Dossier zur Nutzenbewertung gemäß § 35a SGB V

Finerenon (KERENDIA®)

Bayer Vital GmbH

Modul 4A, Anhang H

Erwachsene mit einer symptomatischen chronischen Herzinsuffizienz und LVEF ≥40%

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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Sex, n (%)	Male	1648 (54.88)	1621 (54.07)
	Female	1355 (45.12)	1377 (45.93)
Age	n (missing)	3003 (0)	2998 (0)
	Mean (SD)	71.9 (9.60)	72.0 (9.69)
	Geo.Mean (SD)	71.3 (1.15)	71.3 (1.15)
	Median	73.0	73.0
	Q1, Q3	66.0, 79.0	66.0, 79.0
	Min, Max	40.0, 96.0	40.0, 97.0
Age group (years), n (%)	40 - < 65 years	643 (21.41)	619 (20.65)
	65 - < 75 years	1074 (35.76)	1107 (36.92)
	75 - < 85 years	1060 (35.30)	1030 (34.36)
	>= 85 years	226 (7.53)	242 (8.07)
Age group (years), n (%)	< 65 years	643 (21.41)	619 (20.65)
	65 - < 75 years	1074 (35.76)	1107 (36.92)
	75 - < 85 years	1060 (35.30)	1030 (34.36)
	>= 85 years	226 (7.53)	242 (8.07)
Race, n (%)	White	2366 (78.79)	2369 (79.02)
	Black Or African American	49 (1.63)	39 (1.30)
	Asian	497 (16.55)	499 (16.64)
	American Indian Or Alaska Native	75 (2.50)	74 (2.47)
	Native Hawaiian Or Other Pacific Islander	1 (0.03)	0 (0.00)
	Not Reported	8 (0.27)	9 (0.30)
	Multiple	7 (0.23)	8 (0.27)
Pooled Race Group 01, n (%)	White	2366 (78.79)	2369 (79.02)
	Black	49 (1.63)	39 (1.30)
	Asian	497 (16.55)	499 (16.64)
	Other	91 (3.03)	91 (3.04)
Region (pooled region for stratified analysis), n (%)	Western Europe and Oceania	290 (9.66)	298 (9.94)
	Southwestern Europe	334 (11.12)	334 (11.14)
	Central Europe	498 (16.58)	496 (16.54)
	Southeastern Europe	424 (14.12)	420 (14.01)
	Northeastern Europe	407 (13.55)	405 (13.51)
	Asia	493 (16.42)	490 (16.34)
	North America	235 (7.83)	236 (7.87)
	Latin America	322 (10.72)	319 (10.64)
Region (pooled region for subgroup analysis), n (%)	Western Europe, Oceania and Others	624 (20.78)	632 (21.08)
	Eastern Europe	1329 (44.26)	1321 (44.06)
	Asia	493 (16.42)	490 (16.34)
	North America	235 (7.83)	236 (7.87)
	Latin America	322 (10.72)	319 (10.64)
Baseline Body Mass Index (kg/m2)	n (missing)	2996 (7)	2992 (6)
	Mean (SD)	29.9 (6.10)	30.0 (6.13)
	Geo.Mean (SD)	29.3 (1.22)	29.4 (1.22)
	Median	29.1	29.3
	Q1, Q3	25.5, 33.6	25.6, 33.7
	Min, Max	15.2, 65.1	13.5, 50.2
Baseline BMI (kg/m2) category 2, n (%)	< 30 kg/m2	1658 (55.21)	1638 (54.64)
	>= 30 kg/m2	1338 (44.56)	1354 (45.16)
	Missing	7 (0.23)	6 (0.20)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Smoking History, n (%)	Never	1828 (60.87)	1869 (62.34)
	Former	913 (30.40)	880 (29.35)
	Current	262 (8.72)	249 (8.31)
Alcohol Use, n (%)	Abstinent	2102 (70.00)	2074 (69.18)
	Light	811 (27.01)	805 (26.85)
	Moderate	89 (2.96)	116 (3.87)
	Heavy	1 (0.03)	3 (0.10)
Baseline eGFR (mL/min/1.73m2)	n (missing)	3003 (0)	2998 (0)
	Mean (SD)	61.9 (19.42)	62.3 (20.04)
	Geo.Mean (SD)	58.7 (1.40)	58.8 (1.42)
	Median	60.9	61.0
	Q1, Q3	46.8, 76.1	46.8, 77.8
	Min, Max	19.9, 118.2	4.3, 133.2
Baseline eGFR (mL/min/1.73 m2) category, n (%)	< 60 mL/min/1.73m2	1451 (48.32)	1437 (47.93)
	>= 60 mL/min/1.73m2	1552 (51.68)	1561 (52.07)
Baseline potassium (mmol/L)	n (missing)	3003 (0)	2998 (0)
	Mean (SD)	4.4 (0.48)	4.4 (0.47)
	Geo.Mean (SD)	4.4 (1.12)	4.3 (1.11)
	Median	4.4	4.4
	Q1, Q3	4.1, 4.7	4.1, 4.7
	Min, Max	2.6, 7.3	2.9, 7.3
Baseline serum potassium (mmol/L) category, n (%)	<= 4.5 mmol/L	1969 (65.57)	1958 (65.31)
	> 4.5 mmol/L	1034 (34.43)	1040 (34.69)
Baseline UACR (mg/g)	n (missing)	2901 (102)	2896 (102)
	Mean (SD)	160.8 (615.06)	162.1 (607.38)
	Geo.Mean (SD)	24.7 (5.53)	24.9 (5.54)
	Median	18.0	19.0
	Q1, Q3	7.0, 67.0	7.0, 66.5
	Min, Max	0.8, 10135.0	1.0, 11451.0
Baseline albuminuria (mg/g) category, n (%)	Normalbuminuria (UACR < 30 mg/g)	1765 (58.77)	1746 (58.24)
	High albuminuria (30 mg/g - < 300 mg/g)	844 (28.11)	868 (28.95)
	Very high albuminuria (>= 300 mg/g)	292 (9.72)	282 (9.41)
	Missing	102 (3.40)	102 (3.40)
Atrial fibrill. at BL electrocardiogram, n (%)	present	1165 (38.79)	1128 (37.63)
	absent	1838 (61.21)	1870 (62.37)
Baseline Hemoglobin A1C (%)	n (missing)	2952 (51)	2936 (62)
	Mean (SD)	6.4 (1.22)	6.4 (1.16)
	Geo.Mean (SD)	6.3 (1.18)	6.3 (1.18)
	Median	6.1	6.1
	Q1, Q3	5.7, 6.7	5.7, 6.7
	Min, Max	3.7, 13.6	3.9, 13.7
Baseline Diastolic Blood Pressure (mmHg)	n (missing)	3002 (1)	2997 (1)
	Mean (SD)	75.6 (10.28)	75.4 (10.42)
	Geo.Mean (SD)	74.8 (1.15)	74.6 (1.15)
	Median	76.0	75.5
	Q1, Q3	69.0, 82.5	69.0, 82.5
	Min, Max	38.5, 122.5	38.0, 119.0

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Baseline Systolic Blood Pressure (mmHg)	n (missing)	3002 (1)	2997 (1)
	Mean (SD)	129.5 (15.35)	129.3 (15.30)
	Geo.Mean (SD)	128.5 (1.13)	128.4 (1.13)
	Median	130.0	129.5
	Q1, Q3	119.5, 140.0	119.5, 139.5
	Min, Max	80.5, 180.5	74.0, 181.0

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

Endpoint		Finerenone (N=1066)	Placebo (N=1068)
Sex, n (%)	Male	625 (58.63)	615 (57.58)
	Female	441 (41.37)	453 (42.42)
Age	n (missing)	1066 (0)	1068 (0)
	Mean (SD)	73.4 (9.89)	73.9 (9.84)
	Geo.Mean (SD)	72.7 (1.15)	73.2 (1.15)
	Median	75.0	75.0
	Q1, Q3	68.0, 81.0	68.0, 81.0
	Min, Max	41.0, 96.0	40.0, 95.0
Age group (years), n (%)	40 - < 65 years	199 (18.67)	176 (16.48)
	65 - < 75 years	319 (29.92)	335 (31.37)
	75 - < 85 years	429 (40.24)	425 (39.79)
	>= 85 years	119 (11.16)	132 (12.36)
Age group (years), n (%)	< 65 years	199 (18.67)	176 (16.48)
	65 - < 75 years	319 (29.92)	335 (31.37)
	75 - < 85 years	429 (40.24)	425 (39.79)
	>= 85 years	119 (11.16)	132 (12.36)
Race, n (%)	White	680 (63.79)	680 (63.67)
	Black Or African American	23 (2.16)	24 (2.25)
	Asian	362 (33.96)	362 (33.90)
	American Indian Or Alaska Native	0 (0.00)	0 (0.00)
	Native Hawaiian Or Other Pacific Islander	0 (0.00)	0 (0.00)
	Not Reported	0 (0.00)	0 (0.00)
	Multiple	1 (0.09)	2 (0.19)
Pooled Race Group 01, n (%)	White	680 (63.79)	680 (63.67)
	Black	23 (2.16)	24 (2.25)
	Asian	362 (33.96)	362 (33.90)
	Other	1 (0.09)	2 (0.19)
Region (pooled region for stratified analysis), n (%)	Western Europe and Oceania	56 (5.25)	60 (5.62)
	Southwestern Europe	289 (27.11)	289 (27.06)
	Central Europe	129 (12.10)	130 (12.17)
	Southeastern Europe	0 (0.00)	0 (0.00)
	Northeastern Europe	0 (0.00)	0 (0.00)
	Asia	358 (33.58)	356 (33.33)
	North America	234 (21.95)	233 (21.82)
	Latin America	0 (0.00)	0 (0.00)
Region (pooled region for subgroup analysis), n (%)	Western Europe, Oceania and Others	345 (32.36)	349 (32.68)
	Eastern Europe	129 (12.10)	130 (12.17)
	Asia	358 (33.58)	356 (33.33)
	North America	234 (21.95)	233 (21.82)
	Latin America	0 (0.00)	0 (0.00)
Baseline Body Mass Index (kg/m2)	n (missing)	1061 (5)	1065 (3)
	Mean (SD)	28.6 (6.30)	28.5 (6.20)
	Geo.Mean (SD)	28.0 (1.24)	27.9 (1.24)
	Median	27.7	27.5
	Q1, Q3	24.2, 32.3	24.1, 32.4
	Min, Max	15.2, 65.1	13.5, 49.9
Baseline BMI (kg/m2) category 2, n (%)	< 30 kg/m2	688 (64.54)	688 (64.42)
	>= 30 kg/m2	373 (34.99)	377 (35.30)
	Missing	5 (0.47)	3 (0.28)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

Endpoint		Finerenone (N=1066)	Placebo (N=1068)
Smoking History, n (%)	Never	584 (54.78)	627 (58.71)
	Former	382 (35.83)	363 (33.99)
	Current	100 (9.38)	78 (7.30)
Alcohol Use, n (%)	Abstinent	761 (71.39)	755 (70.69)
	Light	255 (23.92)	251 (23.50)
	Moderate	50 (4.69)	60 (5.62)
	Heavy	0 (0.00)	2 (0.19)
Baseline eGFR (mL/min/1.73m2)	n (missing)	1066 (0)	1068 (0)
	Mean (SD)	60.0 (19.00)	59.4 (20.13)
	Geo.Mean (SD)	56.9 (1.39)	55.8 (1.44)
	Median	58.6	57.3
	Q1, Q3	45.2, 73.6	43.9, 74.4
	Min, Max	23.9, 111.5	4.3, 115.8
Baseline eGFR (mL/min/1.73 m2) category, n (%)	< 60 mL/min/1.73m2	557 (52.25)	581 (54.40)
	>= 60 mL/min/1.73m2	509 (47.75)	487 (45.60)
Baseline potassium (mmol/L)	n (missing)	1066 (0)	1068 (0)
	Mean (SD)	4.3 (0.44)	4.3 (0.46)
	Geo.Mean (SD)	4.3 (1.11)	4.3 (1.11)
	Median	4.3	4.3
	Q1, Q3	4.0, 4.6	4.0, 4.6
	Min, Max	2.6, 5.9	2.9, 6.1
Baseline serum potassium (mmol/L) category, n (%)	<= 4.5 mmol/L	753 (70.64)	745 (69.76)
	> 4.5 mmol/L	313 (29.36)	323 (30.24)
Baseline UACR (mg/g)	n (missing)	1030 (36)	1016 (52)
	Mean (SD)	147.7 (464.39)	163.3 (579.96)
	Geo.Mean (SD)	26.8 (5.36)	29.4 (5.26)
	Median	19.0	25.0
	Q1, Q3	8.0, 79.0	8.0, 79.5
	Min, Max	0.8, 5117.0	1.0, 7398.8
Baseline albuminuria (mg/g) category, n (%)	Normalbuminuria (UACR < 30 mg/g)	609 (57.13)	554 (51.87)
	High albuminuria (30 mg/g - < 300 mg/g)	318 (29.83)	363 (33.99)
	Very high albuminuria (>= 300 mg/g)	103 (9.66)	99 (9.27)
	Missing	36 (3.38)	52 (4.87)
Atrial fibrill. at BL electrocardiogram, n (%)	present	406 (38.09)	414 (38.76)
	absent	660 (61.91)	654 (61.24)
Baseline Hemoglobin A1C (%)	n (missing)	1045 (21)	1043 (25)
	Mean (SD)	6.4 (1.11)	6.4 (1.07)
	Geo.Mean (SD)	6.3 (1.17)	6.3 (1.16)
	Median	6.1	6.1
	Q1, Q3	5.7, 6.7	5.7, 6.8
	Min, Max	3.7, 12.5	4.3, 13.1
Baseline Diastolic Blood Pressure (mmHg)	n (missing)	1065 (1)	1067 (1)
	Mean (SD)	73.1 (10.98)	73.4 (11.10)
	Geo.Mean (SD)	72.3 (1.16)	72.5 (1.17)
	Median	72.5	73.0
	Q1, Q3	65.0, 80.0	65.5, 80.5
	Min, Max	38.5, 111.5	38.0, 111.5

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

Endpoint		Finerenone (N=1066)	Placebo (N=1068)
Baseline Systolic Blood Pressure (mmHg)	n (missing)	1065 (1)	1067 (1)
	Mean (SD)	127.8 (17.13)	128.3 (16.77)
	Geo.Mean (SD)	126.7 (1.15)	127.2 (1.14)
	Median	128.0	128.0
	Q1, Q3	115.0, 140.0	117.5, 140.0
	Min, Max	80.5, 180.5	74.0, 181.0

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Observation Duration of All-Cause Mortality in months	Number of patients in analysis	3003	2998
	Mean (SD)	29.7 (9.61)	29.5 (9.65)
	Median	32.5	32.2
	Min, Max	0.0, 43.9	0.1, 43.9
Observation Duration of CV death and HHF in months	Number of patients in analysis	3003	2998
	Mean (SD)	27.4 (11.25)	26.9 (11.60)
	Median	30.6	30.1
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of CV death or non-fatal CV event in months	Number of patients in analysis	3003	2998
	Mean (SD)	26.6 (11.58)	26.5 (11.77)
	Median	29.8	29.7
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Cardiovascular Death in months	Number of patients in analysis	3003	2998
	Mean (SD)	29.5 (9.73)	29.4 (9.74)
	Median	32.2	32.1
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Composite endpoint of CV death and total HF event in months	Number of patients in analysis	3003	2998
	Mean (SD)	27.2 (11.37)	26.5 (11.85)
	Median	30.3	29.9
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis in months	Number of patients in analysis	3003	2998
	Mean (SD)	26.4 (12.10)	26.2 (12.13)
	Median	29.8	29.3
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Heart Failure (Urgent Visit) in months	Number of patients in analysis	3003	2998
	Mean (SD)	29.1 (10.08)	28.8 (10.32)
	Median	32.0	31.7
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of New onset of atrial fibrillation in months	Number of patients in analysis	1355	1373
	Mean (SD)	29.1 (10.06)	29.2 (10.18)
	Median	32.5	32.2
	Min, Max	0.0, 43.2	0.0, 43.9
Observation Duration of PGI01-Change in months	Number of patients in analysis	937	919
	Mean (SD)	11.5 (1.52)	11.6 (1.51)
	Median	12.0	12.0
	Min, Max	5.5, 14.0	5.3, 13.9
Observation Duration of PGIB01-Severity in months	Number of patients in analysis	1066	1068
	Mean (SD)	10.1 (4.03)	10.0 (4.24)
	Median	12.0	11.9
	Min, Max	0.0, 14.0	0.0, 13.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary in months	Number of patients in analysis	3000	2996
	Mean (SD)	26.3 (12.26)	26.0 (12.41)
	Median	29.9	29.7

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary in months	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary in months	Number of patients in analysis	3000	2996
	Mean (SD)	26.3 (12.26)	26.0 (12.41)
	Median	29.9	29.7
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation in months	Number of patients in analysis	2989	2985
	Mean (SD)	26.1 (12.31)	25.9 (12.39)
	Median	29.9	29.5
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life in months	Number of patients in analysis	3000	2996
	Mean (SD)	26.3 (12.26)	26.0 (12.41)
	Median	29.9	29.7
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation in months	Number of patients in analysis	2952	2946
	Mean (SD)	25.9 (12.36)	25.7 (12.36)
	Median	29.5	29.0
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom in months	Number of patients in analysis	3000	2996
	Mean (SD)	26.3 (12.26)	26.0 (12.41)
	Median	29.9	29.7
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to Heart Failure Hospitalization in months	Number of patients in analysis	3003	2998
	Mean (SD)	27.4 (11.25)	26.9 (11.60)
	Median	30.6	30.1
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to all-cause hospitalization in months	Number of patients in analysis	3003	2998
	Mean (SD)	21.6 (13.09)	21.0 (13.15)
	Median	22.3	21.5
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first CV hospitalization in months	Number of patients in analysis	3003	2998
	Mean (SD)	25.7 (11.94)	25.2 (12.27)
	Median	28.6	28.1
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first myocardial infarction (combined fatal and non-fatal) in months	Number of patients in analysis	3003	2998
	Mean (SD)	29.1 (10.10)	29.2 (9.91)
	Median	32.0	32.0
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Number of patients in analysis	3003	2998
	Mean (SD)	21.7 (13.09)	21.1 (13.14)
	Median	22.5	21.6

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=3003)	Placebo (N=2998)
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) in months	Number of patients in analysis	3003	2998
	Mean (SD)	25.5 (12.08)	25.1 (12.33)
	Median	28.3	28.0
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first stroke (combined fatal and non-fatal) in months	Number of patients in analysis	3003	2998
	Mean (SD)	29.0 (10.02)	29.1 (9.98)
	Median	31.9	31.9
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to first sustained eGFR decline by =25% to <30 mL/min/1.73m2 or <15 mL/min/1.73m2 relative to baseline. in months	Number of patients in analysis	3003	2998
	Mean (SD)	25.9 (12.33)	26.0 (12.22)
	Median	29.2	29.0
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to initiation of dialysis or renal transplantation in months	Number of patients in analysis	3003	2998
	Mean (SD)	26.4 (12.09)	26.3 (12.11)
	Median	29.9	29.5
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks in months	Number of patients in analysis	3003	2998
	Mean (SD)	26.4 (12.10)	26.2 (12.12)
	Median	29.8	29.3
	Min, Max	0.0, 43.9	0.0, 43.9
Observation Duration of VAS in months	Number of patients in analysis	3000	2992
	Mean (SD)	26.3 (12.26)	26.0 (12.38)
	Median	29.9	29.7
	Min, Max	0.0, 43.9	0.0, 43.9
Study Duration in months	Number of patients in analysis	3003	2998
	Mean (SD)	30.2 (9.91)	30.1 (9.94)
	Median	33.1	32.9
	Min, Max	0.0, 45.0	0.0, 44.8
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks in months	Number of patients in analysis	3003	2998
	Mean (SD)	26.4 (12.09)	26.3 (12.11)
	Median	29.8	29.5
	Min, Max	0.0, 43.9	0.0, 43.9

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

Endpoint		Finerenone (N=2993)	Placebo (N=2993)
Observation Duration of Treatment Duration in months	Number of patients in analysis	2993	2993
	Mean (SD)	25.2 (12.42)	25.3 (12.35)
	Median	28.1	28.1
	Min, Max	0.0, 43.9	0.0, 43.9

Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
All-cause mortality
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	491/ 3003 (16.35)	522/ 2998 (17.41)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (41.4, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.83, 1.06)	
p-value	0.2794	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.83, 1.06)	
p-value	0.2890	

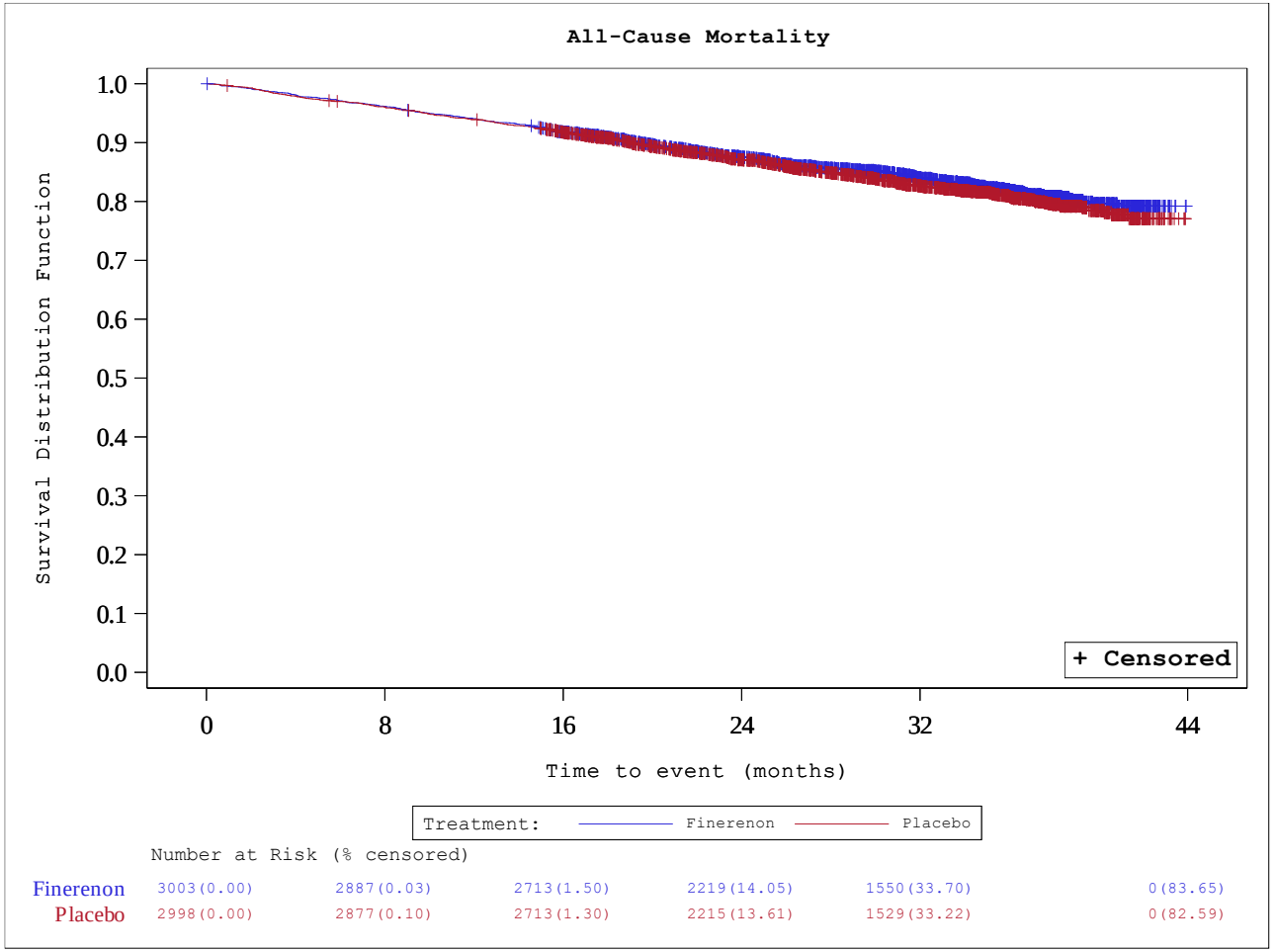
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
All-cause mortality - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.8230
Male	290/ 1648 (17.60)	NE (NE, NE)	304/ 1621 (18.75)	NE (NE, NE)	0.92 (0.79, 1.08)	0.3251	
Female	201/ 1355 (14.83)	NE (NE, NE)	218/ 1377 (15.83)	NE (NE, NE)	0.95 (0.78, 1.15)	0.5972	
Region							0.4849
Western Europe, Oceania and Others	110/ 624 (17.63)	NE (NE, NE)	117/ 632 (18.51)	NE (NE, NE)	0.94 (0.72, 1.22)	0.6363	
Eastern Europe	213/ 1329 (16.03)	NE (NE, NE)	210/ 1321 (15.90)	NE (NE, NE)	1.01 (0.84, 1.23)	0.8946	
Asia	71/ 493 (14.40)	NE (NE, NE)	84/ 490 (17.14)	NE (NE, NE)	0.84 (0.61, 1.15)	0.2621	
North America	40/ 235 (17.02)	NE (NE, NE)	55/ 236 (23.31)	NE (NE, NE)	0.69 (0.46, 1.03)	0.0676	
Latin America	57/ 322 (17.70)	NE (NE, NE)	56/ 319 (17.55)	NE (NE, NE)	1.03 (0.71, 1.48)	0.8892	
Age group (years)							0.6161
<= median in FAS	202/ 1589 (12.71)	NE (NE, NE)	207/ 1579 (13.11)	NE (NE, NE)	0.97 (0.80, 1.18)	0.7726	
> median in FAS	289/ 1414 (20.44)	NE (NE, NE)	315/ 1419 (22.20)	NE (NE, NE)	0.91 (0.78, 1.07)	0.2534	
NYHA class at baseline							0.4793
II	284/ 2081 (13.65)	NE (NE, NE)	310/ 2065 (15.01)	NE (NE, NE)	0.90 (0.77, 1.06)	0.2211	
III/IV	207/ 921 (22.48)	NE (NE, NE)	212/ 933 (22.72)	NE (NE, NE)	0.99 (0.82, 1.20)	0.9220	
LVEF at baseline							0.6784
< 50%	192/ 1093 (17.57)	NE (NE, NE)	201/ 1079 (18.63)	NE (NE, NE)	0.94 (0.77, 1.14)	0.5194	
>= 50% - < 60%	202/ 1329 (15.20)	NE (NE, NE)	228/ 1345 (16.95)	NE (NE, NE)	0.89 (0.74, 1.08)	0.2264	
>= 60%	96/ 575 (16.70)	NE (NE, NE)	93/ 572 (16.26)	NE (NE, NE)	1.04 (0.78, 1.38)	0.8106	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of All-cause mortality
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
CV death
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	242/ 3003 (8.06)	260/ 2998 (8.67)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.78, 1.11)	
p-value	0.4120	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.78, 1.10)	
p-value	0.3993	

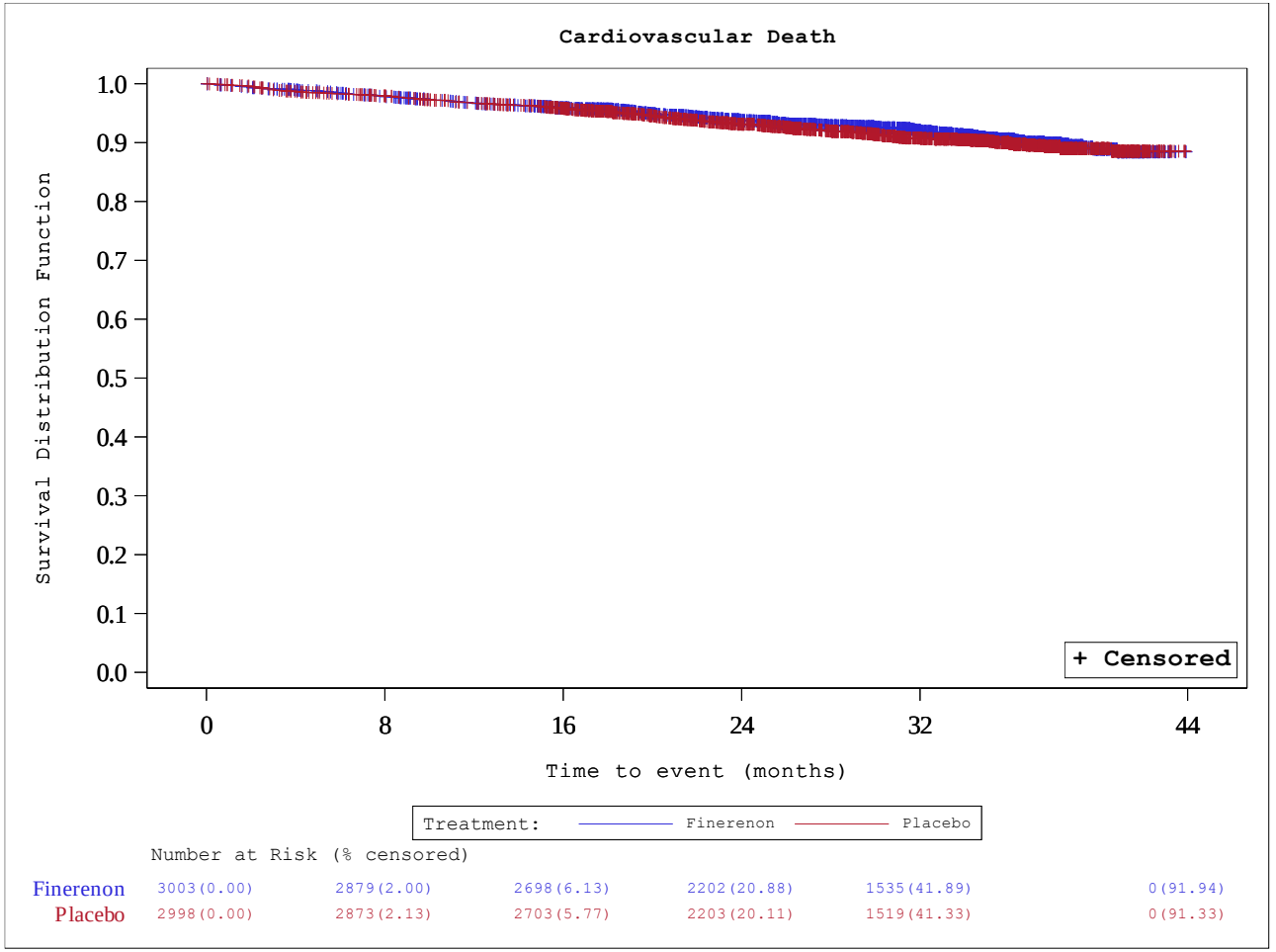
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
CV death - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5994
Male	149/ 1648 (9.04)	NE (NE, NE)	150/ 1621 (9.25)	NE (NE, NE)	0.96 (0.76, 1.20)	0.7197	
Female	93/ 1355 (6.86)	NE (NE, NE)	110/ 1377 (7.99)	NE (NE, NE)	0.87 (0.66, 1.15)	0.3280	
Region							0.7268
Western Europe, Oceania and Others	54/ 624 (8.65)	NE (NE, NE)	53/ 632 (8.39)	NE (NE, NE)	1.02 (0.70, 1.50)	0.8989	
Eastern Europe	109/ 1329 (8.20)	NE (NE, NE)	113/ 1321 (8.55)	NE (NE, NE)	0.97 (0.74, 1.26)	0.7926	
Asia	39/ 493 (7.91)	NE (NE, NE)	39/ 490 (7.96)	NE (NE, NE)	0.99 (0.63, 1.54)	0.9529	
North America	15/ 235 (6.38)	NE (NE, NE)	19/ 236 (8.05)	NE (NE, NE)	0.75 (0.38, 1.47)	0.4019	
Latin America	25/ 322 (7.76)	NE (NE, NE)	36/ 319 (11.29)	NE (NE, NE)	0.70 (0.42, 1.17)	0.1744	
Age group (years)							0.9654
<= median in FAS	112/ 1589 (7.05)	NE (NE, NE)	120/ 1579 (7.60)	NE (NE, NE)	0.93 (0.72, 1.21)	0.5886	
> median in FAS	130/ 1414 (9.19)	NE (NE, NE)	140/ 1419 (9.87)	NE (NE, NE)	0.92 (0.73, 1.17)	0.5196	
NYHA class at baseline							0.8620
II	140/ 2081 (6.73)	NE (NE, NE)	151/ 2065 (7.31)	NE (NE, NE)	0.92 (0.73, 1.16)	0.4668	
III/IV	102/ 921 (11.07)	NE (NE, NE)	109/ 933 (11.68)	NE (NE, NE)	0.95 (0.72, 1.24)	0.6953	
LVEF at baseline							0.6622
< 50%	103/ 1093 (9.42)	NE (NE, NE)	119/ 1079 (11.03)	NE (NE, NE)	0.85 (0.65, 1.10)	0.2154	
>= 50% - < 60%	93/ 1329 (7.00)	NE (NE, NE)	96/ 1345 (7.14)	NE (NE, NE)	0.98 (0.73, 1.30)	0.8698	
>= 60%	46/ 575 (8.00)	NE (NE, NE)	45/ 572 (7.87)	NE (NE, NE)	1.03 (0.68, 1.55)	0.8930	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of CV death
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite endpoint of CV death and total HF event
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	624/ 3003 (20.78)	719/ 2998 (23.98)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	39.4 (35.6, NE)	32.1 (29.5, 35.7)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.76, 0.94)	
p-value	0.0020	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.85 (0.76, 0.94)	
p-value	0.0025	

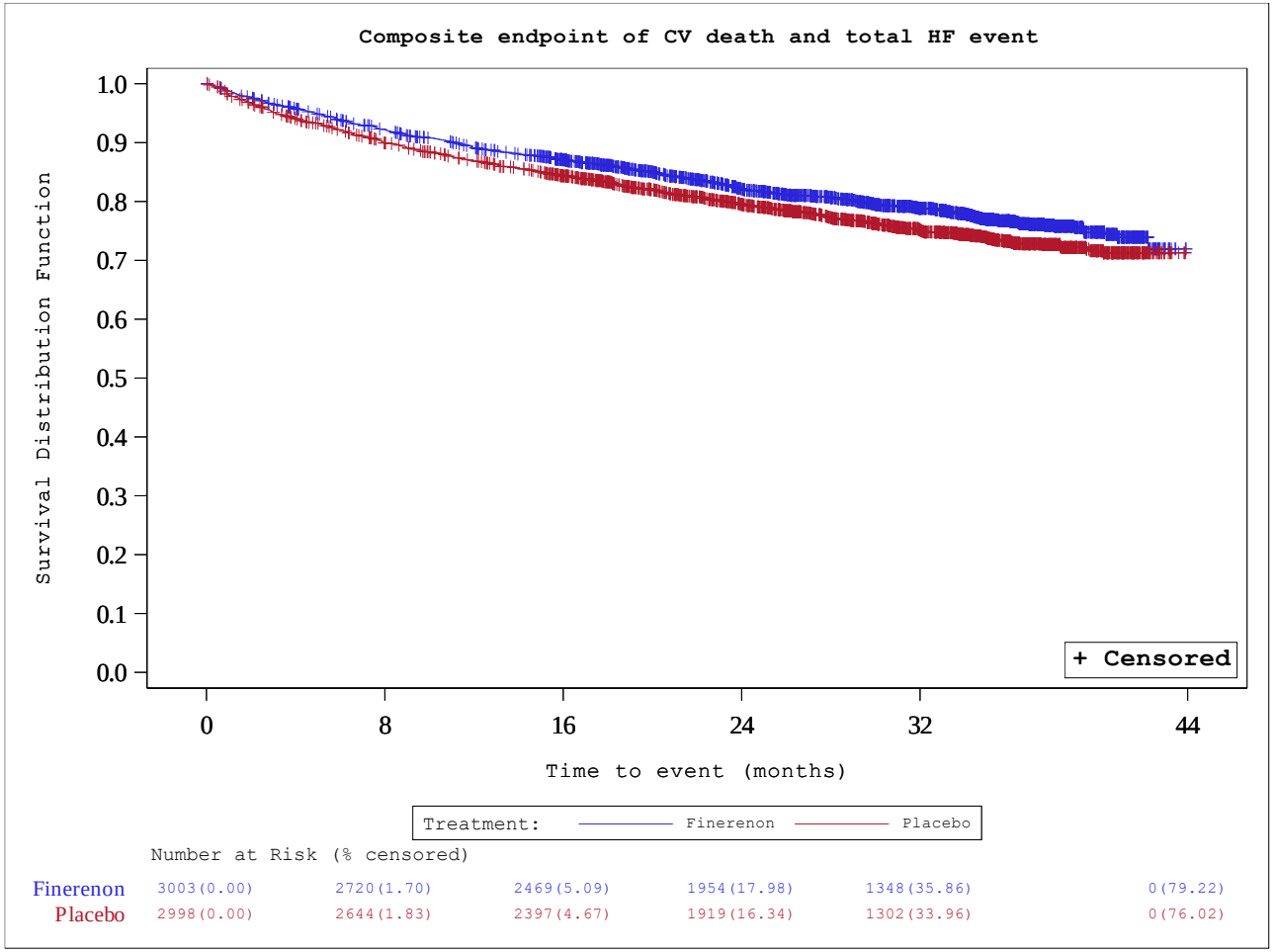
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; HF=heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite endpoint of CV death and total HF event - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5741
Male	358/ 1648 (21.72)	NE (NE, NE)	392/ 1621 (24.18)	NE (NE, NE)	0.87 (0.75, 1.00)	0.0572	
Female	266/ 1355 (19.63)	NE (NE, NE)	327/ 1377 (23.75)	NE (NE, NE)	0.82 (0.70, 0.96)	0.0148	
Region							0.4534
Western Europe, Oceania and Others	171/ 624 (27.40)	NE (42.2, NE)	195/ 632 (30.85)	NE (NE, NE)	0.86 (0.70, 1.06)	0.1491	
Eastern Europe	213/ 1329 (16.03)	NE (NE, NE)	244/ 1321 (18.47)	NE (NE, NE)	0.86 (0.72, 1.03)	0.1094	
Asia	117/ 493 (23.73)	NE (NE, NE)	123/ 490 (25.10)	NE (NE, NE)	0.95 (0.73, 1.22)	0.6647	
North America	63/ 235 (26.81)	NE (NE, NE)	69/ 236 (29.24)	NE (39.6, NE)	0.84 (0.60, 1.19)	0.3306	
Latin America	60/ 322 (18.63)	NE (NE, NE)	88/ 319 (27.59)	NE (NE, NE)	0.64 (0.46, 0.89)	0.0070	
Age group (years)							0.2820
<= median in FAS	278/ 1589 (17.50)	NE (NE, NE)	338/ 1579 (21.41)	NE (NE, NE)	0.80 (0.68, 0.93)	0.0050	
> median in FAS	346/ 1414 (24.47)	NE (NE, NE)	381/ 1419 (26.85)	NE (NE, NE)	0.90 (0.77, 1.04)	0.1397	
NYHA class at baseline							0.6698
II	375/ 2081 (18.02)	NE (NE, NE)	437/ 2065 (21.16)	NE (NE, NE)	0.83 (0.73, 0.96)	0.0095	
III/IV	249/ 921 (27.04)	NE (NE, NE)	282/ 933 (30.23)	NE (NE, NE)	0.88 (0.74, 1.04)	0.1265	
LVEF at baseline							0.6414
< 50%	243/ 1093 (22.23)	NE (NE, NE)	291/ 1079 (26.97)	NE (NE, NE)	0.79 (0.67, 0.94)	0.0078	
>= 50% - < 60%	269/ 1329 (20.24)	NE (NE, NE)	303/ 1345 (22.53)	NE (NE, NE)	0.88 (0.75, 1.04)	0.1334	
>= 60%	112/ 575 (19.48)	NE (NE, NE)	125/ 572 (21.85)	NE (NE, NE)	0.89 (0.69, 1.14)	0.3509	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular; HF=heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite endpoint of CV death and total HF event
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	599/ 3003 (19.95)	664/ 2998 (22.15)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	40.9 (38.0, NE)	36.1 (32.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.79, 0.99)	
p-value	0.0304	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.79, 0.99)	
p-value	0.0335	

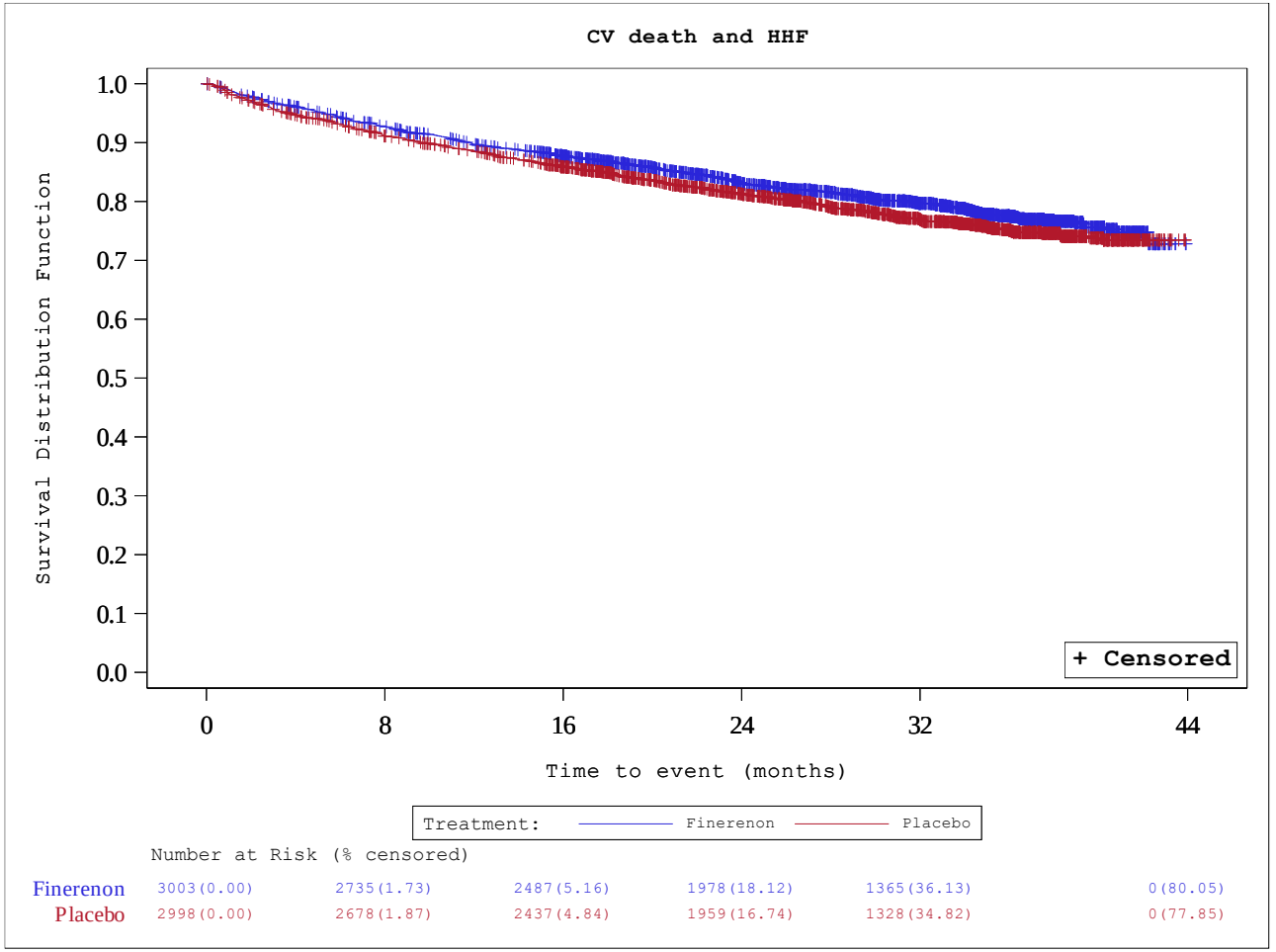
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; HHF=hospitalization for heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.5367
Male	345/ 1648 (20.93)	NE (NE, NE)	362/ 1621 (22.33)	NE (NE, NE)	0.91 (0.79, 1.06)	0.2317	
Female	254/ 1355 (18.75)	NE (NE, NE)	302/ 1377 (21.93)	NE (NE, NE)	0.85 (0.72, 1.01)	0.0588	
Region							0.4665
Western Europe, Oceania and Others	164/ 624 (26.28)	NE (42.2, NE)	172/ 632 (27.22)	NE (NE, NE)	0.95 (0.77, 1.18)	0.6673	
Eastern Europe	208/ 1329 (15.65)	NE (NE, NE)	234/ 1321 (17.71)	NE (NE, NE)	0.88 (0.73, 1.06)	0.1777	
Asia	112/ 493 (22.72)	NE (NE, NE)	116/ 490 (23.67)	NE (NE, NE)	0.96 (0.74, 1.25)	0.7608	
North America	57/ 235 (24.26)	NE (NE, NE)	60/ 236 (25.42)	NE (39.6, NE)	0.88 (0.61, 1.26)	0.4814	
Latin America	58/ 322 (18.01)	NE (NE, NE)	82/ 319 (25.71)	NE (NE, NE)	0.67 (0.48, 0.94)	0.0185	
Age group (years)							0.2947
<= median in FAS	272/ 1589 (17.12)	NE (NE, NE)	318/ 1579 (20.14)	NE (NE, NE)	0.83 (0.71, 0.98)	0.0285	
> median in FAS	327/ 1414 (23.13)	NE (NE, NE)	346/ 1419 (24.38)	NE (NE, NE)	0.94 (0.81, 1.09)	0.4121	
NYHA class at baseline							0.8713
II	357/ 2081 (17.16)	NE (NE, NE)	396/ 2065 (19.18)	NE (NE, NE)	0.88 (0.76, 1.02)	0.0857	
III/IV	242/ 921 (26.28)	NE (NE, NE)	268/ 933 (28.72)	NE (NE, NE)	0.90 (0.76, 1.07)	0.2336	
LVEF at baseline							0.6676
< 50%	234/ 1093 (21.41)	NE (NE, NE)	269/ 1079 (24.93)	NE (NE, NE)	0.83 (0.70, 0.99)	0.0420	
>= 50% - < 60%	256/ 1329 (19.26)	NE (NE, NE)	280/ 1345 (20.82)	NE (NE, NE)	0.91 (0.77, 1.08)	0.3007	
>= 60%	109/ 575 (18.96)	NE (NE, NE)	115/ 572 (20.10)	NE (NE, NE)	0.94 (0.73, 1.23)	0.6588	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular; HHF=hospitalization for heart failure;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite endpoint of CV death and HF hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to Heart Failure Hospitalization
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	450/ 3003 (14.99)	514/ 2998 (17.14)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (42.2, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.76, 0.97)	
p-value	0.0179	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.76, 0.98)	
p-value	0.0206	

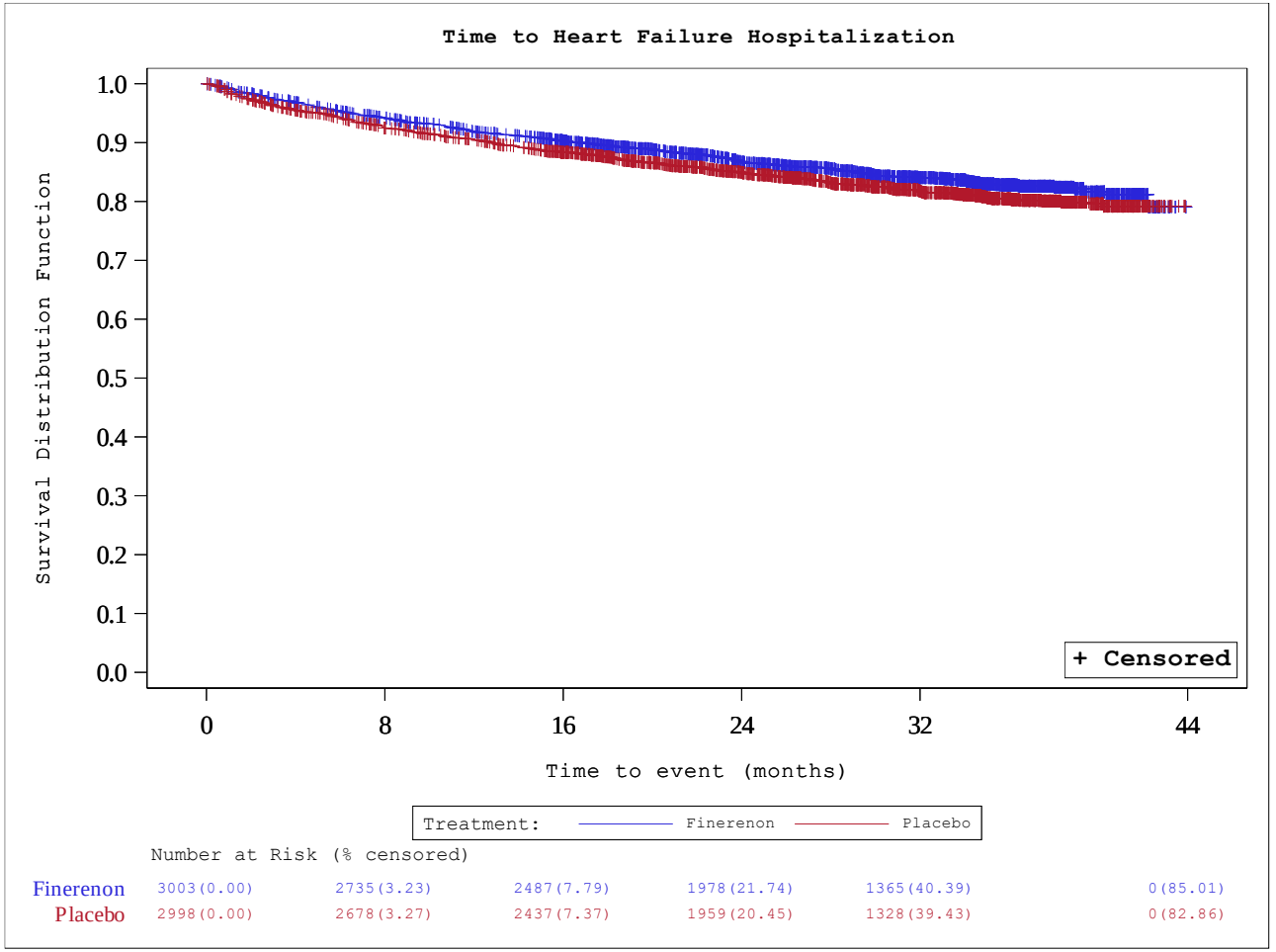
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to Heart Failure Hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.9602
Male	251/ 1648 (15.23)	NE (NE, NE)	279/ 1621 (17.21)	NE (NE, NE)	0.86 (0.73, 1.02)	0.0912	
Female	199/ 1355 (14.69)	NE (NE, NE)	235/ 1377 (17.07)	NE (NE, NE)	0.86 (0.71, 1.04)	0.1102	
Region							0.5560
Western Europe, Oceania and Others	138/ 624 (22.12)	NE (42.2, NE)	150/ 632 (23.73)	NE (NE, NE)	0.92 (0.73, 1.16)	0.4847	
Eastern Europe	131/ 1329 (9.86)	NE (NE, NE)	161/ 1321 (12.19)	NE (NE, NE)	0.81 (0.64, 1.01)	0.0651	
Asia	89/ 493 (18.05)	NE (NE, NE)	94/ 490 (19.18)	NE (NE, NE)	0.94 (0.70, 1.26)	0.6861	
North America	51/ 235 (21.70)	NE (NE, NE)	50/ 236 (21.19)	NE (39.6, NE)	0.94 (0.64, 1.39)	0.7658	
Latin America	41/ 322 (12.73)	NE (NE, NE)	59/ 319 (18.50)	NE (NE, NE)	0.66 (0.44, 0.98)	0.0390	
Age group (years)							0.1429
<= median in FAS	191/ 1589 (12.02)	NE (NE, NE)	240/ 1579 (15.20)	NE (NE, NE)	0.78 (0.64, 0.94)	0.0090	
> median in FAS	259/ 1414 (18.32)	NE (NE, NE)	274/ 1419 (19.31)	NE (NE, NE)	0.94 (0.79, 1.11)	0.4664	
NYHA class at baseline							0.6932
II	266/ 2081 (12.78)	NE (NE, NE)	308/ 2065 (14.92)	NE (NE, NE)	0.85 (0.72, 1.00)	0.0443	
III/IV	184/ 921 (19.98)	NE (NE, NE)	206/ 933 (22.08)	NE (NE, NE)	0.89 (0.73, 1.09)	0.2597	
LVEF at baseline							0.6141
< 50%	164/ 1093 (15.00)	NE (NE, NE)	196/ 1079 (18.16)	NE (NE, NE)	0.80 (0.65, 0.99)	0.0385	
>= 50% - < 60%	206/ 1329 (15.50)	NE (NE, NE)	223/ 1345 (16.58)	NE (NE, NE)	0.92 (0.76, 1.12)	0.4092	
>= 60%	80/ 575 (13.91)	NE (NE, NE)	95/ 572 (16.61)	NE (NE, NE)	0.84 (0.62, 1.13)	0.2463	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to Heart Failure (Urgent Visit)
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	73/ 3003 (2.43)	113/ 2998 (3.77)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.63 (0.47, 0.85)	
p-value	0.0019	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.64 (0.48, 0.86)	
p-value	0.0027	

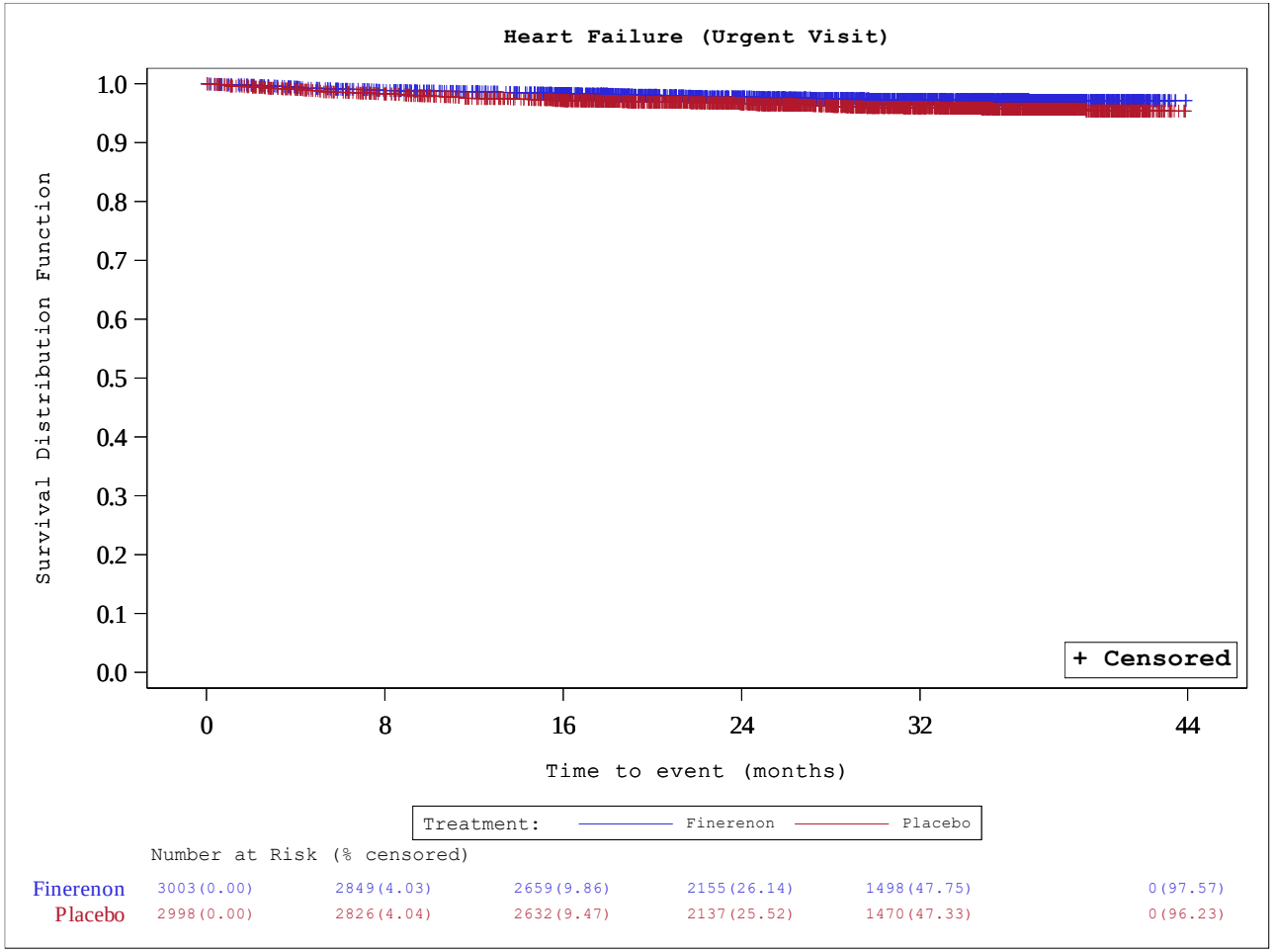
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to Heart Failure (Urgent Visit) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.2806
Male	41/ 1648 (2.49)	NE (NE, NE)	53/ 1621 (3.27)	NE (NE, NE)	0.75 (0.50, 1.13)	0.1661	
Female	32/ 1355 (2.36)	NE (NE, NE)	60/ 1377 (4.36)	NE (NE, NE)	0.54 (0.35, 0.83)	0.0044	
Region							0.3227
Western Europe, Oceania and Others	30/ 624 (4.81)	NE (NE, NE)	48/ 632 (7.59)	NE (NE, NE)	0.62 (0.39, 0.97)	0.0366	
Eastern Europe	8/ 1329 (0.60)	NE (NE, NE)	19/ 1321 (1.44)	NE (NE, NE)	0.42 (0.18, 0.96)	0.0335	
Asia	12/ 493 (2.43)	NE (NE, NE)	17/ 490 (3.47)	NE (NE, NE)	0.70 (0.33, 1.46)	0.3366	
North America	16/ 235 (6.81)	NE (NE, NE)	13/ 236 (5.51)	NE (NE, NE)	1.20 (0.58, 2.50)	0.6188	
Latin America	7/ 322 (2.17)	NE (NE, NE)	16/ 319 (5.02)	NE (NE, NE)	0.43 (0.18, 1.04)	0.0530	
Age group (years)							0.3000
<= median in FAS	23/ 1589 (1.45)	NE (NE, NE)	44/ 1579 (2.79)	NE (NE, NE)	0.52 (0.31, 0.86)	0.0090	
> median in FAS	50/ 1414 (3.54)	NE (NE, NE)	69/ 1419 (4.86)	NE (NE, NE)	0.72 (0.50, 1.03)	0.0734	
NYHA class at baseline							0.7842
II	49/ 2081 (2.35)	NE (NE, NE)	73/ 2065 (3.54)	NE (NE, NE)	0.66 (0.46, 0.95)	0.0235	
III/IV	24/ 921 (2.61)	NE (NE, NE)	40/ 933 (4.29)	NE (NE, NE)	0.61 (0.37, 1.01)	0.0500	
LVEF at baseline							0.7554
< 50%	24/ 1093 (2.20)	NE (NE, NE)	42/ 1079 (3.89)	NE (NE, NE)	0.56 (0.34, 0.92)	0.0197	
>= 50% - < 60%	36/ 1329 (2.71)	NE (NE, NE)	54/ 1345 (4.01)	NE (NE, NE)	0.67 (0.44, 1.02)	0.0592	
>= 60%	13/ 575 (2.26)	NE (NE, NE)	17/ 572 (2.97)	NE (NE, NE)	0.76 (0.37, 1.57)	0.4586	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure (Urgent Visit)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	885/ 3003 (29.47)	951/ 2998 (31.72)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	23.6 (21.4, 25.4)	21.2 (19.3, 23.3)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.84, 1.00)	
p-value	0.0583	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.84, 1.00)	
p-value	0.0591	

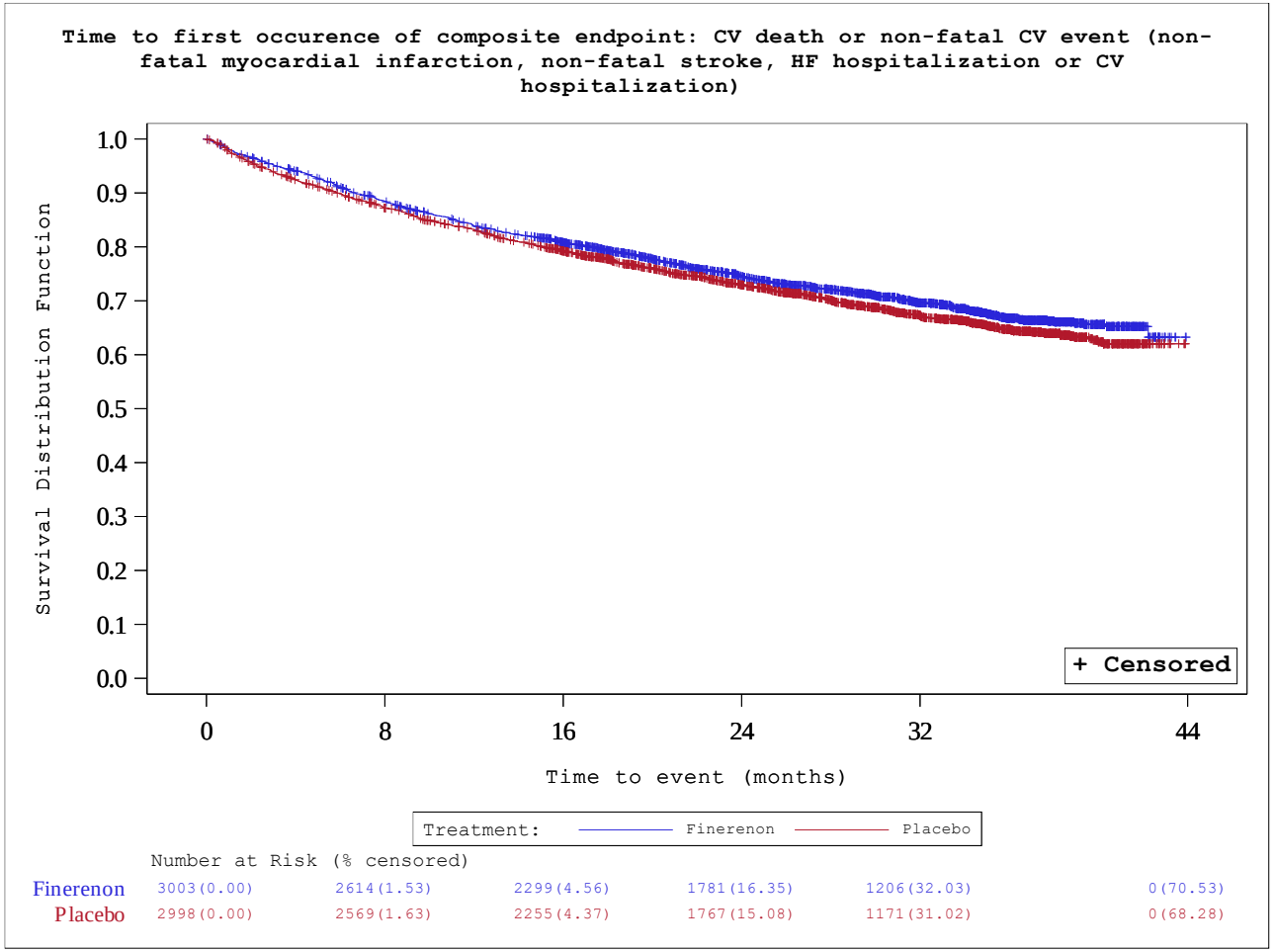
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.4752
Male	512/ 1648 (31.07)	NE (NE, NE)	523/ 1621 (32.26)	NE (NE, NE)	0.94 (0.83, 1.06)	0.3362	
Female	373/ 1355 (27.53)	NE (NE, NE)	428/ 1377 (31.08)	NE (NE, NE)	0.88 (0.77, 1.01)	0.0725	
Region							0.1078
Western Europe, Oceania and Others	215/ 624 (34.46)	42.2 (42.2, NE)	225/ 632 (35.60)	NE (NE, NE)	0.97 (0.80, 1.16)	0.7106	
Eastern Europe	348/ 1329 (26.19)	NE (NE, NE)	353/ 1321 (26.72)	NE (NE, NE)	0.98 (0.84, 1.13)	0.7763	
Asia	164/ 493 (33.27)	NE (NE, NE)	188/ 490 (38.37)	NE (40.2, NE)	0.85 (0.69, 1.04)	0.1146	
North America	83/ 235 (35.32)	NE (NE, NE)	78/ 236 (33.05)	38.9 (34.8, NE)	1.04 (0.76, 1.41)	0.8237	
Latin America	75/ 322 (23.29)	NE (NE, NE)	107/ 319 (33.54)	NE (38.3, NE)	0.65 (0.48, 0.87)	0.0039	
Age group (years)							0.1372
<= median in FAS	428/ 1589 (26.94)	NE (NE, NE)	486/ 1579 (30.78)	NE (NE, NE)	0.86 (0.75, 0.97)	0.0183	
> median in FAS	457/ 1414 (32.32)	NE (42.2, NE)	465/ 1419 (32.77)	NE (NE, NE)	0.98 (0.86, 1.12)	0.7872	
NYHA class at baseline							0.9873
II	549/ 2081 (26.38)	NE (NE, NE)	589/ 2065 (28.52)	NE (NE, NE)	0.91 (0.81, 1.03)	0.1311	
III/IV	335/ 921 (36.37)	NE (NE, NE)	362/ 933 (38.80)	NE (39.6, NE)	0.92 (0.79, 1.06)	0.2564	
LVEF at baseline							0.6342
< 50%	329/ 1093 (30.10)	NE (NE, NE)	364/ 1079 (33.73)	NE (NE, NE)	0.87 (0.75, 1.02)	0.0778	
>= 50% - < 60%	379/ 1329 (28.52)	NE (42.2, NE)	411/ 1345 (30.56)	NE (NE, NE)	0.92 (0.80, 1.05)	0.2240	
>= 60%	175/ 575 (30.43)	NE (NE, NE)	176/ 572 (30.77)	NE (NE, NE)	0.99 (0.80, 1.22)	0.9269	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	99/ 3003 (3.30)	82/ 2998 (2.74)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.21 (0.91, 1.63)	
p-value	0.1948	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.21 (0.90, 1.62)	
p-value	0.2010	

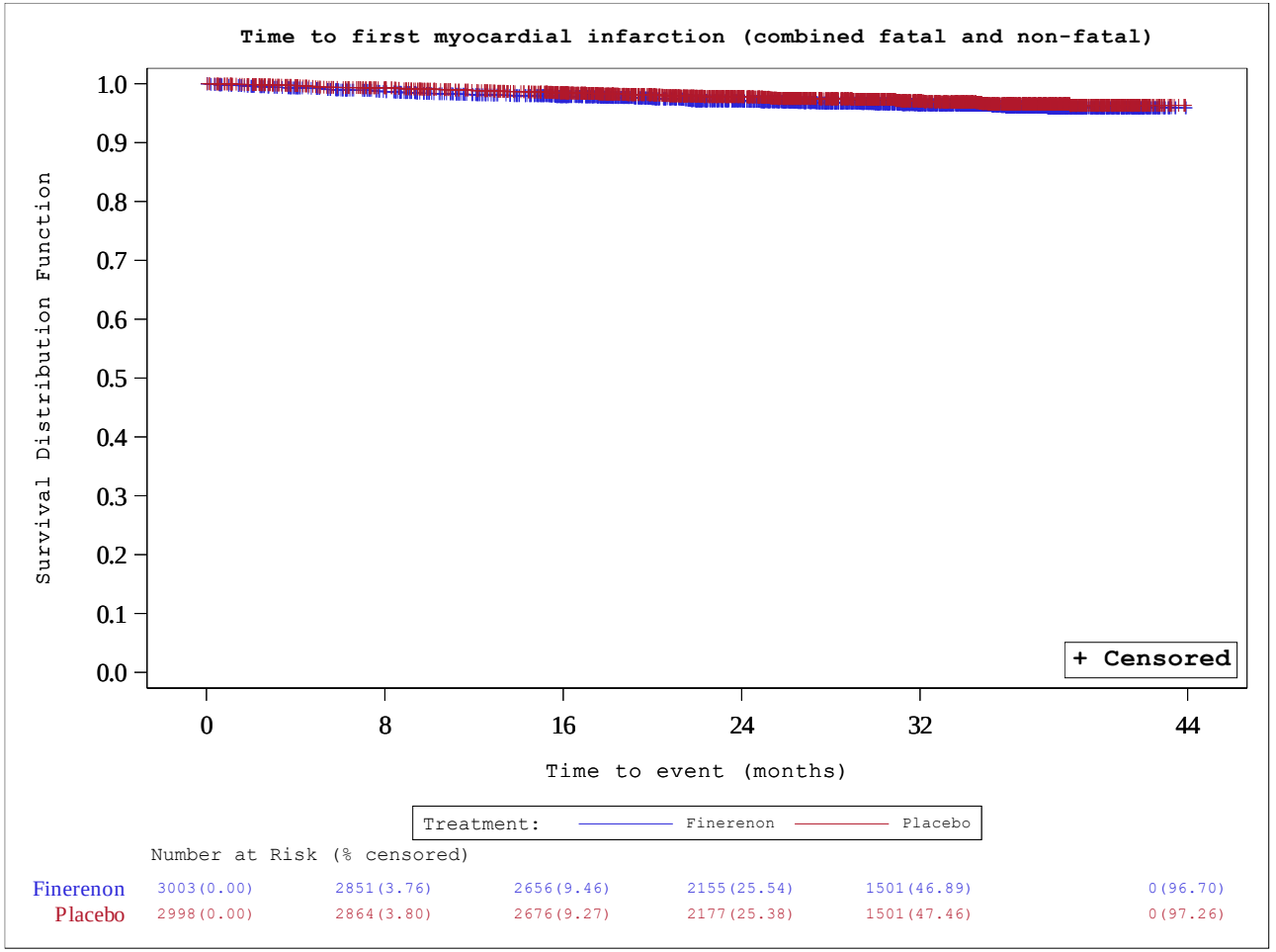
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.2759
Male	67/ 1648 (4.07)	NE (NE, NE)	48/ 1621 (2.96)	NE (NE, NE)	1.37 (0.94, 1.98)	0.0980	
Female	32/ 1355 (2.36)	NE (NE, NE)	34/ 1377 (2.47)	NE (NE, NE)	0.97 (0.60, 1.58)	0.9137	
Region							0.7265
Western Europe, Oceania and Others	27/ 624 (4.33)	NE (NE, NE)	20/ 632 (3.16)	NE (NE, NE)	1.38 (0.77, 2.46)	0.2726	
Eastern Europe	27/ 1329 (2.03)	NE (NE, NE)	27/ 1321 (2.04)	NE (NE, NE)	1.00 (0.59, 1.71)	0.9969	
Asia	14/ 493 (2.84)	NE (NE, NE)	10/ 490 (2.04)	NE (NE, NE)	1.39 (0.62, 3.12)	0.4281	
North America	22/ 235 (9.36)	NE (NE, NE)	14/ 236 (5.93)	NE (NE, NE)	1.54 (0.79, 3.01)	0.2015	
Latin America	9/ 322 (2.80)	NE (NE, NE)	11/ 319 (3.45)	NE (NE, NE)	0.82 (0.34, 1.98)	0.6561	
Age group (years)							0.0685
<= median in FAS	47/ 1589 (2.96)	NE (NE, NE)	50/ 1579 (3.17)	NE (NE, NE)	0.94 (0.63, 1.40)	0.7621	
> median in FAS	52/ 1414 (3.68)	NE (NE, NE)	32/ 1419 (2.26)	NE (NE, NE)	1.63 (1.05, 2.54)	0.0276	
NYHA class at baseline							0.4734
II	71/ 2081 (3.41)	NE (NE, NE)	55/ 2065 (2.66)	NE (NE, NE)	1.29 (0.90, 1.83)	0.1613	
III/IV	27/ 921 (2.93)	NE (NE, NE)	27/ 933 (2.89)	NE (NE, NE)	1.01 (0.59, 1.73)	0.9599	
LVEF at baseline							0.5521
< 50%	33/ 1093 (3.02)	NE (NE, NE)	32/ 1079 (2.97)	NE (NE, NE)	1.02 (0.62, 1.65)	0.9504	
>= 50% - < 60%	47/ 1329 (3.54)	NE (NE, NE)	39/ 1345 (2.90)	NE (NE, NE)	1.22 (0.80, 1.87)	0.3522	
>= 60%	18/ 575 (3.13)	NE (NE, NE)	11/ 572 (1.92)	NE (NE, NE)	1.66 (0.78, 3.51)	0.1815	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	118/ 3003 (3.93)	107/ 2998 (3.57)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.11 (0.85, 1.44)	
p-value	0.4367	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.10 (0.85, 1.43)	
p-value	0.4589	

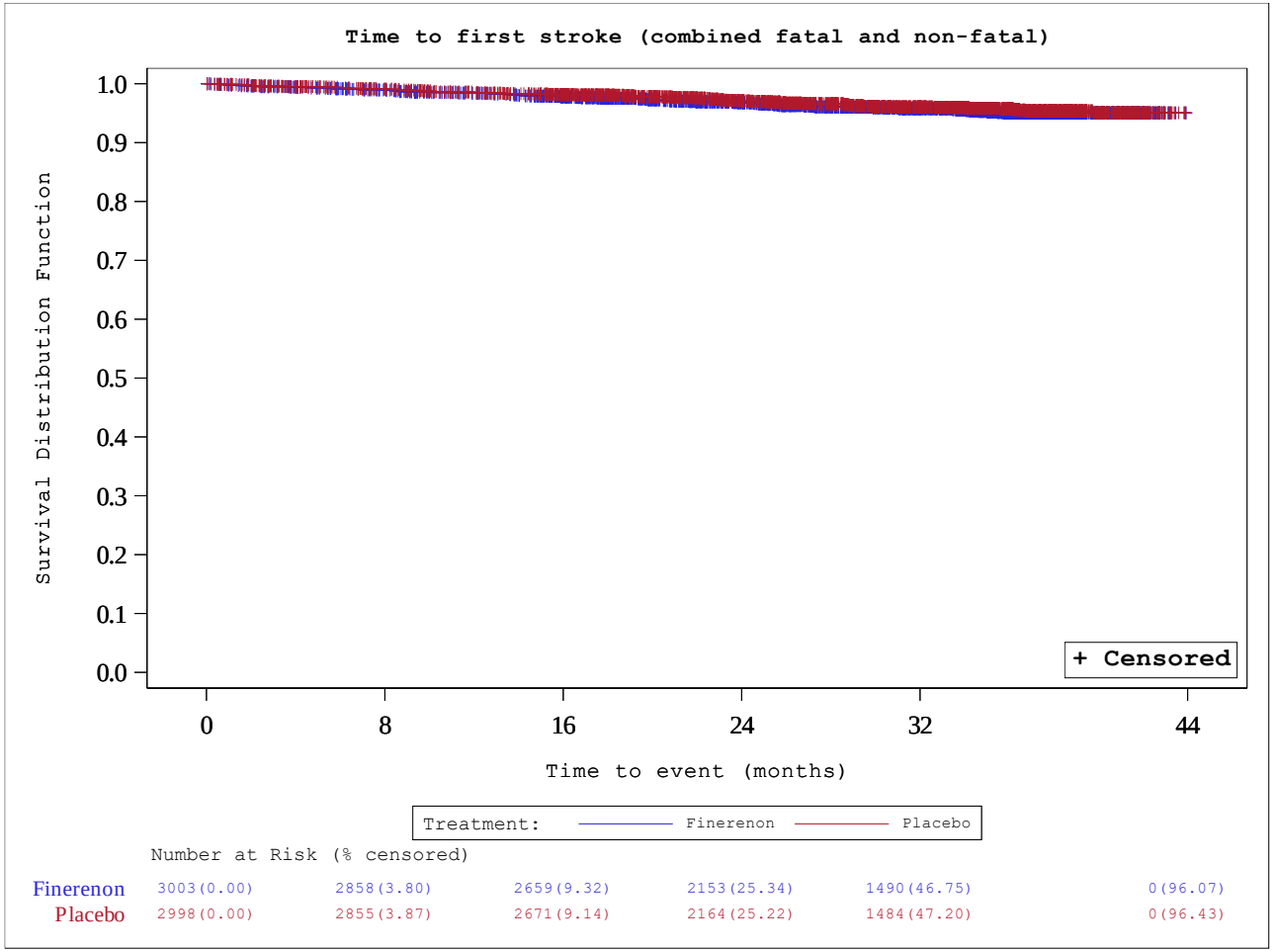
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.0709
Male	71/ 1648 (4.31)	NE (NE, NE)	50/ 1621 (3.08)	NE (NE, NE)	1.39 (0.97, 1.99)	0.0752	
Female	47/ 1355 (3.47)	NE (NE, NE)	57/ 1377 (4.14)	NE (NE, NE)	0.85 (0.58, 1.25)	0.4159	
Region							0.0922
Western Europe, Oceania and Others	17/ 624 (2.72)	NE (NE, NE)	29/ 632 (4.59)	NE (NE, NE)	0.59 (0.33, 1.08)	0.0846	
Eastern Europe	57/ 1329 (4.29)	NE (NE, NE)	36/ 1321 (2.73)	NE (NE, NE)	1.59 (1.05, 2.42)	0.0269	
Asia	31/ 493 (6.29)	NE (NE, NE)	27/ 490 (5.51)	NE (NE, NE)	1.14 (0.68, 1.92)	0.6080	
North America	5/ 235 (2.13)	NE (NE, NE)	4/ 236 (1.69)	NE (NE, NE)	1.18 (0.32, 4.38)	0.8087	
Latin America	8/ 322 (2.48)	NE (NE, NE)	11/ 319 (3.45)	NE (NE, NE)	0.72 (0.29, 1.80)	0.4839	
Age group (years)							0.2162
<= median in FAS	66/ 1589 (4.15)	NE (NE, NE)	51/ 1579 (3.23)	NE (NE, NE)	1.29 (0.90, 1.87)	0.1649	
> median in FAS	52/ 1414 (3.68)	NE (NE, NE)	56/ 1419 (3.95)	NE (NE, NE)	0.93 (0.64, 1.36)	0.7037	
NYHA class at baseline							0.1914
II	81/ 2081 (3.89)	NE (NE, NE)	64/ 2065 (3.10)	NE (NE, NE)	1.26 (0.91, 1.75)	0.1674	
III/IV	37/ 921 (4.02)	NE (NE, NE)	43/ 933 (4.61)	NE (NE, NE)	0.87 (0.56, 1.35)	0.5433	
LVEF at baseline							0.5794
< 50%	39/ 1093 (3.57)	NE (NE, NE)	41/ 1079 (3.80)	NE (NE, NE)	0.94 (0.61, 1.46)	0.7788	
>= 50% - < 60%	52/ 1329 (3.91)	NE (NE, NE)	41/ 1345 (3.05)	NE (NE, NE)	1.28 (0.85, 1.93)	0.2291	
>= 60%	26/ 575 (4.52)	NE (NE, NE)	25/ 572 (4.37)	NE (NE, NE)	1.05 (0.61, 1.82)	0.8540	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first stroke (combined fatal and non-fatal)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first CV hospitalization
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	754/ 3003 (25.11)	819/ 2998 (27.32)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	29.2 (26.0, 32.7)	25.5 (22.9, 28.2)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.90 (0.82, 1.00)	
p-value	0.0397	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.90 (0.82, 1.00)	
p-value	0.0417	

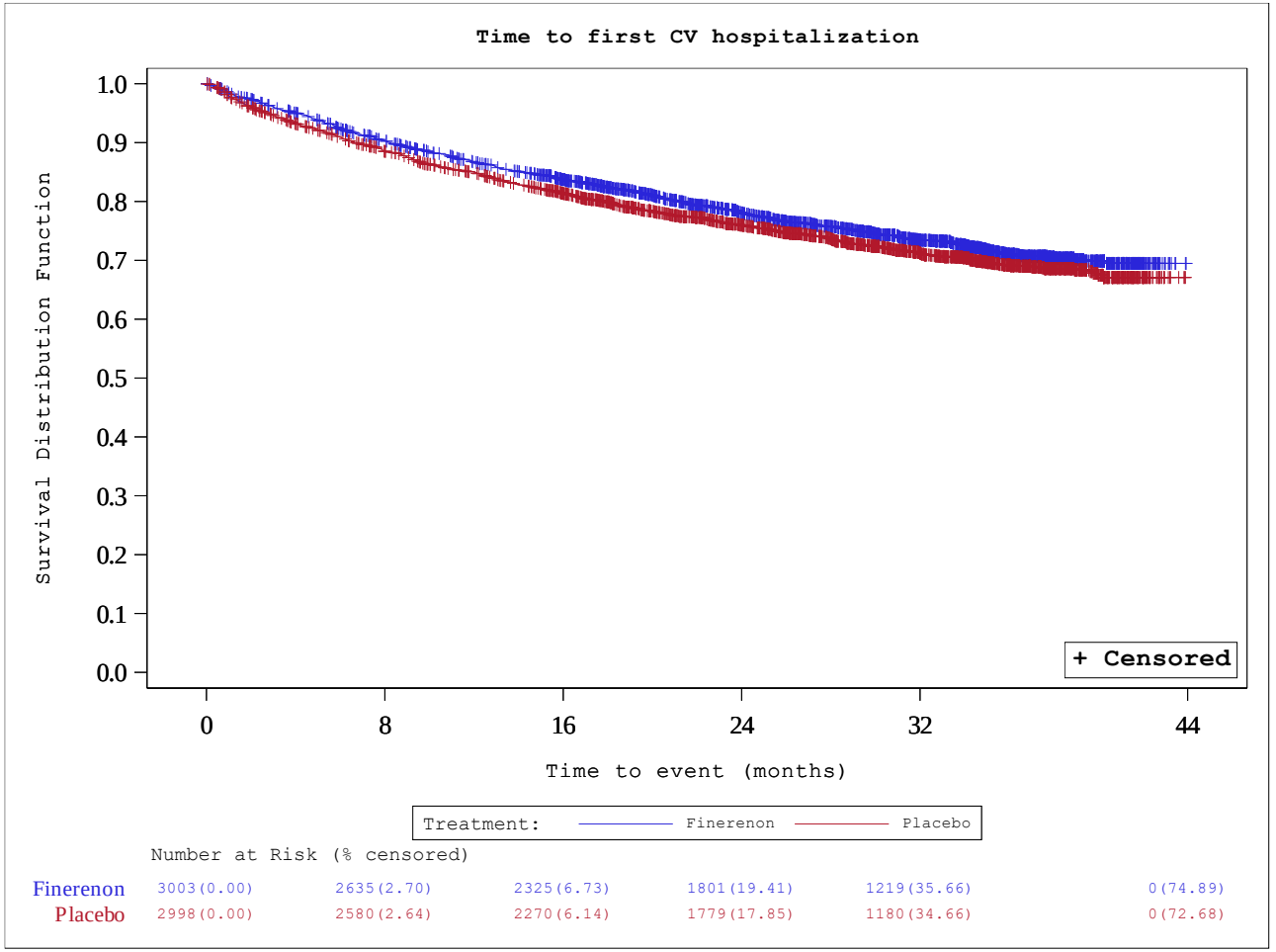
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; Urgent HF visits per investigator not included as events in dossier analyses of CV hospitalization for FINEARTS-HF.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first CV hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5731
Male	431/ 1648 (26.15)	NE (NE, NE)	447/ 1621 (27.58)	NE (NE, NE)	0.92 (0.81, 1.06)	0.2469	
Female	323/ 1355 (23.84)	NE (NE, NE)	372/ 1377 (27.02)	NE (NE, NE)	0.87 (0.75, 1.01)	0.0740	
Region							0.2614
Western Europe, Oceania and Others	190/ 624 (30.45)	NE (NE, NE)	203/ 632 (32.12)	NE (NE, NE)	0.94 (0.77, 1.14)	0.5243	
Eastern Europe	290/ 1329 (21.82)	NE (NE, NE)	297/ 1321 (22.48)	NE (NE, NE)	0.97 (0.82, 1.14)	0.6936	
Asia	137/ 493 (27.79)	NE (NE, NE)	163/ 490 (33.27)	NE (NE, NE)	0.81 (0.64, 1.01)	0.0614	
North America	74/ 235 (31.49)	NE (NE, NE)	70/ 236 (29.66)	39.6 (38.9, NE)	1.02 (0.74, 1.42)	0.9010	
Latin America	63/ 322 (19.57)	NE (NE, NE)	86/ 319 (26.96)	NE (NE, NE)	0.68 (0.49, 0.95)	0.0212	
Age group (years)							0.1915
<= median in FAS	364/ 1589 (22.91)	NE (NE, NE)	418/ 1579 (26.47)	NE (NE, NE)	0.85 (0.73, 0.97)	0.0192	
> median in FAS	390/ 1414 (27.58)	NE (NE, NE)	401/ 1419 (28.26)	NE (NE, NE)	0.96 (0.84, 1.11)	0.6122	
NYHA class at baseline							0.9119
II	467/ 2081 (22.44)	NE (NE, NE)	508/ 2065 (24.60)	NE (NE, NE)	0.90 (0.79, 1.02)	0.0924	
III/IV	286/ 921 (31.05)	NE (NE, NE)	311/ 933 (33.33)	NE (NE, NE)	0.91 (0.78, 1.07)	0.2526	
LVEF at baseline							0.8676
< 50%	275/ 1093 (25.16)	NE (NE, NE)	304/ 1079 (28.17)	NE (NE, NE)	0.87 (0.74, 1.03)	0.1023	
>= 50% - < 60%	331/ 1329 (24.91)	NE (NE, NE)	355/ 1345 (26.39)	NE (NE, NE)	0.93 (0.80, 1.08)	0.3181	
>= 60%	146/ 575 (25.39)	NE (NE, NE)	160/ 572 (27.97)	NE (NE, NE)	0.90 (0.72, 1.12)	0.3410	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular;Urgent HF visits per investigator not included as events in dossier analyses of CV hospitalization for FINEARTS-HF.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first CV hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to new onset of atrial fibrillation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	76/ 1355 (5.61)	99/ 1373 (7.21)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.78 (0.58, 1.05)	
p-value	0.0968	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.78 (0.58, 1.05)	
p-value	0.0973	

