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Brief Report

Generalizability of the Spectrum of Kidney Risk in the FINEARTS-HF Trial to U.S. Adults With Heart Failure

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Introduction

Albuminuria (urine albumin-to-creatinine ratio [UACR] ≥ 30 mg/g) and estimated glomerular filtration rate (eGFR) constitute the basis of contemporary kidney-disease staging and are each independently associated with the onset and progression of heart failure (HF).[1–4] As such, assessment of these complementary domains is important in clinical and research efforts involving individuals with HF. However, because UACR has been infrequently assessed in HF outcomes trials, generalizability of trial-level kidney risk to real-world HF populations remains uncertain.

Finerenone is a nonsteroidal mineralocorticoid receptor antagonist that has been shown to reduce cardiovascular and kidney events in individuals with type 2 diabetes and chronic kidney disease,[5] and it is being studied in HF and mildly reduced or preserved ejection fraction (HFmrEF/HFpEF) in the ongoing FINEARTS-HF (Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients with Heart Failure) trial (NCT04435626). In this analysis, we compared the distribution of Kidney Disease: Improving Global Outcomes (KDIGO) kidney risk among FINEARTS-HF participants with a nationally representative sample of adults in the United States.

Methods

The design of the FINEARTS-HF trial has been published previously.[6] In brief, FINEARTS-HF is a global, randomized, placebo-controlled trial evaluating the safety and efficacy of finerenone in individuals with symptomatic HF with left ventricular ejection fraction (LVEF) ≥ 40%, elevated natriuretic peptide levels and evidence of structural heart disease. Individuals with eGFR < 25 mL/min/1.73 m^2 or serum potassium > 5.0 mmol/L at screening or randomization were ineligible. An independent ethics committee or institutional review board approved the FINEARTS-HF trial protocol at each study center, and all participants provided written informed consent.

To enable comparison of the distribution of kidney risk among FINEARTS-HF participants with the U.S.

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population, we conducted an analysis of U.S. adults from the 2015–2016 and 2017–March 2020 cycles of the serial cross-sectional National Health and Nutrition Examination Survey (NHANES). Samples were weighted to derive an analogous, nationally representative cohort of adults with HF and ages ≥ 40 years, eGFRs ≥ 25 mL/min/1.73 m^2 and serum potassium levels ≤ 5.0 mmol/L.

Kidney risks in the FINEARTS-HF trial population and the NHANES sample were analyzed according to 2024 KDIGO risk categories, as defined by eGFR and UACR levels.[2] Baseline characteristics were compared by KDIGO risk categories (low, moderately increased, high, or very high risk) among FINEARTS-HF participants using linear regression for continuous variables and χ^2 testing for categorical variables. The distribution of KDIGO risk categories was compared between the FINEARTS-HF and NHANES populations using χ^2 testing. Statistical analyses were conducted using R, version 4.2.2 (R Foundation) and Microsoft Excel, version 16.83 (Microsoft). A 2-sided *P* value < 0.05 was considered statistically significant.

Results

Among 6001 FINEARTS participants, 5797 (97%) had available eGFR and UACR readings at baseline. Among them, the median (IQR) baseline eGFR was 61 [47–77] mL/min/1.73m^2, and 2785 (48%) had eGFR levels < 60 mL/min/1.73 m^2. The median (IQR) baseline UACR was 18 [7–67] mg/g, and 2256 (39%) had UACR levels ≥ 30 mg/g. Overall, 35% were classified as low risk, 29% as moderately increased risk, 20% as high risk, and 16% as very high risk, per KDIGO criteria (Fig. 1, A). Participants with higher-risk KDIGO stages were more likely to have older age, female sex, Asian ethnicity, history of atrial fibrillation or flutter, history of diabetes, history of stroke, higher systolic blood pressure, higher LVEF, prior hospitalization due to HF, more symptoms and functional limitations, and higher natriuretic peptide levels (Table 1).

