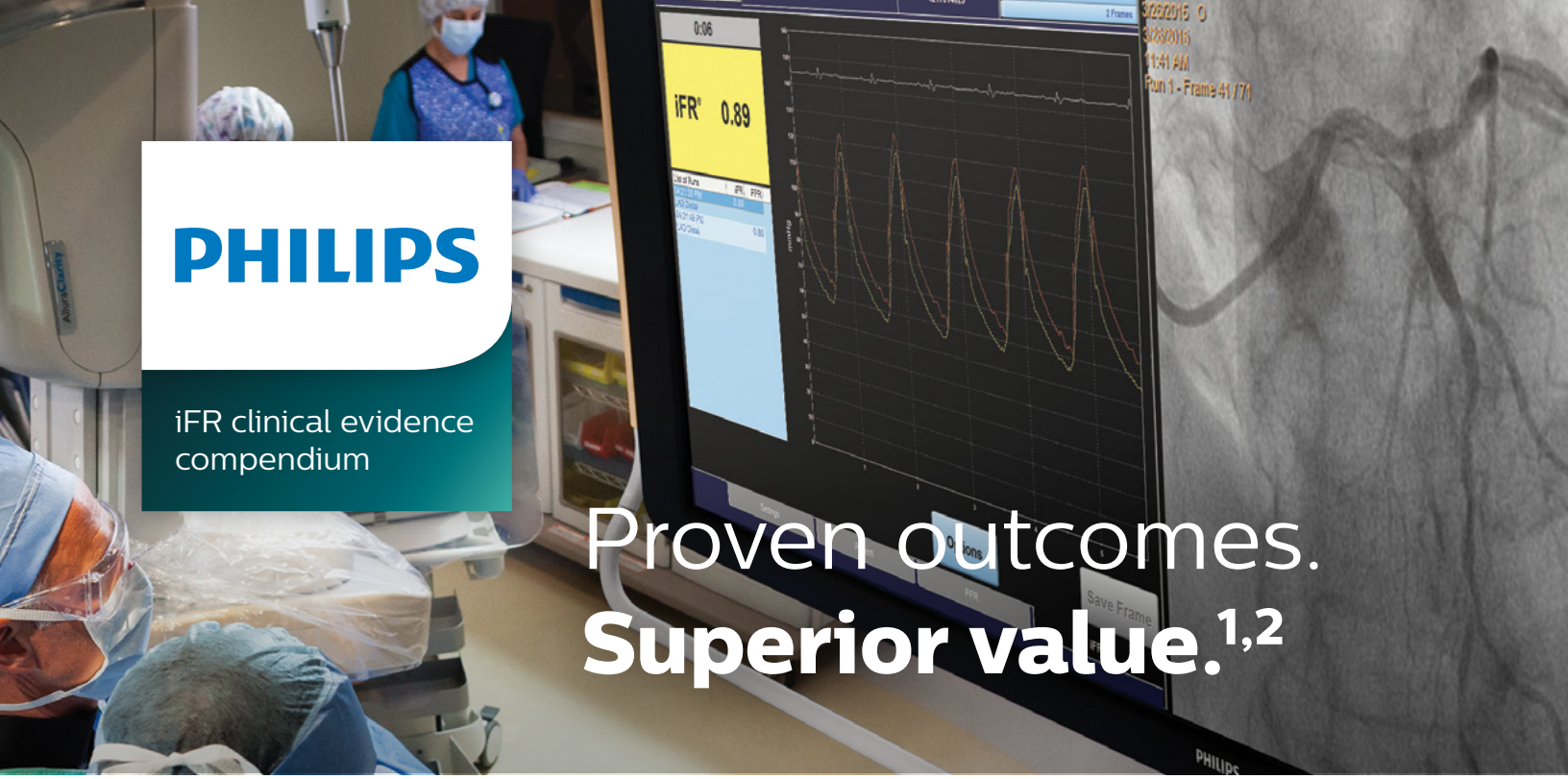


PHILIPS

iFR clinical evidence compendium

Proven outcomes. **Superior value.**[1,2]

DEFINE FLAIR[1]

Functional **L**esion **A**ssessment of **I**ntermediate stenosis to guide **R**evascularisation. First global study of physiology N = 2492 patients.

Primary objective

- To assess safety and efficacy of decision-making on coronary revascularisation based on iFR vs FFR
- To assess whether the iFR is non-inferior to FFR when used to guide treatment of coronary stenosis with PCI

Primary endpoint

- Major adverse cardiac events (MACE) rate in the iFR and FFR groups at 30 days, 1 and 2 years. Data from one year follow up will be presented
- MACE (combined endpoint of death, non-fatal MI, or unplanned revascularisation)

iFR Swedeheart[3]

Evaluation of iFR vs FFR in stable angina or acute coronary syndrome N = 2037 patients.

