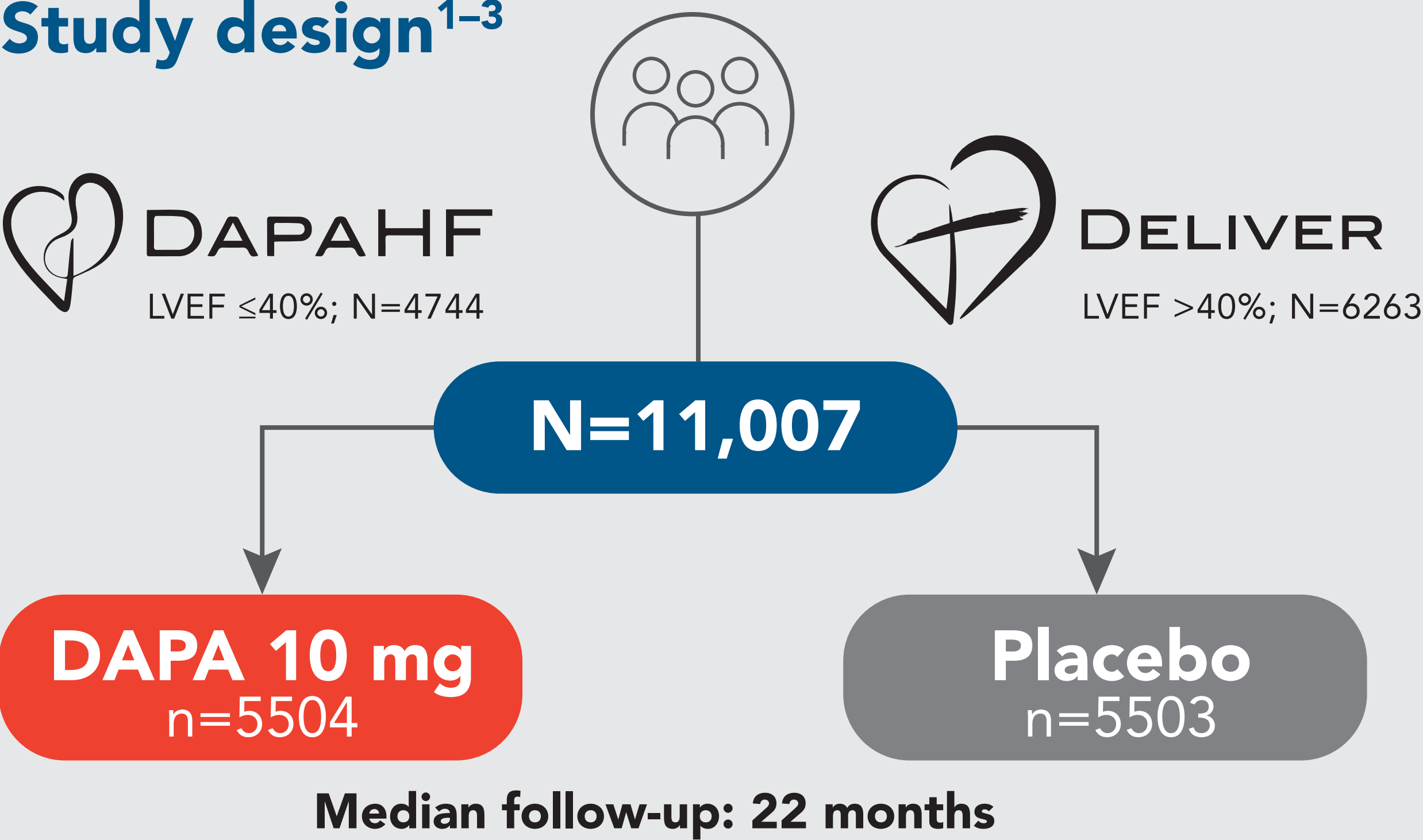




Introducing the unprecedented results from the DAPA-HF and DELIVER pooled analysis^a

