

Stable CAD symptoms; Planned non-emergent NI test or catheterization
Age ≥ 18y; No prior CAD hx; Intermediate pretest probability of CAD



Testing/cath performed and interpreted locally; FFR_{CT} results w/in 24–48 hrs
All F/U testing and management decision by care team following best practices

1° — Cath w/o obstructive CAD (QCA or FFR ≤ 0.80) at 90 days
2° — MACE: death, MI, UA; Radiation (Costs; QOL)

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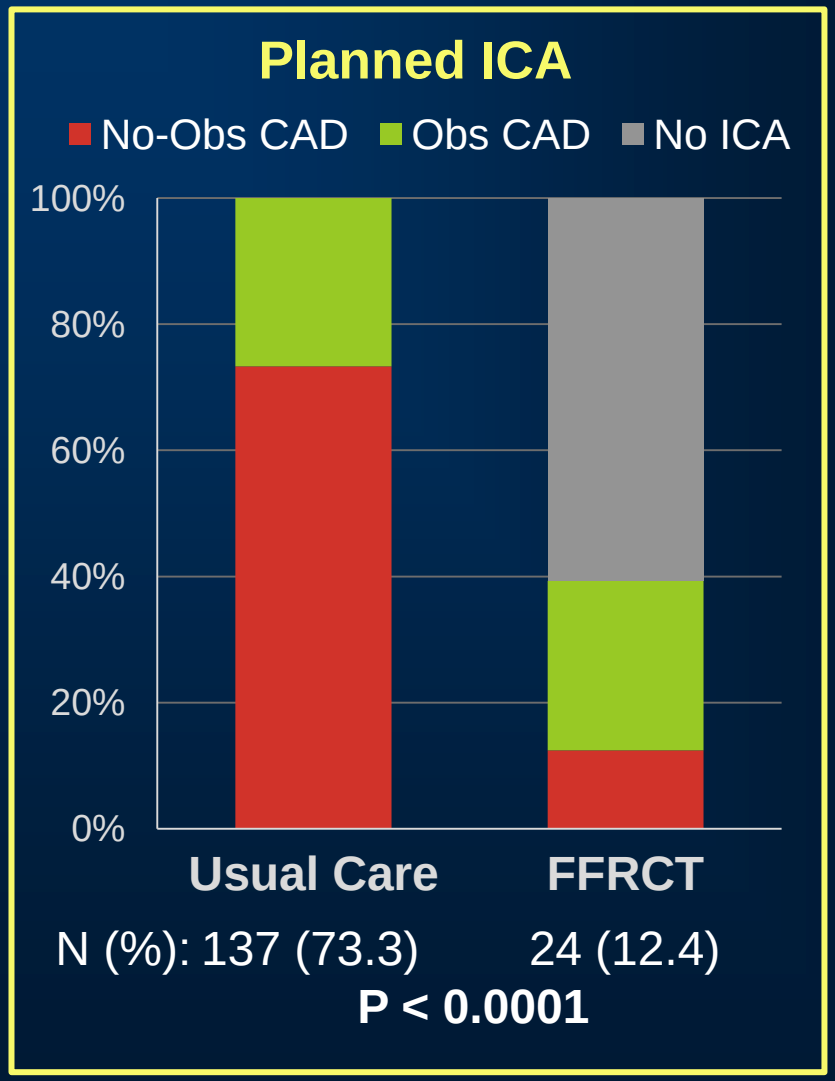
Primary Endpoint
Invasive Catheterization w/o Obstructive CAD

Similar results in all pre-specified subgroups and cohorts

- Site-read ICA w/o obstructive CAD 57% usual care; 9% FFR_{CT}
- Age, sex, race, diabetes, pretest probability of CAD, country
- Propensity matched cohort
- Best practices cohort
- Adequate image cohort



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Safety Endpoints and Data at Revascularization

	Planned NI Test N=204			Planned ICA N=380		
	Usual care strategy N=100	**FFR_{CT} strategy** N=104	**P value**	**Usual care strategy** N=187	**FFR_{CT} strategy** N=193	**P value**
SAFETY: MACE — no. (%)	**0**	**0**		**0**	**2 (1.0)**	**NA**
SAFETY: RADIATION EXPOSURE (enrolment to 90 days)						
Mean ± SD, mSv	**5.8 ± 7.1**	**8.8 ± 9.9**	**0.0002**	**9.4 ± 4.9**	**9.9 ± 8.7**	**0.20**
FUNCTIONAL DATA AT REVASCULARIZATION						
PCI or CABG – no.	**5**	**10**	**0.29**	**59**	**55**	**0.58**
Functional data available	**100%**	**90%**	**1.0**	**51%**	**96%**	**<0.0001**

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Summary and Conclusion

- PLATFORM enrolled a symptomatic, intermediate risk population for whom testing is currently recommended
- Use of CT/FFR_{CT} in patients with planned invasive catheterization was associated with a reduction in the rate of finding no obstructive CAD at ICA, from 73% to 12%
  - Similar results in all subgroups
  - No differences in MACE, radiation or revascularization rates
  - Use of FFR_{CT} resulted in cancellation of 61% of ICAs and doubled the availability of functional data at PCI/CABG
- In conclusion, use of a combined anatomic AND functional strategy employing CTA/FFR_{CT} was safe and improved patient selection for invasive catheterization

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