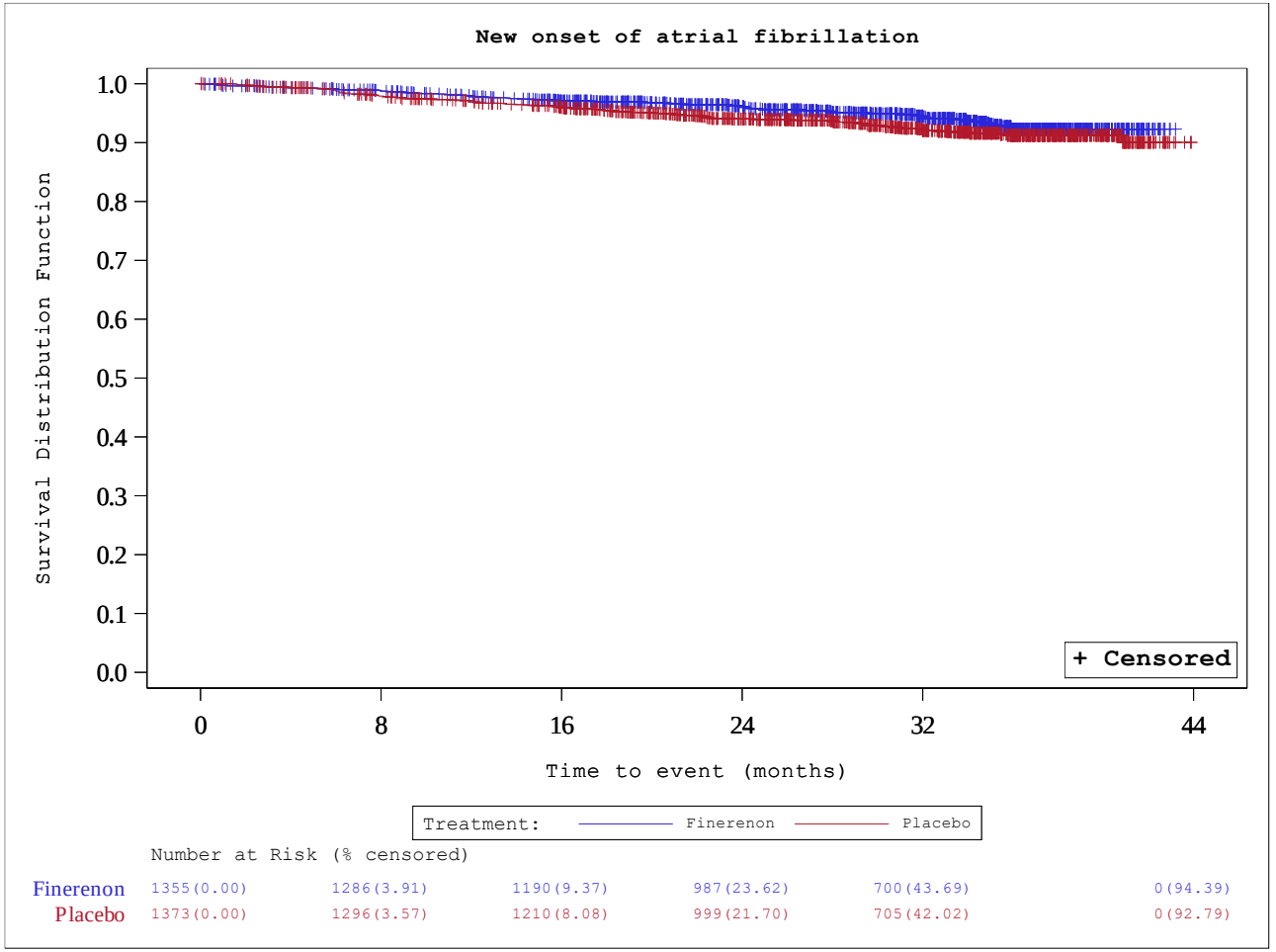
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to new onset of atrial fibrillation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.9025
Male	41/ 767 (5.35)	NE (NE, NE)	53/ 767 (6.91)	NE (NE, NE)	0.76 (0.51, 1.15)	0.1946	
Female	35/ 588 (5.95)	NE (NE, NE)	46/ 606 (7.59)	NE (NE, NE)	0.79 (0.51, 1.23)	0.2979	
Region							0.4838
Western Europe, Oceania and Others	17/ 198 (8.59)	NE (NE, NE)	25/ 204 (12.25)	NE (NE, NE)	0.70 (0.38, 1.30)	0.2596	
Eastern Europe	37/ 618 (5.99)	NE (NE, NE)	36/ 613 (5.87)	NE (NE, NE)	1.02 (0.65, 1.62)	0.9197	
Asia	9/ 232 (3.88)	NE (NE, NE)	15/ 237 (6.33)	NE (40.9, NE)	0.61 (0.26, 1.38)	0.2291	
North America	8/ 106 (7.55)	NE (NE, NE)	9/ 101 (8.91)	NE (NE, NE)	0.78 (0.30, 2.02)	0.6097	
Latin America	5/ 201 (2.49)	NE (NE, NE)	14/ 218 (6.42)	NE (NE, NE)	0.39 (0.14, 1.08)	0.0612	
Age group (years)							0.6432
<= median in FAS	41/ 866 (4.73)	NE (NE, NE)	48/ 853 (5.63)	NE (NE, NE)	0.84 (0.56, 1.28)	0.4180	
> median in FAS	35/ 489 (7.16)	NE (NE, NE)	51/ 520 (9.81)	NE (NE, NE)	0.73 (0.48, 1.12)	0.1525	
NYHA class at baseline							0.6055
II	55/ 980 (5.61)	NE (NE, NE)	70/ 1016 (6.89)	NE (NE, NE)	0.81 (0.57, 1.16)	0.2517	
III/IV	21/ 375 (5.60)	NE (NE, NE)	29/ 357 (8.12)	NE (NE, NE)	0.68 (0.39, 1.19)	0.1780	
LVEF at baseline							0.9956
< 50%	26/ 568 (4.58)	NE (NE, NE)	30/ 535 (5.61)	NE (NE, NE)	0.80 (0.47, 1.36)	0.4099	
>= 50% - < 60%	33/ 539 (6.12)	NE (NE, NE)	45/ 562 (8.01)	NE (NE, NE)	0.77 (0.49, 1.21)	0.2611	
>= 60%	17/ 247 (6.88)	NE (NE, NE)	24/ 275 (8.73)	NE (NE, NE)	0.79 (0.42, 1.47)	0.4537	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to new onset of atrial fibrillation
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	41/ 3003 (1.37)	31/ 2998 (1.03)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.28 (0.80, 2.05)	
p-value	0.2956	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.30 (0.82, 2.08)	
p-value	0.2646	

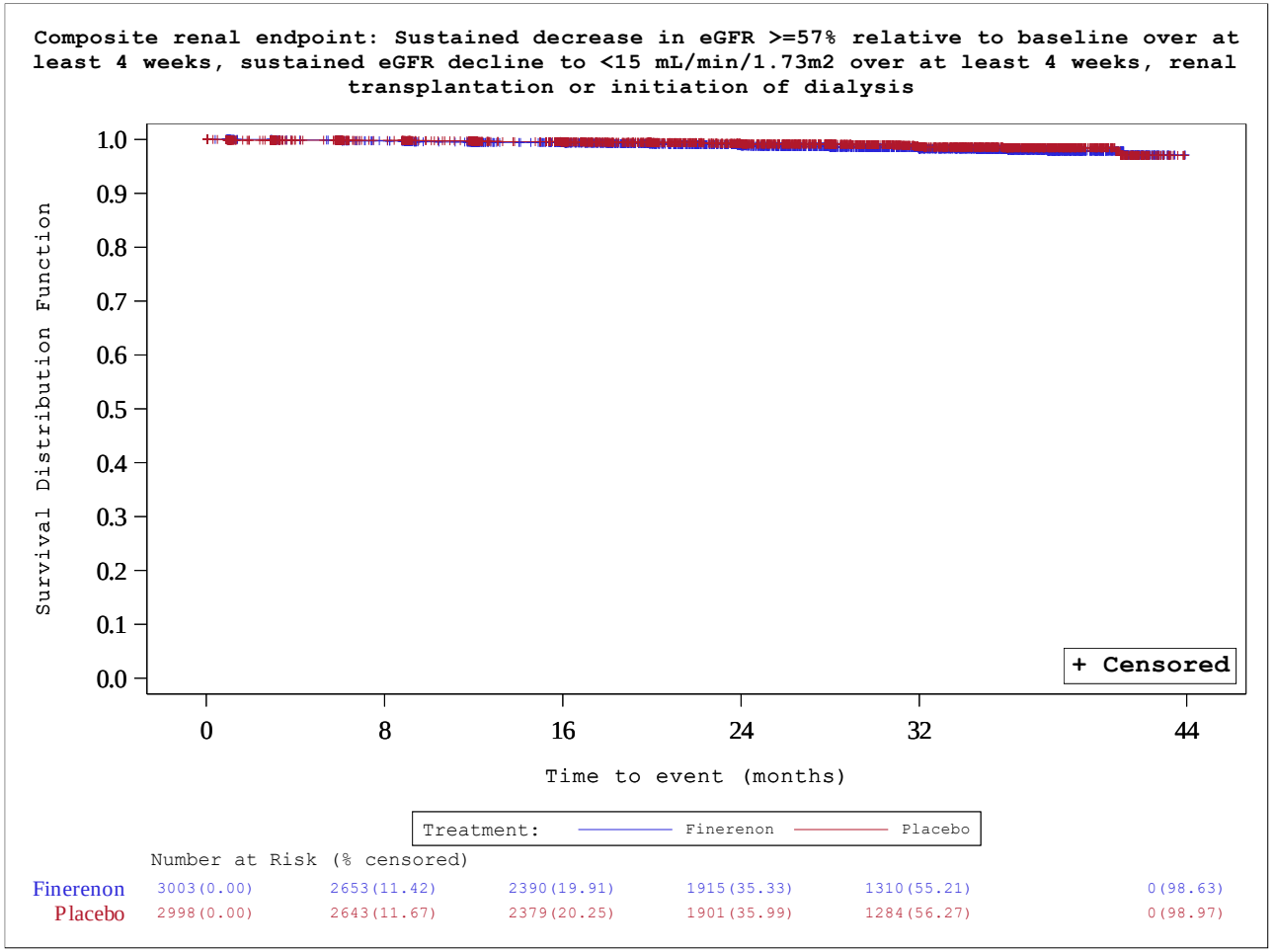
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.0632
Male	28/ 1648 (1.70)	NE (NE, NE)	14/ 1621 (0.86)	NE (NE, NE)	1.93 (1.02, 3.67)	0.0401	
Female	13/ 1355 (0.96)	NE (NE, NE)	17/ 1377 (1.23)	NE (NE, NE)	0.77 (0.37, 1.58)	0.4671	
Region							0.6498
Western Europe, Oceania and Others	9/ 624 (1.44)	NE (NE, NE)	6/ 632 (0.95)	NE (NE, NE)	1.50 (0.53, 4.21)	0.4392	
Eastern Europe	11/ 1329 (0.83)	NE (NE, NE)	13/ 1321 (0.98)	NE (NE, NE)	0.84 (0.37, 1.87)	0.6597	
Asia	9/ 493 (1.83)	NE (NE, NE)	5/ 490 (1.02)	NE (NE, NE)	1.72 (0.58, 5.14)	0.3240	
North America	3/ 235 (1.28)	NE (NE, NE)	3/ 236 (1.27)	NE (NE, NE)	0.97 (0.20, 4.83)	0.9750	
Latin America	9/ 322 (2.80)	NE (NE, NE)	4/ 319 (1.25)	NE (NE, NE)	2.30 (0.71, 7.48)	0.1538	
Age group (years)							0.6973
<= median in FAS	23/ 1589 (1.45)	NE (NE, NE)	16/ 1579 (1.01)	NE (NE, NE)	1.42 (0.75, 2.69)	0.2762	
> median in FAS	18/ 1414 (1.27)	NE (NE, NE)	15/ 1419 (1.06)	NE (NE, NE)	1.17 (0.59, 2.32)	0.6517	
NYHA class at baseline							0.9179
II	27/ 2081 (1.30)	NE (NE, NE)	20/ 2065 (0.97)	NE (NE, NE)	1.33 (0.74, 2.36)	0.3372	
III/IV	14/ 921 (1.52)	NE (NE, NE)	11/ 933 (1.18)	NE (NE, NE)	1.28 (0.58, 2.82)	0.5407	
LVEF at baseline							0.0276
< 50%	18/ 1093 (1.65)	NE (NE, NE)	7/ 1079 (0.65)	NE (NE, NE)	2.49 (1.04, 5.97)	0.0337	
>= 50% - < 60%	19/ 1329 (1.43)	NE (NE, NE)	13/ 1345 (0.97)	NE (NE, NE)	1.48 (0.73, 2.99)	0.2761	
>= 60%	4/ 575 (0.70)	NE (NE, NE)	11/ 572 (1.92)	NE (NE, NE)	0.34 (0.11, 1.08)	0.0561	

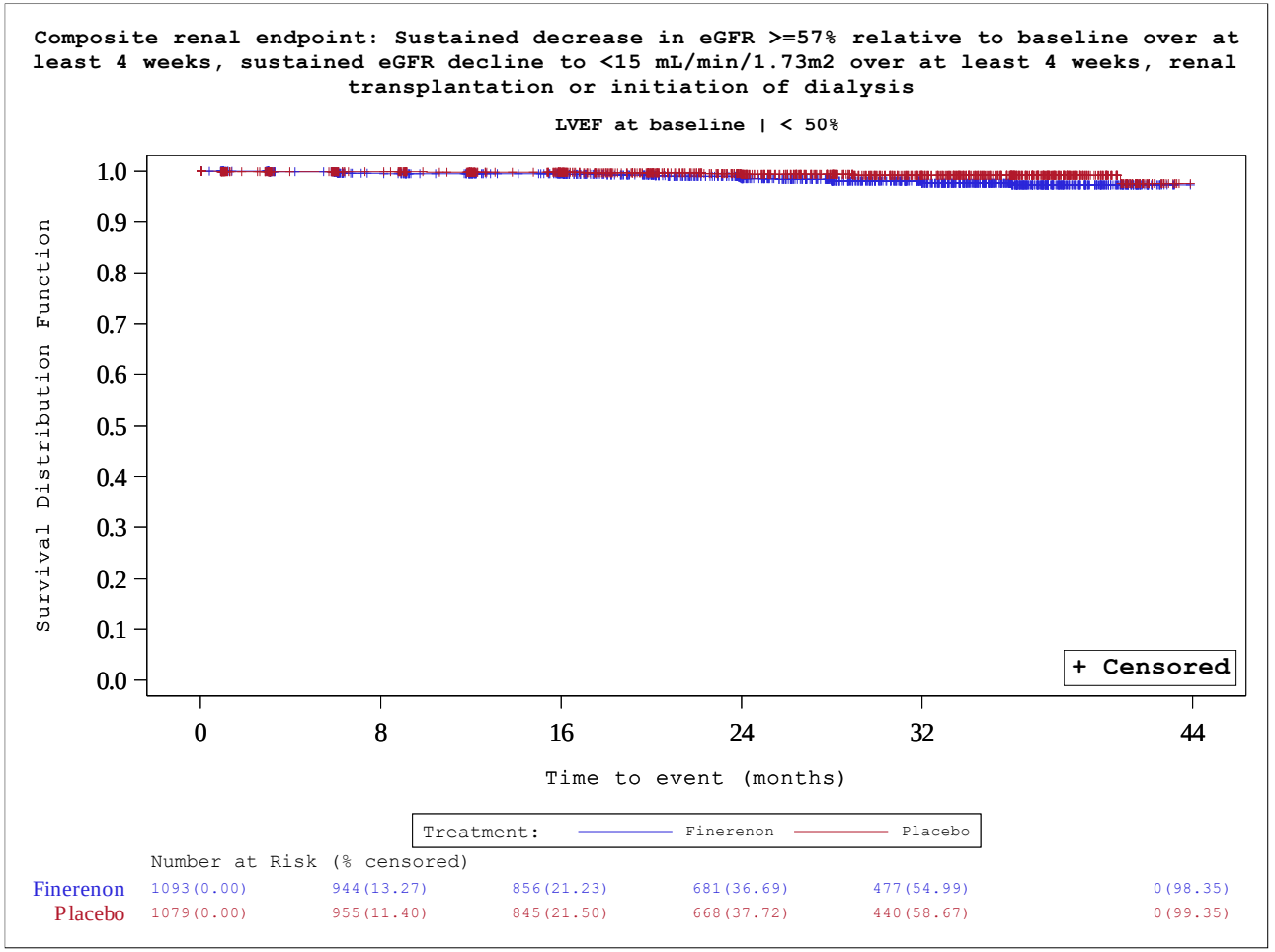
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p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



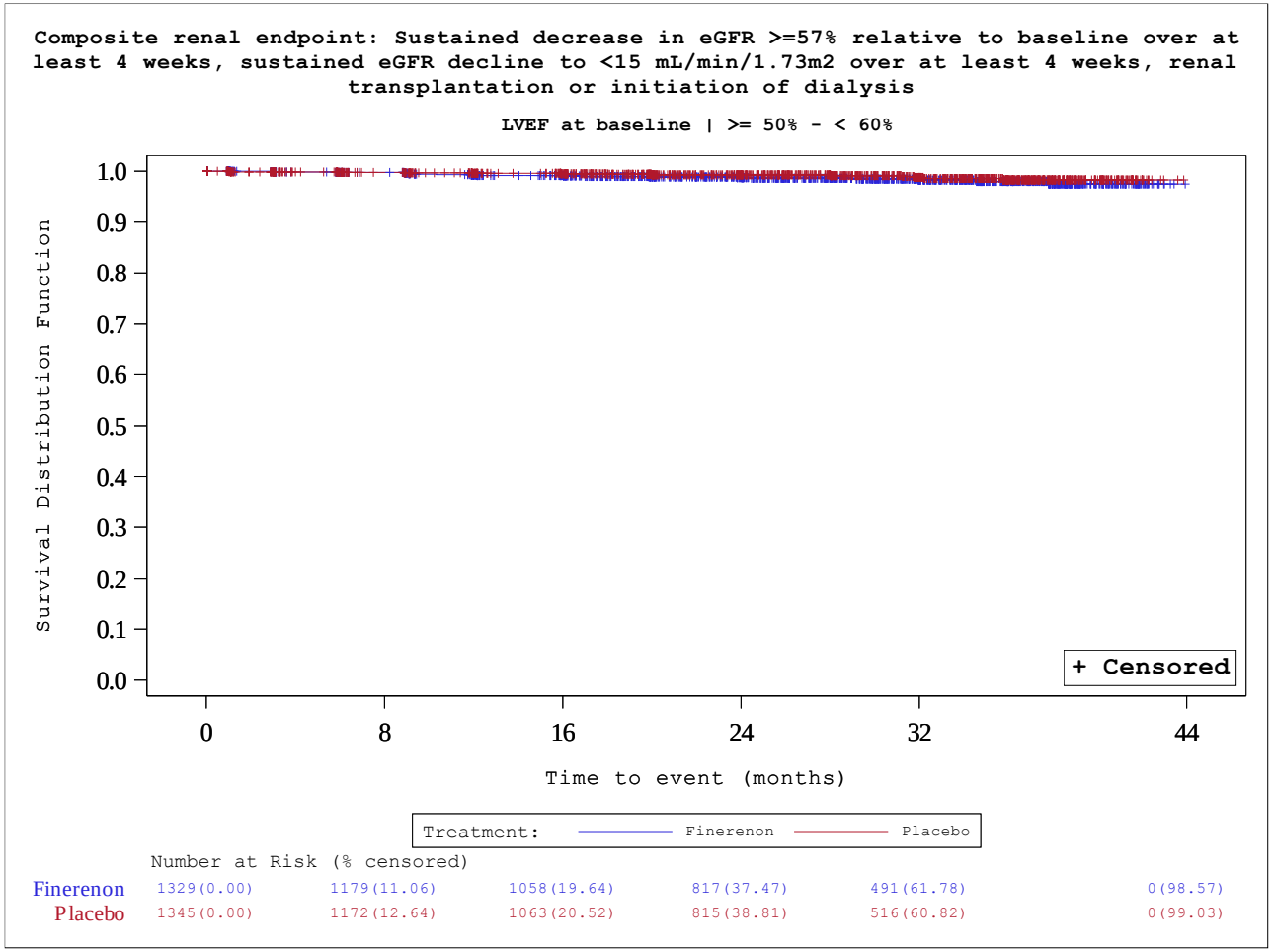
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



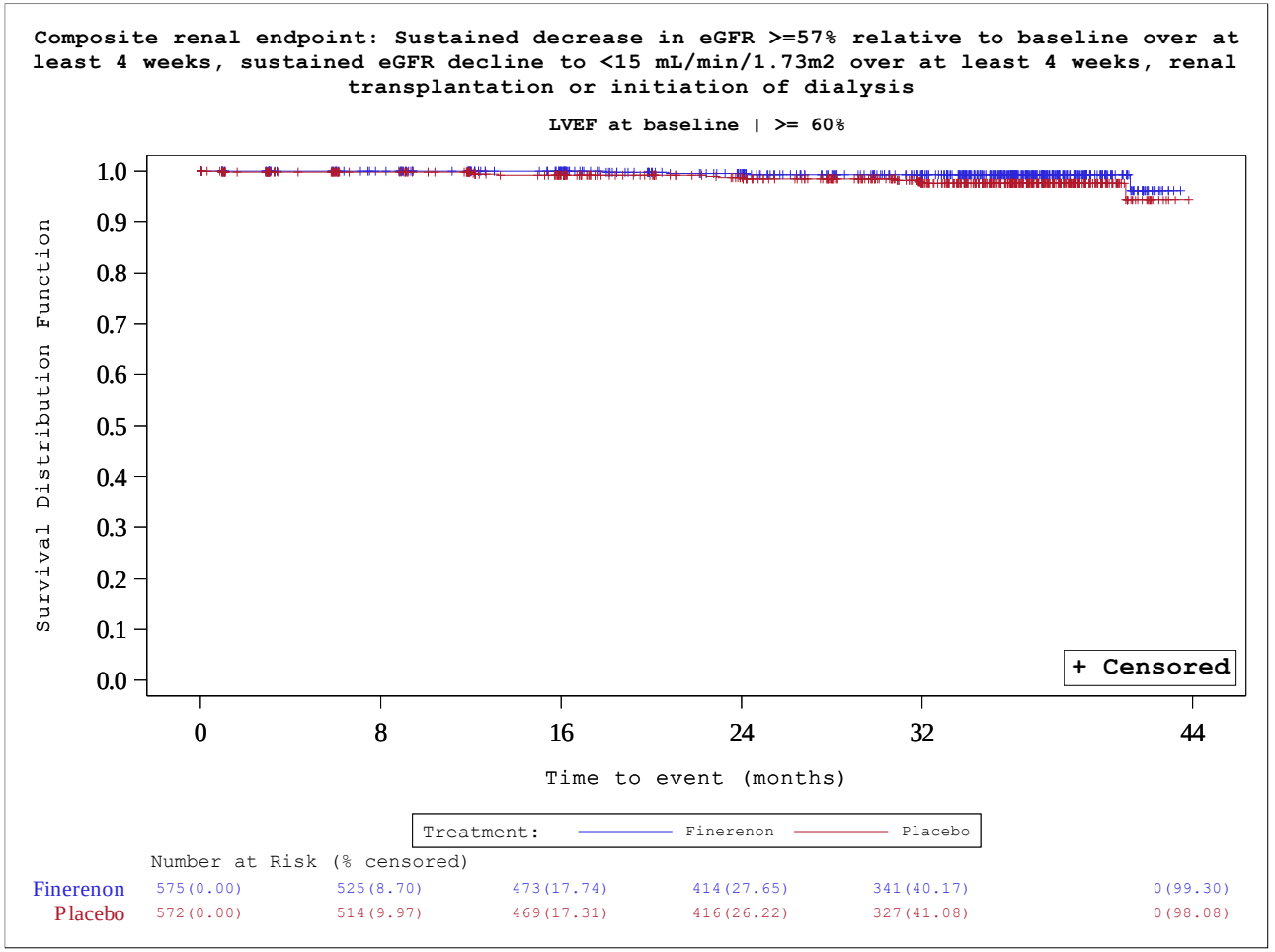
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	35/ 3003 (1.17)	26/ 2998 (0.87)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.29 (0.77, 2.15)	
p-value	0.3266	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.32 (0.80, 2.20)	
p-value	0.2773	

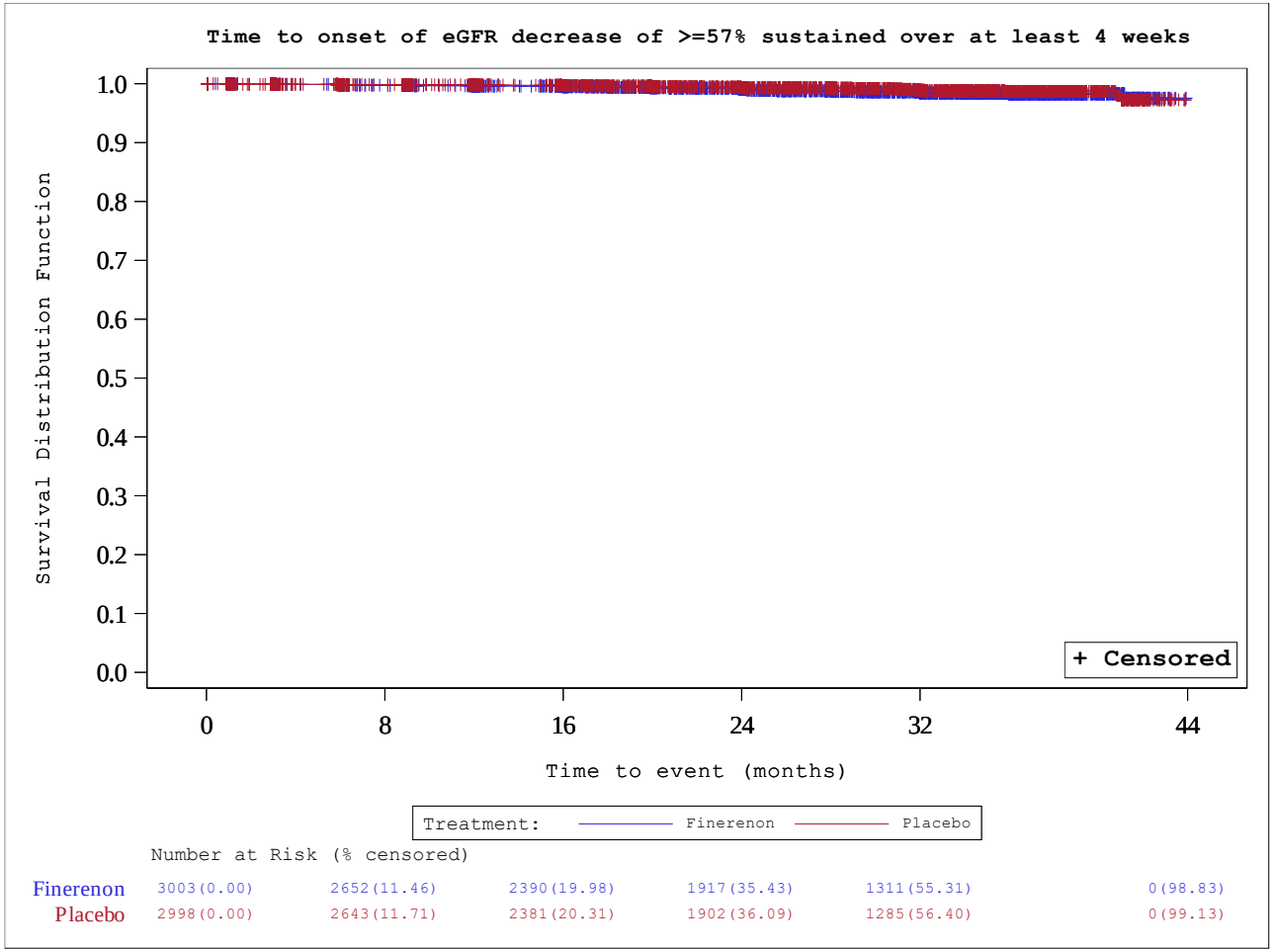
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.0864
Male	23/ 1648 (1.40)	NE (NE, NE)	11/ 1621 (0.68)	NE (NE, NE)	2.02 (0.99, 4.15)	0.0500	
Female	12/ 1355 (0.89)	NE (NE, NE)	15/ 1377 (1.09)	NE (NE, NE)	0.80 (0.37, 1.71)	0.5659	
Region							0.7865
Western Europe, Oceania and Others	6/ 624 (0.96)	NE (NE, NE)	5/ 632 (0.79)	NE (NE, NE)	1.20 (0.37, 3.94)	0.7607	
Eastern Europe	10/ 1329 (0.75)	NE (NE, NE)	11/ 1321 (0.83)	NE (NE, NE)	0.90 (0.38, 2.11)	0.8006	
Asia	9/ 493 (1.83)	NE (NE, NE)	5/ 490 (1.02)	NE (NE, NE)	1.72 (0.58, 5.13)	0.3258	
North America	3/ 235 (1.28)	NE (NE, NE)	2/ 236 (0.85)	NE (NE, NE)	1.44 (0.24, 8.61)	0.6883	
Latin America	7/ 322 (2.17)	NE (NE, NE)	3/ 319 (0.94)	NE (NE, NE)	2.31 (0.60, 8.94)	0.2108	
Age group (years)							0.7867
<= median in FAS	20/ 1589 (1.26)	NE (NE, NE)	14/ 1579 (0.89)	NE (NE, NE)	1.41 (0.71, 2.80)	0.3183	
> median in FAS	15/ 1414 (1.06)	NE (NE, NE)	12/ 1419 (0.85)	NE (NE, NE)	1.21 (0.57, 2.59)	0.6183	
NYHA class at baseline							0.8018
II	24/ 2081 (1.15)	NE (NE, NE)	17/ 2065 (0.82)	NE (NE, NE)	1.38 (0.74, 2.58)	0.3023	
III/IV	11/ 921 (1.19)	NE (NE, NE)	9/ 933 (0.96)	NE (NE, NE)	1.23 (0.51, 2.97)	0.6418	
LVEF at baseline							0.0555
< 50%	17/ 1093 (1.56)	NE (NE, NE)	6/ 1079 (0.56)	NE (NE, NE)	2.74 (1.08, 6.95)	0.0269	
>= 50% - < 60%	14/ 1329 (1.05)	NE (NE, NE)	11/ 1345 (0.82)	NE (NE, NE)	1.29 (0.58, 2.84)	0.5298	
>= 60%	4/ 575 (0.70)	NE (NE, NE)	9/ 572 (1.57)	NE (NE, NE)	0.42 (0.13, 1.36)	0.1347	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	25/ 3003 (0.83)	12/ 2998 (0.40)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	2.09 (1.05, 4.15)	
p-value	0.0325	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	2.07 (1.04, 4.12)	
p-value	0.0341	

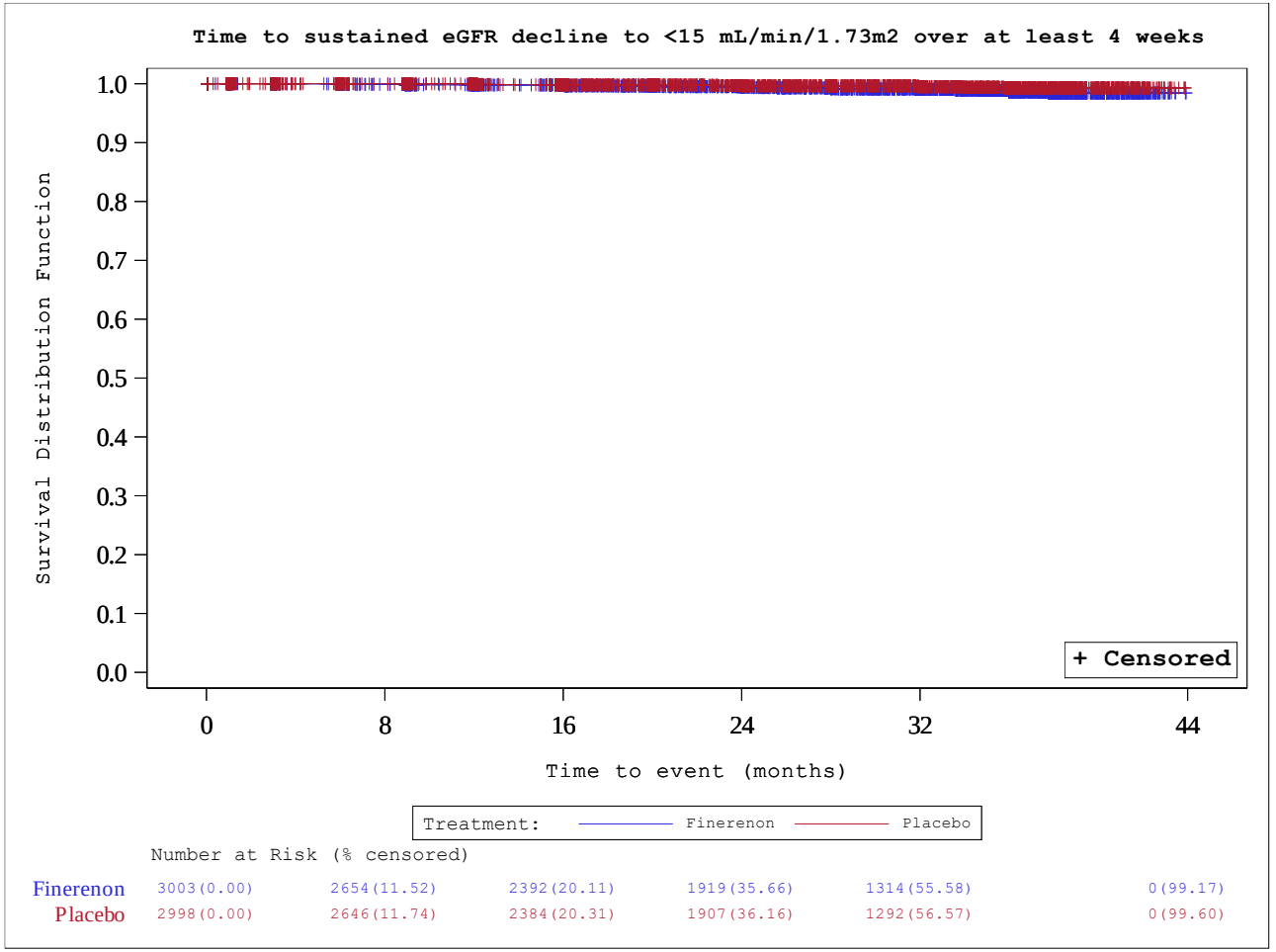
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.1392
Male	19/ 1648 (1.15)	NE (NE, NE)	6/ 1621 (0.37)	NE (NE, NE)	3.07 (1.23, 7.68)	0.0117	
Female	6/ 1355 (0.44)	NE (NE, NE)	6/ 1377 (0.44)	NE (NE, NE)	1.02 (0.33, 3.16)	0.9743	
Region							
Western Europe, Oceania and Others	5/ 624 (0.80)		3/ 632 (0.47)				
Eastern Europe	6/ 1329 (0.45)		2/ 1321 (0.15)				
Asia	6/ 493 (1.22)		2/ 490 (0.41)				
North America	3/ 235 (1.28)		3/ 236 (1.27)				
Latin America	5/ 322 (1.55)		2/ 319 (0.63)				
Age group (years)							0.3007
<= median in FAS	17/ 1589 (1.07)	NE (NE, NE)	6/ 1579 (0.38)	NE (NE, NE)	2.80 (1.11, 7.11)	0.0233	
> median in FAS	8/ 1414 (0.57)	NE (NE, NE)	6/ 1419 (0.42)	NE (NE, NE)	1.33 (0.46, 3.84)	0.5928	
NYHA class at baseline							0.5178
II	14/ 2081 (0.67)	NE (NE, NE)	8/ 2065 (0.39)	NE (NE, NE)	1.73 (0.73, 4.12)	0.2107	
III/IV	11/ 921 (1.19)	NE (NE, NE)	4/ 933 (0.43)	NE (NE, NE)	2.77 (0.88, 8.71)	0.0682	
LVEF at baseline							0.0097
< 50%	10/ 1093 (0.91)	NE (NE, NE)	1/ 1079 (0.09)	NE (NE, NE)	9.73 (1.24, 75.97)	0.0076	
>= 50% - < 60%	14/ 1329 (1.05)	NE (NE, NE)	4/ 1345 (0.30)	NE (NE, NE)	3.56 (1.17, 10.81)	0.0168	
>= 60%	1/ 575 (0.17)	NE (NE, NE)	7/ 572 (1.22)	NE (NE, NE)	0.14 (0.02, 1.15)	0.0332	

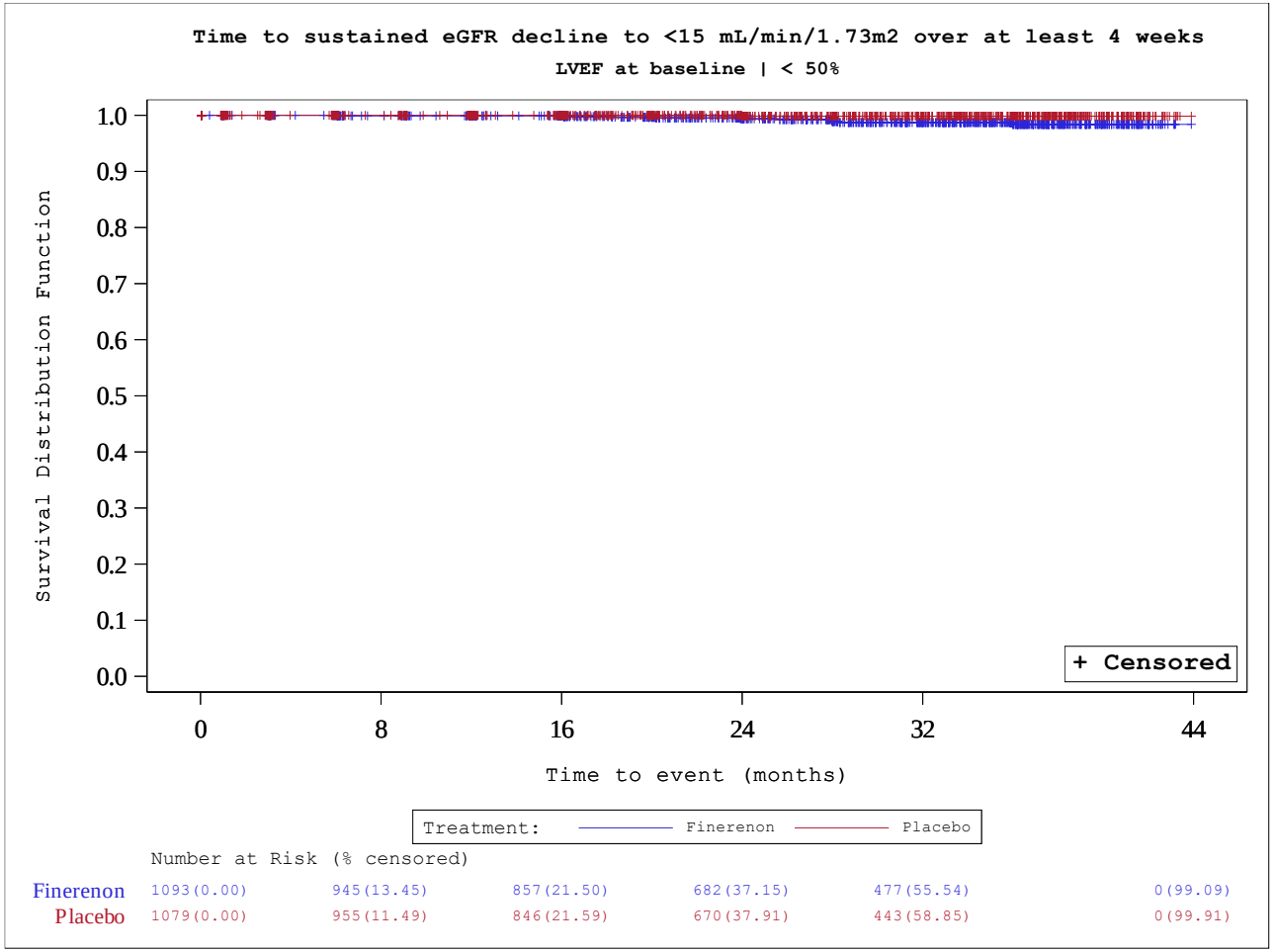
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Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



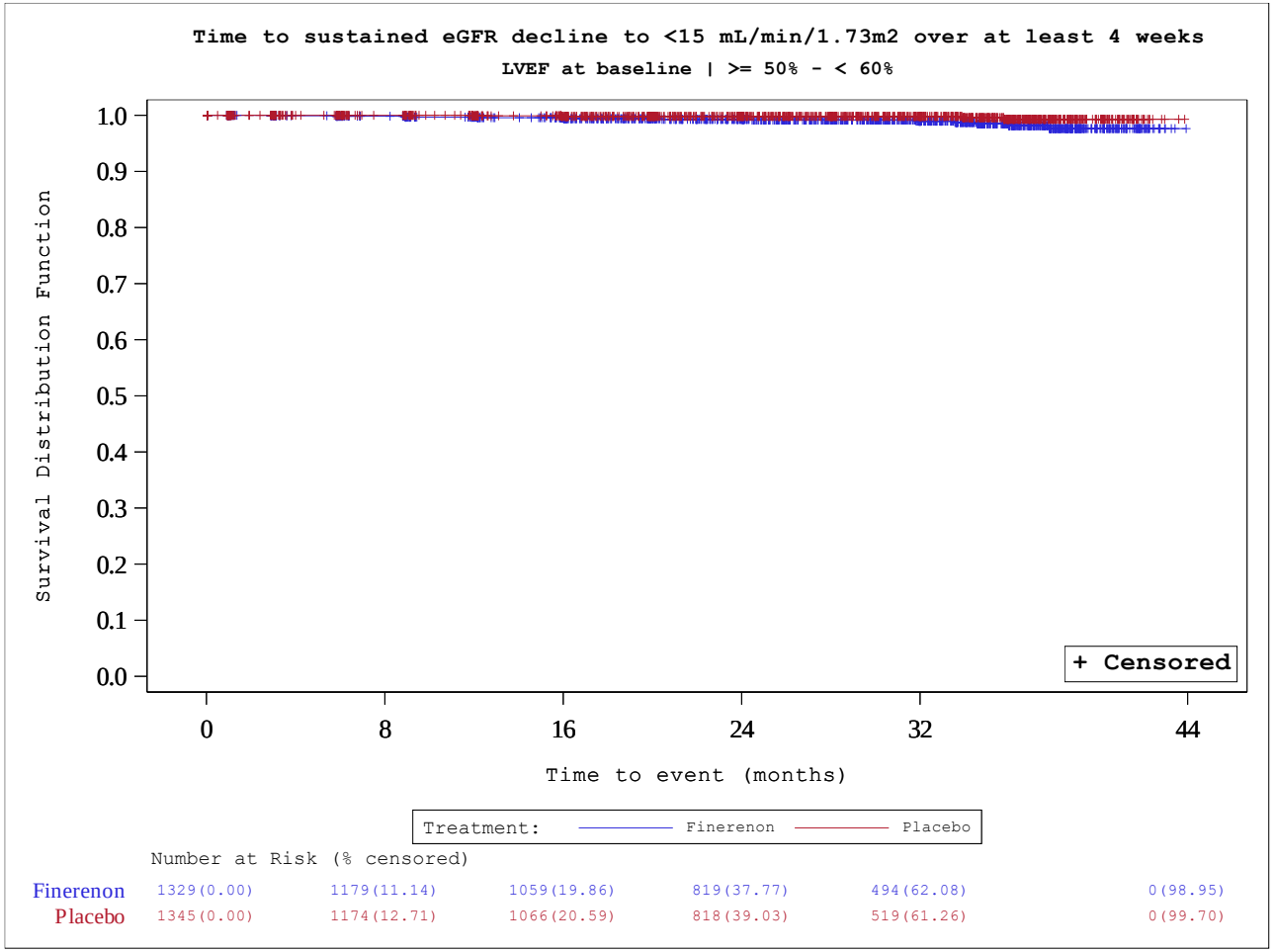
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



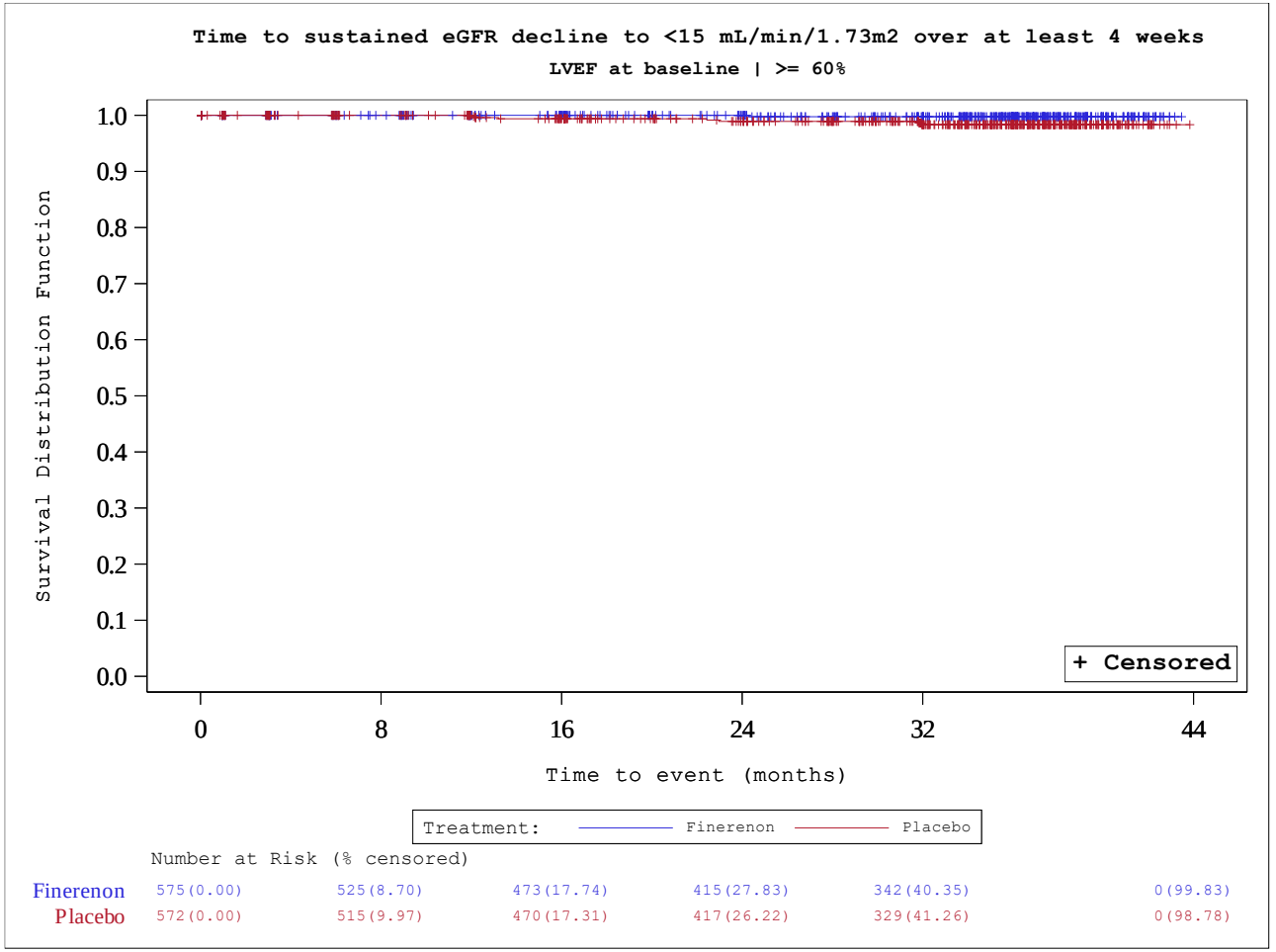
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	7/ 3003 (0.23)	6/ 2998 (0.20)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.14 (0.38, 3.40)	
p-value	0.8097	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.16 (0.39, 3.45)	
p-value	0.7891	

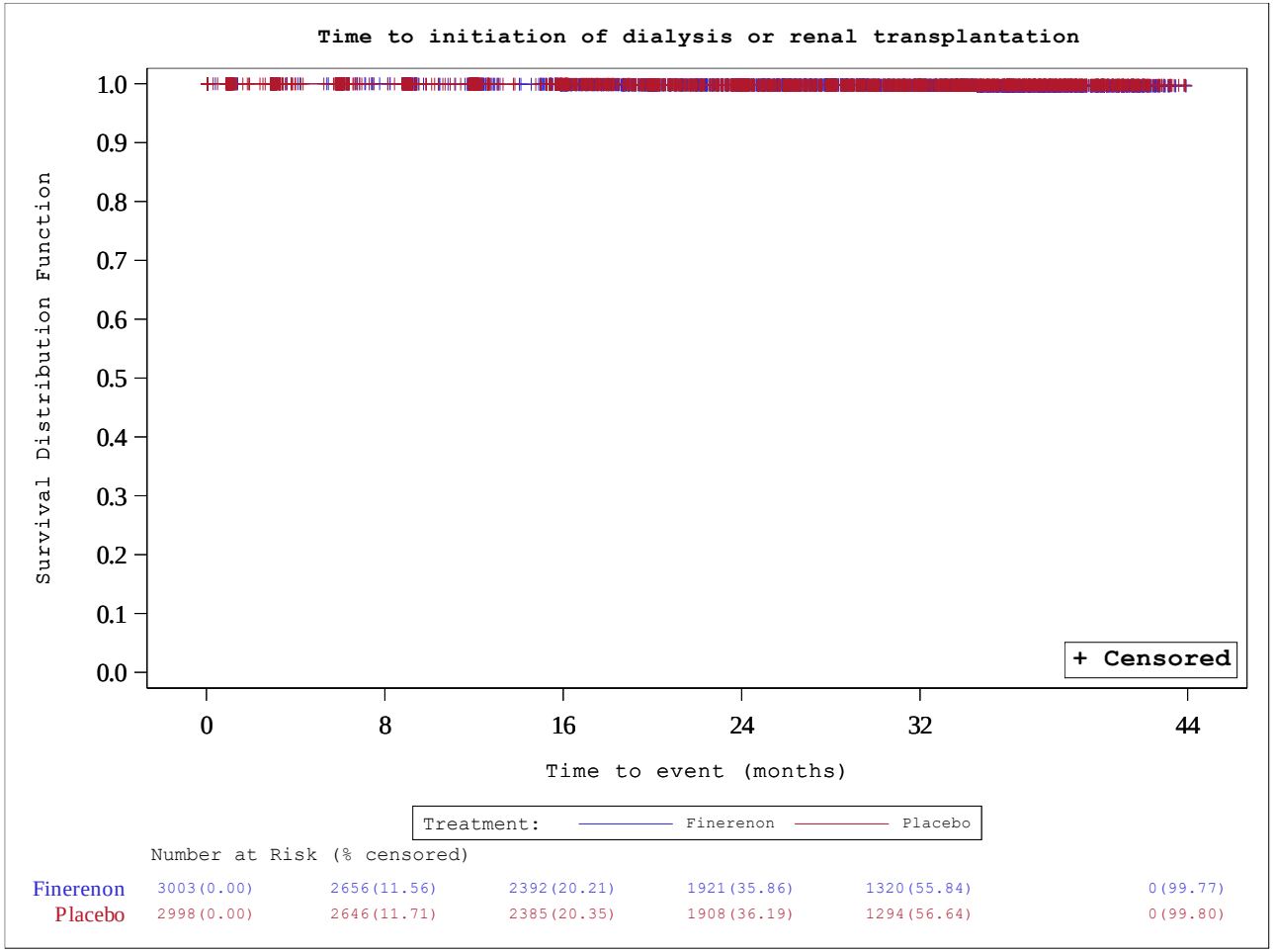
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3003)		Placebo (N=2998)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.9894
Male	7/ 1648 (0.42)	NE (NE, NE)	3/ 1621 (0.19)	NE (NE, NE)	2.27 (0.59, 8.78)	0.2216	
Female	0/ 1355 (0.00)	NE (NE, NE)	3/ 1377 (0.22)	NE (NE, NE)	NE (NE, NE)	NE	
Region							
Western Europe, Oceania and Others	1/ 624 (0.16)		0/ 632 (0.00)				
Eastern Europe	1/ 1329 (0.08)		2/ 1321 (0.15)				
Asia	1/ 493 (0.20)		0/ 490 (0.00)				
North America	3/ 235 (1.28)		2/ 236 (0.85)				
Latin America	1/ 322 (0.31)		2/ 319 (0.63)				
Age group (years)							
<= median in FAS	6/ 1589 (0.38)		3/ 1579 (0.19)				
> median in FAS	1/ 1414 (0.07)		3/ 1419 (0.21)				
NYHA class at baseline							
II	5/ 2081 (0.24)		3/ 2065 (0.15)				
III/IV	2/ 921 (0.22)		3/ 933 (0.32)				
LVEF at baseline							
< 50%	2/ 1093 (0.18)		2/ 1079 (0.19)				
>= 50% - < 60%	5/ 1329 (0.38)		2/ 1345 (0.15)				
>= 60%	0/ 575 (0.00)		2/ 572 (0.35)				

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first all-cause hospitalization
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	1433/ 3003 (47.72)	1481/ 2998 (49.40)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.7 (8.9, 11.1)	9.0 (8.3, 9.7)
Median (95% CI)	33.5 (31.1, 35.6)	31.4 (28.0, 34.1)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.88, 1.02)	
p-value	0.1264	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.88, 1.02)	
p-value	0.1229	

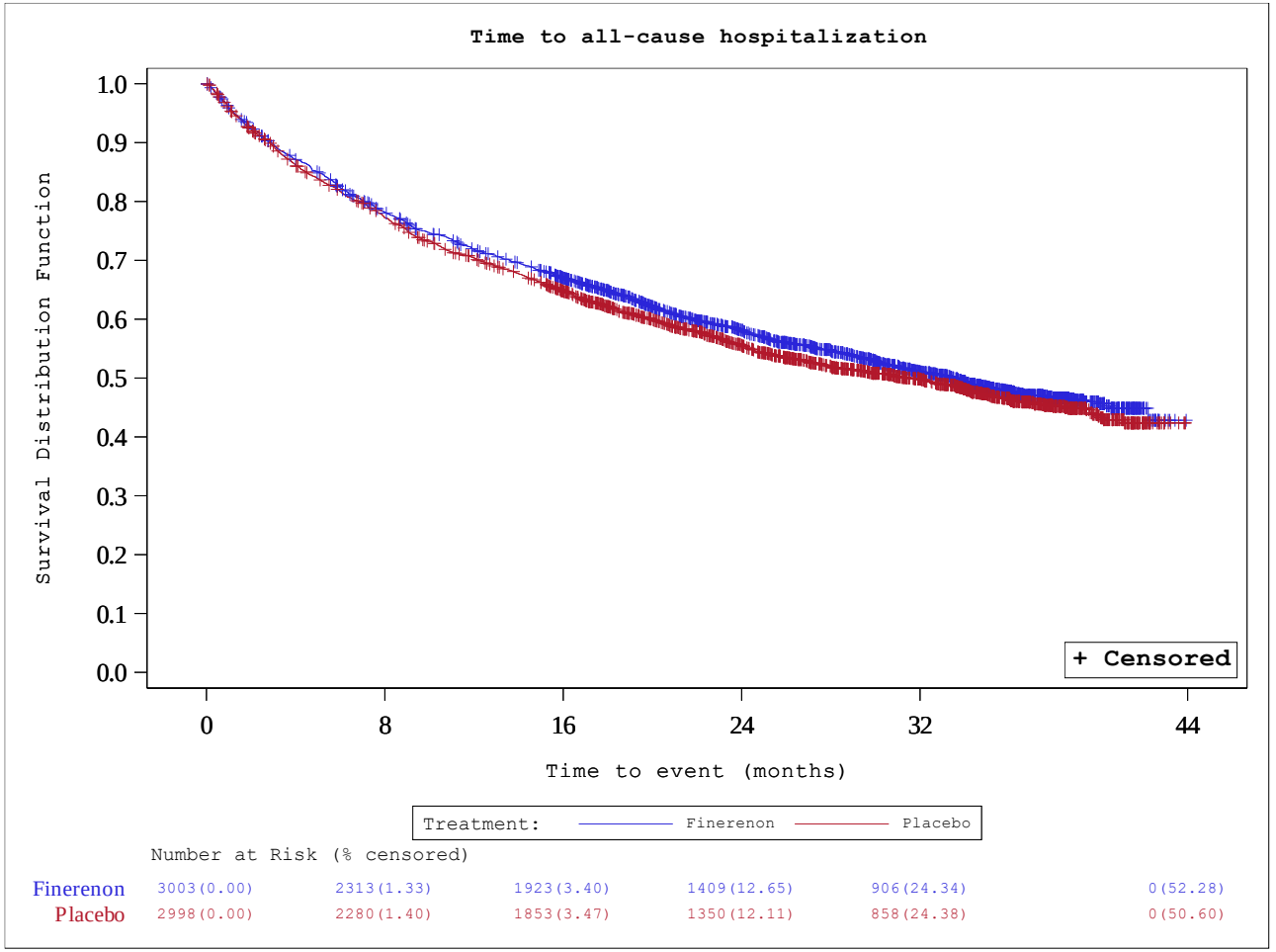
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first all-cause hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.1953
Male	814/ 1648 (49.39)	31.1 (29.1, 34.5)	788/ 1621 (48.61)	32.5 (27.8, 37.1)	0.99 (0.89, 1.09)	0.7781	
Female	619/ 1355 (45.68)	35.6 (32.2, NE)	693/ 1377 (50.33)	30.2 (26.5, 33.9)	0.90 (0.80, 1.00)	0.0451	
Region							0.5975
Western Europe, Oceania and Others	360/ 624 (57.69)	22.3 (19.5, 26.1)	394/ 632 (62.34)	19.5 (17.0, 22.0)	0.89 (0.77, 1.02)	0.1041	
Eastern Europe	555/ 1329 (41.76)	NE (40.5, NE)	550/ 1321 (41.64)	NE (40.0, NE)	0.99 (0.88, 1.12)	0.9093	
Asia	262/ 493 (53.14)	28.6 (23.9, 33.4)	271/ 490 (55.31)	24.2 (19.6, 29.5)	0.94 (0.79, 1.11)	0.4804	
North America	130/ 235 (55.32)	20.5 (17.5, 29.2)	125/ 236 (52.97)	22.0 (17.3, 34.1)	1.03 (0.81, 1.32)	0.7923	
Latin America	126/ 322 (39.13)	NE (34.5, NE)	141/ 319 (44.20)	33.1 (25.3, NE)	0.84 (0.66, 1.06)	0.1430	
Age group (years)							0.0107
<= median in FAS	647/ 1589 (40.72)	NE (40.5, NE)	720/ 1579 (45.60)	38.5 (33.6, NE)	0.86 (0.77, 0.96)	0.0052	
> median in FAS	786/ 1414 (55.59)	25.2 (22.9, 28.3)	761/ 1419 (53.63)	25.3 (23.2, 29.4)	1.04 (0.94, 1.15)	0.4688	
NYHA class at baseline							0.3432
II	935/ 2081 (44.93)	36.7 (34.1, 40.5)	947/ 2065 (45.86)	36.1 (33.9, 40.1)	0.97 (0.88, 1.06)	0.4744	
III/IV	497/ 921 (53.96)	25.1 (22.0, 30.0)	534/ 933 (57.23)	22.4 (19.1, 24.5)	0.90 (0.80, 1.02)	0.1003	
LVEF at baseline							0.8869
< 50%	487/ 1093 (44.56)	37.7 (33.1, NE)	503/ 1079 (46.62)	35.0 (30.8, 39.5)	0.92 (0.81, 1.05)	0.2056	
>= 50% - < 60%	648/ 1329 (48.76)	31.3 (27.4, 35.3)	669/ 1345 (49.74)	29.4 (25.4, 34.1)	0.96 (0.86, 1.07)	0.4792	
>= 60%	295/ 575 (51.30)	31.1 (27.0, 35.9)	308/ 572 (53.85)	28.0 (23.9, 33.1)	0.95 (0.81, 1.11)	0.4915	

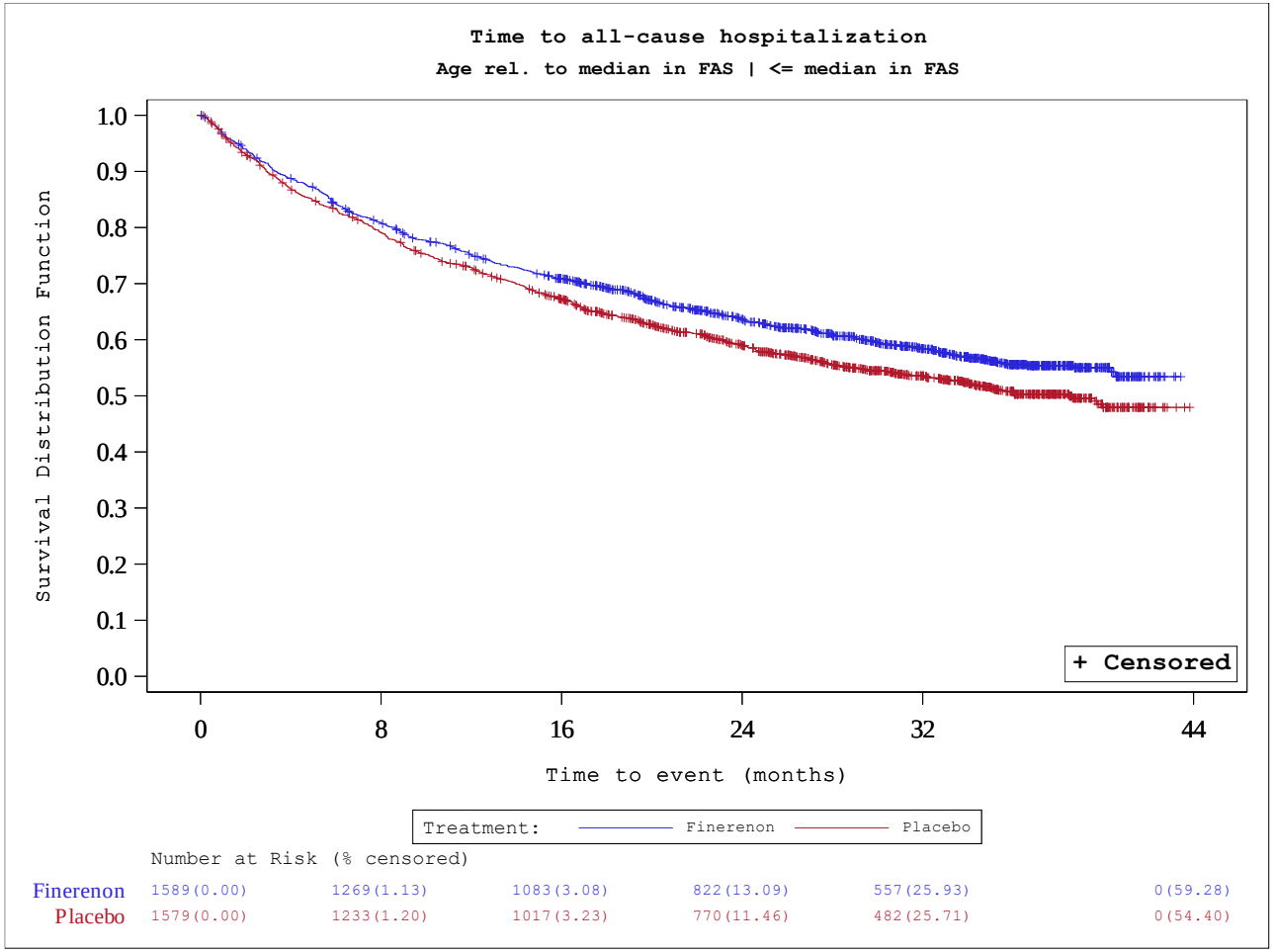
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Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



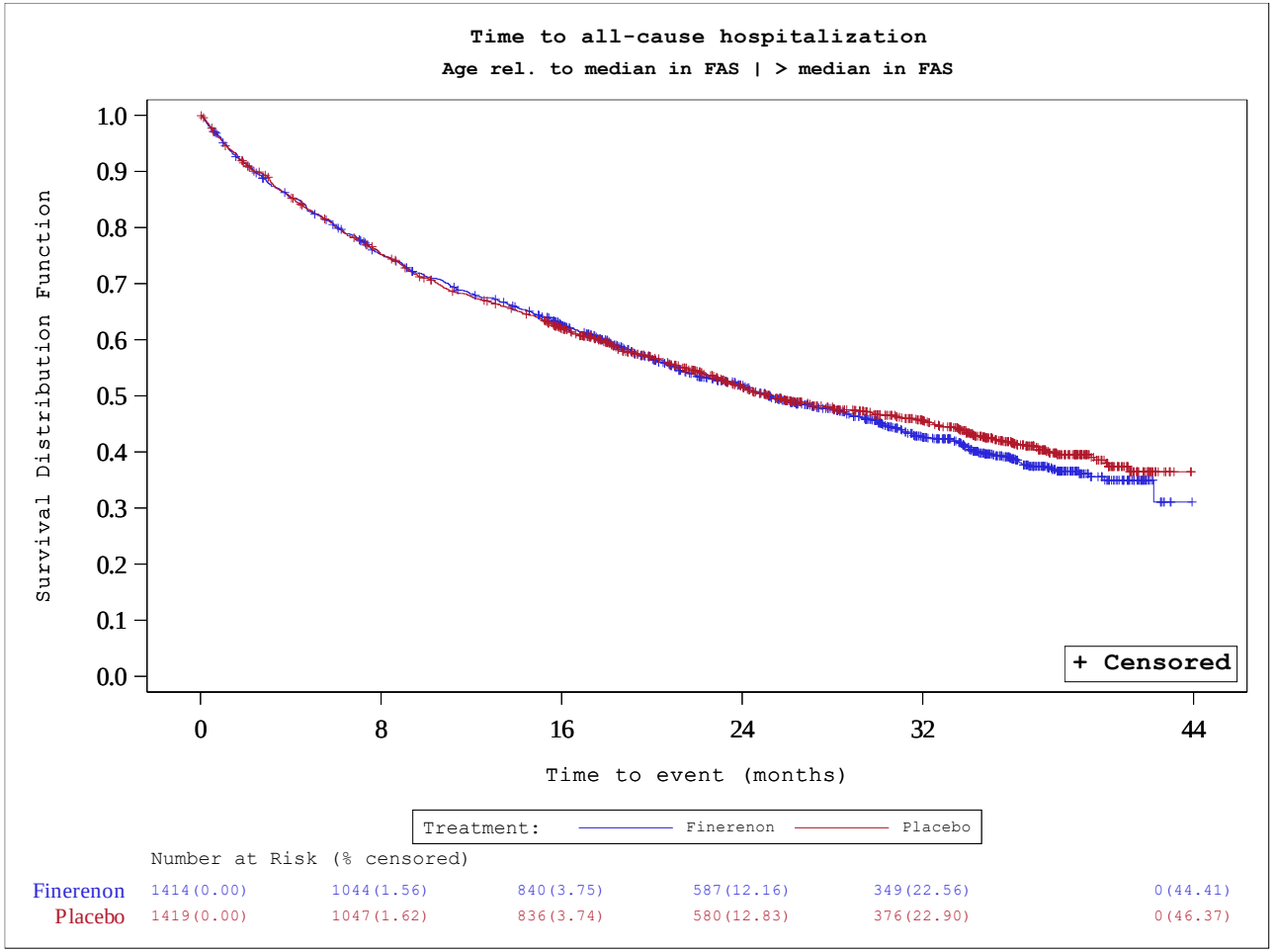
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with event, n/N (%)	1536/ 3003 (51.15)	1596/ 2998 (53.24)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.1 (8.4, 10.1)	8.6 (7.9, 9.2)
Median (95% CI)	30.7 (28.8, 32.9)	27.6 (25.3, 30.1)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.87, 1.01)	
p-value	0.0700	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.87, 1.01)	
p-value	0.0707	

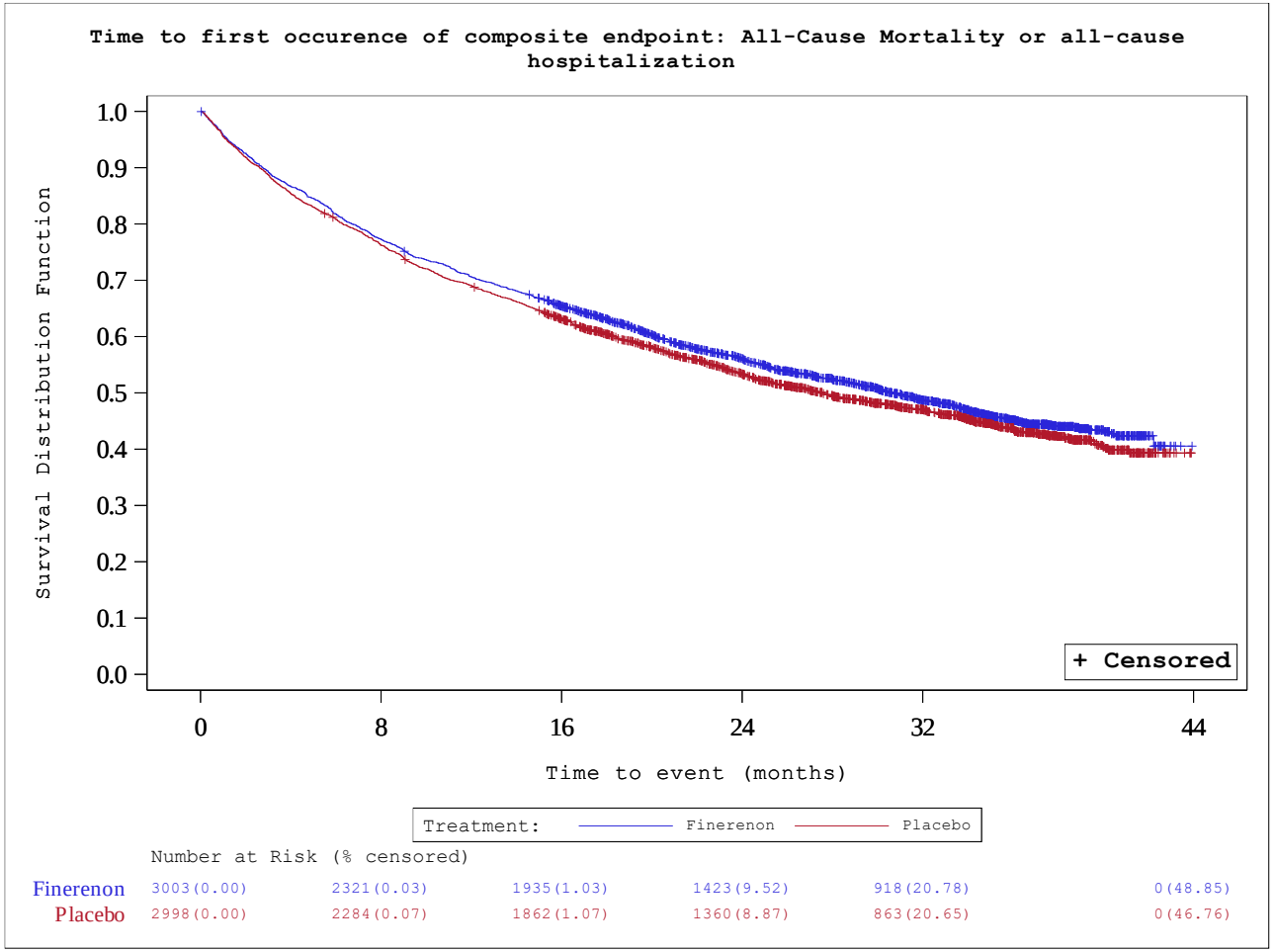
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Finerenone (N=3003) Median (95% CI)	Placebo (N=2998) n/ N (%)	Placebo (N=2998) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.1907
Male	876/ 1648 (53.16)	29.2 (26.4, 31.6)	854/ 1621 (52.68)	27.7 (24.5, 31.4)	0.98 (0.89, 1.07)	0.6331	
Female	660/ 1355 (48.71)	33.4 (29.8, 36.5)	742/ 1377 (53.89)	27.1 (24.6, 30.9)	0.89 (0.80, 0.99)	0.0285	
Region							0.5145
Western Europe, Oceania and Others	374/ 624 (59.94)	21.7 (19.4, 25.2)	405/ 632 (64.08)	19.3 (16.5, 21.2)	0.89 (0.77, 1.03)	0.1069	
Eastern Europe	616/ 1329 (46.35)	40.3 (34.2, NE)	614/ 1321 (46.48)	39.6 (35.0, NE)	0.99 (0.88, 1.10)	0.7989	
Asia	276/ 493 (55.98)	26.7 (21.5, 31.3)	289/ 490 (58.98)	22.7 (18.7, 26.1)	0.93 (0.79, 1.10)	0.3987	
North America	137/ 235 (58.30)	19.9 (16.7, 25.6)	134/ 236 (56.78)	21.0 (15.6, 27.2)	1.02 (0.80, 1.29)	0.8797	
Latin America	133/ 322 (41.30)	NE (32.7, NE)	154/ 319 (48.28)	30.7 (24.0, 38.3)	0.81 (0.64, 1.02)	0.0698	
Age group (years)							0.0038
<= median in FAS	693/ 1589 (43.61)	NE (38.7, NE)	781/ 1579 (49.46)	32.8 (28.5, 36.1)	0.85 (0.76, 0.94)	0.0013	
> median in FAS	843/ 1414 (59.62)	23.8 (21.2, 25.4)	815/ 1419 (57.43)	23.5 (21.6, 25.7)	1.04 (0.94, 1.14)	0.4352	
NYHA class at baseline							0.4025
II	1000/ 2081 (48.05)	34.2 (31.8, 36.7)	1021/ 2065 (49.44)	33.6 (29.7, 36.0)	0.96 (0.88, 1.04)	0.3205	
III/IV	535/ 921 (58.09)	23.1 (20.1, 25.6)	575/ 933 (61.63)	20.2 (17.7, 23.1)	0.90 (0.80, 1.01)	0.0857	
LVEF at baseline							0.7627
< 50%	538/ 1093 (49.22)	32.9 (29.7, 36.2)	563/ 1079 (52.18)	29.3 (25.9, 33.9)	0.91 (0.81, 1.03)	0.1243	
>= 50% - < 60%	679/ 1329 (51.09)	29.8 (25.7, 33.7)	715/ 1345 (53.16)	26.2 (23.5, 29.8)	0.94 (0.85, 1.04)	0.2452	
>= 60%	316/ 575 (54.96)	28.8 (24.9, 33.6)	317/ 572 (55.42)	27.3 (23.2, 32.7)	0.98 (0.84, 1.15)	0.8098	

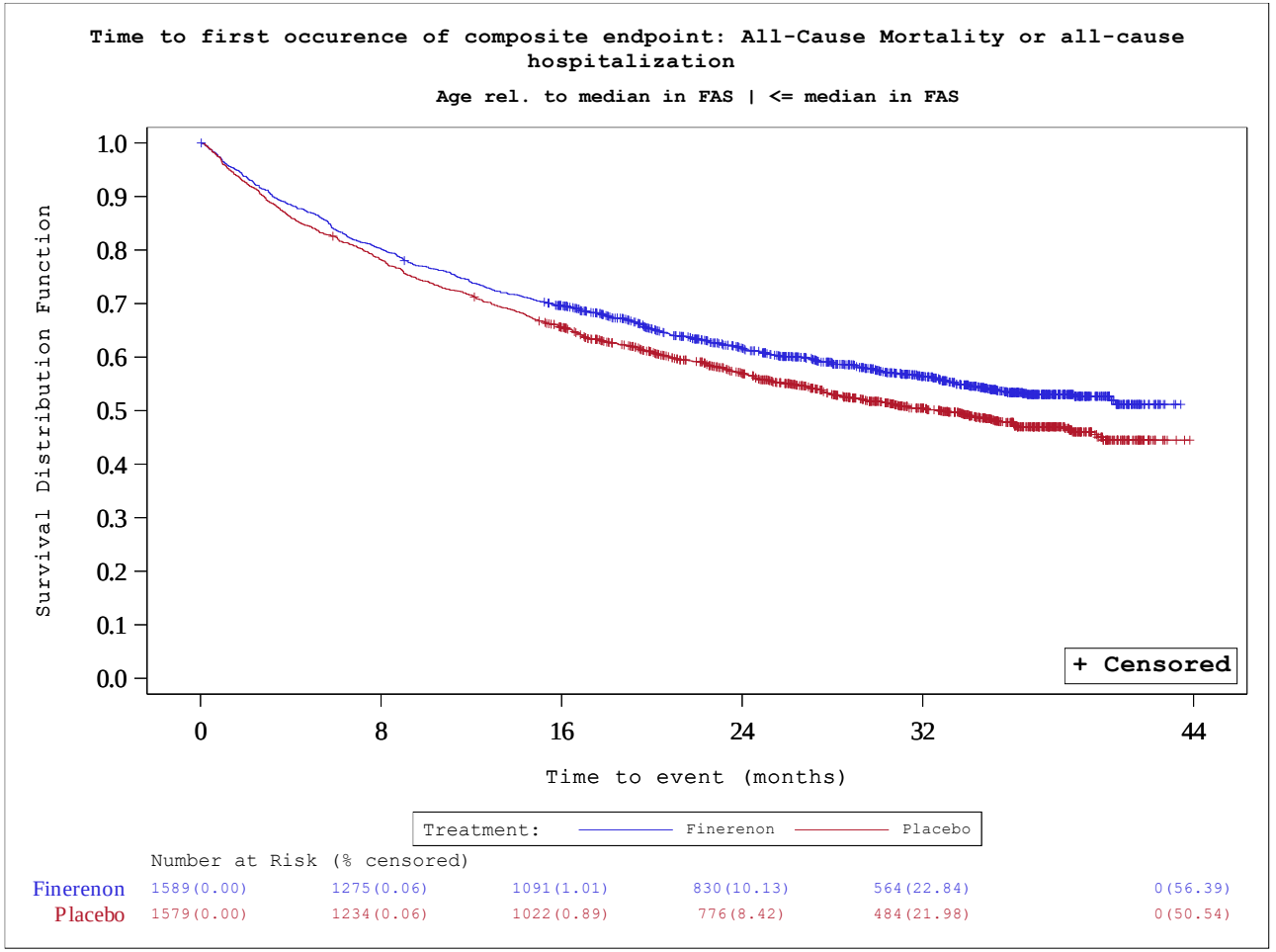
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