Participants with diabetes (41%) at baseline exhibited a greater prevalence of higher-risk KDIGO categories compared with those without diabetes (Fig. 2). Incorporation of UACR in addition to eGFR reclassified 2167 (37%) FINEARTS-HF participants into ≥ 1 higher KDIGO risk categories (Fig. 1, B). Among those without reduced eGFRs at baseline (eGFR ≥ 60 mL/min/1.73 m^2), UACR reclassified 33% (32% among those with eGFR ≥ 90 mL/min/1.73 m^2) to either moderately increased or high KDIGO risk. Among those with eGFRs 45–59 mL/min/1.73 m^2, UACR reclassified 41% to high or very high KDIGO risk. Among those with eGFR 30–44, UACR reclassified 52% to very high KDIGO risk.

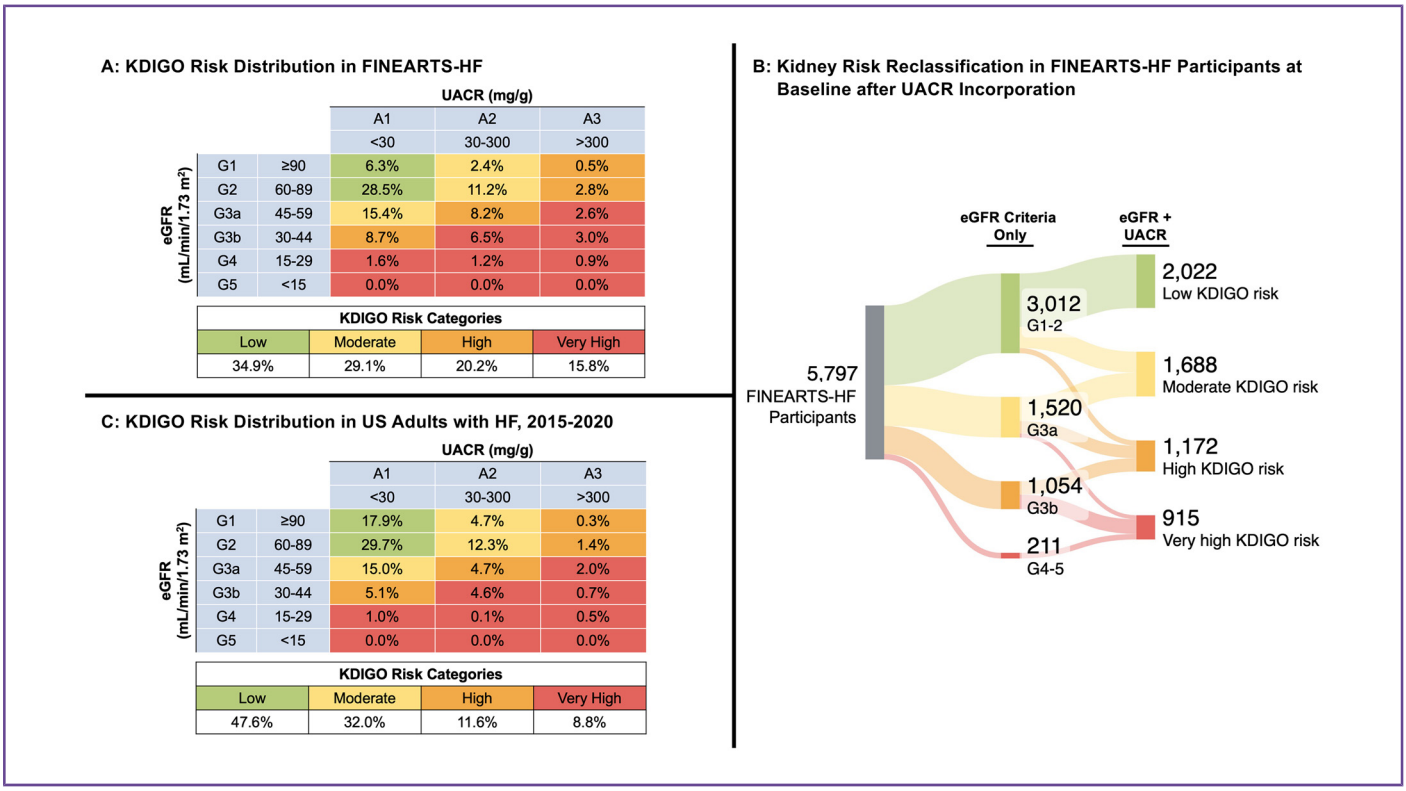

Fig. 1. Distribution of KDIGO kidney risk among FINEARTS-HF participants and U.S. adults with heart failure. A, Distributions of KDIGO kidney risk among FINEARTS-HF participants with available eGFR and UACR data (n = 5797) at baseline. B, Sankey diagram showing reclassification of KDIGO kidney risk after incorporation of eGFR and UACR, compared with eGFR stages alone. C, Distributions of KDIGO kidney risk in an NHANES (2015-March 2020) sample of U. S. adults (weighted n = 5,189,186) with HF, age ≥ 40 years, eGFR ≥ 25 mL/min/1.73 m^2, and serum potassium ≥ 5 mmol/L. eGFR, estimated glomerular filtration rate; HF, heat failure; FINEARTS-HF, Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients with Heart Failure; KDIGO, Kidney Disease: Improving Global Outcomes; NHANES, National Health and Nutrition Examination Survey; UACR, urine albumin-to-creatinine ratio.

Table 1 Baseline characteristics of FINEARTS-HF participants by KDIGO risk category at baseline