Study design¹⁻³



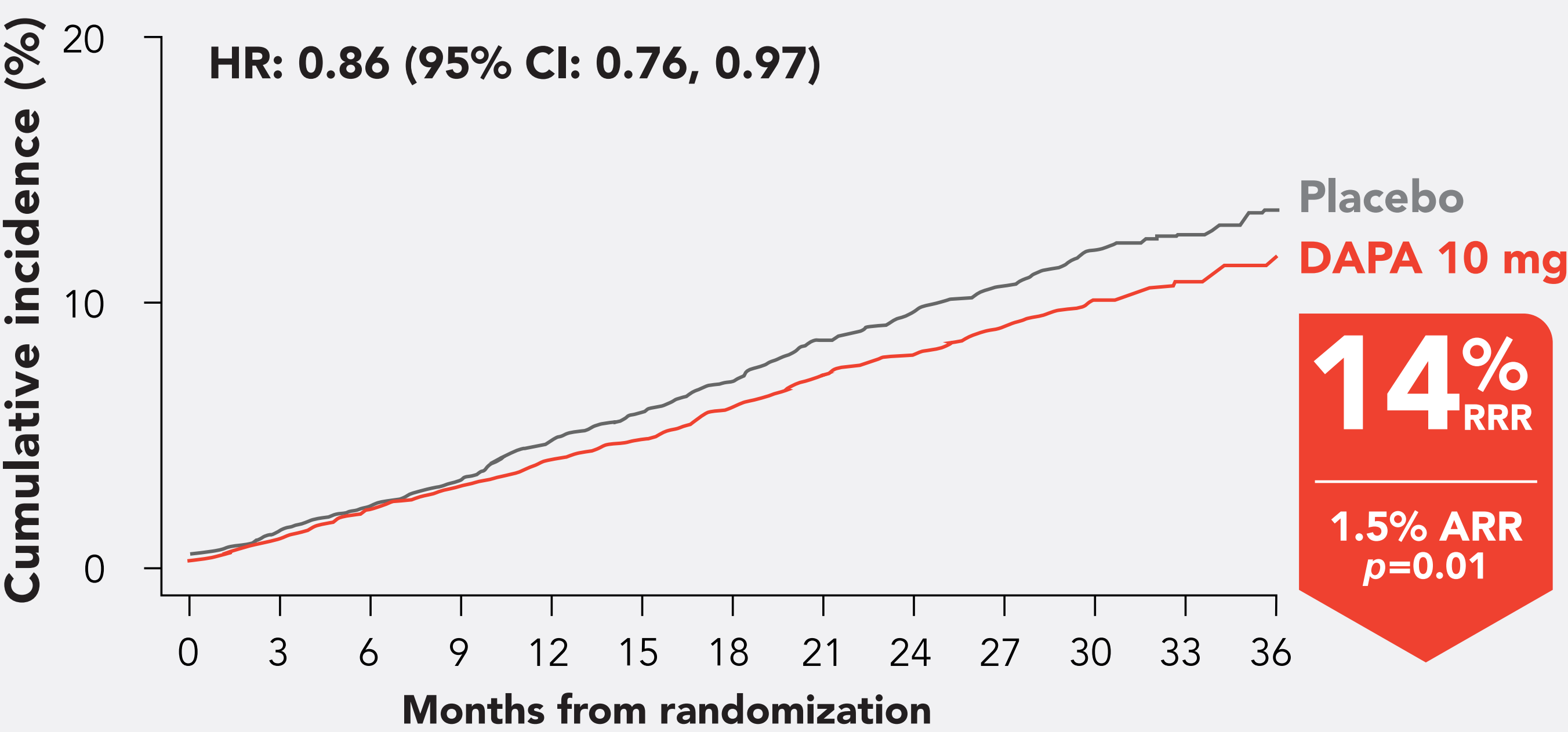
Prespecified pooled analysis

Historically, treatments to manage HF have shown attenuation at higher ejection fractions.⁴ This patient-level analysis examined treatment effect on endpoints neither trial was individually powered for, and tested the consistency of the attenuation of effect of DAPA across the range of LVEF