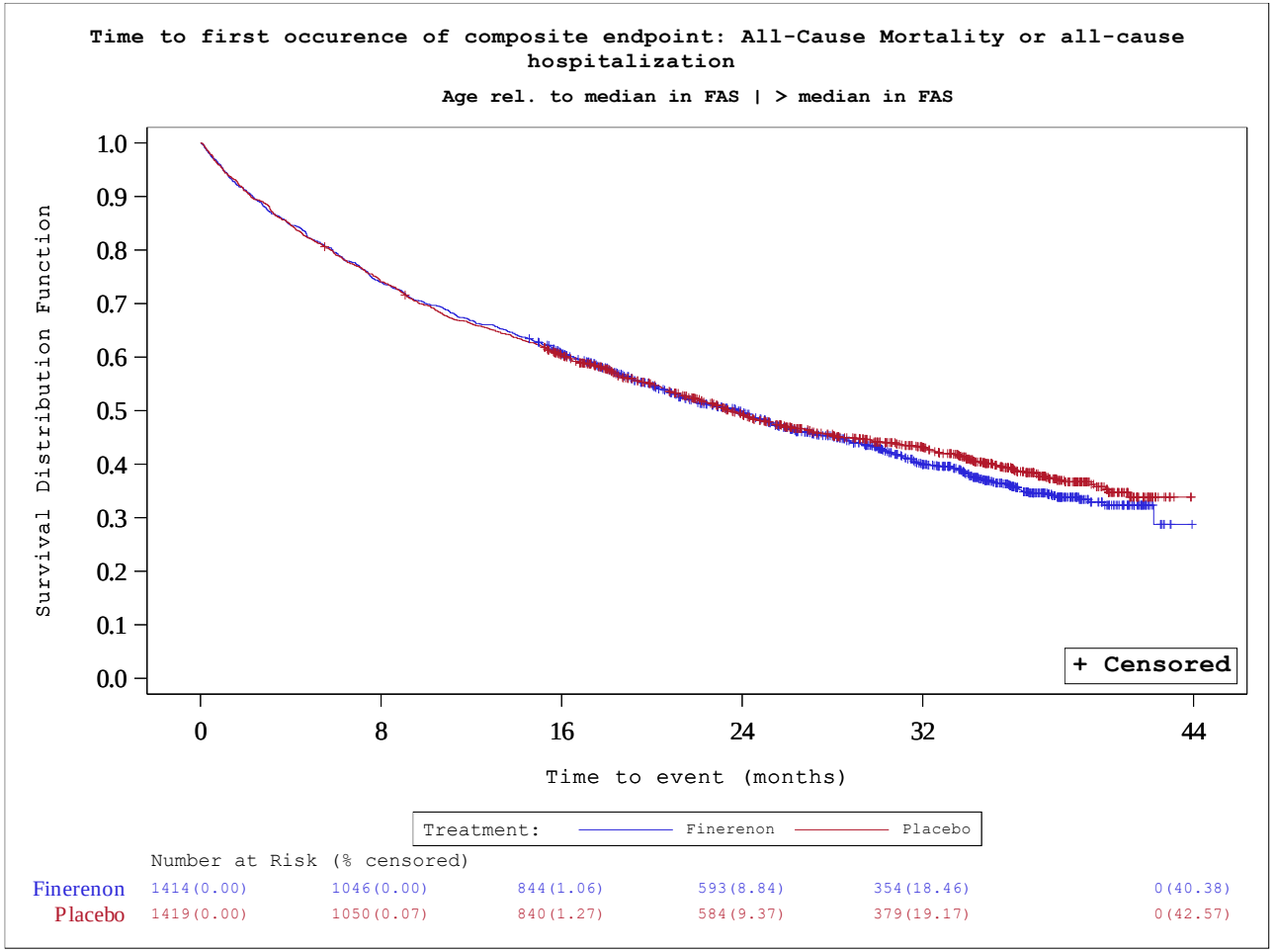
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Event counts per component of composite efficacy endpoints
Full Analysis Set

Endpoint	Finerenone (N=3003) n (%)	Placebo (N=2998) n (%)
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)	885 (29.47 %)	951 (31.72 %)
CV hospitalization	705 (23.48 %)	777 (25.92 %)
Cardiovascular Death	92 (3.06 %)	103 (3.44 %)
Hospitalization due to Heart Failure	57 (1.90 %)	46 (1.53 %)
Non-fatal MI	11 (0.37 %)	9 (0.30 %)
Non-fatal Stroke	20 (0.67 %)	16 (0.53 %)
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis	41 (1.37 %)	31 (1.03 %)
Renal transplantation or initiation of dialysis	2 (0.07 %)	2 (0.07 %)
Sustained decrease in eGFR <15	17 (0.57 %)	11 (0.37 %)
Sustained decrease in eGFR >=57%	22 (0.73 %)	18 (0.60 %)
Time to first CV hospitalization	754 (25.11 %)	819 (27.32 %)
Cardiac failure (SMQ)	13 (0.43 %)	15 (0.50 %)
Central nervous system vascular disorders (SMQ)	98 (3.26 %)	88 (2.94 %)
Hospitalization due to Heart Failure	425 (14.15 %)	511 (17.04 %)
Myocardial infarction (SMQ)	88 (2.93 %)	75 (2.50 %)
Other ischaemic heart disease (SMQ)	38 (1.27 %)	41 (1.37 %)
Supraventricular tachyarrhythmias (SMQ)	92 (3.06 %)	89 (2.97 %)
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization	1536 (51.15 %)	1596 (53.24 %)
All-cause hospitalization	1433 (47.72 %)	1481 (49.40 %)
Cardiovascular Death	61 (2.03 %)	77 (2.57 %)
Non-Cardiovascular Death	16 (0.53 %)	13 (0.43 %)
Undetermined Death	26 (0.87 %)	25 (0.83 %)
CV death and HHF	599 (19.95 %)	664 (22.15 %)
Cardiovascular Death	149 (4.96 %)	150 (5.00 %)
Hospitalization due to Heart Failure	450 (14.99 %)	514 (17.14 %)
Composite endpoint of CV death and total HF event	624 (20.78 %)	719 (23.98 %)
Cardiovascular Death	145 (4.83 %)	146 (4.87 %)
Heart Failure (Urgent)	51 (1.70 %)	80 (2.67 %)
Hospitalization due to Heart Failure	428 (14.25 %)	493 (16.44 %)

n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	800/ 2841 (28.16)	790/ 2826 (27.95)
Number of imputed values	349	327
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.04 (0.92, 1.17)	
p-value	0.5134	
Risk Ratio (95% CI)	1.02 (0.96, 1.08)	
p-value	0.6272	
Risk Difference (95% CI)	0.01 (-0.02, 0.03)	
p-value	0.5786	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.01 (0.90, 1.13)	
p-value	0.8640	
Risk Ratio (95% CI)	1.01 (0.93, 1.09)	
p-value	0.8640	
Risk Difference (95% CI)	0.00 (-0.02, 0.03)	
p-value	0.8640	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.3059
Male	453/ 1575 (28.76)	425/ 1548 (27.45)	1.05 (0.94, 1.17)	0.4167	1.07 (0.91, 1.25)	0.4166	0.01 (-0.02, 0.04)	0.4165	
Female	347/ 1266 (27.41)	365/ 1278 (28.56)	0.96 (0.85, 1.09)	0.5180	0.94 (0.79, 1.12)	0.5179	-0.01 (-0.05, 0.02)	0.5178	
Region									0.9053
Western Europe, Oceania and Others	141/ 576 (24.48)	134/ 588 (22.79)	1.07 (0.87, 1.32)	0.4975	1.10 (0.84, 1.44)	0.4974	0.02 (-0.03, 0.07)	0.4974	
Eastern Europe	352/ 1282 (27.46)	350/ 1268 (27.60)	0.99 (0.88, 1.13)	0.9345	0.99 (0.83, 1.18)	0.9345	-0.00 (-0.04, 0.03)	0.9345	
Asia	134/ 458 (29.26)	141/ 454 (31.06)	0.94 (0.77, 1.15)	0.5539	0.92 (0.69, 1.22)	0.5538	-0.02 (-0.08, 0.04)	0.5537	
North America	64/ 217 (29.49)	63/ 212 (29.72)	0.99 (0.74, 1.33)	0.9595	0.99 (0.65, 1.50)	0.9595	-0.00 (-0.09, 0.08)	0.9595	
Latin America	109/ 308 (35.39)	102/ 304 (33.55)	1.05 (0.85, 1.31)	0.6327	1.08 (0.78, 1.51)	0.6326	0.02 (-0.06, 0.09)	0.6325	
Age group (years)									0.9302
<= median in FAS	453/ 1509 (30.02)	442/ 1487 (29.72)	1.01 (0.90, 1.13)	0.8597	1.01 (0.87, 1.19)	0.8597	0.00 (-0.03, 0.04)	0.8597	
> median in FAS	347/ 1332 (26.05)	348/ 1339 (25.99)	1.00 (0.88, 1.14)	0.9711	1.00 (0.84, 1.19)	0.9711	0.00 (-0.03, 0.03)	0.9711	
NYHA class at baseline									0.3414
II	550/ 1973 (27.88)	555/ 1953 (28.42)	0.98 (0.89, 1.08)	0.7060	0.97 (0.85, 1.12)	0.7060	-0.01 (-0.03, 0.02)	0.7060	
III/IV	250/ 867 (28.84)	235/ 873 (26.92)	1.07 (0.92, 1.25)	0.3729	1.10 (0.89, 1.36)	0.3728	0.02 (-0.02, 0.06)	0.3726	
LVEF at baseline									0.9257
< 50%	308/ 1034 (29.79)	295/ 1019 (28.95)	1.03 (0.90, 1.18)	0.6771	1.04 (0.86, 1.26)	0.6771	0.01 (-0.03, 0.05)	0.6770	
>= 50% - < 60%	351/ 1247 (28.15)	358/ 1268 (28.23)	1.00 (0.88, 1.13)	0.9618	1.00 (0.84, 1.18)	0.9618	-0.00 (-0.04, 0.03)	0.9618	
>= 60%	140/ 555 (25.23)	137/ 537 (25.51)	0.99 (0.81, 1.21)	0.9133	0.98 (0.75, 1.29)	0.9133	-0.00 (-0.05, 0.05)	0.9133	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	549/ 2841 (19.32)	563/ 2826 (19.92)
Number of imputed values	349	327
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.95 (0.83, 1.08)	
p-value	0.4307	
Risk Ratio (95% CI)	0.95 (0.86, 1.06)	
p-value	0.3713	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.2673	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.96 (0.84, 1.10)	
p-value	0.5709	
Risk Ratio (95% CI)	0.97 (0.87, 1.08)	
p-value	0.5709	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.5709	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.1365
Male	285/ 1575 (18.10)	311/ 1548 (20.09)	0.90 (0.78, 1.04)	0.1563	0.88 (0.73, 1.05)	0.1562	-0.02 (-0.05, 0.01)	0.1560	
Female	264/ 1266 (20.85)	252/ 1278 (19.72)	1.06 (0.91, 1.23)	0.4767	1.07 (0.88, 1.30)	0.4767	0.01 (-0.02, 0.04)	0.4767	
Region									0.9485
Western Europe, Oceania and Others	138/ 576 (23.96)	154/ 588 (26.19)	0.91 (0.75, 1.12)	0.3802	0.89 (0.68, 1.16)	0.3799	-0.02 (-0.07, 0.03)	0.3795	
Eastern Europe	235/ 1282 (18.33)	229/ 1268 (18.06)	1.01 (0.86, 1.20)	0.8593	1.02 (0.83, 1.25)	0.8593	0.00 (-0.03, 0.03)	0.8593	
Asia	70/ 458 (15.28)	74/ 454 (16.30)	0.94 (0.69, 1.27)	0.6741	0.93 (0.65, 1.32)	0.6741	-0.01 (-0.06, 0.04)	0.6741	
North America	47/ 217 (21.66)	48/ 212 (22.64)	0.96 (0.67, 1.36)	0.8064	0.94 (0.60, 1.49)	0.8064	-0.01 (-0.09, 0.07)	0.8064	
Latin America	59/ 308 (19.16)	58/ 304 (19.08)	1.00 (0.72, 1.39)	0.9807	1.00 (0.67, 1.50)	0.9807	0.00 (-0.06, 0.06)	0.9807	
Age group (years)									0.8726
<= median in FAS	242/ 1509 (16.04)	243/ 1487 (16.34)	0.98 (0.83, 1.16)	0.8210	0.98 (0.81, 1.19)	0.8210	-0.00 (-0.03, 0.02)	0.8210	
> median in FAS	307/ 1332 (23.05)	320/ 1339 (23.90)	0.96 (0.84, 1.11)	0.6042	0.95 (0.80, 1.14)	0.6041	-0.01 (-0.04, 0.02)	0.6041	
NYHA class at baseline									0.4320
II	350/ 1973 (17.74)	368/ 1953 (18.84)	0.94 (0.82, 1.07)	0.3713	0.93 (0.79, 1.09)	0.3713	-0.01 (-0.04, 0.01)	0.3712	
III/IV	199/ 867 (22.95)	195/ 873 (22.34)	1.03 (0.86, 1.22)	0.7589	1.04 (0.83, 1.30)	0.7589	0.01 (-0.03, 0.05)	0.7589	
LVEF at baseline									0.4692
< 50%	203/ 1034 (19.63)	201/ 1019 (19.73)	1.00 (0.84, 1.19)	0.9579	0.99 (0.80, 1.24)	0.9579	-0.00 (-0.04, 0.03)	0.9579	
>= 50% - < 60%	232/ 1247 (18.60)	261/ 1268 (20.58)	0.90 (0.77, 1.06)	0.2117	0.88 (0.72, 1.07)	0.2115	-0.02 (-0.05, 0.01)	0.2110	
>= 60%	112/ 555 (20.18)	101/ 537 (18.81)	1.07 (0.84, 1.37)	0.5675	1.09 (0.81, 1.47)	0.5674	0.01 (-0.03, 0.06)	0.5671	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
EQ5D-VAS: Completion rates
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)	
Timepoint	n/ N	Completion	n/ N	Completion
Baseline	2990 /3003	99.57 %	2981 /2998	99.43 %
Month 6	2691 /2915	92.32 %	2671 /2905	91.94 %
Month 9	2516 /2868	87.73 %	2524 /2859	88.28 %
Month 12	2498 /2823	88.49 %	2508 /2813	89.16 %
Month 16	2339 /2713	86.21 %	2314 /2713	85.29 %
Month 24	1874 /2219	84.45 %	1840 /2215	83.07 %
Month 32	1245 /1550	80.32 %	1231 /1529	80.51 %
Month 40	184 /272	67.65 %	176 /269	65.43 %

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	937/ 2847 (32.91)	942/ 2835 (33.23)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.98 (0.88, 1.10)	
p-value	0.7717	
Risk Ratio (95% CI)	0.99 (0.92, 1.06)	
p-value	0.6892	
Risk Difference (95% CI)	-0.00 (-0.03, 0.02)	
p-value	0.8741	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.99 (0.88, 1.10)	
p-value	0.8004	
Risk Ratio (95% CI)	0.99 (0.92, 1.07)	
p-value	0.8004	
Risk Difference (95% CI)	-0.00 (-0.03, 0.02)	
p-value	0.8004	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.1537
Male	570/ 1579 (36.10)	542/ 1554 (34.88)	1.04 (0.94, 1.14)	0.4752	1.05 (0.91, 1.22)	0.4751	0.01 (-0.02, 0.05)	0.4751	
Female	367/ 1268 (28.94)	400/ 1281 (31.23)	0.93 (0.82, 1.04)	0.2093	0.90 (0.76, 1.06)	0.2091	-0.02 (-0.06, 0.01)	0.2089	
Region									0.3016
Western Europe, Oceania and Others	155/ 578 (26.82)	143/ 590 (24.24)	1.11 (0.91, 1.35)	0.3124	1.15 (0.88, 1.49)	0.3122	0.03 (-0.02, 0.08)	0.3120	
Eastern Europe	376/ 1286 (29.24)	402/ 1270 (31.65)	0.92 (0.82, 1.04)	0.1847	0.89 (0.75, 1.06)	0.1846	-0.02 (-0.06, 0.01)	0.1844	
Asia	204/ 458 (44.54)	215/ 454 (47.36)	0.94 (0.82, 1.08)	0.3939	0.89 (0.69, 1.16)	0.3937	-0.03 (-0.09, 0.04)	0.3935	
North America	57/ 217 (26.27)	51/ 216 (23.61)	1.11 (0.80, 1.54)	0.5234	1.15 (0.75, 1.78)	0.5232	0.03 (-0.05, 0.11)	0.5228	
Latin America	145/ 308 (47.08)	131/ 305 (42.95)	1.10 (0.92, 1.31)	0.3051	1.18 (0.86, 1.62)	0.3046	0.04 (-0.04, 0.12)	0.3040	
Age group (years)									0.5839
<= median in FAS	565/ 1512 (37.37)	554/ 1492 (37.13)	1.01 (0.92, 1.10)	0.8934	1.01 (0.87, 1.17)	0.8934	0.00 (-0.03, 0.04)	0.8934	
> median in FAS	372/ 1335 (27.87)	388/ 1343 (28.89)	0.96 (0.86, 1.09)	0.5563	0.95 (0.80, 1.12)	0.5562	-0.01 (-0.04, 0.02)	0.5562	
NYHA class at baseline									0.7255
II	679/ 1977 (34.34)	674/ 1960 (34.39)	1.00 (0.92, 1.09)	0.9775	1.00 (0.88, 1.14)	0.9775	-0.00 (-0.03, 0.03)	0.9775	
III/IV	258/ 869 (29.69)	268/ 875 (30.63)	0.97 (0.84, 1.12)	0.6692	0.96 (0.78, 1.17)	0.6691	-0.01 (-0.05, 0.03)	0.6691	
LVEF at baseline									0.1350
< 50%	362/ 1034 (35.01)	372/ 1022 (36.40)	0.96 (0.86, 1.08)	0.5109	0.94 (0.79, 1.13)	0.5109	-0.01 (-0.06, 0.03)	0.5108	
>= 50% - < 60%	399/ 1252 (31.87)	425/ 1272 (33.41)	0.95 (0.85, 1.07)	0.4087	0.93 (0.79, 1.10)	0.4085	-0.02 (-0.05, 0.02)	0.4084	
>= 60%	176/ 556 (31.65)	145/ 539 (26.90)	1.18 (0.98, 1.42)	0.0850	1.26 (0.97, 1.63)	0.0844	0.05 (-0.01, 0.10)	0.0835	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	364/ 2847 (12.79)	390/ 2835 (13.76)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.92 (0.79, 1.08)	
p-value	0.3025	
Risk Ratio (95% CI)	0.93 (0.81, 1.06)	
p-value	0.2882	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.3782	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.92 (0.79, 1.07)	
p-value	0.2807	
Risk Ratio (95% CI)	0.93 (0.81, 1.06)	
p-value	0.2807	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.2806	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.8116
Male	218/ 1579 (13.81)	228/ 1554 (14.67)	0.94 (0.79, 1.12)	0.4882	0.93 (0.76, 1.14)	0.4882	-0.01 (-0.03, 0.02)	0.4882	
Female	146/ 1268 (11.51)	162/ 1281 (12.65)	0.91 (0.74, 1.12)	0.3808	0.90 (0.71, 1.14)	0.3807	-0.01 (-0.04, 0.01)	0.3804	
Region									0.4975
Western Europe, Oceania and Others	84/ 578 (14.53)	105/ 590 (17.80)	0.82 (0.63, 1.06)	0.1311	0.79 (0.57, 1.07)	0.1305	-0.03 (-0.07, 0.01)	0.1293	
Eastern Europe	150/ 1286 (11.66)	144/ 1270 (11.34)	1.03 (0.83, 1.28)	0.7965	1.03 (0.81, 1.32)	0.7965	0.00 (-0.02, 0.03)	0.7965	
Asia	55/ 458 (12.01)	54/ 454 (11.89)	1.01 (0.71, 1.44)	0.9575	1.01 (0.68, 1.51)	0.9575	0.00 (-0.04, 0.04)	0.9575	
North America	28/ 217 (12.90)	39/ 216 (18.06)	0.71 (0.46, 1.12)	0.1411	0.67 (0.40, 1.14)	0.1399	-0.05 (-0.12, 0.02)	0.1374	
Latin America	47/ 308 (15.26)	48/ 305 (15.74)	0.97 (0.67, 1.40)	0.8701	0.96 (0.62, 1.49)	0.8701	-0.00 (-0.06, 0.05)	0.8701	
Age group (years)									0.8537
<= median in FAS	160/ 1512 (10.58)	172/ 1492 (11.53)	0.92 (0.75, 1.12)	0.4084	0.91 (0.72, 1.14)	0.4084	-0.01 (-0.03, 0.01)	0.4083	
> median in FAS	204/ 1335 (15.28)	218/ 1343 (16.23)	0.94 (0.79, 1.12)	0.4994	0.93 (0.76, 1.15)	0.4993	-0.01 (-0.04, 0.02)	0.4992	
NYHA class at baseline									0.4095
II	223/ 1977 (11.28)	248/ 1960 (12.65)	0.89 (0.75, 1.06)	0.1846	0.88 (0.72, 1.06)	0.1845	-0.01 (-0.03, 0.01)	0.1843	
III/IV	141/ 869 (16.23)	142/ 875 (16.23)	1.00 (0.81, 1.24)	0.9986	1.00 (0.78, 1.29)	0.9986	-0.00 (-0.03, 0.03)	0.9986	
LVEF at baseline									0.9273
< 50%	143/ 1034 (13.83)	147/ 1022 (14.38)	0.96 (0.78, 1.19)	0.7184	0.96 (0.75, 1.22)	0.7183	-0.01 (-0.04, 0.02)	0.7183	
>= 50% - < 60%	154/ 1252 (12.30)	172/ 1272 (13.52)	0.91 (0.74, 1.11)	0.3605	0.90 (0.71, 1.13)	0.3603	-0.01 (-0.04, 0.01)	0.3599	
>= 60%	66/ 556 (11.87)	70/ 539 (12.99)	0.91 (0.67, 1.25)	0.5756	0.90 (0.63, 1.29)	0.5756	-0.01 (-0.05, 0.03)	0.5756	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	922/ 2847 (32.38)	913/ 2835 (32.20)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.01 (0.90, 1.13)	
p-value	0.8518	
Risk Ratio (95% CI)	1.01 (0.93, 1.08)	
p-value	0.8849	
Risk Difference (95% CI)	0.00 (-0.02, 0.03)	
p-value	0.7668	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.01 (0.90, 1.13)	
p-value	0.8844	
Risk Ratio (95% CI)	1.01 (0.93, 1.08)	
p-value	0.8844	
Risk Difference (95% CI)	0.00 (-0.02, 0.03)	
p-value	0.8844	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.3038
Male	538/ 1579 (34.07)	509/ 1554 (32.75)	1.04 (0.94, 1.15)	0.4343	1.06 (0.91, 1.23)	0.4343	0.01 (-0.02, 0.05)	0.4342	
Female	384/ 1268 (30.28)	404/ 1281 (31.54)	0.96 (0.85, 1.08)	0.4935	0.94 (0.80, 1.12)	0.4934	-0.01 (-0.05, 0.02)	0.4933	
Region									0.1289
Western Europe, Oceania and Others	165/ 578 (28.55)	136/ 590 (23.05)	1.24 (1.02, 1.51)	0.0324	1.33 (1.03, 1.74)	0.0320	0.05 (0.00, 0.11)	0.0316	
Eastern Europe	380/ 1286 (29.55)	405/ 1270 (31.89)	0.93 (0.82, 1.04)	0.1998	0.90 (0.76, 1.06)	0.1997	-0.02 (-0.06, 0.01)	0.1995	
Asia	183/ 458 (39.96)	188/ 454 (41.41)	0.96 (0.82, 1.13)	0.6551	0.94 (0.72, 1.23)	0.6551	-0.01 (-0.08, 0.05)	0.6550	
North America	61/ 217 (28.11)	53/ 216 (24.54)	1.15 (0.84, 1.57)	0.3993	1.20 (0.78, 1.85)	0.3988	0.04 (-0.05, 0.12)	0.3981	
Latin America	133/ 308 (43.18)	131/ 305 (42.95)	1.01 (0.84, 1.21)	0.9539	1.01 (0.73, 1.39)	0.9539	0.00 (-0.08, 0.08)	0.9539	
Age group (years)									0.2200
<= median in FAS	553/ 1512 (36.57)	522/ 1492 (34.99)	1.05 (0.95, 1.15)	0.3643	1.07 (0.92, 1.24)	0.3642	0.02 (-0.02, 0.05)	0.3640	
> median in FAS	369/ 1335 (27.64)	391/ 1343 (29.11)	0.95 (0.84, 1.07)	0.3979	0.93 (0.79, 1.10)	0.3978	-0.01 (-0.05, 0.02)	0.3977	
NYHA class at baseline									0.4674
II	670/ 1977 (33.89)	649/ 1960 (33.11)	1.02 (0.94, 1.12)	0.6053	1.04 (0.91, 1.18)	0.6053	0.01 (-0.02, 0.04)	0.6053	
III/IV	252/ 869 (29.00)	264/ 875 (30.17)	0.96 (0.83, 1.11)	0.5917	0.95 (0.77, 1.16)	0.5917	-0.01 (-0.05, 0.03)	0.5916	
LVEF at baseline									0.6825
< 50%	357/ 1034 (34.53)	348/ 1022 (34.05)	1.01 (0.90, 1.14)	0.8204	1.02 (0.85, 1.23)	0.8204	0.00 (-0.04, 0.05)	0.8204	
>= 50% - < 60%	394/ 1252 (31.47)	411/ 1272 (32.31)	0.97 (0.87, 1.09)	0.6501	0.96 (0.81, 1.14)	0.6501	-0.01 (-0.04, 0.03)	0.6501	
>= 60%	170/ 556 (30.58)	154/ 539 (28.57)	1.07 (0.89, 1.29)	0.4679	1.10 (0.85, 1.43)	0.4677	0.02 (-0.03, 0.07)	0.4674	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	357/ 2847 (12.54)	371/ 2835 (13.09)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.96 (0.82, 1.12)	
p-value	0.5729	
Risk Ratio (95% CI)	0.96 (0.84, 1.10)	
p-value	0.5410	
Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
p-value	0.7300	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.95 (0.81, 1.11)	
p-value	0.5374	
Risk Ratio (95% CI)	0.96 (0.84, 1.10)	
p-value	0.5375	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.5374	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.6355
Male	213/ 1579 (13.49)	225/ 1554 (14.48)	0.93 (0.78, 1.11)	0.4248	0.92 (0.75, 1.13)	0.4248	-0.01 (-0.03, 0.01)	0.4248	
Female	144/ 1268 (11.36)	146/ 1281 (11.40)	1.00 (0.80, 1.24)	0.9741	1.00 (0.78, 1.27)	0.9741	-0.00 (-0.03, 0.02)	0.9741	
Region									0.4543
Western Europe, Oceania and Others	83/ 578 (14.36)	108/ 590 (18.31)	0.78 (0.60, 1.02)	0.0695	0.75 (0.55, 1.02)	0.0689	-0.04 (-0.08, 0.00)	0.0677	
Eastern Europe	147/ 1286 (11.43)	135/ 1270 (10.63)	1.08 (0.86, 1.34)	0.5183	1.09 (0.85, 1.39)	0.5183	0.01 (-0.02, 0.03)	0.5181	
Asia	50/ 458 (10.92)	48/ 454 (10.57)	1.03 (0.71, 1.50)	0.8667	1.04 (0.68, 1.58)	0.8667	0.00 (-0.04, 0.04)	0.8667	
North America	31/ 217 (14.29)	35/ 216 (16.20)	0.88 (0.56, 1.38)	0.5791	0.86 (0.51, 1.46)	0.5790	-0.02 (-0.09, 0.05)	0.5787	
Latin America	46/ 308 (14.94)	45/ 305 (14.75)	1.01 (0.69, 1.48)	0.9498	1.01 (0.65, 1.58)	0.9498	0.00 (-0.05, 0.06)	0.9498	
Age group (years)									0.2392
<= median in FAS	147/ 1512 (9.72)	166/ 1492 (11.13)	0.87 (0.71, 1.08)	0.2084	0.86 (0.68, 1.09)	0.2083	-0.01 (-0.04, 0.01)	0.2080	
> median in FAS	210/ 1335 (15.73)	205/ 1343 (15.26)	1.03 (0.86, 1.23)	0.7390	1.04 (0.84, 1.28)	0.7390	0.00 (-0.02, 0.03)	0.7390	
NYHA class at baseline									0.2595
II	214/ 1977 (10.82)	235/ 1960 (11.99)	0.90 (0.76, 1.07)	0.2504	0.89 (0.73, 1.08)	0.2503	-0.01 (-0.03, 0.01)	0.2501	
III/IV	143/ 869 (16.46)	136/ 875 (15.54)	1.06 (0.85, 1.31)	0.6032	1.07 (0.83, 1.38)	0.6031	0.01 (-0.03, 0.04)	0.6031	
LVEF at baseline									0.3125
< 50%	147/ 1034 (14.22)	133/ 1022 (13.01)	1.09 (0.88, 1.36)	0.4268	1.11 (0.86, 1.43)	0.4267	0.01 (-0.02, 0.04)	0.4264	
>= 50% - < 60%	151/ 1252 (12.06)	177/ 1272 (13.92)	0.87 (0.71, 1.06)	0.1665	0.85 (0.67, 1.07)	0.1663	-0.02 (-0.04, 0.01)	0.1656	
>= 60%	58/ 556 (10.43)	59/ 539 (10.95)	0.95 (0.68, 1.34)	0.7829	0.95 (0.65, 1.39)	0.7829	-0.01 (-0.04, 0.03)	0.7830	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	937/ 2790 (33.58)	909/ 2783 (32.66)
Number of imputed values	372	353
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.04 (0.93, 1.17)	
p-value	0.4903	
Risk Ratio (95% CI)	1.03 (0.96, 1.11)	
p-value	0.4001	
Risk Difference (95% CI)	0.01 (-0.02, 0.03)	
p-value	0.5669	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.04 (0.93, 1.17)	
p-value	0.4648	
Risk Ratio (95% CI)	1.03 (0.95, 1.11)	
p-value	0.4649	
Risk Difference (95% CI)	0.01 (-0.02, 0.03)	
p-value	0.4648	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.8471
Male	566/ 1550 (36.52)	541/ 1531 (35.34)	1.03 (0.94, 1.14)	0.4951	1.05 (0.91, 1.22)	0.4950	0.01 (-0.02, 0.05)	0.4949	
Female	371/ 1240 (29.92)	368/ 1252 (29.39)	1.02 (0.90, 1.15)	0.7736	1.03 (0.86, 1.22)	0.7736	0.01 (-0.03, 0.04)	0.7736	
Region									0.3955
Western Europe, Oceania and Others	137/ 564 (24.29)	155/ 577 (26.86)	0.90 (0.74, 1.10)	0.3200	0.87 (0.67, 1.14)	0.3196	-0.03 (-0.08, 0.02)	0.3191	
Eastern Europe	376/ 1271 (29.58)	372/ 1264 (29.43)	1.01 (0.89, 1.13)	0.9329	1.01 (0.85, 1.19)	0.9329	0.00 (-0.03, 0.04)	0.9329	
Asia	225/ 450 (50.00)	206/ 448 (45.98)	1.09 (0.95, 1.25)	0.2288	1.17 (0.90, 1.53)	0.2283	0.04 (-0.03, 0.11)	0.2278	
North America	64/ 212 (30.19)	50/ 210 (23.81)	1.27 (0.92, 1.74)	0.1421	1.38 (0.90, 2.13)	0.1408	0.06 (-0.02, 0.15)	0.1389	
Latin America	135/ 293 (46.08)	126/ 284 (44.37)	1.04 (0.87, 1.24)	0.6802	1.07 (0.77, 1.49)	0.6801	0.02 (-0.06, 0.10)	0.6800	
Age group (years)									0.5885
<= median in FAS	571/ 1500 (38.07)	538/ 1475 (36.47)	1.04 (0.95, 1.15)	0.3694	1.07 (0.92, 1.24)	0.3693	0.02 (-0.02, 0.05)	0.3691	
> median in FAS	366/ 1290 (28.37)	371/ 1308 (28.36)	1.00 (0.89, 1.13)	0.9963	1.00 (0.84, 1.19)	0.9963	0.00 (-0.03, 0.03)	0.9963	
NYHA class at baseline									0.5699
II	699/ 1941 (36.01)	668/ 1930 (34.61)	1.04 (0.96, 1.13)	0.3619	1.06 (0.93, 1.21)	0.3619	0.01 (-0.02, 0.04)	0.3618	
III/IV	237/ 848 (27.95)	241/ 853 (28.25)	0.99 (0.85, 1.15)	0.8887	0.99 (0.80, 1.22)	0.8887	-0.00 (-0.05, 0.04)	0.8887	
LVEF at baseline									0.1855
< 50%	370/ 1016 (36.42)	373/ 1006 (37.08)	0.98 (0.88, 1.10)	0.7582	0.97 (0.81, 1.16)	0.7582	-0.01 (-0.05, 0.04)	0.7582	
>= 50% - < 60%	388/ 1222 (31.75)	391/ 1245 (31.41)	1.01 (0.90, 1.14)	0.8535	1.02 (0.86, 1.20)	0.8535	0.00 (-0.03, 0.04)	0.8535	
>= 60%	179/ 547 (32.72)	145/ 531 (27.31)	1.20 (1.00, 1.44)	0.0533	1.29 (1.00, 1.68)	0.0527	0.05 (-0.00, 0.11)	0.0519	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	490/ 2790 (17.56)	502/ 2783 (18.04)
Number of imputed values	372	353
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.97 (0.84, 1.11)	
p-value	0.6544	
Risk Ratio (95% CI)	0.97 (0.87, 1.09)	
p-value	0.6216	
Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
p-value	0.7596	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.97 (0.84, 1.11)	
p-value	0.6428	
Risk Ratio (95% CI)	0.97 (0.87, 1.09)	
p-value	0.6428	
Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
p-value	0.6427	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.9514
Male	279/ 1550 (18.00)	284/ 1531 (18.55)	0.97 (0.84, 1.13)	0.6929	0.96 (0.80, 1.16)	0.6929	-0.01 (-0.03, 0.02)	0.6929	
Female	211/ 1240 (17.02)	218/ 1252 (17.41)	0.98 (0.82, 1.16)	0.7935	0.97 (0.79, 1.20)	0.7935	-0.00 (-0.03, 0.03)	0.7934	
Region									0.1120
Western Europe, Oceania and Others	128/ 564 (22.70)	142/ 577 (24.61)	0.92 (0.75, 1.14)	0.4470	0.90 (0.68, 1.18)	0.4468	-0.02 (-0.07, 0.03)	0.4464	
Eastern Europe	209/ 1271 (16.44)	198/ 1264 (15.66)	1.05 (0.88, 1.25)	0.5932	1.06 (0.86, 1.31)	0.5932	0.01 (-0.02, 0.04)	0.5931	
Asia	68/ 450 (15.11)	65/ 448 (14.51)	1.04 (0.76, 1.43)	0.7995	1.05 (0.73, 1.52)	0.7995	0.01 (-0.04, 0.05)	0.7995	
North America	29/ 212 (13.68)	49/ 210 (23.33)	0.59 (0.39, 0.89)	0.0122	0.52 (0.31, 0.86)	0.0114	-0.10 (-0.17, -0.02)	0.0101	
Latin America	56/ 293 (19.11)	48/ 284 (16.90)	1.13 (0.80, 1.60)	0.4902	1.16 (0.76, 1.78)	0.4899	0.02 (-0.04, 0.08)	0.4892	
Age group (years)									0.2208
<= median in FAS	212/ 1500 (14.13)	231/ 1475 (15.66)	0.90 (0.76, 1.07)	0.2422	0.89 (0.72, 1.08)	0.2421	-0.02 (-0.04, 0.01)	0.2420	
> median in FAS	278/ 1290 (21.55)	271/ 1308 (20.72)	1.04 (0.90, 1.21)	0.6036	1.05 (0.87, 1.27)	0.6036	0.01 (-0.02, 0.04)	0.6036	
NYHA class at baseline									0.6193
II	306/ 1941 (15.77)	319/ 1930 (16.53)	0.95 (0.83, 1.10)	0.5187	0.95 (0.80, 1.12)	0.5187	-0.01 (-0.03, 0.02)	0.5186	
III/IV	184/ 848 (21.70)	183/ 853 (21.45)	1.01 (0.84, 1.21)	0.9025	1.01 (0.81, 1.28)	0.9025	0.00 (-0.04, 0.04)	0.9025	
LVEF at baseline									0.8339
< 50%	182/ 1016 (17.91)	189/ 1006 (18.79)	0.95 (0.79, 1.15)	0.6118	0.94 (0.75, 1.18)	0.6118	-0.01 (-0.04, 0.03)	0.6117	
>= 50% - < 60%	206/ 1222 (16.86)	219/ 1245 (17.59)	0.96 (0.81, 1.14)	0.6299	0.95 (0.77, 1.17)	0.6299	-0.01 (-0.04, 0.02)	0.6298	
>= 60%	101/ 547 (18.46)	94/ 531 (17.70)	1.04 (0.81, 1.34)	0.7453	1.05 (0.77, 1.44)	0.7453	0.01 (-0.04, 0.05)	0.7452	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	1051/ 2846 (36.93)	1076/ 2834 (37.97)
Number of imputed values	347	329
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.96 (0.86, 1.07)	
p-value	0.4525	
Risk Ratio (95% CI)	0.97 (0.91, 1.04)	
p-value	0.3952	
Risk Difference (95% CI)	-0.01 (-0.03, 0.02)	
p-value	0.4401	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.96 (0.86, 1.07)	
p-value	0.4188	
Risk Ratio (95% CI)	0.97 (0.91, 1.04)	
p-value	0.4188	
Risk Difference (95% CI)	-0.01 (-0.04, 0.01)	
p-value	0.4187	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.1539
Male	595/ 1578 (37.71)	576/ 1553 (37.09)	1.02 (0.93, 1.11)	0.7215	1.03 (0.89, 1.19)	0.7215	0.01 (-0.03, 0.04)	0.7215	
Female	456/ 1268 (35.96)	500/ 1281 (39.03)	0.92 (0.83, 1.02)	0.1098	0.88 (0.75, 1.03)	0.1095	-0.03 (-0.07, 0.01)	0.1092	
Region									0.2722
Western Europe, Oceania and Others	202/ 577 (35.01)	190/ 590 (32.20)	1.09 (0.93, 1.28)	0.3106	1.13 (0.89, 1.45)	0.3105	0.03 (-0.03, 0.08)	0.3103	
Eastern Europe	456/ 1286 (35.46)	487/ 1270 (38.35)	0.92 (0.84, 1.02)	0.1305	0.88 (0.75, 1.04)	0.1304	-0.03 (-0.07, 0.01)	0.1302	
Asia	167/ 458 (36.46)	184/ 453 (40.62)	0.90 (0.76, 1.06)	0.1981	0.84 (0.64, 1.10)	0.1977	-0.04 (-0.10, 0.02)	0.1972	
North America	89/ 217 (41.01)	79/ 216 (36.57)	1.12 (0.88, 1.42)	0.3440	1.21 (0.82, 1.78)	0.3434	0.04 (-0.05, 0.14)	0.3426	
Latin America	137/ 308 (44.48)	136/ 305 (44.59)	1.00 (0.84, 1.19)	0.9782	1.00 (0.72, 1.37)	0.9782	-0.00 (-0.08, 0.08)	0.9782	
Age group (years)									0.1794
<= median in FAS	591/ 1511 (39.11)	625/ 1492 (41.89)	0.93 (0.86, 1.02)	0.1213	0.89 (0.77, 1.03)	0.1212	-0.03 (-0.06, 0.01)	0.1210	
> median in FAS	460/ 1335 (34.46)	451/ 1342 (33.61)	1.03 (0.92, 1.14)	0.6425	1.04 (0.89, 1.22)	0.6424	0.01 (-0.03, 0.04)	0.6424	
NYHA class at baseline									0.8256
II	760/ 1976 (38.46)	771/ 1959 (39.36)	0.98 (0.90, 1.06)	0.5647	0.96 (0.85, 1.09)	0.5647	-0.01 (-0.04, 0.02)	0.5646	
III/IV	291/ 869 (33.49)	305/ 875 (34.86)	0.96 (0.84, 1.09)	0.5464	0.94 (0.77, 1.15)	0.5463	-0.01 (-0.06, 0.03)	0.5463	
LVEF at baseline									0.6286
< 50%	408/ 1034 (39.46)	405/ 1022 (39.63)	1.00 (0.89, 1.11)	0.9373	0.99 (0.83, 1.18)	0.9373	-0.00 (-0.04, 0.04)	0.9373	
>= 50% - < 60%	450/ 1251 (35.97)	488/ 1271 (38.39)	0.94 (0.85, 1.04)	0.2083	0.90 (0.77, 1.06)	0.2080	-0.02 (-0.06, 0.01)	0.2078	
>= 60%	191/ 556 (34.35)	183/ 539 (33.95)	1.01 (0.86, 1.19)	0.8888	1.02 (0.79, 1.31)	0.8888	0.00 (-0.05, 0.06)	0.8888	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	431/ 2846 (15.14)	450/ 2834 (15.88)
Number of imputed values	347	329
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.95 (0.82, 1.09)	
p-value	0.4442	
Risk Ratio (95% CI)	0.95 (0.84, 1.07)	
p-value	0.4142	
Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
p-value	0.6288	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.95 (0.82, 1.09)	
p-value	0.4445	
Risk Ratio (95% CI)	0.95 (0.84, 1.08)	
p-value	0.4446	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.4445	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.8905
Male	249/ 1578 (15.78)	259/ 1553 (16.68)	0.95 (0.81, 1.11)	0.4957	0.94 (0.77, 1.13)	0.4957	-0.01 (-0.03, 0.02)	0.4957	
Female	182/ 1268 (14.35)	191/ 1281 (14.91)	0.96 (0.80, 1.16)	0.6908	0.96 (0.77, 1.19)	0.6908	-0.01 (-0.03, 0.02)	0.6908	
Region									0.6453
Western Europe, Oceania and Others	103/ 577 (17.85)	126/ 590 (21.36)	0.84 (0.66, 1.06)	0.1327	0.80 (0.60, 1.07)	0.1321	-0.04 (-0.08, 0.01)	0.1311	
Eastern Europe	178/ 1286 (13.84)	165/ 1270 (12.99)	1.07 (0.87, 1.30)	0.5289	1.08 (0.86, 1.35)	0.5289	0.01 (-0.02, 0.03)	0.5287	
Asia	64/ 458 (13.97)	67/ 453 (14.79)	0.94 (0.69, 1.30)	0.7255	0.94 (0.65, 1.36)	0.7255	-0.01 (-0.05, 0.04)	0.7255	
North America	39/ 217 (17.97)	41/ 216 (18.98)	0.95 (0.64, 1.41)	0.7868	0.94 (0.58, 1.52)	0.7868	-0.01 (-0.08, 0.06)	0.7867	
Latin America	47/ 308 (15.26)	51/ 305 (16.72)	0.91 (0.63, 1.31)	0.6217	0.90 (0.58, 1.38)	0.6216	-0.01 (-0.07, 0.04)	0.6215	
Age group (years)									0.0378
<= median in FAS	184/ 1511 (12.18)	219/ 1492 (14.68)	0.83 (0.69, 1.00)	0.0448	0.81 (0.65, 0.99)	0.0447	-0.03 (-0.05, -0.00)	0.0444	
> median in FAS	247/ 1335 (18.50)	231/ 1342 (17.21)	1.07 (0.91, 1.26)	0.3842	1.09 (0.90, 1.33)	0.3841	0.01 (-0.02, 0.04)	0.3840	
NYHA class at baseline									0.1775
II	264/ 1976 (13.36)	292/ 1959 (14.91)	0.90 (0.77, 1.05)	0.1644	0.88 (0.74, 1.05)	0.1643	-0.02 (-0.04, 0.01)	0.1641	
III/IV	167/ 869 (19.22)	158/ 875 (18.06)	1.06 (0.87, 1.29)	0.5339	1.08 (0.85, 1.37)	0.5339	0.01 (-0.02, 0.05)	0.5338	
LVEF at baseline									0.9880
< 50%	162/ 1034 (15.67)	170/ 1022 (16.63)	0.94 (0.77, 1.15)	0.5515	0.93 (0.74, 1.18)	0.5515	-0.01 (-0.04, 0.02)	0.5515	
>= 50% - < 60%	192/ 1251 (15.35)	203/ 1271 (15.97)	0.96 (0.80, 1.15)	0.6665	0.95 (0.77, 1.18)	0.6664	-0.01 (-0.03, 0.02)	0.6664	
>= 60%	74/ 556 (13.31)	76/ 539 (14.10)	0.94 (0.70, 1.27)	0.7036	0.94 (0.66, 1.32)	0.7036	-0.01 (-0.05, 0.03)	0.7037	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	1194/ 2624 (45.50)	1122/ 2624 (42.76)
Number of imputed values	397	386
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.12 (1.00, 1.25)	
p-value	0.0500	
Risk Ratio (95% CI)	1.07 (1.00, 1.13)	
p-value	0.0352	
Risk Difference (95% CI)	0.03 (-0.00, 0.05)	
p-value	0.0540	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.12 (1.00, 1.25)	
p-value	0.0454	
Risk Ratio (95% CI)	1.06 (1.00, 1.13)	
p-value	0.0454	
Risk Difference (95% CI)	0.03 (0.00, 0.05)	
p-value	0.0452	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.0072
Male	712/ 1468 (48.50)	617/ 1455 (42.41)	1.14 (1.06, 1.24)	0.0010	1.28 (1.11, 1.48)	0.0009	0.06 (0.02, 0.10)	0.0009	
Female	482/ 1156 (41.70)	505/ 1169 (43.20)	0.97 (0.88, 1.06)	0.4634	0.94 (0.80, 1.11)	0.4633	-0.02 (-0.06, 0.03)	0.4632	
Region									0.9129
Western Europe, Oceania and Others	187/ 529 (35.35)	174/ 537 (32.40)	1.09 (0.92, 1.29)	0.3096	1.14 (0.88, 1.47)	0.3094	0.03 (-0.03, 0.09)	0.3091	
Eastern Europe	529/ 1228 (43.08)	508/ 1221 (41.61)	1.04 (0.94, 1.14)	0.4608	1.06 (0.90, 1.25)	0.4608	0.01 (-0.02, 0.05)	0.4607	
Asia	235/ 401 (58.60)	218/ 401 (54.36)	1.08 (0.95, 1.22)	0.2265	1.19 (0.90, 1.57)	0.2261	0.04 (-0.03, 0.11)	0.2255	
North America	81/ 200 (40.50)	79/ 202 (39.11)	1.04 (0.81, 1.32)	0.7757	1.06 (0.71, 1.58)	0.7757	0.01 (-0.08, 0.11)	0.7757	
Latin America	162/ 266 (60.90)	143/ 263 (54.37)	1.12 (0.97, 1.30)	0.1298	1.31 (0.93, 1.85)	0.1289	0.07 (-0.02, 0.15)	0.1278	
Age group (years)									0.1086
<= median in FAS	731/ 1444 (50.62)	650/ 1422 (45.71)	1.11 (1.03, 1.20)	0.0086	1.22 (1.05, 1.41)	0.0085	0.05 (0.01, 0.09)	0.0084	
> median in FAS	463/ 1180 (39.24)	472/ 1202 (39.27)	1.00 (0.90, 1.10)	0.9878	1.00 (0.85, 1.18)	0.9878	-0.00 (-0.04, 0.04)	0.9878	
NYHA class at baseline									0.9148
II	877/ 1830 (47.92)	815/ 1812 (44.98)	1.07 (0.99, 1.14)	0.0750	1.13 (0.99, 1.28)	0.0748	0.03 (-0.00, 0.06)	0.0746	
III/IV	317/ 793 (39.97)	307/ 812 (37.81)	1.06 (0.94, 1.20)	0.3734	1.10 (0.90, 1.34)	0.3733	0.02 (-0.03, 0.07)	0.3732	
LVEF at baseline									0.0834
< 50%	475/ 971 (48.92)	418/ 957 (43.68)	1.12 (1.02, 1.23)	0.0213	1.23 (1.03, 1.48)	0.0211	0.05 (0.01, 0.10)	0.0209	
>= 50% - < 60%	475/ 1139 (41.70)	501/ 1177 (42.57)	0.98 (0.89, 1.08)	0.6743	0.97 (0.82, 1.14)	0.6743	-0.01 (-0.05, 0.03)	0.6742	
>= 60%	242/ 509 (47.54)	203/ 488 (41.60)	1.14 (0.99, 1.31)	0.0600	1.27 (0.99, 1.63)	0.0592	0.06 (-0.00, 0.12)	0.0585	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	508/ 2624 (19.36)	518/ 2624 (19.74)
Number of imputed values	397	386
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.98 (0.85, 1.12)	
p-value	0.7300	
Risk Ratio (95% CI)	0.98 (0.88, 1.09)	
p-value	0.6641	
Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
p-value	0.8875	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.98 (0.85, 1.12)	
p-value	0.7278	
Risk Ratio (95% CI)	0.98 (0.88, 1.09)	
p-value	0.7278	
Risk Difference (95% CI)	-0.00 (-0.03, 0.02)	
p-value	0.7278	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.0807
Male	274/ 1468 (18.66)	302/ 1455 (20.76)	0.90 (0.78, 1.04)	0.1556	0.88 (0.73, 1.05)	0.1554	-0.02 (-0.05, 0.01)	0.1552	
Female	234/ 1156 (20.24)	216/ 1169 (18.48)	1.10 (0.93, 1.29)	0.2817	1.12 (0.91, 1.38)	0.2816	0.02 (-0.01, 0.05)	0.2815	
Region									0.2890
Western Europe, Oceania and Others	117/ 529 (22.12)	147/ 537 (27.37)	0.81 (0.65, 1.00)	0.0477	0.75 (0.57, 1.00)	0.0471	-0.05 (-0.10, -0.00)	0.0463	
Eastern Europe	225/ 1228 (18.32)	206/ 1221 (16.87)	1.09 (0.91, 1.29)	0.3460	1.11 (0.90, 1.36)	0.3459	0.01 (-0.02, 0.04)	0.3456	
Asia	67/ 401 (16.71)	71/ 401 (17.71)	0.94 (0.70, 1.28)	0.7083	0.93 (0.65, 1.35)	0.7083	-0.01 (-0.06, 0.04)	0.7082	
North America	50/ 200 (25.00)	49/ 202 (24.26)	1.03 (0.73, 1.45)	0.8628	1.04 (0.66, 1.64)	0.8628	0.01 (-0.08, 0.09)	0.8628	
Latin America	49/ 266 (18.42)	45/ 263 (17.11)	1.08 (0.75, 1.55)	0.6935	1.09 (0.70, 1.71)	0.6934	0.01 (-0.05, 0.08)	0.6932	
Age group (years)									0.2178
<= median in FAS	230/ 1444 (15.93)	248/ 1422 (17.44)	0.91 (0.78, 1.08)	0.2778	0.90 (0.74, 1.09)	0.2777	-0.02 (-0.04, 0.01)	0.2776	
> median in FAS	278/ 1180 (23.56)	270/ 1202 (22.46)	1.05 (0.91, 1.21)	0.5249	1.06 (0.88, 1.29)	0.5249	0.01 (-0.02, 0.04)	0.5249	
NYHA class at baseline									0.2237
II	316/ 1830 (17.27)	335/ 1812 (18.49)	0.93 (0.81, 1.07)	0.3367	0.92 (0.78, 1.09)	0.3367	-0.01 (-0.04, 0.01)	0.3366	
III/IV	192/ 793 (24.21)	183/ 812 (22.54)	1.07 (0.90, 1.28)	0.4280	1.10 (0.87, 1.38)	0.4280	0.02 (-0.02, 0.06)	0.4279	
LVEF at baseline									0.6372
< 50%	193/ 971 (19.88)	180/ 957 (18.81)	1.06 (0.88, 1.27)	0.5530	1.07 (0.85, 1.34)	0.5530	0.01 (-0.02, 0.05)	0.5528	
>= 50% - < 60%	227/ 1139 (19.93)	247/ 1177 (20.99)	0.95 (0.81, 1.12)	0.5291	0.94 (0.77, 1.15)	0.5290	-0.01 (-0.04, 0.02)	0.5288	
>= 60%	87/ 509 (17.09)	89/ 488 (18.24)	0.94 (0.72, 1.23)	0.6354	0.92 (0.67, 1.28)	0.6354	-0.01 (-0.06, 0.04)	0.6355	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	1227/ 2846 (43.11)	1131/ 2834 (39.91)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.15 (1.03, 1.28)	
p-value	0.0112	
Risk Ratio (95% CI)	1.08 (1.02, 1.15)	
p-value	0.0137	
Risk Difference (95% CI)	0.03 (0.01, 0.06)	
p-value	0.0109	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.14 (1.03, 1.27)	
p-value	0.0143	
Risk Ratio (95% CI)	1.08 (1.02, 1.15)	
p-value	0.0143	
Risk Difference (95% CI)	0.03 (0.01, 0.06)	
p-value	0.0142	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.5872
Male	708/ 1578 (44.87)	655/ 1553 (42.18)	1.06 (0.98, 1.15)	0.1292	1.12 (0.97, 1.29)	0.1290	0.03 (-0.01, 0.06)	0.1288	
Female	519/ 1268 (40.93)	476/ 1281 (37.16)	1.10 (1.00, 1.21)	0.0512	1.17 (1.00, 1.37)	0.0510	0.04 (-0.00, 0.08)	0.0508	
Region									0.5504
Western Europe, Oceania and Others	210/ 577 (36.40)	176/ 590 (29.83)	1.22 (1.04, 1.44)	0.0176	1.35 (1.05, 1.72)	0.0173	0.07 (0.01, 0.12)	0.0170	
Eastern Europe	512/ 1286 (39.81)	477/ 1270 (37.56)	1.06 (0.96, 1.17)	0.2422	1.10 (0.94, 1.29)	0.2421	0.02 (-0.02, 0.06)	0.2418	
Asia	256/ 458 (55.90)	247/ 453 (54.53)	1.03 (0.91, 1.15)	0.6777	1.06 (0.81, 1.37)	0.6776	0.01 (-0.05, 0.08)	0.6776	
North America	82/ 217 (37.79)	78/ 216 (36.11)	1.05 (0.82, 1.34)	0.7178	1.07 (0.73, 1.59)	0.7178	0.02 (-0.07, 0.11)	0.7177	
Latin America	167/ 308 (54.22)	153/ 305 (50.16)	1.08 (0.93, 1.26)	0.3153	1.18 (0.86, 1.62)	0.3148	0.04 (-0.04, 0.12)	0.3143	
Age group (years)									0.6298
<= median in FAS	711/ 1511 (47.05)	659/ 1492 (44.17)	1.07 (0.99, 1.15)	0.1126	1.12 (0.97, 1.30)	0.1124	0.03 (-0.01, 0.06)	0.1122	
> median in FAS	516/ 1335 (38.65)	472/ 1342 (35.17)	1.10 (1.00, 1.21)	0.0623	1.16 (0.99, 1.36)	0.0621	0.03 (-0.00, 0.07)	0.0619	
NYHA class at baseline									0.1629
II	900/ 1976 (45.55)	804/ 1959 (41.04)	1.11 (1.03, 1.19)	0.0044	1.20 (1.06, 1.36)	0.0044	0.05 (0.01, 0.08)	0.0043	
III/IV	326/ 869 (37.51)	327/ 875 (37.37)	1.00 (0.89, 1.13)	0.9508	1.01 (0.83, 1.22)	0.9508	0.00 (-0.04, 0.05)	0.9508	
LVEF at baseline									0.7273
< 50%	474/ 1034 (45.84)	431/ 1022 (42.17)	1.09 (0.99, 1.20)	0.0942	1.16 (0.98, 1.38)	0.0939	0.04 (-0.01, 0.08)	0.0935	
>= 50% - < 60%	514/ 1251 (41.09)	495/ 1271 (38.95)	1.05 (0.96, 1.16)	0.2725	1.09 (0.93, 1.28)	0.2725	0.02 (-0.02, 0.06)	0.2723	
>= 60%	238/ 556 (42.81)	204/ 539 (37.85)	1.13 (0.98, 1.31)	0.0954	1.23 (0.96, 1.57)	0.0947	0.05 (-0.01, 0.11)	0.0941	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
Number of subjects with reponse, n/N (%)	363/ 2846 (12.75)	385/ 2834 (13.59)
Number of imputed values	348	328
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.93 (0.80, 1.08)	
p-value	0.3409	
Risk Ratio (95% CI)	0.93 (0.82, 1.07)	
p-value	0.3214	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.4724	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.93 (0.80, 1.08)	
p-value	0.3549	
Risk Ratio (95% CI)	0.94 (0.82, 1.07)	
p-value	0.3549	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.3548	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=20 points of The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3003) n/ N (%)	Placebo (N=2998) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.6709
Male	214/ 1578 (13.56)	219/ 1553 (14.10)	0.96 (0.81, 1.15)	0.6615	0.96 (0.78, 1.17)	0.6615	-0.01 (-0.03, 0.02)	0.6615	
Female	149/ 1268 (11.75)	166/ 1281 (12.96)	0.91 (0.74, 1.12)	0.3545	0.89 (0.71, 1.13)	0.3544	-0.01 (-0.04, 0.01)	0.3540	
Region									0.4783
Western Europe, Oceania and Others	80/ 577 (13.86)	97/ 590 (16.44)	0.84 (0.64, 1.11)	0.2209	0.82 (0.59, 1.13)	0.2205	-0.03 (-0.07, 0.02)	0.2194	
Eastern Europe	156/ 1286 (12.13)	143/ 1270 (11.26)	1.08 (0.87, 1.33)	0.4936	1.09 (0.85, 1.39)	0.4935	0.01 (-0.02, 0.03)	0.4933	
Asia	50/ 458 (10.92)	52/ 453 (11.48)	0.95 (0.66, 1.37)	0.7880	0.95 (0.63, 1.43)	0.7880	-0.01 (-0.05, 0.04)	0.7880	
North America	34/ 217 (15.67)	37/ 216 (17.13)	0.91 (0.60, 1.40)	0.6815	0.90 (0.54, 1.50)	0.6814	-0.01 (-0.08, 0.06)	0.6813	
Latin America	43/ 308 (13.96)	56/ 305 (18.36)	0.76 (0.53, 1.09)	0.1408	0.72 (0.47, 1.11)	0.1399	-0.04 (-0.10, 0.01)	0.1384	
Age group (years)									0.6456
<= median in FAS	160/ 1511 (10.59)	174/ 1492 (11.66)	0.91 (0.74, 1.11)	0.3499	0.90 (0.71, 1.13)	0.3498	-0.01 (-0.03, 0.01)	0.3497	
> median in FAS	203/ 1335 (15.21)	211/ 1342 (15.72)	0.97 (0.81, 1.15)	0.7116	0.96 (0.78, 1.19)	0.7116	-0.01 (-0.03, 0.02)	0.7115	
NYHA class at baseline									0.5348
II	224/ 1976 (11.34)	244/ 1959 (12.46)	0.91 (0.77, 1.08)	0.2784	0.90 (0.74, 1.09)	0.2783	-0.01 (-0.03, 0.01)	0.2782	
III/IV	139/ 869 (16.00)	141/ 875 (16.11)	0.99 (0.80, 1.23)	0.9461	0.99 (0.77, 1.28)	0.9461	-0.00 (-0.04, 0.03)	0.9461	
LVEF at baseline									0.7004
< 50%	145/ 1034 (14.02)	143/ 1022 (13.99)	1.00 (0.81, 1.24)	0.9838	1.00 (0.78, 1.29)	0.9838	0.00 (-0.03, 0.03)	0.9838	
>= 50% - < 60%	153/ 1251 (12.23)	170/ 1271 (13.38)	0.91 (0.75, 1.12)	0.3898	0.90 (0.71, 1.14)	0.3897	-0.01 (-0.04, 0.01)	0.3894	
>= 60%	63/ 556 (11.33)	71/ 539 (13.17)	0.86 (0.63, 1.18)	0.3531	0.84 (0.59, 1.21)	0.3530	-0.02 (-0.06, 0.02)	0.3528	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Kansas City Cardiomyopathy Questionnaire (KCCQ) - At least 1 question answered: Completion rates
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)	
Timepoint	n/ N	Completion	n/ N	Completion
Baseline	2995 /3003	99.73 %	2992 /2998	99.80 %
Month 6	2693 /2915	92.38 %	2673 /2905	92.01 %
Month 9	2516 /2868	87.73 %	2526 /2859	88.35 %
Month 12	2500 /2823	88.56 %	2508 /2813	89.16 %
Month 16	2338 /2713	86.18 %	2316 /2713	85.37 %
Month 24	1876 /2219	84.54 %	1841 /2215	83.12 %
Month 32	1247 /1550	80.45 %	1231 /1529	80.51 %
Month 40	184 /272	67.65 %	176 /269	65.43 %

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=1 point of Patient Global Impressions (PGI) scale - Change
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)	Placebo (N=1068)
Number of subjects with reponse, n/N (%)	522/ 940 (55.53)	518/ 946 (54.76)
Number of imputed values	128	138
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.03 (0.86, 1.24)	
p-value	0.7291	
Risk Ratio (95% CI)	1.01 (0.94, 1.10)	
p-value	0.7194	
Risk Difference (95% CI)	0.01 (-0.04, 0.05)	
p-value	0.7197	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.03 (0.86, 1.24)	
p-value	0.7351	
Risk Ratio (95% CI)	1.01 (0.93, 1.10)	
p-value	0.7351	
Risk Difference (95% CI)	0.01 (-0.04, 0.05)	
p-value	0.7351	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=1 point of Patient Global Impressions (PGI) scale - Change - Subgroup analysis
Full Analysis Set: PGI Subpopulation

Subgroup Level	Finerenone (N=1066) n/ N (%)	Placebo (N=1068) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.9858
Male	318/ 563 (56.48)	310/ 556 (55.76)	1.01 (0.91, 1.12)	0.8063	1.03 (0.81, 1.30)	0.8062	0.01 (-0.05, 0.07)	0.8062	
Female	204/ 377 (54.11)	208/ 390 (53.33)	1.01 (0.89, 1.16)	0.8289	1.03 (0.78, 1.37)	0.8289	0.01 (-0.06, 0.08)	0.8289	
Region									<.0001
Western Europe, Oceania and Others	152/ 300 (50.67)	150/ 303 (49.50)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Eastern Europe	62/ 124 (50.00)	59/ 125 (47.20)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Asia	208/ 320 (65.00)	207/ 323 (64.09)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
North America	100/ 196 (51.02)	102/ 195 (52.31)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Latin America	0/ 0 ( )	0/ 0 ( )	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Age group (years)									0.9819
<= median in FAS	272/ 430 (63.26)	257/ 409 (62.84)	1.01 (0.91, 1.12)	0.8998	1.02 (0.77, 1.35)	0.8998	0.00 (-0.06, 0.07)	0.8998	
> median in FAS	250/ 510 (49.02)	261/ 537 (48.60)	1.01 (0.89, 1.14)	0.8929	1.02 (0.80, 1.30)	0.8929	0.00 (-0.06, 0.06)	0.8929	
NYHA class at baseline									0.8245
II	419/ 745 (56.24)	408/ 732 (55.74)	1.01 (0.92, 1.10)	0.8454	1.02 (0.83, 1.25)	0.8453	0.01 (-0.05, 0.06)	0.8453	
III/IV	103/ 194 (53.09)	110/ 214 (51.40)	1.03 (0.86, 1.24)	0.7326	1.07 (0.73, 1.58)	0.7328	0.02 (-0.08, 0.11)	0.7327	
LVEF at baseline									0.9259
< 50%	214/ 356 (60.11)	218/ 363 (60.06)	1.00 (0.89, 1.13)	0.9875	1.00 (0.74, 1.35)	0.9875	0.00 (-0.07, 0.07)	0.9875	
>= 50% - < 60%	217/ 396 (54.80)	209/ 395 (52.91)	1.04 (0.91, 1.18)	0.5947	1.08 (0.82, 1.43)	0.5946	0.02 (-0.05, 0.09)	0.5945	
>= 60%	90/ 185 (48.65)	90/ 186 (48.39)	1.01 (0.82, 1.24)	0.9598	1.01 (0.67, 1.52)	0.9598	0.00 (-0.10, 0.10)	0.9598	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=1 point of Patient Global Impressions (PGI) scale - Change
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)	Placebo (N=1068)
Number of subjects with reponse, n/N (%)	116/ 940 (12.34)	150/ 946 (15.86)
Number of imputed values	128	138
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.74 (0.57, 0.97)	
p-value	0.0270	
Risk Ratio (95% CI)	0.78 (0.62, 0.97)	
p-value	0.0267	
Risk Difference (95% CI)	-0.03 (-0.06, -0.00)	
p-value	0.0487	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.75 (0.58, 0.97)	
p-value	0.0286	
Risk Ratio (95% CI)	0.78 (0.62, 0.97)	
p-value	0.0289	
Risk Difference (95% CI)	-0.04 (-0.07, -0.00)	
p-value	0.0280	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=1 point of Patient Global Impressions (PGI) scale - Change - Subgroup analysis
Full Analysis Set: PGI Subpopulation

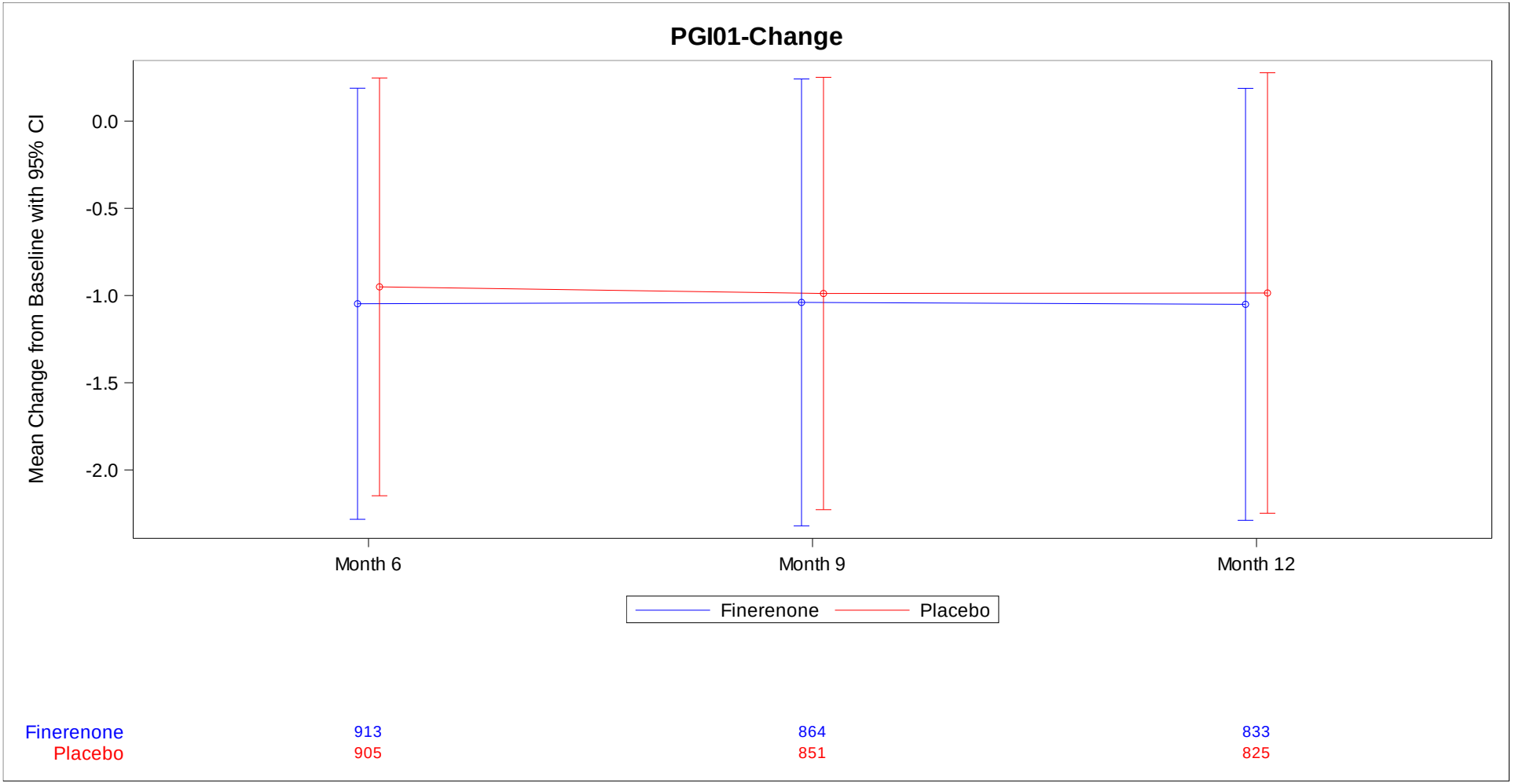
Subgroup Level	Finerenone (N=1066) n/ N (%)	Placebo (N=1068) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.6675
Male	65/ 563 (11.55)	86/ 556 (15.47)	0.75 (0.55, 1.01)	0.0561	0.71 (0.50, 1.01)	0.0556	-0.04 (-0.08, 0.00)	0.0546	
Female	51/ 377 (13.53)	64/ 390 (16.41)	0.82 (0.59, 1.16)	0.2649	0.80 (0.53, 1.19)	0.2643	-0.03 (-0.08, 0.02)	0.2626	
Region									<.0001
Western Europe, Oceania and Others	50/ 300 (16.67)	59/ 303 (19.47)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Eastern Europe	12/ 124 (9.68)	28/ 125 (22.40)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Asia	24/ 320 (7.50)	28/ 323 (8.67)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
North America	30/ 196 (15.31)	35/ 195 (17.95)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Latin America	0/ 0 ( )	0/ 0 ( )	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Age group (years)									0.0551
<= median in FAS	27/ 430 (6.28)	47/ 409 (11.49)	0.55 (0.35, 0.86)	0.0090	0.52 (0.31, 0.85)	0.0087	-0.05 (-0.09, -0.01)	0.0079	
> median in FAS	89/ 510 (17.45)	103/ 537 (19.18)	0.91 (0.70, 1.18)	0.4701	0.89 (0.65, 1.22)	0.4699	-0.02 (-0.06, 0.03)	0.4692	
NYHA class at baseline									0.7381
II	76/ 745 (10.20)	97/ 732 (13.25)	0.77 (0.58, 1.02)	0.0694	0.74 (0.54, 1.02)	0.0691	-0.03 (-0.06, 0.00)	0.0683	
III/IV	40/ 194 (20.62)	53/ 214 (24.77)	0.83 (0.58, 1.20)	0.3205	0.79 (0.50, 1.26)	0.3191	-0.04 (-0.12, 0.04)	0.3165	
LVEF at baseline									0.3441
< 50%	48/ 356 (13.48)	51/ 363 (14.05)	0.96 (0.67, 1.38)	0.8256	0.95 (0.62, 1.46)	0.8256	-0.01 (-0.06, 0.04)	0.8255	
>= 50% - < 60%	44/ 396 (11.11)	62/ 395 (15.70)	0.71 (0.49, 1.01)	0.0602	0.67 (0.44, 1.02)	0.0595	-0.05 (-0.09, 0.00)	0.0579	
>= 60%	23/ 185 (12.43)	36/ 186 (19.35)	0.64 (0.40, 1.04)	0.0719	0.59 (0.34, 1.04)	0.0702	-0.07 (-0.14, 0.00)	0.0669	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Patient Global Impressions (PGI) scale - Change: Completion rates
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)		Placebo (N=1068)	
Timepoint	n/ N	Completion	n/ N	Completion
Month 6	913 /1046	87.28 %	905 /1029	87.95 %
Month 9	864 /1030	83.88 %	851 /1009	84.34 %
Month 12	833 /1018	81.83 %	825 /993	83.08 %

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of change from baseline of Patient Global Impressions (PGI) scale - Change over time
Full Analysis Set: PGI Subpopulation



Only medications with available start date are included.
Patients who received SGLT2 before randomsiation date were set to time = 0.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=1 point of Patient Global Impressions (PGI) scale - Severity
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)	Placebo (N=1068)
Number of subjects with reponse, n/N (%)	437/ 939 (46.54)	407/ 946 (43.02)
Number of imputed values	126	138
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.16 (0.97, 1.40)	
p-value	0.1116	
Risk Ratio (95% CI)	1.08 (0.98, 1.20)	
p-value	0.1029	
Risk Difference (95% CI)	0.04 (-0.01, 0.08)	
p-value	0.1169	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.15 (0.96, 1.38)	
p-value	0.1249	
Risk Ratio (95% CI)	1.08 (0.98, 1.20)	
p-value	0.1251	
Risk Difference (95% CI)	0.04 (-0.01, 0.08)	
p-value	0.1246	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=1 point of Patient Global Impressions (PGI) scale - Severity - Subgroup analysis
Full Analysis Set: PGI Subpopulation

Subgroup Level	Finerenone (N=1066) n/ N (%)	Placebo (N=1068) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.4830
Male	279/ 563 (49.56)	248/ 556 (44.60)	1.11 (0.98, 1.26)	0.0977	1.22 (0.96, 1.54)	0.0972	0.05 (-0.01, 0.11)	0.0967	
Female	158/ 376 (42.02)	159/ 390 (40.77)	1.03 (0.87, 1.22)	0.7250	1.05 (0.79, 1.40)	0.7250	0.01 (-0.06, 0.08)	0.7250	
Region									<.0001
Western Europe, Oceania and Others	124/ 300 (41.33)	120/ 303 (39.60)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Eastern Europe	58/ 124 (46.77)	51/ 125 (40.80)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Asia	168/ 320 (52.50)	157/ 323 (48.61)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
North America	87/ 195 (44.62)	79/ 195 (40.51)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Latin America	0/ 0 ( )	0/ 0 ( )	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Age group (years)									0.9009
<= median in FAS	221/ 430 (51.40)	194/ 409 (47.43)	1.08 (0.94, 1.24)	0.2521	1.17 (0.89, 1.54)	0.2513	0.04 (-0.03, 0.11)	0.2508	
> median in FAS	216/ 509 (42.44)	213/ 537 (39.66)	1.07 (0.93, 1.24)	0.3624	1.12 (0.88, 1.43)	0.3625	0.03 (-0.03, 0.09)	0.3623	
NYHA class at baseline									0.5957
II	358/ 745 (48.05)	322/ 732 (43.99)	1.09 (0.98, 1.22)	0.1177	1.18 (0.96, 1.45)	0.1172	0.04 (-0.01, 0.09)	0.1168	
III/IV	78/ 193 (40.41)	85/ 214 (39.72)	1.02 (0.80, 1.29)	0.8864	1.03 (0.69, 1.53)	0.8864	0.01 (-0.09, 0.10)	0.8864	
LVEF at baseline									0.2748
< 50%	172/ 356 (48.31)	178/ 363 (49.04)	0.99 (0.85, 1.14)	0.8466	0.97 (0.73, 1.30)	0.8466	-0.01 (-0.08, 0.07)	0.8466	
>= 50% - < 60%	178/ 396 (44.95)	153/ 395 (38.73)	1.16 (0.98, 1.37)	0.0773	1.29 (0.97, 1.71)	0.0767	0.06 (-0.01, 0.13)	0.0758	
>= 60%	87/ 185 (47.03)	75/ 186 (40.32)	1.17 (0.92, 1.47)	0.1944	1.31 (0.87, 1.98)	0.1933	0.07 (-0.03, 0.17)	0.1920	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=1 point of Patient Global Impressions (PGI) scale - Severity
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)	Placebo (N=1068)
Number of subjects with reponse, n/N (%)	192/ 939 (20.45)	226/ 946 (23.89)
Number of imputed values	126	138
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.80 (0.63, 1.00)	
p-value	0.0499	
Risk Ratio (95% CI)	0.88 (0.75, 1.03)	
p-value	0.1062	
Risk Difference (95% CI)	(,)	
p-value	NE	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.82 (0.66, 1.02)	
p-value	0.0722	
Risk Ratio (95% CI)	0.86 (0.72, 1.01)	
p-value	0.0726	
Risk Difference (95% CI)	-0.03 (-0.07, 0.00)	
p-value	0.0717	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=1 point of Patient Global Impressions (PGI) scale - Severity - Subgroup analysis
Full Analysis Set: PGI Subpopulation

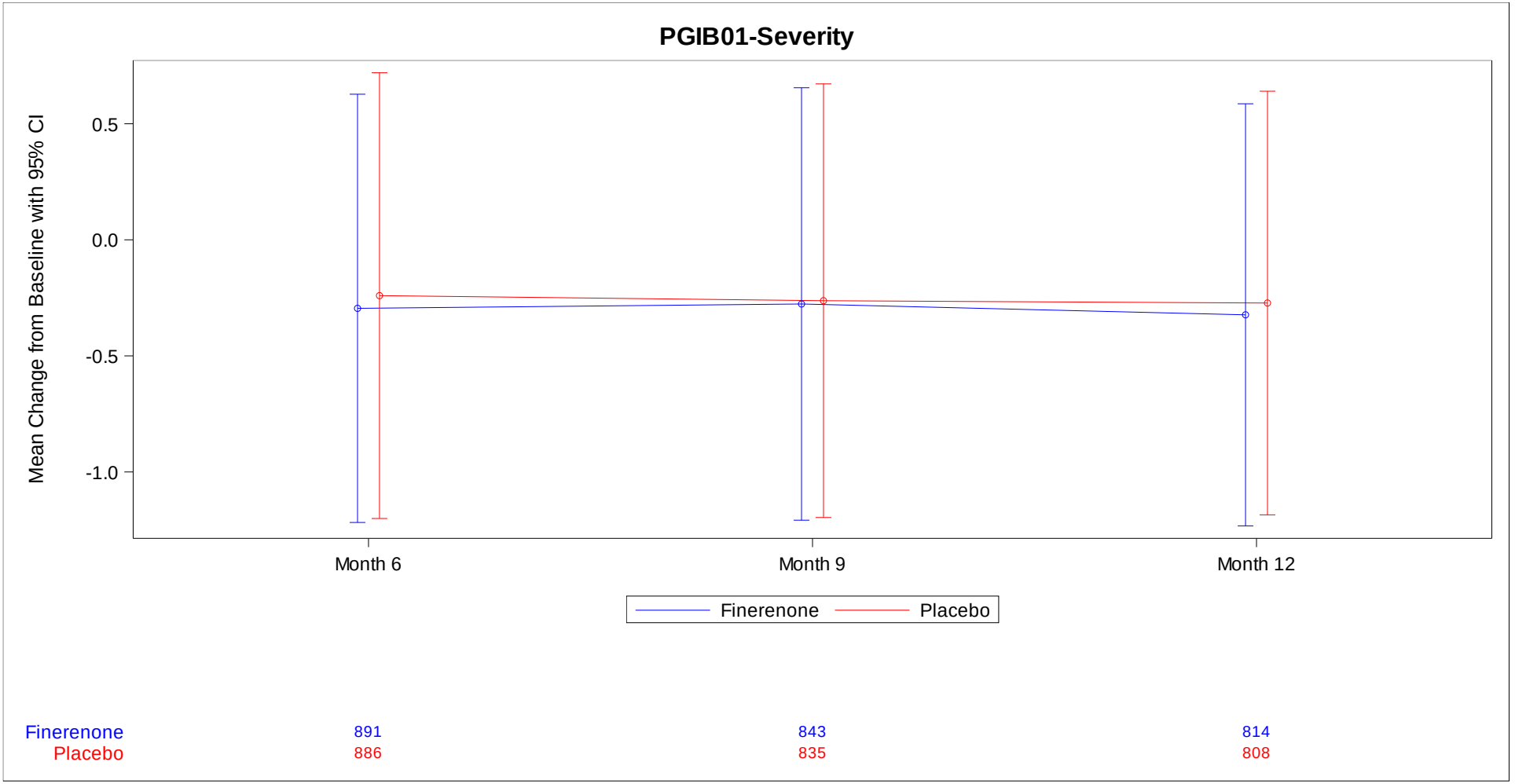
Subgroup Level	Finerenone (N=1066) n/ N (%)	Placebo (N=1068) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.9341
Male	123/ 563 (21.85)	143/ 556 (25.72)	0.85 (0.69, 1.05)	0.1289	0.81 (0.61, 1.06)	0.1285	-0.04 (-0.09, 0.01)	0.1279	
Female	69/ 376 (18.35)	83/ 390 (21.28)	0.86 (0.65, 1.15)	0.3102	0.83 (0.58, 1.19)	0.3096	-0.03 (-0.09, 0.03)	0.3084	
Region									<.0001
Western Europe, Oceania and Others	71/ 300 (23.67)	75/ 303 (24.75)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Eastern Europe	22/ 124 (17.74)	32/ 125 (25.60)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Asia	52/ 320 (16.25)	73/ 323 (22.60)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
North America	47/ 195 (24.10)	46/ 195 (23.59)	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Latin America	0/ 0 ( )	0/ 0 ( )	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	NE (NE, NE)	<.0001	
Age group (years)									0.3240
<= median in FAS	74/ 430 (17.21)	91/ 409 (22.25)	0.77 (0.59, 1.02)	0.0675	0.73 (0.52, 1.02)	0.0670	-0.05 (-0.10, 0.00)	0.0665	
> median in FAS	118/ 509 (23.18)	135/ 537 (25.14)	0.92 (0.74, 1.14)	0.4605	0.90 (0.68, 1.19)	0.4602	-0.02 (-0.07, 0.03)	0.4596	
NYHA class at baseline									0.5468
II	155/ 745 (20.81)	173/ 732 (23.63)	0.88 (0.73, 1.07)	0.1915	0.85 (0.66, 1.09)	0.1912	-0.03 (-0.07, 0.01)	0.1909	
III/IV	37/ 193 (19.17)	53/ 214 (24.77)	0.77 (0.53, 1.12)	0.1774	0.72 (0.45, 1.16)	0.1754	-0.06 (-0.14, 0.02)	0.1714	
LVEF at baseline									0.7735
< 50%	73/ 356 (20.51)	92/ 363 (25.34)	0.81 (0.62, 1.06)	0.1243	0.76 (0.54, 1.08)	0.1235	-0.05 (-0.11, 0.01)	0.1220	
>= 50% - < 60%	87/ 396 (21.97)	95/ 395 (24.05)	0.91 (0.71, 1.18)	0.4872	0.89 (0.64, 1.24)	0.4870	-0.02 (-0.08, 0.04)	0.4868	
>= 60%	31/ 185 (16.76)	39/ 186 (20.97)	0.80 (0.52, 1.22)	0.3017	0.76 (0.45, 1.28)	0.3008	-0.04 (-0.12, 0.04)	0.2991	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Patient Global Impressions (PGI) scale - Severity: Completion rates
Full Analysis Set: PGI Subpopulation

	Finerenone (N=1066)		Placebo (N=1068)	
Timepoint	n/ N	Completion	n/ N	Completion
Baseline	1042 /1066	97.75 %	1049 /1068	98.22 %
Month 6	913 /1046	87.28 %	903 /1029	87.76 %
Month 9	866 /1030	84.08 %	852 /1009	84.44 %
Month 12	834 /1018	81.93 %	825 /993	83.08 %

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of change from baseline of Patient Global Impressions (PGI) scale - Severity over time
Full Analysis Set: PGI Subpopulation



Only medications with available start date are included.
Patients who received SGLT2 before randomsiation date were set to time = 0.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