Characteristic	FINEARTS-HF KDIGO Risk Categories (n = 5797 with eGFR and UACR Data at Baseline)				
	Low Risk (n = 2002)	Moderately Increased Risk (n = 1688)	High Risk (n = 1172)	Very High Risk (n = 915)	*P* value*
Age, years	68.2 ± 9.7	72.2 ± 8.9	75.1 ± 9.0	75.4 ± 8.8	<0.001
Women	833 (41.2%)	800 (47.4%)	574 (49.0%)	422 (46.1%)	<0.001
Race					<0.001
Asian	316 (15.7%)	278 (16.5%)	207 (17.8%)	190 (20.8%)	
Black	25 (1.2%)	27 (1.6%)	18 (1.5%)	11 (1.2%)	
Other	56 (2.8%)	38 (2.3%)	37 (3.2%)	33 (3.6%)	
White	1618 (80.3%)	1342 (79.6%)	904 (77.5%)	680 (74.4%)	
Geographic Region					<0.001
Asia	312 (15.4%)	273 (16.2%)	207 (17.7%)	188 (20.5%)	
Eastern Europe	1075 (53.2%)	784 (46.4%)	440 (37.5%)	271 (29.6%)	
Latin America	218 (10.8%)	163 (9.7%)	150 (12.8%)	97 (10.6%)	
North America	112 (5.5%)	127 (7.5%)	101 (8.6%)	95 (10.4%)	
Western Europe, Oceania, Others	305 (15.1%)	341 (20.2%)	274 (23.4%)	264 (28.9%)	
History of AFF	923 (45.6%)	960 (56.9%)	749 (63.9%)	554 (60.5%)	<0.001
History of type 2 diabetes	620 (30.7%)	640 (37.9%)	539 (46.0%)	555 (60.7%)	<0.001
History of hypertension	1732 (85.7%)	1499 (88.8%)	1061 (90.5%)	849 (92.8%)	<0.001
History of myocardial infarction	574 (28.4%)	406 (24.1%)	298 (25.4%)	214 (23.4%)	0.005
History of stroke	185 (9.1%)	188 (11.1%)	154 (13.1%)	152 (16.6%)	<0.001
Baseline body mass index, kg/m^2	29.8 ± 5.9	30.2 ± 6.1	29.6 ± 6.4	30.0 ± 6.3	0.80
Prior HF hospitalization	1365 (67.5%)	1146 (67.9%)	824 (70.3%)	688 (75.2%)	<0.001
History of LVEF <40%	87 (4.3%)	72 (4.3%)	54 (4.6%)	48 (5.2%)	0.27
KCCQ, total symptom score	70.1 ± 22.4	67.4 ± 23.5	64.8 ± 24.6	62.3 ± 26.0	<0.001
NYHA Functional Class at Baseline					<0.001
II	1500 (74.2%)	1175 (69.6%)	791 (67.5%)	551 (60.2%)	
III	508 (25.1%)	506 (30.0%)	371 (31.7%)	356 (38.9%)	
IV	13 (0.6%)	7 (0.4 %)	10 (0.9%)	8 (0.9%)	
Baseline LVEF, %	52.0 ± 7.7	52.7 ± 7.9	52.9 ± 8.1	53.1 ± 7.8	<0.001
Baseline NT-proBNP, pg/mL	630 [302, 1279]	1047 [478, 1826]	1412 [682, 2439]	1789 [849, 3551]	<0.001
Baseline ECG AF	1439 (71.2%)	979 (58.0%)	63 (53.8%)	532 (58.1%)	<0.001
Baseline heart rate, beats/min	70.6 ± 11.0	71.8 ± 11.7	72.4 ± 12.4	71.8 ± 12.7	<0.001
Baseline systolic blood pressure, mmHg	128.4 ± 14.5	129.7 ± 15.3	129.2 ± 15.7	131.3 ± 16.7	<0.001
