Generalizability of the FINEARTS-HF Trial to the US Population across the Spectrum of Kidney Risk

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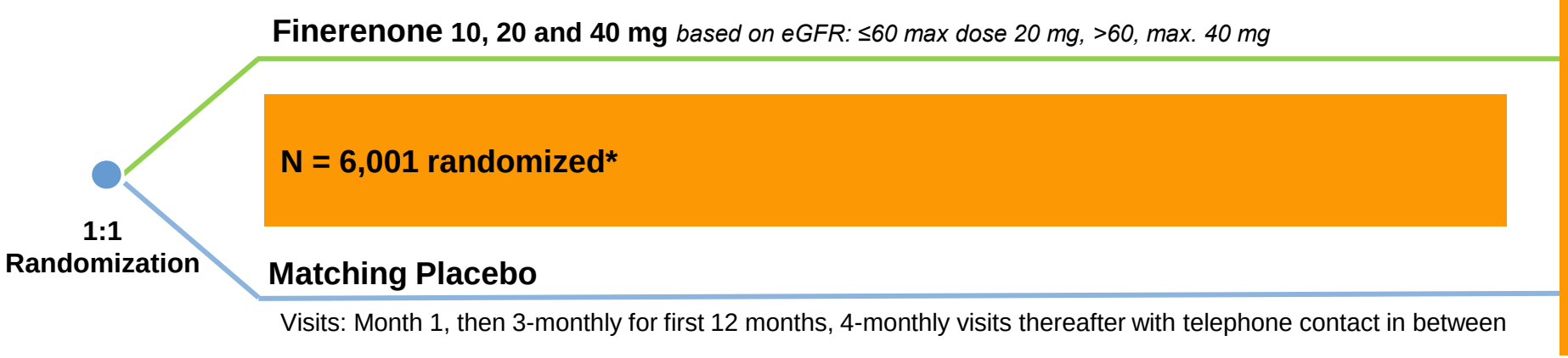
FINEARTS-HF

FINerenone trial to investigate **E**fficacy and s**A**fety superio**R** to placebo in pa**T**ient**S** with **H**eart **F**ailure

FINEARTS-HF Design, Endpoints & Eligibility Criteria

FINEARTS-HF designed to evaluate the efficacy and safety of finerenone in patients with HF and LVEF ≥40%, with or without diabetes, and across a broad range of renal function



Study Endpoints

Primary Endpoint

- CV death and total HF events (hospitalizations/urgent visits)

Secondary Endpoints

- Total HF events
- NYHA class at 12 months
- KCCQ-TSS at 6,9, and 12 months
- Renal composite endpoint
- All-cause mortality

Key Inclusion Criteria

- **Symptomatic HF (NYHA class II-V) with LVEF ≥ 40%**
  - *LVEF ≥ 60% capped at 20%*
- **Hospitalized, Recently Hospitalized, or Ambulatory**
- **Elevated Natriuretic Peptide Levels (300/900 AF)**
- **Structural Heart Disease (LA Enlargement or LVH)**
- **Diuretics in the 30d prior to randomization**

Key Exclusion Criteria

- **Potassium > 5.0 mmol/L; eGFR <25 mL/min/1.73 m²**
- **MRA use 30d prior to randomization**
- **MI or PCI 30d prior to randomization**
- **Cardiogenic shock**
- **History of dilated, peripartum, chemotherapy induced, or infiltrative cardiomyopathy (e.g., amyloidosis)**
- **Alternative causes of signs or symptoms**

*validly randomized patients

FINEARTS-HF

Comparison of KDIGO Kidney Risk Distribution in FINEARTS-HF & US Population

FINEARTS-HF

eGFR (mL/min/1.73 m²)			UACR (mg/g) A1 <30	A2 30-300	A3 >300
G1	≥90		6.3%	2.4%	0.5%
G2	60-89		28.5%	11.2%	2.8%
G3a	45-59		15.4%	8.2%	2.6%
G3b	30-44		8.7%	6.5%	3.0%
G4	15-29		1.6%	1.2%	0.9%
G5	<15		0.0%	0.0%	0.0%

