Real-World Effectiveness and Safety of Finerenone in Patients With CKD and Type 2 Diabetes in the United States: *A FOUNTAIN Platform Analysis*

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Background

Chronic kidney disease (CKD) and type 2 diabetes (T2D) occur together frequently and are associated with substantial cardiovascular and renal morbidity.

Finerenone is an oral, selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA); US FDA approval: 09 July 2021.

Pivotal trials have demonstrated cardiovascular and renal efficacy of finerenone. Real-world evidence on effectiveness and safety is lacking.

This study was conducted within the **F**inerenOne m**U**lti-database **N**e**T**work for evidence gener**A**t**I**o**N** (FOUNTAIN) research program.

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Study Objectives

Research Objective: *To evaluate the effectiveness and safety of finerenone in adults with CKD and T2D initiating finerenone compared with that in patients with CKD and T2D not using finerenone.*

1

Primary objective

Composite cardiovascular outcome (fatal or nonfatal acute myocardial infarction and/or hospitalization for heart failure)

2

Secondary objectives

Acute myocardial infarction (fatal/nonfatal)

Hospitalization for heart failure

New-onset heart failure

Hyperkalemia (safety outcome)

3

Exploratory objective

All-cause mortality

CKD = chronic kidney disease; T2D = type 2 diabetes.

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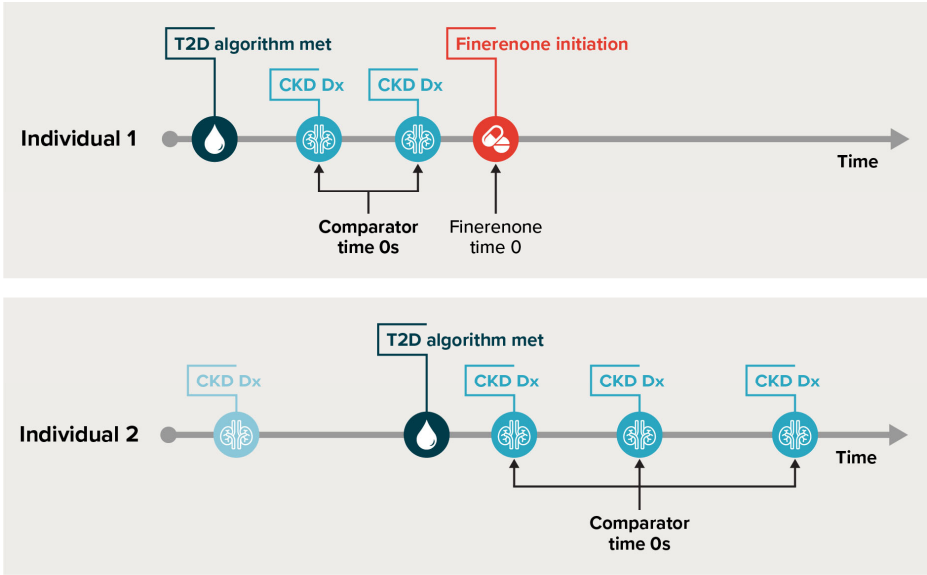
Methods – Study Design and Setting

Study population and data source	Adults in the US with CKD and T2D in the HealthVerity CKD Masterset
Study period	09 Jul 2021 (finerenone approval) to 31 Mar 2025
Treatment groups	New-user study design comparing finerenone initiators and nonusers
Study entry and Time 0	Finerenone initiator group • Date of first observed prescription Nonuser group • Dates with an outpatient/professional provider encounter with a recorded diagnosis of CKD • Multiple Time 0s per individual allowed
Statistical analysis	• Propensity score matched cohort • Estimate IPCW HRs

Schematic of treated and untreated Time 0s



CKD = chronic kidney disease; D_x = diagnosis; IPCW = inverse probability of censoring weighting; HR = hazard ratios; T2D = type 2 diabetes; US = United States.

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Select Baseline Characteristics

After propensity score matching

Characteristic	Finerenone initiators (N = 14,287)	Finerenone nonusers (N = 57,148)	ASD
Age, mean (SD)	66.1 (12.42)	66.1 (12.32)	0.0014
Male (%)	52.6	52.8	0.0043
eGFR, mean (SD)	55.7 (21.88)	56.2 (21.64)	0.0261
Mean uACR (SD)	775.4 (1,316.80)	685.4 (1,219.17)	0.0709
Proteinuria (%)	56.5	56.3	0.0035
Nephrotic syndrome (%)	20.3	19.2	0.0299
Congestive heart failure (%)	27.8	27.7	0.0018
GLP-1 RA (%)	35.2	35.2	< 0.0001
SGLT2i (%)	59.6	60.0	0.0085
Insulin (%)	35.7	36.2	0.0096
ACEi/ARB (%)	84.7	85.8	0.0310
Statins (%)	84.3	85.1	0.0226

ACEi = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ASD = absolute standardized difference; eGFR = estimated glomerular filtration rate; GLP-1 RA = glucagon-like peptide-1 receptor agonist; SD = standard deviation; SGLT2i = sodium-glucose cotransporter 2 inhibitor; uACR = urine albumin-to-creatinine ratio.