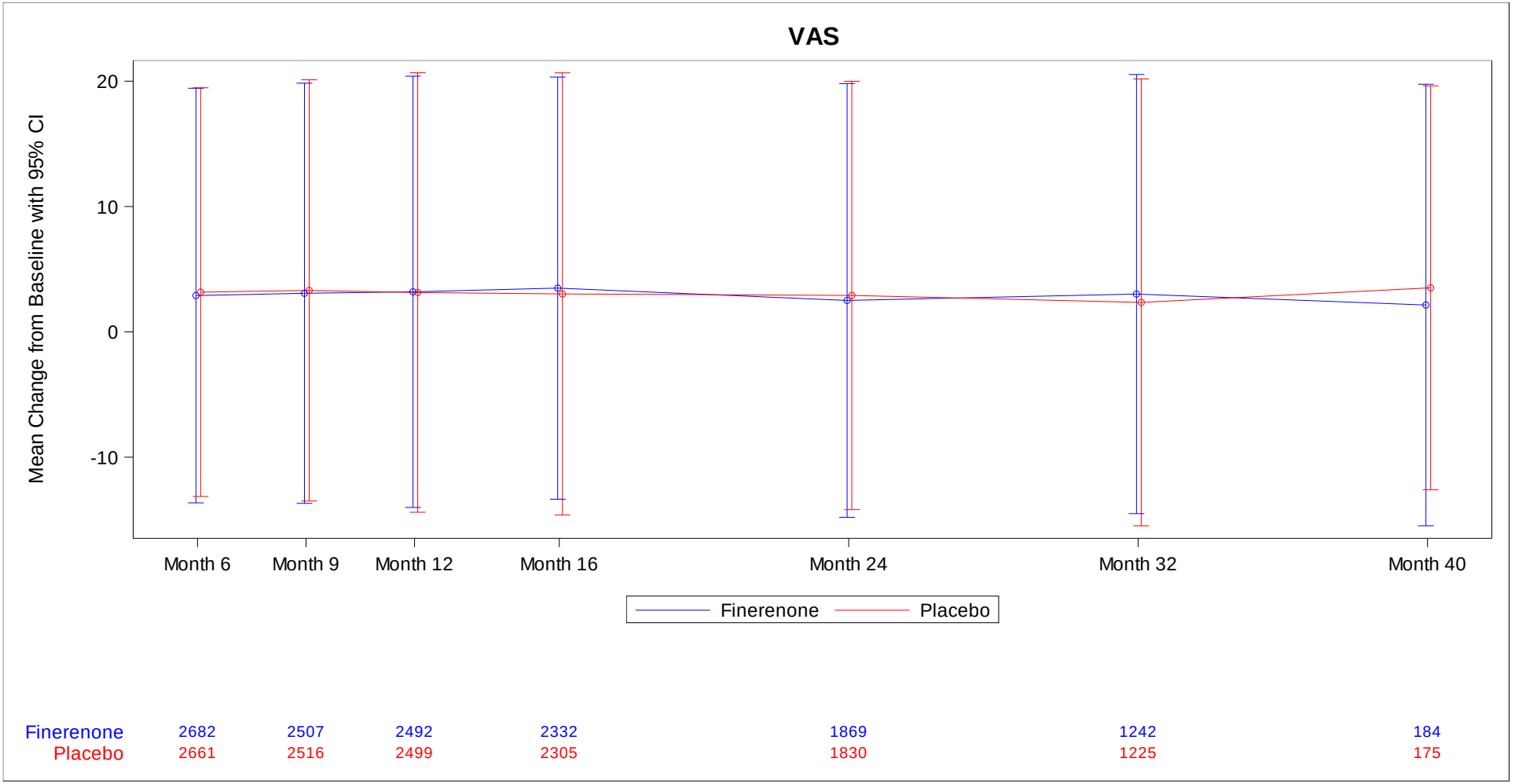
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2990	67.91 (17.29)	-	-	2981	67.12 (17.71)	-	-
Month 6	2691	71.20 (17.11)	2682	2.90 (16.54)	2671	70.60 (17.24)	2661	3.17 (16.30)
Month 9	2516	71.42 (17.01)	2507	3.08 (16.76)	2524	70.93 (17.09)	2516	3.31 (16.80)
Month 12	2498	71.75 (17.14)	2492	3.19 (17.20)	2508	70.74 (17.35)	2499	3.14 (17.53)
Month 16	2339	72.20 (16.77)	2332	3.49 (16.84)	2314	70.78 (17.62)	2305	3.02 (17.64)
Month 24	1874	71.38 (16.97)	1869	2.51 (17.31)	1840	70.91 (16.91)	1830	2.91 (17.09)
Month 32	1245	71.52 (16.93)	1242	3.01 (17.52)	1231	69.99 (16.80)	1225	2.35 (17.83)
Month 40	184	69.36 (18.28)	184	2.14 (17.61)	176	69.30 (16.38)	175	3.51 (16.11)
Premature discontinuation	111	62.80 (21.94)	111	-2.25 (19.86)	124	63.43 (19.93)	124	-3.99 (21.54)
End of Study Visit	2131	72.35 (16.98)	2125	3.17 (17.64)	2067	71.34 (17.16)	2060	3.19 (17.95)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

Timepoint	Finerenone (N=3003) N	Finerenone (N=3003) LSMean (SE)	Placebo (N=2998) N	Placebo (N=2998) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2726	2.48 (0.26)	2703	2.22 (0.26)	0.26 (-0.37, 0.89)	0.4173	0.02 (-0.03, 0.07)	0.4827

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary over time
Full Analysis Set

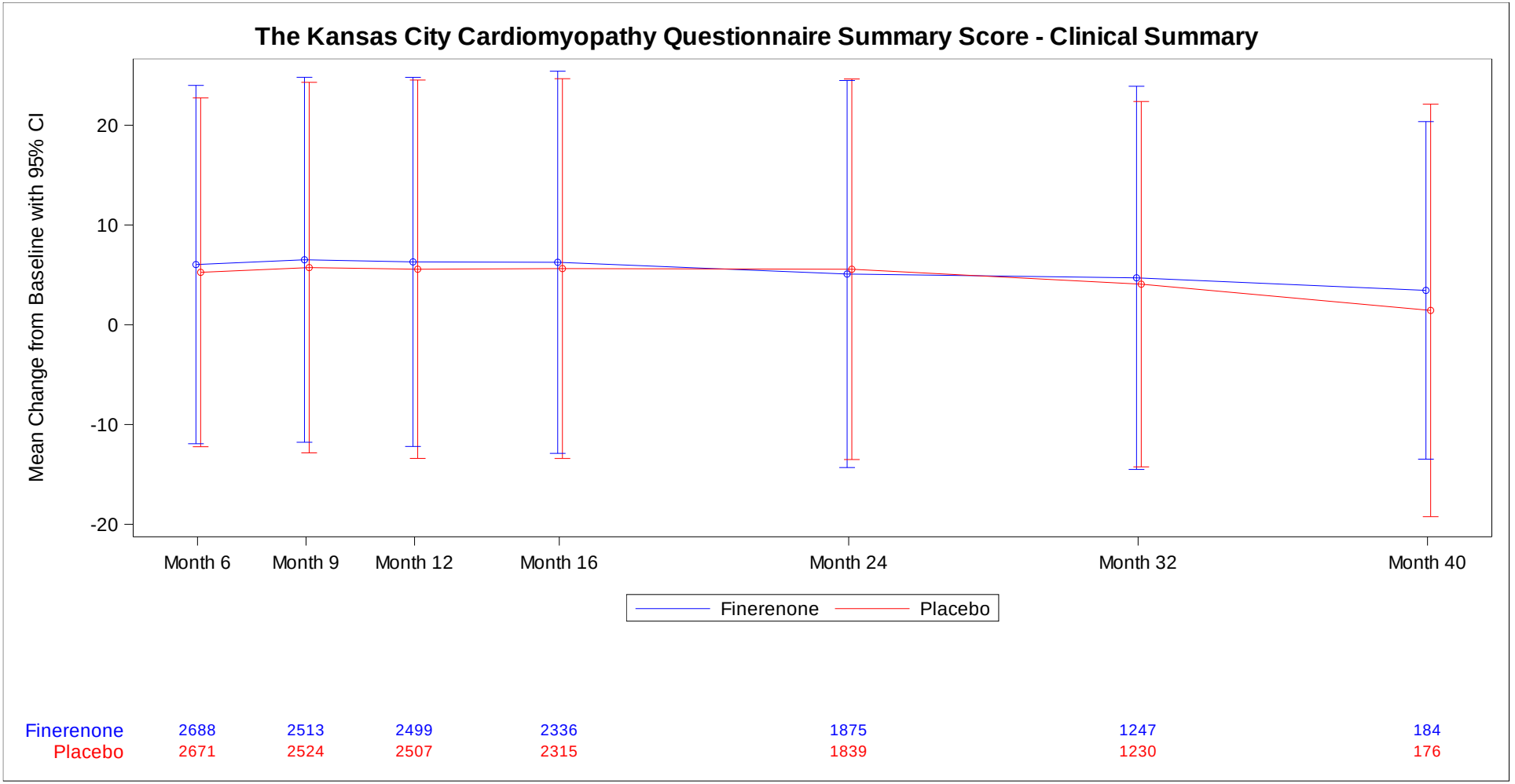
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2995	65.82 (22.29)	-	-	2992	64.90 (22.66)	-	-
Month 6	2693	72.38 (20.65)	2688	6.03 (17.96)	2673	70.80 (21.01)	2671	5.25 (17.48)
Month 9	2516	73.16 (20.29)	2513	6.51 (18.29)	2526	71.50 (21.14)	2524	5.73 (18.57)
Month 12	2500	73.17 (20.69)	2499	6.30 (18.50)	2508	71.38 (21.60)	2507	5.57 (18.96)
Month 16	2338	73.42 (20.58)	2336	6.26 (19.15)	2316	71.76 (21.60)	2315	5.63 (19.03)
Month 24	1876	72.69 (20.53)	1875	5.08 (19.40)	1841	72.18 (20.95)	1839	5.56 (19.07)
Month 32	1247	73.14 (20.57)	1247	4.70 (19.20)	1231	71.83 (21.11)	1230	4.07 (18.31)
Month 40	184	70.33 (21.53)	184	3.44 (16.92)	176	69.96 (22.79)	176	1.44 (20.67)
Premature discontinuation	111	63.97 (23.23)	111	-1.34 (16.90)	124	63.06 (24.93)	124	-3.92 (23.08)
End of Study Visit	2132	73.51 (20.99)	2130	5.49 (19.84)	2068	72.11 (21.58)	2066	5.35 (20.50)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Clinical Summary over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2732	5.53 (0.30)	2711	4.43 (0.30)	1.10 (0.38, 1.82)	0.0029	0.07 (0.02, 0.12)	0.0100

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary over time
Full Analysis Set

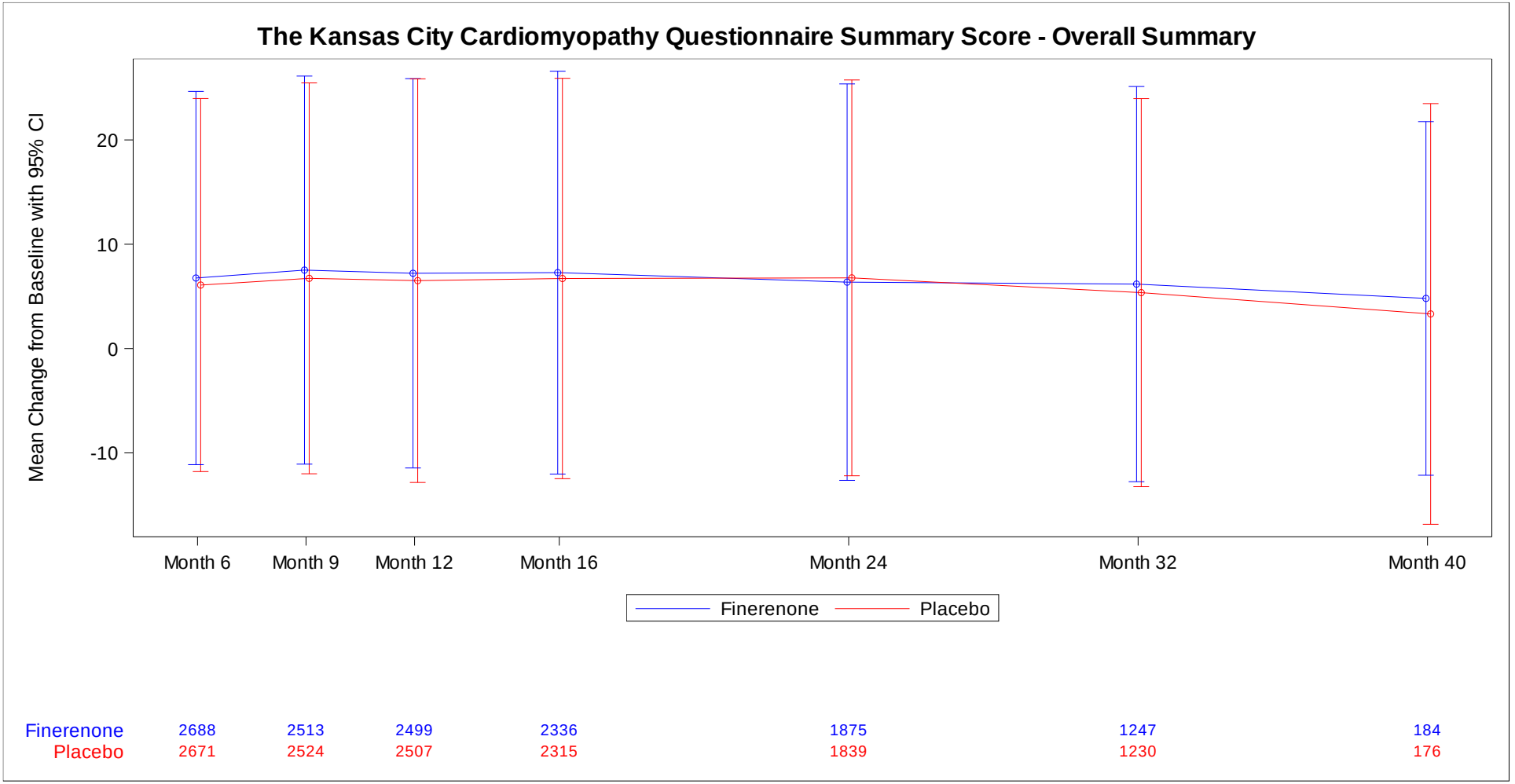
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2995	63.15 (22.00)	-	-	2992	62.44 (22.39)	-	-
Month 6	2693	70.47 (20.54)	2688	6.76 (17.89)	2673	69.23 (20.87)	2671	6.09 (17.88)
Month 9	2516	71.53 (20.35)	2513	7.52 (18.60)	2526	70.07 (20.87)	2524	6.73 (18.73)
Month 12	2500	71.47 (20.44)	2499	7.22 (18.66)	2508	69.97 (21.38)	2507	6.51 (19.34)
Month 16	2338	71.83 (20.45)	2336	7.28 (19.31)	2316	70.45 (21.40)	2315	6.72 (19.19)
Month 24	1876	71.23 (20.21)	1875	6.37 (19.00)	1841	71.13 (20.40)	1839	6.78 (18.97)
Month 32	1247	71.73 (20.17)	1247	6.18 (18.94)	1231	70.90 (20.71)	1230	5.36 (18.60)
Month 40	184	69.26 (20.64)	184	4.81 (16.95)	176	70.36 (22.13)	176	3.32 (20.16)
Premature discontinuation	111	59.69 (24.21)	111	-1.53 (17.92)	124	60.09 (25.43)	124	-4.38 (22.59)
End of Study Visit	2132	71.96 (20.72)	2130	6.84 (20.10)	2068	70.94 (21.13)	2066	6.61 (20.49)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Overall Summary over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2732	6.37 (0.31)	2711	5.44 (0.31)	0.93 (0.19, 1.67)	0.0136	0.06 (0.00, 0.11)	0.0328

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation over time
Full Analysis Set

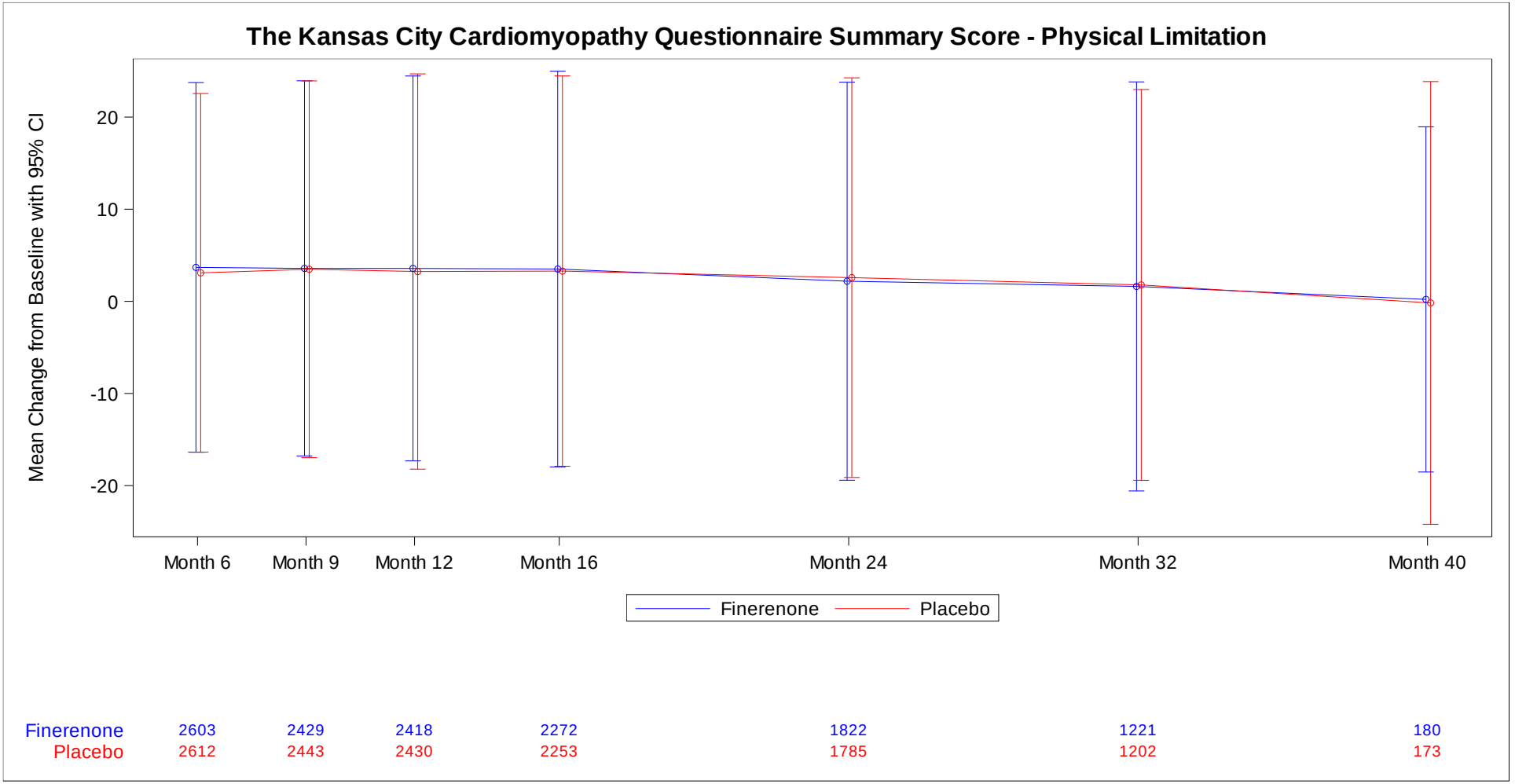
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2947	64.12 (24.62)	-	-	2945	63.20 (25.17)	-	-
Month 6	2632	68.42 (24.10)	2603	3.68 (20.06)	2641	67.15 (24.49)	2612	3.09 (19.46)
Month 9	2455	68.73 (24.05)	2429	3.58 (20.36)	2471	67.76 (24.77)	2443	3.48 (20.45)
Month 12	2443	68.83 (24.68)	2418	3.57 (20.89)	2464	67.48 (24.96)	2430	3.23 (21.45)
Month 16	2300	69.07 (24.24)	2272	3.51 (21.47)	2280	67.86 (25.09)	2253	3.28 (21.18)
Month 24	1841	68.26 (24.14)	1822	2.18 (21.60)	1804	67.80 (24.39)	1785	2.57 (21.69)
Month 32	1232	68.67 (24.82)	1221	1.62 (22.20)	1211	67.56 (24.73)	1202	1.78 (21.21)
Month 40	182	65.15 (24.14)	180	0.21 (18.74)	174	65.57 (25.86)	173	-0.17 (24.03)
Premature discontinuation	111	58.27 (28.28)	107	-3.76 (19.94)	119	59.39 (28.29)	117	-5.19 (23.52)
End of Study Visit	2086	69.19 (25.12)	2062	2.61 (22.66)	2027	67.58 (25.41)	2005	2.32 (22.85)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Physical Limitation over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2676	2.70 (0.35)	2662	2.09 (0.35)	0.61 (-0.22, 1.45)	0.1496	0.03 (-0.02, 0.09)	0.2136

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life over time
Full Analysis Set

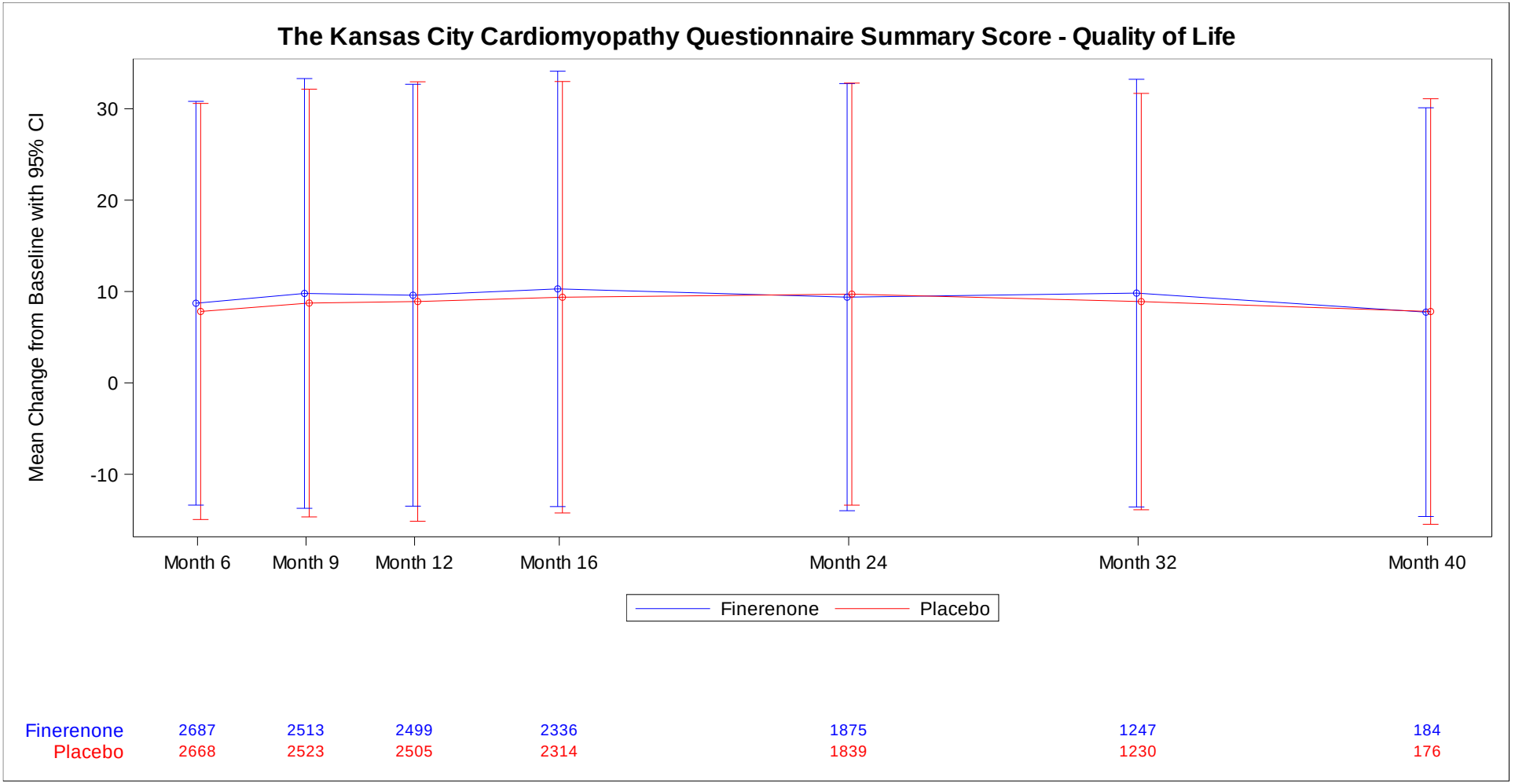
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2995	57.29 (24.37)	-	-	2991	56.98 (24.51)	-	-
Month 6	2692	66.61 (22.94)	2687	8.72 (22.09)	2671	65.55 (22.59)	2668	7.82 (22.77)
Month 9	2516	67.84 (22.85)	2513	9.79 (23.51)	2526	66.51 (22.72)	2523	8.74 (23.40)
Month 12	2500	67.89 (22.43)	2499	9.60 (23.08)	2507	66.94 (22.90)	2505	8.91 (24.05)
Month 16	2338	68.76 (22.42)	2336	10.29 (23.82)	2316	67.46 (22.64)	2314	9.38 (23.61)
Month 24	1876	68.19 (22.40)	1875	9.38 (23.37)	1841	68.62 (21.68)	1839	9.72 (23.09)
Month 32	1247	69.20 (21.46)	1247	9.83 (23.40)	1231	68.83 (21.95)	1230	8.90 (22.78)
Month 40	184	68.57 (21.02)	184	7.74 (22.36)	176	70.31 (21.89)	176	7.81 (23.28)
Premature discontinuation	111	54.50 (26.70)	111	0.90 (24.91)	124	55.68 (27.35)	124	-2.59 (26.18)
End of Study Visit	2132	69.05 (22.42)	2130	10.48 (24.53)	2068	68.41 (22.42)	2065	9.79 (24.33)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Quality of Life over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2731	8.43 (0.36)	2710	7.51 (0.36)	0.92 (0.06, 1.78)	0.0365	0.05 (-0.00, 0.10)	0.0702

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation over time
Full Analysis Set

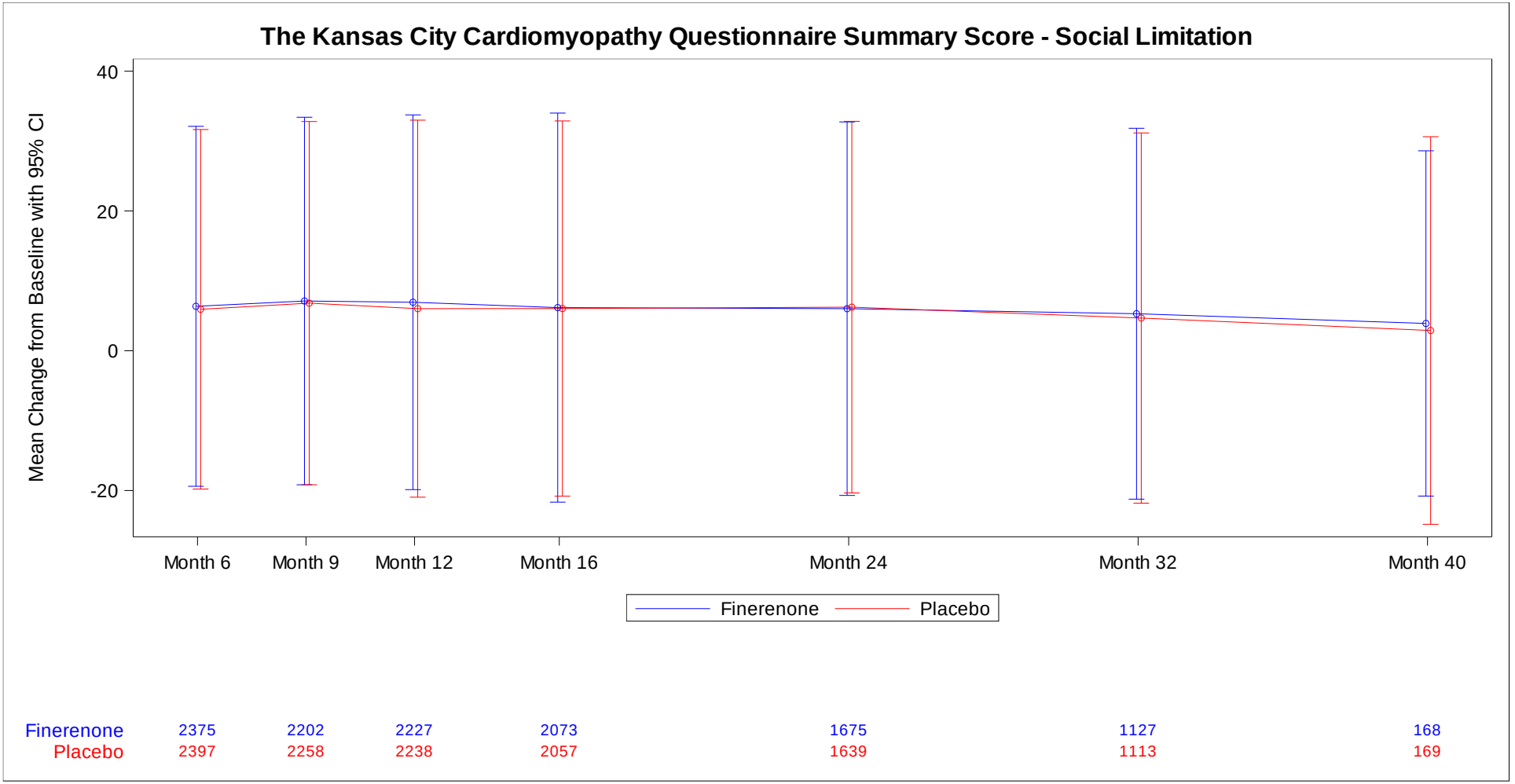
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2787	63.61 (28.49)	-	-	2787	62.90 (28.63)	-	-
Month 6	2492	70.46 (26.54)	2375	6.36 (25.76)	2510	69.75 (26.99)	2397	5.93 (25.72)
Month 9	2311	71.88 (26.19)	2202	7.12 (26.29)	2372	70.82 (26.71)	2258	6.81 (25.99)
Month 12	2335	71.72 (26.40)	2227	6.94 (26.81)	2339	70.13 (27.36)	2238	6.02 (26.97)
Month 16	2183	71.57 (26.66)	2073	6.17 (27.83)	2154	70.59 (27.48)	2057	6.04 (26.85)
Month 24	1757	71.30 (25.89)	1675	6.02 (26.72)	1724	71.37 (26.26)	1639	6.24 (26.59)
Month 32	1179	71.34 (26.18)	1127	5.30 (26.53)	1166	71.23 (26.66)	1113	4.68 (26.49)
Month 40	172	67.88 (26.13)	168	3.91 (24.70)	171	71.19 (27.73)	169	2.90 (27.73)
Premature discontinuation	104	56.57 (31.88)	98	-4.68 (27.13)	118	58.69 (32.74)	110	-6.91 (32.63)
End of Study Visit	1976	71.68 (27.08)	1893	6.21 (29.05)	1943	71.07 (26.95)	1853	6.15 (27.57)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Social Limitation over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2513	6.30 (0.43)	2513	5.35 (0.44)	0.95 (-0.09, 1.99)	0.0733	0.04 (-0.01, 0.10)	0.1230

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom over time
Full Analysis Set

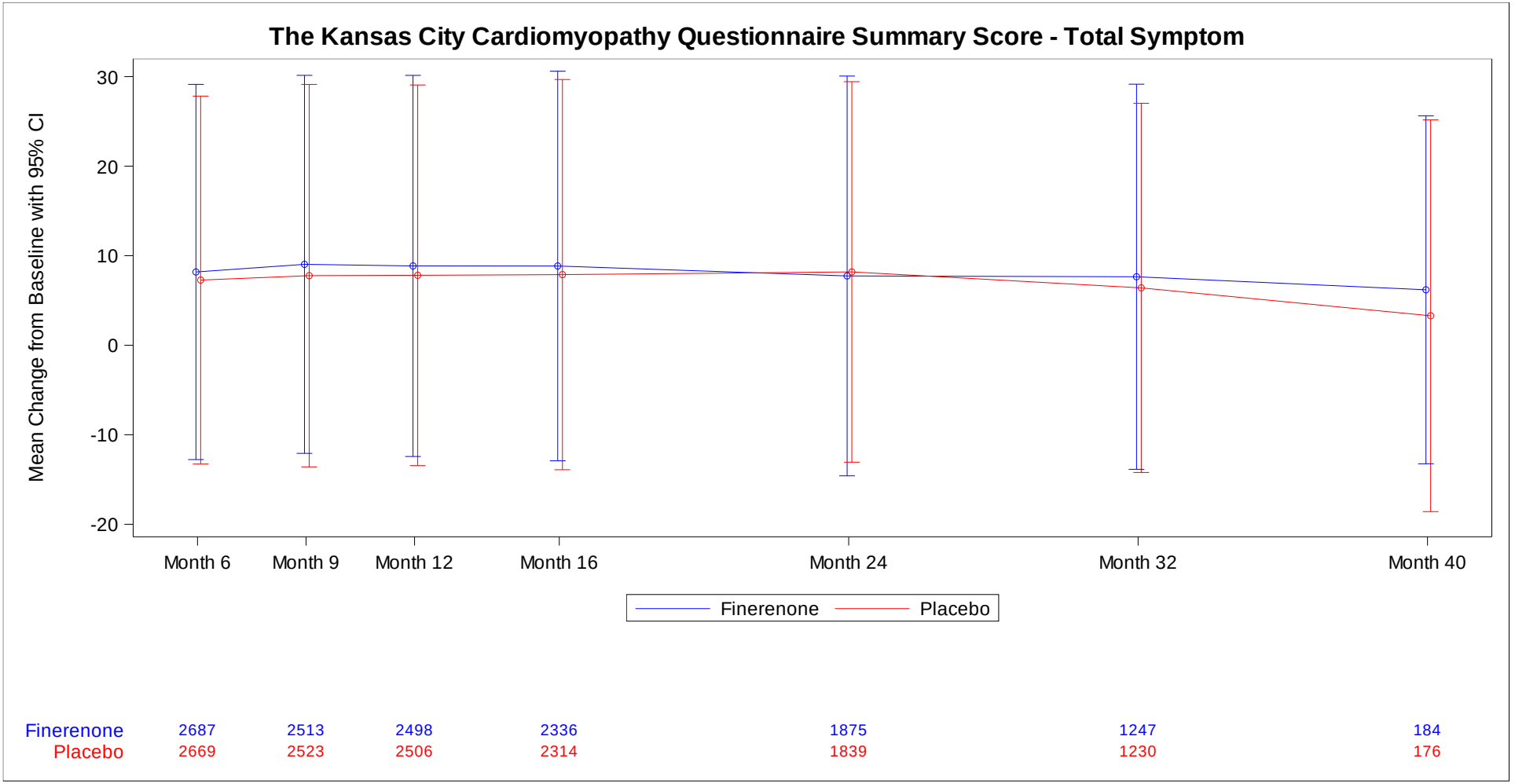
	Finerenone (N=3003)				Placebo (N=2998)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	2995	67.55 (23.91)	-	-	2991	66.51 (23.91)	-	-
Month 6	2692	76.24 (20.74)	2687	8.18 (20.95)	2672	74.36 (21.33)	2669	7.28 (20.55)
Month 9	2516	77.32 (20.18)	2513	9.03 (21.11)	2526	75.07 (21.42)	2523	7.77 (21.36)
Month 12	2499	77.37 (20.16)	2498	8.86 (21.28)	2508	75.10 (21.61)	2506	7.81 (21.26)
Month 16	2338	77.59 (20.28)	2336	8.85 (21.76)	2316	75.50 (21.46)	2314	7.89 (21.79)
Month 24	1876	76.89 (20.47)	1875	7.74 (22.33)	1841	76.34 (20.78)	1839	8.19 (21.25)
Month 32	1247	77.49 (19.93)	1247	7.65 (21.51)	1231	75.98 (21.07)	1230	6.41 (20.62)
Month 40	184	75.24 (21.87)	184	6.19 (19.43)	176	74.07 (22.83)	176	3.29 (21.88)
Premature discontinuation	111	69.68 (23.36)	111	1.51 (19.75)	124	66.05 (26.56)	124	-1.68 (26.18)
End of Study Visit	2132	77.66 (20.26)	2130	8.13 (22.04)	2068	76.38 (21.12)	2065	8.08 (22.85)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in The Kansas City Cardiomyopathy Questionnaire Summary Score - Total Symptom over time
Full Analysis Set

	Finerenone (N=3003)		Placebo (N=2998)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	2731	7.99 (0.32)	2710	6.43 (0.33)	1.56 (0.79, 2.34)	<.0001	0.09 (0.04, 0.15)	0.0006

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	2580/ 2993 (86.20)	2519/ 2993 (84.16)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.18 (1.02, 1.36)	
p-value	0.0266	
Risk Ratio (95% CI)	1.02 (1.00, 1.05)	
p-value	0.0265	
Risk Difference (95% CI)	0.02 (0.00, 0.04)	
p-value	0.0264	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.5796
Male	1407/ 1643 (85.64)	1361/ 1619 (84.06)	1.02 (0.99, 1.05)	0.2108	1.13 (0.93, 1.37)	0.2107	0.02 (-0.01, 0.04)	0.2106	
Female	1173/ 1350 (86.89)	1158/ 1374 (84.28)	1.03 (1.00, 1.06)	0.0526	1.24 (1.00, 1.53)	0.0529	0.03 (-0.00, 0.05)	0.0523	
Region									0.5298
Western Europe, Oceania and Others	576/ 618 (93.20)	577/ 631 (91.44)	1.02 (0.99, 1.05)	0.2423	1.28 (0.84, 1.95)	0.2435	0.02 (-0.01, 0.05)	0.2418	
Eastern Europe	1075/ 1327 (81.01)	1044/ 1319 (79.15)	1.02 (0.99, 1.06)	0.2315	1.12 (0.93, 1.36)	0.2314	0.02 (-0.01, 0.05)	0.2312	
Asia	457/ 492 (92.89)	452/ 488 (92.62)	1.00 (0.97, 1.04)	0.8737	1.04 (0.64, 1.69)	0.8737	0.00 (-0.03, 0.04)	0.8737	
North America	212/ 234 (90.60)	200/ 236 (84.75)	1.07 (1.00, 1.14)	0.0545	1.73 (0.99, 3.05)	0.0558	0.06 (-0.00, 0.12)	0.0526	
Latin America	260/ 322 (80.75)	246/ 319 (77.12)	1.05 (0.97, 1.13)	0.2605	1.24 (0.85, 1.82)	0.2603	0.04 (-0.03, 0.10)	0.2595	
Age group (years)									0.4436
<= median in FAS	1306/ 1585 (82.40)	1277/ 1575 (81.08)	1.02 (0.98, 1.05)	0.3377	1.09 (0.91, 1.31)	0.3377	0.01 (-0.01, 0.04)	0.3376	
> median in FAS	1274/ 1408 (90.48)	1242/ 1418 (87.59)	1.03 (1.01, 1.06)	0.0139	1.35 (1.06, 1.71)	0.0141	0.03 (0.01, 0.05)	0.0137	
NYHA class at baseline									0.7302
II	1768/ 2074 (85.25)	1711/ 2061 (83.02)	1.03 (1.00, 1.05)	0.0501	1.18 (1.00, 1.40)	0.0501	0.02 (0.00, 0.04)	0.0499	
III/IV	811/ 918 (88.34)	808/ 932 (86.70)	1.02 (0.98, 1.05)	0.2833	1.16 (0.88, 1.53)	0.2837	0.02 (-0.01, 0.05)	0.2830	
LVEF at baseline									0.5056
< 50%	928/ 1092 (84.98)	886/ 1078 (82.19)	1.03 (1.00, 1.07)	0.0794	1.23 (0.98, 1.54)	0.0793	0.03 (-0.00, 0.06)	0.0790	
>= 50% - < 60%	1148/ 1323 (86.77)	1152/ 1342 (85.84)	1.01 (0.98, 1.04)	0.4848	1.08 (0.87, 1.35)	0.4849	0.01 (-0.02, 0.04)	0.4847	
>= 60%	499/ 572 (87.24)	479/ 571 (83.89)	1.04 (0.99, 1.09)	0.1076	1.31 (0.94, 1.83)	0.1078	0.03 (-0.01, 0.07)	0.1068	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	2571/ 2993 (85.90)	2510/ 2993 (83.86)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.17 (1.02, 1.35)	
p-value	0.0278	
Risk Ratio (95% CI)	1.02 (1.00, 1.05)	
p-value	0.0278	
Risk Difference (95% CI)	0.02 (0.00, 0.04)	
p-value	0.0277	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	1359/ 2993 (45.41)	1378/ 2993 (46.04)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.97 (0.88, 1.08)	
p-value	0.6220	
Risk Ratio (95% CI)	0.99 (0.93, 1.04)	
p-value	0.6221	
Risk Difference (95% CI)	-0.01 (-0.03, 0.02)	
p-value	0.6220	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.1246
Male	767/ 1643 (46.68)	737/ 1619 (45.52)	1.03 (0.95, 1.10)	0.5061	1.05 (0.91, 1.20)	0.5060	0.01 (-0.02, 0.05)	0.5060	
Female	592/ 1350 (43.85)	641/ 1374 (46.65)	0.94 (0.87, 1.02)	0.1424	0.89 (0.77, 1.04)	0.1421	-0.03 (-0.07, 0.01)	0.1419	
Region									0.8914
Western Europe, Oceania and Others	334/ 618 (54.05)	357/ 631 (56.58)	0.96 (0.86, 1.06)	0.3686	0.90 (0.72, 1.13)	0.3683	-0.03 (-0.08, 0.03)	0.3681	
Eastern Europe	529/ 1327 (39.86)	523/ 1319 (39.65)	1.01 (0.92, 1.10)	0.9108	1.01 (0.86, 1.18)	0.9108	0.00 (-0.04, 0.04)	0.9108	
Asia	236/ 492 (47.97)	244/ 488 (50.00)	0.96 (0.84, 1.09)	0.5246	0.92 (0.72, 1.18)	0.5245	-0.02 (-0.08, 0.04)	0.5244	
North America	132/ 234 (56.41)	129/ 236 (54.66)	1.03 (0.88, 1.21)	0.7028	1.07 (0.75, 1.54)	0.7028	0.02 (-0.07, 0.11)	0.7027	
Latin America	128/ 322 (39.75)	125/ 319 (39.18)	1.01 (0.84, 1.23)	0.8833	1.02 (0.75, 1.41)	0.8833	0.01 (-0.07, 0.08)	0.8833	
Age group (years)									0.0013
<= median in FAS	596/ 1585 (37.60)	662/ 1575 (42.03)	0.89 (0.82, 0.97)	0.0111	0.83 (0.72, 0.96)	0.0110	-0.04 (-0.08, -0.01)	0.0109	
> median in FAS	763/ 1408 (54.19)	716/ 1418 (50.49)	1.07 (1.00, 1.15)	0.0493	1.16 (1.00, 1.34)	0.0492	0.04 (0.00, 0.07)	0.0490	
NYHA class at baseline									0.5070
II	871/ 2074 (42.00)	889/ 2061 (43.13)	0.97 (0.91, 1.05)	0.4592	0.95 (0.84, 1.08)	0.4592	-0.01 (-0.04, 0.02)	0.4592	
III/IV	487/ 918 (53.05)	489/ 932 (52.47)	1.01 (0.93, 1.10)	0.8019	1.02 (0.85, 1.23)	0.8019	0.01 (-0.04, 0.05)	0.8019	
LVEF at baseline									0.9199
< 50%	448/ 1092 (41.03)	455/ 1078 (42.21)	0.97 (0.88, 1.07)	0.5765	0.95 (0.80, 1.13)	0.5765	-0.01 (-0.05, 0.03)	0.5764	
>= 50% - < 60%	622/ 1323 (47.01)	632/ 1342 (47.09)	1.00 (0.92, 1.08)	0.9672	1.00 (0.86, 1.16)	0.9672	-0.00 (-0.04, 0.04)	0.9672	
>= 60%	287/ 572 (50.17)	290/ 571 (50.79)	0.99 (0.88, 1.11)	0.8357	0.98 (0.77, 1.23)	0.8357	-0.01 (-0.06, 0.05)	0.8357	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	1343/ 2993 (44.87)	1359/ 2993 (45.41)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.98 (0.88, 1.08)	
p-value	0.6777	
Risk Ratio (95% CI)	0.99 (0.93, 1.04)	
p-value	0.6777	
Risk Difference (95% CI)	-0.01 (-0.03, 0.02)	
p-value	0.6777	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	789/ 2993 (26.36)	827/ 2993 (27.63)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.94 (0.84, 1.05)	
p-value	0.2686	
Risk Ratio (95% CI)	0.95 (0.88, 1.04)	
p-value	0.2687	
Risk Difference (95% CI)	-0.01 (-0.04, 0.01)	
p-value	0.2685	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.7931
Male	459/ 1643 (27.94)	470/ 1619 (29.03)	0.96 (0.86, 1.07)	0.4890	0.95 (0.81, 1.10)	0.4890	-0.01 (-0.04, 0.02)	0.4890	
Female	330/ 1350 (24.44)	357/ 1374 (25.98)	0.94 (0.83, 1.07)	0.3556	0.92 (0.78, 1.10)	0.3554	-0.02 (-0.05, 0.02)	0.3552	
Region									0.8840
Western Europe, Oceania and Others	203/ 618 (32.85)	209/ 631 (33.12)	0.99 (0.85, 1.16)	0.9179	0.99 (0.78, 1.25)	0.9179	-0.00 (-0.05, 0.05)	0.9179	
Eastern Europe	285/ 1327 (21.48)	290/ 1319 (21.99)	0.98 (0.85, 1.13)	0.7508	0.97 (0.81, 1.17)	0.7508	-0.01 (-0.04, 0.03)	0.7508	
Asia	130/ 492 (26.42)	145/ 488 (29.71)	0.89 (0.73, 1.09)	0.2522	0.85 (0.64, 1.12)	0.2519	-0.03 (-0.09, 0.02)	0.2514	
North America	85/ 234 (36.32)	96/ 236 (40.68)	0.89 (0.71, 1.12)	0.3330	0.83 (0.57, 1.21)	0.3324	-0.04 (-0.13, 0.04)	0.3317	
Latin America	86/ 322 (26.71)	87/ 319 (27.27)	0.98 (0.76, 1.26)	0.8721	0.97 (0.69, 1.38)	0.8721	-0.01 (-0.07, 0.06)	0.8721	
Age group (years)									0.6466
<= median in FAS	347/ 1585 (21.89)	369/ 1575 (23.43)	0.93 (0.82, 1.06)	0.3026	0.92 (0.78, 1.08)	0.3025	-0.02 (-0.04, 0.01)	0.3024	
> median in FAS	442/ 1408 (31.39)	458/ 1418 (32.30)	0.97 (0.87, 1.08)	0.6049	0.96 (0.82, 1.12)	0.6049	-0.01 (-0.04, 0.03)	0.6048	
NYHA class at baseline									0.6280
II	499/ 2074 (24.06)	527/ 2061 (25.57)	0.94 (0.85, 1.05)	0.2610	0.92 (0.80, 1.06)	0.2610	-0.02 (-0.04, 0.01)	0.2609	
III/IV	290/ 918 (31.59)	300/ 932 (32.19)	0.98 (0.86, 1.12)	0.7825	0.97 (0.80, 1.18)	0.7824	-0.01 (-0.05, 0.04)	0.7824	
LVEF at baseline									0.5109
< 50%	294/ 1092 (26.92)	289/ 1078 (26.81)	1.00 (0.87, 1.15)	0.9522	1.01 (0.83, 1.22)	0.9522	0.00 (-0.04, 0.04)	0.9522	
>= 50% - < 60%	336/ 1323 (25.40)	377/ 1342 (28.09)	0.90 (0.80, 1.03)	0.1164	0.87 (0.73, 1.03)	0.1161	-0.03 (-0.06, 0.01)	0.1158	
>= 60%	158/ 572 (27.62)	160/ 571 (28.02)	0.99 (0.82, 1.19)	0.8805	0.98 (0.76, 1.27)	0.8805	-0.00 (-0.06, 0.05)	0.8805	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	776/ 2993 (25.93)	807/ 2993 (26.96)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.95 (0.85, 1.06)	
p-value	0.3636	
Risk Ratio (95% CI)	0.96 (0.88, 1.05)	
p-value	0.3637	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.3636	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	147/ 2993 (4.91)	128/ 2993 (4.28)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.16 (0.91, 1.47)	
p-value	0.2412	
Risk Ratio (95% CI)	1.15 (0.91, 1.45)	
p-value	0.2412	
Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
p-value	0.2407	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.5549
Male	88/ 1643 (5.36)	80/ 1619 (4.94)	1.08 (0.81, 1.46)	0.5922	1.09 (0.80, 1.49)	0.5922	0.00 (-0.01, 0.02)	0.5919	
Female	59/ 1350 (4.37)	48/ 1374 (3.49)	1.25 (0.86, 1.82)	0.2399	1.26 (0.86, 1.86)	0.2398	0.01 (-0.01, 0.02)	0.2391	
Region									0.9947
Western Europe, Oceania and Others	49/ 618 (7.93)	42/ 631 (6.66)	1.19 (0.80, 1.77)	0.3876	1.21 (0.79, 1.85)	0.3875	0.01 (-0.02, 0.04)	0.3872	
Eastern Europe	41/ 1327 (3.09)	38/ 1319 (2.88)	1.07 (0.69, 1.66)	0.7525	1.07 (0.69, 1.68)	0.7525	0.00 (-0.01, 0.02)	0.7524	
Asia	24/ 492 (4.88)	21/ 488 (4.30)	1.13 (0.64, 2.01)	0.6676	1.14 (0.63, 2.08)	0.6675	0.01 (-0.02, 0.03)	0.6672	
North America	20/ 234 (8.55)	16/ 236 (6.78)	1.26 (0.67, 2.37)	0.4725	1.29 (0.65, 2.55)	0.4722	0.02 (-0.03, 0.07)	0.4713	
Latin America	13/ 322 (4.04)	11/ 319 (3.45)	1.17 (0.53, 2.57)	0.6948	1.18 (0.52, 2.67)	0.6948	0.01 (-0.02, 0.04)	0.6944	
Age group (years)									0.9587
<= median in FAS	54/ 1585 (3.41)	47/ 1575 (2.98)	1.14 (0.78, 1.68)	0.4996	1.15 (0.77, 1.71)	0.4996	0.00 (-0.01, 0.02)	0.4992	
> median in FAS	93/ 1408 (6.61)	81/ 1418 (5.71)	1.16 (0.87, 1.54)	0.3240	1.17 (0.86, 1.59)	0.3239	0.01 (-0.01, 0.03)	0.3235	
NYHA class at baseline									0.3578
II	110/ 2074 (5.30)	89/ 2061 (4.32)	1.23 (0.94, 1.61)	0.1396	1.24 (0.93, 1.65)	0.1394	0.01 (-0.00, 0.02)	0.1385	
III/IV	37/ 918 (4.03)	39/ 932 (4.18)	0.96 (0.62, 1.50)	0.8674	0.96 (0.61, 1.52)	0.8674	-0.00 (-0.02, 0.02)	0.8674	
LVEF at baseline									0.3608
< 50%	48/ 1092 (4.40)	44/ 1078 (4.08)	1.08 (0.72, 1.61)	0.7167	1.08 (0.71, 1.64)	0.7167	0.00 (-0.01, 0.02)	0.7166	
>= 50% - < 60%	75/ 1323 (5.67)	57/ 1342 (4.25)	1.33 (0.95, 1.87)	0.0921	1.35 (0.95, 1.93)	0.0919	0.01 (-0.00, 0.03)	0.0910	
>= 60%	23/ 572 (4.02)	27/ 571 (4.73)	0.85 (0.49, 1.46)	0.5592	0.84 (0.48, 1.49)	0.5591	-0.01 (-0.03, 0.02)	0.5586	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	143/ 2993 (4.78)	121/ 2993 (4.04)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.19 (0.93, 1.53)	
p-value	0.1666	
Risk Ratio (95% CI)	1.18 (0.93, 1.50)	
p-value	0.1666	
Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
p-value	0.1660	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	96/ 2993 (3.21)	92/ 2993 (3.07)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.04 (0.78, 1.40)	
p-value	0.7669	
Risk Ratio (95% CI)	1.04 (0.79, 1.38)	
p-value	0.7669	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.7669	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Serious)
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	90/ 2993 (3.01)	84/ 2993 (2.81)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.07 (0.79, 1.45)	
p-value	0.6444	
Risk Ratio (95% CI)	1.07 (0.80, 1.44)	
p-value	0.6444	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.6443	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Severe)
Safety Analysis Set