Baseline eGFR, mL/min/1.73 m^2	78.3 ± 12.0	64.3 ± 15.3	50.6 ± 14.7	37.6 ± 8.8	<0.001
Baseline eGFR <60 mL/min/1.73 m^2	0 (0.0%)	894 (53.0%)	976 (83.4%)	915 (100.0%)	<0.001
Baseline pharmacotherapy					
Beta-blocker	1725 (85.3%)	1436 (85.1%)	1008 (86.0%)	763 (83.4%)	0.40
ACEi	838 (41.4%)	595 (35.2%)	377 (32.2%)	264 (28.9%)	<0.001
ARB	814 (40.3%)	767 (45.4%)	557 (47.5%)	406 (44.4%)	0.002
ARNI	179 (8.9%)	139 (8.2%)	102 (8.7%)	76 (8.3%)	0.70
SGLT2i	202 (10.0%)	216 (12.8%)	186 (15.9%)	183 (20.0%)	<0.001
Loop diuretic	1689 (83.5%)	1447 (85.7%)	1068 (91.1%)	848 (92.7%)	<0.001

Values are n (%), mean ± SD, or median [IQR].

ACEi, angiotensin-converting enzyme inhibitor; AF, atrial fibrillation; AFF, atrial fibrillation or flutter; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; CCB, calcium channel blocker; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; FINEARTS-HF, Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients with Heart Failure; HF, heart failure; KDIGO, Kidney Disease: Improving Global Outcomes; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal prohormone of B-type natriuretic peptide; NYHA, New York Heart Association; SGLT2i, sodium-glucose co-transporter 2 inhibitor; SR, sinus rhythm; UACR, urinary albumin-to-creatinine ratio.

Between 2015 and March 2020, we identified 25,531 (weighted n, 5,189,186 [95% CI, 4,333,114−6,045,257]) U.S. adults with HF and other key FINEARTS-HF entry criteria. Of these, 48% were classified as low risk, 32% as moderately increased risk, 12% as high risk, and 9% as very high risk per KDIGO criteria (Fig. 1, C); $P < 0.001$ for comparison with the KDIGO risk distribution in FINEARTS-HF. Incorporating UACR reclassified an estimated 31% (~1.5 million U.S. adults) in the NHANES sample to ≥ 1 higher KDIGO risk categories. Among those with eGFR ≥ 60 mL/min/1.73 m^2 at baseline, UACR reclassified 28% (22% of those with eGFRs ≥ 90 mL/min/1.73 m^2) to either moderately increased or high KDIGO risk. Among those with eGFR 45−59 mL/min/1.73 m^2, UACR reclassified 31% to high KDIGO risk. Among those with eGFR 30−44, UACR reclassified 51% to very high KDIGO risk.