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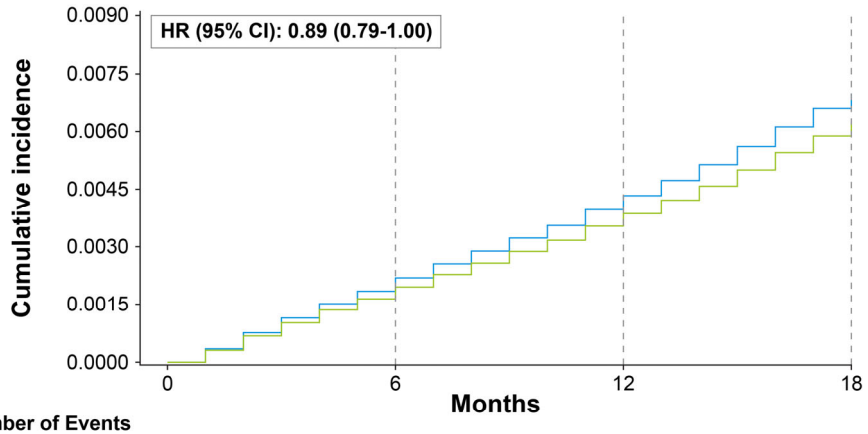
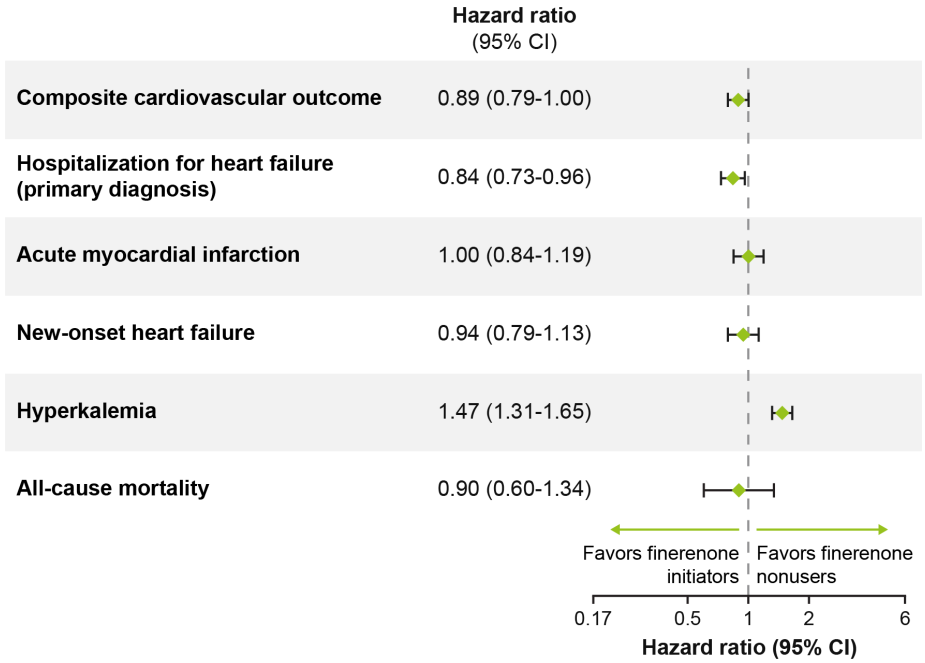
Main Results

Cumulative incidence of composite cardiovascular outcome (primary outcome)



Number of Events				
Finerenone nonuser	0	1,417	2,216	2,686
Finerenone initiator	0	264	351	411

Forest plot of hazard ratios for all outcomes



CI = confidence interval; HR = hazard ratio.
Note: Cumulative incidence and hazard ratios were estimated from the matched and an inverse probability of censoring weighted cohort.

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Strengths and Limitations

Strengths

- Large real-world data set using linked claims, electronic medical records, and laboratory data
- New-user design
- Propensity score matching
- Evaluation of both effectiveness and safety outcomes

Limitations

- Exposure misclassification: dispensed prescription does not reflect actual patient use
- Despite use of validated algorithms, potential for outcome misclassification
- Systematic differences between initiators and nonusers from unmeasured confounding

Conclusions

- In US adults with CKD and T2D in routine care, finerenone initiation was associated with:
  - Lower risk of composite cardiovascular events, primarily heart failure hospitalization
  - Higher risk of hyperkalemia compared with no treatment
- Results from this study are consistent with those observed in clinical trials.
- Findings support real-world effectiveness of finerenone for cardiovascular outcomes in patients with CKD and T2D while underscoring the importance of safety monitoring.

Thank you

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