	Finerenone (N=2993)	Placebo (N=2993)
Number of subjects with event, n/N (%)	67/ 2993 (2.24)	64/ 2993 (2.14)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.05 (0.74, 1.48)	
p-value	0.7910	
Risk Ratio (95% CI)	1.05 (0.75, 1.47)	
p-value	0.7910	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.7910	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	349/ 2993 (11.66)	345/ 2993 (11.53)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.86, 1.19)	
	p-value	0.8717	
	Risk Ratio (95% CI)	1.01 (0.88, 1.16)	
	p-value	0.8717	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.8717	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	236/ 2993 (7.89)	218/ 2993 (7.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.90, 1.32)	
	p-value	0.3796	
	Risk Ratio (95% CI)	1.08 (0.91, 1.29)	
	p-value	0.3797	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.3795	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Iron deficiency anaemia	Number of subjects with event, n/N (%)	40/ 2993 (1.34)	67/ 2993 (2.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.59 (0.40, 0.88)	
	p-value	0.0092	
	Risk Ratio (95% CI)	0.60 (0.40, 0.88)	
	p-value	0.0092	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0084	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	757/ 2993 (25.29)	742/ 2993 (24.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.91, 1.15)	
	p-value	0.6545	
	Risk Ratio (95% CI)	1.02 (0.93, 1.11)	
	p-value	0.6545	
	Risk Difference (95% CI)	0.01 (-0.02, 0.03)	
	p-value	0.6545	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Angina pectoris	Number of subjects with event, n/N (%)	53/ 2993 (1.77)	65/ 2993 (2.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.81 (0.56, 1.17)	
	p-value	0.2653	
	Risk Ratio (95% CI)	0.82 (0.57, 1.17)	
	p-value	0.2654	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2645	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	50/ 2993 (1.67)	40/ 2993 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.83, 1.91)	
	p-value	0.2892	
	Risk Ratio (95% CI)	1.25 (0.83, 1.89)	
	p-value	0.2892	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2881	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Atrial fibrillation	Number of subjects with event, n/N (%)	160/ 2993 (5.35)	163/ 2993 (5.45)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.78, 1.23)	
	p-value	0.8637	
	Risk Ratio (95% CI)	0.98 (0.79, 1.21)	
	p-value	0.8637	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8637	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Atrial flutter	Number of subjects with event, n/N (%)	30/ 2993 (1.00)	27/ 2993 (0.90)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.11 (0.66, 1.88)	
	p-value	0.6898	
	Risk Ratio (95% CI)	1.11 (0.66, 1.86)	
	p-value	0.6898	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.6897	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Bradycardia	Number of subjects with event, n/N (%)	59/ 2993 (1.97)	49/ 2993 (1.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.21 (0.82, 1.77)	
	p-value	0.3322	
	Risk Ratio (95% CI)	1.20 (0.83, 1.75)	
	p-value	0.3323	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3315	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	194/ 2993 (6.48)	212/ 2993 (7.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.74, 1.11)	
	p-value	0.3550	
	Risk Ratio (95% CI)	0.92 (0.76, 1.10)	
	p-value	0.3550	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.3548	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Coronary artery disease	Number of subjects with event, n/N (%)	42/ 2993 (1.40)	35/ 2993 (1.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.77, 1.89)	
	p-value	0.4227	
	Risk Ratio (95% CI)	1.20 (0.77, 1.87)	
	p-value	0.4227	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4220	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Mitral valve incompetence	Number of subjects with event, n/N (%)	26/ 2993 (0.87)	30/ 2993 (1.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.51, 1.47)	
	p-value	0.5916	
	Risk Ratio (95% CI)	0.87 (0.51, 1.46)	
	p-value	0.5916	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5912	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Palpitations	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	46/ 2993 (1.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.44, 1.09)	
	p-value	0.1125	
	Risk Ratio (95% CI)	0.70 (0.44, 1.09)	
	p-value	0.1126	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.1105	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Ventricular extrasystoles	Number of subjects with event, n/N (%)	30/ 2993 (1.00)	25/ 2993 (0.84)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.71, 2.05)	
	p-value	0.4988	
	Risk Ratio (95% CI)	1.20 (0.71, 2.04)	
	p-value	0.4988	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4982	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	91/ 2993 (3.04)	83/ 2993 (2.77)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.10 (0.81, 1.49)	
	p-value	0.5384	
	Risk Ratio (95% CI)	1.10 (0.82, 1.47)	
	p-value	0.5384	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5382	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Ear and labyrinth disorders; PT: Vertigo	Number of subjects with event, n/N (%)	42/ 2993 (1.40)	47/ 2993 (1.57)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.59, 1.36)	
	p-value	0.5935	
	Risk Ratio (95% CI)	0.89 (0.59, 1.35)	
	p-value	0.5936	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5933	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Endocrine disorders	Number of subjects with event, n/N (%)	76/ 2993 (2.54)	80/ 2993 (2.67)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.69, 1.30)	
	p-value	0.7456	
	Risk Ratio (95% CI)	0.95 (0.70, 1.30)	
	p-value	0.7456	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.7455	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Endocrine disorders; PT: Hypothyroidism	Number of subjects with event, n/N (%)	36/ 2993 (1.20)	44/ 2993 (1.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.82 (0.52, 1.27)	
	p-value	0.3687	
	Risk Ratio (95% CI)	0.82 (0.53, 1.27)	
	p-value	0.3687	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3678	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Eye disorders	Number of subjects with event, n/N (%)	161/ 2993 (5.38)	169/ 2993 (5.65)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.76, 1.19)	
	p-value	0.6505	
	Risk Ratio (95% CI)	0.95 (0.77, 1.18)	
	p-value	0.6505	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.6505	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Eye disorders; PT: Cataract	Number of subjects with event, n/N (%)	54/ 2993 (1.80)	63/ 2993 (2.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.59, 1.23)	
	p-value	0.4012	
	Risk Ratio (95% CI)	0.86 (0.60, 1.23)	
	p-value	0.4012	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4007	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	757/ 2993 (25.29)	687/ 2993 (22.95)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (1.01, 1.28)	
	p-value	0.0345	
	Risk Ratio (95% CI)	1.10 (1.01, 1.21)	
	p-value	0.0346	
	Risk Difference (95% CI)	0.02 (0.00, 0.05)	
	p-value	0.0344	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Abdominal pain	Number of subjects with event, n/N (%)	46/ 2993 (1.54)	47/ 2993 (1.57)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.65, 1.47)	
	p-value	0.9168	
	Risk Ratio (95% CI)	0.98 (0.65, 1.46)	
	p-value	0.9168	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9168	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Abdominal pain upper	Number of subjects with event, n/N (%)	40/ 2993 (1.34)	36/ 2993 (1.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.11 (0.71, 1.75)	
	p-value	0.6444	
	Risk Ratio (95% CI)	1.11 (0.71, 1.74)	
	p-value	0.6444	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.6442	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Constipation	Number of subjects with event, n/N (%)	139/ 2993 (4.64)	99/ 2993 (3.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.42 (1.09, 1.85)	
	p-value	0.0084	
	Risk Ratio (95% CI)	1.40 (1.09, 1.81)	
	p-value	0.0085	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0081	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	189/ 2993 (6.31)	148/ 2993 (4.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.30 (1.04, 1.62)	
	p-value	0.0218	
	Risk Ratio (95% CI)	1.28 (1.04, 1.57)	
	p-value	0.0219	
	Risk Difference (95% CI)	0.01 (0.00, 0.03)	
	p-value	0.0214	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Dyspepsia	Number of subjects with event, n/N (%)	33/ 2993 (1.10)	34/ 2993 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.60, 1.57)	
	p-value	0.9022	
	Risk Ratio (95% CI)	0.97 (0.60, 1.56)	
	p-value	0.9022	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.9022	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Gastritis	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	26/ 2993 (0.87)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.23 (0.73, 2.07)	
	p-value	0.4294	
	Risk Ratio (95% CI)	1.23 (0.74, 2.06)	
	p-value	0.4294	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4285	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Gastrointestinal haemorrhage	Number of subjects with event, n/N (%)	31/ 2993 (1.04)	19/ 2993 (0.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.64 (0.92, 2.91)	
	p-value	0.0915	
	Risk Ratio (95% CI)	1.63 (0.92, 2.88)	
	p-value	0.0916	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0883	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Gastrooesophageal reflux disease	Number of subjects with event, n/N (%)	38/ 2993 (1.27)	33/ 2993 (1.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.15 (0.72, 1.84)	
	p-value	0.5509	
	Risk Ratio (95% CI)	1.15 (0.72, 1.83)	
	p-value	0.5509	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5505	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Haemorrhoids	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	28/ 2993 (0.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.69, 1.91)	
	p-value	0.6040	
	Risk Ratio (95% CI)	1.14 (0.69, 1.89)	
	p-value	0.6040	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.6037	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	81/ 2993 (2.71)	69/ 2993 (2.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.18 (0.85, 1.63)	
	p-value	0.3216	
	Risk Ratio (95% CI)	1.17 (0.85, 1.61)	
	p-value	0.3216	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3210	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Vomiting	Number of subjects with event, n/N (%)	57/ 2993 (1.90)	43/ 2993 (1.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.33 (0.89, 1.99)	
	p-value	0.1594	
	Risk Ratio (95% CI)	1.33 (0.90, 1.96)	
	p-value	0.1594	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1579	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	581/ 2993 (19.41)	630/ 2993 (21.05)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.80, 1.03)	
	p-value	0.1150	
	Risk Ratio (95% CI)	0.92 (0.83, 1.02)	
	p-value	0.1151	
	Risk Difference (95% CI)	-0.02 (-0.04, 0.00)	
	p-value	0.1148	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	67/ 2993 (2.24)	56/ 2993 (1.87)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.84, 1.72)	
	p-value	0.3169	
	Risk Ratio (95% CI)	1.20 (0.84, 1.70)	
	p-value	0.3169	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3162	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Chest pain	Number of subjects with event, n/N (%)	99/ 2993 (3.31)	114/ 2993 (3.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.66, 1.14)	
	p-value	0.2957	
	Risk Ratio (95% CI)	0.87 (0.67, 1.13)	
	p-value	0.2957	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.2953	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	70/ 2993 (2.34)	97/ 2993 (3.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.52, 0.98)	
	p-value	0.0349	
	Risk Ratio (95% CI)	0.72 (0.53, 0.98)	
	p-value	0.0350	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0340	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Fatigue	Number of subjects with event, n/N (%)	76/ 2993 (2.54)	57/ 2993 (1.90)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.34 (0.95, 1.90)	
	p-value	0.0968	
	Risk Ratio (95% CI)	1.33 (0.95, 1.87)	
	p-value	0.0969	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.0956	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	114/ 2993 (3.81)	109/ 2993 (3.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.80, 1.37)	
	p-value	0.7329	
	Risk Ratio (95% CI)	1.05 (0.81, 1.35)	
	p-value	0.7329	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.7329	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Peripheral swelling	Number of subjects with event, n/N (%)	34/ 2993 (1.14)	33/ 2993 (1.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.64, 1.67)	
	p-value	0.9022	
	Risk Ratio (95% CI)	1.03 (0.64, 1.66)	
	p-value	0.9022	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.9022	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Pyrexia	Number of subjects with event, n/N (%)	56/ 2993 (1.87)	68/ 2993 (2.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.82 (0.57, 1.17)	
	p-value	0.2769	
	Risk Ratio (95% CI)	0.82 (0.58, 1.17)	
	p-value	0.2770	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2761	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	123/ 2993 (4.11)	148/ 2993 (4.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.82 (0.65, 1.05)	
	p-value	0.1206	
	Risk Ratio (95% CI)	0.83 (0.66, 1.05)	
	p-value	0.1207	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1201	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	1358/ 2993 (45.37)	1329/ 2993 (44.40)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.94, 1.15)	
	p-value	0.4511	
	Risk Ratio (95% CI)	1.02 (0.97, 1.08)	
	p-value	0.4511	
	Risk Difference (95% CI)	0.01 (-0.02, 0.03)	
	p-value	0.4511	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Bronchitis	Number of subjects with event, n/N (%)	109/ 2993 (3.64)	105/ 2993 (3.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.79, 1.37)	
	p-value	0.7807	
	Risk Ratio (95% CI)	1.04 (0.80, 1.35)	
	p-value	0.7807	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.7807	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	396/ 2993 (13.23)	382/ 2993 (12.76)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.90, 1.21)	
	p-value	0.5905	
	Risk Ratio (95% CI)	1.04 (0.91, 1.18)	
	p-value	0.5905	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.5905	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19 pneumonia	Number of subjects with event, n/N (%)	33/ 2993 (1.10)	39/ 2993 (1.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.53, 1.35)	
	p-value	0.4773	
	Risk Ratio (95% CI)	0.85 (0.53, 1.34)	
	p-value	0.4774	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4768	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	65/ 2993 (2.17)	68/ 2993 (2.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.68, 1.35)	
	p-value	0.7925	
	Risk Ratio (95% CI)	0.96 (0.68, 1.34)	
	p-value	0.7925	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.7925	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Cystitis	Number of subjects with event, n/N (%)	29/ 2993 (0.97)	31/ 2993 (1.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.56, 1.56)	
	p-value	0.7953	
	Risk Ratio (95% CI)	0.94 (0.57, 1.55)	
	p-value	0.7953	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.7952	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Gastroenteritis	Number of subjects with event, n/N (%)	34/ 2993 (1.14)	16/ 2993 (0.53)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.14 (1.18, 3.88)	
	p-value	0.0125	
	Risk Ratio (95% CI)	2.13 (1.18, 3.84)	
	p-value	0.0126	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0105	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Herpes zoster	Number of subjects with event, n/N (%)	35/ 2993 (1.17)	41/ 2993 (1.37)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.54, 1.34)	
	p-value	0.4890	
	Risk Ratio (95% CI)	0.85 (0.55, 1.34)	
	p-value	0.4890	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4885	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Influenza	Number of subjects with event, n/N (%)	84/ 2993 (2.81)	82/ 2993 (2.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.75, 1.40)	
	p-value	0.8749	
	Risk Ratio (95% CI)	1.02 (0.76, 1.38)	
	p-value	0.8749	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8749	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	118/ 2993 (3.94)	98/ 2993 (3.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.21 (0.92, 1.59)	
	p-value	0.1663	
	Risk Ratio (95% CI)	1.20 (0.93, 1.57)	
	p-value	0.1664	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.1657	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	238/ 2993 (7.95)	221/ 2993 (7.38)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.90, 1.31)	
	p-value	0.4090	
	Risk Ratio (95% CI)	1.08 (0.90, 1.28)	
	p-value	0.4091	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.4089	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Respiratory tract infection	Number of subjects with event, n/N (%)	75/ 2993 (2.51)	69/ 2993 (2.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.78, 1.52)	
	p-value	0.6129	
	Risk Ratio (95% CI)	1.09 (0.79, 1.50)	
	p-value	0.6129	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.6128	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Respiratory tract infection viral	Number of subjects with event, n/N (%)	30/ 2993 (1.00)	22/ 2993 (0.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.37 (0.79, 2.38)	
	p-value	0.2671	
	Risk Ratio (95% CI)	1.36 (0.79, 2.36)	
	p-value	0.2671	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2651	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	45/ 2993 (1.50)	27/ 2993 (0.90)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.68 (1.04, 2.71)	
	p-value	0.0347	
	Risk Ratio (95% CI)	1.67 (1.04, 2.68)	
	p-value	0.0348	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0328	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Upper respiratory tract infection	Number of subjects with event, n/N (%)	92/ 2993 (3.07)	95/ 2993 (3.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.72, 1.29)	
	p-value	0.8236	
	Risk Ratio (95% CI)	0.97 (0.73, 1.28)	
	p-value	0.8236	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8236	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	217/ 2993 (7.25)	204/ 2993 (6.82)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.88, 1.30)	
	p-value	0.5112	
	Risk Ratio (95% CI)	1.06 (0.88, 1.28)	
	p-value	0.5112	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.5111	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	466/ 2993 (15.57)	492/ 2993 (16.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.94 (0.82, 1.08)	
	p-value	0.3594	
	Risk Ratio (95% CI)	0.95 (0.84, 1.06)	
	p-value	0.3595	
	Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
	p-value	0.3593	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Contusion	Number of subjects with event, n/N (%)	45/ 2993 (1.50)	58/ 2993 (1.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.52, 1.14)	
	p-value	0.1975	
	Risk Ratio (95% CI)	0.78 (0.53, 1.14)	
	p-value	0.1976	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.1963	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Fall	Number of subjects with event, n/N (%)	107/ 2993 (3.58)	91/ 2993 (3.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.18 (0.89, 1.57)	
	p-value	0.2480	
	Risk Ratio (95% CI)	1.18 (0.89, 1.55)	
	p-value	0.2481	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.2475	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Limb injury	Number of subjects with event, n/N (%)	35/ 2993 (1.17)	29/ 2993 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.21 (0.74, 1.98)	
	p-value	0.4515	
	Risk Ratio (95% CI)	1.21 (0.74, 1.97)	
	p-value	0.4515	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4508	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations	Number of subjects with event, n/N (%)	509/ 2993 (17.01)	468/ 2993 (15.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.11 (0.96, 1.27)	
	p-value	0.1517	
	Risk Ratio (95% CI)	1.09 (0.97, 1.22)	
	p-value	0.1518	
	Risk Difference (95% CI)	0.01 (-0.01, 0.03)	
	p-value	0.1515	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Blood creatinine increased	Number of subjects with event, n/N (%)	38/ 2993 (1.27)	26/ 2993 (0.87)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.47 (0.89, 2.42)	
	p-value	0.1338	
	Risk Ratio (95% CI)	1.46 (0.89, 2.40)	
	p-value	0.1339	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1315	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Blood potassium increased	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	15/ 2993 (0.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.15 (1.16, 3.97)	
	p-value	0.0150	
	Risk Ratio (95% CI)	2.13 (1.16, 3.93)	
	p-value	0.0151	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0127	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Blood pressure increased	Number of subjects with event, n/N (%)	23/ 2993 (0.77)	40/ 2993 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.57 (0.34, 0.96)	
	p-value	0.0335	
	Risk Ratio (95% CI)	0.58 (0.35, 0.96)	
	p-value	0.0336	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0312	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	161/ 2993 (5.38)	112/ 2993 (3.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.46 (1.14, 1.87)	
	p-value	0.0025	
	Risk Ratio (95% CI)	1.44 (1.14, 1.82)	
	p-value	0.0026	
	Risk Difference (95% CI)	0.02 (0.01, 0.03)	
	p-value	0.0024	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Weight decreased	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	31/ 2993 (1.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.63, 1.70)	
	p-value	0.8992	
	Risk Ratio (95% CI)	1.03 (0.63, 1.69)	
	p-value	0.8992	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.8992	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	856/ 2993 (28.60)	777/ 2993 (25.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (1.02, 1.28)	
	p-value	0.0219	
	Risk Ratio (95% CI)	1.10 (1.01, 1.20)	
	p-value	0.0220	
	Risk Difference (95% CI)	0.03 (0.00, 0.05)	
	p-value	0.0218	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Dehydration	Number of subjects with event, n/N (%)	72/ 2993 (2.41)	46/ 2993 (1.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.58 (1.09, 2.29)	
	p-value	0.0165	
	Risk Ratio (95% CI)	1.57 (1.08, 2.26)	
	p-value	0.0166	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0156	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Diabetes mellitus	Number of subjects with event, n/N (%)	42/ 2993 (1.40)	50/ 2993 (1.67)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.55, 1.27)	
	p-value	0.4012	
	Risk Ratio (95% CI)	0.84 (0.56, 1.26)	
	p-value	0.4012	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4006	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Gout	Number of subjects with event, n/N (%)	67/ 2993 (2.24)	78/ 2993 (2.61)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.61, 1.19)	
	p-value	0.3555	
	Risk Ratio (95% CI)	0.86 (0.62, 1.19)	
	p-value	0.3556	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3551	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	285/ 2993 (9.52)	123/ 2993 (4.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.46 (1.97, 3.05)	
	p-value	<.0001	
	Risk Ratio (95% CI)	2.32 (1.89, 2.85)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.05 (0.04, 0.07)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hyperuricaemia	Number of subjects with event, n/N (%)	84/ 2993 (2.81)	72/ 2993 (2.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.85, 1.61)	
	p-value	0.3308	
	Risk Ratio (95% CI)	1.17 (0.86, 1.59)	
	p-value	0.3308	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3302	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hypoglycaemia	Number of subjects with event, n/N (%)	30/ 2993 (1.00)	20/ 2993 (0.67)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.51 (0.85, 2.66)	
	p-value	0.1584	
	Risk Ratio (95% CI)	1.50 (0.85, 2.64)	
	p-value	0.1585	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1555	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hypokalaemia	Number of subjects with event, n/N (%)	118/ 2993 (3.94)	223/ 2993 (7.45)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.51 (0.41, 0.64)	
	p-value	<.0001	
	Risk Ratio (95% CI)	0.53 (0.43, 0.66)	
	p-value	<.0001	
	Risk Difference (95% CI)	-0.04 (-0.05, -0.02)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hyponatraemia	Number of subjects with event, n/N (%)	68/ 2993 (2.27)	33/ 2993 (1.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.09 (1.37, 3.17)	
	p-value	0.0006	
	Risk Ratio (95% CI)	2.06 (1.36, 3.11)	
	p-value	0.0006	
	Risk Difference (95% CI)	0.01 (0.01, 0.02)	
	p-value	0.0004	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Iron deficiency	Number of subjects with event, n/N (%)	49/ 2993 (1.64)	40/ 2993 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.23 (0.81, 1.87)	
	p-value	0.3373	
	Risk Ratio (95% CI)	1.23 (0.81, 1.85)	
	p-value	0.3373	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3364	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Type 2 diabetes mellitus	Number of subjects with event, n/N (%)	76/ 2993 (2.54)	83/ 2993 (2.77)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.67, 1.25)	
	p-value	0.5738	
	Risk Ratio (95% CI)	0.92 (0.67, 1.24)	
	p-value	0.5738	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5737	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Vitamin D deficiency	Number of subjects with event, n/N (%)	38/ 2993 (1.27)	26/ 2993 (0.87)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.47 (0.89, 2.42)	
	p-value	0.1338	
	Risk Ratio (95% CI)	1.46 (0.89, 2.40)	
	p-value	0.1339	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1315	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	592/ 2993 (19.78)	602/ 2993 (20.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.86, 1.11)	
	p-value	0.7464	
	Risk Ratio (95% CI)	0.98 (0.89, 1.09)	
	p-value	0.7464	
	Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
	p-value	0.7464	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	120/ 2993 (4.01)	139/ 2993 (4.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.67, 1.10)	
	p-value	0.2278	
	Risk Ratio (95% CI)	0.86 (0.68, 1.10)	
	p-value	0.2279	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.2274	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	123/ 2993 (4.11)	136/ 2993 (4.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.70, 1.16)	
	p-value	0.4091	
	Risk Ratio (95% CI)	0.90 (0.71, 1.15)	
	p-value	0.4091	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.4089	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms	Number of subjects with event, n/N (%)	37/ 2993 (1.24)	29/ 2993 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (0.78, 2.09)	
	p-value	0.3233	
	Risk Ratio (95% CI)	1.28 (0.79, 2.07)	
	p-value	0.3233	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3220	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia	Number of subjects with event, n/N (%)	33/ 2993 (1.10)	18/ 2993 (0.60)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.84 (1.04, 3.28)	
	p-value	0.0377	
	Risk Ratio (95% CI)	1.83 (1.03, 3.25)	
	p-value	0.0378	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0348	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Osteoarthritis	Number of subjects with event, n/N (%)	66/ 2993 (2.21)	74/ 2993 (2.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.64, 1.24)	
	p-value	0.4941	
	Risk Ratio (95% CI)	0.89 (0.64, 1.24)	
	p-value	0.4941	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4939	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity	Number of subjects with event, n/N (%)	81/ 2993 (2.71)	69/ 2993 (2.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.18 (0.85, 1.63)	
	p-value	0.3216	
	Risk Ratio (95% CI)	1.17 (0.85, 1.61)	
	p-value	0.3216	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3210	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	205/ 2993 (6.85)	209/ 2993 (6.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.80, 1.20)	
	p-value	0.8385	
	Risk Ratio (95% CI)	0.98 (0.81, 1.18)	
	p-value	0.8385	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8385	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	637/ 2993 (21.28)	605/ 2993 (20.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.94, 1.21)	
	p-value	0.3078	
	Risk Ratio (95% CI)	1.05 (0.95, 1.16)	
	p-value	0.3078	
	Risk Difference (95% CI)	0.01 (-0.01, 0.03)	
	p-value	0.3077	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	189/ 2993 (6.31)	157/ 2993 (5.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.22 (0.98, 1.51)	
	p-value	0.0767	
	Risk Ratio (95% CI)	1.20 (0.98, 1.48)	
	p-value	0.0768	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.0763	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Headache	Number of subjects with event, n/N (%)	106/ 2993 (3.54)	103/ 2993 (3.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.78, 1.36)	
	p-value	0.8327	
	Risk Ratio (95% CI)	1.03 (0.79, 1.34)	
	p-value	0.8327	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8327	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Syncope	Number of subjects with event, n/N (%)	83/ 2993 (2.77)	56/ 2993 (1.87)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.50 (1.06, 2.11)	
	p-value	0.0213	
	Risk Ratio (95% CI)	1.48 (1.06, 2.07)	
	p-value	0.0214	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0204	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	229/ 2993 (7.65)	219/ 2993 (7.32)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.87, 1.27)	
	p-value	0.6233	
	Risk Ratio (95% CI)	1.05 (0.87, 1.25)	
	p-value	0.6233	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.6233	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Anxiety	Number of subjects with event, n/N (%)	34/ 2993 (1.14)	29/ 2993 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.71, 1.93)	
	p-value	0.5270	
	Risk Ratio (95% CI)	1.17 (0.72, 1.92)	
	p-value	0.5270	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5265	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Depression	Number of subjects with event, n/N (%)	39/ 2993 (1.30)	39/ 2993 (1.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.64, 1.56)	
	p-value	1.0000	
	Risk Ratio (95% CI)	1.00 (0.64, 1.55)	
	p-value	1.0000	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	1.0000	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Insomnia	Number of subjects with event, n/N (%)	83/ 2993 (2.77)	74/ 2993 (2.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.82, 1.55)	
	p-value	0.4669	
	Risk Ratio (95% CI)	1.12 (0.82, 1.53)	
	p-value	0.4669	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.4667	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	662/ 2993 (22.12)	542/ 2993 (18.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (1.13, 1.46)	
	p-value	0.0001	
	Risk Ratio (95% CI)	1.22 (1.10, 1.35)	
	p-value	0.0001	
	Risk Difference (95% CI)	0.04 (0.02, 0.06)	
	p-value	0.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	146/ 2993 (4.88)	93/ 2993 (3.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.60 (1.23, 2.08)	
	p-value	0.0005	
	Risk Ratio (95% CI)	1.57 (1.22, 2.03)	
	p-value	0.0005	
	Risk Difference (95% CI)	0.02 (0.01, 0.03)	
	p-value	0.0005	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Chronic kidney disease	Number of subjects with event, n/N (%)	67/ 2993 (2.24)	66/ 2993 (2.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.72, 1.43)	
	p-value	0.9301	
	Risk Ratio (95% CI)	1.02 (0.73, 1.42)	
	p-value	0.9301	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.9301	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Haematuria	Number of subjects with event, n/N (%)	37/ 2993 (1.24)	33/ 2993 (1.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.12 (0.70, 1.80)	
	p-value	0.6308	
	Risk Ratio (95% CI)	1.12 (0.70, 1.79)	
	p-value	0.6308	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.6306	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Microalbuminuria	Number of subjects with event, n/N (%)	39/ 2993 (1.30)	58/ 2993 (1.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.44, 1.01)	
	p-value	0.0533	
	Risk Ratio (95% CI)	0.67 (0.45, 1.01)	
	p-value	0.0534	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.0517	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Renal cyst	Number of subjects with event, n/N (%)	21/ 2993 (0.70)	40/ 2993 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.52 (0.31, 0.89)	
	p-value	0.0162	
	Risk Ratio (95% CI)	0.53 (0.31, 0.89)	
	p-value	0.0163	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0144	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Renal failure	Number of subjects with event, n/N (%)	90/ 2993 (3.01)	54/ 2993 (1.80)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.69 (1.20, 2.37)	
	p-value	0.0027	
	Risk Ratio (95% CI)	1.67 (1.19, 2.33)	
	p-value	0.0027	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0024	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	216/ 2993 (7.22)	128/ 2993 (4.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.74 (1.39, 2.18)	
	p-value	<.0001	
	Risk Ratio (95% CI)	1.69 (1.36, 2.09)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.03 (0.02, 0.04)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	99/ 2993 (3.31)	97/ 2993 (3.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.77, 1.36)	
	p-value	0.8845	
	Risk Ratio (95% CI)	1.02 (0.77, 1.34)	
	p-value	0.8845	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8845	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Reproductive system and breast disorders; PT: Benign prostatic hyperplasia	Number of subjects with event, n/N (%)	46/ 2993 (1.54)	30/ 2993 (1.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.54 (0.97, 2.45)	
	p-value	0.0668	
	Risk Ratio (95% CI)	1.53 (0.97, 2.42)	
	p-value	0.0669	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.0647	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	590/ 2993 (19.71)	577/ 2993 (19.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.90, 1.17)	
	p-value	0.6715	
	Risk Ratio (95% CI)	1.02 (0.92, 1.13)	
	p-value	0.6715	
	Risk Difference (95% CI)	0.00 (-0.02, 0.02)	
	p-value	0.6715	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	76/ 2993 (2.54)	73/ 2993 (2.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.75, 1.44)	
	p-value	0.8035	
	Risk Ratio (95% CI)	1.04 (0.76, 1.43)	
	p-value	0.8035	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8034	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough	Number of subjects with event, n/N (%)	93/ 2993 (3.11)	90/ 2993 (3.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.77, 1.39)	
	p-value	0.8218	
	Risk Ratio (95% CI)	1.03 (0.78, 1.37)	
	p-value	0.8218	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8218	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	160/ 2993 (5.35)	148/ 2993 (4.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.86, 1.37)	
	p-value	0.4827	
	Risk Ratio (95% CI)	1.08 (0.87, 1.34)	
	p-value	0.4828	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.4826	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Epistaxis	Number of subjects with event, n/N (%)	44/ 2993 (1.47)	65/ 2993 (2.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.46, 0.99)	
	p-value	0.0437	
	Risk Ratio (95% CI)	0.68 (0.46, 0.99)	
	p-value	0.0437	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0423	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleural effusion	Number of subjects with event, n/N (%)	34/ 2993 (1.14)	33/ 2993 (1.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.64, 1.67)	
	p-value	0.9022	
	Risk Ratio (95% CI)	1.03 (0.64, 1.66)	
	p-value	0.9022	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.9022	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Respiratory failure	Number of subjects with event, n/N (%)	33/ 2993 (1.10)	20/ 2993 (0.67)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.66 (0.95, 2.89)	
	p-value	0.0759	
	Risk Ratio (95% CI)	1.65 (0.95, 2.87)	
	p-value	0.0760	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0728	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	296/ 2993 (9.89)	277/ 2993 (9.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.91, 1.28)	
	p-value	0.4040	
	Risk Ratio (95% CI)	1.07 (0.91, 1.25)	
	p-value	0.4040	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.4039	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Pruritus	Number of subjects with event, n/N (%)	41/ 2993 (1.37)	45/ 2993 (1.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.59, 1.39)	
	p-value	0.6641	
	Risk Ratio (95% CI)	0.91 (0.60, 1.39)	
	p-value	0.6641	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.6639	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Rash	Number of subjects with event, n/N (%)	40/ 2993 (1.34)	31/ 2993 (1.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.29 (0.81, 2.07)	
	p-value	0.2839	
	Risk Ratio (95% CI)	1.29 (0.81, 2.06)	
	p-value	0.2839	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2826	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Skin ulcer	Number of subjects with event, n/N (%)	38/ 2993 (1.27)	41/ 2993 (1.37)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.59, 1.44)	
	p-value	0.7341	
	Risk Ratio (95% CI)	0.93 (0.60, 1.44)	
	p-value	0.7341	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.7340	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	151/ 2993 (5.05)	120/ 2993 (4.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.27 (1.00, 1.63)	
	p-value	0.0545	
	Risk Ratio (95% CI)	1.26 (1.00, 1.59)	
	p-value	0.0546	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.0539	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	556/ 2993 (18.58)	521/ 2993 (17.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.95, 1.24)	
	p-value	0.2390	
	Risk Ratio (95% CI)	1.07 (0.96, 1.19)	
	p-value	0.2391	
	Risk Difference (95% CI)	0.01 (-0.01, 0.03)	
	p-value	0.2389	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Hypertension	Number of subjects with event, n/N (%)	129/ 2993 (4.31)	190/ 2993 (6.35)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.66 (0.53, 0.84)	
	p-value	0.0005	
	Risk Ratio (95% CI)	0.68 (0.55, 0.84)	
	p-value	0.0005	
	Risk Difference (95% CI)	-0.02 (-0.03, -0.01)	
	p-value	0.0004	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	236/ 2993 (7.89)	158/ 2993 (5.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.54 (1.25, 1.89)	
	p-value	<.0001	
	Risk Ratio (95% CI)	1.49 (1.23, 1.82)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.03 (0.01, 0.04)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Peripheral arterial occlusive disease	Number of subjects with event, n/N (%)	36/ 2993 (1.20)	30/ 2993 (1.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.74, 1.96)	
	p-value	0.4583	
	Risk Ratio (95% CI)	1.20 (0.74, 1.94)	
	p-value	0.4583	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4577	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Iron deficiency anaemia	Sex									0.8851
	Male	20/ 1643 (1.22)	32/ 1619 (1.98)	0.62 (0.35, 1.07)	0.0866	0.61 (0.35, 1.07)	0.0864	-0.01 (-0.02, 0.00)	0.0838	
	Female	20/ 1350 (1.48)	35/ 1374 (2.55)	0.58 (0.34, 1.00)	0.0509	0.58 (0.33, 1.00)	0.0507	-0.01 (-0.02, -0.00)	0.0473	
	Region									0.8033
	Western Europe, Oceania and Others	14/ 618 (2.27)	21/ 631 (3.33)	0.68 (0.35, 1.33)	0.2584	0.67 (0.34, 1.34)	0.2581	-0.01 (-0.03, 0.01)	0.2541	
	Eastern Europe	16/ 1327 (1.21)	31/ 1319 (2.35)	0.51 (0.28, 0.93)	0.0288	0.51 (0.28, 0.93)	0.0286	-0.01 (-0.02, -0.00)	0.0258	
	Asia	6/ 492 (1.22)	11/ 488 (2.25)	0.54 (0.20, 1.45)	0.2224	0.54 (0.20, 1.46)	0.2220	-0.01 (-0.03, 0.01)	0.2150	
	North America	4/ 234 (1.71)	4/ 236 (1.69)	1.01 (0.26, 3.99)	0.9903	1.01 (0.25, 4.08)	0.9903	0.00 (-0.02, 0.02)	0.9903	
	Latin America	0/ 322 (0.00)	0/ 319 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Age group (years)									0.1607
	<= median in FAS	12/ 1585 (0.76)	29/ 1575 (1.84)	0.41 (0.21, 0.80)	0.0092	0.41 (0.21, 0.80)	0.0091	-0.01 (-0.02, -0.00)	0.0071	
	> median in FAS	28/ 1408 (1.99)	38/ 1418 (2.68)	0.74 (0.46, 1.20)	0.2257	0.74 (0.45, 1.21)	0.2255	-0.01 (-0.02, 0.00)	0.2235	
	NYHA class at baseline									0.3448
	II	26/ 2074 (1.25)	49/ 2061 (2.38)	0.53 (0.33, 0.85)	0.0078	0.52 (0.32, 0.84)	0.0077	-0.01 (-0.02, -0.00)	0.0068	
	III/IV	14/ 918 (1.53)	18/ 932 (1.93)	0.79 (0.40, 1.58)	0.5038	0.79 (0.39, 1.59)	0.5037	-0.00 (-0.02, 0.01)	0.5023	
	LVEF at baseline									0.3726
	< 50%	13/ 1092 (1.19)	28/ 1078 (2.60)	0.46 (0.24, 0.88)	0.0191	0.45 (0.23, 0.88)	0.0189	-0.01 (-0.03, -0.00)	0.0162	
	>= 50% - < 60%	17/ 1323 (1.28)	29/ 1342 (2.16)	0.59 (0.33, 1.08)	0.0862	0.59 (0.32, 1.08)	0.0860	-0.01 (-0.02, 0.00)	0.0818	
	>= 60%	10/ 572 (1.75)	10/ 571 (1.75)	1.00 (0.42, 2.38)	0.9969	1.00 (0.41, 2.42)	0.9969	-0.00 (-0.02, 0.02)	0.9969	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders	Sex									0.4018
	Male	414/ 1643 (25.20)	357/ 1619 (22.05)	1.14 (1.01, 1.29)	0.0347	1.19 (1.01, 1.40)	0.0345	0.03 (0.00, 0.06)	0.0342	
	Female	343/ 1350 (25.41)	330/ 1374 (24.02)	1.06 (0.93, 1.21)	0.4005	1.08 (0.91, 1.28)	0.4004	0.01 (-0.02, 0.05)	0.4004	
	Region									0.2312
	Western Europe, Oceania and Others	208/ 618 (33.66)	200/ 631 (31.70)	1.06 (0.91, 1.25)	0.4601	1.09 (0.86, 1.39)	0.4600	0.02 (-0.03, 0.07)	0.4599	
	Eastern Europe	223/ 1327 (16.80)	206/ 1319 (15.62)	1.08 (0.90, 1.28)	0.4077	1.09 (0.89, 1.34)	0.4076	0.01 (-0.02, 0.04)	0.4074	
	Asia	189/ 492 (38.41)	179/ 488 (36.68)	1.05 (0.89, 1.23)	0.5752	1.08 (0.83, 1.39)	0.5751	0.02 (-0.04, 0.08)	0.5750	
	North America	76/ 234 (32.48)	49/ 236 (20.76)	1.56 (1.15, 2.13)	0.0047	1.84 (1.21, 2.79)	0.0043	0.12 (0.04, 0.20)	0.0038	
	Latin America	61/ 322 (18.94)	53/ 319 (16.61)	1.14 (0.82, 1.59)	0.4411	1.17 (0.78, 1.76)	0.4408	0.02 (-0.04, 0.08)	0.4402	
	Age group (years)									0.3090
	<= median in FAS	332/ 1585 (20.95)	315/ 1575 (20.00)	1.05 (0.91, 1.20)	0.5098	1.06 (0.89, 1.26)	0.5098	0.01 (-0.02, 0.04)	0.5097	
	> median in FAS	425/ 1408 (30.18)	372/ 1418 (26.23)	1.15 (1.02, 1.29)	0.0198	1.22 (1.03, 1.43)	0.0197	0.04 (0.01, 0.07)	0.0195	
	NYHA class at baseline									0.3010
	II	504/ 2074 (24.30)	470/ 2061 (22.80)	1.07 (0.95, 1.19)	0.2570	1.09 (0.94, 1.25)	0.2569	0.01 (-0.01, 0.04)	0.2568	
	III/IV	252/ 918 (27.45)	217/ 932 (23.28)	1.18 (1.01, 1.38)	0.0398	1.25 (1.01, 1.54)	0.0395	0.04 (0.00, 0.08)	0.0392	
	LVEF at baseline									0.3115
	< 50%	241/ 1092 (22.07)	224/ 1078 (20.78)	1.06 (0.90, 1.25)	0.4640	1.08 (0.88, 1.33)	0.4639	0.01 (-0.02, 0.05)	0.4638	
	>= 50% - < 60%	359/ 1323 (27.14)	308/ 1342 (22.95)	1.18 (1.04, 1.35)	0.0128	1.25 (1.05, 1.49)	0.0127	0.04 (0.01, 0.07)	0.0126	
	>= 60%	155/ 572 (27.10)	155/ 571 (27.15)	1.00 (0.83, 1.21)	0.9856	1.00 (0.77, 1.29)	0.9856	-0.00 (-0.05, 0.05)	0.9856	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Constipation	Sex									0.1759
	Male	82/ 1643 (4.99)	49/ 1619 (3.03)	1.65 (1.17, 2.33)	0.0047	1.68 (1.17, 2.41)	0.0047	0.02 (0.01, 0.03)	0.0042	
	Female	57/ 1350 (4.22)	50/ 1374 (3.64)	1.16 (0.80, 1.68)	0.4338	1.17 (0.79, 1.72)	0.4338	0.01 (-0.01, 0.02)	0.4336	
	Region									0.1743
	Western Europe, Oceania and Others	34/ 618 (5.50)	29/ 631 (4.60)	1.20 (0.74, 1.94)	0.4653	1.21 (0.73, 2.01)	0.4652	0.01 (-0.02, 0.03)	0.4649	
	Eastern Europe	25/ 1327 (1.88)	28/ 1319 (2.12)	0.89 (0.52, 1.51)	0.6612	0.89 (0.51, 1.53)	0.6612	-0.00 (-0.01, 0.01)	0.6611	
	Asia	56/ 492 (11.38)	32/ 488 (6.56)	1.74 (1.15, 2.63)	0.0094	1.83 (1.16, 2.88)	0.0090	0.05 (0.01, 0.08)	0.0080	
	North America	14/ 234 (5.98)	6/ 236 (2.54)	2.35 (0.92, 6.02)	0.0741	2.44 (0.92, 6.46)	0.0728	0.03 (-0.00, 0.07)	0.0641	
	Latin America	10/ 322 (3.11)	4/ 319 (1.25)	2.48 (0.78, 7.82)	0.1219	2.52 (0.78, 8.13)	0.1209	0.02 (-0.00, 0.04)	0.1074	
	Age group (years)									0.5236
	<= median in FAS	58/ 1585 (3.66)	37/ 1575 (2.35)	1.56 (1.04, 2.34)	0.0326	1.58 (1.04, 2.40)	0.0324	0.01 (0.00, 0.02)	0.0308	
	> median in FAS	81/ 1408 (5.75)	62/ 1418 (4.37)	1.32 (0.95, 1.82)	0.0953	1.34 (0.95, 1.87)	0.0951	0.01 (-0.00, 0.03)	0.0941	
	NYHA class at baseline									0.5768
	II	90/ 2074 (4.34)	67/ 2061 (3.25)	1.33 (0.98, 1.82)	0.0681	1.35 (0.98, 1.86)	0.0680	0.01 (-0.00, 0.02)	0.0668	
	III/IV	49/ 918 (5.34)	32/ 932 (3.43)	1.55 (1.01, 2.40)	0.0473	1.59 (1.01, 2.50)	0.0470	0.02 (0.00, 0.04)	0.0455	
	LVEF at baseline									0.3351
	< 50%	50/ 1092 (4.58)	27/ 1078 (2.50)	1.83 (1.15, 2.90)	0.0102	1.87 (1.16, 3.01)	0.0101	0.02 (0.01, 0.04)	0.0088	
	>= 50% - < 60%	59/ 1323 (4.46)	46/ 1342 (3.43)	1.30 (0.89, 1.90)	0.1724	1.32 (0.89, 1.95)	0.1722	0.01 (-0.00, 0.03)	0.1712	
	>= 60%	29/ 572 (5.07)	26/ 571 (4.55)	1.11 (0.66, 1.87)	0.6835	1.12 (0.65, 1.93)	0.6834	0.01 (-0.02, 0.03)	0.6833	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Diarrhoea									
Sex									0.4039
Male	94/ 1643 (5.72)	79/ 1619 (4.88)	1.17 (0.88, 1.57)	0.2841	1.18 (0.87, 1.61)	0.2840	0.01 (-0.01, 0.02)	0.2831	
Female	95/ 1350 (7.04)	69/ 1374 (5.02)	1.40 (1.04, 1.89)	0.0279	1.43 (1.04, 1.97)	0.0277	0.02 (0.00, 0.04)	0.0271	
Region									0.6402
Western Europe, Oceania and Others	60/ 618 (9.71)	55/ 631 (8.72)	1.11 (0.79, 1.58)	0.5444	1.13 (0.77, 1.65)	0.5444	0.01 (-0.02, 0.04)	0.5443	
Eastern Europe	59/ 1327 (4.45)	45/ 1319 (3.41)	1.30 (0.89, 1.91)	0.1724	1.32 (0.89, 1.96)	0.1722	0.01 (-0.00, 0.03)	0.1706	
Asia	41/ 492 (8.33)	33/ 488 (6.76)	1.23 (0.79, 1.92)	0.3531	1.25 (0.78, 2.02)	0.3528	0.02 (-0.02, 0.05)	0.3516	
North America	17/ 234 (7.26)	8/ 236 (3.39)	2.14 (0.94, 4.87)	0.0687	2.23 (0.94, 5.28)	0.0674	0.04 (-0.00, 0.08)	0.0607	
Latin America	12/ 322 (3.73)	7/ 319 (2.19)	1.70 (0.68, 4.26)	0.2588	1.73 (0.67, 4.44)	0.2581	0.02 (-0.01, 0.04)	0.2517	
Age group (years)									0.7438
<= median in FAS	74/ 1585 (4.67)	60/ 1575 (3.81)	1.23 (0.88, 1.71)	0.2316	1.24 (0.87, 1.75)	0.2315	0.01 (-0.01, 0.02)	0.2305	
> median in FAS	115/ 1408 (8.17)	88/ 1418 (6.21)	1.32 (1.01, 1.72)	0.0443	1.34 (1.01, 1.79)	0.0441	0.02 (0.00, 0.04)	0.0434	
NYHA class at baseline									0.0561
II	106/ 2074 (5.11)	97/ 2061 (4.71)	1.09 (0.83, 1.42)	0.5474	1.09 (0.82, 1.45)	0.5474	0.00 (-0.01, 0.02)	0.5472	
III/IV	83/ 918 (9.04)	51/ 932 (5.47)	1.65 (1.18, 2.31)	0.0035	1.72 (1.20, 2.46)	0.0034	0.04 (0.01, 0.06)	0.0030	
LVEF at baseline									0.0369
< 50%	53/ 1092 (4.85)	41/ 1078 (3.80)	1.28 (0.86, 1.90)	0.2309	1.29 (0.85, 1.96)	0.2307	0.01 (-0.01, 0.03)	0.2291	
>= 50% - < 60%	107/ 1323 (8.09)	69/ 1342 (5.14)	1.57 (1.17, 2.11)	0.0024	1.62 (1.19, 2.22)	0.0024	0.03 (0.01, 0.05)	0.0022	
>= 60%	29/ 572 (5.07)	38/ 571 (6.65)	0.76 (0.48, 1.22)	0.2558	0.75 (0.46, 1.23)	0.2554	-0.02 (-0.04, 0.01)	0.2538	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death	Sex									0.8808
	Male	38/ 1643 (2.31)	53/ 1619 (3.27)	0.71 (0.47, 1.07)	0.0975	0.70 (0.46, 1.07)	0.0973	-0.01 (-0.02, 0.00)	0.0960	
	Female	32/ 1350 (2.37)	44/ 1374 (3.20)	0.74 (0.47, 1.16)	0.1892	0.73 (0.46, 1.16)	0.1890	-0.01 (-0.02, 0.00)	0.1867	
	Region									0.7472
	Western Europe, Oceania and Others	15/ 618 (2.43)	16/ 631 (2.54)	0.96 (0.48, 1.92)	0.9020	0.96 (0.47, 1.95)	0.9020	-0.00 (-0.02, 0.02)	0.9019	
	Eastern Europe	35/ 1327 (2.64)	50/ 1319 (3.79)	0.70 (0.45, 1.06)	0.0945	0.69 (0.44, 1.07)	0.0943	-0.01 (-0.02, 0.00)	0.0925	
	Asia	10/ 492 (2.03)	16/ 488 (3.28)	0.62 (0.28, 1.35)	0.2296	0.61 (0.27, 1.36)	0.2292	-0.01 (-0.03, 0.01)	0.2249	
	North America	8/ 234 (3.42)	9/ 236 (3.81)	0.90 (0.35, 2.28)	0.8188	0.89 (0.34, 2.36)	0.8188	-0.00 (-0.04, 0.03)	0.8187	
	Latin America	2/ 322 (0.62)	6/ 319 (1.88)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.03, 0.00)	0.1512	
	Age group (years)									0.4066
	<= median in FAS	24/ 1585 (1.51)	39/ 1575 (2.48)	0.61 (0.37, 1.01)	0.0556	0.61 (0.36, 1.01)	0.0555	-0.01 (-0.02, 0.00)	0.0531	
	> median in FAS	46/ 1408 (3.27)	58/ 1418 (4.09)	0.80 (0.55, 1.17)	0.2463	0.79 (0.53, 1.17)	0.2461	-0.01 (-0.02, 0.01)	0.2449	
	NYHA class at baseline									0.9913
	II	40/ 2074 (1.93)	55/ 2061 (2.67)	0.72 (0.48, 1.08)	0.1140	0.72 (0.48, 1.08)	0.1138	-0.01 (-0.02, 0.00)	0.1124	
	III/IV	30/ 918 (3.27)	42/ 932 (4.51)	0.73 (0.46, 1.15)	0.1706	0.72 (0.44, 1.15)	0.1702	-0.01 (-0.03, 0.01)	0.1678	
	LVEF at baseline									0.4454
	< 50%	36/ 1092 (3.30)	41/ 1078 (3.80)	0.87 (0.56, 1.35)	0.5240	0.86 (0.55, 1.36)	0.5239	-0.01 (-0.02, 0.01)	0.5237	
	>= 50% - < 60%	24/ 1323 (1.81)	43/ 1342 (3.20)	0.57 (0.35, 0.93)	0.0239	0.56 (0.34, 0.93)	0.0237	-0.01 (-0.03, -0.00)	0.0215	
	>= 60%	10/ 572 (1.75)	13/ 571 (2.28)	0.77 (0.34, 1.74)	0.5259	0.76 (0.33, 1.76)	0.5258	-0.01 (-0.02, 0.01)	0.5246	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Gastroenteritis	Sex									0.0821
	Male	20/ 1643 (1.22)	5/ 1619 (0.31)	3.94 (1.48, 10.48)	0.0060	3.98 (1.49, 10.62)	0.0059	0.01 (0.00, 0.02)	0.0028	
	Female	14/ 1350 (1.04)	11/ 1374 (0.80)	1.30 (0.59, 2.84)	0.5188	1.30 (0.59, 2.87)	0.5188	0.00 (-0.00, 0.01)	0.5180	
	Region									0.3728
	Western Europe, Oceania and Others	13/ 618 (2.10)	3/ 631 (0.48)	4.42 (1.27, 15.45)	0.0198	4.50 (1.28, 15.86)	0.0194	0.02 (0.00, 0.03)	0.0108	
	Eastern Europe	3/ 1327 (0.23)	3/ 1319 (0.23)	0.99 (0.20, 4.92)	0.9941	0.99 (0.20, 4.93)	0.9941	-0.00 (-0.00, 0.00)	0.9941	
	Asia	8/ 492 (1.63)	4/ 488 (0.82)	1.98 (0.60, 6.54)	0.2607	2.00 (0.60, 6.69)	0.2603	0.01 (-0.01, 0.02)	0.2502	
	North America	5/ 234 (2.14)	1/ 236 (0.42)	5.04 (0.59, 42.83)	0.1383	5.13 (0.59, 44.26)	0.1369	0.02 (-0.00, 0.04)	0.0981	
	Latin America	5/ 322 (1.55)	5/ 319 (1.57)	0.99 (0.29, 3.39)	0.9881	0.99 (0.28, 3.46)	0.9881	-0.00 (-0.02, 0.02)	0.9881	
	Age group (years)									0.0689
	<= median in FAS	10/ 1585 (0.63)	9/ 1575 (0.57)	1.10 (0.45, 2.71)	0.8288	1.10 (0.45, 2.73)	0.8288	0.00 (-0.00, 0.01)	0.8287	
	> median in FAS	24/ 1408 (1.70)	7/ 1418 (0.49)	3.45 (1.49, 7.99)	0.0038	3.50 (1.50, 8.14)	0.0037	0.01 (0.00, 0.02)	0.0020	
	NYHA class at baseline									0.1875
	II	19/ 2074 (0.92)	12/ 2061 (0.58)	1.57 (0.77, 3.23)	0.2174	1.58 (0.76, 3.26)	0.2172	0.00 (-0.00, 0.01)	0.2129	
	III/IV	15/ 918 (1.63)	4/ 932 (0.43)	3.81 (1.27, 11.43)	0.0171	3.85 (1.27, 11.66)	0.0169	0.01 (0.00, 0.02)	0.0104	
	LVEF at baseline									0.9328
	< 50%	8/ 1092 (0.73)	4/ 1078 (0.37)	1.97 (0.60, 6.54)	0.2655	1.98 (0.59, 6.60)	0.2653	0.00 (-0.00, 0.01)	0.2550	
	>= 50% - < 60%	18/ 1323 (1.36)	9/ 1342 (0.67)	2.03 (0.91, 4.50)	0.0817	2.04 (0.91, 4.56)	0.0815	0.01 (-0.00, 0.01)	0.0759	
	>= 60%	8/ 572 (1.40)	3/ 571 (0.53)	2.66 (0.71, 9.98)	0.1466	2.69 (0.71, 10.17)	0.1460	0.01 (-0.00, 0.02)	0.1300	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Sex									0.5275
	Male	27/ 1643 (1.64)	18/ 1619 (1.11)	1.48 (0.82, 2.67)	0.1961	1.49 (0.82, 2.71)	0.1959	0.01 (-0.00, 0.01)	0.1924	
	Female	18/ 1350 (1.33)	9/ 1374 (0.66)	2.04 (0.92, 4.51)	0.0803	2.05 (0.92, 4.58)	0.0801	0.01 (-0.00, 0.01)	0.0747	
	Region									0.5171
	Western Europe, Oceania and Others	8/ 618 (1.29)	5/ 631 (0.79)	1.63 (0.54, 4.97)	0.3869	1.64 (0.53, 5.05)	0.3867	0.01 (-0.01, 0.02)	0.3831	
	Eastern Europe	12/ 1327 (0.90)	4/ 1319 (0.30)	2.98 (0.96, 9.22)	0.0579	3.00 (0.97, 9.33)	0.0576	0.01 (0.00, 0.01)	0.0457	
	Asia	6/ 492 (1.22)	6/ 488 (1.23)	0.99 (0.32, 3.05)	0.9886	0.99 (0.32, 3.10)	0.9886	-0.00 (-0.01, 0.01)	0.9886	
	North America	12/ 234 (5.13)	10/ 236 (4.24)	1.21 (0.53, 2.75)	0.6481	1.22 (0.52, 2.89)	0.6480	0.01 (-0.03, 0.05)	0.6476	
	Latin America	7/ 322 (2.17)	2/ 319 (0.63)	3.47 (0.73, 16.56)	0.1191	3.52 (0.73, 17.09)	0.1181	0.02 (-0.00, 0.03)	0.0945	
	Age group (years)									0.7379
	<= median in FAS	20/ 1585 (1.26)	13/ 1575 (0.83)	1.53 (0.76, 3.06)	0.2312	1.54 (0.76, 3.10)	0.2310	0.00 (-0.00, 0.01)	0.2271	
	> median in FAS	25/ 1408 (1.78)	14/ 1418 (0.99)	1.80 (0.94, 3.45)	0.0768	1.81 (0.94, 3.50)	0.0766	0.01 (-0.00, 0.02)	0.0726	
	NYHA class at baseline									0.4287
	II	31/ 2074 (1.49)	16/ 2061 (0.78)	1.93 (1.06, 3.51)	0.0324	1.94 (1.06, 3.56)	0.0323	0.01 (0.00, 0.01)	0.0291	
	III/IV	14/ 918 (1.53)	11/ 932 (1.18)	1.29 (0.59, 2.83)	0.5219	1.30 (0.59, 2.87)	0.5219	0.00 (-0.01, 0.01)	0.5211	
	LVEF at baseline									0.7847
	< 50%	11/ 1092 (1.01)	8/ 1078 (0.74)	1.36 (0.55, 3.36)	0.5090	1.36 (0.55, 3.40)	0.5089	0.00 (-0.01, 0.01)	0.5068	
	>= 50% - < 60%	20/ 1323 (1.51)	10/ 1342 (0.75)	2.03 (0.95, 4.32)	0.0664	2.04 (0.95, 4.38)	0.0662	0.01 (-0.00, 0.02)	0.0612	
	>= 60%	14/ 572 (2.45)	9/ 571 (1.58)	1.55 (0.68, 3.56)	0.2983	1.57 (0.67, 3.65)	0.2980	0.01 (-0.01, 0.02)	0.2939	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood potassium increased									
Sex									0.9246
Male	22/ 1643 (1.34)	10/ 1619 (0.62)	2.17 (1.03, 4.56)	0.0416	2.18 (1.03, 4.63)	0.0414	0.01 (0.00, 0.01)	0.0360	
Female	10/ 1350 (0.74)	5/ 1374 (0.36)	2.04 (0.70, 5.94)	0.1933	2.04 (0.70, 5.99)	0.1931	0.00 (-0.00, 0.01)	0.1851	
Region									0.3582
Western Europe, Oceania and Others	12/ 618 (1.94)	4/ 631 (0.63)	3.06 (0.99, 9.45)	0.0514	3.10 (1.00, 9.68)	0.0509	0.01 (0.00, 0.03)	0.0406	
Eastern Europe	7/ 1327 (0.53)	8/ 1319 (0.61)	0.87 (0.32, 2.39)	0.7868	0.87 (0.31, 2.40)	0.7868	-0.00 (-0.01, 0.00)	0.7867	
Asia	7/ 492 (1.42)	2/ 488 (0.41)	3.47 (0.72, 16.63)	0.1194	3.51 (0.72, 16.97)	0.1187	0.01 (-0.00, 0.02)	0.0953	
North America	4/ 234 (1.71)	1/ 236 (0.42)	4.03 (0.45, 35.82)	0.2106	4.09 (0.45, 36.84)	0.2095	0.01 (-0.01, 0.03)	0.1746	
Latin America	2/ 322 (0.62)	0/ 319 (0.00)	4.95 (0.24, 102.77)	0.3010	4.98 (0.24, 104.23)	0.3004	0.01 (-0.00, 0.01)	0.1560	
Age group (years)									0.0939
<= median in FAS	9/ 1585 (0.57)	8/ 1575 (0.51)	1.12 (0.43, 2.89)	0.8181	1.12 (0.43, 2.91)	0.8181	0.00 (-0.00, 0.01)	0.8180	
> median in FAS	23/ 1408 (1.63)	7/ 1418 (0.49)	3.31 (1.42, 7.69)	0.0054	3.35 (1.43, 7.83)	0.0053	0.01 (0.00, 0.02)	0.0031	
NYHA class at baseline									0.0213
II	26/ 2074 (1.25)	7/ 2061 (0.34)	3.69 (1.61, 8.48)	0.0021	3.73 (1.61, 8.60)	0.0021	0.01 (0.00, 0.01)	0.0009	
III/IV	6/ 918 (0.65)	8/ 932 (0.86)	0.76 (0.27, 2.19)	0.6125	0.76 (0.26, 2.20)	0.6124	-0.00 (-0.01, 0.01)	0.6110	
LVEF at baseline									0.7581
< 50%	11/ 1092 (1.01)	5/ 1078 (0.46)	2.17 (0.76, 6.23)	0.1492	2.18 (0.76, 6.31)	0.1489	0.01 (-0.00, 0.01)	0.1378	
>= 50% - < 60%	14/ 1323 (1.06)	8/ 1342 (0.60)	1.78 (0.75, 4.22)	0.1937	1.78 (0.75, 4.27)	0.1935	0.00 (-0.00, 0.01)	0.1882	
>= 60%	7/ 572 (1.22)	2/ 571 (0.35)	3.49 (0.73, 16.75)	0.1177	3.52 (0.73, 17.04)	0.1171	0.01 (-0.00, 0.02)	0.0942	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood pressure increased	Sex									0.8188
	Male	11/ 1643 (0.67)	20/ 1619 (1.24)	0.54 (0.26, 1.13)	0.1012	0.54 (0.26, 1.13)	0.1010	-0.01 (-0.01, 0.00)	0.0964	
	Female	12/ 1350 (0.89)	20/ 1374 (1.46)	0.61 (0.30, 1.24)	0.1744	0.61 (0.30, 1.25)	0.1742	-0.01 (-0.01, 0.00)	0.1689	
	Region									0.9995
	Western Europe, Oceania and Others	3/ 618 (0.49)	5/ 631 (0.79)	0.61 (0.15, 2.55)	0.5010	0.61 (0.15, 2.57)	0.5008	-0.00 (-0.01, 0.01)	0.4954	
	Eastern Europe	12/ 1327 (0.90)	20/ 1319 (1.52)	0.60 (0.29, 1.21)	0.1546	0.59 (0.29, 1.22)	0.1544	-0.01 (-0.01, 0.00)	0.1500	
	Asia	5/ 492 (1.02)	9/ 488 (1.84)	0.55 (0.19, 1.63)	0.2821	0.55 (0.18, 1.64)	0.2818	-0.01 (-0.02, 0.01)	0.2750	
	North America	2/ 234 (0.85)	4/ 236 (1.69)	0.50 (0.09, 2.73)	0.4266	0.50 (0.09, 2.76)	0.4261	-0.01 (-0.03, 0.01)	0.4162	
	Latin America	1/ 322 (0.31)	2/ 319 (0.63)	0.50 (0.05, 5.44)	0.5654	0.49 (0.04, 5.47)	0.5653	-0.00 (-0.01, 0.01)	0.5578	
	Age group (years)									0.0731
	<= median in FAS	19/ 1585 (1.20)	24/ 1575 (1.52)	0.79 (0.43, 1.43)	0.4315	0.78 (0.43, 1.44)	0.4314	-0.00 (-0.01, 0.00)	0.4305	
	> median in FAS	4/ 1408 (0.28)	16/ 1418 (1.13)	0.25 (0.08, 0.75)	0.0134	0.25 (0.08, 0.75)	0.0133	-0.01 (-0.01, -0.00)	0.0072	
	NYHA class at baseline									0.3747
	II	17/ 2074 (0.82)	25/ 2061 (1.21)	0.68 (0.37, 1.25)	0.2102	0.67 (0.36, 1.25)	0.2101	-0.00 (-0.01, 0.00)	0.2074	
	III/IV	6/ 918 (0.65)	15/ 932 (1.61)	0.41 (0.16, 1.04)	0.0609	0.40 (0.16, 1.04)	0.0605	-0.01 (-0.02, 0.00)	0.0514	
	LVEF at baseline									0.5903
	< 50%	8/ 1092 (0.73)	10/ 1078 (0.93)	0.79 (0.31, 1.99)	0.6173	0.79 (0.31, 2.00)	0.6173	-0.00 (-0.01, 0.01)	0.6167	
	>= 50% - < 60%	10/ 1323 (0.76)	17/ 1342 (1.27)	0.60 (0.27, 1.30)	0.1930	0.59 (0.27, 1.30)	0.1928	-0.01 (-0.01, 0.00)	0.1870	
	>= 60%	5/ 572 (0.87)	13/ 571 (2.28)	0.38 (0.14, 1.07)	0.0671	0.38 (0.13, 1.07)	0.0666	-0.01 (-0.03, 0.00)	0.0566	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Glomerular filtration rate decreased	Sex									0.8097
	Male	87/ 1643 (5.30)	58/ 1619 (3.58)	1.48 (1.07, 2.05)	0.0185	1.50 (1.07, 2.11)	0.0183	0.02 (0.00, 0.03)	0.0174	
	Female	74/ 1350 (5.48)	54/ 1374 (3.93)	1.39 (0.99, 1.96)	0.0570	1.42 (0.99, 2.03)	0.0568	0.02 (-0.00, 0.03)	0.0559	
	Region									0.1848
	Western Europe, Oceania and Others	45/ 618 (7.28)	27/ 631 (4.28)	1.70 (1.07, 2.71)	0.0247	1.76 (1.08, 2.87)	0.0244	0.03 (0.00, 0.06)	0.0229	
	Eastern Europe	63/ 1327 (4.75)	48/ 1319 (3.64)	1.30 (0.90, 1.88)	0.1564	1.32 (0.90, 1.94)	0.1562	0.01 (-0.00, 0.03)	0.1547	
	Asia	17/ 492 (3.46)	4/ 488 (0.82)	4.22 (1.43, 12.44)	0.0092	4.33 (1.45, 12.96)	0.0088	0.03 (0.01, 0.04)	0.0041	
	North America	10/ 234 (4.27)	11/ 236 (4.66)	0.92 (0.40, 2.12)	0.8389	0.91 (0.38, 2.19)	0.8389	-0.00 (-0.04, 0.03)	0.8389	
	Latin America	26/ 322 (8.07)	22/ 319 (6.90)	1.17 (0.68, 2.02)	0.5715	1.19 (0.66, 2.14)	0.5714	0.01 (-0.03, 0.05)	0.5708	
	Age group (years)									0.9824
	<= median in FAS	87/ 1585 (5.49)	60/ 1575 (3.81)	1.44 (1.04, 1.99)	0.0259	1.47 (1.05, 2.05)	0.0258	0.02 (0.00, 0.03)	0.0248	
	> median in FAS	74/ 1408 (5.26)	52/ 1418 (3.67)	1.43 (1.01, 2.03)	0.0420	1.46 (1.01, 2.09)	0.0418	0.02 (0.00, 0.03)	0.0408	
	NYHA class at baseline									0.2879
	II	107/ 2074 (5.16)	67/ 2061 (3.25)	1.59 (1.18, 2.14)	0.0025	1.62 (1.19, 2.21)	0.0024	0.02 (0.01, 0.03)	0.0022	
	III/IV	54/ 918 (5.88)	45/ 932 (4.83)	1.22 (0.83, 1.79)	0.3147	1.23 (0.82, 1.85)	0.3146	0.01 (-0.01, 0.03)	0.3141	
	LVEF at baseline									0.2855
	< 50%	67/ 1092 (6.14)	36/ 1078 (3.34)	1.84 (1.24, 2.73)	0.0026	1.89 (1.25, 2.86)	0.0025	0.03 (0.01, 0.05)	0.0021	
	>= 50% - < 60%	58/ 1323 (4.38)	47/ 1342 (3.50)	1.25 (0.86, 1.83)	0.2432	1.26 (0.85, 1.87)	0.2430	0.01 (-0.01, 0.02)	0.2423	
	>= 60%	35/ 572 (6.12)	29/ 571 (5.08)	1.20 (0.75, 1.94)	0.4452	1.22 (0.73, 2.02)	0.4451	0.01 (-0.02, 0.04)	0.4443	

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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Sex									0.9670
	Male	482/ 1643 (29.34)	432/ 1619 (26.68)	1.10 (0.98, 1.23)	0.0919	1.14 (0.98, 1.33)	0.0917	0.03 (-0.00, 0.06)	0.0914	
	Female	374/ 1350 (27.70)	345/ 1374 (25.11)	1.10 (0.97, 1.25)	0.1248	1.14 (0.96, 1.36)	0.1246	0.03 (-0.01, 0.06)	0.1245	
	Region									0.4801
	Western Europe, Oceania and Others	216/ 618 (34.95)	205/ 631 (32.49)	1.08 (0.92, 1.26)	0.3573	1.12 (0.88, 1.41)	0.3572	0.02 (-0.03, 0.08)	0.3571	
	Eastern Europe	287/ 1327 (21.63)	240/ 1319 (18.20)	1.19 (1.02, 1.39)	0.0274	1.24 (1.02, 1.50)	0.0272	0.03 (0.00, 0.06)	0.0269	
	Asia	205/ 492 (41.67)	205/ 488 (42.01)	0.99 (0.86, 1.15)	0.9137	0.99 (0.77, 1.27)	0.9137	-0.00 (-0.07, 0.06)	0.9137	
	North America	72/ 234 (30.77)	59/ 236 (25.00)	1.23 (0.92, 1.65)	0.1646	1.33 (0.89, 2.00)	0.1637	0.06 (-0.02, 0.14)	0.1623	
	Latin America	76/ 322 (23.60)	68/ 319 (21.32)	1.11 (0.83, 1.48)	0.4885	1.14 (0.79, 1.65)	0.4882	0.02 (-0.04, 0.09)	0.4879	
	Age group (years)									0.8120
	<= median in FAS	415/ 1585 (26.18)	378/ 1575 (24.00)	1.09 (0.97, 1.23)	0.1573	1.12 (0.96, 1.32)	0.1571	0.02 (-0.01, 0.05)	0.1568	
	> median in FAS	441/ 1408 (31.32)	399/ 1418 (28.14)	1.11 (0.99, 1.25)	0.0644	1.16 (0.99, 1.37)	0.0643	0.03 (-0.00, 0.07)	0.0640	
	NYHA class at baseline									0.1002
	II	579/ 2074 (27.92)	547/ 2061 (26.54)	1.05 (0.95, 1.16)	0.3202	1.07 (0.93, 1.23)	0.3201	0.01 (-0.01, 0.04)	0.3200	
	III/IV	277/ 918 (30.17)	230/ 932 (24.68)	1.22 (1.05, 1.42)	0.0083	1.32 (1.07, 1.62)	0.0081	0.05 (0.01, 0.10)	0.0080	
	LVEF at baseline									0.1038
	< 50%	329/ 1092 (30.13)	263/ 1078 (24.40)	1.23 (1.08, 1.42)	0.0028	1.34 (1.11, 1.62)	0.0028	0.06 (0.02, 0.09)	0.0027	
	>= 50% - < 60%	362/ 1323 (27.36)	346/ 1342 (25.78)	1.06 (0.94, 1.20)	0.3561	1.08 (0.91, 1.29)	0.3560	0.02 (-0.02, 0.05)	0.3559	
	>= 60%	164/ 572 (28.67)	167/ 571 (29.25)	0.98 (0.82, 1.18)	0.8301	0.97 (0.75, 1.26)	0.8301	-0.01 (-0.06, 0.05)	0.8301	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Dehydration	Sex									0.9349
	Male	48/ 1643 (2.92)	30/ 1619 (1.85)	1.58 (1.00, 2.48)	0.0478	1.59 (1.00, 2.53)	0.0477	0.01 (0.00, 0.02)	0.0453	
	Female	24/ 1350 (1.78)	16/ 1374 (1.16)	1.53 (0.81, 2.86)	0.1868	1.54 (0.81, 2.90)	0.1866	0.01 (-0.00, 0.02)	0.1840	
	Region									0.7698
	Western Europe, Oceania and Others	16/ 618 (2.59)	14/ 631 (2.22)	1.17 (0.57, 2.37)	0.6695	1.17 (0.57, 2.42)	0.6694	0.00 (-0.01, 0.02)	0.6693	
	Eastern Europe	21/ 1327 (1.58)	13/ 1319 (0.99)	1.61 (0.81, 3.19)	0.1770	1.62 (0.81, 3.24)	0.1768	0.01 (-0.00, 0.01)	0.1724	
	Asia	24/ 492 (4.88)	12/ 488 (2.46)	1.98 (1.00, 3.92)	0.0489	2.03 (1.01, 4.12)	0.0482	0.02 (0.00, 0.05)	0.0434	
	North America	11/ 234 (4.70)	7/ 236 (2.97)	1.58 (0.63, 4.02)	0.3319	1.61 (0.61, 4.24)	0.3313	0.02 (-0.02, 0.05)	0.3271	
	Latin America	0/ 322 (0.00)	0/ 319 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Age group (years)									0.8640
	<= median in FAS	20/ 1585 (1.26)	12/ 1575 (0.76)	1.66 (0.81, 3.38)	0.1651	1.66 (0.81, 3.42)	0.1649	0.00 (-0.00, 0.01)	0.1600	
	> median in FAS	52/ 1408 (3.69)	34/ 1418 (2.40)	1.54 (1.01, 2.36)	0.0468	1.56 (1.01, 2.42)	0.0466	0.01 (0.00, 0.03)	0.0450	
	NYHA class at baseline									0.8916
	II	48/ 2074 (2.31)	31/ 2061 (1.50)	1.54 (0.98, 2.41)	0.0591	1.55 (0.98, 2.45)	0.0589	0.01 (-0.00, 0.02)	0.0568	
	III/IV	24/ 918 (2.61)	15/ 932 (1.61)	1.62 (0.86, 3.08)	0.1365	1.64 (0.86, 3.15)	0.1362	0.01 (-0.00, 0.02)	0.1329	
	LVEF at baseline									0.3387
	< 50%	31/ 1092 (2.84)	14/ 1078 (1.30)	2.19 (1.17, 4.09)	0.0143	2.22 (1.17, 4.20)	0.0141	0.02 (0.00, 0.03)	0.0115	
	>= 50% - < 60%	32/ 1323 (2.42)	23/ 1342 (1.71)	1.41 (0.83, 2.40)	0.2030	1.42 (0.83, 2.44)	0.2028	0.01 (-0.00, 0.02)	0.2010	
	>= 60%	9/ 572 (1.57)	9/ 571 (1.58)	1.00 (0.40, 2.50)	0.9970	1.00 (0.39, 2.53)	0.9970	-0.00 (-0.01, 0.01)	0.9970	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyperkalaemia	Sex									0.9590
	Male	166/ 1643 (10.10)	71/ 1619 (4.39)	2.30 (1.76, 3.02)	<.0001	2.45 (1.84, 3.26)	<.0001	0.06 (0.04, 0.07)	<.0001	
	Female	119/ 1350 (8.81)	52/ 1374 (3.78)	2.33 (1.70, 3.20)	<.0001	2.46 (1.76, 3.44)	<.0001	0.05 (0.03, 0.07)	<.0001	
	Region									0.8107
	Western Europe, Oceania and Others	65/ 618 (10.52)	29/ 631 (4.60)	2.29 (1.50, 3.49)	0.0001	2.44 (1.55, 3.84)	0.0001	0.06 (0.03, 0.09)	<.0001	
	Eastern Europe	108/ 1327 (8.14)	41/ 1319 (3.11)	2.62 (1.84, 3.72)	<.0001	2.76 (1.91, 3.99)	<.0001	0.05 (0.03, 0.07)	<.0001	
	Asia	61/ 492 (12.40)	30/ 488 (6.15)	2.02 (1.33, 3.07)	0.0010	2.16 (1.37, 3.41)	0.0009	0.06 (0.03, 0.10)	0.0007	
	North America	27/ 234 (11.54)	10/ 236 (4.24)	2.72 (1.35, 5.50)	0.0052	2.95 (1.39, 6.24)	0.0047	0.07 (0.02, 0.12)	0.0031	
	Latin America	24/ 322 (7.45)	13/ 319 (4.08)	1.83 (0.95, 3.53)	0.0717	1.90 (0.95, 3.79)	0.0707	0.03 (-0.00, 0.07)	0.0656	
	Age group (years)									0.0350
	<= median in FAS	139/ 1585 (8.77)	46/ 1575 (2.92)	3.00 (2.17, 4.16)	<.0001	3.20 (2.27, 4.49)	<.0001	0.06 (0.04, 0.07)	<.0001	
	> median in FAS	146/ 1408 (10.37)	77/ 1418 (5.43)	1.91 (1.46, 2.49)	<.0001	2.01 (1.51, 2.68)	<.0001	0.05 (0.03, 0.07)	<.0001	
	NYHA class at baseline									0.5237
	II	187/ 2074 (9.02)	84/ 2061 (4.08)	2.21 (1.72, 2.84)	<.0001	2.33 (1.79, 3.04)	<.0001	0.05 (0.03, 0.06)	<.0001	
	III/IV	98/ 918 (10.68)	39/ 932 (4.18)	2.55 (1.78, 3.66)	<.0001	2.74 (1.87, 4.01)	<.0001	0.06 (0.04, 0.09)	<.0001	
	LVEF at baseline									0.2513
	< 50%	97/ 1092 (8.88)	35/ 1078 (3.25)	2.74 (1.88, 3.99)	<.0001	2.91 (1.95, 4.32)	<.0001	0.06 (0.04, 0.08)	<.0001	
	>= 50% - < 60%	135/ 1323 (10.20)	57/ 1342 (4.25)	2.40 (1.78, 3.24)	<.0001	2.56 (1.86, 3.53)	<.0001	0.06 (0.04, 0.08)	<.0001	
	>= 60%	53/ 572 (9.27)	31/ 571 (5.43)	1.71 (1.11, 2.62)	0.0143	1.78 (1.12, 2.82)	0.0140	0.04 (0.01, 0.07)	0.0127	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Sex									0.0558
	Male	68/ 1643 (4.14)	103/ 1619 (6.36)	0.65 (0.48, 0.88)	0.0048	0.64 (0.46, 0.87)	0.0047	-0.02 (-0.04, -0.01)	0.0044	
	Female	50/ 1350 (3.70)	120/ 1374 (8.73)	0.42 (0.31, 0.58)	<.0001	0.40 (0.29, 0.56)	<.0001	-0.05 (-0.07, -0.03)	<.0001	
	Region									0.5281
	Western Europe, Oceania and Others	33/ 618 (5.34)	57/ 631 (9.03)	0.59 (0.39, 0.89)	0.0128	0.57 (0.36, 0.89)	0.0125	-0.04 (-0.07, -0.01)	0.0112	
	Eastern Europe	15/ 1327 (1.13)	43/ 1319 (3.26)	0.35 (0.19, 0.62)	0.0004	0.34 (0.19, 0.61)	0.0004	-0.02 (-0.03, -0.01)	0.0002	
	Asia	50/ 492 (10.16)	84/ 488 (17.21)	0.59 (0.43, 0.82)	0.0016	0.54 (0.37, 0.79)	0.0015	-0.07 (-0.11, -0.03)	0.0013	
	North America	12/ 234 (5.13)	20/ 236 (8.47)	0.61 (0.30, 1.21)	0.1551	0.58 (0.28, 1.22)	0.1539	-0.03 (-0.08, 0.01)	0.1486	
	Latin America	8/ 322 (2.48)	19/ 319 (5.96)	0.42 (0.19, 0.94)	0.0347	0.40 (0.17, 0.93)	0.0338	-0.03 (-0.07, -0.00)	0.0284	
	Age group (years)									0.8618
	<= median in FAS	49/ 1585 (3.09)	94/ 1575 (5.97)	0.52 (0.37, 0.73)	0.0001	0.50 (0.35, 0.72)	0.0001	-0.03 (-0.04, -0.01)	<.0001	
	> median in FAS	69/ 1408 (4.90)	129/ 1418 (9.10)	0.54 (0.41, 0.71)	<.0001	0.51 (0.38, 0.70)	<.0001	-0.04 (-0.06, -0.02)	<.0001	
	NYHA class at baseline									0.2083
	II	86/ 2074 (4.15)	147/ 2061 (7.13)	0.58 (0.45, 0.75)	<.0001	0.56 (0.43, 0.74)	<.0001	-0.03 (-0.04, -0.02)	<.0001	
	III/IV	32/ 918 (3.49)	76/ 932 (8.15)	0.43 (0.29, 0.64)	<.0001	0.41 (0.27, 0.62)	<.0001	-0.05 (-0.07, -0.03)	<.0001	
	LVEF at baseline									0.1545
	< 50%	45/ 1092 (4.12)	73/ 1078 (6.77)	0.61 (0.42, 0.87)	0.0071	0.59 (0.40, 0.87)	0.0070	-0.03 (-0.05, -0.01)	0.0065	
	>= 50% - < 60%	56/ 1323 (4.23)	98/ 1342 (7.30)	0.58 (0.42, 0.80)	0.0008	0.56 (0.40, 0.79)	0.0008	-0.03 (-0.05, -0.01)	0.0007	
	>= 60%	17/ 572 (2.97)	51/ 571 (8.93)	0.33 (0.19, 0.57)	<.0001	0.31 (0.18, 0.55)	<.0001	-0.06 (-0.09, -0.03)	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyponatraemia	Sex									0.6221
	Male	30/ 1643 (1.83)	16/ 1619 (0.99)	1.85 (1.01, 3.38)	0.0459	1.86 (1.01, 3.43)	0.0458	0.01 (0.00, 0.02)	0.0419	
	Female	38/ 1350 (2.81)	17/ 1374 (1.24)	2.28 (1.29, 4.01)	0.0045	2.31 (1.30, 4.12)	0.0044	0.02 (0.01, 0.03)	0.0035	
	Region									0.0058
	Western Europe, Oceania and Others	19/ 618 (3.07)	3/ 631 (0.48)	6.47 (1.92, 21.74)	0.0026	6.64 (1.95, 22.55)	0.0024	0.03 (0.01, 0.04)	0.0005	
	Eastern Europe	8/ 1327 (0.60)	12/ 1319 (0.91)	0.66 (0.27, 1.62)	0.3655	0.66 (0.27, 1.62)	0.3654	-0.00 (-0.01, 0.00)	0.3623	
	Asia	14/ 492 (2.85)	9/ 488 (1.84)	1.54 (0.67, 3.53)	0.3046	1.56 (0.67, 3.64)	0.3043	0.01 (-0.01, 0.03)	0.2999	
	North America	20/ 234 (8.55)	3/ 236 (1.27)	6.72 (2.03, 22.32)	0.0019	7.26 (2.13, 24.77)	0.0016	0.07 (0.03, 0.11)	0.0002	
	Latin America	7/ 322 (2.17)	6/ 319 (1.88)	1.16 (0.39, 3.40)	0.7926	1.16 (0.39, 3.49)	0.7926	0.00 (-0.02, 0.02)	0.7923	
	Age group (years)									0.5236
	<= median in FAS	23/ 1585 (1.45)	9/ 1575 (0.57)	2.54 (1.18, 5.47)	0.0173	2.56 (1.18, 5.55)	0.0172	0.01 (0.00, 0.02)	0.0133	
	> median in FAS	45/ 1408 (3.20)	24/ 1418 (1.69)	1.89 (1.16, 3.08)	0.0110	1.92 (1.16, 3.16)	0.0109	0.02 (0.00, 0.03)	0.0096	
	NYHA class at baseline									0.8395
	II	47/ 2074 (2.27)	22/ 2061 (1.07)	2.12 (1.28, 3.51)	0.0033	2.15 (1.29, 3.58)	0.0033	0.01 (0.00, 0.02)	0.0026	
	III/IV	21/ 918 (2.29)	11/ 932 (1.18)	1.94 (0.94, 4.00)	0.0731	1.96 (0.94, 4.09)	0.0728	0.01 (-0.00, 0.02)	0.0682	
	LVEF at baseline									0.9964
	< 50%	17/ 1092 (1.56)	8/ 1078 (0.74)	2.10 (0.91, 4.84)	0.0824	2.12 (0.91, 4.92)	0.0821	0.01 (-0.00, 0.02)	0.0745	
	>= 50% - < 60%	34/ 1323 (2.57)	17/ 1342 (1.27)	2.03 (1.14, 3.61)	0.0163	2.06 (1.14, 3.70)	0.0162	0.01 (0.00, 0.02)	0.0142	
	>= 60%	16/ 572 (2.80)	8/ 571 (1.40)	2.00 (0.86, 4.63)	0.1070	2.03 (0.86, 4.77)	0.1065	0.01 (-0.00, 0.03)	0.0992	

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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia									
Sex									0.2067
Male	21/ 1643 (1.28)	8/ 1619 (0.49)	2.59 (1.15, 5.82)	0.0217	2.61 (1.15, 5.90)	0.0215	0.01 (0.00, 0.01)	0.0166	
Female	12/ 1350 (0.89)	10/ 1374 (0.73)	1.22 (0.53, 2.82)	0.6392	1.22 (0.53, 2.84)	0.6392	0.00 (-0.01, 0.01)	0.6389	
Region									0.4293
Western Europe, Oceania and Others	9/ 618 (1.46)	10/ 631 (1.58)	0.92 (0.38, 2.25)	0.8529	0.92 (0.37, 2.27)	0.8529	-0.00 (-0.01, 0.01)	0.8528	
Eastern Europe	13/ 1327 (0.98)	4/ 1319 (0.30)	3.23 (1.06, 9.88)	0.0398	3.25 (1.06, 10.00)	0.0396	0.01 (0.00, 0.01)	0.0291	
Asia	6/ 492 (1.22)	3/ 488 (0.61)	1.98 (0.50, 7.89)	0.3307	2.00 (0.50, 8.03)	0.3304	0.01 (-0.01, 0.02)	0.3201	
North America	1/ 234 (0.43)	0/ 236 (0.00)	3.03 (0.12, 73.89)	0.4971	3.04 (0.12, 74.97)	0.4968	0.00 (-0.00, 0.01)	0.3163	
Latin America	4/ 322 (1.24)	1/ 319 (0.31)	3.96 (0.45, 35.26)	0.2170	4.00 (0.44, 35.99)	0.2161	0.01 (-0.00, 0.02)	0.1796	
Age group (years)									0.8231
<= median in FAS	14/ 1585 (0.88)	7/ 1575 (0.44)	1.99 (0.80, 4.91)	0.1367	2.00 (0.80, 4.96)	0.1365	0.00 (-0.00, 0.01)	0.1285	
> median in FAS	19/ 1408 (1.35)	11/ 1418 (0.78)	1.74 (0.83, 3.64)	0.1420	1.75 (0.83, 3.69)	0.1418	0.01 (-0.00, 0.01)	0.1370	
NYHA class at baseline									0.1467
II	28/ 2074 (1.35)	12/ 2061 (0.58)	2.32 (1.18, 4.55)	0.0144	2.34 (1.18, 4.61)	0.0143	0.01 (0.00, 0.01)	0.0115	
III/IV	5/ 918 (0.54)	6/ 932 (0.64)	0.85 (0.26, 2.76)	0.7818	0.85 (0.26, 2.78)	0.7818	-0.00 (-0.01, 0.01)	0.7815	
LVEF at baseline									0.9677
< 50%	9/ 1092 (0.82)	5/ 1078 (0.46)	1.78 (0.60, 5.28)	0.3013	1.78 (0.60, 5.34)	0.3011	0.00 (-0.00, 0.01)	0.2935	
>= 50% - < 60%	12/ 1323 (0.91)	6/ 1342 (0.45)	2.03 (0.76, 5.39)	0.1559	2.04 (0.76, 5.45)	0.1557	0.00 (-0.00, 0.01)	0.1480	
>= 60%	12/ 572 (2.10)	7/ 571 (1.23)	1.71 (0.68, 4.32)	0.2549	1.73 (0.67, 4.42)	0.2546	0.01 (-0.01, 0.02)	0.2486	

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Syncope	Sex									0.6834
	Male	48/ 1643 (2.92)	30/ 1619 (1.85)	1.58 (1.00, 2.48)	0.0478	1.59 (1.00, 2.53)	0.0477	0.01 (0.00, 0.02)	0.0453	
	Female	35/ 1350 (2.59)	26/ 1374 (1.89)	1.37 (0.83, 2.26)	0.2188	1.38 (0.83, 2.31)	0.2187	0.01 (-0.00, 0.02)	0.2173	
	Region									0.3116
	Western Europe, Oceania and Others	27/ 618 (4.37)	21/ 631 (3.33)	1.31 (0.75, 2.30)	0.3403	1.33 (0.74, 2.37)	0.3401	0.01 (-0.01, 0.03)	0.3392	
	Eastern Europe	25/ 1327 (1.88)	23/ 1319 (1.74)	1.08 (0.62, 1.89)	0.7871	1.08 (0.61, 1.92)	0.7871	0.00 (-0.01, 0.01)	0.7870	
	Asia	13/ 492 (2.64)	3/ 488 (0.61)	4.30 (1.23, 14.99)	0.0221	4.39 (1.24, 15.49)	0.0216	0.02 (0.00, 0.04)	0.0118	
	North America	9/ 234 (3.85)	5/ 236 (2.12)	1.82 (0.62, 5.34)	0.2784	1.85 (0.61, 5.60)	0.2776	0.02 (-0.01, 0.05)	0.2706	
	Latin America	9/ 322 (2.80)	4/ 319 (1.25)	2.23 (0.69, 7.16)	0.1784	2.26 (0.69, 7.43)	0.1776	0.02 (-0.01, 0.04)	0.1650	
	Age group (years)									0.5097
	<= median in FAS	36/ 1585 (2.27)	21/ 1575 (1.33)	1.70 (1.00, 2.90)	0.0504	1.72 (1.00, 2.96)	0.0502	0.01 (0.00, 0.02)	0.0473	
	> median in FAS	47/ 1408 (3.34)	35/ 1418 (2.47)	1.35 (0.88, 2.08)	0.1702	1.36 (0.88, 2.13)	0.1700	0.01 (-0.00, 0.02)	0.1685	
	NYHA class at baseline									0.5964
	II	54/ 2074 (2.60)	39/ 2061 (1.89)	1.38 (0.92, 2.07)	0.1246	1.39 (0.91, 2.10)	0.1245	0.01 (-0.00, 0.02)	0.1226	
	III/IV	28/ 918 (3.05)	17/ 932 (1.82)	1.67 (0.92, 3.03)	0.0907	1.69 (0.92, 3.12)	0.0904	0.01 (-0.00, 0.03)	0.0873	
	LVEF at baseline									0.9214
	< 50%	27/ 1092 (2.47)	20/ 1078 (1.86)	1.33 (0.75, 2.36)	0.3251	1.34 (0.75, 2.41)	0.3250	0.01 (-0.01, 0.02)	0.3228	
	>= 50% - < 60%	38/ 1323 (2.87)	25/ 1342 (1.86)	1.54 (0.94, 2.54)	0.0890	1.56 (0.93, 2.60)	0.0888	0.01 (-0.00, 0.02)	0.0867	
	>= 60%	17/ 572 (2.97)	11/ 571 (1.93)	1.54 (0.73, 3.26)	0.2569	1.56 (0.72, 3.36)	0.2565	0.01 (-0.01, 0.03)	0.2525	

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Sex									0.4392
	Male	409/ 1643 (24.89)	320/ 1619 (19.77)	1.26 (1.11, 1.43)	0.0005	1.35 (1.14, 1.59)	0.0004	0.05 (0.02, 0.08)	0.0004	
	Female	253/ 1350 (18.74)	222/ 1374 (16.16)	1.16 (0.98, 1.37)	0.0760	1.20 (0.98, 1.46)	0.0758	0.03 (-0.00, 0.05)	0.0756	
	Region									0.1485
	Western Europe, Oceania and Others	199/ 618 (32.20)	140/ 631 (22.19)	1.45 (1.21, 1.75)	<.0001	1.67 (1.29, 2.14)	<.0001	0.10 (0.05, 0.15)	<.0001	
	Eastern Europe	199/ 1327 (15.00)	177/ 1319 (13.42)	1.12 (0.93, 1.35)	0.2458	1.14 (0.91, 1.42)	0.2456	0.02 (-0.01, 0.04)	0.2452	
	Asia	130/ 492 (26.42)	97/ 488 (19.88)	1.33 (1.05, 1.68)	0.0158	1.45 (1.07, 1.95)	0.0154	0.07 (0.01, 0.12)	0.0148	
	North America	67/ 234 (28.63)	63/ 236 (26.69)	1.07 (0.80, 1.44)	0.6388	1.10 (0.74, 1.65)	0.6387	0.02 (-0.06, 0.10)	0.6386	
	Latin America	67/ 322 (20.81)	65/ 319 (20.38)	1.02 (0.75, 1.38)	0.8926	1.03 (0.70, 1.51)	0.8926	0.00 (-0.06, 0.07)	0.8926	
	Age group (years)									0.4875
	<= median in FAS	303/ 1585 (19.12)	256/ 1575 (16.25)	1.18 (1.01, 1.37)	0.0353	1.22 (1.01, 1.46)	0.0351	0.03 (0.00, 0.06)	0.0348	
	> median in FAS	359/ 1408 (25.50)	286/ 1418 (20.17)	1.26 (1.10, 1.45)	0.0008	1.35 (1.14, 1.62)	0.0008	0.05 (0.02, 0.08)	0.0007	
	NYHA class at baseline									0.9471
	II	429/ 2074 (20.68)	350/ 2061 (16.98)	1.22 (1.07, 1.38)	0.0024	1.27 (1.09, 1.49)	0.0024	0.04 (0.01, 0.06)	0.0023	
	III/IV	232/ 918 (25.27)	192/ 932 (20.60)	1.23 (1.04, 1.45)	0.0172	1.30 (1.05, 1.62)	0.0170	0.05 (0.01, 0.08)	0.0167	
	LVEF at baseline									0.6753
	< 50%	209/ 1092 (19.14)	180/ 1078 (16.70)	1.15 (0.96, 1.37)	0.1387	1.18 (0.95, 1.47)	0.1384	0.02 (-0.01, 0.06)	0.1378	
	>= 50% - < 60%	313/ 1323 (23.66)	253/ 1342 (18.85)	1.25 (1.08, 1.45)	0.0025	1.33 (1.11, 1.61)	0.0025	0.05 (0.02, 0.08)	0.0024	
	>= 60%	140/ 572 (24.48)	109/ 571 (19.09)	1.28 (1.03, 1.60)	0.0281	1.37 (1.04, 1.82)	0.0277	0.05 (0.01, 0.10)	0.0271	

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Sex									0.2230
	Male	88/ 1643 (5.36)	48/ 1619 (2.96)	1.81 (1.28, 2.55)	0.0008	1.85 (1.29, 2.65)	0.0008	0.02 (0.01, 0.04)	0.0006	
	Female	58/ 1350 (4.30)	45/ 1374 (3.28)	1.31 (0.90, 1.92)	0.1638	1.33 (0.89, 1.97)	0.1636	0.01 (-0.00, 0.02)	0.1627	
	Region									0.8779
	Western Europe, Oceania and Others	52/ 618 (8.41)	29/ 631 (4.60)	1.83 (1.18, 2.84)	0.0071	1.91 (1.19, 3.05)	0.0069	0.04 (0.01, 0.07)	0.0061	
	Eastern Europe	29/ 1327 (2.19)	17/ 1319 (1.29)	1.70 (0.94, 3.07)	0.0814	1.71 (0.94, 3.13)	0.0811	0.01 (-0.00, 0.02)	0.0773	
	Asia	16/ 492 (3.25)	13/ 488 (2.66)	1.22 (0.59, 2.51)	0.5877	1.23 (0.58, 2.58)	0.5876	0.01 (-0.02, 0.03)	0.5868	
	North America	37/ 234 (15.81)	25/ 236 (10.59)	1.49 (0.93, 2.40)	0.0978	1.59 (0.92, 2.73)	0.0965	0.05 (-0.01, 0.11)	0.0938	
	Latin America	12/ 322 (3.73)	9/ 319 (2.82)	1.32 (0.56, 3.09)	0.5212	1.33 (0.55, 3.21)	0.5210	0.01 (-0.02, 0.04)	0.5193	
	Age group (years)									0.7831
	<= median in FAS	56/ 1585 (3.53)	37/ 1575 (2.35)	1.50 (1.00, 2.26)	0.0507	1.52 (1.00, 2.32)	0.0505	0.01 (0.00, 0.02)	0.0487	
	> median in FAS	90/ 1408 (6.39)	56/ 1418 (3.95)	1.62 (1.17, 2.24)	0.0037	1.66 (1.18, 2.34)	0.0037	0.02 (0.01, 0.04)	0.0033	
	NYHA class at baseline									0.7535
	II	90/ 2074 (4.34)	55/ 2061 (2.67)	1.63 (1.17, 2.26)	0.0039	1.65 (1.18, 2.33)	0.0038	0.02 (0.01, 0.03)	0.0034	
	III/IV	56/ 918 (6.10)	38/ 932 (4.08)	1.50 (1.00, 2.24)	0.0493	1.53 (1.00, 2.33)	0.0490	0.02 (0.00, 0.04)	0.0477	
	LVEF at baseline									0.1290
	< 50%	38/ 1092 (3.48)	27/ 1078 (2.50)	1.39 (0.85, 2.26)	0.1849	1.40 (0.85, 2.32)	0.1846	0.01 (-0.00, 0.02)	0.1821	
	>= 50% - < 60%	80/ 1323 (6.05)	40/ 1342 (2.98)	2.03 (1.40, 2.94)	0.0002	2.09 (1.42, 3.09)	0.0002	0.03 (0.01, 0.05)	0.0001	
	>= 60%	28/ 572 (4.90)	26/ 571 (4.55)	1.08 (0.64, 1.81)	0.7855	1.08 (0.62, 1.86)	0.7855	0.00 (-0.02, 0.03)	0.7854	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal cyst	Sex									0.9310
	Male	13/ 1643 (0.79)	24/ 1619 (1.48)	0.53 (0.27, 1.04)	0.0669	0.53 (0.27, 1.04)	0.0667	-0.01 (-0.01, 0.00)	0.0628	
	Female	8/ 1350 (0.59)	16/ 1374 (1.16)	0.51 (0.22, 1.19)	0.1173	0.51 (0.22, 1.19)	0.1171	-0.01 (-0.01, 0.00)	0.1091	
	Region									0.3091
	Western Europe, Oceania and Others	1/ 618 (0.16)	3/ 631 (0.48)	0.34 (0.04, 3.26)	0.3500	0.34 (0.04, 3.27)	0.3498	-0.00 (-0.01, 0.00)	0.3240	
	Eastern Europe	18/ 1327 (1.36)	24/ 1319 (1.82)	0.75 (0.41, 1.37)	0.3424	0.74 (0.40, 1.37)	0.3423	-0.00 (-0.01, 0.00)	0.3407	
	Asia	2/ 492 (0.41)	7/ 488 (1.43)	0.28 (0.06, 1.36)	0.1146	0.28 (0.06, 1.36)	0.1140	-0.01 (-0.02, 0.00)	0.0919	
	North America	0/ 234 (0.00)	0/ 236 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Latin America	0/ 322 (0.00)	6/ 319 (1.88)	0.08 (0.00, 1.35)	0.0790	0.07 (0.00, 1.33)	0.0777	-0.02 (-0.03, -0.00)	0.0134	
	Age group (years)									0.7916
	<= median in FAS	13/ 1585 (0.82)	26/ 1575 (1.65)	0.50 (0.26, 0.96)	0.0384	0.49 (0.25, 0.96)	0.0382	-0.01 (-0.02, -0.00)	0.0345	
	> median in FAS	8/ 1408 (0.57)	14/ 1418 (0.99)	0.58 (0.24, 1.37)	0.2109	0.57 (0.24, 1.37)	0.2107	-0.00 (-0.01, 0.00)	0.2044	
	NYHA class at baseline									0.2220
	II	16/ 2074 (0.77)	24/ 2061 (1.16)	0.66 (0.35, 1.24)	0.1999	0.66 (0.35, 1.25)	0.1998	-0.00 (-0.01, 0.00)	0.1969	
	III/IV	5/ 918 (0.54)	16/ 932 (1.72)	0.32 (0.12, 0.86)	0.0245	0.31 (0.11, 0.86)	0.0242	-0.01 (-0.02, -0.00)	0.0167	
	LVEF at baseline									0.0789
	< 50%	11/ 1092 (1.01)	10/ 1078 (0.93)	1.09 (0.46, 2.55)	0.8497	1.09 (0.46, 2.57)	0.8497	0.00 (-0.01, 0.01)	0.8496	
	>= 50% - < 60%	9/ 1323 (0.68)	21/ 1342 (1.56)	0.43 (0.20, 0.95)	0.0357	0.43 (0.20, 0.94)	0.0354	-0.01 (-0.02, -0.00)	0.0299	
	>= 60%	1/ 572 (0.17)	9/ 571 (1.58)	0.11 (0.01, 0.87)	0.0367	0.11 (0.01, 0.87)	0.0361	-0.01 (-0.02, -0.00)	0.0108	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal failure	Sex									0.4813
	Male	56/ 1643 (3.41)	30/ 1619 (1.85)	1.84 (1.19, 2.85)	0.0064	1.87 (1.19, 2.93)	0.0063	0.02 (0.00, 0.03)	0.0054	
	Female	34/ 1350 (2.52)	24/ 1374 (1.75)	1.44 (0.86, 2.42)	0.1655	1.45 (0.86, 2.46)	0.1653	0.01 (-0.00, 0.02)	0.1635	
	Region									0.3040
	Western Europe, Oceania and Others	40/ 618 (6.47)	26/ 631 (4.12)	1.57 (0.97, 2.54)	0.0658	1.61 (0.97, 2.67)	0.0654	0.02 (-0.00, 0.05)	0.0634	
	Eastern Europe	18/ 1327 (1.36)	10/ 1319 (0.76)	1.79 (0.83, 3.86)	0.1383	1.80 (0.83, 3.91)	0.1381	0.01 (-0.00, 0.01)	0.1321	
	Asia	27/ 492 (5.49)	10/ 488 (2.05)	2.68 (1.31, 5.47)	0.0069	2.78 (1.33, 5.80)	0.0066	0.03 (0.01, 0.06)	0.0045	
	North America	2/ 234 (0.85)	4/ 236 (1.69)	0.50 (0.09, 2.73)	0.4266	0.50 (0.09, 2.76)	0.4261	-0.01 (-0.03, 0.01)	0.4162	
	Latin America	3/ 322 (0.93)	4/ 319 (1.25)	0.74 (0.17, 3.29)	0.6958	0.74 (0.16, 3.34)	0.6957	-0.00 (-0.02, 0.01)	0.6949	
	Age group (years)									0.5375
	<= median in FAS	34/ 1585 (2.15)	23/ 1575 (1.46)	1.47 (0.87, 2.48)	0.1508	1.48 (0.87, 2.52)	0.1506	0.01 (-0.00, 0.02)	0.1477	
	> median in FAS	56/ 1408 (3.98)	31/ 1418 (2.19)	1.82 (1.18, 2.80)	0.0067	1.85 (1.19, 2.89)	0.0066	0.02 (0.01, 0.03)	0.0058	
	NYHA class at baseline									0.7754
	II	55/ 2074 (2.65)	34/ 2061 (1.65)	1.61 (1.05, 2.45)	0.0279	1.62 (1.05, 2.50)	0.0278	0.01 (0.00, 0.02)	0.0262	
	III/IV	35/ 918 (3.81)	20/ 932 (2.15)	1.78 (1.03, 3.05)	0.0376	1.81 (1.04, 3.16)	0.0373	0.02 (0.00, 0.03)	0.0350	
	LVEF at baseline									0.8801
	< 50%	29/ 1092 (2.66)	15/ 1078 (1.39)	1.91 (1.03, 3.54)	0.0403	1.93 (1.03, 3.63)	0.0400	0.01 (0.00, 0.02)	0.0361	
	>= 50% - < 60%	47/ 1323 (3.55)	30/ 1342 (2.24)	1.59 (1.01, 2.50)	0.0444	1.61 (1.01, 2.56)	0.0442	0.01 (0.00, 0.03)	0.0426	
	>= 60%	14/ 572 (2.45)	9/ 571 (1.58)	1.55 (0.68, 3.56)	0.2983	1.57 (0.67, 3.65)	0.2980	0.01 (-0.01, 0.02)	0.2939	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal impairment	Sex									0.8508
	Male	117/ 1643 (7.12)	67/ 1619 (4.14)	1.72 (1.28, 2.31)	0.0003	1.78 (1.30, 2.42)	0.0003	0.03 (0.01, 0.05)	0.0002	
	Female	99/ 1350 (7.33)	61/ 1374 (4.44)	1.65 (1.21, 2.25)	0.0015	1.70 (1.23, 2.37)	0.0015	0.03 (0.01, 0.05)	0.0013	
	Region									0.6051
	Western Europe, Oceania and Others	82/ 618 (13.27)	55/ 631 (8.72)	1.52 (1.10, 2.10)	0.0108	1.60 (1.12, 2.30)	0.0106	0.05 (0.01, 0.08)	0.0100	
	Eastern Europe	54/ 1327 (4.07)	31/ 1319 (2.35)	1.73 (1.12, 2.68)	0.0134	1.76 (1.13, 2.76)	0.0132	0.02 (0.00, 0.03)	0.0120	
	Asia	42/ 492 (8.54)	19/ 488 (3.89)	2.19 (1.29, 3.71)	0.0035	2.30 (1.32, 4.02)	0.0033	0.05 (0.02, 0.08)	0.0025	
	North America	17/ 234 (7.26)	7/ 236 (2.97)	2.45 (1.03, 5.80)	0.0415	2.56 (1.04, 6.30)	0.0403	0.04 (0.00, 0.08)	0.0337	
	Latin America	21/ 322 (6.52)	16/ 319 (5.02)	1.30 (0.69, 2.45)	0.4153	1.32 (0.68, 2.58)	0.4149	0.02 (-0.02, 0.05)	0.4131	
	Age group (years)									0.7670
	<= median in FAS	80/ 1585 (5.05)	49/ 1575 (3.11)	1.62 (1.14, 2.30)	0.0065	1.66 (1.15, 2.38)	0.0064	0.02 (0.01, 0.03)	0.0059	
	> median in FAS	136/ 1408 (9.66)	79/ 1418 (5.57)	1.73 (1.33, 2.26)	<.0001	1.81 (1.36, 2.42)	<.0001	0.04 (0.02, 0.06)	<.0001	
	NYHA class at baseline									0.7048
	II	137/ 2074 (6.61)	78/ 2061 (3.78)	1.75 (1.33, 2.29)	<.0001	1.80 (1.35, 2.39)	<.0001	0.03 (0.01, 0.04)	<.0001	
	III/IV	79/ 918 (8.61)	50/ 932 (5.36)	1.60 (1.14, 2.26)	0.0068	1.66 (1.15, 2.40)	0.0067	0.03 (0.01, 0.06)	0.0062	
	LVEF at baseline									0.0018
	< 50%	48/ 1092 (4.40)	50/ 1078 (4.64)	0.95 (0.64, 1.40)	0.7856	0.95 (0.63, 1.42)	0.7856	-0.00 (-0.02, 0.02)	0.7856	
	>= 50% - < 60%	111/ 1323 (8.39)	48/ 1342 (3.58)	2.35 (1.69, 3.26)	<.0001	2.47 (1.74, 3.49)	<.0001	0.05 (0.03, 0.07)	<.0001	
	>= 60%	57/ 572 (9.97)	30/ 571 (5.25)	1.90 (1.24, 2.91)	0.0033	2.00 (1.26, 3.16)	0.0031	0.05 (0.02, 0.08)	0.0026	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis	Sex									0.5828
	Male	29/ 1643 (1.77)	39/ 1619 (2.41)	0.73 (0.46, 1.18)	0.2001	0.73 (0.45, 1.18)	0.1999	-0.01 (-0.02, 0.00)	0.1985	
	Female	15/ 1350 (1.11)	26/ 1374 (1.89)	0.59 (0.31, 1.10)	0.0982	0.58 (0.31, 1.10)	0.0980	-0.01 (-0.02, 0.00)	0.0932	
	Region									0.2303
	Western Europe, Oceania and Others	10/ 618 (1.62)	23/ 631 (3.65)	0.44 (0.21, 0.92)	0.0301	0.43 (0.21, 0.92)	0.0297	-0.02 (-0.04, -0.00)	0.0247	
	Eastern Europe	13/ 1327 (0.98)	25/ 1319 (1.90)	0.52 (0.27, 1.01)	0.0521	0.51 (0.26, 1.01)	0.0518	-0.01 (-0.02, -0.00)	0.0478	
	Asia	11/ 492 (2.24)	10/ 488 (2.05)	1.09 (0.47, 2.55)	0.8402	1.09 (0.46, 2.60)	0.8402	0.00 (-0.02, 0.02)	0.8401	
	North America	6/ 234 (2.56)	5/ 236 (2.12)	1.21 (0.37, 3.91)	0.7498	1.22 (0.37, 4.04)	0.7498	0.00 (-0.02, 0.03)	0.7495	
	Latin America	4/ 322 (1.24)	2/ 319 (0.63)	1.98 (0.37, 10.74)	0.4279	1.99 (0.36, 10.96)	0.4275	0.01 (-0.01, 0.02)	0.4177	
	Age group (years)									0.6162
	<= median in FAS	15/ 1585 (0.95)	25/ 1575 (1.59)	0.60 (0.32, 1.13)	0.1112	0.59 (0.31, 1.13)	0.1110	-0.01 (-0.01, 0.00)	0.1072	
	> median in FAS	29/ 1408 (2.06)	40/ 1418 (2.82)	0.73 (0.46, 1.17)	0.1918	0.72 (0.45, 1.18)	0.1917	-0.01 (-0.02, 0.00)	0.1895	
	NYHA class at baseline									0.8615
	II	32/ 2074 (1.54)	46/ 2061 (2.23)	0.69 (0.44, 1.08)	0.1055	0.69 (0.44, 1.08)	0.1054	-0.01 (-0.02, 0.00)	0.1035	
	III/IV	12/ 918 (1.31)	19/ 932 (2.04)	0.64 (0.31, 1.31)	0.2244	0.64 (0.31, 1.32)	0.2241	-0.01 (-0.02, 0.00)	0.2195	
	LVEF at baseline									0.5420
	< 50%	15/ 1092 (1.37)	16/ 1078 (1.48)	0.93 (0.46, 1.86)	0.8282	0.92 (0.45, 1.88)	0.8282	-0.00 (-0.01, 0.01)	0.8282	
	>= 50% - < 60%	20/ 1323 (1.51)	35/ 1342 (2.61)	0.58 (0.34, 1.00)	0.0495	0.57 (0.33, 1.00)	0.0492	-0.01 (-0.02, -0.00)	0.0460	
	>= 60%	8/ 572 (1.40)	14/ 571 (2.45)	0.57 (0.24, 1.35)	0.2012	0.56 (0.23, 1.36)	0.2008	-0.01 (-0.03, 0.01)	0.1948	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypertension	Sex									0.2908
	Male	67/ 1643 (4.08)	86/ 1619 (5.31)	0.77 (0.56, 1.05)	0.0967	0.76 (0.55, 1.05)	0.0965	-0.01 (-0.03, 0.00)	0.0957	
	Female	62/ 1350 (4.59)	104/ 1374 (7.57)	0.61 (0.45, 0.82)	0.0013	0.59 (0.43, 0.81)	0.0013	-0.03 (-0.05, -0.01)	0.0011	
	Region									0.7384
	Western Europe, Oceania and Others	29/ 618 (4.69)	36/ 631 (5.71)	0.82 (0.51, 1.32)	0.4214	0.81 (0.49, 1.34)	0.4212	-0.01 (-0.03, 0.01)	0.4199	
	Eastern Europe	58/ 1327 (4.37)	88/ 1319 (6.67)	0.66 (0.47, 0.90)	0.0102	0.64 (0.45, 0.90)	0.0101	-0.02 (-0.04, -0.01)	0.0095	
	Asia	14/ 492 (2.85)	20/ 488 (4.10)	0.69 (0.35, 1.36)	0.2869	0.69 (0.34, 1.37)	0.2865	-0.01 (-0.04, 0.01)	0.2840	
	North America	11/ 234 (4.70)	13/ 236 (5.51)	0.85 (0.39, 1.87)	0.6912	0.85 (0.37, 1.93)	0.6911	-0.01 (-0.05, 0.03)	0.6907	
	Latin America	17/ 322 (5.28)	33/ 319 (10.34)	0.51 (0.29, 0.90)	0.0195	0.48 (0.26, 0.89)	0.0188	-0.05 (-0.09, -0.01)	0.0165	
	Age group (years)									0.7368
	<= median in FAS	70/ 1585 (4.42)	106/ 1575 (6.73)	0.66 (0.49, 0.88)	0.0049	0.64 (0.47, 0.87)	0.0049	-0.02 (-0.04, -0.01)	0.0045	
	> median in FAS	59/ 1408 (4.19)	84/ 1418 (5.92)	0.71 (0.51, 0.98)	0.0366	0.69 (0.49, 0.98)	0.0364	-0.02 (-0.03, -0.00)	0.0353	
	NYHA class at baseline									0.2669
	II	92/ 2074 (4.44)	145/ 2061 (7.04)	0.63 (0.49, 0.81)	0.0004	0.61 (0.47, 0.80)	0.0004	-0.03 (-0.04, -0.01)	0.0003	
	III/IV	37/ 918 (4.03)	45/ 932 (4.83)	0.83 (0.55, 1.28)	0.4052	0.83 (0.53, 1.29)	0.4051	-0.01 (-0.03, 0.01)	0.4041	
	LVEF at baseline									0.9411
	< 50%	37/ 1092 (3.39)	57/ 1078 (5.29)	0.64 (0.43, 0.96)	0.0313	0.63 (0.41, 0.96)	0.0311	-0.02 (-0.04, -0.00)	0.0298	
	>= 50% - < 60%	60/ 1323 (4.54)	87/ 1342 (6.48)	0.70 (0.51, 0.96)	0.0286	0.69 (0.49, 0.96)	0.0284	-0.02 (-0.04, -0.00)	0.0273	
	>= 60%	32/ 572 (5.59)	46/ 571 (8.06)	0.69 (0.45, 1.07)	0.1012	0.68 (0.42, 1.08)	0.1007	-0.02 (-0.05, 0.00)	0.0985	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypotension	Sex									0.5588
	Male	125/ 1643 (7.61)	87/ 1619 (5.37)	1.42 (1.09, 1.85)	0.0101	1.45 (1.09, 1.92)	0.0100	0.02 (0.01, 0.04)	0.0095	
	Female	111/ 1350 (8.22)	71/ 1374 (5.17)	1.59 (1.19, 2.12)	0.0016	1.64 (1.21, 2.24)	0.0015	0.03 (0.01, 0.05)	0.0014	
	Region									0.3448
	Western Europe, Oceania and Others	68/ 618 (11.00)	61/ 631 (9.67)	1.14 (0.82, 1.58)	0.4383	1.16 (0.80, 1.66)	0.4382	0.01 (-0.02, 0.05)	0.4381	
	Eastern Europe	74/ 1327 (5.58)	40/ 1319 (3.03)	1.84 (1.26, 2.68)	0.0015	1.89 (1.28, 2.80)	0.0015	0.03 (0.01, 0.04)	0.0012	
	Asia	48/ 492 (9.76)	27/ 488 (5.53)	1.76 (1.12, 2.78)	0.0145	1.85 (1.13, 3.01)	0.0141	0.04 (0.01, 0.08)	0.0125	
	North America	27/ 234 (11.54)	19/ 236 (8.05)	1.43 (0.82, 2.50)	0.2065	1.49 (0.80, 2.76)	0.2055	0.03 (-0.02, 0.09)	0.2028	
	Latin America	19/ 322 (5.90)	11/ 319 (3.45)	1.71 (0.83, 3.54)	0.1471	1.76 (0.82, 3.75)	0.1462	0.02 (-0.01, 0.06)	0.1405	
	Age group (years)									0.5334
	<= median in FAS	93/ 1585 (5.87)	57/ 1575 (3.62)	1.62 (1.17, 2.24)	0.0033	1.66 (1.18, 2.33)	0.0032	0.02 (0.01, 0.04)	0.0029	
	> median in FAS	143/ 1408 (10.16)	101/ 1418 (7.12)	1.43 (1.12, 1.82)	0.0043	1.47 (1.13, 1.92)	0.0043	0.03 (0.01, 0.05)	0.0041	
	NYHA class at baseline									0.0275
	II	150/ 2074 (7.23)	116/ 2061 (5.63)	1.28 (1.02, 1.62)	0.0361	1.31 (1.02, 1.68)	0.0360	0.02 (0.00, 0.03)	0.0354	
	III/IV	86/ 918 (9.37)	42/ 932 (4.51)	2.08 (1.45, 2.97)	<.0001	2.19 (1.50, 3.21)	<.0001	0.05 (0.03, 0.07)	<.0001	
	LVEF at baseline									0.7043
	< 50%	80/ 1092 (7.33)	57/ 1078 (5.29)	1.39 (1.00, 1.93)	0.0522	1.42 (1.00, 2.01)	0.0519	0.02 (-0.00, 0.04)	0.0505	
	>= 50% - < 60%	104/ 1323 (7.86)	64/ 1342 (4.77)	1.65 (1.22, 2.23)	0.0012	1.70 (1.24, 2.35)	0.0011	0.03 (0.01, 0.05)	0.0010	
	>= 60%	52/ 572 (9.09)	37/ 571 (6.48)	1.40 (0.94, 2.10)	0.1016	1.44 (0.93, 2.24)	0.1010	0.03 (-0.00, 0.06)	0.0991	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	65/ 2993 (2.17)	66/ 2993 (2.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.70, 1.39)	
	p-value	0.9296	
	Risk Ratio (95% CI)	0.98 (0.70, 1.38)	
	p-value	0.9296	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9296	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	43/ 2993 (1.44)	44/ 2993 (1.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.64, 1.49)	
	p-value	0.9140	
	Risk Ratio (95% CI)	0.98 (0.64, 1.48)	
	p-value	0.9140	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9140	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	361/ 2993 (12.06)	340/ 2993 (11.36)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.91, 1.25)	
	p-value	0.3987	
	Risk Ratio (95% CI)	1.06 (0.92, 1.22)	
	p-value	0.3987	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.3986	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	44/ 2993 (1.47)	39/ 2993 (1.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.73, 1.74)	
	p-value	0.5807	
	Risk Ratio (95% CI)	1.13 (0.74, 1.73)	
	p-value	0.5807	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5805	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Atrial fibrillation	Number of subjects with event, n/N (%)	96/ 2993 (3.21)	81/ 2993 (2.71)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.19 (0.88, 1.61)	
	p-value	0.2530	
	Risk Ratio (95% CI)	1.19 (0.89, 1.59)	
	p-value	0.2530	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.2524	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	45/ 2993 (1.50)	35/ 2993 (1.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.29 (0.83, 2.01)	
	p-value	0.2616	
	Risk Ratio (95% CI)	1.29 (0.83, 1.99)	
	p-value	0.2616	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2603	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	187/ 2993 (6.25)	152/ 2993 (5.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (1.00, 1.55)	
	p-value	0.0507	
	Risk Ratio (95% CI)	1.23 (1.00, 1.51)	
	p-value	0.0508	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.0503	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	182/ 2993 (6.08)	207/ 2993 (6.92)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.71, 1.07)	
	p-value	0.1902	
	Risk Ratio (95% CI)	0.88 (0.73, 1.07)	
	p-value	0.1903	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1898	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	70/ 2993 (2.34)	97/ 2993 (3.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.52, 0.98)	
	p-value	0.0349	
	Risk Ratio (95% CI)	0.72 (0.53, 0.98)	
	p-value	0.0350	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0340	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	37/ 2993 (1.24)	48/ 2993 (1.60)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.50, 1.18)	
	p-value	0.2308	
	Risk Ratio (95% CI)	0.77 (0.50, 1.18)	
	p-value	0.2309	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2294	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	486/ 2993 (16.24)	480/ 2993 (16.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.88, 1.16)	
	p-value	0.8330	
	Risk Ratio (95% CI)	1.01 (0.90, 1.14)	
	p-value	0.8330	
	Risk Difference (95% CI)	0.00 (-0.02, 0.02)	
	p-value	0.8330	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	85/ 2993 (2.84)	82/ 2993 (2.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.76, 1.41)	
	p-value	0.8139	
	Risk Ratio (95% CI)	1.04 (0.77, 1.40)	
	p-value	0.8139	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8139	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19 pneumonia	Number of subjects with event, n/N (%)	31/ 2993 (1.04)	32/ 2993 (1.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.59, 1.59)	
	p-value	0.8992	
	Risk Ratio (95% CI)	0.97 (0.59, 1.58)	
	p-value	0.8992	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.8992	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	140/ 2993 (4.68)	143/ 2993 (4.78)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.77, 1.24)	
	p-value	0.8550	
	Risk Ratio (95% CI)	0.98 (0.78, 1.23)	
	p-value	0.8550	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8550	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	44/ 2993 (1.47)	25/ 2993 (0.84)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.77 (1.08, 2.90)	
	p-value	0.0232	
	Risk Ratio (95% CI)	1.76 (1.08, 2.87)	
	p-value	0.0233	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0214	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	43/ 2993 (1.44)	40/ 2993 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.70, 1.66)	
	p-value	0.7402	
	Risk Ratio (95% CI)	1.08 (0.70, 1.65)	
	p-value	0.7402	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.7402	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	151/ 2993 (5.05)	172/ 2993 (5.75)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.70, 1.09)	
	p-value	0.2299	
	Risk Ratio (95% CI)	0.88 (0.71, 1.09)	
	p-value	0.2300	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.2296	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	91/ 2993 (3.04)	73/ 2993 (2.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.92, 1.71)	
	p-value	0.1549	
	Risk Ratio (95% CI)	1.25 (0.92, 1.69)	
	p-value	0.1550	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.1540	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	66/ 2993 (2.21)	75/ 2993 (2.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.88 (0.63, 1.23)	
	p-value	0.4434	
	Risk Ratio (95% CI)	0.88 (0.63, 1.22)	
	p-value	0.4434	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4430	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	113/ 2993 (3.78)	136/ 2993 (4.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.82 (0.64, 1.06)	
	p-value	0.1371	
	Risk Ratio (95% CI)	0.83 (0.65, 1.06)	
	p-value	0.1372	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1365	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	112/ 2993 (3.74)	120/ 2993 (4.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.72, 1.21)	
	p-value	0.5922	
	Risk Ratio (95% CI)	0.93 (0.73, 1.20)	
	p-value	0.5922	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5922	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Syncope	Number of subjects with event, n/N (%)	31/ 2993 (1.04)	31/ 2993 (1.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.61, 1.65)	
	p-value	1.0000	
	Risk Ratio (95% CI)	1.00 (0.61, 1.64)	
	p-value	1.0000	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	1.0000	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	144/ 2993 (4.81)	94/ 2993 (3.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.56 (1.20, 2.03)	
	p-value	0.0010	
	Risk Ratio (95% CI)	1.53 (1.19, 1.98)	
	p-value	0.0010	
	Risk Difference (95% CI)	0.02 (0.01, 0.03)	
	p-value	0.0009	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	78/ 2993 (2.61)	44/ 2993 (1.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.79 (1.23, 2.60)	
	p-value	0.0021	
	Risk Ratio (95% CI)	1.77 (1.23, 2.56)	
	p-value	0.0022	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0019	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	172/ 2993 (5.75)	162/ 2993 (5.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.85, 1.33)	
	p-value	0.5734	
	Risk Ratio (95% CI)	1.06 (0.86, 1.31)	
	p-value	0.5734	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5733	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	28/ 2993 (0.94)	35/ 2993 (1.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.48, 1.32)	
	p-value	0.3763	
	Risk Ratio (95% CI)	0.80 (0.49, 1.31)	
	p-value	0.3763	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3753	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	69/ 2993 (2.31)	63/ 2993 (2.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.10 (0.78, 1.55)	
	p-value	0.5976	
	Risk Ratio (95% CI)	1.10 (0.78, 1.54)	
	p-value	0.5976	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5974	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	105/ 2993 (3.51)	97/ 2993 (3.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.82, 1.44)	
	p-value	0.5670	
	Risk Ratio (95% CI)	1.08 (0.83, 1.42)	
	p-value	0.5670	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5669	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death	Sex									0.8808
	Male	38/ 1643 (2.31)	53/ 1619 (3.27)	0.71 (0.47, 1.07)	0.0975	0.70 (0.46, 1.07)	0.0973	-0.01 (-0.02, 0.00)	0.0960	
	Female	32/ 1350 (2.37)	44/ 1374 (3.20)	0.74 (0.47, 1.16)	0.1892	0.73 (0.46, 1.16)	0.1890	-0.01 (-0.02, 0.00)	0.1867	
	Region									0.7472
	Western Europe, Oceania and Others	15/ 618 (2.43)	16/ 631 (2.54)	0.96 (0.48, 1.92)	0.9020	0.96 (0.47, 1.95)	0.9020	-0.00 (-0.02, 0.02)	0.9019	
	Eastern Europe	35/ 1327 (2.64)	50/ 1319 (3.79)	0.70 (0.45, 1.06)	0.0945	0.69 (0.44, 1.07)	0.0943	-0.01 (-0.02, 0.00)	0.0925	
	Asia	10/ 492 (2.03)	16/ 488 (3.28)	0.62 (0.28, 1.35)	0.2296	0.61 (0.27, 1.36)	0.2292	-0.01 (-0.03, 0.01)	0.2249	
	North America	8/ 234 (3.42)	9/ 236 (3.81)	0.90 (0.35, 2.28)	0.8188	0.89 (0.34, 2.36)	0.8188	-0.00 (-0.04, 0.03)	0.8187	
	Latin America	2/ 322 (0.62)	6/ 319 (1.88)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.03, 0.00)	0.1512	
	Age group (years)									0.4066
	<= median in FAS	24/ 1585 (1.51)	39/ 1575 (2.48)	0.61 (0.37, 1.01)	0.0556	0.61 (0.36, 1.01)	0.0555	-0.01 (-0.02, 0.00)	0.0531	
	> median in FAS	46/ 1408 (3.27)	58/ 1418 (4.09)	0.80 (0.55, 1.17)	0.2463	0.79 (0.53, 1.17)	0.2461	-0.01 (-0.02, 0.01)	0.2449	
	NYHA class at baseline									0.9913
	II	40/ 2074 (1.93)	55/ 2061 (2.67)	0.72 (0.48, 1.08)	0.1140	0.72 (0.48, 1.08)	0.1138	-0.01 (-0.02, 0.00)	0.1124	
	III/IV	30/ 918 (3.27)	42/ 932 (4.51)	0.73 (0.46, 1.15)	0.1706	0.72 (0.44, 1.15)	0.1702	-0.01 (-0.03, 0.01)	0.1678	
	LVEF at baseline									0.4454
	< 50%	36/ 1092 (3.30)	41/ 1078 (3.80)	0.87 (0.56, 1.35)	0.5240	0.86 (0.55, 1.36)	0.5239	-0.01 (-0.02, 0.01)	0.5237	
	>= 50% - < 60%	24/ 1323 (1.81)	43/ 1342 (3.20)	0.57 (0.35, 0.93)	0.0239	0.56 (0.34, 0.93)	0.0237	-0.01 (-0.03, -0.00)	0.0215	
	>= 60%	10/ 572 (1.75)	13/ 571 (2.28)	0.77 (0.34, 1.74)	0.5259	0.76 (0.33, 1.76)	0.5258	-0.01 (-0.02, 0.01)	0.5246	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Sex									0.4251
	Male	26/ 1643 (1.58)	17/ 1619 (1.05)	1.51 (0.82, 2.77)	0.1857	1.52 (0.82, 2.80)	0.1855	0.01 (-0.00, 0.01)	0.1817	
	Female	18/ 1350 (1.33)	8/ 1374 (0.58)	2.29 (1.00, 5.25)	0.0502	2.31 (1.00, 5.32)	0.0500	0.01 (0.00, 0.01)	0.0444	
	Region									0.5268
	Western Europe, Oceania and Others	8/ 618 (1.29)	5/ 631 (0.79)	1.63 (0.54, 4.97)	0.3869	1.64 (0.53, 5.05)	0.3867	0.01 (-0.01, 0.02)	0.3831	
	Eastern Europe	11/ 1327 (0.83)	3/ 1319 (0.23)	3.64 (1.02, 13.03)	0.0467	3.67 (1.02, 13.17)	0.0465	0.01 (0.00, 0.01)	0.0325	
	Asia	6/ 492 (1.22)	5/ 488 (1.02)	1.19 (0.37, 3.87)	0.7724	1.19 (0.36, 3.93)	0.7724	0.00 (-0.01, 0.02)	0.7720	
	North America	12/ 234 (5.13)	10/ 236 (4.24)	1.21 (0.53, 2.75)	0.6481	1.22 (0.52, 2.89)	0.6480	0.01 (-0.03, 0.05)	0.6476	
	Latin America	7/ 322 (2.17)	2/ 319 (0.63)	3.47 (0.73, 16.56)	0.1191	3.52 (0.73, 17.09)	0.1181	0.02 (-0.00, 0.03)	0.0945	
	Age group (years)									0.6778
	<= median in FAS	19/ 1585 (1.20)	12/ 1575 (0.76)	1.57 (0.77, 3.23)	0.2169	1.58 (0.76, 3.27)	0.2167	0.00 (-0.00, 0.01)	0.2124	
	> median in FAS	25/ 1408 (1.78)	13/ 1418 (0.92)	1.94 (0.99, 3.77)	0.0518	1.95 (1.00, 3.83)	0.0516	0.01 (0.00, 0.02)	0.0476	
	NYHA class at baseline									0.3972
	II	31/ 2074 (1.49)	15/ 2061 (0.73)	2.05 (1.11, 3.79)	0.0215	2.07 (1.11, 3.85)	0.0214	0.01 (0.00, 0.01)	0.0185	
	III/IV	13/ 918 (1.42)	10/ 932 (1.07)	1.32 (0.58, 2.99)	0.5068	1.32 (0.58, 3.04)	0.5068	0.00 (-0.01, 0.01)	0.5058	
	LVEF at baseline									0.8866
	< 50%	10/ 1092 (0.92)	6/ 1078 (0.56)	1.65 (0.60, 4.51)	0.3333	1.65 (0.60, 4.56)	0.3331	0.00 (-0.00, 0.01)	0.3273	
	>= 50% - < 60%	20/ 1323 (1.51)	10/ 1342 (0.75)	2.03 (0.95, 4.32)	0.0664	2.04 (0.95, 4.38)	0.0662	0.01 (-0.00, 0.02)	0.0612	
	>= 60%	14/ 572 (2.45)	9/ 571 (1.58)	1.55 (0.68, 3.56)	0.2983	1.57 (0.67, 3.65)	0.2980	0.01 (-0.01, 0.02)	0.2939	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Sex									0.1103
	Male	88/ 1643 (5.36)	47/ 1619 (2.90)	1.84 (1.30, 2.61)	0.0005	1.89 (1.32, 2.72)	0.0005	0.02 (0.01, 0.04)	0.0004	
	Female	56/ 1350 (4.15)	47/ 1374 (3.42)	1.21 (0.83, 1.77)	0.3204	1.22 (0.82, 1.81)	0.3203	0.01 (-0.01, 0.02)	0.3199	
	Region									0.9522
	Western Europe, Oceania and Others	41/ 618 (6.63)	26/ 631 (4.12)	1.61 (1.00, 2.60)	0.0512	1.65 (1.00, 2.74)	0.0507	0.03 (0.00, 0.05)	0.0488	
	Eastern Europe	40/ 1327 (3.01)	24/ 1319 (1.82)	1.66 (1.00, 2.73)	0.0480	1.68 (1.01, 2.80)	0.0478	0.01 (0.00, 0.02)	0.0452	
	Asia	21/ 492 (4.27)	17/ 488 (3.48)	1.23 (0.65, 2.29)	0.5255	1.24 (0.64, 2.37)	0.5253	0.01 (-0.02, 0.03)	0.5244	
	North America	25/ 234 (10.68)	17/ 236 (7.20)	1.48 (0.82, 2.67)	0.1896	1.54 (0.81, 2.94)	0.1886	0.03 (-0.02, 0.09)	0.1855	
	Latin America	17/ 322 (5.28)	10/ 319 (3.13)	1.68 (0.78, 3.62)	0.1821	1.72 (0.78, 3.82)	0.1812	0.02 (-0.01, 0.05)	0.1754	
	Age group (years)									0.6811
	<= median in FAS	61/ 1585 (3.85)	42/ 1575 (2.67)	1.44 (0.98, 2.12)	0.0630	1.46 (0.98, 2.18)	0.0628	0.01 (-0.00, 0.02)	0.0611	
	> median in FAS	83/ 1408 (5.89)	52/ 1418 (3.67)	1.61 (1.15, 2.26)	0.0060	1.65 (1.15, 2.35)	0.0059	0.02 (0.01, 0.04)	0.0055	
	NYHA class at baseline									0.8299
	II	90/ 2074 (4.34)	57/ 2061 (2.77)	1.57 (1.13, 2.17)	0.0068	1.59 (1.14, 2.24)	0.0067	0.02 (0.00, 0.03)	0.0062	
	III/IV	54/ 918 (5.88)	37/ 932 (3.97)	1.48 (0.99, 2.23)	0.0591	1.51 (0.98, 2.32)	0.0587	0.02 (-0.00, 0.04)	0.0573	
	LVEF at baseline									0.8290
	< 50%	37/ 1092 (3.39)	24/ 1078 (2.23)	1.52 (0.92, 2.53)	0.1043	1.54 (0.92, 2.59)	0.1040	0.01 (-0.00, 0.03)	0.1009	
	>= 50% - < 60%	76/ 1323 (5.74)	47/ 1342 (3.50)	1.64 (1.15, 2.34)	0.0064	1.68 (1.16, 2.44)	0.0063	0.02 (0.01, 0.04)	0.0058	
	>= 60%	31/ 572 (5.42)	23/ 571 (4.03)	1.35 (0.79, 2.28)	0.2696	1.37 (0.79, 2.37)	0.2692	0.01 (-0.01, 0.04)	0.2672	