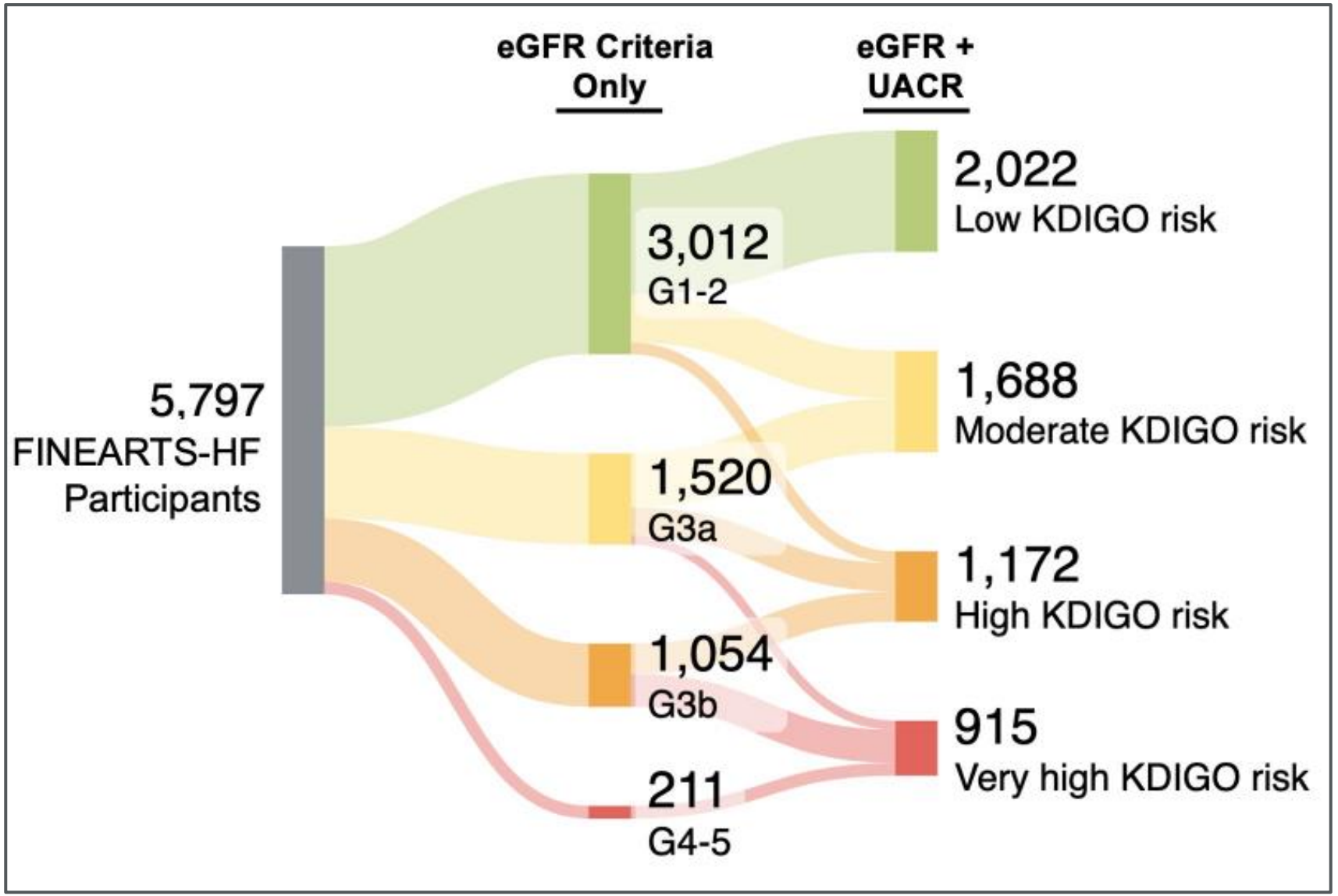
KDIGO Risk Categories			
Low	Moderate	High	Very High
34.9%	29.1%	20.2%	15.8%

US Population (NHANES 2015-2020)

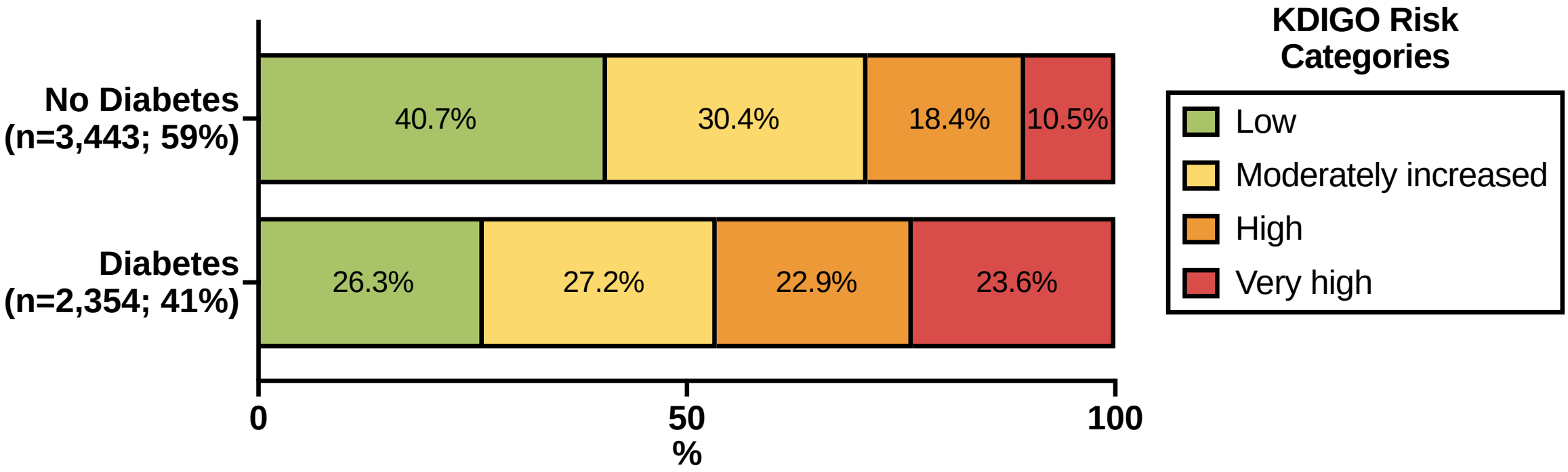
eGFR (mL/min/1.73 m²)			UACR (mg/g) A1 <30	A2 30-300	A3 >300
G1	≥90		17.9%	4.7%	0.3%
G2	60-89		29.7%	12.3%	1.4%
G3a	45-59		15.0%	4.7%	2.0%
G3b	30-44		5.1%	4.6%	0.7%
G4	15-29		1.0%	0.1%	0.5%
G5	<15		0.0%	0.0%	0.0%

KDIGO Risk Categories			
Low	Moderate	High	Very High
47.6%	32.0%	11.6%	8.8%

Importance of UACR Testing in Kidney Risk Estimation in HF



Distribution of KDIGO Kidney Risk Among FINEARTS-HF Participants by Diabetes Status



Conclusions

- 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 US adults with HF, emphasizing the importance of albuminuria as part of comprehensive risk assessment in the HF population.

FINEARTS-HF

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