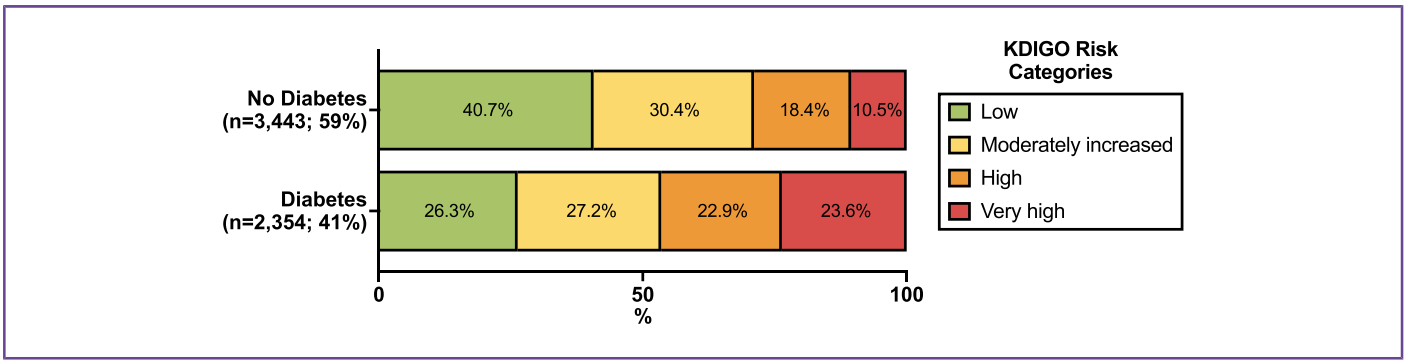

Fig. 2. Distribution of KDIGO kidney risk among FINEARTS-HF participants by diabetes status at baseline. Stacked bar graphs display distribution of KDIGO kidney risk categories among FINEARTS-HF participants with and without diabetes at baseline. FINEARTS-HF, Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients with Heart Failure; KDIGO, Kidney Disease: Improving Global Outcomes.

Discussion

FINEARTS-HF enrolled a global HFmrEF/HFpEF population exhibiting a broad range of baseline kidney risk, which, although higher-risk, overlapped substantially with an analogous population of U.S. adults with HF. Consistent with other studies,[1,3] incorporating UACR in FINEARTS-HF and NHANES reclassified kidney risk in a large number of individuals across the eGFR spectrum, amplifying the importance of this readily attainable but frequently overlooked parameter for enhancing personalized risk stratification. Finally, the proportion of individuals without diabetes and without albuminuria in the FINEARTS-HF study is noteworthy, because these populations have been excluded from prior outcomes trials that evaluated finerenone.[5]

This analysis has some limitations. First, HF subtype, natriuretic peptides and echocardiography parameters were unavailable in NHANES; lack of inclusion of these elements may have contributed to differences in kidney risk compared with FINEARTS-HF. Second, cystatin C and markers of kidney damage other than UACR were unavailable. Hence, there is potential for KDIGO risk misclassification. Third, generalizability to other global populations may be limited.

Conclusion

FINEARTS-HF will evaluate the safety and efficacy of finerenone across a wide and largely representative spectrum of kidney risk. Incorporating UACR reclassified kidney risk in approximately 1 in 3 FINEARTS-HF participants and U.S. adults with HF, emphasizing the importance of albuminuria as part of comprehensive risk assessment in the HF population.