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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Sex									0.4590
	Male	45/ 1643 (2.74)	22/ 1619 (1.36)	2.02 (1.22, 3.34)	0.0065	2.04 (1.22, 3.42)	0.0065	0.01 (0.00, 0.02)	0.0053	
	Female	33/ 1350 (2.44)	22/ 1374 (1.60)	1.53 (0.89, 2.60)	0.1206	1.54 (0.89, 2.66)	0.1204	0.01 (-0.00, 0.02)	0.1182	
	Region									0.6615
	Western Europe, Oceania and Others	27/ 618 (4.37)	15/ 631 (2.38)	1.84 (0.99, 3.42)	0.0549	1.88 (0.99, 3.56)	0.0544	0.02 (-0.00, 0.04)	0.0512	
	Eastern Europe	17/ 1327 (1.28)	8/ 1319 (0.61)	2.11 (0.91, 4.88)	0.0799	2.13 (0.91, 4.94)	0.0797	0.01 (-0.00, 0.01)	0.0724	
	Asia	7/ 492 (1.42)	8/ 488 (1.64)	0.87 (0.32, 2.37)	0.7826	0.87 (0.31, 2.41)	0.7826	-0.00 (-0.02, 0.01)	0.7825	
	North America	22/ 234 (9.40)	11/ 236 (4.66)	2.02 (1.00, 4.07)	0.0497	2.12 (1.00, 4.48)	0.0485	0.05 (0.00, 0.09)	0.0437	
	Latin America	5/ 322 (1.55)	2/ 319 (0.63)	2.48 (0.48, 12.67)	0.2762	2.50 (0.48, 12.98)	0.2756	0.01 (-0.01, 0.03)	0.2580	
	Age group (years)									0.3485
	<= median in FAS	29/ 1585 (1.83)	20/ 1575 (1.27)	1.44 (0.82, 2.54)	0.2055	1.45 (0.82, 2.57)	0.2053	0.01 (-0.00, 0.01)	0.2025	
	> median in FAS	49/ 1408 (3.48)	24/ 1418 (1.69)	2.06 (1.27, 3.33)	0.0034	2.09 (1.28, 3.43)	0.0034	0.02 (0.01, 0.03)	0.0027	
	NYHA class at baseline									0.7229
	II	49/ 2074 (2.36)	26/ 2061 (1.26)	1.87 (1.17, 3.00)	0.0091	1.89 (1.17, 3.06)	0.0090	0.01 (0.00, 0.02)	0.0079	
	III/IV	29/ 918 (3.16)	18/ 932 (1.93)	1.64 (0.91, 2.92)	0.0969	1.66 (0.91, 3.00)	0.0966	0.01 (-0.00, 0.03)	0.0937	
	LVEF at baseline									0.0353
	< 50%	17/ 1092 (1.56)	15/ 1078 (1.39)	1.12 (0.56, 2.23)	0.7495	1.12 (0.56, 2.26)	0.7495	0.00 (-0.01, 0.01)	0.7493	
	>= 50% - < 60%	47/ 1323 (3.55)	16/ 1342 (1.19)	2.98 (1.70, 5.23)	0.0001	3.05 (1.72, 5.41)	0.0001	0.02 (0.01, 0.04)	<.0001	
	>= 60%	14/ 572 (2.45)	13/ 571 (2.28)	1.08 (0.51, 2.27)	0.8492	1.08 (0.50, 2.31)	0.8492	0.00 (-0.02, 0.02)	0.8492	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	33/ 2993 (1.10)	43/ 2993 (1.44)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.76 (0.48, 1.21)	
	p-value	0.2497	
	Risk Ratio (95% CI)	0.77 (0.49, 1.20)	
	p-value	0.2498	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2483	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	24/ 2993 (0.80)	30/ 2993 (1.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.47, 1.37)	
	p-value	0.4131	
	Risk Ratio (95% CI)	0.80 (0.47, 1.37)	
	p-value	0.4131	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4121	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	159/ 2993 (5.31)	148/ 2993 (4.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.86, 1.36)	
	p-value	0.5193	
	Risk Ratio (95% CI)	1.07 (0.86, 1.34)	
	p-value	0.5193	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5192	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	76/ 2993 (2.54)	67/ 2993 (2.24)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.82, 1.59)	
	p-value	0.4465	
	Risk Ratio (95% CI)	1.13 (0.82, 1.57)	
	p-value	0.4465	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4462	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	142/ 2993 (4.74)	174/ 2993 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.81 (0.64, 1.01)	
	p-value	0.0648	
	Risk Ratio (95% CI)	0.82 (0.66, 1.01)	
	p-value	0.0649	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.0643	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	68/ 2993 (2.27)	96/ 2993 (3.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.70 (0.51, 0.96)	
	p-value	0.0274	
	Risk Ratio (95% CI)	0.71 (0.52, 0.96)	
	p-value	0.0274	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0266	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	231/ 2993 (7.72)	254/ 2993 (8.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.75, 1.09)	
	p-value	0.2761	
	Risk Ratio (95% CI)	0.91 (0.77, 1.08)	
	p-value	0.2762	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.2759	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	27/ 2993 (0.90)	32/ 2993 (1.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.50, 1.41)	
	p-value	0.5135	
	Risk Ratio (95% CI)	0.84 (0.51, 1.40)	
	p-value	0.5135	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5130	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	66/ 2993 (2.21)	65/ 2993 (2.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.72, 1.44)	
	p-value	0.9296	
	Risk Ratio (95% CI)	1.02 (0.72, 1.42)	
	p-value	0.9296	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.9296	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	32/ 2993 (1.07)	15/ 2993 (0.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.15 (1.16, 3.97)	
	p-value	0.0150	
	Risk Ratio (95% CI)	2.13 (1.16, 3.93)	
	p-value	0.0151	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0127	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	79/ 2993 (2.64)	90/ 2993 (3.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.64, 1.19)	
	p-value	0.3910	
	Risk Ratio (95% CI)	0.88 (0.65, 1.18)	
	p-value	0.3911	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3907	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	49/ 2993 (1.64)	44/ 2993 (1.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.12 (0.74, 1.68)	
	p-value	0.6015	
	Risk Ratio (95% CI)	1.11 (0.74, 1.67)	
	p-value	0.6015	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.6013	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	34/ 2993 (1.14)	34/ 2993 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.62, 1.61)	
	p-value	1.0000	
	Risk Ratio (95% CI)	1.00 (0.62, 1.60)	
	p-value	1.0000	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	1.0000	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	67/ 2993 (2.24)	82/ 2993 (2.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.81 (0.59, 1.13)	
	p-value	0.2141	
	Risk Ratio (95% CI)	0.82 (0.59, 1.12)	
	p-value	0.2142	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.2133	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	52/ 2993 (1.74)	66/ 2993 (2.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.54, 1.13)	
	p-value	0.1941	
	Risk Ratio (95% CI)	0.79 (0.55, 1.13)	
	p-value	0.1941	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.1930	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	103/ 2993 (3.44)	58/ 2993 (1.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.80 (1.30, 2.50)	
	p-value	0.0004	
	Risk Ratio (95% CI)	1.78 (1.29, 2.44)	
	p-value	0.0004	
	Risk Difference (95% CI)	0.02 (0.01, 0.02)	
	p-value	0.0003	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	55/ 2993 (1.84)	29/ 2993 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.91 (1.22, 3.01)	
	p-value	0.0050	
	Risk Ratio (95% CI)	1.90 (1.21, 2.97)	
	p-value	0.0050	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0043	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	97/ 2993 (3.24)	92/ 2993 (3.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.06 (0.79, 1.41)	
	p-value	0.7117	
	Risk Ratio (95% CI)	1.05 (0.80, 1.40)	
	p-value	0.7117	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.7117	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	62/ 2993 (2.07)	53/ 2993 (1.77)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.81, 1.70)	
	p-value	0.3972	
	Risk Ratio (95% CI)	1.17 (0.81, 1.68)	
	p-value	0.3973	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3967	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=2993)_ n/ N (%)	_Placebo (N=2993)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death	Sex									0.6935
	Male	36/ 1643 (2.19)	53/ 1619 (3.27)	0.67 (0.44, 1.02)	0.0596	0.66 (0.43, 1.02)	0.0594	-0.01 (-0.02, 0.00)	0.0580	
	Female	32/ 1350 (2.37)	43/ 1374 (3.13)	0.76 (0.48, 1.19)	0.2276	0.75 (0.47, 1.20)	0.2275	-0.01 (-0.02, 0.00)	0.2253	
	Region									0.7593
	Western Europe, Oceania and Others	14/ 618 (2.27)	16/ 631 (2.54)	0.89 (0.44, 1.81)	0.7552	0.89 (0.43, 1.84)	0.7552	-0.00 (-0.02, 0.01)	0.7550	
	Eastern Europe	35/ 1327 (2.64)	49/ 1319 (3.71)	0.71 (0.46, 1.09)	0.1159	0.70 (0.45, 1.09)	0.1157	-0.01 (-0.02, 0.00)	0.1140	
	Asia	9/ 492 (1.83)	16/ 488 (3.28)	0.56 (0.25, 1.25)	0.1564	0.55 (0.24, 1.26)	0.1559	-0.01 (-0.03, 0.01)	0.1502	
	North America	8/ 234 (3.42)	9/ 236 (3.81)	0.90 (0.35, 2.28)	0.8188	0.89 (0.34, 2.36)	0.8188	-0.00 (-0.04, 0.03)	0.8187	
	Latin America	2/ 322 (0.62)	6/ 319 (1.88)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.03, 0.00)	0.1512	
	Age group (years)									0.3492
	<= median in FAS	23/ 1585 (1.45)	39/ 1575 (2.48)	0.59 (0.35, 0.98)	0.0402	0.58 (0.34, 0.98)	0.0400	-0.01 (-0.02, -0.00)	0.0378	
	> median in FAS	45/ 1408 (3.20)	57/ 1418 (4.02)	0.80 (0.54, 1.17)	0.2416	0.79 (0.53, 1.17)	0.2415	-0.01 (-0.02, 0.01)	0.2402	
	NYHA class at baseline									0.8023
	II	38/ 2074 (1.83)	55/ 2061 (2.67)	0.69 (0.46, 1.03)	0.0715	0.68 (0.45, 1.03)	0.0713	-0.01 (-0.02, 0.00)	0.0698	
	III/IV	30/ 918 (3.27)	41/ 932 (4.40)	0.74 (0.47, 1.18)	0.2073	0.73 (0.45, 1.19)	0.2070	-0.01 (-0.03, 0.01)	0.2047	
	LVEF at baseline									0.4664
	< 50%	35/ 1092 (3.21)	41/ 1078 (3.80)	0.84 (0.54, 1.31)	0.4491	0.84 (0.53, 1.33)	0.4490	-0.01 (-0.02, 0.01)	0.4487	
	>= 50% - < 60%	23/ 1323 (1.74)	42/ 1342 (3.13)	0.56 (0.34, 0.92)	0.0219	0.55 (0.33, 0.92)	0.0217	-0.01 (-0.03, -0.00)	0.0196	
	>= 60%	10/ 572 (1.75)	13/ 571 (2.28)	0.77 (0.34, 1.74)	0.5259	0.76 (0.33, 1.76)	0.5258	-0.01 (-0.02, 0.01)	0.5246	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Sex									0.2452
	Male	18/ 1643 (1.10)	11/ 1619 (0.68)	1.61 (0.76, 3.40)	0.2100	1.62 (0.76, 3.44)	0.2098	0.00 (-0.00, 0.01)	0.2047	
	Female	14/ 1350 (1.04)	4/ 1374 (0.29)	3.56 (1.18, 10.79)	0.0247	3.59 (1.18, 10.93)	0.0245	0.01 (0.00, 0.01)	0.0167	
	Region									0.1231
	Western Europe, Oceania and Others	7/ 618 (1.13)	2/ 631 (0.32)	3.57 (0.75, 17.14)	0.1113	3.60 (0.75, 17.41)	0.1108	0.01 (-0.00, 0.02)	0.0898	
	Eastern Europe	9/ 1327 (0.68)	0/ 1319 (0.00)	18.89 (1.10, 324.14)	0.0428	19.01 (1.11, 327.02)	0.0424	0.01 (0.00, 0.01)	0.0026	
	Asia	5/ 492 (1.02)	5/ 488 (1.02)	0.99 (0.29, 3.40)	0.9896	0.99 (0.29, 3.45)	0.9896	-0.00 (-0.01, 0.01)	0.9896	
	North America	4/ 234 (1.71)	6/ 236 (2.54)	0.67 (0.19, 2.35)	0.5344	0.67 (0.19, 2.39)	0.5341	-0.01 (-0.03, 0.02)	0.5310	
	Latin America	7/ 322 (2.17)	2/ 319 (0.63)	3.47 (0.73, 16.56)	0.1191	3.52 (0.73, 17.09)	0.1181	0.02 (-0.00, 0.03)	0.0945	
	Age group (years)									0.2906
	<= median in FAS	14/ 1585 (0.88)	9/ 1575 (0.57)	1.55 (0.67, 3.56)	0.3064	1.55 (0.67, 3.59)	0.3063	0.00 (-0.00, 0.01)	0.3021	
	> median in FAS	18/ 1408 (1.28)	6/ 1418 (0.42)	3.02 (1.20, 7.59)	0.0186	3.05 (1.21, 7.70)	0.0185	0.01 (0.00, 0.02)	0.0133	
	NYHA class at baseline									0.9115
	II	22/ 2074 (1.06)	10/ 2061 (0.49)	2.19 (1.04, 4.61)	0.0396	2.20 (1.04, 4.66)	0.0395	0.01 (0.00, 0.01)	0.0344	
	III/IV	10/ 918 (1.09)	5/ 932 (0.54)	2.03 (0.70, 5.92)	0.1943	2.04 (0.70, 6.00)	0.1941	0.01 (-0.00, 0.01)	0.1858	
	LVEF at baseline									0.9388
	< 50%	9/ 1092 (0.82)	4/ 1078 (0.37)	2.22 (0.69, 7.19)	0.1831	2.23 (0.69, 7.27)	0.1828	0.00 (-0.00, 0.01)	0.1702	
	>= 50% - < 60%	11/ 1323 (0.83)	6/ 1342 (0.45)	1.86 (0.69, 5.01)	0.2202	1.87 (0.69, 5.06)	0.2200	0.00 (-0.00, 0.01)	0.2136	
	>= 60%	12/ 572 (2.10)	5/ 571 (0.88)	2.40 (0.85, 6.76)	0.0986	2.43 (0.85, 6.93)	0.0980	0.01 (-0.00, 0.03)	0.0873	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Sex									0.5308
	Male	65/ 1643 (3.96)	39/ 1619 (2.41)	1.64 (1.11, 2.43)	0.0129	1.67 (1.12, 2.50)	0.0128	0.02 (0.00, 0.03)	0.0117	
	Female	38/ 1350 (2.81)	19/ 1374 (1.38)	2.04 (1.18, 3.51)	0.0107	2.07 (1.18, 3.60)	0.0105	0.01 (0.00, 0.03)	0.0092	
	Region									0.4552
	Western Europe, Oceania and Others	32/ 618 (5.18)	14/ 631 (2.22)	2.33 (1.26, 4.33)	0.0072	2.41 (1.27, 4.56)	0.0070	0.03 (0.01, 0.05)	0.0055	
	Eastern Europe	32/ 1327 (2.41)	14/ 1319 (1.06)	2.27 (1.22, 4.24)	0.0099	2.30 (1.22, 4.34)	0.0097	0.01 (0.00, 0.02)	0.0077	
	Asia	16/ 492 (3.25)	14/ 488 (2.87)	1.13 (0.56, 2.30)	0.7279	1.14 (0.55, 2.36)	0.7279	0.00 (-0.02, 0.03)	0.7276	
	North America	12/ 234 (5.13)	7/ 236 (2.97)	1.73 (0.69, 4.31)	0.2406	1.77 (0.68, 4.57)	0.2397	0.02 (-0.01, 0.06)	0.2339	
	Latin America	11/ 322 (3.42)	9/ 319 (2.82)	1.21 (0.51, 2.88)	0.6655	1.22 (0.50, 2.98)	0.6654	0.01 (-0.02, 0.03)	0.6648	
	Age group (years)									0.1457
	<= median in FAS	45/ 1585 (2.84)	32/ 1575 (2.03)	1.40 (0.89, 2.19)	0.1431	1.41 (0.89, 2.23)	0.1429	0.01 (-0.00, 0.02)	0.1407	
	> median in FAS	58/ 1408 (4.12)	26/ 1418 (1.83)	2.25 (1.42, 3.55)	0.0005	2.30 (1.44, 3.68)	0.0005	0.02 (0.01, 0.04)	0.0003	
	NYHA class at baseline									0.7039
	II	64/ 2074 (3.09)	34/ 2061 (1.65)	1.87 (1.24, 2.82)	0.0029	1.90 (1.25, 2.89)	0.0028	0.01 (0.01, 0.02)	0.0024	
	III/IV	39/ 918 (4.25)	24/ 932 (2.58)	1.65 (1.00, 2.72)	0.0498	1.68 (1.00, 2.81)	0.0495	0.02 (0.00, 0.03)	0.0474	
	LVEF at baseline									0.3582
	< 50%	28/ 1092 (2.56)	21/ 1078 (1.95)	1.32 (0.75, 2.30)	0.3358	1.32 (0.75, 2.35)	0.3356	0.01 (-0.01, 0.02)	0.3336	
	>= 50% - < 60%	55/ 1323 (4.16)	25/ 1342 (1.86)	2.23 (1.40, 3.56)	0.0007	2.29 (1.42, 3.69)	0.0007	0.02 (0.01, 0.04)	0.0005	
	>= 60%	20/ 572 (3.50)	12/ 571 (2.10)	1.66 (0.82, 3.37)	0.1577	1.69 (0.82, 3.49)	0.1572	0.01 (-0.01, 0.03)	0.1524	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=2993) n/ N (%)	Placebo (N=2993) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Sex									0.9271
	Male	34/ 1643 (2.07)	18/ 1619 (1.11)	1.86 (1.06, 3.28)	0.0318	1.88 (1.06, 3.34)	0.0316	0.01 (0.00, 0.02)	0.0285	
	Female	21/ 1350 (1.56)	11/ 1374 (0.80)	1.94 (0.94, 4.01)	0.0728	1.96 (0.94, 4.08)	0.0726	0.01 (-0.00, 0.02)	0.0681	
	Region									0.9051
	Western Europe, Oceania and Others	16/ 618 (2.59)	8/ 631 (1.27)	2.04 (0.88, 4.74)	0.0963	2.07 (0.88, 4.87)	0.0958	0.01 (-0.00, 0.03)	0.0898	
	Eastern Europe	16/ 1327 (1.21)	8/ 1319 (0.61)	1.99 (0.85, 4.63)	0.1111	2.00 (0.85, 4.69)	0.1109	0.01 (-0.00, 0.01)	0.1035	
	Asia	7/ 492 (1.42)	6/ 488 (1.23)	1.16 (0.39, 3.42)	0.7917	1.16 (0.39, 3.48)	0.7917	0.00 (-0.01, 0.02)	0.7914	
	North America	11/ 234 (4.70)	5/ 236 (2.12)	2.22 (0.78, 6.29)	0.1337	2.28 (0.78, 6.66)	0.1324	0.03 (-0.01, 0.06)	0.1223	
	Latin America	5/ 322 (1.55)	2/ 319 (0.63)	2.48 (0.48, 12.67)	0.2762	2.50 (0.48, 12.98)	0.2756	0.01 (-0.01, 0.03)	0.2580	
	Age group (years)									0.0238
	<= median in FAS	20/ 1585 (1.26)	18/ 1575 (1.14)	1.10 (0.59, 2.08)	0.7591	1.11 (0.58, 2.10)	0.7591	0.00 (-0.01, 0.01)	0.7590	
	> median in FAS	35/ 1408 (2.49)	11/ 1418 (0.78)	3.20 (1.63, 6.28)	0.0007	3.26 (1.65, 6.45)	0.0007	0.02 (0.01, 0.03)	0.0003	
	NYHA class at baseline									0.9385
	II	33/ 2074 (1.59)	17/ 2061 (0.82)	1.93 (1.08, 3.45)	0.0269	1.94 (1.08, 3.50)	0.0268	0.01 (0.00, 0.01)	0.0240	
	III/IV	22/ 918 (2.40)	12/ 932 (1.29)	1.86 (0.93, 3.74)	0.0808	1.88 (0.93, 3.83)	0.0805	0.01 (-0.00, 0.02)	0.0762	
	LVEF at baseline									0.2912
	< 50%	15/ 1092 (1.37)	12/ 1078 (1.11)	1.23 (0.58, 2.62)	0.5849	1.24 (0.58, 2.66)	0.5849	0.00 (-0.01, 0.01)	0.5839	
	>= 50% - < 60%	30/ 1323 (2.27)	11/ 1342 (0.82)	2.77 (1.39, 5.50)	0.0037	2.81 (1.40, 5.63)	0.0036	0.01 (0.01, 0.02)	0.0024	
	>= 60%	10/ 572 (1.75)	6/ 571 (1.05)	1.66 (0.61, 4.55)	0.3210	1.68 (0.60, 4.64)	0.3207	0.01 (-0.01, 0.02)	0.3153	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Blood and lymphatic system disorders; PT: Nephrogenic anaemia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	14/ 2993 (0.47)	12/ 2993 (0.40)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac amyloidosis	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac arrest	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiac failure congestive	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Cardiogenic shock	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Coronary artery disease	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Coronary artery occlusion	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Heart failure with preserved ejection fraction	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Heart failure with reduced ejection fraction	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Left ventricular dysfunction	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Mitral valve incompetence	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Palpitations	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Supraventricular tachycardia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Cardiac disorders; PT: Ventricular tachycardia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Ear and labyrinth disorders; PT: Vertigo	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	14/ 2993 (0.47)	10/ 2993 (0.33)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Abdominal pain upper	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Acid peptic disease	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Constipation Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	5/ 2993 (0.17)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Dyspepsia	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Gastrointestinal pain	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Intestinal ischaemia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	3/ 2993 (0.10)	3/ 2993 (0.10)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Pancreatitis Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Rectal haemorrhage	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Swollen tongue	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Gastrointestinal disorders; PT: Upper gastrointestinal haemorrhage	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	7/ 2993 (0.23)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	6/ 2993 (0.20)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Chest discomfort	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Chest pain	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Discomfort	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Fatigue	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: General disorders and administration site conditions; PT: Malaise	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	3/ 2993 (0.10)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders; PT: Cardiac cirrhosis	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders; PT: Cirrhosis alcoholic	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Hepatobiliary disorders; PT: Hepatic failure Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Immune system disorders	Number of subjects with event, n/N (%)	5/ 2993 (0.17)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Immune system disorders; PT: Amyloidosis	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Immune system disorders; PT: Hypersensitivity Number of subjects with event, n/N (%)	2/ 2993 (0.07)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Immune system disorders; PT: Primary amyloidosis	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	10/ 2993 (0.33)	15/ 2993 (0.50)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: COVID-19 pneumonia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Eczema infected	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Endocarditis staphylococcal	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Erysipelas	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Gastroenteritis	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Pneumonia aspiration	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Post procedural infection	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Postoperative wound infection	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Septic shock Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	3/ 2993 (0.10)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	4/ 2993 (0.13)	3/ 2993 (0.10)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Extradural haematoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Fall	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Femoral neck fracture	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Hip fracture	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Multiple injuries	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Spinal cord injury cervical	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Spinal fracture	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Injury, poisoning and procedural complications; PT: Subdural haematoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations	Number of subjects with event, n/N (%)	6/ 2993 (0.20)	8/ 2993 (0.27)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Blood creatinine increased	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Blood potassium increased Number of subjects with event, n/N (%)	3/ 2993 (0.10)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Ejection fraction decreased	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	6/ 2993 (0.20)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Investigations; PT: Weight decreased	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	24/ 2993 (0.80)	9/ 2993 (0.30)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Cachexia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Decreased appetite	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Electrolyte imbalance	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Failure to thrive	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Gout Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	20/ 2993 (0.67)	5/ 2993 (0.17)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hyponatraemia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Hypovolaemia	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Metabolism and nutrition disorders; PT: Malnutrition	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	4/ 2993 (0.13)	5/ 2993 (0.17)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Immobilisation syndrome	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Mobility decreased	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	24/ 2993 (0.80)	15/ 2993 (0.50)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Adenocarcinoma gastric	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Bile duct cancer	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Bladder cancer	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Brain neoplasm	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Breast cancer	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Cholangiocarcinoma	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Colon cancer	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Colon neoplasm	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Hepatic cancer	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Hodgkin's disease	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Laryngeal neoplasm	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lung infiltration malignant	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lung neoplasm malignant	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lymphoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Malignant neoplasm of renal pelvis	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Metastases to liver	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Neuroendocrine carcinoma of the skin	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Neuroendocrine tumour of the lung	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Non-small cell lung cancer	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Oesophageal adenocarcinoma	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Oesophageal squamous cell carcinoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Pancreatic carcinoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Papillary serous endometrial carcinoma	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Papillary thyroid cancer	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Prostate cancer	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Prostate cancer metastatic	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Small cell lung cancer	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Squamous cell carcinoma of skin	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Tongue neoplasm malignant stage unspecified	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	9/ 2993 (0.30)	18/ 2993 (0.60)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Aphasia	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Cerebral haemorrhage	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Cerebral infarction	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Cognitive disorder	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Dementia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	2/ 2993 (0.07)	3/ 2993 (0.10)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Dysstasia	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Encephalopathy Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Essential tremor	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Guillain-Barre syndrome	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Headache	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Metabolic encephalopathy	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Orthostatic intolerance	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Parkinson's disease	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Sciatica	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Somnolence	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Nervous system disorders; PT: Vascular dementia	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	5/ 2993 (0.17)	7/ 2993 (0.23)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Anxiety	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Anxiety disorder	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Confusional state Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Delusion	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Depression	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Insomnia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Schizophrenia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Psychiatric disorders; PT: Stress	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	24/ 2993 (0.80)	16/ 2993 (0.53)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	3/ 2993 (0.10)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Chronic kidney disease	Number of subjects with event, n/N (%)	5/ 2993 (0.17)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Incontinence Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Renal failure	Number of subjects with event, n/N (%)	4/ 2993 (0.13)	4/ 2993 (0.13)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	11/ 2993 (0.37)	6/ 2993 (0.20)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Renal and urinary disorders; PT: Urinary retention	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Reproductive system and breast disorders; PT: Gynaecomastia	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	7/ 2993 (0.23)	8/ 2993 (0.27)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Acute respiratory failure	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	4/ 2993 (0.13)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea exertional	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Interstitial lung disease	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleural effusion	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleurisy	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Rales	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	3/ 2993 (0.10)	6/ 2993 (0.20)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Dermatitis allergic	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Eczema	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Henoch-Schonlein purpura	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Pruritus	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Rash	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Skin and subcutaneous tissue disorders; PT: Rash pruritic	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	5/ 2993 (0.17)	2/ 2993 (0.07)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Flushing	Number of subjects with event, n/N (%)	0/ 2993 (0.00)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	4/ 2993 (0.13)	1/ 2993 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=2993)	Placebo (N=2993)
SOC: Vascular disorders; PT: Vasculitis	Number of subjects with event, n/N (%)	1/ 2993 (0.03)	0/ 2993 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication ongoing at baseline
Full Analysis Set

Standard drug grouping	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	2378 (79.19 %)	2380 (79.39 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	256 (8.52 %)	257 (8.57 %)
Beta-Blocker	2541 (84.62 %)	2554 (85.19 %)
Loop diuretics	2618 (87.18 %)	2621 (87.42 %)
Thiazide diuretics	429 (14.29 %)	402 (13.41 %)
Digoxin	241 (8.03 %)	230 (7.67 %)
Nitrate	308 (10.26 %)	266 (8.87 %)
Potassium supplements	349 (11.62 %)	365 (12.17 %)
Potassium lowering (incl.binders)	5 (0.17 %)	8 (0.27 %)
Alpha blocking agents	726 (24.18 %)	755 (25.18 %)
Calcium channel blockers	958 (31.90 %)	1010 (33.69 %)
Centrally acting antihypertensivs	103 (3.43 %)	108 (3.60 %)
Strong CYP3A4 inhibitors	22 (0.73 %)	23 (0.77 %)
Moderate CYP3A4 inhibitors	71 (2.36 %)	65 (2.17 %)
Weak CYP3A4 inhibitors	1778 (59.21 %)	1777 (59.27 %)
Unclassified CYP3A4 inhibitors	48 (1.60 %)	45 (1.50 %)
Strong CYP3A4 inducers	5 (0.17 %)	5 (0.17 %)
Moderate CYP3A4 inducers	13 (0.43 %)	7 (0.23 %)
Weak CYP3A4 inducers	32 (1.07 %)	41 (1.37 %)
Unclassified CYP3A4 inducers	15 (0.50 %)	23 (0.77 %)
Acetylsalycylic acid and its salts	956 (31.83 %)	989 (32.99 %)
Statins	2036 (67.80 %)	2013 (67.14 %)
MRA	4 (0.13 %)	2 (0.07 %)
OATP substrates	2288 (76.19 %)	2286 (76.25 %)
Insulin and insulin analogues	337 (11.22 %)	353 (11.77 %)
Glycosurics as SGLT-2 inhibitors	393 (13.09 %)	424 (14.14 %)
Anticoagulants	1574 (52.41 %)	1541 (51.40 %)
Injectable glucagon-like peptide	79 (2.63 %)	88 (2.94 %)
Antiarrhythmic drugs	521 (17.35 %)	519 (17.31 %)
Biguanides	626 (20.85 %)	632 (21.08 %)
Sulfonylureas	202 (6.73 %)	208 (6.94 %)
Combinations of oral blood glucose lowering drugs	91 (3.03 %)	90 (3.00 %)
Combinations of various lipid modifying agents	55 (1.83 %)	51 (1.70 %)
Other lipid modifying agents	216 (7.19 %)	196 (6.54 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1259 (75.43 %)	1252 (75.88 %)
	Chronic Kidney Disease (PT)	Yes	423 (75.00 %)	405 (73.77 %)
	Coronary Artery Disease (PBMQ)	Yes	944 (82.59 %)	957 (82.71 %)
	Hyperlipidemia (MLG)	Yes	607 (79.35 %)	596 (77.71 %)
	Hypertension (MLG)	Yes	2172 (82.27 %)	2201 (81.97 %)
	Region	Western Europe, Oceania and Others	464 (74.36 %)	469 (74.21 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1004 (82.50 %)	986 (80.62 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	120 (7.19 %)	121 (7.33 %)
	Chronic Kidney Disease (PT)	Yes	43 (7.62 %)	45 (8.20 %)
	Coronary Artery Disease (PBMQ)	Yes	132 (11.55 %)	126 (10.89 %)
	Hyperlipidemia (MLG)	Yes	68 (8.89 %)	65 (8.47 %)
	Hypertension (MLG)	Yes	186 (7.05 %)	202 (7.52 %)
	Region	Western Europe, Oceania and Others	31 (4.97 %)	29 (4.59 %)
	Type 2 Diabetes Mellitus (PT)	Yes	104 (8.55 %)	109 (8.91 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1443 (86.46 %)	1428 (86.55 %)
	Chronic Kidney Disease (PT)	Yes	481 (85.28 %)	474 (86.34 %)
	Coronary Artery Disease (PBMQ)	Yes	999 (87.40 %)	1015 (87.73 %)
	Hyperlipidemia (MLG)	Yes	666 (87.06 %)	662 (86.31 %)
	Hypertension (MLG)	Yes	2239 (84.81 %)	2295 (85.47 %)
	Region	Western Europe, Oceania and Others	493 (79.01 %)	523 (82.75 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1044 (85.78 %)	1054 (86.18 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1506 (90.23 %)	1513 (91.70 %)
	Chronic Kidney Disease (PT)	Yes	503 (89.18 %)	498 (90.71 %)
	Coronary Artery Disease (PBMQ)	Yes	987 (86.35 %)	1010 (87.29 %)
	Hyperlipidemia (MLG)	Yes	654 (85.49 %)	659 (85.92 %)
	Hypertension (MLG)	Yes	2276 (86.21 %)	2325 (86.59 %)
	Region	Western Europe, Oceania and Others	570 (91.35 %)	589 (93.20 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1072 (88.09 %)	1085 (88.72 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	201 (12.04 %)	187 (11.33 %)
	Chronic Kidney Disease (PT)	Yes	70 (12.41 %)	67 (12.20 %)
	Coronary Artery Disease (PBMQ)	Yes	156 (13.65 %)	161 (13.92 %)
	Hyperlipidemia (MLG)	Yes	114 (14.90 %)	104 (13.56 %)
	Hypertension (MLG)	Yes	416 (15.76 %)	388 (14.45 %)
	Region	Western Europe, Oceania and Others	99 (15.87 %)	84 (13.29 %)
	Type 2 Diabetes Mellitus (PT)	Yes	183 (15.04 %)	171 (13.98 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	227 (13.60 %)	221 (13.39 %)
	Chronic Kidney Disease (PT)	Yes	32 (5.67 %)	24 (4.37 %)
	Coronary Artery Disease (PBMQ)	Yes	88 (7.70 %)	75 (6.48 %)
	Hyperlipidemia (MLG)	Yes	57 (7.45 %)	47 (6.13 %)
	Hypertension (MLG)	Yes	202 (7.65 %)	198 (7.37 %)
	Region	Western Europe, Oceania and Others	45 (7.21 %)	52 (8.23 %)
	Type 2 Diabetes Mellitus (PT)	Yes	73 (6.00 %)	83 (6.79 %)
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	151 (9.05 %)	130 (7.88 %)
	Chronic Kidney Disease (PT)	Yes	75 (13.30 %)	69 (12.57 %)
	Coronary Artery Disease (PBMQ)	Yes	210 (18.37 %)	178 (15.38 %)
	Hyperlipidemia (MLG)	Yes	105 (13.73 %)	83 (10.82 %)
	Hypertension (MLG)	Yes	276 (10.45 %)	244 (9.09 %)
	Region	Western Europe, Oceania and Others	78 (12.50 %)	57 (9.02 %)
	Type 2 Diabetes Mellitus (PT)	Yes	149 (12.24 %)	130 (10.63 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	231 (13.84 %)	260 (15.76 %)
	Chronic Kidney Disease (PT)	Yes	49 (8.69 %)	56 (10.20 %)
	Coronary Artery Disease (PBMQ)	Yes	133 (11.64 %)	150 (12.96 %)
	Hyperlipidemia (MLG)	Yes	140 (18.30 %)	151 (19.69 %)
	Hypertension (MLG)	Yes	308 (11.67 %)	320 (11.92 %)
	Region	Western Europe, Oceania and Others	66 (10.58 %)	77 (12.18 %)
	Type 2 Diabetes Mellitus (PT)	Yes	120 (9.86 %)	142 (11.61 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (0.18 %)	5 (0.30 %)
	Chronic Kidney Disease (PT)	Yes	4 (0.71 %)	6 (1.09 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (0.26 %)	1 (0.09 %)
	Hyperlipidemia (MLG)	Yes	1 (0.13 %)	1 (0.13 %)
	Hypertension (MLG)	Yes	5 (0.19 %)	7 (0.26 %)
	Region	Western Europe, Oceania and Others	1 (0.16 %)	3 (0.47 %)
	Type 2 Diabetes Mellitus (PT)	Yes	5 (0.41 %)	3 (0.25 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	384 (23.01 %)	379 (22.97 %)
	Chronic Kidney Disease (PT)	Yes	173 (30.67 %)	202 (36.79 %)
	Coronary Artery Disease (PBMQ)	Yes	282 (24.67 %)	304 (26.27 %)
	Hyperlipidemia (MLG)	Yes	206 (26.93 %)	234 (30.51 %)
	Hypertension (MLG)	Yes	661 (25.04 %)	687 (25.59 %)
	Region	Western Europe, Oceania and Others	163 (26.12 %)	165 (26.11 %)
	Type 2 Diabetes Mellitus (PT)	Yes	350 (28.76 %)	371 (30.34 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	488 (29.24 %)	509 (30.85 %)
	Chronic Kidney Disease (PT)	Yes	216 (38.30 %)	209 (38.07 %)
	Coronary Artery Disease (PBMQ)	Yes	395 (34.56 %)	383 (33.10 %)
	Hyperlipidemia (MLG)	Yes	266 (34.77 %)	270 (35.20 %)
	Hypertension (MLG)	Yes	940 (35.61 %)	986 (36.72 %)
	Region	Western Europe, Oceania and Others	183 (29.33 %)	199 (31.49 %)
	Type 2 Diabetes Mellitus (PT)	Yes	445 (36.57 %)	472 (38.59 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	48 (2.88 %)	54 (3.27 %)
	Chronic Kidney Disease (PT)	Yes	30 (5.32 %)	21 (3.83 %)
	Coronary Artery Disease (PBMQ)	Yes	50 (4.37 %)	46 (3.98 %)
	Hyperlipidemia (MLG)	Yes	31 (4.05 %)	28 (3.65 %)
	Hypertension (MLG)	Yes	103 (3.90 %)	108 (4.02 %)
	Region	Western Europe, Oceania and Others	13 (2.08 %)	10 (1.58 %)
	Type 2 Diabetes Mellitus (PT)	Yes	54 (4.44 %)	52 (4.25 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	11 (0.66 %)	7 (0.42 %)
	Chronic Kidney Disease (PT)	Yes	4 (0.71 %)	6 (1.09 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (0.79 %)	14 (1.21 %)
	Hyperlipidemia (MLG)	Yes	6 (0.78 %)	8 (1.04 %)
	Hypertension (MLG)	Yes	14 (0.53 %)	15 (0.56 %)
	Region	Western Europe, Oceania and Others	3 (0.48 %)	2 (0.32 %)
	Type 2 Diabetes Mellitus (PT)	Yes	6 (0.49 %)	9 (0.74 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	47 (2.82 %)	47 (2.85 %)
	Chronic Kidney Disease (PT)	Yes	15 (2.66 %)	17 (3.10 %)
	Coronary Artery Disease (PBMQ)	Yes	33 (2.89 %)	15 (1.30 %)
	Hyperlipidemia (MLG)	Yes	26 (3.40 %)	23 (3.00 %)
	Hypertension (MLG)	Yes	65 (2.46 %)	54 (2.01 %)
	Region	Western Europe, Oceania and Others	19 (3.04 %)	17 (2.69 %)
	Type 2 Diabetes Mellitus (PT)	Yes	29 (2.38 %)	25 (2.04 %)

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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	943 (56.50 %)	925 (56.06 %)
	Chronic Kidney Disease (PT)	Yes	371 (65.78 %)	367 (66.85 %)
	Coronary Artery Disease (PBMQ)	Yes	743 (65.00 %)	755 (65.25 %)
	Hyperlipidemia (MLG)	Yes	504 (65.88 %)	513 (66.88 %)
	Hypertension (MLG)	Yes	1619 (61.33 %)	1643 (61.19 %)
	Region	Western Europe, Oceania and Others	368 (58.97 %)	363 (57.44 %)
	Type 2 Diabetes Mellitus (PT)	Yes	785 (64.50 %)	791 (64.68 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	28 (1.68 %)	33 (2.00 %)
	Chronic Kidney Disease (PT)	Yes	12 (2.13 %)	11 (2.00 %)
	Coronary Artery Disease (PBMQ)	Yes	12 (1.05 %)	11 (0.95 %)
	Hyperlipidemia (MLG)	Yes	9 (1.18 %)	10 (1.30 %)
	Hypertension (MLG)	Yes	44 (1.67 %)	40 (1.49 %)
	Region	Western Europe, Oceania and Others	22 (3.53 %)	20 (3.16 %)
	Type 2 Diabetes Mellitus (PT)	Yes	16 (1.31 %)	15 (1.23 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (0.12 %)	0 (0.00 %)
	Chronic Kidney Disease (PT)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (0.17 %)	3 (0.26 %)
	Hyperlipidemia (MLG)	Yes	1 (0.13 %)	1 (0.13 %)
	Hypertension (MLG)	Yes	5 (0.19 %)	5 (0.19 %)
	Region	Western Europe, Oceania and Others	1 (0.16 %)	0 (0.00 %)
	Type 2 Diabetes Mellitus (PT)	Yes	2 (0.16 %)	1 (0.08 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (0.36 %)	4 (0.24 %)
	Chronic Kidney Disease (PT)	Yes	2 (0.35 %)	2 (0.36 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (0.61 %)	5 (0.43 %)
	Hyperlipidemia (MLG)	Yes	4 (0.52 %)	3 (0.39 %)
	Hypertension (MLG)	Yes	12 (0.45 %)	7 (0.26 %)
	Region	Western Europe, Oceania and Others	4 (0.64 %)	0 (0.00 %)
	Type 2 Diabetes Mellitus (PT)	Yes	4 (0.33 %)	2 (0.16 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	13 (0.78 %)	20 (1.21 %)
	Chronic Kidney Disease (PT)	Yes	3 (0.53 %)	12 (2.19 %)
	Coronary Artery Disease (PBMQ)	Yes	13 (1.14 %)	15 (1.30 %)
	Hyperlipidemia (MLG)	Yes	15 (1.96 %)	14 (1.83 %)
	Hypertension (MLG)	Yes	28 (1.06 %)	38 (1.42 %)
	Region	Western Europe, Oceania and Others	11 (1.76 %)	18 (2.85 %)
	Type 2 Diabetes Mellitus (PT)	Yes	18 (1.48 %)	24 (1.96 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	10 (0.60 %)	12 (0.73 %)
	Chronic Kidney Disease (PT)	Yes	3 (0.53 %)	9 (1.64 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (0.26 %)	12 (1.04 %)
	Hyperlipidemia (MLG)	Yes	4 (0.52 %)	6 (0.78 %)
	Hypertension (MLG)	Yes	15 (0.57 %)	18 (0.67 %)
	Region	Western Europe, Oceania and Others	7 (1.12 %)	8 (1.27 %)
	Type 2 Diabetes Mellitus (PT)	Yes	6 (0.49 %)	8 (0.65 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	157 (9.41 %)	182 (11.03 %)
	Chronic Kidney Disease (PT)	Yes	181 (32.09 %)	190 (34.61 %)
	Coronary Artery Disease (PBMQ)	Yes	548 (47.94 %)	570 (49.27 %)
	Hyperlipidemia (MLG)	Yes	279 (36.47 %)	290 (37.81 %)
	Hypertension (MLG)	Yes	860 (32.58 %)	904 (33.67 %)
	Region	Western Europe, Oceania and Others	132 (21.15 %)	150 (23.73 %)
	Type 2 Diabetes Mellitus (PT)	Yes	451 (37.06 %)	481 (39.33 %)

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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1051 (62.97 %)	1001 (60.67 %)
	Chronic Kidney Disease (PT)	Yes	407 (72.16 %)	400 (72.86 %)
	Coronary Artery Disease (PBMQ)	Yes	937 (81.98 %)	943 (81.50 %)
	Hyperlipidemia (MLG)	Yes	660 (86.27 %)	647 (84.35 %)
	Hypertension (MLG)	Yes	1834 (69.47 %)	1834 (68.31 %)
	Region	Western Europe, Oceania and Others	428 (68.59 %)	414 (65.51 %)
	Type 2 Diabetes Mellitus (PT)	Yes	920 (75.60 %)	919 (75.14 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (0.18 %)	2 (0.12 %)
	Chronic Kidney Disease (PT)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (0.17 %)	1 (0.09 %)
	Hyperlipidemia (MLG)	Yes	1 (0.13 %)	1 (0.13 %)
	Hypertension (MLG)	Yes	2 (0.08 %)	2 (0.07 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
	Type 2 Diabetes Mellitus (PT)	Yes	2 (0.16 %)	0 (0.00 %)
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1198 (71.78 %)	1162 (70.42 %)
	Chronic Kidney Disease (PT)	Yes	448 (79.43 %)	439 (79.96 %)
	Coronary Artery Disease (PBMQ)	Yes	988 (86.44 %)	1000 (86.43 %)
	Hyperlipidemia (MLG)	Yes	702 (91.76 %)	681 (88.79 %)
	Hypertension (MLG)	Yes	2049 (77.61 %)	2074 (77.24 %)
	Region	Western Europe, Oceania and Others	476 (76.28 %)	473 (74.84 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1011 (83.07 %)	1001 (81.85 %)
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	128 (7.67 %)	160 (9.70 %)
	Chronic Kidney Disease (PT)	Yes	99 (17.55 %)	102 (18.58 %)
	Coronary Artery Disease (PBMQ)	Yes	161 (14.09 %)	161 (13.92 %)
	Hyperlipidemia (MLG)	Yes	110 (14.38 %)	121 (15.78 %)
	Hypertension (MLG)	Yes	316 (11.97 %)	331 (12.33 %)
	Region	Western Europe, Oceania and Others	70 (11.22 %)	91 (14.40 %)
	Type 2 Diabetes Mellitus (PT)	Yes	328 (26.95 %)	346 (28.29 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	213 (12.76 %)	237 (14.36 %)
	Chronic Kidney Disease (PT)	Yes	85 (15.07 %)	86 (15.66 %)
	Coronary Artery Disease (PBMQ)	Yes	140 (12.25 %)	152 (13.14 %)
	Hyperlipidemia (MLG)	Yes	99 (12.94 %)	107 (13.95 %)
	Hypertension (MLG)	Yes	346 (13.11 %)	386 (14.38 %)
	Region	Western Europe, Oceania and Others	118 (18.91 %)	129 (20.41 %)
	Type 2 Diabetes Mellitus (PT)	Yes	305 (25.06 %)	311 (25.43 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1482 (88.80 %)	1461 (88.55 %)
	Chronic Kidney Disease (PT)	Yes	294 (52.13 %)	293 (53.37 %)
	Coronary Artery Disease (PBMQ)	Yes	488 (42.69 %)	456 (39.41 %)
	Hyperlipidemia (MLG)	Yes	401 (52.42 %)	401 (52.28 %)
	Hypertension (MLG)	Yes	1372 (51.97 %)	1374 (51.17 %)
	Region	Western Europe, Oceania and Others	420 (67.31 %)	425 (67.25 %)
	Type 2 Diabetes Mellitus (PT)	Yes	557 (45.77 %)	577 (47.18 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	40 (2.40 %)	53 (3.21 %)
	Chronic Kidney Disease (PT)	Yes	27 (4.79 %)	33 (6.01 %)
	Coronary Artery Disease (PBMQ)	Yes	32 (2.80 %)	30 (2.59 %)
	Hyperlipidemia (MLG)	Yes	34 (4.44 %)	43 (5.61 %)
	Hypertension (MLG)	Yes	71 (2.69 %)	85 (3.17 %)
	Region	Western Europe, Oceania and Others	29 (4.65 %)	43 (6.80 %)
	Type 2 Diabetes Mellitus (PT)	Yes	77 (6.33 %)	87 (7.11 %)

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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	470 (28.16 %)	476 (28.85 %)
	Chronic Kidney Disease (PT)	Yes	90 (15.96 %)	86 (15.66 %)
	Coronary Artery Disease (PBMQ)	Yes	179 (15.66 %)	178 (15.38 %)
	Hyperlipidemia (MLG)	Yes	129 (16.86 %)	109 (14.21 %)
	Hypertension (MLG)	Yes	451 (17.08 %)	458 (17.06 %)
	Region	Western Europe, Oceania and Others	112 (17.95 %)	126 (19.94 %)
	Type 2 Diabetes Mellitus (PT)	Yes	172 (14.13 %)	194 (15.86 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	300 (17.97 %)	309 (18.73 %)
	Chronic Kidney Disease (PT)	Yes	113 (20.04 %)	124 (22.59 %)
	Coronary Artery Disease (PBMQ)	Yes	289 (25.28 %)	280 (24.20 %)
	Hyperlipidemia (MLG)	Yes	182 (23.79 %)	196 (25.55 %)
	Hypertension (MLG)	Yes	587 (22.23 %)	592 (22.05 %)
	Region	Western Europe, Oceania and Others	113 (18.11 %)	131 (20.73 %)
	Type 2 Diabetes Mellitus (PT)	Yes	615 (50.53 %)	625 (51.10 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	98 (5.87 %)	86 (5.21 %)
	Chronic Kidney Disease (PT)	Yes	39 (6.91 %)	42 (7.65 %)
	Coronary Artery Disease (PBMQ)	Yes	99 (8.66 %)	114 (9.85 %)
	Hyperlipidemia (MLG)	Yes	50 (6.54 %)	54 (7.04 %)
	Hypertension (MLG)	Yes	193 (7.31 %)	193 (7.19 %)
	Region	Western Europe, Oceania and Others	12 (1.92 %)	17 (2.69 %)
	Type 2 Diabetes Mellitus (PT)	Yes	202 (16.60 %)	207 (16.93 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	50 (3.00 %)	51 (3.09 %)
	Chronic Kidney Disease (PT)	Yes	13 (2.30 %)	16 (2.91 %)
	Coronary Artery Disease (PBMQ)	Yes	29 (2.54 %)	28 (2.42 %)
	Hyperlipidemia (MLG)	Yes	32 (4.18 %)	26 (3.39 %)
	Hypertension (MLG)	Yes	81 (3.07 %)	82 (3.05 %)
	Region	Western Europe, Oceania and Others	25 (4.01 %)	26 (4.11 %)
	Type 2 Diabetes Mellitus (PT)	Yes	91 (7.48 %)	89 (7.28 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	24 (1.44 %)	21 (1.27 %)
	Chronic Kidney Disease (PT)	Yes	8 (1.42 %)	11 (2.00 %)
	Coronary Artery Disease (PBMQ)	Yes	20 (1.75 %)	17 (1.47 %)
	Hyperlipidemia (MLG)	Yes	19 (2.48 %)	20 (2.61 %)
	Hypertension (MLG)	Yes	45 (1.70 %)	41 (1.53 %)
	Region	Western Europe, Oceania and Others	19 (3.04 %)	25 (3.96 %)
	Type 2 Diabetes Mellitus (PT)	Yes	21 (1.73 %)	24 (1.96 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	115 (6.89 %)	92 (5.58 %)
	Chronic Kidney Disease (PT)	Yes	49 (8.69 %)	52 (9.47 %)
	Coronary Artery Disease (PBMQ)	Yes	95 (8.31 %)	98 (8.47 %)
	Hyperlipidemia (MLG)	Yes	105 (13.73 %)	87 (11.34 %)
	Hypertension (MLG)	Yes	193 (7.31 %)	180 (6.70 %)
	Region	Western Europe, Oceania and Others	72 (11.54 %)	68 (10.76 %)
	Type 2 Diabetes Mellitus (PT)	Yes	116 (9.53 %)	101 (8.26 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication taken within the treatment period
Full Analysis Set

Standard drug grouping	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	2513 (83.68 %)	2538 (84.66 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	367 (12.22 %)	402 (13.41 %)
Beta-Blocker	2681 (89.28 %)	2664 (88.86 %)
Loop diuretics	2744 (91.38 %)	2739 (91.36 %)
Thiazide diuretics	551 (18.35 %)	543 (18.11 %)
Digoxin	374 (12.45 %)	377 (12.58 %)
Nitrate	487 (16.22 %)	477 (15.91 %)
Potassium supplements	613 (20.41 %)	776 (25.88 %)
Potassium lowering (incl.binders)	103 (3.43 %)	47 (1.57 %)
Alpha blocking agents	930 (30.97 %)	967 (32.25 %)
Calcium channel blockers	1200 (39.96 %)	1294 (43.16 %)
Centrally acting antihypertensivs	147 (4.90 %)	165 (5.50 %)
Strong CYP3A4 inhibitors	151 (5.03 %)	148 (4.94 %)
Moderate CYP3A4 inhibitors	303 (10.09 %)	299 (9.97 %)
Weak CYP3A4 inhibitors	2092 (69.66 %)	2082 (69.45 %)
Unclassified CYP3A4 inhibitors	426 (14.19 %)	457 (15.24 %)
Strong CYP3A4 inducers	20 (0.67 %)	14 (0.47 %)
Moderate CYP3A4 inducers	205 (6.83 %)	197 (6.57 %)
Weak CYP3A4 inducers	158 (5.26 %)	163 (5.44 %)
Unclassified CYP3A4 inducers	85 (2.83 %)	105 (3.50 %)
Acetylsalycylic acid and its salts	1141 (38.00 %)	1145 (38.19 %)
Statins	2182 (72.66 %)	2158 (71.98 %)
MRA	414 (13.79 %)	420 (14.01 %)
OATP substrates	2429 (80.89 %)	2439 (81.35 %)
Insulin and insulin analogues	494 (16.45 %)	498 (16.61 %)
Glycosurics as SGLT-2 inhibitors	881 (29.34 %)	971 (32.39 %)
Anticoagulants	1758 (58.54 %)	1739 (58.01 %)
Injectable glucagon-like peptide	146 (4.86 %)	162 (5.40 %)
Antiarrhythmic drugs	790 (26.31 %)	789 (26.32 %)
Biguanides	736 (24.51 %)	740 (24.68 %)
Sulfonylureas	257 (8.56 %)	252 (8.41 %)
Combinations of oral blood glucose lowering drugs	129 (4.30 %)	128 (4.27 %)
Combinations of various lipid modifying agents	69 (2.30 %)	74 (2.47 %)
Other lipid modifying agents	304 (10.12 %)	278 (9.27 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1341 (80.35 %)	1343 (81.39 %)
	Chronic Kidney Disease (PT)	Yes	454 (80.50 %)	446 (81.24 %)
	Coronary Artery Disease (PBMQ)	Yes	1006 (88.01 %)	1023 (88.42 %)
	Hyperlipidemia (MLG)	Yes	641 (83.79 %)	645 (84.09 %)
	Hypertension (MLG)	Yes	2290 (86.74 %)	2338 (87.08 %)
	Region	Western Europe, Oceania and Others	493 (79.01 %)	508 (80.38 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1053 (86.52 %)	1058 (86.51 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	178 (10.67 %)	201 (12.18 %)
	Chronic Kidney Disease (PT)	Yes	76 (13.48 %)	73 (13.30 %)
	Coronary Artery Disease (PBMQ)	Yes	188 (16.45 %)	199 (17.20 %)
	Hyperlipidemia (MLG)	Yes	101 (13.20 %)	96 (12.52 %)
	Hypertension (MLG)	Yes	284 (10.76 %)	336 (12.51 %)
	Region	Western Europe, Oceania and Others	50 (8.01 %)	56 (8.86 %)
	Type 2 Diabetes Mellitus (PT)	Yes	151 (12.41 %)	172 (14.06 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1517 (90.89 %)	1487 (90.12 %)
	Chronic Kidney Disease (PT)	Yes	512 (90.78 %)	493 (89.80 %)
	Coronary Artery Disease (PBMQ)	Yes	1055 (92.30 %)	1058 (91.44 %)
	Hyperlipidemia (MLG)	Yes	695 (90.85 %)	690 (89.96 %)
	Hypertension (MLG)	Yes	2364 (89.55 %)	2395 (89.20 %)
	Region	Western Europe, Oceania and Others	533 (85.42 %)	546 (86.39 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1094 (89.89 %)	1104 (90.27 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1567 (93.89 %)	1563 (94.73 %)
	Chronic Kidney Disease (PT)	Yes	528 (93.62 %)	517 (94.17 %)
	Coronary Artery Disease (PBMQ)	Yes	1032 (90.29 %)	1058 (91.44 %)
	Hyperlipidemia (MLG)	Yes	692 (90.46 %)	698 (91.00 %)
	Hypertension (MLG)	Yes	2393 (90.64 %)	2437 (90.76 %)
	Region	Western Europe, Oceania and Others	593 (95.03 %)	611 (96.68 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1121 (92.11 %)	1128 (92.23 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	275 (16.48 %)	263 (15.94 %)
	Chronic Kidney Disease (PT)	Yes	108 (19.15 %)	109 (19.85 %)
	Coronary Artery Disease (PBMQ)	Yes	199 (17.41 %)	221 (19.10 %)
	Hyperlipidemia (MLG)	Yes	143 (18.69 %)	138 (17.99 %)
	Hypertension (MLG)	Yes	530 (20.08 %)	518 (19.29 %)
	Region	Western Europe, Oceania and Others	119 (19.07 %)	120 (18.99 %)
	Type 2 Diabetes Mellitus (PT)	Yes	237 (19.47 %)	232 (18.97 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	341 (20.43 %)	336 (20.36 %)
	Chronic Kidney Disease (PT)	Yes	63 (11.17 %)	47 (8.56 %)
	Coronary Artery Disease (PBMQ)	Yes	133 (11.64 %)	131 (11.32 %)
	Hyperlipidemia (MLG)	Yes	78 (10.20 %)	77 (10.04 %)
	Hypertension (MLG)	Yes	317 (12.01 %)	332 (12.36 %)
	Region	Western Europe, Oceania and Others	87 (13.94 %)	86 (13.61 %)
	Type 2 Diabetes Mellitus (PT)	Yes	126 (10.35 %)	145 (11.86 %)
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	235 (14.08 %)	245 (14.85 %)
	Chronic Kidney Disease (PT)	Yes	120 (21.28 %)	117 (21.31 %)
	Coronary Artery Disease (PBMQ)	Yes	307 (26.86 %)	282 (24.37 %)
	Hyperlipidemia (MLG)	Yes	161 (21.05 %)	141 (18.38 %)
	Hypertension (MLG)	Yes	436 (16.52 %)	433 (16.13 %)
	Region	Western Europe, Oceania and Others	110 (17.63 %)	108 (17.09 %)
	Type 2 Diabetes Mellitus (PT)	Yes	238 (19.56 %)	226 (18.48 %)

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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	407 (24.39 %)	500 (30.30 %)
	Chronic Kidney Disease (PT)	Yes	129 (22.87 %)	137 (24.95 %)
	Coronary Artery Disease (PBMQ)	Yes	263 (23.01 %)	316 (27.31 %)
	Hyperlipidemia (MLG)	Yes	214 (27.97 %)	263 (34.29 %)
	Hypertension (MLG)	Yes	535 (20.27 %)	680 (25.33 %)
	Region	Western Europe, Oceania and Others	128 (20.51 %)	185 (29.27 %)
	Type 2 Diabetes Mellitus (PT)	Yes	227 (18.65 %)	311 (25.43 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	61 (3.65 %)	28 (1.70 %)
	Chronic Kidney Disease (PT)	Yes	39 (6.91 %)	21 (3.83 %)
	Coronary Artery Disease (PBMQ)	Yes	36 (3.15 %)	16 (1.38 %)
	Hyperlipidemia (MLG)	Yes	36 (4.71 %)	21 (2.74 %)
	Hypertension (MLG)	Yes	91 (3.45 %)	40 (1.49 %)
	Region	Western Europe, Oceania and Others	28 (4.49 %)	18 (2.85 %)
	Type 2 Diabetes Mellitus (PT)	Yes	61 (5.01 %)	28 (2.29 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	496 (29.72 %)	505 (30.61 %)
	Chronic Kidney Disease (PT)	Yes	223 (39.54 %)	251 (45.72 %)
	Coronary Artery Disease (PBMQ)	Yes	374 (32.72 %)	393 (33.97 %)
	Hyperlipidemia (MLG)	Yes	261 (34.12 %)	292 (38.07 %)
	Hypertension (MLG)	Yes	847 (32.08 %)	881 (32.81 %)
	Region	Western Europe, Oceania and Others	196 (31.41 %)	214 (33.86 %)
	Type 2 Diabetes Mellitus (PT)	Yes	436 (35.83 %)	474 (38.76 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	621 (37.21 %)	667 (40.42 %)
	Chronic Kidney Disease (PT)	Yes	275 (48.76 %)	275 (50.09 %)
	Coronary Artery Disease (PBMQ)	Yes	494 (43.22 %)	490 (42.35 %)
	Hyperlipidemia (MLG)	Yes	326 (42.61 %)	348 (45.37 %)
	Hypertension (MLG)	Yes	1162 (44.02 %)	1252 (46.63 %)
	Region	Western Europe, Oceania and Others	234 (37.50 %)	266 (42.09 %)
	Type 2 Diabetes Mellitus (PT)	Yes	542 (44.54 %)	588 (48.08 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	70 (4.19 %)	81 (4.91 %)
	Chronic Kidney Disease (PT)	Yes	47 (8.33 %)	39 (7.10 %)
	Coronary Artery Disease (PBMQ)	Yes	69 (6.04 %)	71 (6.14 %)
	Hyperlipidemia (MLG)	Yes	41 (5.36 %)	39 (5.08 %)
	Hypertension (MLG)	Yes	147 (5.57 %)	165 (6.15 %)
	Region	Western Europe, Oceania and Others	18 (2.88 %)	18 (2.85 %)
	Type 2 Diabetes Mellitus (PT)	Yes	75 (6.16 %)	80 (6.54 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	84 (5.03 %)	76 (4.61 %)
	Chronic Kidney Disease (PT)	Yes	34 (6.03 %)	28 (5.10 %)
	Coronary Artery Disease (PBMQ)	Yes	76 (6.65 %)	77 (6.66 %)
	Hyperlipidemia (MLG)	Yes	44 (5.75 %)	43 (5.61 %)
	Hypertension (MLG)	Yes	124 (4.70 %)	122 (4.54 %)
	Region	Western Europe, Oceania and Others	37 (5.93 %)	35 (5.54 %)
	Type 2 Diabetes Mellitus (PT)	Yes	58 (4.77 %)	61 (4.99 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	189 (11.32 %)	190 (11.52 %)
	Chronic Kidney Disease (PT)	Yes	69 (12.23 %)	59 (10.75 %)
	Coronary Artery Disease (PBMQ)	Yes	125 (10.94 %)	107 (9.25 %)
	Hyperlipidemia (MLG)	Yes	96 (12.55 %)	91 (11.86 %)
	Hypertension (MLG)	Yes	275 (10.42 %)	269 (10.02 %)
	Region	Western Europe, Oceania and Others	81 (12.98 %)	93 (14.72 %)
	Type 2 Diabetes Mellitus (PT)	Yes	132 (10.85 %)	130 (10.63 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1136 (68.06 %)	1104 (66.91 %)
	Chronic Kidney Disease (PT)	Yes	432 (76.60 %)	433 (78.87 %)
	Coronary Artery Disease (PBMQ)	Yes	838 (73.32 %)	865 (74.76 %)
	Hyperlipidemia (MLG)	Yes	579 (75.69 %)	574 (74.84 %)
	Hypertension (MLG)	Yes	1885 (71.40 %)	1903 (70.88 %)
	Region	Western Europe, Oceania and Others	432 (69.23 %)	435 (68.83 %)
	Type 2 Diabetes Mellitus (PT)	Yes	881 (72.39 %)	907 (74.16 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	261 (15.64 %)	286 (17.33 %)
	Chronic Kidney Disease (PT)	Yes	98 (17.38 %)	102 (18.58 %)
	Coronary Artery Disease (PBMQ)	Yes	168 (14.70 %)	174 (15.04 %)
	Hyperlipidemia (MLG)	Yes	119 (15.56 %)	133 (17.34 %)
	Hypertension (MLG)	Yes	368 (13.94 %)	400 (14.90 %)
	Region	Western Europe, Oceania and Others	108 (17.31 %)	125 (19.78 %)
	Type 2 Diabetes Mellitus (PT)	Yes	175 (14.38 %)	197 (16.11 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	9 (0.54 %)	4 (0.24 %)
	Chronic Kidney Disease (PT)	Yes	6 (1.06 %)	2 (0.36 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (0.70 %)	8 (0.69 %)
	Hyperlipidemia (MLG)	Yes	4 (0.52 %)	4 (0.52 %)
	Hypertension (MLG)	Yes	18 (0.68 %)	12 (0.45 %)
	Region	Western Europe, Oceania and Others	4 (0.64 %)	2 (0.32 %)
	Type 2 Diabetes Mellitus (PT)	Yes	9 (0.74 %)	7 (0.57 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	109 (6.53 %)	108 (6.55 %)
	Chronic Kidney Disease (PT)	Yes	51 (9.04 %)	49 (8.93 %)
	Coronary Artery Disease (PBMQ)	Yes	87 (7.61 %)	96 (8.30 %)
	Hyperlipidemia (MLG)	Yes	60 (7.84 %)	52 (6.78 %)
	Hypertension (MLG)	Yes	190 (7.20 %)	175 (6.52 %)
	Region	Western Europe, Oceania and Others	49 (7.85 %)	45 (7.12 %)
	Type 2 Diabetes Mellitus (PT)	Yes	89 (7.31 %)	83 (6.79 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	82 (4.91 %)	96 (5.82 %)
	Chronic Kidney Disease (PT)	Yes	41 (7.27 %)	41 (7.47 %)
	Coronary Artery Disease (PBMQ)	Yes	58 (5.07 %)	63 (5.45 %)
	Hyperlipidemia (MLG)	Yes	63 (8.24 %)	62 (8.08 %)
	Hypertension (MLG)	Yes	143 (5.42 %)	151 (5.62 %)
	Region	Western Europe, Oceania and Others	76 (12.18 %)	75 (11.87 %)
	Type 2 Diabetes Mellitus (PT)	Yes	75 (6.16 %)	75 (6.13 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	54 (3.24 %)	70 (4.24 %)
	Chronic Kidney Disease (PT)	Yes	15 (2.66 %)	26 (4.74 %)
	Coronary Artery Disease (PBMQ)	Yes	33 (2.89 %)	33 (2.85 %)
	Hyperlipidemia (MLG)	Yes	26 (3.40 %)	19 (2.48 %)
	Hypertension (MLG)	Yes	75 (2.84 %)	91 (3.39 %)
	Region	Western Europe, Oceania and Others	31 (4.97 %)	38 (6.01 %)
	Type 2 Diabetes Mellitus (PT)	Yes	34 (2.79 %)	32 (2.62 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	278 (16.66 %)	276 (16.73 %)
	Chronic Kidney Disease (PT)	Yes	225 (39.89 %)	223 (40.62 %)
	Coronary Artery Disease (PBMQ)	Yes	630 (55.12 %)	644 (55.66 %)
	Hyperlipidemia (MLG)	Yes	336 (43.92 %)	329 (42.89 %)
	Hypertension (MLG)	Yes	1032 (39.09 %)	1043 (38.85 %)
	Region	Western Europe, Oceania and Others	172 (27.56 %)	188 (29.75 %)
	Type 2 Diabetes Mellitus (PT)	Yes	532 (43.71 %)	538 (43.99 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1141 (68.36 %)	1098 (66.55 %)
	Chronic Kidney Disease (PT)	Yes	441 (78.19 %)	427 (77.78 %)
	Coronary Artery Disease (PBMQ)	Yes	981 (85.83 %)	984 (85.05 %)
	Hyperlipidemia (MLG)	Yes	684 (89.41 %)	669 (87.22 %)
	Hypertension (MLG)	Yes	1957 (74.13 %)	1964 (73.15 %)
	Region	Western Europe, Oceania and Others	462 (74.04 %)	448 (70.89 %)
	Type 2 Diabetes Mellitus (PT)	Yes	975 (80.12 %)	973 (79.56 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	269 (16.12 %)	270 (16.36 %)
	Chronic Kidney Disease (PT)	Yes	88 (15.60 %)	77 (14.03 %)
	Coronary Artery Disease (PBMQ)	Yes	156 (13.65 %)	164 (14.17 %)
	Hyperlipidemia (MLG)	Yes	109 (14.25 %)	106 (13.82 %)
	Hypertension (MLG)	Yes	350 (13.26 %)	365 (13.59 %)
	Region	Western Europe, Oceania and Others	111 (17.79 %)	125 (19.78 %)
	Type 2 Diabetes Mellitus (PT)	Yes	175 (14.38 %)	189 (15.45 %)
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1294 (77.53 %)	1261 (76.42 %)
	Chronic Kidney Disease (PT)	Yes	481 (85.28 %)	471 (85.79 %)
	Coronary Artery Disease (PBMQ)	Yes	1023 (89.50 %)	1041 (89.97 %)
	Hyperlipidemia (MLG)	Yes	718 (93.86 %)	704 (91.79 %)
	Hypertension (MLG)	Yes	2169 (82.16 %)	2211 (82.35 %)
	Region	Western Europe, Oceania and Others	507 (81.25 %)	509 (80.54 %)
	Type 2 Diabetes Mellitus (PT)	Yes	1053 (86.52 %)	1058 (86.51 %)
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	220 (13.18 %)	243 (14.73 %)
	Chronic Kidney Disease (PT)	Yes	134 (23.76 %)	143 (26.05 %)
	Coronary Artery Disease (PBMQ)	Yes	237 (20.73 %)	219 (18.93 %)
	Hyperlipidemia (MLG)	Yes	151 (19.74 %)	168 (21.90 %)
	Hypertension (MLG)	Yes	462 (17.50 %)	464 (17.28 %)
	Region	Western Europe, Oceania and Others	115 (18.43 %)	132 (20.89 %)
	Type 2 Diabetes Mellitus (PT)	Yes	454 (37.30 %)	460 (37.61 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	516 (30.92 %)	563 (34.12 %)
	Chronic Kidney Disease (PT)	Yes	204 (36.17 %)	202 (36.79 %)
	Coronary Artery Disease (PBMQ)	Yes	320 (28.00 %)	353 (30.51 %)
	Hyperlipidemia (MLG)	Yes	248 (32.42 %)	252 (32.86 %)
	Hypertension (MLG)	Yes	782 (29.62 %)	876 (32.63 %)
	Region	Western Europe, Oceania and Others	278 (44.55 %)	316 (50.00 %)
	Type 2 Diabetes Mellitus (PT)	Yes	562 (46.18 %)	554 (45.30 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1552 (92.99 %)	1531 (92.79 %)
	Chronic Kidney Disease (PT)	Yes	326 (57.80 %)	325 (59.20 %)
	Coronary Artery Disease (PBMQ)	Yes	568 (49.69 %)	556 (48.06 %)
	Hyperlipidemia (MLG)	Yes	443 (57.91 %)	444 (57.89 %)
	Hypertension (MLG)	Yes	1538 (58.26 %)	1558 (58.03 %)
	Region	Western Europe, Oceania and Others	454 (72.76 %)	456 (72.15 %)
	Type 2 Diabetes Mellitus (PT)	Yes	637 (52.34 %)	670 (54.78 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	72 (4.31 %)	90 (5.45 %)
	Chronic Kidney Disease (PT)	Yes	43 (7.62 %)	51 (9.29 %)
	Coronary Artery Disease (PBMQ)	Yes	60 (5.25 %)	57 (4.93 %)
	Hyperlipidemia (MLG)	Yes	63 (8.24 %)	69 (9.00 %)
	Hypertension (MLG)	Yes	133 (5.04 %)	155 (5.77 %)
	Region	Western Europe, Oceania and Others	58 (9.29 %)	75 (11.87 %)
	Type 2 Diabetes Mellitus (PT)	Yes	133 (10.93 %)	152 (12.43 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	667 (39.96 %)	663 (40.18 %)
	Chronic Kidney Disease (PT)	Yes	148 (26.24 %)	143 (26.05 %)
	Coronary Artery Disease (PBMQ)	Yes	273 (23.88 %)	278 (24.03 %)
	Hyperlipidemia (MLG)	Yes	190 (24.84 %)	179 (23.34 %)
	Hypertension (MLG)	Yes	684 (25.91 %)	697 (25.96 %)
	Region	Western Europe, Oceania and Others	187 (29.97 %)	193 (30.54 %)
	Type 2 Diabetes Mellitus (PT)	Yes	276 (22.68 %)	307 (25.10 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	351 (21.03 %)	369 (22.36 %)
	Chronic Kidney Disease (PT)	Yes	140 (24.82 %)	144 (26.23 %)
	Coronary Artery Disease (PBMQ)	Yes	338 (29.57 %)	329 (28.44 %)
	Hyperlipidemia (MLG)	Yes	216 (28.24 %)	230 (29.99 %)
	Hypertension (MLG)	Yes	683 (25.87 %)	690 (25.70 %)
	Region	Western Europe, Oceania and Others	135 (21.63 %)	153 (24.21 %)
	Type 2 Diabetes Mellitus (PT)	Yes	687 (56.45 %)	685 (56.01 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	128 (7.67 %)	104 (6.30 %)
	Chronic Kidney Disease (PT)	Yes	50 (8.87 %)	50 (9.11 %)
	Coronary Artery Disease (PBMQ)	Yes	127 (11.11 %)	135 (11.67 %)
	Hyperlipidemia (MLG)	Yes	68 (8.89 %)	71 (9.26 %)
	Hypertension (MLG)	Yes	244 (9.24 %)	236 (8.79 %)
	Region	Western Europe, Oceania and Others	15 (2.40 %)	17 (2.69 %)
	Type 2 Diabetes Mellitus (PT)	Yes	253 (20.79 %)	241 (19.71 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	70 (4.19 %)	66 (4.00 %)
	Chronic Kidney Disease (PT)	Yes	20 (3.55 %)	24 (4.37 %)
	Coronary Artery Disease (PBMQ)	Yes	49 (4.29 %)	43 (3.72 %)
	Hyperlipidemia (MLG)	Yes	43 (5.62 %)	43 (5.61 %)
	Hypertension (MLG)	Yes	116 (4.39 %)	120 (4.47 %)
	Region	Western Europe, Oceania and Others	36 (5.77 %)	37 (5.85 %)
	Type 2 Diabetes Mellitus (PT)	Yes	128 (10.52 %)	121 (9.89 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	30 (1.80 %)	30 (1.82 %)
	Chronic Kidney Disease (PT)	Yes	10 (1.77 %)	17 (3.10 %)
	Coronary Artery Disease (PBMQ)	Yes	26 (2.27 %)	25 (2.16 %)
	Hyperlipidemia (MLG)	Yes	27 (3.53 %)	31 (4.04 %)
	Hypertension (MLG)	Yes	59 (2.23 %)	62 (2.31 %)
	Region	Western Europe, Oceania and Others	24 (3.85 %)	36 (5.70 %)
	Type 2 Diabetes Mellitus (PT)	Yes	26 (2.14 %)	36 (2.94 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	158 (9.47 %)	130 (7.88 %)
	Chronic Kidney Disease (PT)	Yes	63 (11.17 %)	67 (12.20 %)
	Coronary Artery Disease (PBMQ)	Yes	143 (12.51 %)	137 (11.84 %)
	Hyperlipidemia (MLG)	Yes	137 (17.91 %)	105 (13.69 %)
	Hypertension (MLG)	Yes	271 (10.27 %)	250 (9.31 %)
	Region	Western Europe, Oceania and Others	93 (14.90 %)	94 (14.87 %)
	Type 2 Diabetes Mellitus (PT)	Yes	157 (12.90 %)	134 (10.96 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication that started after start of study drug
Full Analysis Set