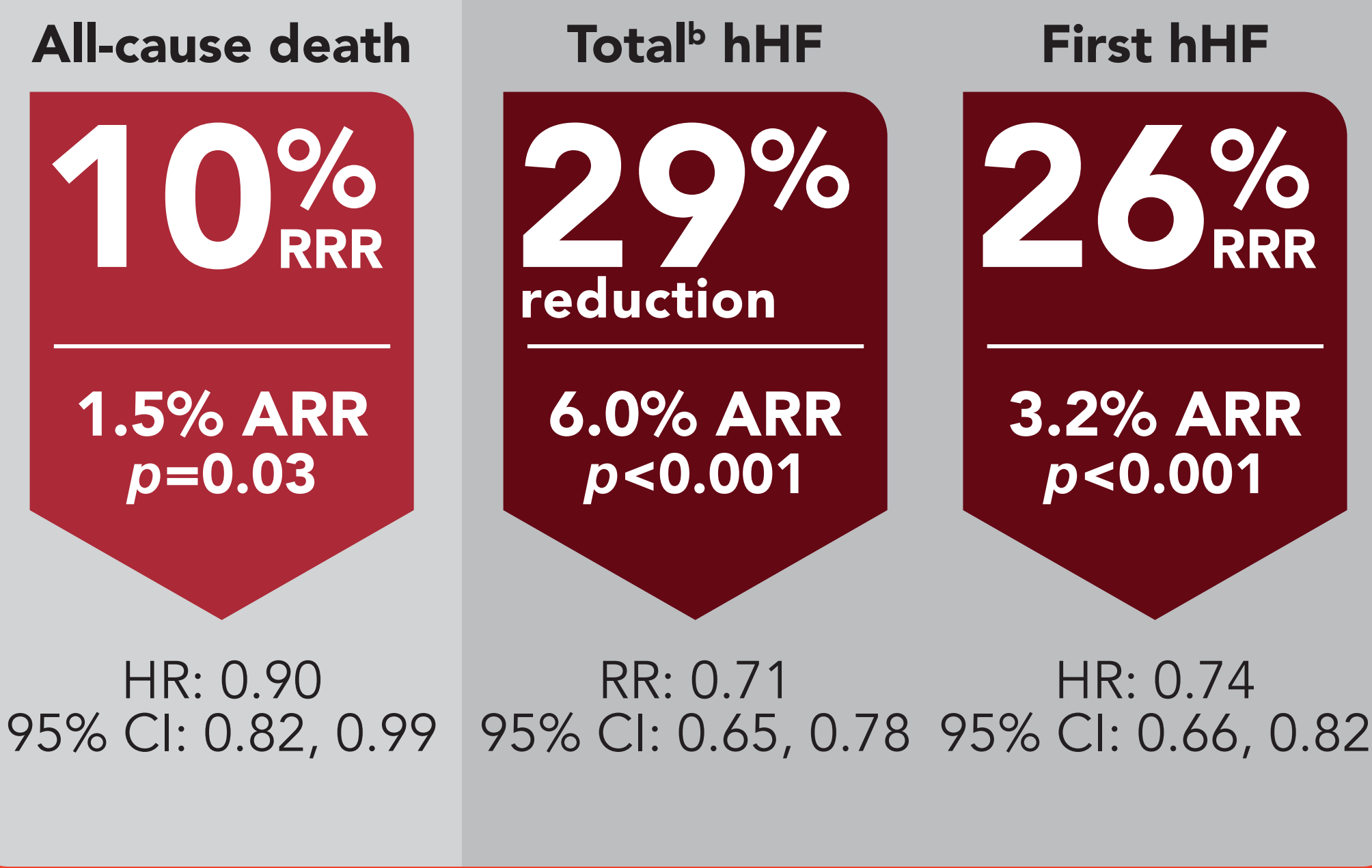
Endpoints:

- CV death
- All-cause death
- Total^b hHF
- MACE^c
- CV death or hHF

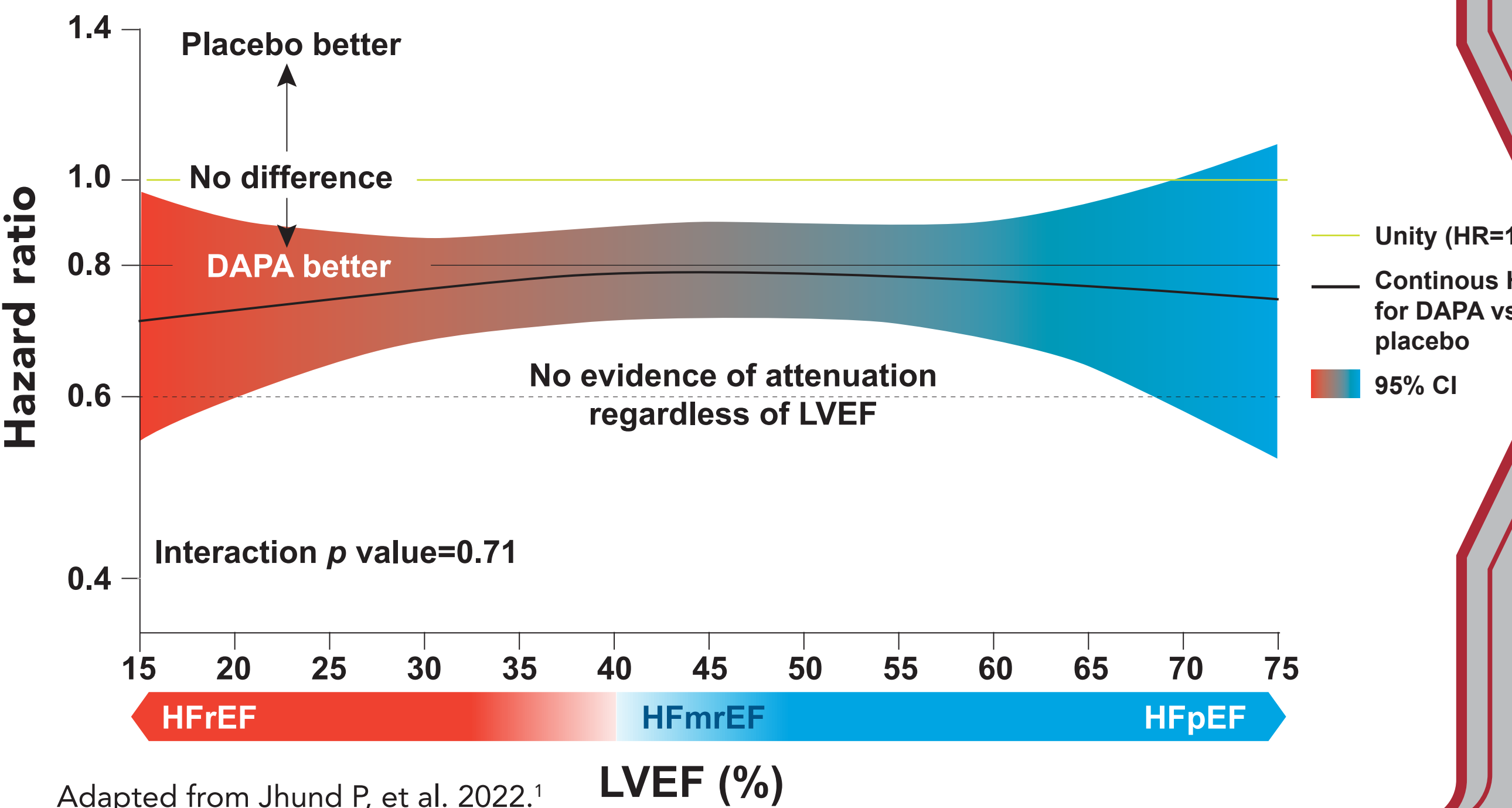
DAPA significantly reduced the risk of CV death across the range of LVEF¹



Adapted from Jhund P, et al. 2022.¹



DAPA has shown no evidence of attenuation across the EF range, providing consistent efficacy in lowering the risk of CV death or hHF^{1,d}