Disclosures

RA reports receiving grants from the Bristol Myers Squibb Pfizer alliance, serving as a consultant for Lexicon Pharmaceuticals and an unpaid research collaboration with Novartis, all outside the submitted work. BLC reports personal fees from Alnylam, personal fees from Cardior, Cardurion, Corvia, Cytokinetics, CVRx, Intellia, and Rocket, outside the submitted work. ASD has received honoraria for consulting or speaking from Abbott, AstraZeneca, Alnylam, Avidity Biopharma, Axon Therapeutics, Bayer, Biofourmis, Boston Scientific, GlaxoSmithKline, Medpace, Medtronic, Merck, New Amsterdam Pharma, Novartis, Parexel, Regeneron, River2Renal, Roche, scPharmaceuticals, Verily, Veristat, and Zydus and has received institutional research grant support from Abbott, Alnylam, AstraZeneca, Bayer, Novartis, and Pfizer. PSJ reports receiving speaker fees from Novartis and AstraZeneca, Alkem metabolomics, Sun Pharmaceuticals and ProAdWise Communications and his employer, University of Glasgow has been paid for his time working on clinical trials by Novartis, AstraZeneca, Bayer and NovoNordisk, and grants from Analog Devices Inc, Boehringer Ingelheim, and Roche Diagnostics outside the submitted work, Director GCTP Ltd. CSPL is supported by a Clinician Scientist Award from the National Medical Research Council of Singapore; has received research support from Novo Nordisk and Roche Diagnostics, has served as consultant to or on the advisory board/steering committee/ executive committee for Alleviant Medical, Allysta Pharma, AnaCardio AB, Applied Therapeutics, AstraZeneca, Bayer, Biopeutics, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, CardioRenal, CPC Clinical Research, Eli Lilly, Impulse Dynamics, Intellia Therapeutics, Ionis Pharmaceutical, Janssen Research & Development, Medscape/WebMD Global, Merck, Novartis, Novo Nordisk, Prosciento, Quidel Corporation, Radcliffe Group, Recardio, ReCor Medical, Roche Diagnostics, Sanofi, Siemens Healthcare Diagnostics and Us2.ai, and serves as cofounder and nonexecutive director of Us2.ai. BP has served as a consultant for Bayer, AstraZeneca, Bristol Meyers Squibb, Boehringer Ingelheim, Lexicon, Anacardia, and G3 Pharmaceuticvals and has served as a consultant and received stock options or stocks from Sea Star Medical, Vifor, Scpharmaceuticals, SQinnovations, KBP