Standard drug grouping	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	995 (33.13 %)	1022 (34.09 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	217 (7.23 %)	250 (8.34 %)
Beta-Blocker	999 (33.27 %)	1014 (33.82 %)
Loop diuretics	1441 (47.99 %)	1441 (48.07 %)
Thiazide diuretics	208 (6.93 %)	213 (7.10 %)
Digoxin	199 (6.63 %)	189 (6.30 %)
Nitrate	266 (8.86 %)	282 (9.41 %)
Potassium supplements	385 (12.82 %)	557 (18.58 %)
Potassium lowering (incl.binders)	102 (3.40 %)	41 (1.37 %)
Alpha blocking agents	400 (13.32 %)	456 (15.21 %)
Calcium channel blockers	523 (17.42 %)	591 (19.71 %)
Centrally acting antihypertensivs	67 (2.23 %)	70 (2.33 %)
Strong CYP3A4 inhibitors	133 (4.43 %)	133 (4.44 %)
Moderate CYP3A4 inhibitors	257 (8.56 %)	252 (8.41 %)
Weak CYP3A4 inhibitors	938 (31.24 %)	941 (31.39 %)
Unclassified CYP3A4 inhibitors	392 (13.05 %)	427 (14.24 %)
Strong CYP3A4 inducers	16 (0.53 %)	9 (0.30 %)
Moderate CYP3A4 inducers	196 (6.53 %)	191 (6.37 %)
Weak CYP3A4 inducers	134 (4.46 %)	137 (4.57 %)
Unclassified CYP3A4 inducers	77 (2.56 %)	93 (3.10 %)
Acetylsalycylic acid and its salts	276 (9.19 %)	265 (8.84 %)
Statins	530 (17.65 %)	519 (17.31 %)
MRA	410 (13.65 %)	418 (13.94 %)
OATP substrates	846 (28.17 %)	876 (29.22 %)
Insulin and insulin analogues	305 (10.16 %)	289 (9.64 %)
Glycosurics as SGLT-2 inhibitors	596 (19.85 %)	656 (21.88 %)
Anticoagulants	720 (23.98 %)	704 (23.48 %)
Injectable glucagon-like peptide	92 (3.06 %)	112 (3.74 %)
Antiarrhythmic drugs	450 (14.99 %)	427 (14.24 %)
Biguanides	226 (7.53 %)	235 (7.84 %)
Sulfonylureas	88 (2.93 %)	79 (2.64 %)
Combinations of oral blood glucose lowering drugs	56 (1.86 %)	53 (1.77 %)
Combinations of various lipid modifying agents	18 (0.60 %)	34 (1.13 %)
Other lipid modifying agents	122 (4.06 %)	117 (3.90 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	553 (33.13 %)	577 (34.97 %)
	Chronic Kidney Disease (PT)	Yes	223 (39.54 %)	222 (40.44 %)
	Coronary Artery Disease (PBMQ)	Yes	415 (36.31 %)	402 (34.75 %)
	Hyperlipidemia (MLG)	Yes	270 (35.29 %)	271 (35.33 %)
	Hypertension (MLG)	Yes	910 (34.47 %)	940 (35.01 %)
	Region	Western Europe, Oceania and Others	236 (37.82 %)	261 (41.30 %)
	Type 2 Diabetes Mellitus (PT)	Yes	438 (35.99 %)	425 (34.75 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	107 (6.41 %)	131 (7.94 %)
	Chronic Kidney Disease (PT)	Yes	51 (9.04 %)	54 (9.84 %)
	Coronary Artery Disease (PBMQ)	Yes	126 (11.02 %)	133 (11.50 %)
	Hyperlipidemia (MLG)	Yes	66 (8.63 %)	64 (8.34 %)
	Hypertension (MLG)	Yes	179 (6.78 %)	217 (8.08 %)
	Region	Western Europe, Oceania and Others	32 (5.13 %)	37 (5.85 %)
	Type 2 Diabetes Mellitus (PT)	Yes	88 (7.23 %)	106 (8.67 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	608 (36.43 %)	635 (38.48 %)
	Chronic Kidney Disease (PT)	Yes	227 (40.25 %)	218 (39.71 %)
	Coronary Artery Disease (PBMQ)	Yes	383 (33.51 %)	390 (33.71 %)
	Hyperlipidemia (MLG)	Yes	267 (34.90 %)	264 (34.42 %)
	Hypertension (MLG)	Yes	875 (33.14 %)	912 (33.97 %)
	Region	Western Europe, Oceania and Others	257 (41.19 %)	248 (39.24 %)
	Type 2 Diabetes Mellitus (PT)	Yes	424 (34.84 %)	423 (34.59 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	888 (53.21 %)	891 (54.00 %)
	Chronic Kidney Disease (PT)	Yes	335 (59.40 %)	324 (59.02 %)
	Coronary Artery Disease (PBMQ)	Yes	530 (46.37 %)	525 (45.38 %)
	Hyperlipidemia (MLG)	Yes	404 (52.81 %)	378 (49.28 %)
	Hypertension (MLG)	Yes	1272 (48.18 %)	1294 (48.19 %)
	Region	Western Europe, Oceania and Others	405 (64.90 %)	428 (67.72 %)
	Type 2 Diabetes Mellitus (PT)	Yes	615 (50.53 %)	607 (49.63 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	114 (6.83 %)	113 (6.85 %)
	Chronic Kidney Disease (PT)	Yes	62 (10.99 %)	59 (10.75 %)
	Coronary Artery Disease (PBMQ)	Yes	81 (7.09 %)	83 (7.17 %)
	Hyperlipidemia (MLG)	Yes	59 (7.71 %)	60 (7.82 %)
	Hypertension (MLG)	Yes	196 (7.42 %)	198 (7.37 %)
	Region	Western Europe, Oceania and Others	47 (7.53 %)	57 (9.02 %)
	Type 2 Diabetes Mellitus (PT)	Yes	94 (7.72 %)	90 (7.36 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	174 (10.43 %)	156 (9.45 %)
	Chronic Kidney Disease (PT)	Yes	40 (7.09 %)	26 (4.74 %)
	Coronary Artery Disease (PBMQ)	Yes	70 (6.12 %)	69 (5.96 %)
	Hyperlipidemia (MLG)	Yes	33 (4.31 %)	39 (5.08 %)
	Hypertension (MLG)	Yes	172 (6.52 %)	172 (6.41 %)
	Region	Western Europe, Oceania and Others	54 (8.65 %)	51 (8.07 %)
	Type 2 Diabetes Mellitus (PT)	Yes	67 (5.51 %)	79 (6.46 %)
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	134 (8.03 %)	148 (8.97 %)
	Chronic Kidney Disease (PT)	Yes	69 (12.23 %)	69 (12.57 %)
	Coronary Artery Disease (PBMQ)	Yes	163 (14.26 %)	147 (12.71 %)
	Hyperlipidemia (MLG)	Yes	88 (11.50 %)	82 (10.69 %)
	Hypertension (MLG)	Yes	240 (9.09 %)	253 (9.42 %)
	Region	Western Europe, Oceania and Others	58 (9.29 %)	72 (11.39 %)
	Type 2 Diabetes Mellitus (PT)	Yes	137 (11.26 %)	132 (10.79 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	255 (15.28 %)	360 (21.82 %)
	Chronic Kidney Disease (PT)	Yes	102 (18.09 %)	108 (19.67 %)
	Coronary Artery Disease (PBMQ)	Yes	173 (15.14 %)	231 (19.97 %)
	Hyperlipidemia (MLG)	Yes	125 (16.34 %)	155 (20.21 %)
	Hypertension (MLG)	Yes	337 (12.77 %)	485 (18.06 %)
	Region	Western Europe, Oceania and Others	92 (14.74 %)	154 (24.37 %)
	Type 2 Diabetes Mellitus (PT)	Yes	147 (12.08 %)	220 (17.99 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	60 (3.59 %)	22 (1.33 %)
	Chronic Kidney Disease (PT)	Yes	38 (6.74 %)	17 (3.10 %)
	Coronary Artery Disease (PBMQ)	Yes	35 (3.06 %)	14 (1.21 %)
	Hyperlipidemia (MLG)	Yes	36 (4.71 %)	19 (2.48 %)
	Hypertension (MLG)	Yes	90 (3.41 %)	34 (1.27 %)
	Region	Western Europe, Oceania and Others	28 (4.49 %)	16 (2.53 %)
	Type 2 Diabetes Mellitus (PT)	Yes	60 (4.93 %)	26 (2.13 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	200 (11.98 %)	250 (15.15 %)
	Chronic Kidney Disease (PT)	Yes	113 (20.04 %)	125 (22.77 %)
	Coronary Artery Disease (PBMQ)	Yes	173 (15.14 %)	191 (16.51 %)
	Hyperlipidemia (MLG)	Yes	108 (14.12 %)	131 (17.08 %)
	Hypertension (MLG)	Yes	362 (13.71 %)	418 (15.57 %)
	Region	Western Europe, Oceania and Others	87 (13.94 %)	95 (15.03 %)
	Type 2 Diabetes Mellitus (PT)	Yes	188 (15.45 %)	217 (17.74 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	291 (17.44 %)	327 (19.82 %)
	Chronic Kidney Disease (PT)	Yes	142 (25.18 %)	145 (26.41 %)
	Coronary Artery Disease (PBMQ)	Yes	215 (18.81 %)	222 (19.19 %)
	Hyperlipidemia (MLG)	Yes	152 (19.87 %)	147 (19.17 %)
	Hypertension (MLG)	Yes	499 (18.90 %)	563 (20.97 %)
	Region	Western Europe, Oceania and Others	118 (18.91 %)	138 (21.84 %)
	Type 2 Diabetes Mellitus (PT)	Yes	230 (18.90 %)	265 (21.67 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	35 (2.10 %)	33 (2.00 %)
	Chronic Kidney Disease (PT)	Yes	23 (4.08 %)	23 (4.19 %)
	Coronary Artery Disease (PBMQ)	Yes	27 (2.36 %)	31 (2.68 %)
	Hyperlipidemia (MLG)	Yes	15 (1.96 %)	17 (2.22 %)
	Hypertension (MLG)	Yes	67 (2.54 %)	70 (2.61 %)
	Region	Western Europe, Oceania and Others	10 (1.60 %)	10 (1.58 %)
	Type 2 Diabetes Mellitus (PT)	Yes	32 (2.63 %)	31 (2.53 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	74 (4.43 %)	72 (4.36 %)
	Chronic Kidney Disease (PT)	Yes	31 (5.50 %)	24 (4.37 %)
	Coronary Artery Disease (PBMQ)	Yes	69 (6.04 %)	68 (5.88 %)
	Hyperlipidemia (MLG)	Yes	41 (5.36 %)	39 (5.08 %)
	Hypertension (MLG)	Yes	113 (4.28 %)	112 (4.17 %)
	Region	Western Europe, Oceania and Others	34 (5.45 %)	33 (5.22 %)
	Type 2 Diabetes Mellitus (PT)	Yes	53 (4.35 %)	55 (4.50 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	162 (9.71 %)	159 (9.64 %)
	Chronic Kidney Disease (PT)	Yes	59 (10.46 %)	47 (8.56 %)
	Coronary Artery Disease (PBMQ)	Yes	102 (8.92 %)	96 (8.30 %)
	Hyperlipidemia (MLG)	Yes	80 (10.46 %)	76 (9.91 %)
	Hypertension (MLG)	Yes	233 (8.83 %)	230 (8.57 %)
	Region	Western Europe, Oceania and Others	68 (10.90 %)	80 (12.66 %)
	Type 2 Diabetes Mellitus (PT)	Yes	112 (9.20 %)	112 (9.16 %)

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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	553 (33.13 %)	542 (32.85 %)
	Chronic Kidney Disease (PT)	Yes	233 (41.31 %)	217 (39.53 %)
	Coronary Artery Disease (PBMQ)	Yes	371 (32.46 %)	388 (33.54 %)
	Hyperlipidemia (MLG)	Yes	260 (33.99 %)	241 (31.42 %)
	Hypertension (MLG)	Yes	839 (31.78 %)	836 (31.14 %)
	Region	Western Europe, Oceania and Others	206 (33.01 %)	219 (34.65 %)
	Type 2 Diabetes Mellitus (PT)	Yes	383 (31.47 %)	411 (33.61 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	242 (14.50 %)	266 (16.12 %)
	Chronic Kidney Disease (PT)	Yes	91 (16.13 %)	94 (17.12 %)
	Coronary Artery Disease (PBMQ)	Yes	159 (13.91 %)	167 (14.43 %)
	Hyperlipidemia (MLG)	Yes	114 (14.90 %)	129 (16.82 %)
	Hypertension (MLG)	Yes	338 (12.80 %)	373 (13.89 %)
	Region	Western Europe, Oceania and Others	93 (14.90 %)	111 (17.56 %)
	Type 2 Diabetes Mellitus (PT)	Yes	162 (13.31 %)	187 (15.29 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (0.48 %)	4 (0.24 %)
	Chronic Kidney Disease (PT)	Yes	6 (1.06 %)	2 (0.36 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (0.52 %)	5 (0.43 %)
	Hyperlipidemia (MLG)	Yes	3 (0.39 %)	3 (0.39 %)
	Hypertension (MLG)	Yes	14 (0.53 %)	7 (0.26 %)
	Region	Western Europe, Oceania and Others	3 (0.48 %)	2 (0.32 %)
	Type 2 Diabetes Mellitus (PT)	Yes	7 (0.58 %)	6 (0.49 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	104 (6.23 %)	104 (6.30 %)
	Chronic Kidney Disease (PT)	Yes	49 (8.69 %)	48 (8.74 %)
	Coronary Artery Disease (PBMQ)	Yes	83 (7.26 %)	92 (7.95 %)
	Hyperlipidemia (MLG)	Yes	57 (7.45 %)	49 (6.39 %)
	Hypertension (MLG)	Yes	182 (6.89 %)	169 (6.29 %)
	Region	Western Europe, Oceania and Others	46 (7.37 %)	45 (7.12 %)
	Type 2 Diabetes Mellitus (PT)	Yes	87 (7.15 %)	81 (6.62 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	74 (4.43 %)	83 (5.03 %)
	Chronic Kidney Disease (PT)	Yes	40 (7.09 %)	35 (6.38 %)
	Coronary Artery Disease (PBMQ)	Yes	48 (4.20 %)	52 (4.49 %)
	Hyperlipidemia (MLG)	Yes	51 (6.67 %)	53 (6.91 %)
	Hypertension (MLG)	Yes	123 (4.66 %)	128 (4.77 %)
	Region	Western Europe, Oceania and Others	68 (10.90 %)	63 (9.97 %)
	Type 2 Diabetes Mellitus (PT)	Yes	62 (5.09 %)	59 (4.82 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	49 (2.94 %)	61 (3.70 %)
	Chronic Kidney Disease (PT)	Yes	15 (2.66 %)	20 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	31 (2.71 %)	29 (2.51 %)
	Hyperlipidemia (MLG)	Yes	23 (3.01 %)	15 (1.96 %)
	Hypertension (MLG)	Yes	67 (2.54 %)	81 (3.02 %)
	Region	Western Europe, Oceania and Others	28 (4.49 %)	34 (5.38 %)
	Type 2 Diabetes Mellitus (PT)	Yes	30 (2.47 %)	27 (2.21 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	139 (8.33 %)	112 (6.79 %)
	Chronic Kidney Disease (PT)	Yes	67 (11.88 %)	60 (10.93 %)
	Coronary Artery Disease (PBMQ)	Yes	140 (12.25 %)	133 (11.50 %)
	Hyperlipidemia (MLG)	Yes	86 (11.24 %)	65 (8.47 %)
	Hypertension (MLG)	Yes	255 (9.66 %)	241 (8.98 %)
	Region	Western Europe, Oceania and Others	55 (8.81 %)	62 (9.81 %)
	Type 2 Diabetes Mellitus (PT)	Yes	122 (10.02 %)	117 (9.57 %)

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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	275 (16.48 %)	292 (17.70 %)
	Chronic Kidney Disease (PT)	Yes	129 (22.87 %)	112 (20.40 %)
	Coronary Artery Disease (PBMQ)	Yes	249 (21.78 %)	237 (20.48 %)
	Hyperlipidemia (MLG)	Yes	142 (18.56 %)	137 (17.86 %)
	Hypertension (MLG)	Yes	467 (17.69 %)	460 (17.13 %)
	Region	Western Europe, Oceania and Others	116 (18.59 %)	127 (20.09 %)
	Type 2 Diabetes Mellitus (PT)	Yes	230 (18.90 %)	237 (19.38 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	265 (15.88 %)	269 (16.30 %)
	Chronic Kidney Disease (PT)	Yes	88 (15.60 %)	77 (14.03 %)
	Coronary Artery Disease (PBMQ)	Yes	155 (13.56 %)	164 (14.17 %)
	Hyperlipidemia (MLG)	Yes	109 (14.25 %)	106 (13.82 %)
	Hypertension (MLG)	Yes	348 (13.18 %)	363 (13.52 %)
	Region	Western Europe, Oceania and Others	109 (17.47 %)	125 (19.78 %)
	Type 2 Diabetes Mellitus (PT)	Yes	173 (14.22 %)	189 (15.45 %)
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	456 (27.32 %)	479 (29.03 %)
	Chronic Kidney Disease (PT)	Yes	199 (35.28 %)	194 (35.34 %)
	Coronary Artery Disease (PBMQ)	Yes	380 (33.25 %)	375 (32.41 %)
	Hyperlipidemia (MLG)	Yes	242 (31.63 %)	240 (31.29 %)
	Hypertension (MLG)	Yes	749 (28.37 %)	780 (29.05 %)
	Region	Western Europe, Oceania and Others	180 (28.85 %)	218 (34.49 %)
	Type 2 Diabetes Mellitus (PT)	Yes	362 (29.75 %)	386 (31.56 %)
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	149 (8.93 %)	151 (9.15 %)
	Chronic Kidney Disease (PT)	Yes	80 (14.18 %)	87 (15.85 %)
	Coronary Artery Disease (PBMQ)	Yes	149 (13.04 %)	126 (10.89 %)
	Hyperlipidemia (MLG)	Yes	87 (11.37 %)	93 (12.13 %)
	Hypertension (MLG)	Yes	288 (10.91 %)	265 (9.87 %)
	Region	Western Europe, Oceania and Others	81 (12.98 %)	87 (13.77 %)
	Type 2 Diabetes Mellitus (PT)	Yes	271 (22.27 %)	255 (20.85 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	361 (21.63 %)	386 (23.39 %)
	Chronic Kidney Disease (PT)	Yes	146 (25.89 %)	142 (25.87 %)
	Coronary Artery Disease (PBMQ)	Yes	221 (19.34 %)	244 (21.09 %)
	Hyperlipidemia (MLG)	Yes	174 (22.75 %)	174 (22.69 %)
	Hypertension (MLG)	Yes	534 (20.23 %)	590 (21.97 %)
	Region	Western Europe, Oceania and Others	196 (31.41 %)	220 (34.81 %)
	Type 2 Diabetes Mellitus (PT)	Yes	346 (28.43 %)	330 (26.98 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	574 (34.39 %)	552 (33.45 %)
	Chronic Kidney Disease (PT)	Yes	159 (28.19 %)	143 (26.05 %)
	Coronary Artery Disease (PBMQ)	Yes	248 (21.70 %)	253 (21.87 %)
	Hyperlipidemia (MLG)	Yes	182 (23.79 %)	189 (24.64 %)
	Hypertension (MLG)	Yes	628 (23.79 %)	638 (23.76 %)
	Region	Western Europe, Oceania and Others	180 (28.85 %)	179 (28.32 %)
	Type 2 Diabetes Mellitus (PT)	Yes	294 (24.16 %)	291 (23.79 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	50 (3.00 %)	63 (3.82 %)
	Chronic Kidney Disease (PT)	Yes	22 (3.90 %)	32 (5.83 %)
	Coronary Artery Disease (PBMQ)	Yes	37 (3.24 %)	37 (3.20 %)
	Hyperlipidemia (MLG)	Yes	40 (5.23 %)	44 (5.74 %)
	Hypertension (MLG)	Yes	85 (3.22 %)	105 (3.91 %)
	Region	Western Europe, Oceania and Others	41 (6.57 %)	56 (8.86 %)
	Type 2 Diabetes Mellitus (PT)	Yes	81 (6.66 %)	102 (8.34 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=3003)	Placebo (N=2998)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	359 (21.51 %)	334 (20.24 %)
	Chronic Kidney Disease (PT)	Yes	95 (16.84 %)	82 (14.94 %)
	Coronary Artery Disease (PBMQ)	Yes	161 (14.09 %)	155 (13.40 %)
	Hyperlipidemia (MLG)	Yes	108 (14.12 %)	100 (13.04 %)
	Hypertension (MLG)	Yes	393 (14.89 %)	376 (14.00 %)
	Region	Western Europe, Oceania and Others	113 (18.11 %)	113 (17.88 %)
	Type 2 Diabetes Mellitus (PT)	Yes	156 (12.82 %)	173 (14.15 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	101 (6.05 %)	130 (7.88 %)
	Chronic Kidney Disease (PT)	Yes	51 (9.04 %)	47 (8.56 %)
	Coronary Artery Disease (PBMQ)	Yes	109 (9.54 %)	106 (9.16 %)
	Hyperlipidemia (MLG)	Yes	65 (8.50 %)	63 (8.21 %)
	Hypertension (MLG)	Yes	205 (7.77 %)	216 (8.04 %)
	Region	Western Europe, Oceania and Others	56 (8.97 %)	53 (8.39 %)
	Type 2 Diabetes Mellitus (PT)	Yes	186 (15.28 %)	186 (15.21 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	47 (2.82 %)	35 (2.12 %)
	Chronic Kidney Disease (PT)	Yes	22 (3.90 %)	18 (3.28 %)
	Coronary Artery Disease (PBMQ)	Yes	43 (3.76 %)	43 (3.72 %)
	Hyperlipidemia (MLG)	Yes	28 (3.66 %)	26 (3.39 %)
	Hypertension (MLG)	Yes	82 (3.11 %)	78 (2.91 %)
	Region	Western Europe, Oceania and Others	4 (0.64 %)	4 (0.63 %)
	Type 2 Diabetes Mellitus (PT)	Yes	84 (6.90 %)	69 (5.64 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	29 (1.74 %)	25 (1.52 %)
	Chronic Kidney Disease (PT)	Yes	11 (1.95 %)	12 (2.19 %)
	Coronary Artery Disease (PBMQ)	Yes	29 (2.54 %)	20 (1.73 %)
	Hyperlipidemia (MLG)	Yes	22 (2.88 %)	23 (3.00 %)
	Hypertension (MLG)	Yes	52 (1.97 %)	51 (1.90 %)
	Region	Western Europe, Oceania and Others	14 (2.24 %)	14 (2.22 %)
	Type 2 Diabetes Mellitus (PT)	Yes	55 (4.52 %)	47 (3.84 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (0.42 %)	14 (0.85 %)
	Chronic Kidney Disease (PT)	Yes	2 (0.35 %)	10 (1.82 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (0.52 %)	10 (0.86 %)
	Hyperlipidemia (MLG)	Yes	9 (1.18 %)	15 (1.96 %)
	Hypertension (MLG)	Yes	16 (0.61 %)	32 (1.19 %)
	Region	Western Europe, Oceania and Others	8 (1.28 %)	17 (2.69 %)
	Type 2 Diabetes Mellitus (PT)	Yes	7 (0.58 %)	21 (1.72 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	62 (3.71 %)	58 (3.52 %)
	Chronic Kidney Disease (PT)	Yes	22 (3.90 %)	25 (4.55 %)
	Coronary Artery Disease (PBMQ)	Yes	62 (5.42 %)	60 (5.19 %)
	Hyperlipidemia (MLG)	Yes	49 (6.41 %)	29 (3.78 %)
	Hypertension (MLG)	Yes	110 (4.17 %)	103 (3.84 %)
	Region	Western Europe, Oceania and Others	39 (6.25 %)	41 (6.49 %)
	Type 2 Diabetes Mellitus (PT)	Yes	61 (5.01 %)	52 (4.25 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time
Safety Analysis Set

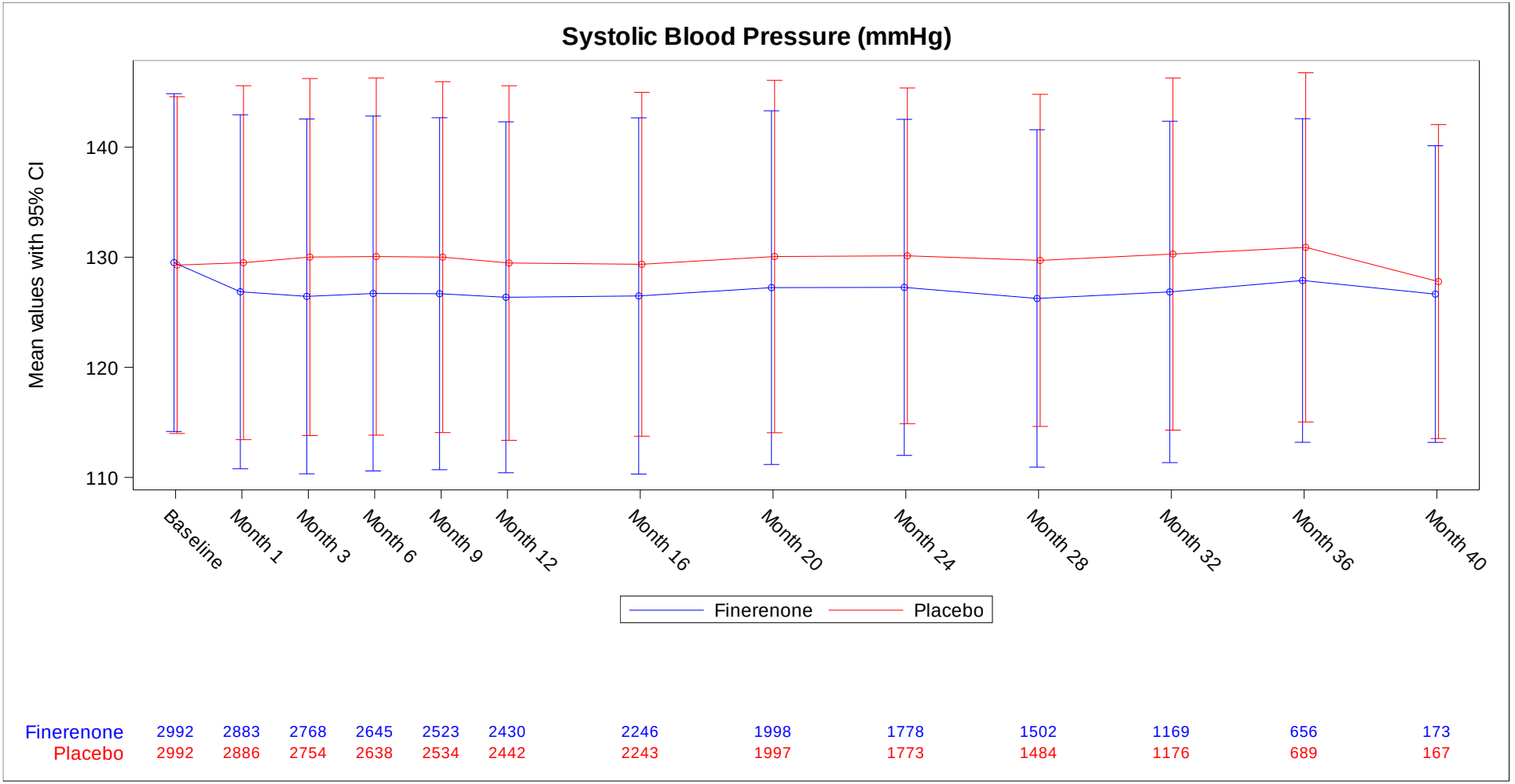
		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2992	129.51 (15.34)	130.00	80.50, 180.50	-	-	-	-
	Placebo	2992	129.29 (15.29)	129.50	74.00, 181.00	-	-	-	-
Month 1	Finerenone	2883	126.86 (16.07)	127.00	71.50, 196.00	2882	-2.65 (14.36)	-2.25	-57.50, 61.50
	Placebo	2886	129.50 (16.07)	129.50	78.00, 210.00	2885	0.17 (14.39)	0.00	-59.50, 79.00
Month 3	Finerenone	2768	126.44 (16.11)	126.50	74.00, 206.50	2767	-3.14 (15.69)	-2.50	-71.50, 60.00
	Placebo	2754	130.01 (16.21)	130.00	81.00, 206.00	2753	0.41 (15.66)	0.00	-58.00, 85.00
Month 6	Finerenone	2645	126.70 (16.12)	127.00	60.50, 193.00	2644	-3.03 (16.25)	-2.50	-59.50, 70.50
	Placebo	2638	130.06 (16.22)	130.00	78.00, 207.00	2637	0.38 (16.18)	0.00	-52.50, 75.00
Month 9	Finerenone	2523	126.68 (15.98)	126.50	76.50, 200.00	2522	-3.22 (16.65)	-3.00	-67.00, 86.50
	Placebo	2534	130.01 (15.93)	130.00	79.50, 197.50	2533	0.33 (16.17)	0.00	-69.00, 82.00
Month 12	Finerenone	2430	126.36 (15.94)	127.00	71.50, 214.00	2429	-3.51 (16.33)	-3.00	-64.00, 64.50
	Placebo	2442	129.47 (16.10)	129.50	75.00, 206.00	2442	-0.35 (16.56)	-0.50	-67.50, 78.50
Month 16	Finerenone	2246	126.48 (16.18)	127.00	71.50, 201.00	2245	-3.40 (16.99)	-3.00	-65.50, 60.00
	Placebo	2243	129.36 (15.61)	129.50	74.50, 198.00	2243	-0.49 (16.53)	-0.50	-60.00, 69.50
Month 20	Finerenone	1998	127.24 (16.06)	127.50	74.00, 186.00	1997	-2.64 (17.45)	-2.50	-58.50, 67.50
	Placebo	1997	130.06 (16.00)	130.00	72.50, 215.00	1997	-0.03 (16.76)	-0.50	-57.50, 70.00
Month 24	Finerenone	1778	127.26 (15.26)	128.00	80.00, 187.50	1778	-3.07 (16.31)	-2.50	-61.50, 60.00
	Placebo	1773	130.12 (15.24)	130.00	79.50, 189.50	1773	-0.03 (16.95)	0.00	-56.50, 73.00
Month 28	Finerenone	1502	126.25 (15.32)	127.00	71.50, 180.00	1502	-3.74 (17.11)	-3.50	-63.50, 64.00
	Placebo	1484	129.71 (15.08)	129.75	77.00, 201.00	1484	-0.69 (16.50)	-0.50	-69.00, 67.00
Month 32	Finerenone	1169	126.85 (15.50)	127.00	77.00, 191.50	1169	-3.14 (17.20)	-3.50	-59.00, 71.50
	Placebo	1176	130.29 (15.99)	130.00	73.50, 234.50	1176	-0.05 (16.97)	0.00	-67.50, 82.00
Month 36	Finerenone	656	127.88 (14.69)	127.50	85.00, 181.00	656	-2.85 (16.63)	-3.00	-57.00, 59.50
	Placebo	689	130.89 (15.86)	130.50	82.50, 237.50	689	0.48 (16.71)	1.00	-65.50, 75.50
Month 40	Finerenone	173	126.65 (13.47)	127.00	87.50, 165.50	173	-3.92 (15.83)	-4.50	-41.00, 34.00
	Placebo	167	127.78 (14.26)	127.50	82.50, 183.00	167	-1.77 (17.21)	-1.50	-65.00, 49.50
Premature discontinuation	Finerenone	135	124.00 (19.03)	123.00	62.50, 177.00	135	-5.38 (18.79)	-2.50	-69.50, 54.50
	Placebo	152	124.27 (18.16)	122.00	85.00, 169.00	152	-3.15 (19.36)	-3.50	-55.00, 39.50
End of Study Visit	Finerenone	2089	126.93 (15.99)	126.50	80.50, 201.00	2088	-2.78 (17.38)	-2.50	-71.00, 89.50
	Placebo	2020	128.80 (15.83)	129.00	77.00, 199.00	2020	-0.85 (17.02)	-1.00	-67.00, 64.50

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

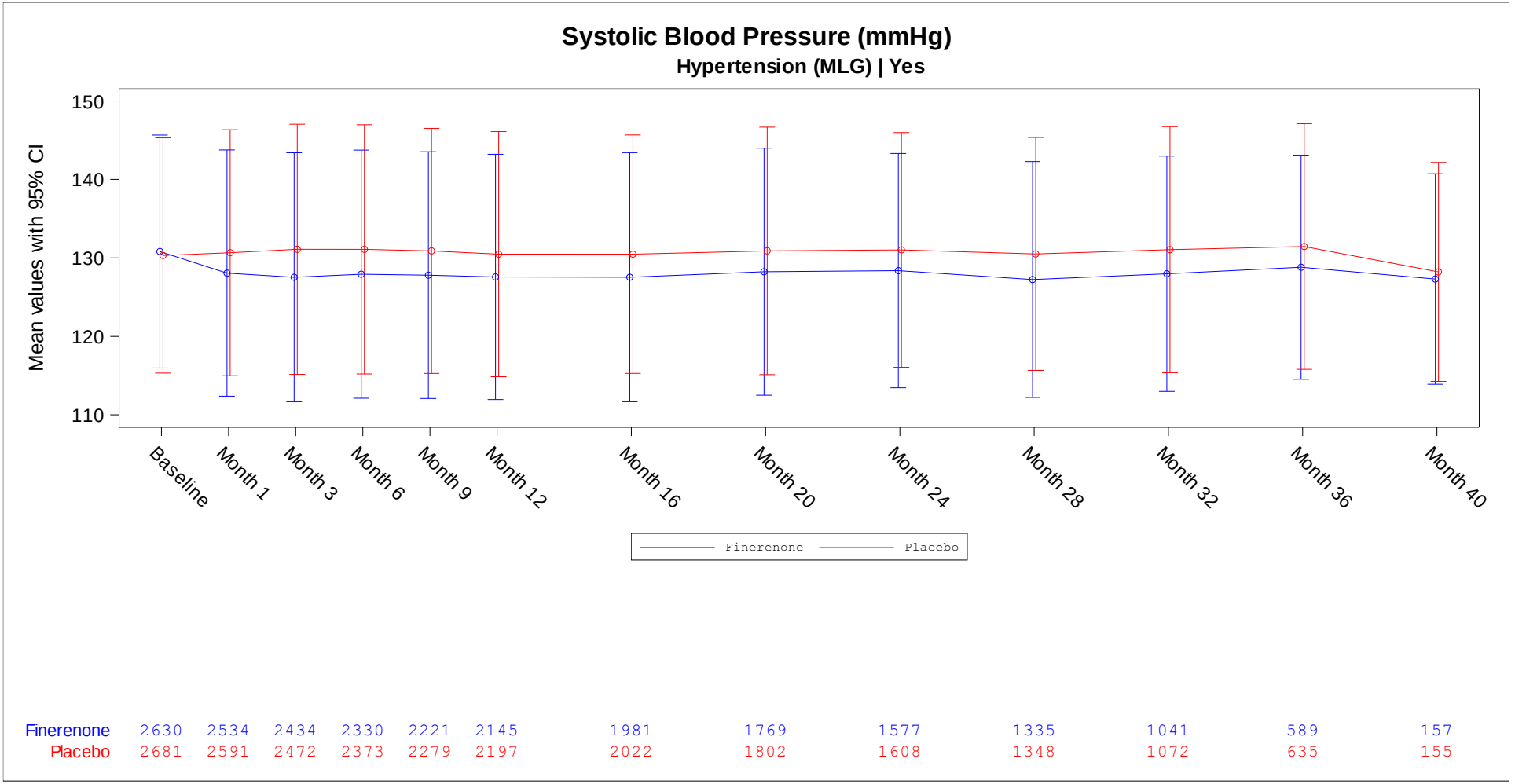
BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2630	130.81 (14.84)	131.00	89.50, 180.50	-	-	-	-
	Placebo	2681	130.31 (14.98)	130.00	74.00, 181.00	-	-	-	-
Month 1	Finerenone	2534	128.06 (15.69)	128.00	77.00, 196.00	2533	-2.72 (14.41)	-2.50	-57.50, 61.50
	Placebo	2591	130.66 (15.67)	130.00	78.00, 210.00	2591	0.31 (14.46)	0.00	-59.50, 79.00
Month 3	Finerenone	2434	127.53 (15.87)	127.50	75.00, 206.50	2433	-3.33 (15.86)	-2.50	-71.50, 60.00
	Placebo	2472	131.09 (15.94)	131.00	81.00, 206.00	2472	0.44 (15.83)	0.00	-58.00, 85.00
Month 6	Finerenone	2330	127.92 (15.81)	127.75	60.50, 193.00	2329	-3.10 (16.42)	-2.50	-59.50, 70.50
	Placebo	2373	131.09 (15.88)	130.50	78.00, 207.00	2373	0.39 (16.28)	0.00	-52.50, 75.00
Month 9	Finerenone	2221	127.80 (15.72)	127.50	76.50, 200.00	2220	-3.40 (16.83)	-3.00	-67.00, 86.50
	Placebo	2279	130.89 (15.61)	130.00	79.50, 197.50	2279	0.20 (16.29)	0.00	-69.00, 82.00
Month 12	Finerenone	2145	127.57 (15.63)	128.00	71.50, 214.00	2144	-3.59 (16.47)	-3.00	-64.00, 64.50
	Placebo	2197	130.48 (15.62)	130.00	75.00, 206.00	2197	-0.34 (16.70)	-0.50	-67.50, 78.50
Month 16	Finerenone	1981	127.54 (15.87)	127.50	78.00, 200.00	1980	-3.58 (17.12)	-3.50	-65.50, 60.00
	Placebo	2022	130.47 (15.19)	130.00	80.00, 198.00	2022	-0.31 (16.58)	-0.50	-60.00, 69.50
Month 20	Finerenone	1769	128.24 (15.74)	128.00	74.00, 186.00	1768	-2.89 (17.57)	-3.00	-58.50, 67.50
	Placebo	1802	130.89 (15.77)	130.50	72.50, 215.00	1802	-0.15 (16.90)	-0.50	-57.50, 70.00
Month 24	Finerenone	1577	128.37 (14.93)	129.00	80.00, 187.50	1577	-3.07 (16.38)	-2.50	-61.50, 60.00
	Placebo	1608	131.02 (14.95)	130.50	79.50, 189.50	1608	0.01 (17.11)	0.00	-56.50, 73.00
Month 28	Finerenone	1335	127.24 (15.03)	127.50	71.50, 180.00	1335	-3.92 (17.26)	-3.50	-63.50, 64.00
	Placebo	1348	130.50 (14.84)	130.00	77.00, 201.00	1348	-0.79 (16.66)	-0.75	-69.00, 67.00
Month 32	Finerenone	1041	127.98 (14.99)	127.50	80.50, 191.50	1041	-3.08 (17.34)	-3.50	-59.00, 71.50
	Placebo	1072	131.05 (15.68)	130.50	73.50, 234.50	1072	-0.08 (17.15)	0.00	-67.50, 82.00
Month 36	Finerenone	589	128.81 (14.28)	128.00	85.50, 181.00	589	-2.80 (16.77)	-2.50	-57.00, 59.50
	Placebo	635	131.45 (15.65)	131.00	82.50, 237.50	635	0.24 (16.76)	1.00	-65.50, 75.50
Month 40	Finerenone	157	127.31 (13.41)	127.00	87.50, 165.50	157	-3.70 (16.24)	-4.50	-41.00, 34.00
	Placebo	155	128.22 (13.95)	128.00	82.50, 183.00	155	-2.09 (17.36)	-1.50	-65.00, 49.50
Premature discontinuation	Finerenone	119	125.47 (18.47)	123.50	62.50, 177.00	119	-5.16 (19.08)	-2.50	-69.50, 54.50
	Placebo	132	125.84 (17.96)	124.00	85.00, 169.00	132	-3.50 (19.94)	-3.75	-55.00, 38.00
End of Study Visit	Finerenone	1840	128.01 (15.77)	127.50	80.50, 201.00	1839	-2.98 (17.60)	-2.50	-71.00, 89.50
	Placebo	1820	129.66 (15.62)	130.00	77.00, 199.00	1820	-1.01 (17.17)	-1.00	-67.00, 64.50

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.



Only visits with N>=5 patients in each treatment group are displayed.



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2992	75.58 (10.28)	76.00	38.50, 122.50	-	-	-	-
	Placebo	2992	75.35 (10.42)	75.50	38.00, 119.00	-	-	-	-
Month 1	Finerenone	2883	74.24 (10.39)	74.50	39.00, 125.50	2882	-1.41 (9.30)	-1.50	-44.50, 38.00
	Placebo	2886	75.35 (10.40)	75.50	36.50, 120.50	2885	-0.06 (9.09)	0.00	-38.00, 46.50
Month 3	Finerenone	2768	74.20 (10.35)	74.00	39.50, 113.00	2767	-1.50 (9.79)	-1.50	-42.00, 36.50
	Placebo	2754	75.32 (10.57)	75.00	37.00, 133.00	2753	-0.23 (9.72)	0.00	-40.00, 48.50
Month 6	Finerenone	2645	73.91 (10.28)	74.00	37.00, 111.50	2644	-1.84 (10.15)	-1.50	-39.00, 36.00
	Placebo	2638	75.72 (10.40)	76.00	36.00, 140.00	2637	0.15 (10.12)	0.00	-39.50, 45.50
Month 9	Finerenone	2523	74.07 (10.21)	74.00	41.00, 125.00	2522	-1.78 (10.27)	-1.50	-42.00, 54.50
	Placebo	2534	75.47 (10.40)	75.50	41.00, 135.00	2533	-0.18 (10.22)	0.00	-40.00, 43.00
Month 12	Finerenone	2430	73.64 (10.41)	74.00	37.00, 126.00	2429	-2.24 (10.36)	-2.00	-49.00, 55.50
	Placebo	2442	75.22 (10.26)	75.50	39.50, 117.00	2442	-0.49 (10.25)	0.00	-44.00, 40.50
Month 16	Finerenone	2246	74.06 (10.42)	74.00	38.00, 144.50	2245	-1.95 (10.52)	-1.50	-51.50, 42.50
	Placebo	2243	74.97 (10.29)	75.00	37.50, 113.50	2243	-0.98 (10.55)	-0.50	-40.00, 42.50
Month 20	Finerenone	1998	74.13 (10.20)	74.00	40.50, 113.00	1997	-1.91 (10.55)	-2.00	-44.00, 40.50
	Placebo	1997	75.48 (10.62)	76.00	37.00, 123.00	1997	-0.50 (10.40)	-0.50	-35.00, 38.00
Month 24	Finerenone	1778	74.16 (10.12)	74.50	39.50, 124.00	1778	-2.21 (10.58)	-2.00	-48.00, 50.00
	Placebo	1773	75.54 (10.35)	76.00	40.50, 130.50	1773	-0.59 (10.70)	-0.50	-44.50, 46.50
Month 28	Finerenone	1502	74.04 (10.11)	74.50	43.50, 121.50	1502	-2.33 (10.98)	-2.00	-39.00, 54.50
	Placebo	1484	75.42 (10.14)	76.00	41.50, 118.00	1484	-0.79 (10.43)	-0.50	-45.50, 38.00
Month 32	Finerenone	1169	74.36 (10.19)	75.00	39.50, 125.50	1169	-2.03 (10.96)	-2.00	-36.50, 51.50
	Placebo	1176	75.83 (10.53)	76.50	41.00, 135.00	1176	-0.58 (10.61)	-0.50	-45.00, 51.00
Month 36	Finerenone	656	75.37 (10.18)	75.50	48.00, 120.50	656	-1.52 (10.92)	-1.25	-37.50, 37.50
	Placebo	689	76.32 (10.28)	77.00	37.50, 120.50	689	-0.47 (10.63)	0.00	-39.00, 36.00
Month 40	Finerenone	173	74.86 (9.88)	75.00	47.00, 112.00	173	-2.41 (9.76)	-1.00	-37.50, 20.50
	Placebo	167	75.68 (9.95)	76.50	45.50, 110.50	167	-1.84 (11.05)	-2.00	-36.00, 27.00
Premature discontinuation	Finerenone	135	70.97 (11.85)	71.00	39.50, 103.50	135	-3.21 (10.56)	-2.50	-45.50, 31.50
	Placebo	152	72.78 (11.64)	72.75	42.00, 135.50	152	-0.91 (10.86)	-0.75	-41.50, 31.00
End of Study Visit	Finerenone	2089	74.31 (10.50)	74.50	37.00, 132.50	2088	-1.80 (11.16)	-2.00	-49.00, 51.50
	Placebo	2020	75.09 (10.25)	75.50	40.00, 127.00	2020	-0.93 (10.75)	-0.50	-41.50, 42.50

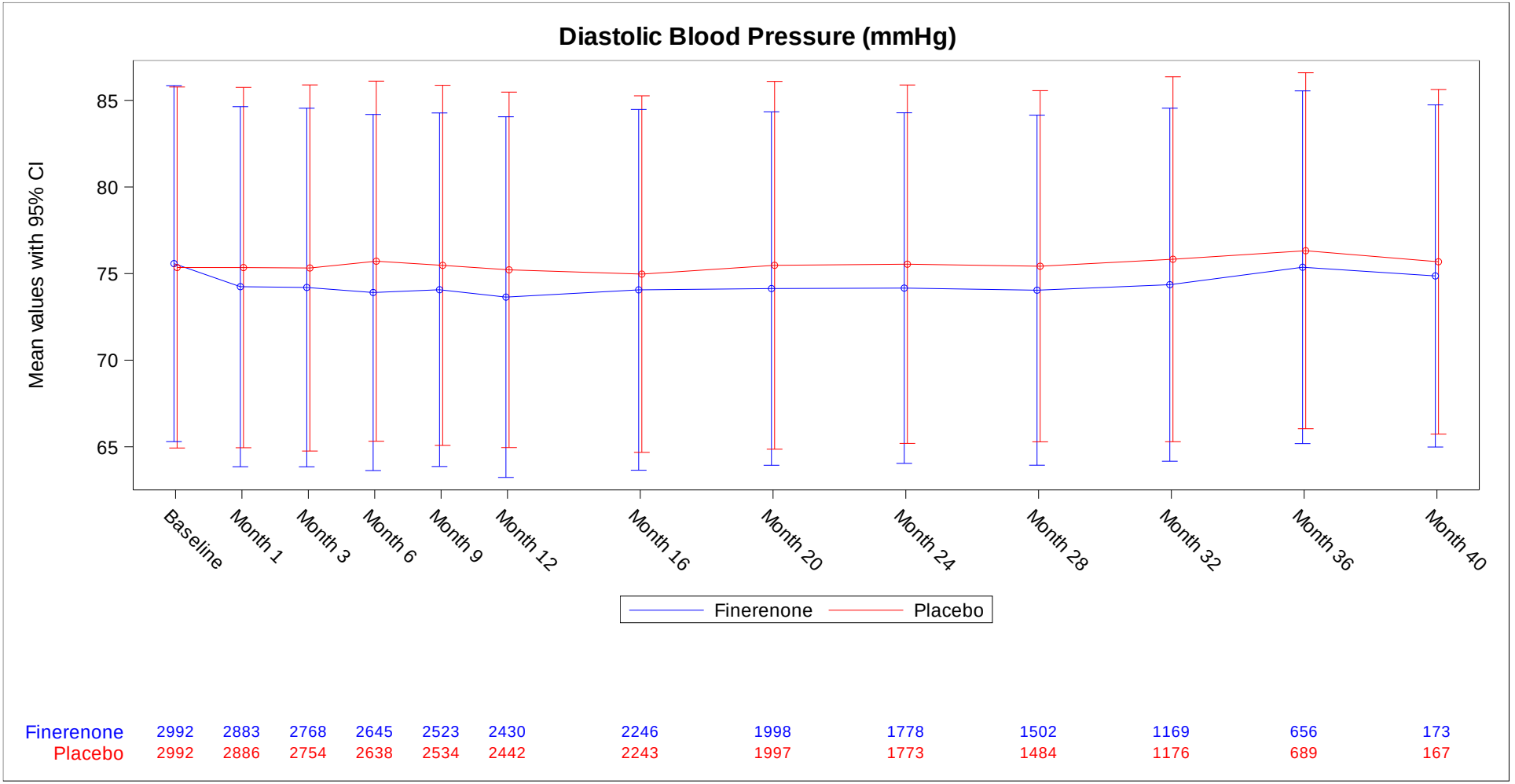
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2630	75.92 (10.28)	76.50	38.50, 122.50	-	-	-	-
	Placebo	2681	75.78 (10.36)	75.50	38.00, 119.00	-	-	-	-
Month 1	Finerenone	2534	74.61 (10.30)	75.00	39.00, 125.50	2533	-1.38 (9.29)	-1.50	-44.50, 38.00
	Placebo	2591	75.81 (10.31)	76.00	36.50, 120.50	2591	-0.02 (8.98)	0.00	-38.00, 46.50
Month 3	Finerenone	2434	74.53 (10.32)	74.50	39.50, 113.00	2433	-1.54 (9.84)	-1.50	-42.00, 36.50
	Placebo	2472	75.79 (10.49)	75.50	37.00, 133.00	2472	-0.19 (9.69)	0.00	-40.00, 48.50
Month 6	Finerenone	2330	74.22 (10.26)	74.50	37.00, 111.50	2329	-1.88 (10.18)	-1.50	-39.00, 36.00
	Placebo	2373	76.20 (10.25)	77.00	36.00, 140.00	2373	0.20 (10.14)	0.00	-39.50, 45.50
Month 9	Finerenone	2221	74.45 (10.14)	74.50	41.00, 125.00	2220	-1.76 (10.29)	-1.50	-42.00, 54.50
	Placebo	2279	75.81 (10.32)	76.00	41.00, 135.00	2279	-0.29 (10.20)	0.00	-40.00, 43.00
Month 12	Finerenone	2145	74.02 (10.35)	74.50	37.00, 126.00	2144	-2.20 (10.35)	-2.00	-49.00, 55.50
	Placebo	2197	75.69 (10.06)	76.00	42.50, 117.00	2197	-0.44 (10.30)	0.00	-44.00, 40.50
Month 16	Finerenone	1981	74.35 (10.38)	74.50	38.00, 144.50	1980	-1.98 (10.46)	-2.00	-51.50, 42.50
	Placebo	2022	75.49 (10.11)	75.50	37.50, 113.50	2022	-0.86 (10.54)	-0.50	-40.00, 42.50
Month 20	Finerenone	1769	74.49 (10.09)	74.50	40.50, 113.00	1768	-1.91 (10.49)	-2.00	-44.00, 36.50
	Placebo	1802	75.88 (10.52)	76.50	37.00, 123.00	1802	-0.54 (10.44)	-0.50	-35.00, 38.00
Month 24	Finerenone	1577	74.55 (10.16)	74.50	39.50, 124.00	1577	-2.11 (10.58)	-2.00	-48.00, 50.00
	Placebo	1608	75.97 (10.26)	76.50	40.50, 130.50	1608	-0.56 (10.79)	0.00	-44.50, 46.50
Month 28	Finerenone	1335	74.50 (10.05)	75.00	44.00, 121.50	1335	-2.19 (10.96)	-2.00	-39.00, 54.50
	Placebo	1348	75.83 (10.04)	76.50	41.50, 118.00	1348	-0.82 (10.46)	-0.50	-45.50, 38.00
Month 32	Finerenone	1041	74.80 (10.19)	75.00	43.50, 125.50	1041	-1.85 (10.95)	-2.00	-36.50, 51.50
	Placebo	1072	76.22 (10.42)	76.75	42.50, 135.00	1072	-0.60 (10.64)	-0.50	-45.00, 51.00
Month 36	Finerenone	589	75.86 (10.09)	76.50	48.00, 120.50	589	-1.29 (10.96)	-1.00	-37.50, 37.50
	Placebo	635	76.71 (9.94)	77.00	37.50, 120.50	635	-0.50 (10.55)	0.00	-39.00, 36.00
Month 40	Finerenone	157	75.88 (9.50)	75.50	47.00, 112.00	157	-1.80 (9.90)	0.00	-37.50, 20.50
	Placebo	155	75.78 (9.84)	76.50	50.00, 110.50	155	-2.19 (10.88)	-2.50	-36.00, 27.00
Premature discontinuation	Finerenone	119	71.29 (11.91)	72.00	39.50, 103.50	119	-2.95 (10.65)	-2.50	-45.50, 31.50
	Placebo	132	72.83 (12.15)	73.00	42.00, 135.50	132	-1.28 (11.28)	-1.00	-41.50, 31.00
End of Study Visit	Finerenone	1840	74.69 (10.50)	75.00	37.00, 132.50	1839	-1.75 (11.20)	-2.00	-49.00, 51.50
	Placebo	1820	75.57 (10.15)	76.00	40.00, 127.00	1820	-0.89 (10.85)	-0.50	-41.50, 42.50

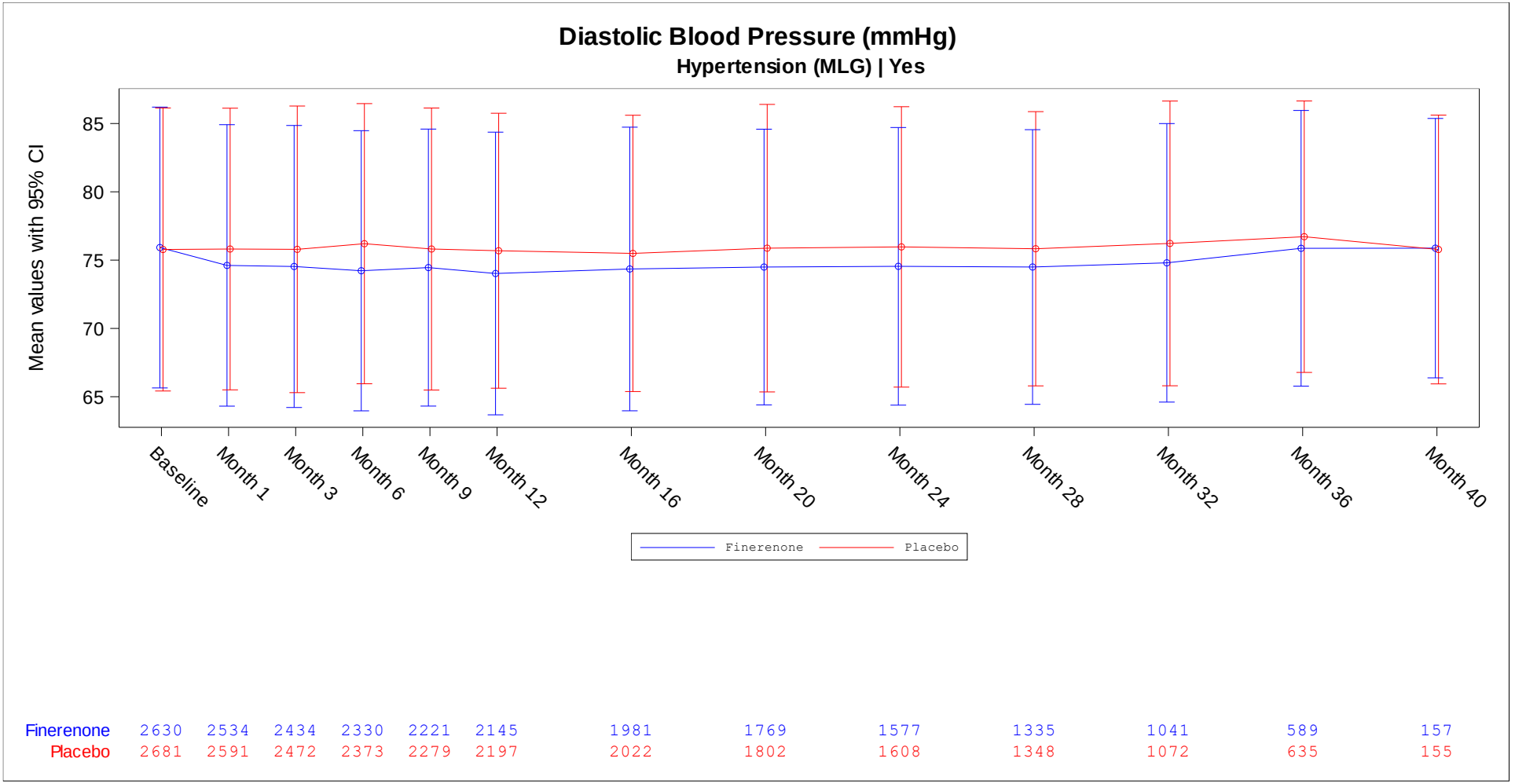
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BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Hemoglobin A1C (%) in Blood over time
Safety Analysis Set

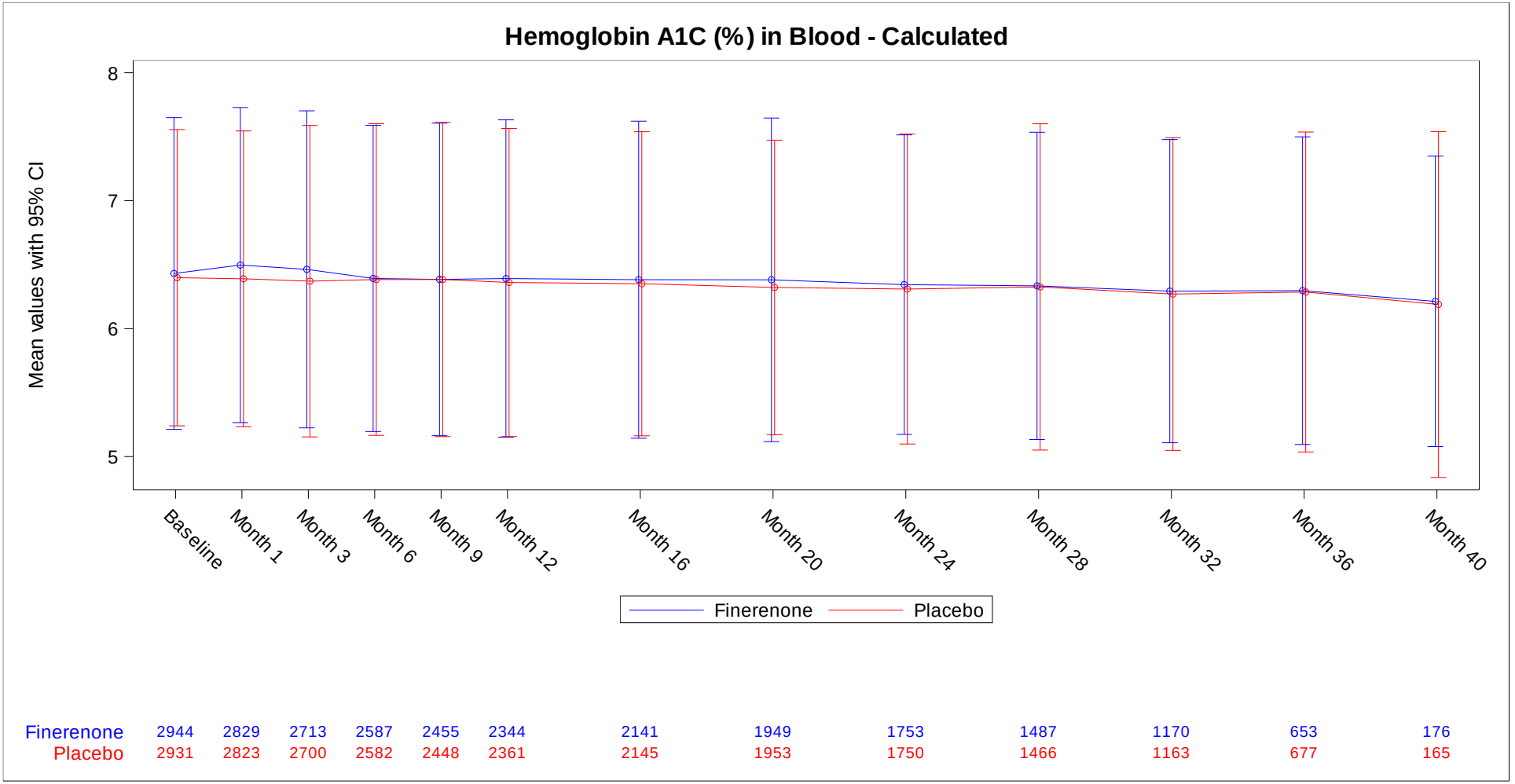
		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2944	6.43 (1.22)	6.10	3.70, 13.60	-	-	-	-
	Placebo	2931	6.40 (1.16)	6.10	3.90, 13.70	-	-	-	-
Month 1	Finerenone	2829	6.50 (1.23)	6.20	3.80, 13.30	2797	0.07 (0.44)	0.10	-7.30, 2.70
	Placebo	2823	6.39 (1.16)	6.10	4.00, 13.20	2771	-0.00 (0.46)	0.00	-7.40, 6.80
Month 3	Finerenone	2713	6.46 (1.24)	6.10	3.80, 14.10	2675	0.03 (0.67)	0.00	-7.30, 4.50
	Placebo	2700	6.37 (1.22)	6.00	1.80, 14.10	2655	-0.02 (0.71)	0.00	-7.50, 7.20
Month 6	Finerenone	2587	6.39 (1.20)	6.10	3.90, 15.40	2549	-0.03 (0.70)	0.00	-5.00, 5.50
	Placebo	2582	6.38 (1.22)	6.00	1.80, 15.80	2536	0.00 (0.81)	0.00	-7.20, 8.50
Month 9	Finerenone	2455	6.38 (1.22)	6.00	1.80, 14.60	2418	-0.03 (0.75)	0.00	-5.40, 5.80
	Placebo	2448	6.38 (1.23)	6.00	4.00, 17.40	2405	0.00 (0.86)	0.00	-7.40, 9.20
Month 12	Finerenone	2344	6.39 (1.24)	6.05	1.80, 15.00	2308	-0.00 (0.78)	0.00	-5.30, 5.90
	Placebo	2361	6.36 (1.20)	6.00	3.70, 14.90	2321	-0.01 (0.84)	0.00	-7.10, 6.80
Month 16	Finerenone	2141	6.38 (1.24)	6.00	3.70, 13.80	2111	0.00 (0.84)	0.00	-5.10, 5.70
	Placebo	2145	6.35 (1.19)	6.00	4.00, 15.20	2110	-0.01 (0.88)	0.00	-7.30, 7.50
Month 20	Finerenone	1949	6.38 (1.26)	6.00	3.80, 15.10	1920	-0.02 (0.90)	0.00	-5.30, 7.80
	Placebo	1953	6.32 (1.15)	6.00	4.20, 13.00	1919	-0.04 (0.84)	0.00	-7.20, 7.20
Month 24	Finerenone	1753	6.34 (1.17)	6.00	4.00, 13.20	1732	-0.05 (0.82)	0.00	-5.10, 5.70
	Placebo	1750	6.31 (1.21)	6.00	4.30, 13.90	1721	-0.02 (0.85)	0.00	-7.20, 6.40
Month 28	Finerenone	1487	6.33 (1.20)	6.00	3.70, 13.90	1469	-0.06 (0.86)	-0.10	-5.20, 6.80
	Placebo	1466	6.33 (1.28)	6.00	4.30, 16.50	1447	-0.01 (0.95)	0.00	-7.40, 6.80
Month 32	Finerenone	1170	6.29 (1.18)	5.90	4.10, 13.00	1159	-0.08 (0.86)	-0.10	-7.30, 7.30
	Placebo	1163	6.27 (1.22)	5.90	4.30, 17.40	1150	-0.05 (0.92)	-0.10	-7.50, 7.00
Month 36	Finerenone	653	6.30 (1.20)	5.90	4.20, 13.50	646	-0.09 (0.74)	-0.10	-5.10, 3.60
	Placebo	677	6.29 (1.25)	5.90	4.10, 15.20	672	-0.06 (0.89)	-0.10	-7.30, 5.50
Month 40	Finerenone	176	6.21 (1.14)	6.00	3.90, 11.60	172	-0.12 (0.77)	-0.10	-2.70, 3.90
	Placebo	165	6.19 (1.35)	5.90	1.80, 13.80	164	-0.15 (0.97)	-0.10	-5.50, 4.10
Premature discontinuation	Finerenone	122	6.22 (1.06)	6.00	1.80, 9.80	119	-0.12 (0.89)	0.00	-4.20, 2.50
	Placebo	140	6.32 (1.11)	6.10	4.00, 12.20	138	-0.02 (0.60)	0.00	-3.10, 1.70
End of Study Visit	Finerenone	1937	6.32 (1.21)	6.00	3.90, 13.70	1914	-0.06 (0.87)	-0.10	-6.80, 5.10
	Placebo	1903	6.25 (1.17)	5.90	3.90, 16.90	1866	-0.09 (0.91)	-0.10	-7.40, 6.20

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Hemoglobin A1C (%) in Blood over time - Patients with type 2 diabetes mellitus in medical history
Safety Analysis Set

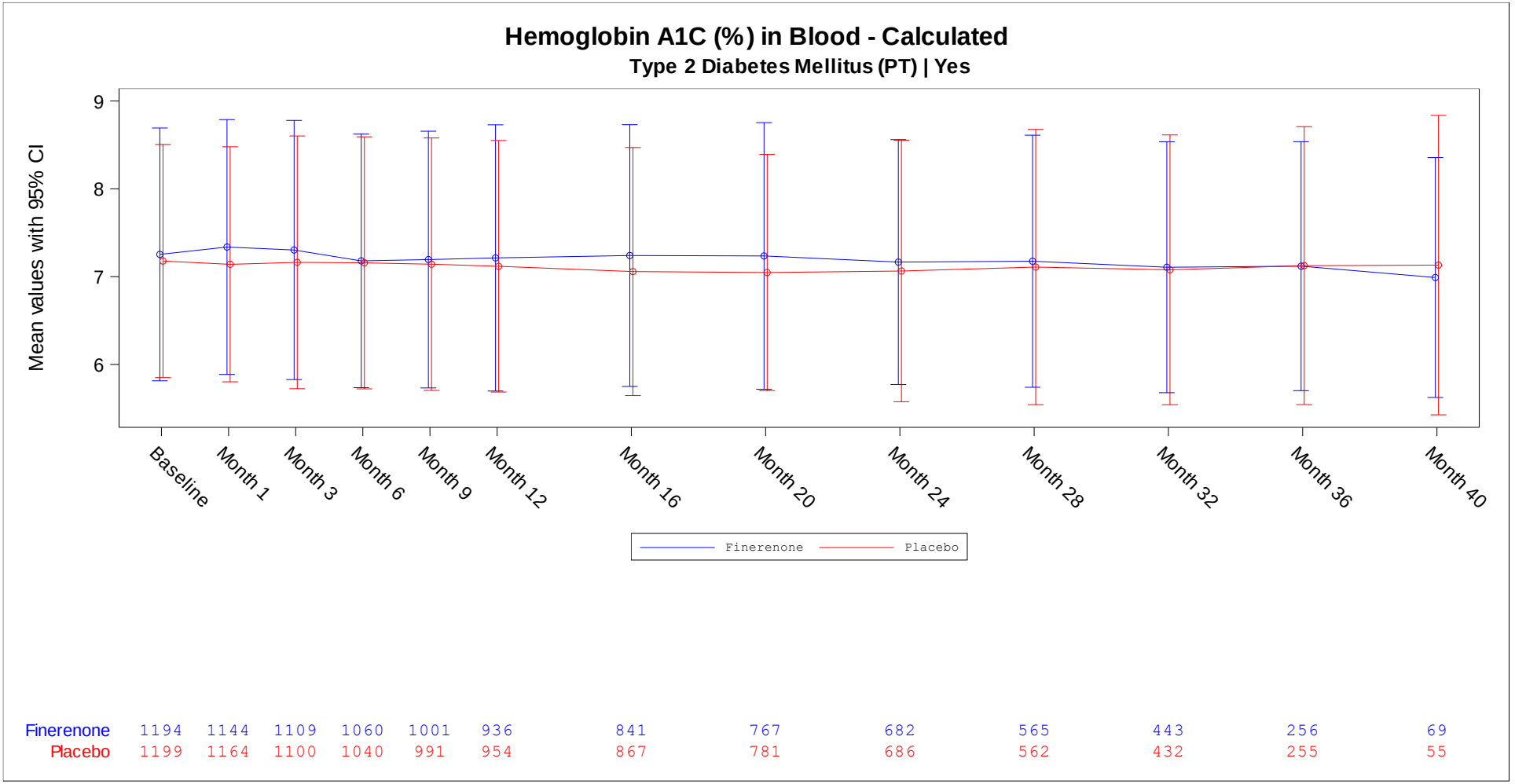
		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	1194	7.25 (1.44)	6.90	3.70, 13.60	-	-	-	-
	Placebo	1199	7.18 (1.33)	6.90	4.70, 13.70	-	-	-	-
Month 1	Finerenone	1144	7.34 (1.45)	7.00	4.00, 13.30	1133	0.09 (0.60)	0.10	-7.30, 2.70
	Placebo	1164	7.14 (1.34)	6.80	4.50, 13.20	1145	-0.02 (0.59)	0.00	-2.50, 6.80
Month 3	Finerenone	1109	7.30 (1.48)	6.90	3.80, 14.10	1096	0.06 (0.94)	0.10	-7.30, 4.50
	Placebo	1100	7.16 (1.44)	6.80	4.10, 14.10	1083	-0.00 (0.95)	0.00	-5.60, 7.20
Month 6	Finerenone	1060	7.18 (1.44)	6.80	3.90, 15.40	1046	-0.05 (1.00)	0.00	-4.70, 5.50
	Placebo	1040	7.16 (1.44)	6.80	1.80, 14.30	1024	-0.00 (1.08)	0.00	-7.20, 6.40
Month 9	Finerenone	1001	7.19 (1.46)	6.80	3.90, 14.60	989	-0.04 (1.04)	0.00	-5.30, 5.80
	Placebo	991	7.14 (1.44)	6.80	4.20, 17.40	977	-0.01 (1.15)	0.00	-6.90, 7.60
Month 12	Finerenone	936	7.21 (1.52)	6.80	1.80, 15.00	926	0.01 (1.12)	0.00	-5.10, 5.90
	Placebo	954	7.12 (1.43)	6.80	4.60, 14.90	940	-0.02 (1.14)	0.00	-6.60, 6.10
Month 16	Finerenone	841	7.24 (1.49)	6.90	4.10, 13.80	832	0.02 (1.22)	0.00	-4.80, 5.70
	Placebo	867	7.06 (1.41)	6.80	4.30, 15.20	857	-0.05 (1.20)	0.00	-6.70, 7.50
Month 20	Finerenone	767	7.24 (1.52)	6.80	3.80, 15.10	757	-0.03 (1.29)	0.00	-5.20, 7.80
	Placebo	781	7.05 (1.34)	6.80	4.20, 12.80	769	-0.07 (1.11)	-0.10	-6.30, 5.00
Month 24	Finerenone	682	7.17 (1.39)	6.80	4.00, 13.20	674	-0.09 (1.17)	-0.10	-4.50, 5.70
	Placebo	686	7.06 (1.49)	6.80	4.50, 13.90	677	-0.03 (1.18)	0.00	-6.10, 6.40
Month 28	Finerenone	565	7.18 (1.44)	6.80	3.80, 13.90	558	-0.11 (1.23)	-0.10	-5.20, 6.80
	Placebo	562	7.11 (1.57)	6.80	4.70, 16.50	557	0.00 (1.29)	-0.10	-7.00, 6.80
Month 32	Finerenone	443	7.11 (1.43)	6.70	4.10, 13.00	440	-0.13 (1.25)	-0.10	-7.30, 7.30
	Placebo	432	7.08 (1.54)	6.70	4.60, 17.40	428	-0.05 (1.27)	0.00	-6.20, 6.60
Month 36	Finerenone	256	7.12 (1.42)	6.70	4.60, 13.50	253	-0.15 (1.03)	-0.10	-5.10, 3.60
	Placebo	255	7.13 (1.58)	6.80	4.70, 15.20	254	-0.01 (1.24)	0.00	-4.00, 5.50
Month 40	Finerenone	69	6.99 (1.37)	6.60	5.10, 11.60	68	-0.10 (1.08)	0.00	-2.70, 3.90
	Placebo	55	7.13 (1.70)	6.70	5.00, 13.80	55	-0.13 (1.42)	-0.10	-5.50, 4.10
Premature discontinuation	Finerenone	48	6.93 (1.23)	6.75	1.80, 9.80	46	-0.29 (1.31)	-0.10	-4.20, 2.50
	Placebo	58	6.91 (1.42)	6.60	4.00, 12.20	57	-0.10 (0.76)	-0.10	-3.10, 1.60
End of Study Visit	Finerenone	754	7.15 (1.42)	6.80	4.20, 13.70	747	-0.07 (1.22)	-0.10	-6.80, 5.00
	Placebo	734	6.96 (1.44)	6.60	4.30, 16.90	721	-0.15 (1.25)	-0.10	-4.80, 6.20

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of mean values of Hemoglobin A1C (%) in Blood over time - Patients with type 2 diabetes mellitus in medical history
Safety Analysis Set