Adapted from Jhund P, et al. 2022.¹

Safety profile has been established across trials^{2,3}

Event, n (%)	DAPA-HF ²		DELIVER ³	
	DAPA n=2368 ^e	Placebo n=2368 ^e	DAPA n=3126 ^e	Placebo n=3127 ^e
Volume depletion	178 (7.5)	162 (6.8)	42 (1.3) ^f	32 (1.0) ^f
Renal AE	153 (6.5)	170 (7.2)	73 (2.3) ^f	79 (2.5) ^f
Fracture	49 (2.1)	50 (2.1)	NR	NR
Amputation	13 (0.5)	12 (0.5)	19 (0.6)	25 (0.8)
Major hypoglycemia	4 (0.2)	4 (0.2)	6 (0.2)	7 (0.2)
DKA ^g	3 (0.1)	0 (0.0)	2 (0.1)	0 (0.0)
Fournier's gangrene	0 (0)	1 (<0.1)	0 (0.0)	0 (0.0)

^aIn the DAPA-HF trial, DAPA significantly reduced the risk of the primary composite endpoint of CV death or worsening of heart failure, CV mortality alone, and all-cause mortality. The DELIVER trial, which included recently hospitalized patients in addition to patients with ejection fraction >40%, was the largest and broadest trial in patients with heart failure. In DELIVER, DAPA significantly reduced risk of the primary composite endpoint of CV death or worsening of heart failure but did not reach significance in CV death or all-cause death. In a prespecified pooled analysis of the DAPA-HF and DELIVER trials, DAPA significantly reduced risk of CV mortality and all-cause mortality. Patients with NT-proBNP under 300 pg/mL were excluded from DELIVER; ^bFirst and recurrent; ^cComposite of CV death, MI, or stroke; ^d11,007 participants were included in this pooled meta-analysis of the DAPA-HF and DELIVER trials. 4744 participants had an LVEF ≤40% and 6263 had an LVEF >40%. 5503 participants were randomised to placebo and 5504 to DAPA. DAPA reduced the risk of CV death or worsening HF (defined as hHF or urgent HF visit requiring initiation or intensification of treatment specifically for HF) by 22% (HR 0.78 [CI: 0.72-0.86]; P<0.001). Results were unchanged in sensitivity analyses if undetermined deaths were excluded from the definition of death from CV causes or if the definition from the individual trials was used. LVEF was measured by investigators. Patients with NT-proBNP under 300 pg/mL were excluded from DELIVER; ^eThe safety population included patients who received at least 1 dose of the trial medication; ^fOnly includes serious AE or treatment discontinuation AE; ^gDefinite or probable.

AE, adverse event; ARR, absolute risk reduction; CI, confidence interval; CV, cardiovascular; DAPA, dapagliflozin; DKA, diabetic ketoacidosis; HF_{mr}EF, heart failure with mildly reduced ejection fraction; HF_pEF, heart failure with preserved ejection fraction; HF_{Fr}EF, heart failure with reduced ejection fraction; hHF, hospitalization for heart failure; HR, hazard ratio; LVEF, left ventricular ejection fraction; MACE, major adverse cardiovascular events; NR, not reported; RR, rate ratio; RRR, relative risk reduction