Primary objective

- Compare the clinical outcome of patients assessed by iFR with patients assessed by FFR
- Registry based randomized clinical trial (RRCT) in SCAAR/SWEDEHEART

Primary endpoint

- All cause death: national death registry, 100% follow-up adjudication
- Myocardial infarction
- Unplanned revascularization
- Follow up: SCAAR (Swedeheart/Iceland) > 99%, Denmark follow-up in the Danish registry
- Angiographic assessment by experienced observer (blinded to the randomization)

FAME[4]

Primary objective

- To assess safety and efficacy of FFR guided PCI in patients with multivessel coronary artery disease who are undergoing PCI, compared to angiography alone

Primary endpoint

- Rate of death, nonfatal myocardial infarction, and repeat revascularization at 1 year

FAME II[5]

Primary objective

- To assess outcome in patients with functionally significant stenoses, as determined by measurement of FFR, between PCI plus the best available medical therapy versus the best available medical therapy alone.

Primary endpoint

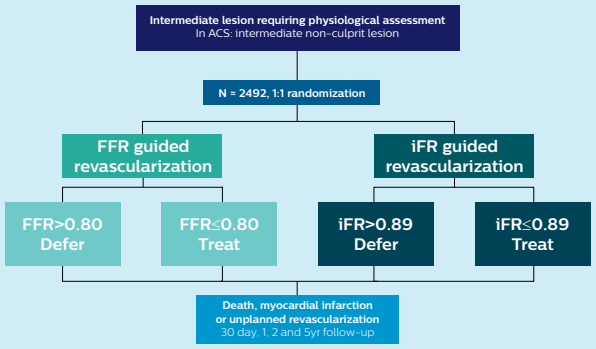
- Composite of death, myocardial infarction, or urgent revascularization

Trial comparisons

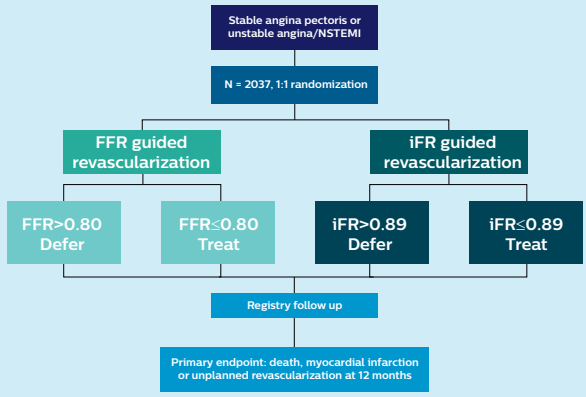
	DEFINE FLAIR[1]	iFR Swedeheart[3]	FAME[4]	FAME II[5]
# of physiology-guided patients	2492	2037	509	441
Centers	Global	EU	EU & US	EU & US
Core lab analysis	Yes	Yes	No	No
Follow-up blinded	Yes	Yes	No	No
Inclusive of all stable CAD patients	Yes	Yes	No (MVD patients only)	Yes
Inclusive of ACS patients	Yes	Yes	No	No

DEFINE FLAIR

Functional **L**esion **A**ssessment of **I**ntermediate stenosis to guide **R**evascularisation

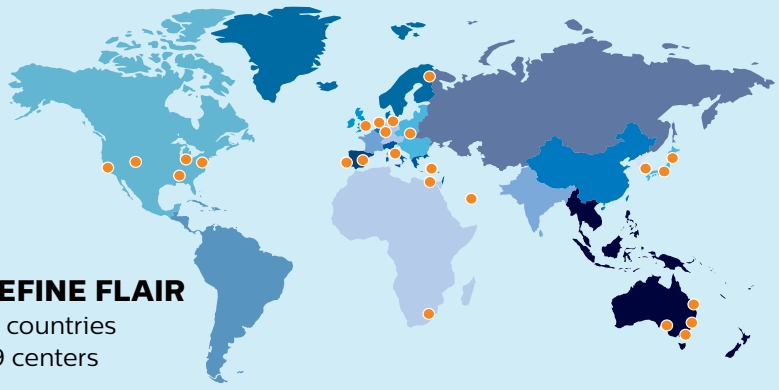


iFR Swedeheart



First set of global physiology studies

iFR Swedeheart



DEFINE FLAIR
19 countries
49 centers

1. DEFINE FLAIR: Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularisation https://clinicaltrials.gov/ct2/show/NCT02053038
2. Late breaker presentation "DEFINE-FLAIR: Comparative Cost Effectiveness of the Instantaneous Wave-free Ratio versus Fractional Flow Reserve in Coronary Revascularization Decision-making" ACC Marc 10, 2018.
3. iFR Swedeheart: Evaluation of iFR vs FFR in Stable Angina or Acute Coronary Syndrome https://clinicaltrials.gov/ct2/show/NCT02166736
4. Tonino PA, et al., FAME Study Investigators. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. 2009 Jan 15;360(3):213-24.
5. De Bruyne B, et al., FAME 2 Trial Investigators. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. N Engl J Med. 2012 Sep 13;367(11):991-1001.

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