Biosciences, Sarfez, Cereno Scientific, Prointel, and Brainstorm Medical; holds a U.S. patent (9931412-site specific delivery of Eplerenone to the myocardium) and has a U.S. patent pending (63/045,783 Histone Modulating agents for the prevention and treatment of organ damage). MS reports personal fees from Novartis, Bayer, Vifor, Abbott, AstraZeneca, Merck, Boehringer Ingelheim, Novo Nordisk, MSD, and Cardurion outside the submitted work. SJS reports personal fees from Bayer during the conduct of the study. The employer of AAV received consultancy fees and/or research support from Adrenomed, Anacardio, AstraZeneca, Bayer AG, BMS, Boehringer Ingelheim, Corteria, EliLilly, Merck, Moderna, Novartis, Novo Nordisk, Roche diagnostics, SalubrisBio. FZ reports steering committee fees during the conduct of the study, personal fees from Boehringer, BMS, CVRx, Cardior, Cereno, Cellprothera, Merck, Owkin, Roche, and Northsea outside the submitted work and stock options at G3Pharmaceutical and equities at Cereno, Cardiorenal, Eshmoun Clinical and is a researchr and founder of CVCT. JL-F is a full-time employee of Bayer and reports personal fees from Bayer outside the submitted work. PV reports that he is a full-time employee of Bayer Pharmaceuticals. JJVM reports payments to his employer, Glasgow University, from Bayer, time spent as coprincipal investigator of the FINEARTS trial with finerenone; other fees from AstraZeneca, Amgen, Cardurion, Cytokinetics, Glaxo Smith Kline, KBP Biosciences, Novartis, and personal fees from George Clinical PTY, Abbott, Alkem Metabolics, AstraZeneca, Blue Ocean Scientific Solutions, Boehringer Ingelheim, Canadian Medical and Surgical Knowledge, Emcure Pharmaceuticals, Eris Lifesciences, European Academy of CME, Hikma Pharmaceuticals, Imagica Health, Intas Pharmaceuticals, J.B. Chemicals & Pharmaceuticals, Lupin Pharmaceuticals, Medscape/Heart.Org., ProAdWise Communications, Radcliffe Cardiology, Sun Pharmaceuticals, The Corpus, Translation Research Group, Translational Medicine Academy, Global Clinical Trial Partners , Alnylam Pharmaceuticals, Bayer, BMS, Ionis Pharmaceuticals, Novartis, Regeneron Pharmaceuticals, and River 2 Renal outside the submitted work. SDS has received research grants from Alexion, Alnylam, AstraZeneca, Bellerophon, Bayer, BMS, Boston Scientific, Cytokinetics, Edgewise, Eidos, Gossamer, GSK, Ionis, Eli Lilly, MyoKardia, NIH/NHLBI, Novartis, Novo Nordisk, Respicardia, Sanofi Pasteur, Theracos, US2.AI and has consulted for Abbott, Action, Akros, Alexion, Alnylam, Amgen, Arena, AstraZeneca, Bayer, Boehringer-Ingelheim, BMS, Cardior, Cardurion, Corvia, Cytokinetics, Daiichi-Sankyo, GSK, Lilly, Merck, Myokardia, Novartis, Roche, Theracos, Quantum Genomics, Janssen, Cardiac Dimensions, Tenaya, Sanofi-Pasteur, Dinaqor, Tremeau, CellProThera, Moderna, American Regent, Sarepta, Lexicon, Anacardio, Akros, and Valo. MV has received research grant support, served on advisory boards or had speaker engagements with American Regent, Amgen, AstraZeneca, Bayer AG, Baxter Healthcare, BMS, Boehringer Ingelheim, Chiesi, Cytokinetics, Lexicon Pharmaceuticals, Merck, Novartis, Novo Nordisk, Pharmacosmos, Relypsa, Roche Diagnostics, Sanofi, and Tricog Health and participates in clinical trial committees for studies sponsored by AstraZeneca, Galmed, Novartis, Bayer AG, Occlutech, and Impulse Dynamics. JWO has nothing to disclose.

CRediT authorship contribution statement

JOHN W. OSTROMINSKI: Conceptualization, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **RAHUL AGGARWAL:** Conceptualization, Formal analysis, Methodology, Writing – review & editing. **BRIAN L. CLAGGETT:** Formal analysis, Methodology, Writing – review & editing. **IAN J. KULAC:** Formal analysis, Methodology, Writing – review & editing. **AKSHAY S. DESAI:** Writing – review & editing. **PARDEEP S. JHUND:** Writing – review & editing. **CAROLYN S.P. LAM:** Writing – review & editing. **BERTRAM PITT:** Writing – review & editing. **MICHELE SENNI:** Writing – review & editing. **SANJIV J. SHAH:** Writing – review & editing. **ADRIAAN A. VOORS:** Writing – review & editing. **FAIEZ ZANNAD:** Writing – review & editing. **JAMES LAY-FLURRIE:** Writing – review & editing. **PRABHAKAR VISWANATHAN:** Writing – review & editing. **JOHN J.V. MCMURRAY:** Writing – review & editing. **SCOTT D. SOLOMON:** Funding acquisition, Methodology, Supervision, Writing – review & editing. **MUTHIAH VADUGANATHAN:** Conceptualization, Methodology, Supervision, Writing – review & editing.

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