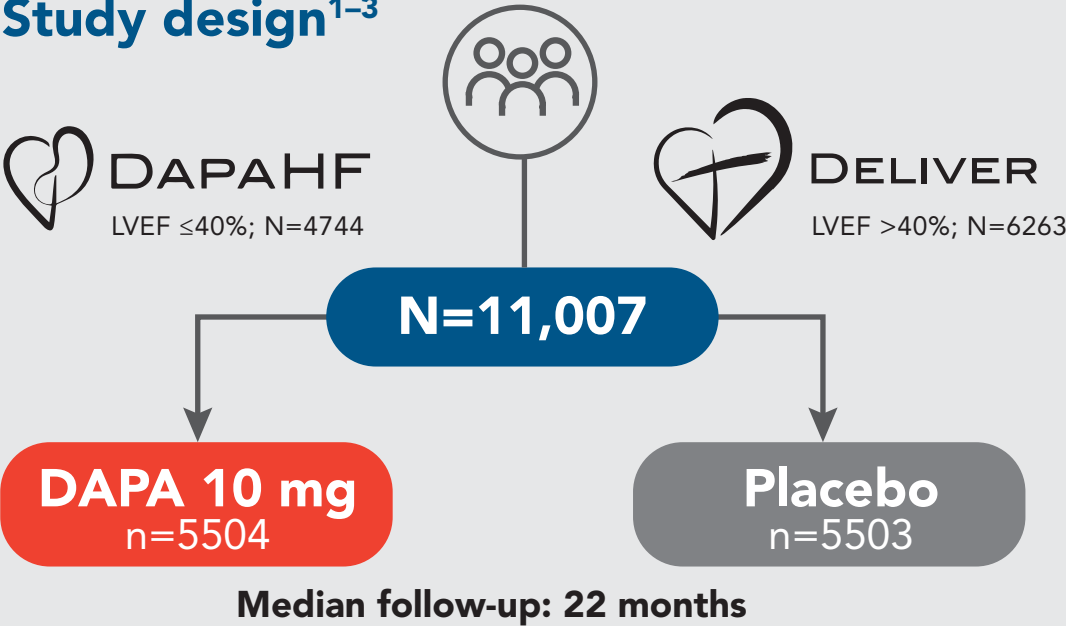
References: 1. Jhund P, et al. Nat Med 2022;28:1956–1964; 2. McMurray JJV, et al. Article and supplementary appendix. N Engl J Med 2019;381(21):1995–2008; 3. Solomon SD, et al. N Engl J Med 2022;387:1089–1098; 4. Kondo K, McMurray J. Eur Heart J 2022;43:427–429

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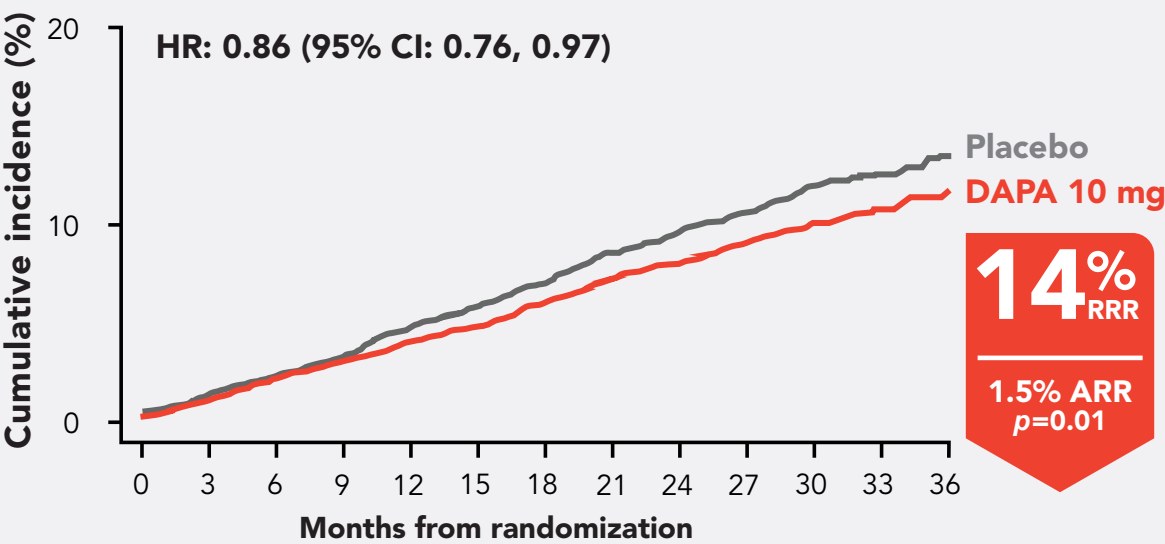
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- Total^b hHF
- MACE^c
- CV death or hHF

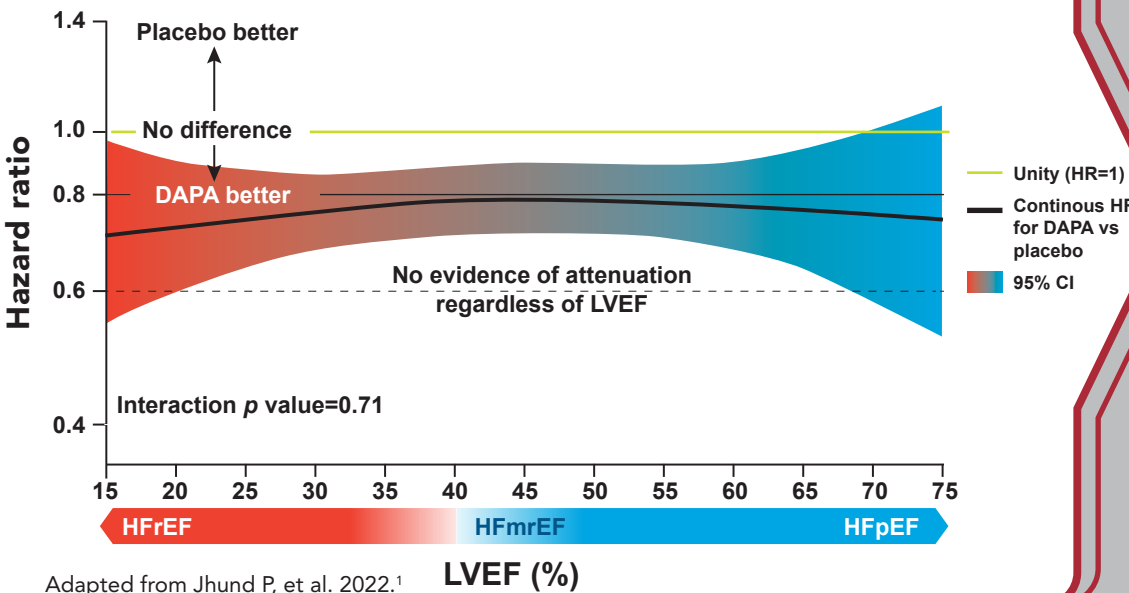
DAPA significantly reduced the risk of CV death across the range of LVEF¹



Adapted from Jhund P, et al. 2022.¹

All-cause death	Total ^b hHF	First hHF
10% RRR	29% reduction	26% RRR
1.5% ARR <i>p</i> =0.03	6.0% ARR <i>p</i> <0.001	3.2% ARR <i>p</i> <0.001
HR: 0.90 95% CI: 0.82, 0.99	RR: 0.71 95% CI: 0.65, 0.78	HR: 0.74 95% CI: 0.66, 0.82

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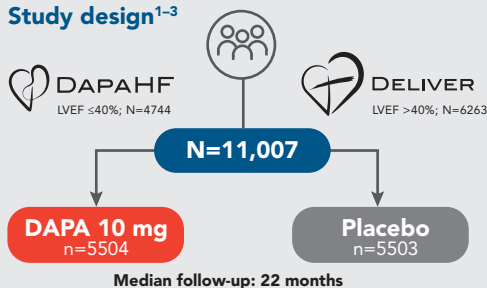
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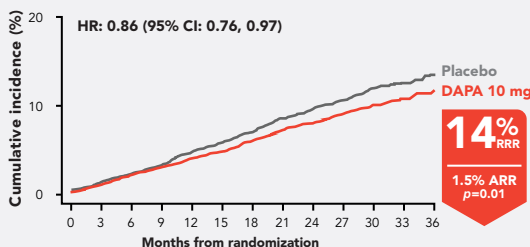
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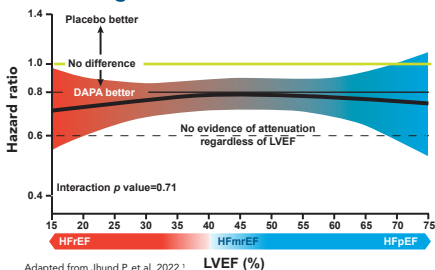
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