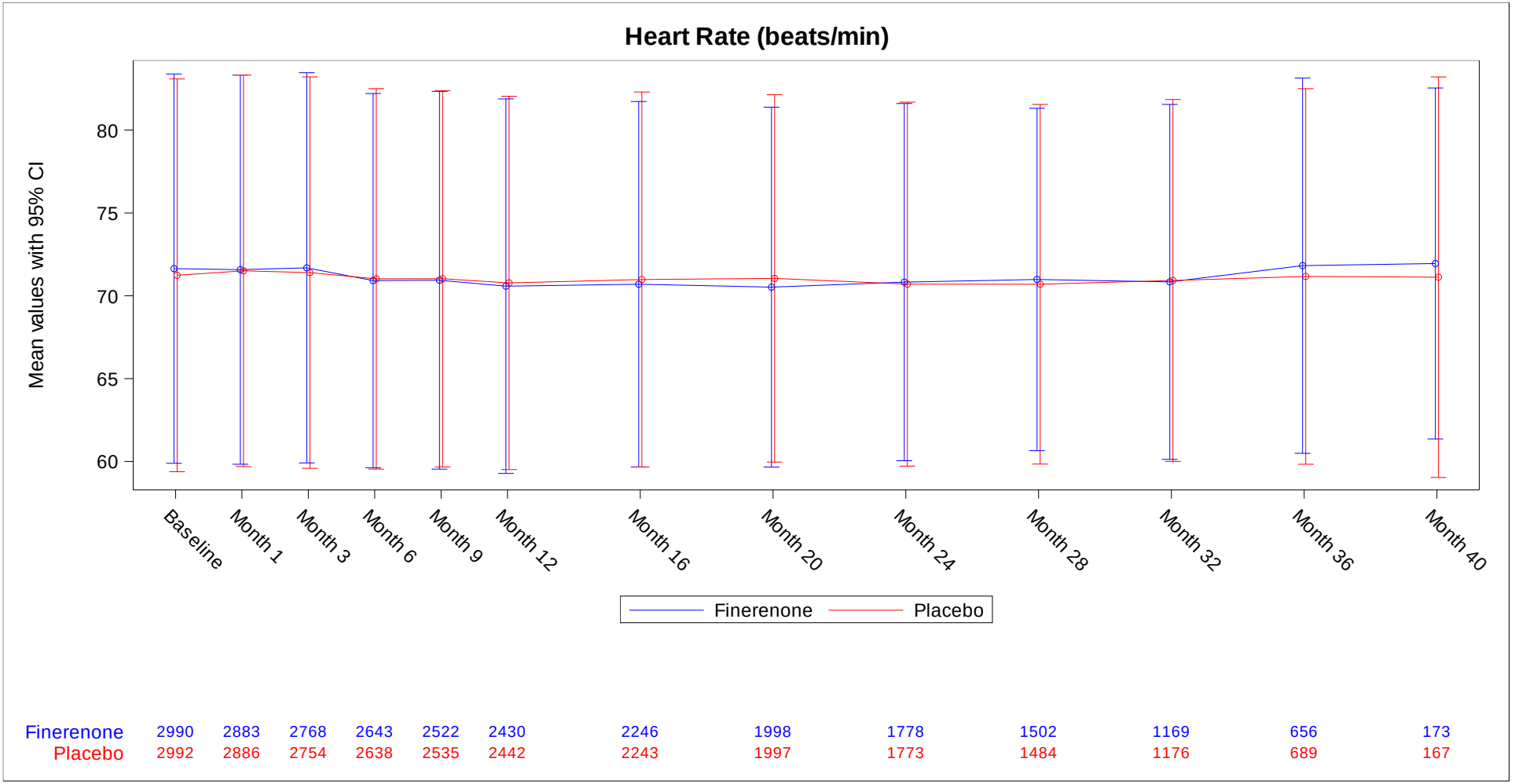
Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Heart Rate over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	2990	71.64 (11.75)	70.50	42.50, 134.00	-	-	-	-
	Placebo	2992	71.24 (11.86)	70.00	39.00, 149.50	-	-	-	-
Month 1	Finerenone	2883	71.58 (11.74)	70.50	40.00, 147.00	2880	-0.06 (10.10)	0.00	-51.00, 67.00
	Placebo	2886	71.51 (11.81)	70.00	40.50, 145.00	2885	0.33 (9.90)	0.00	-52.50, 66.50
Month 3	Finerenone	2768	71.69 (11.77)	70.50	36.50, 134.00	2765	0.01 (11.13)	0.00	-69.00, 56.00
	Placebo	2754	71.40 (11.81)	70.00	39.00, 134.00	2753	0.29 (11.20)	0.00	-61.50, 73.50
Month 6	Finerenone	2643	70.92 (11.29)	70.00	41.00, 124.00	2640	-0.54 (11.46)	0.00	-72.00, 61.50
	Placebo	2638	71.02 (11.48)	70.00	36.50, 157.50	2637	0.07 (11.33)	0.00	-59.00, 73.00
Month 9	Finerenone	2522	70.94 (11.40)	70.00	40.50, 152.00	2519	-0.50 (11.91)	-0.50	-67.50, 66.50
	Placebo	2535	71.03 (11.36)	70.00	18.50, 127.50	2534	0.08 (11.55)	0.00	-67.00, 61.00
Month 12	Finerenone	2430	70.58 (11.30)	70.00	31.00, 146.00	2427	-0.82 (11.98)	-0.50	-66.00, 83.50
	Placebo	2442	70.78 (11.26)	70.00	35.50, 132.00	2442	-0.15 (11.89)	0.00	-80.00, 57.00
Month 16	Finerenone	2246	70.70 (11.03)	70.00	31.00, 131.00	2243	-0.63 (11.95)	-0.50	-72.00, 68.50
	Placebo	2243	70.98 (11.32)	70.00	37.50, 126.50	2243	-0.03 (12.07)	0.00	-80.00, 64.50
Month 20	Finerenone	1998	70.52 (10.86)	69.75	39.50, 133.00	1995	-0.67 (12.10)	-0.50	-64.50, 63.50
	Placebo	1997	71.05 (11.09)	70.00	34.50, 147.50	1997	0.17 (12.44)	0.00	-76.50, 65.50
Month 24	Finerenone	1778	70.83 (10.78)	70.00	41.50, 122.00	1776	-0.20 (11.78)	0.00	-59.50, 52.00
	Placebo	1773	70.70 (10.98)	70.00	38.50, 122.50	1773	-0.18 (12.63)	0.00	-86.50, 57.50
Month 28	Finerenone	1502	70.98 (10.33)	70.00	41.50, 111.50	1502	0.09 (11.88)	0.00	-55.50, 60.50
	Placebo	1484	70.70 (10.85)	70.00	36.50, 121.50	1484	0.14 (12.04)	0.00	-60.50, 52.50
Month 32	Finerenone	1169	70.84 (10.71)	70.50	41.50, 129.50	1169	0.06 (12.08)	0.00	-40.00, 67.50
	Placebo	1176	70.92 (10.92)	70.00	38.00, 120.00	1176	0.40 (11.76)	0.50	-45.50, 58.00
Month 36	Finerenone	656	71.82 (11.33)	70.50	41.00, 122.00	656	0.72 (12.94)	0.00	-36.00, 68.00
	Placebo	689	71.17 (11.33)	70.00	37.50, 165.00	689	0.21 (12.39)	0.50	-44.00, 78.50
Month 40	Finerenone	173	71.95 (10.59)	70.50	49.00, 107.50	173	1.60 (12.17)	0.50	-34.00, 37.50
	Placebo	167	71.12 (12.08)	70.00	48.00, 123.50	167	0.67 (11.73)	1.00	-29.00, 47.50
Premature discontinuation	Finerenone	135	70.79 (10.98)	68.50	45.00, 109.50	135	-1.54 (12.08)	0.00	-44.50, 34.00
	Placebo	152	73.87 (12.79)	72.50	50.00, 115.00	152	2.81 (12.02)	1.75	-33.50, 35.00
End of Study Visit	Finerenone	2089	70.95 (10.84)	70.00	40.50, 115.00	2086	-0.28 (12.69)	0.00	-68.00, 56.00
	Placebo	2020	71.00 (11.18)	70.00	40.00, 132.00	2020	0.09 (12.97)	0.00	-82.00, 75.50

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Graphical summary of mean values of Heart Rate over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 20103 - Datacut: 25JUL2024
FINEARTS-HF - Finerenone vs. Placebo
Summary of medical history of interest
Full Analysis Set

	Finerenone (N=3003)	Placebo (N=2998)
	n (%)	n (%)
Atrial Fibrillation And Atrial Flutter (PBMQ)	1669 (55.58)	1650 (55.04)
Hyperlipidemia (MLG)	765 (25.47)	767 (25.58)
Type 2 Diabetes Mellitus (PT)	1217 (40.53)	1223 (40.79)
Chronic Kidney Disease (PT)	564 (18.78)	549 (18.31)
Hypertension (MLG)	2640 (87.91)	2685 (89.56)
Ischaemic Stroke/Transitory Ischaemic Attack (PBMQ)	427 (14.22)	404 (13.48)
Cardiac Failure (MLG)	3003 (100.00)	2998 (100.00)
Carotid Endarterectomy (PT)	17 (0.57)	7 (0.23)
Coronary Artery Bypass Graft (PBMQ)	460 (15.32)	456 (15.21)
Myocardial Infarction (MLG)	784 (26.11)	757 (25.25)
Percutaneous Coronary Intervention (PBMQ)	746 (24.84)	725 (24.18)
Coronary Artery Disease (PBMQ)	1143 (38.06)	1157 (38.59)
Peripheral Arterial Disease (PBMQ)	284 (9.46)	273 (9.11)

	Finerenone (N=290)	Placebo (N=281)
	n (%)	n (%)
Full analysis set	290 (100.00)	281 (100.00)
Study drug never administered	1 (0.34)	0 (0.00)
Treated	289 (99.66)	281 (100.00)
Completed study	290 (100.00)	280 (99.64)
Did not complete study	0 (0.00)	1 (0.36)
Completed	190 (65.52)	191 (67.97)
Not completed	100 (34.48)	90 (32.03)
PROTOCOL DEVIATION	0 (0.00)	1 (0.36)
ADVERSE EVENT / OUTCOME EVENT	16 (5.52)	17 (6.05)
DEATH	31 (10.69)	34 (12.10)
DETERIORATION OF GENERAL CONDITIONS	0 (0.00)	1 (0.36)
LOGISTICAL DIFFICULTIES	3 (1.03)	4 (1.42)
NON-COMPLIANCE WITH STUDY DRUG	1 (0.34)	2 (0.71)
PHYSICIAN DECISION	12 (4.14)	12 (4.27)
PROTOCOL DEVIATION	2 (0.69)	3 (1.07)
SITE CLOSED BY HEALTH AUTHORITY	1 (0.34)	0 (0.00)
SPONSOR DECISION	1 (0.34)	0 (0.00)
SUBJECT DECISION	0 (0.00)	1 (0.36)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	5 (1.72)	2 (0.71)
SWITCHING TO OTHER THERAPY	2 (0.69)	0 (0.00)
WITHDRAWAL BY SUBJECT	26 (8.97)	14 (4.98)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=290)	Placebo (N=281)
Sex, n (%)	Male	182 (62.76)	168 (59.79)
	Female	108 (37.24)	113 (40.21)
Age	n (missing)	290 (0)	281 (0)
	Mean (SD)	64.9 (8.95)	66.3 (8.75)
	Geo.Mean (SD)	64.2 (1.16)	65.7 (1.15)
	Median	66.0	67.0
	Q1, Q3	60.0, 71.0	62.0, 72.0
	Min, Max	35.0, 89.0	33.0, 87.0
Age group (years), n (%)	< 65 years	128 (44.14)	107 (38.08)
	65 - < 75 years	118 (40.69)	130 (46.26)
	75 - < 85 years	43 (14.83)	42 (14.95)
	>= 85 years	1 (0.34)	2 (0.71)
Pooled Race Group 01, n (%)	White	263 (90.69)	239 (85.05)
	Black	15 (5.17)	11 (3.91)
	Asian	10 (3.45)	18 (6.41)
	Other	2 (0.69)	13 (4.63)
Region (pooled region for subgroup analysis), n (%)	Western Europe, Oceania and Others	33 (11.38)	39 (13.88)
	Eastern Europe	173 (59.66)	151 (53.74)
	Asia	24 (8.28)	30 (10.68)
	North America	46 (15.86)	35 (12.46)
	Latin America	14 (4.83)	26 (9.25)
Baseline Body Mass Index (kg/m2)	n (missing)	289 (1)	281 (0)
	Mean (SD)	33.3 (6.42)	32.4 (5.88)
	Geo.Mean (SD)	32.7 (1.20)	31.8 (1.20)
	Median	32.0	32.0
	Q1, Q3	28.4, 37.1	28.4, 35.9
	Min, Max	17.9, 64.4	17.6, 50.3
Baseline BMI (kg/m2) category 2, n (%)	< 30 kg/m2	96 (33.10)	110 (39.15)
	>= 30 kg/m2	193 (66.55)	171 (60.85)
	Missing	1 (0.34)	0 (0.00)
Smoking History, n (%)	Never	164 (56.55)	157 (55.87)
	Former	88 (30.34)	84 (29.89)
	Current	38 (13.10)	40 (14.23)
Alcohol Use, n (%)	Abstinent	189 (65.17)	173 (61.57)
	Light	94 (32.41)	88 (31.32)
	Moderate	7 (2.41)	20 (7.12)
	Heavy	0 (0.00)	0 (0.00)
Baseline eGFR (mL/min/1.73m2)	n (missing)	290 (0)	280 (1)
	Mean (SD)	64.0 (21.39)	62.8 (22.00)
	Geo.Mean (SD)	60.3 (1.43)	58.8 (1.45)
	Median	62.3	59.9
	Q1, Q3	47.2, 79.0	44.2, 78.1
	Min, Max	23.9, 137.1	23.4, 119.5
Baseline eGFR (mL/min/1.73 m2) category, n (%)	< 60 mL/min/1.73m2	132 (45.52)	141 (50.18)
	>= 60 mL/min/1.73m2	158 (54.48)	139 (49.47)
	Missing	0 (0.00)	1 (0.36)
Baseline potassium (mmol/L)	n (missing)	290 (0)	280 (1)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=290)	Placebo (N=281)
Baseline potassium (mmol/L)	Mean (SD)	4.4 (0.50)	4.4 (0.45)
	Geo.Mean (SD)	4.4 (1.12)	4.4 (1.11)
	Median	4.4	4.4
	Q1, Q3	4.1, 4.7	4.1, 4.7
	Min, Max	2.9, 6.3	2.8, 5.8
Baseline serum potassium (mmol/L) category, n (%)	<= 4.5 mmol/L	184 (63.45)	182 (64.77)
	> 4.5 mmol/L	106 (36.55)	98 (34.88)
	Missing	0 (0.00)	1 (0.36)
Baseline UACR (mg/g)	n (missing)	290 (0)	281 (0)
	Mean (SD)	595.0 (763.57)	538.2 (700.55)
	Geo.Mean (SD)	279.5 (3.69)	245.5 (3.82)
	Median	274.6	246.2
	Q1, Q3	110.7, 745.0	84.9, 729.2
	Min, Max	15.0, 4199.3	5.0, 5039.6
Baseline albuminuria (mg/g) category, n (%)	Normalbuminuria (UACR < 30 mg/g)	12 (4.14)	11 (3.91)
	High albuminuria (30 mg/g - < 300 mg/g)	138 (47.59)	145 (51.60)
	Very high albuminuria (>= 300 mg/g)	140 (48.28)	125 (44.48)
Baseline Hemoglobin A1C (%)	n (missing)	289 (1)	279 (2)
	Mean (SD)	8.0 (1.48)	7.9 (1.33)
	Geo.Mean (SD)	7.9 (1.19)	7.8 (1.18)
	Median	7.8	7.8
	Q1, Q3	7.0, 8.8	6.9, 8.8
	Min, Max	5.3, 14.5	5.3, 11.5
Baseline Diastolic Blood Pressure (mmHg)	n (missing)	290 (0)	281 (0)
	Mean (SD)	77.6 (9.71)	75.9 (10.46)
	Geo.Mean (SD)	77.0 (1.14)	75.2 (1.16)
	Median	79.0	76.7
	Q1, Q3	71.3, 83.3	70.0, 83.0
	Min, Max	51.3, 105.0	45.0, 103.7
Baseline Systolic Blood Pressure (mmHg)	n (missing)	290 (0)	281 (0)
	Mean (SD)	135.7 (13.58)	135.0 (13.88)
	Geo.Mean (SD)	135.0 (1.11)	134.2 (1.11)
	Median	134.7	134.7
	Q1, Q3	127.0, 144.7	126.7, 144.7
	Min, Max	100.0, 180.7	98.0, 181.7

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=290)	Placebo (N=281)
Observation Duration of All-Cause Mortality in months	Number of patients in analysis	290	281
	Mean (SD)	36.8 (12.39)	36.5 (12.15)
	Median	35.6	36.0
	Min, Max	1.0, 59.9	2.8, 61.4
Observation Duration of CV death and HHF in months	Number of patients in analysis	290	281
	Mean (SD)	34.5 (13.84)	34.0 (13.93)
	Median	33.8	33.5
	Min, Max	0.3, 59.9	0.5, 61.4
Observation Duration of CV death or non-fatal CV event in months	Number of patients in analysis	290	281
	Mean (SD)	33.6 (14.43)	32.8 (14.29)
	Median	33.2	31.7
	Min, Max	0.3, 59.9	0.5, 61.4
Observation Duration of Cardiovascular Death in months	Number of patients in analysis	290	281
	Mean (SD)	36.8 (12.39)	36.5 (12.15)
	Median	35.6	36.0
	Min, Max	1.0, 59.9	2.8, 61.4
Observation Duration of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis in months	Number of patients in analysis	290	281
	Mean (SD)	33.0 (13.79)	34.6 (13.22)
	Median	32.2	34.4
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of New onset of atrial fibrillation in months	Number of patients in analysis	230	226
	Mean (SD)	35.7 (13.26)	35.3 (12.93)
	Median	34.4	34.7
	Min, Max	1.0, 59.9	2.8, 61.4
Observation Duration of Time to Heart Failure Hospitalization in months	Number of patients in analysis	290	281
	Mean (SD)	34.5 (13.84)	34.0 (13.93)
	Median	33.8	33.5
	Min, Max	0.3, 59.9	0.5, 61.4
Observation Duration of Time to all-cause hospitalization in months	Number of patients in analysis	290	281
	Mean (SD)	25.2 (16.22)	24.8 (16.47)
	Median	27.5	26.0
	Min, Max	0.1, 59.9	0.4, 61.4
Observation Duration of Time to first CV hospitalization in months	Number of patients in analysis	290	281
	Mean (SD)	31.0 (15.24)	29.0 (15.81)
	Median	31.7	29.5
	Min, Max	0.3, 59.9	0.5, 61.4
Observation Duration of Time to first myocardial infarction (combined fatal and non-fatal) in months	Number of patients in analysis	290	281
	Mean (SD)	35.8 (12.94)	35.1 (12.82)
	Median	34.6	33.9
	Min, Max	0.4, 59.9	2.8, 61.4
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Number of patients in analysis	290	281
	Mean (SD)	25.3 (16.25)	25.0 (16.54)

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=290)	Placebo (N=281)
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Median	27.8	26.0
	Min, Max	0.1, 59.9	0.4, 61.4
Observation Duration of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) in months	Number of patients in analysis	290	281
	Mean (SD)	31.0 (15.24)	29.0 (15.81)
	Median	31.7	29.5
	Min, Max	0.3, 59.9	0.5, 61.4
Observation Duration of Time to first stroke (combined fatal and non-fatal) in months	Number of patients in analysis	290	281
	Mean (SD)	36.0 (12.91)	36.0 (12.39)
	Median	34.6	35.0
	Min, Max	1.0, 59.9	0.8, 61.4
Observation Duration of Time to initiation of dialysis or renal transplantation in months	Number of patients in analysis	290	281
	Mean (SD)	36.5 (12.54)	36.3 (12.22)
	Median	35.0	35.7
	Min, Max	1.0, 59.9	2.8, 61.4
Observation Duration of Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks in months	Number of patients in analysis	290	281
	Mean (SD)	33.0 (13.78)	34.6 (13.21)
	Median	32.2	34.4
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of VAS in months	Number of patients in analysis	289	278
	Mean (SD)	32.1 (15.28)	33.7 (14.63)
	Median	32.4	34.6
	Min, Max	0.0, 59.9	0.0, 61.4
Study Duration in months	Number of patients in analysis	290	281
	Mean (SD)	37.1 (12.64)	36.9 (12.38)
	Median	35.8	36.2
	Min, Max	1.0, 60.9	2.8, 62.3
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks in months	Number of patients in analysis	290	281
	Mean (SD)	33.2 (13.83)	34.7 (13.22)
	Median	32.2	34.5
	Min, Max	0.0, 59.9	0.0, 61.4

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Safety endpoints
Safety Analysis Set

Endpoint		Finerenone (N=289)	Placebo (N=281)
Observation Duration of Treatment Duration in months	Number of patients in analysis	289	281
	Mean (SD)	30.9 (14.86)	32.0 (14.68)
	Median	31.3	31.0
	Min, Max	0.3, 59.9	0.2, 61.3

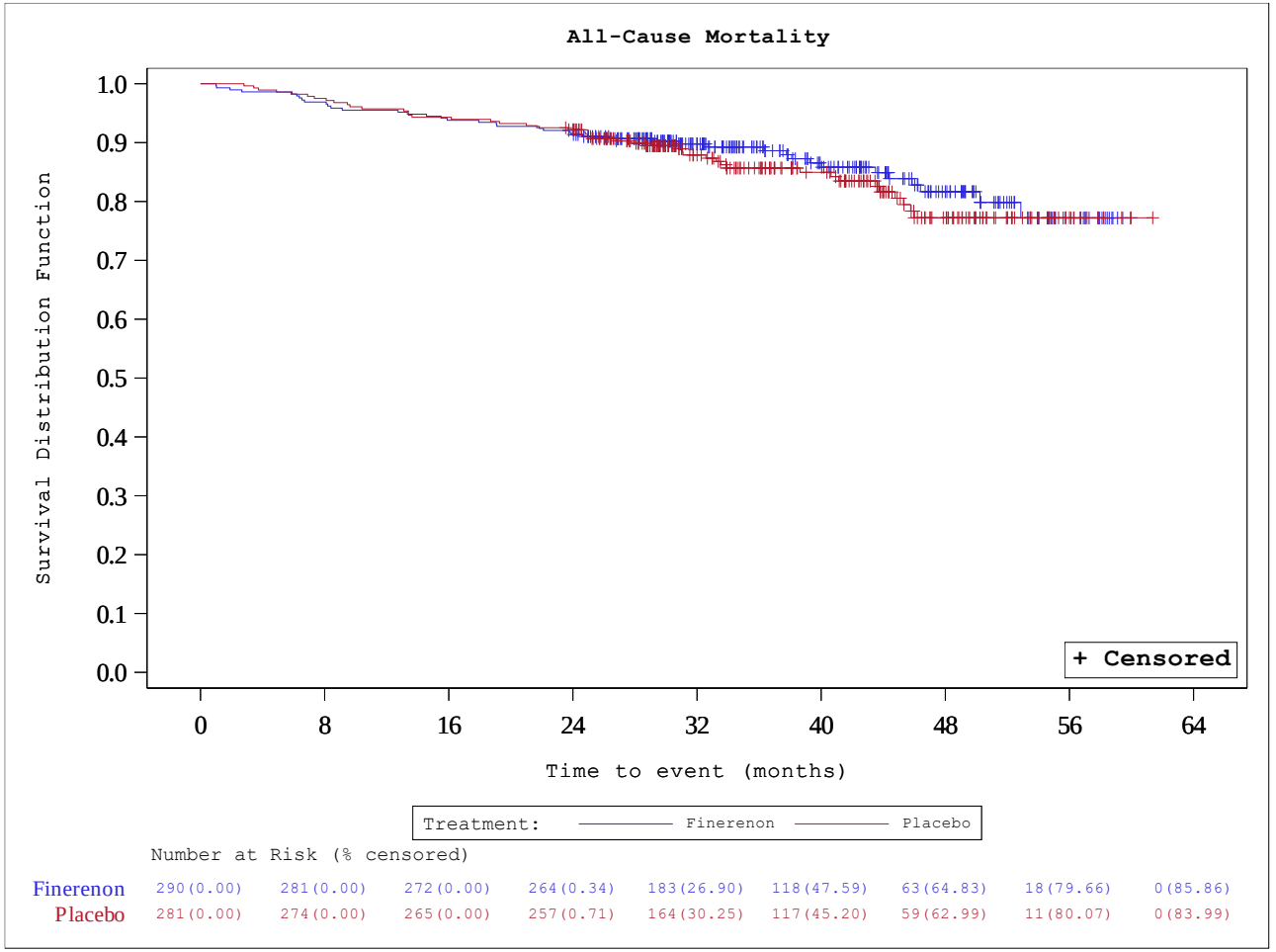
Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
All-cause mortality
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	41/ 290 (14.14)	45/ 281 (16.01)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (46.4, NE)	NE (44.8, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.00 (0.65, 1.55)	
p-value	0.9873	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.87 (0.57, 1.33)	
p-value	0.5317	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of All-cause mortality
Full Analysis Set



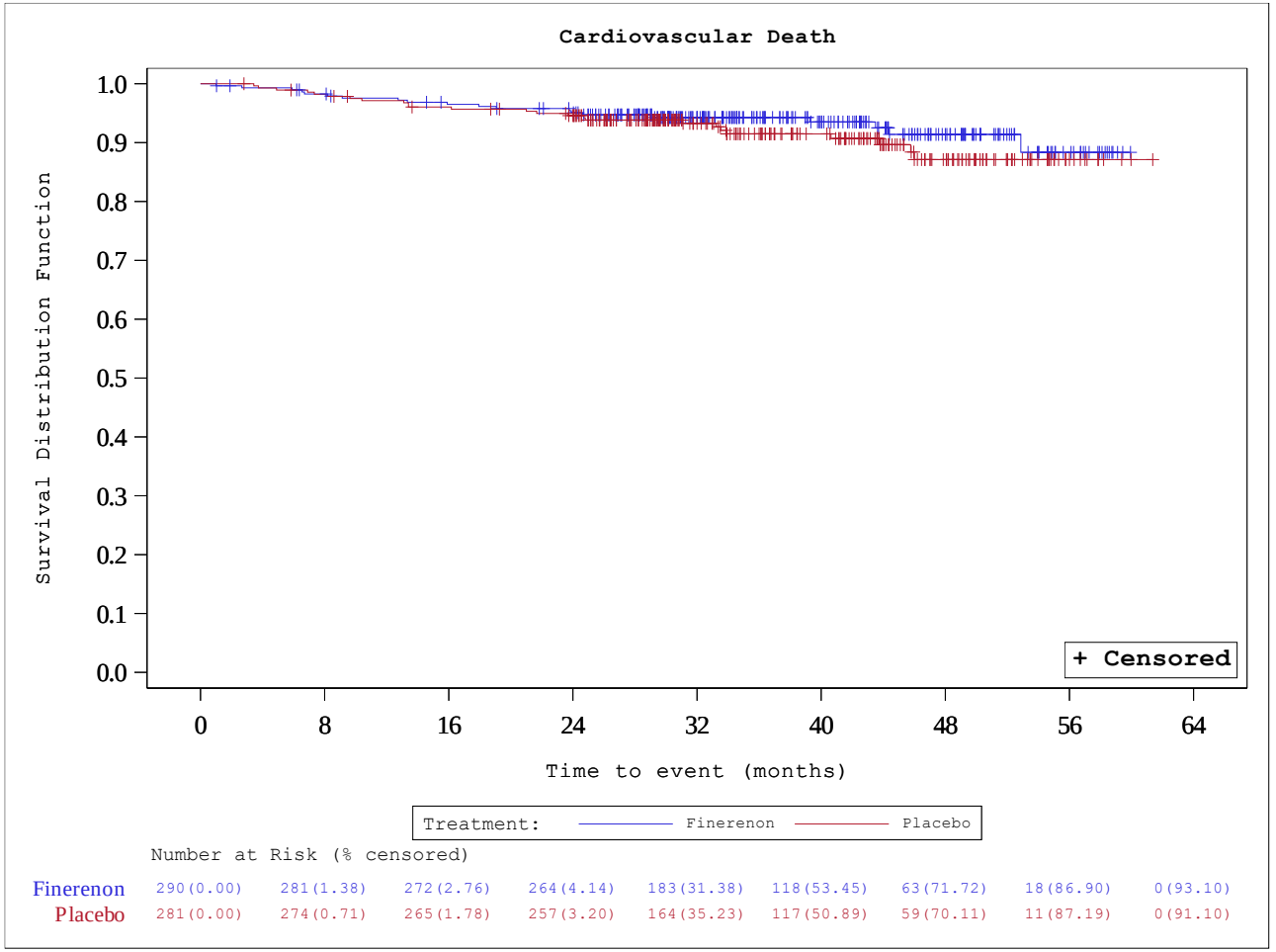
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
CV death
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	20/ 290 (6.90)	25/ 281 (8.90)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.91 (0.49, 1.67)	
p-value	0.7487	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.77 (0.43, 1.39)	
p-value	0.3827	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of CV death
Full Analysis Set



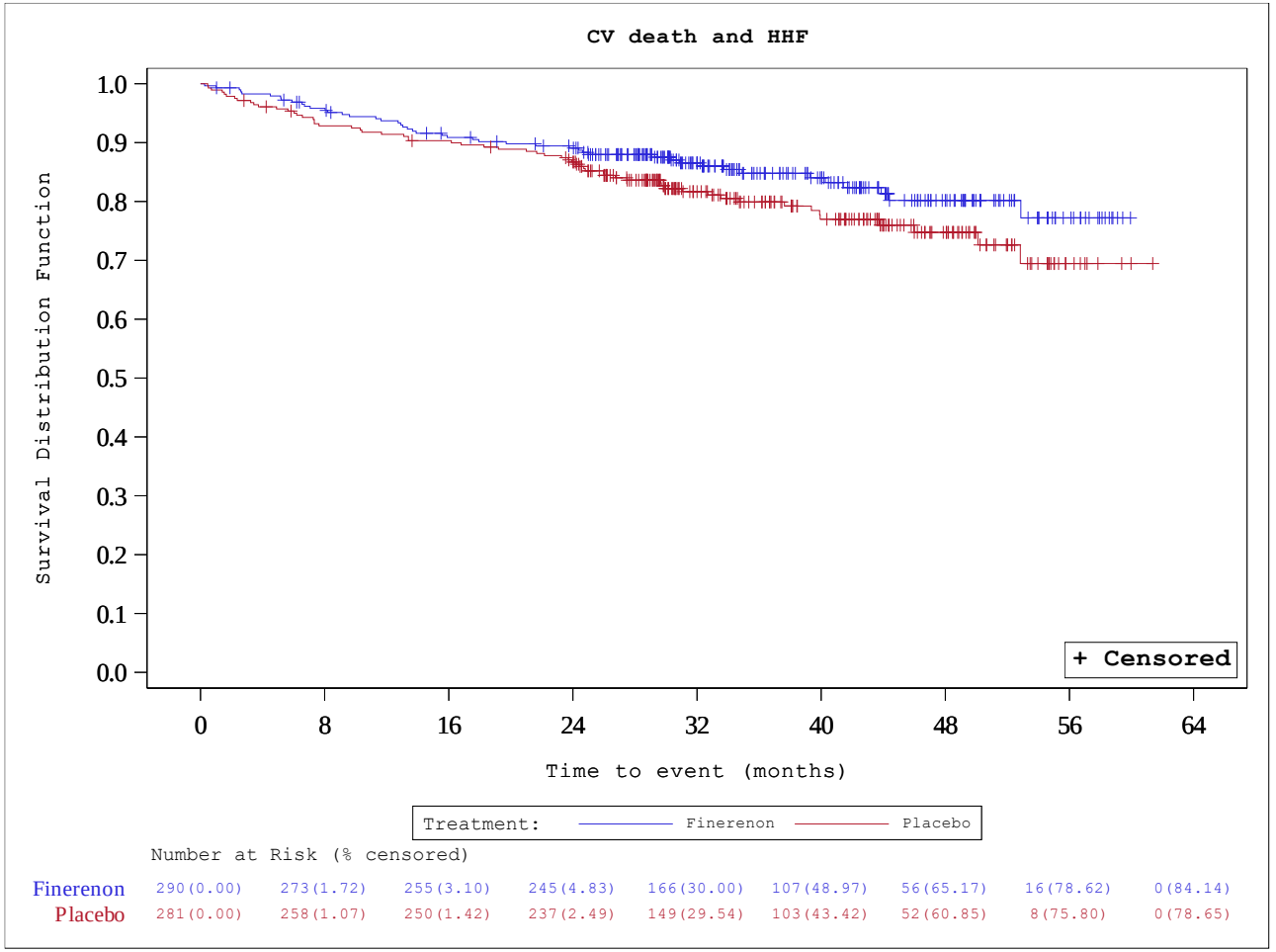
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	46/ 290 (15.86)	60/ 281 (21.35)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (44.4, NE)	46.0 (34.7, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.78 (0.52, 1.16)	
p-value	0.2162	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.73 (0.50, 1.07)	
p-value	0.1090	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; HHF=hospitalization for heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite endpoint of CV death and HF hospitalization
Full Analysis Set



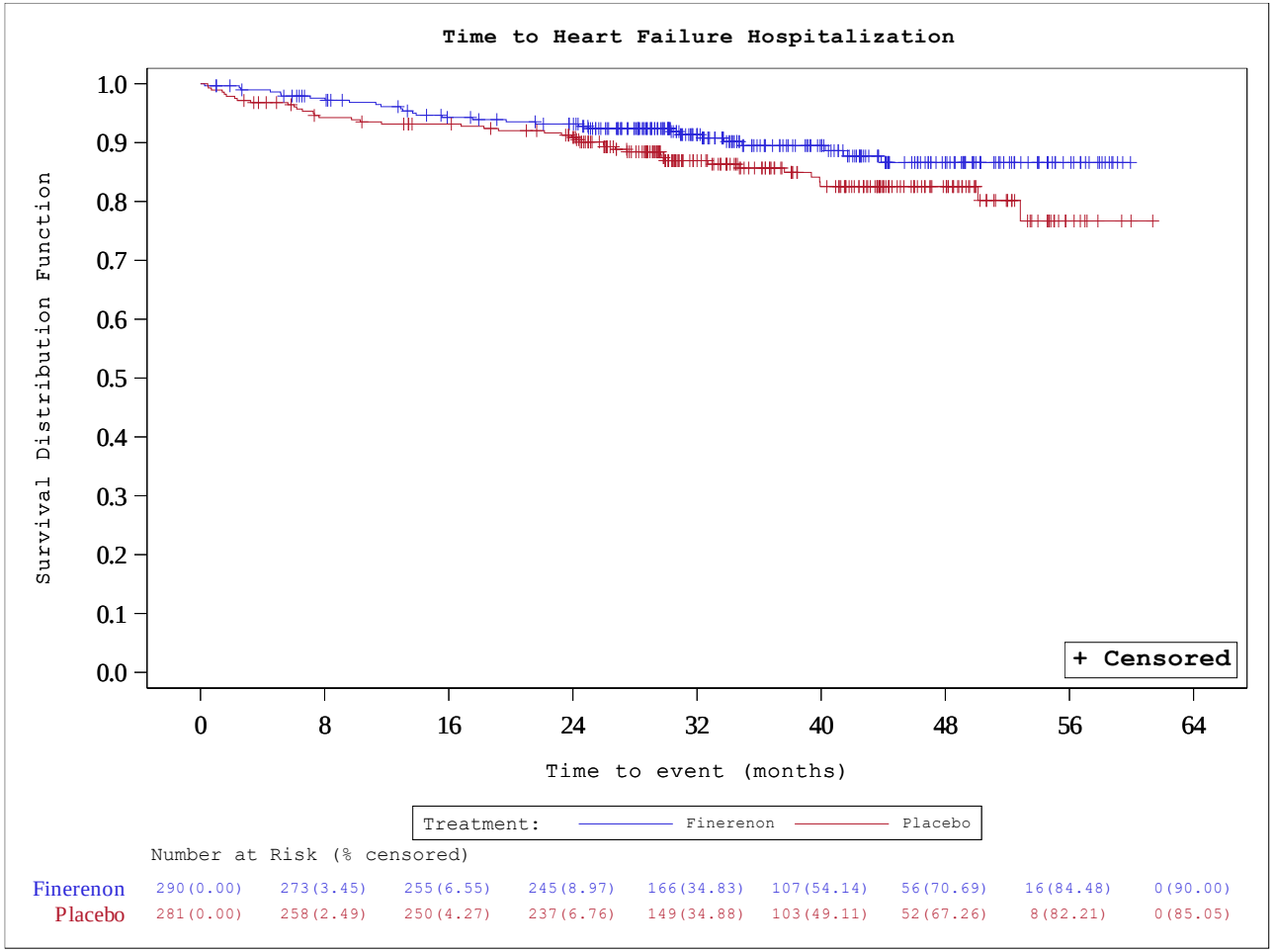
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to Heart Failure Hospitalization
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	29/ 290 (10.00)	42/ 281 (14.95)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (50.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.70 (0.43, 1.14)	
p-value	0.1454	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.66 (0.41, 1.06)	
p-value	0.0819	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



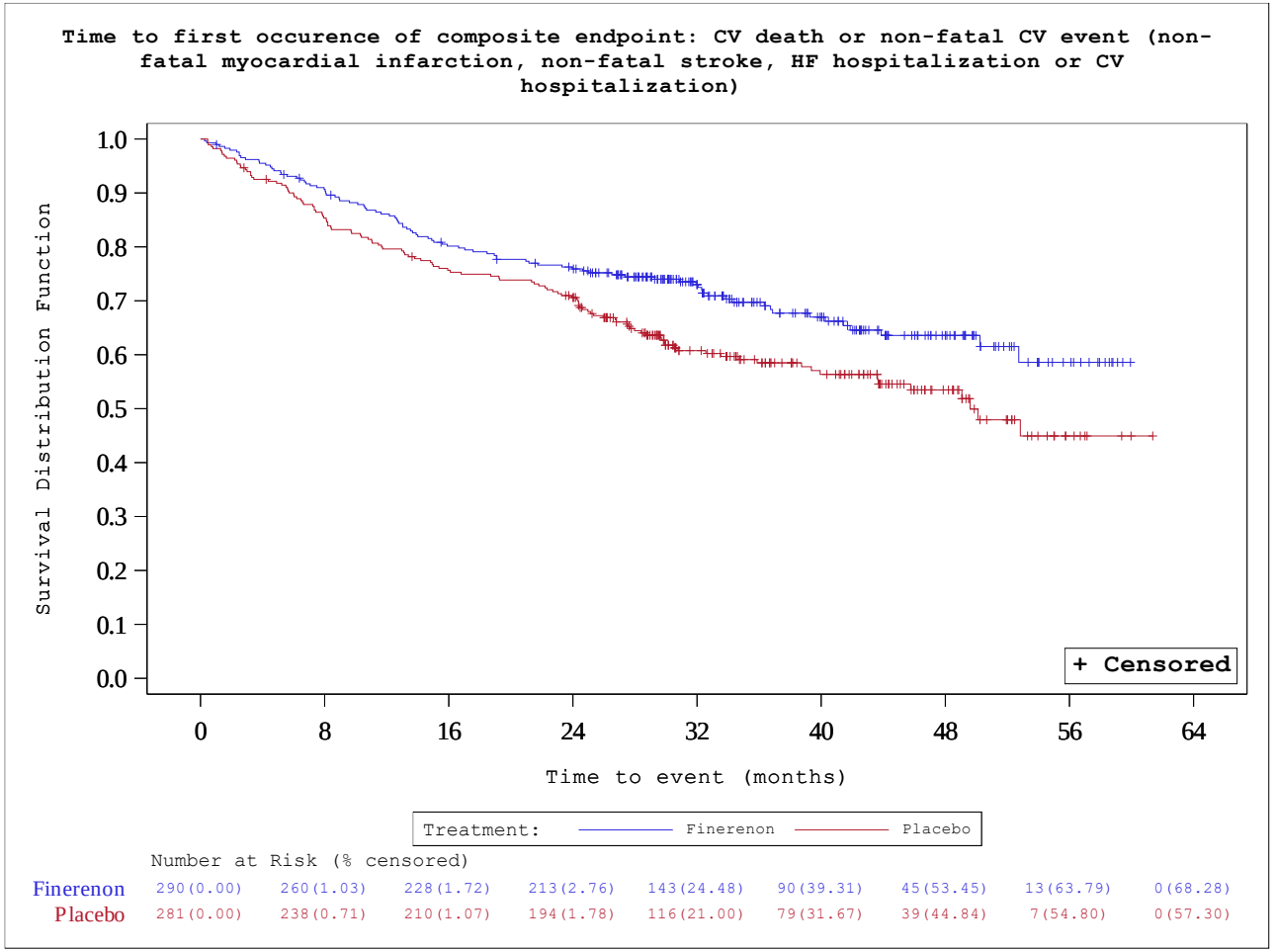
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	92/ 290 (31.72)	120/ 281 (42.70)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	26.5 (16.6, 34.3)	16.8 (11.7, 24.3)
Median (95% CI)	NE (52.7, NE)	49.6 (39.9, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.74 (0.56, 0.98)	
p-value	0.0378	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.70 (0.53, 0.91)	
p-value	0.0086	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set



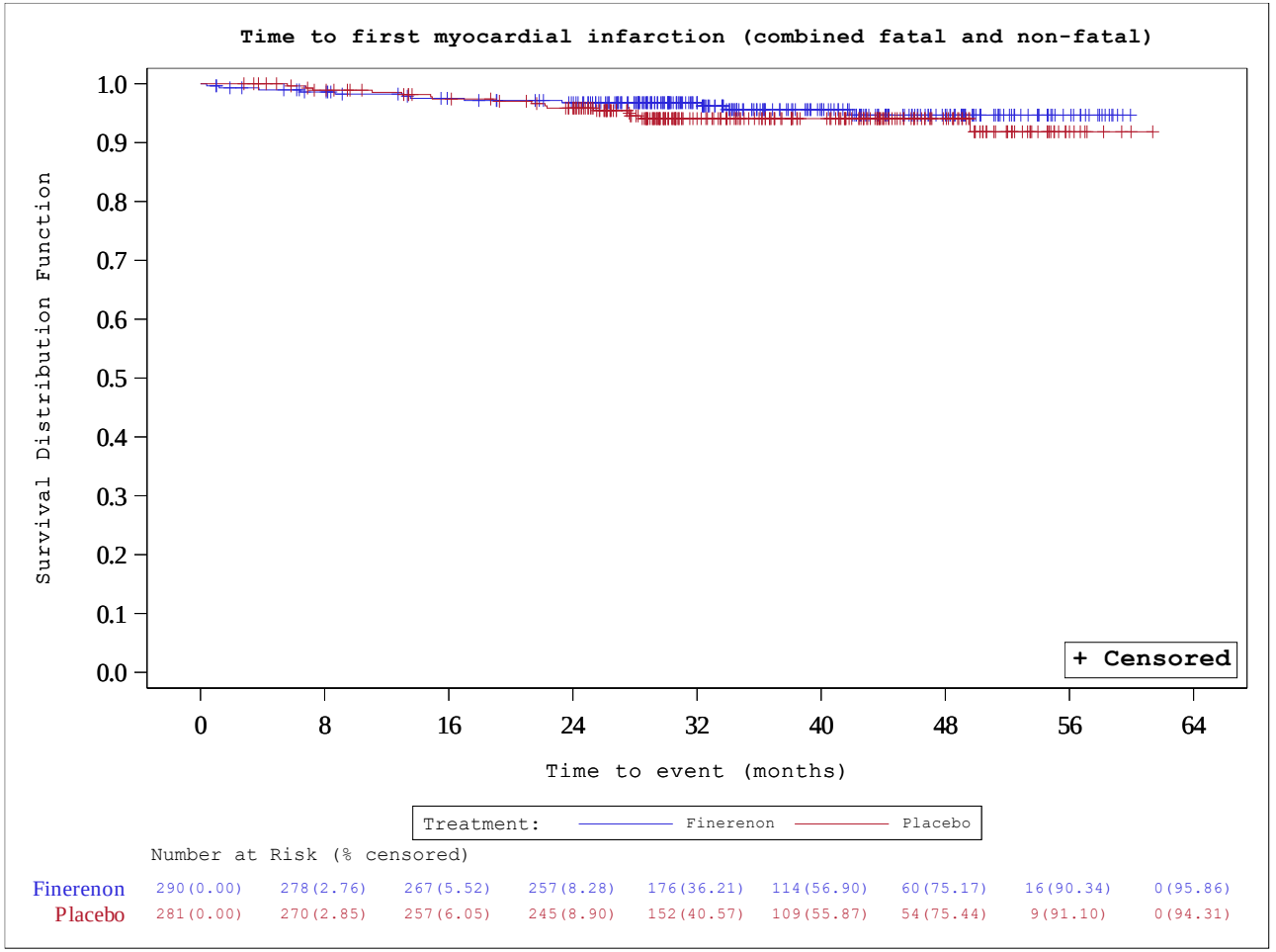
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	12/ 290 (4.14)	16/ 281 (5.69)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.79 (0.37, 1.72)	
p-value	0.5572	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.71 (0.34, 1.51)	
p-value	0.3770	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



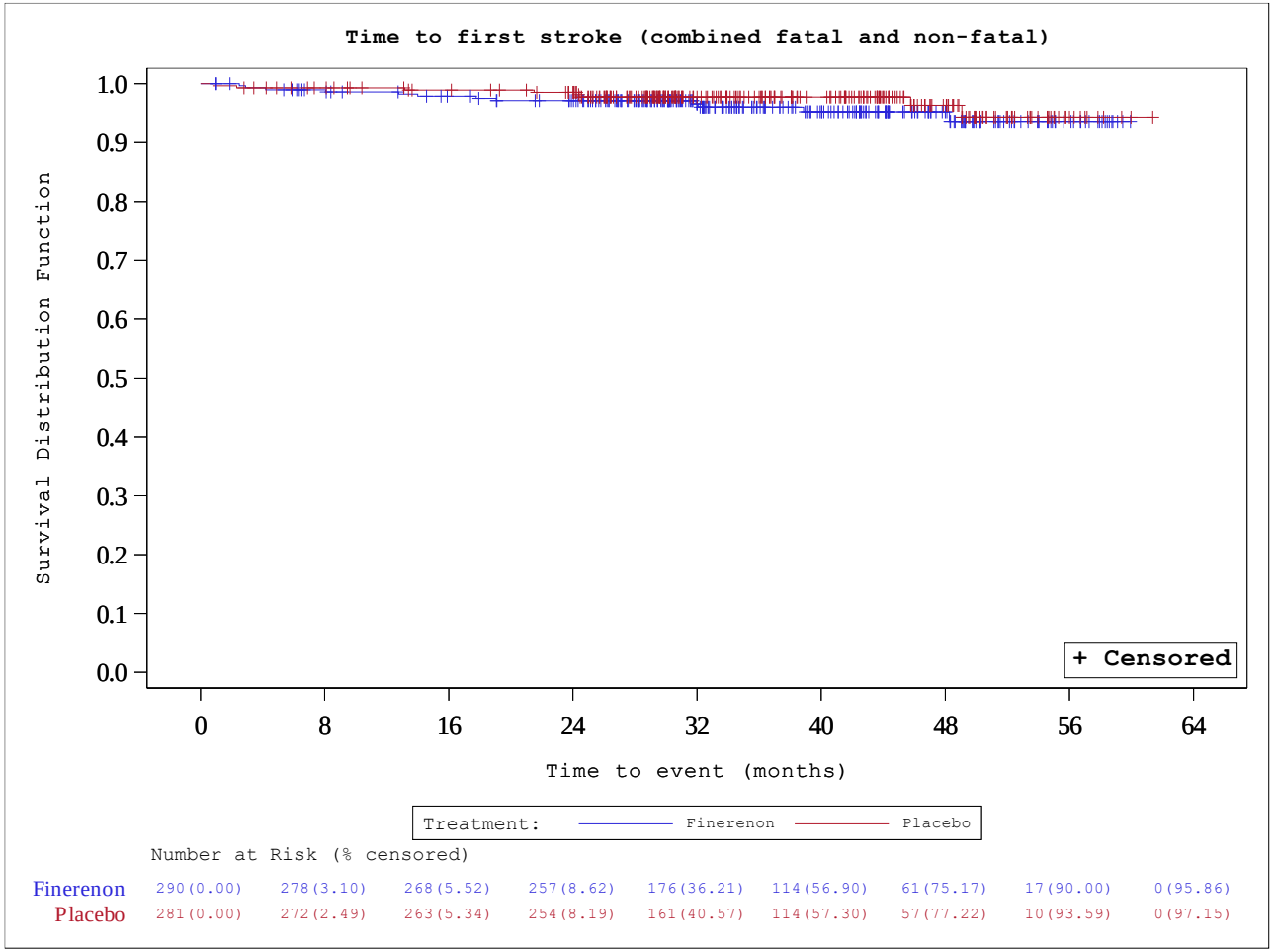
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	12/ 290 (4.14)	8/ 281 (2.85)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.33 (0.54, 3.29)	
p-value	0.5291	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.44 (0.59, 3.52)	
p-value	0.4225	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first stroke (combined fatal and non-fatal)
Full Analysis Set



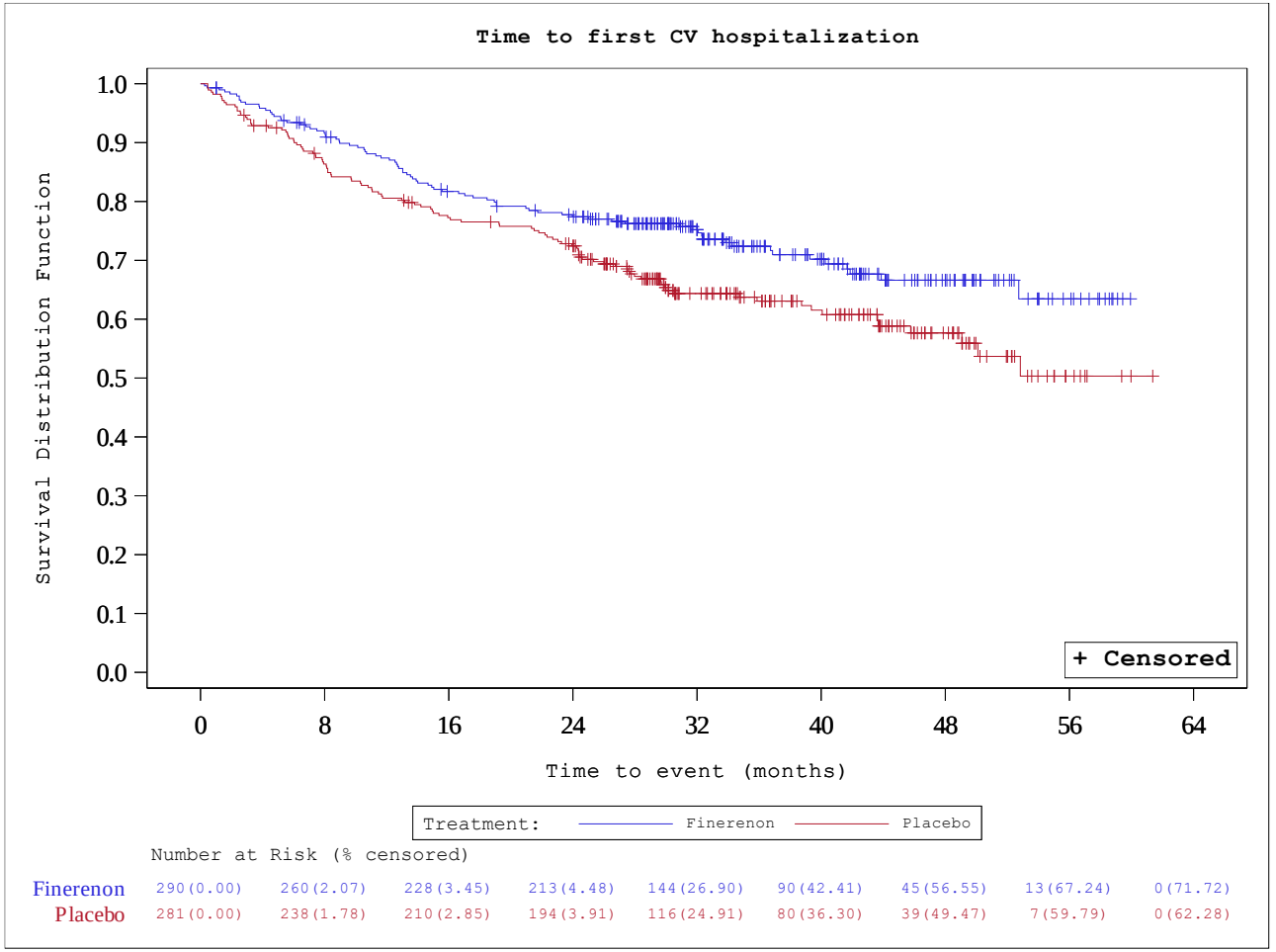
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first CV hospitalization
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	82/ 290 (28.28)	106/ 281 (37.72)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	32.1 (18.9, 40.3)	21.8 (13.2, 25.3)
Median (95% CI)	NE (NE, NE)	NE (49.1, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.75 (0.56, 1.01)	
p-value	0.0576	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.71 (0.53, 0.94)	
p-value	0.0170	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first CV hospitalization
Full Analysis Set



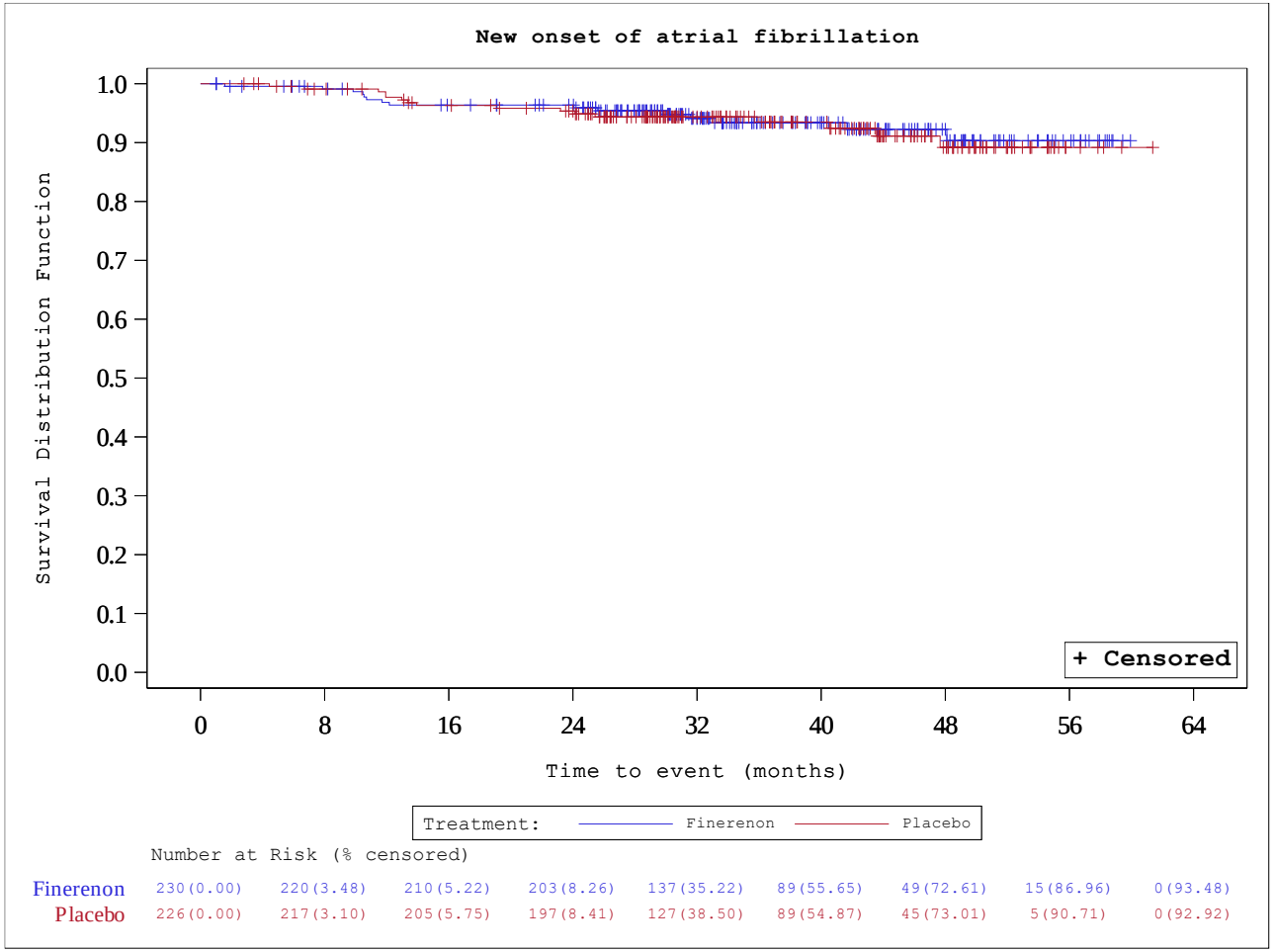
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to new onset of atrial fibrillation
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	15/ 230 (6.52)	16/ 226 (7.08)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.46, 1.91)	
p-value	0.8470	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.45, 1.86)	
p-value	0.8139	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to new onset of atrial fibrillation
Full Analysis Set



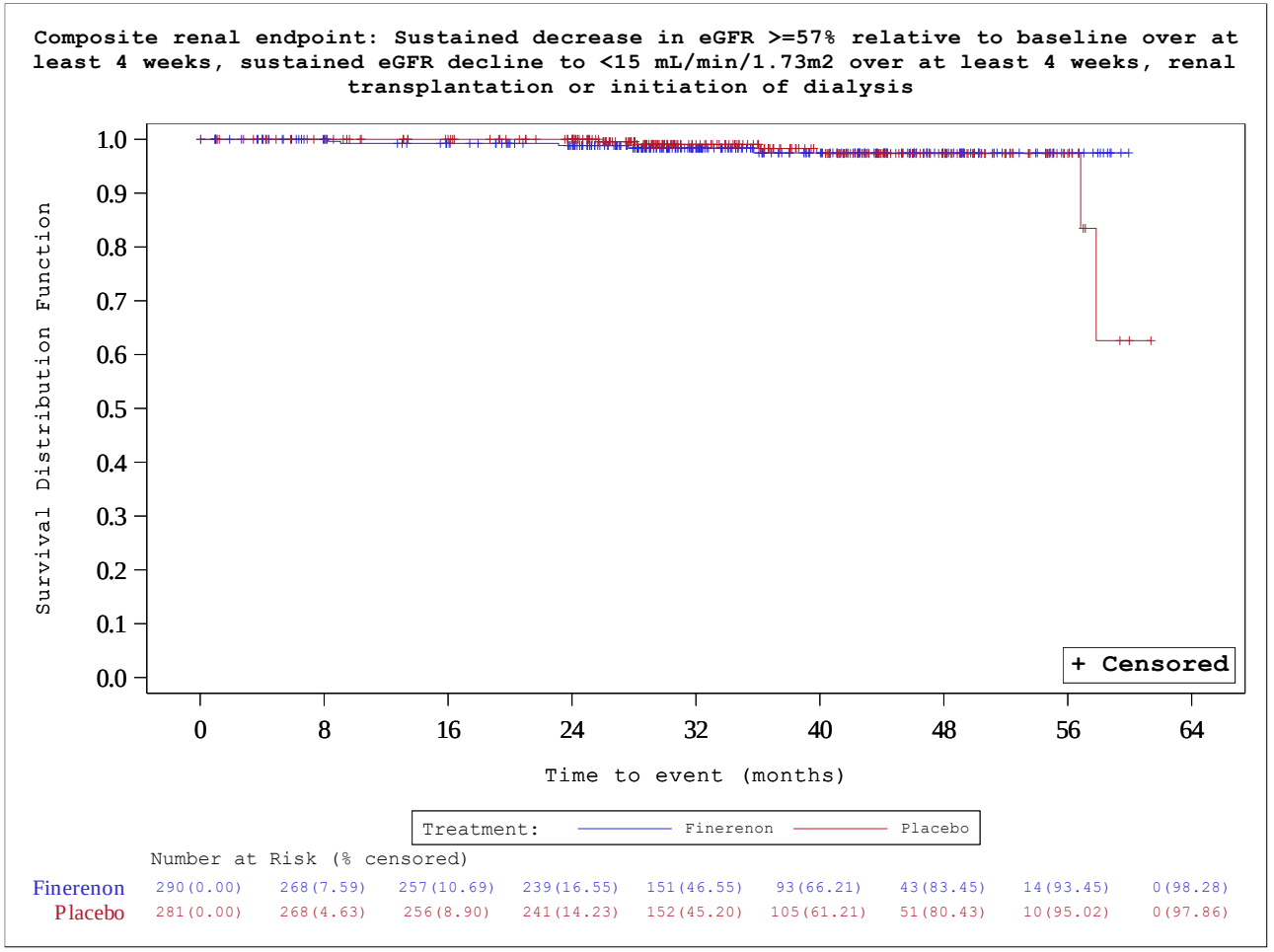
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	5/ 290 (1.72)	6/ 281 (2.14)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	57.8 (56.8, NE)
Median (95% CI)	NE (NE, NE)	NE (56.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (57.8, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.47 (0.41, 5.22)	
p-value	0.5513	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.79 (0.24, 2.62)	
p-value	0.7014	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



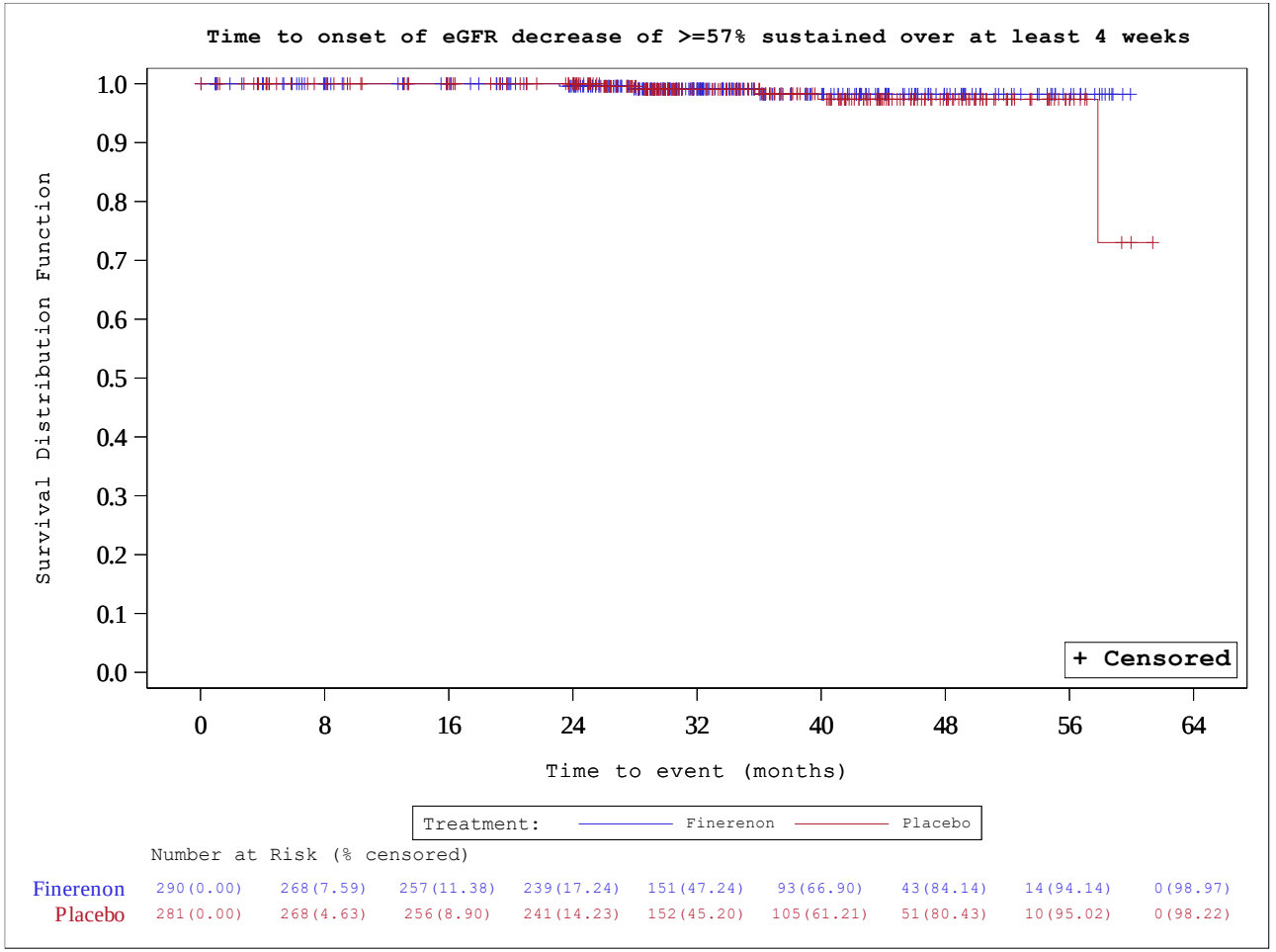
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	3/ 290 (1.03)	5/ 281 (1.78)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	57.8 (57.8, NE)
Median (95% CI)	NE (NE, NE)	NE (57.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (57.8, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.18 (0.25, 5.49)	
p-value	0.8352	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.58 (0.14, 2.46)	
p-value	0.4555	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set



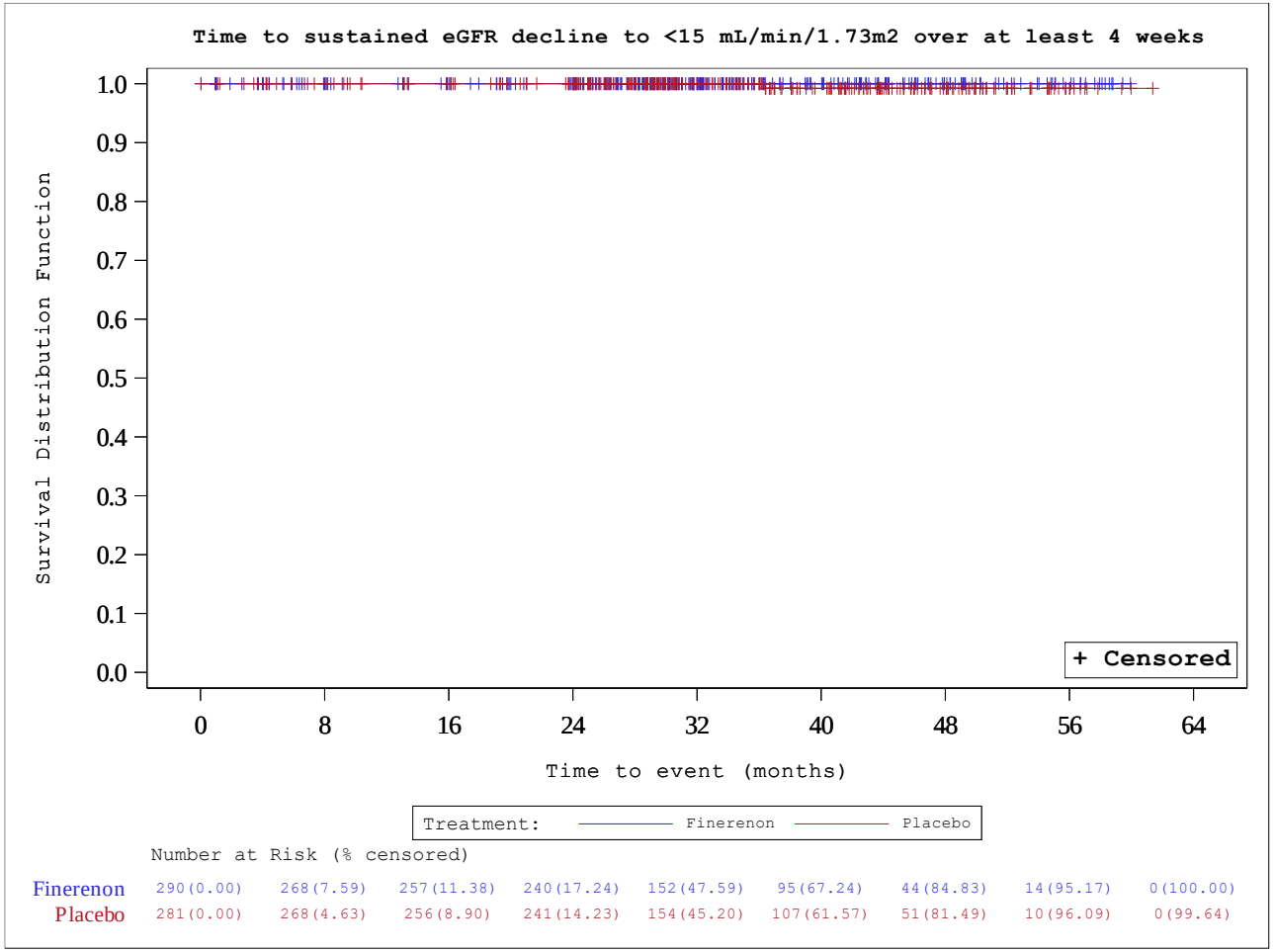
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	0/ 290 (0.00)	1/ 281 (0.36)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



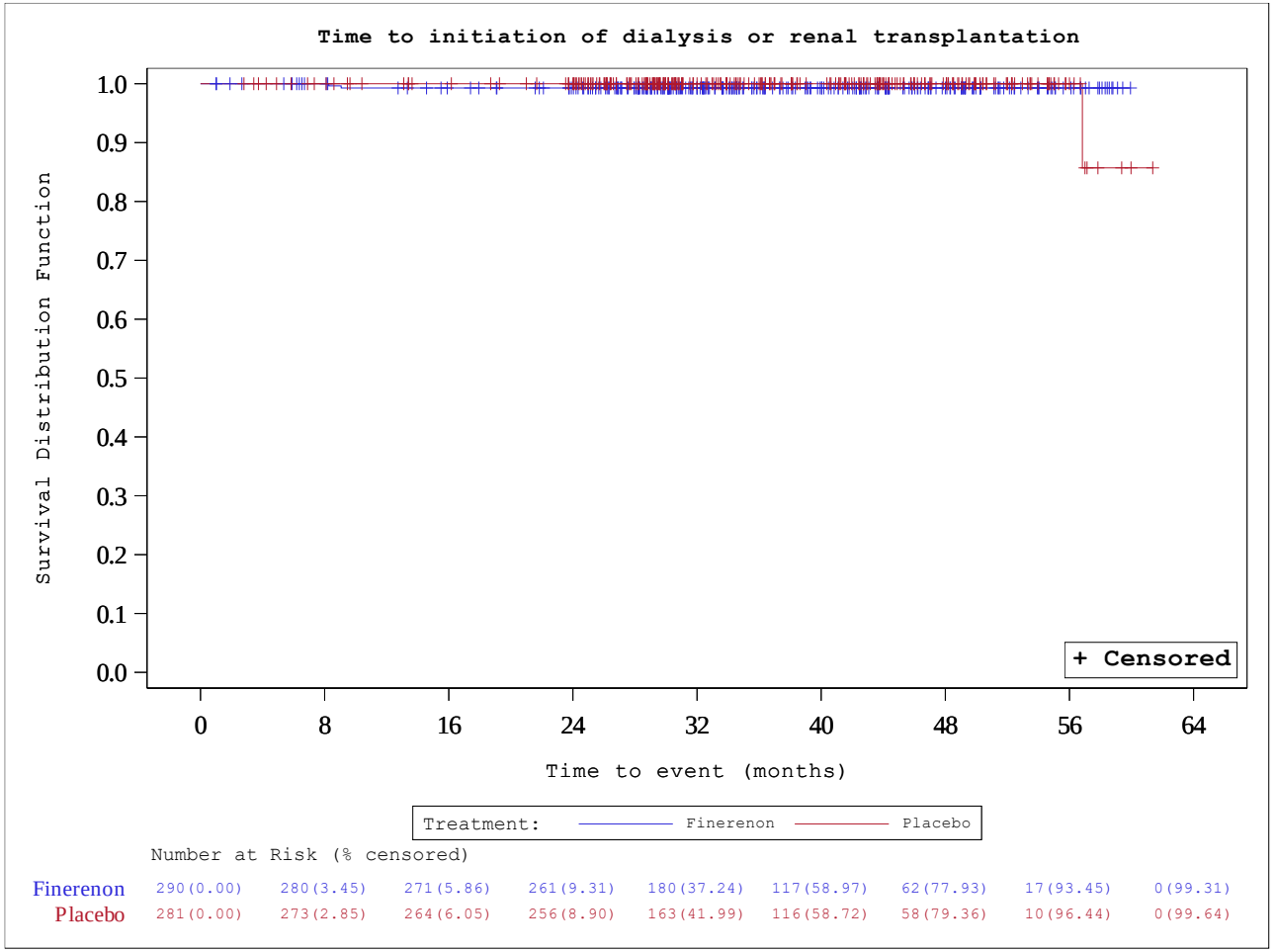
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	2/ 290 (0.69)	1/ 281 (0.36)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (56.8, NE)
Median (95% CI)	NE (NE, NE)	NE (56.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	2.40 (0.22, 26.72)	
p-value	0.4613	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.63 (0.14, 18.29)	
p-value	0.6910	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



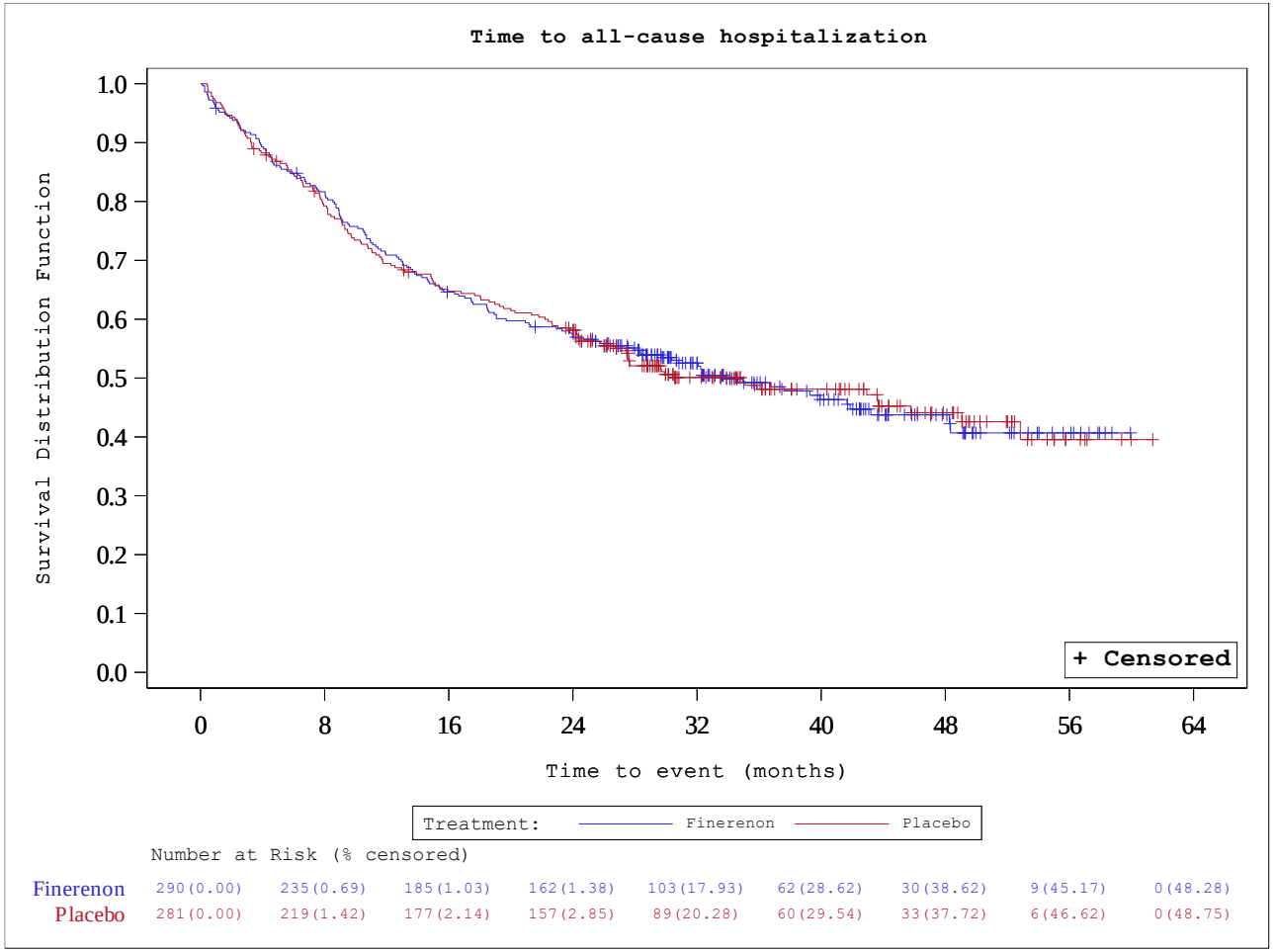
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first all-cause hospitalization
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	150/ 290 (51.72)	144/ 281 (51.25)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	10.5 (8.5, 12.9)	9.5 (7.8, 11.7)
Median (95% CI)	33.8 (25.8, 48.3)	34.9 (25.7, 49.1)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.07 (0.85, 1.36)	
p-value	0.5690	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.00 (0.79, 1.25)	
p-value	0.9665	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



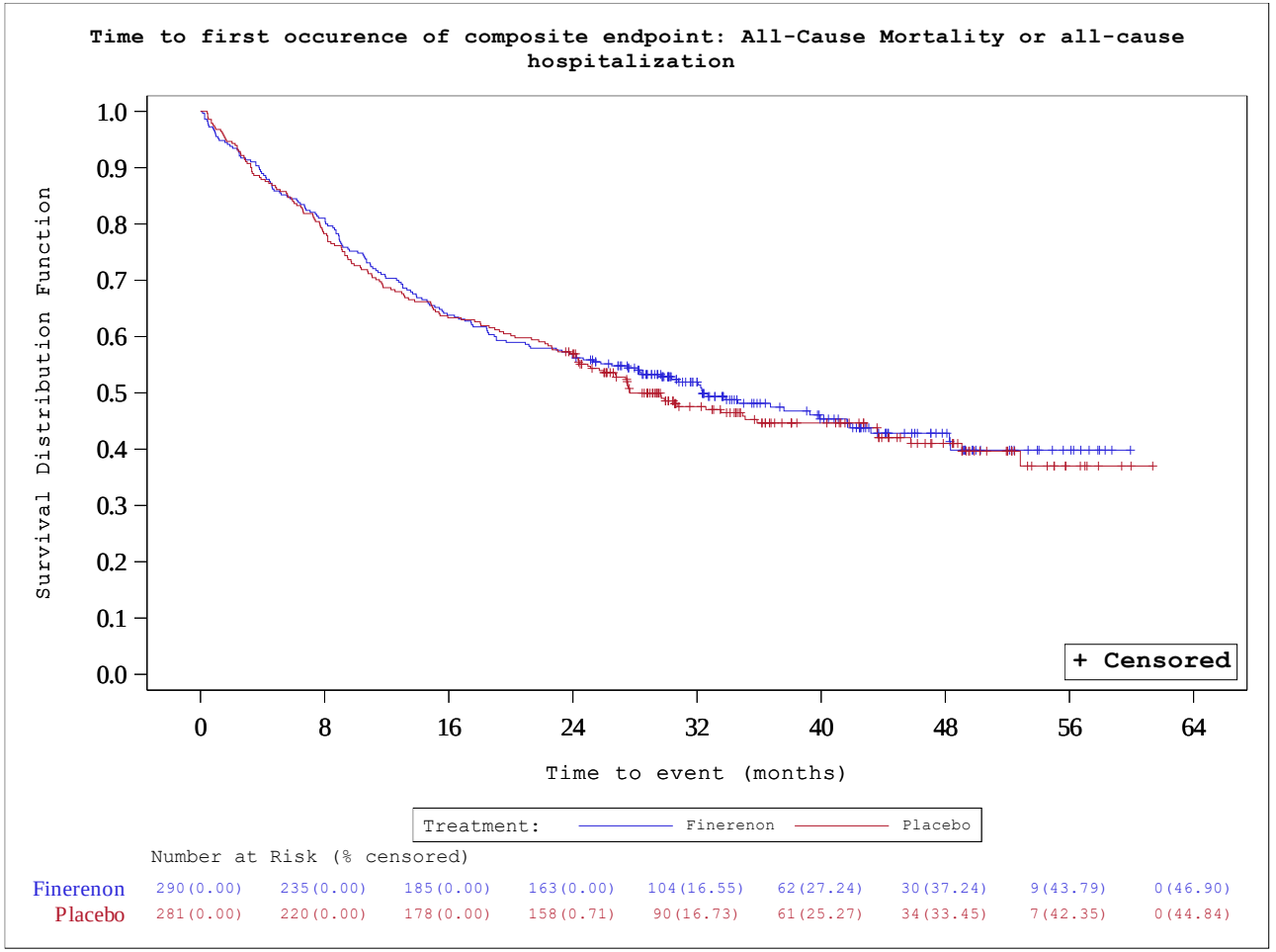
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with event, n/N (%)	154/ 290 (53.10)	155/ 281 (55.16)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	10.1 (8.1, 12.6)	9.3 (7.7, 11.5)
Median (95% CI)	32.3 (24.7, 43.2)	27.7 (24.3, 42.9)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.02 (0.81, 1.29)	
p-value	0.8410	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.95 (0.76, 1.19)	
p-value	0.6605	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Event counts per component of composite efficacy endpoints
Full Analysis Set

Endpoint	Finerenone (N=290) n (%)	Placebo (N=281) n (%)
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)	92 (31.72 %)	120 (42.70 %)
CV hospitalization	78 (26.90 %)	101 (35.94 %)
Cardiovascular Death	10 (3.45 %)	13 (4.63 %)
Hospitalization due to Heart Failure	1 (0.34 %)	4 (1.42 %)
Non-fatal MI	2 (0.69 %)	1 (0.36 %)
Non-fatal Stroke	1 (0.34 %)	1 (0.36 %)
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis	5 (1.72 %)	6 (2.14 %)
Renal transplantation or initiation of dialysis	2 (0.69 %)	1 (0.36 %)
Sustained decrease in eGFR >=57%	3 (1.03 %)	5 (1.78 %)
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization	154 (53.10 %)	155 (55.16 %)
All-cause hospitalization	150 (51.72 %)	144 (51.25 %)
Cardiovascular Death	4 (1.38 %)	11 (3.91 %)
CV death and HHF	46 (15.86 %)	60 (21.35 %)
Cardiovascular Death	17 (5.86 %)	18 (6.41 %)
Hospitalization due to Heart Failure	29 (10.00 %)	42 (14.95 %)

n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with reponse, n/N (%)	34/ 267 (12.73)	53/ 262 (20.23)
Number of imputed values	12	13
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.56 (0.34, 0.90)	
p-value	0.0164	
Risk Ratio (95% CI)	0.61 (0.41, 0.90)	
p-value	0.0134	
Risk Difference (95% CI)	-0.07 (-0.14, -0.01)	
p-value	0.0273	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.58 (0.36, 0.92)	
p-value	0.0210	
Risk Ratio (95% CI)	0.63 (0.42, 0.93)	
p-value	0.0218	
Risk Difference (95% CI)	-0.07 (-0.14, -0.01)	
p-value	0.0197	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
Number of subjects with reponse, n/N (%)	48/ 267 (17.98)	47/ 262 (17.94)
Number of imputed values	12	13
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.07 (0.68, 1.70)	
p-value	0.7671	
Risk Ratio (95% CI)	1.06 (0.74, 1.51)	
p-value	0.7615	
Risk Difference (95% CI)	0.01 (-0.06, 0.09)	
p-value	0.6910	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.00 (0.64, 1.56)	
p-value	0.9908	
Risk Ratio (95% CI)	1.00 (0.70, 1.44)	
p-value	0.9908	
Risk Difference (95% CI)	0.00 (-0.07, 0.07)	
p-value	0.9908	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
EQ5D-VAS: Completion rates
Full Analysis Set

	Finerenone (N=290)		Placebo (N=281)	
Timepoint	n/ N	Completion	n/ N	Completion
Baseline	288 /290	99.31 %	274 /281	97.51 %
Month 12	255 /277	92.06 %	252 /269	93.68 %
Month 24	222 /264	84.09 %	216 /257	84.05 %
Month 36	106 /142	74.65 %	119 /141	84.40 %
Month 48	40 /63	63.49 %	46 /59	77.97 %

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

	Finerenone (N=290)				Placebo (N=281)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	288	65.58 (17.37)	-	-	274	68.16 (16.65)	-	-
Month 12	255	66.01 (17.39)	255	-0.22 (14.03)	252	68.32 (17.22)	249	-0.01 (16.02)
Month 24	222	65.24 (17.43)	221	-0.62 (15.91)	216	66.69 (18.79)	213	-1.52 (16.95)
Month 36	106	65.82 (18.32)	105	-1.72 (17.39)	119	65.67 (18.62)	117	-3.88 (14.84)
Month 48	40	68.00 (16.08)	40	-1.25 (16.36)	46	66.48 (17.15)	46	-6.46 (16.48)
Premature discontinuation	7	72.14 (14.68)	7	-3.86 (13.93)	13	69.00 (19.40)	13	-9.31 (16.77)
End of Study Visit	209	65.17 (19.13)	208	-0.82 (18.00)	211	67.18 (18.17)	208	-1.71 (17.42)

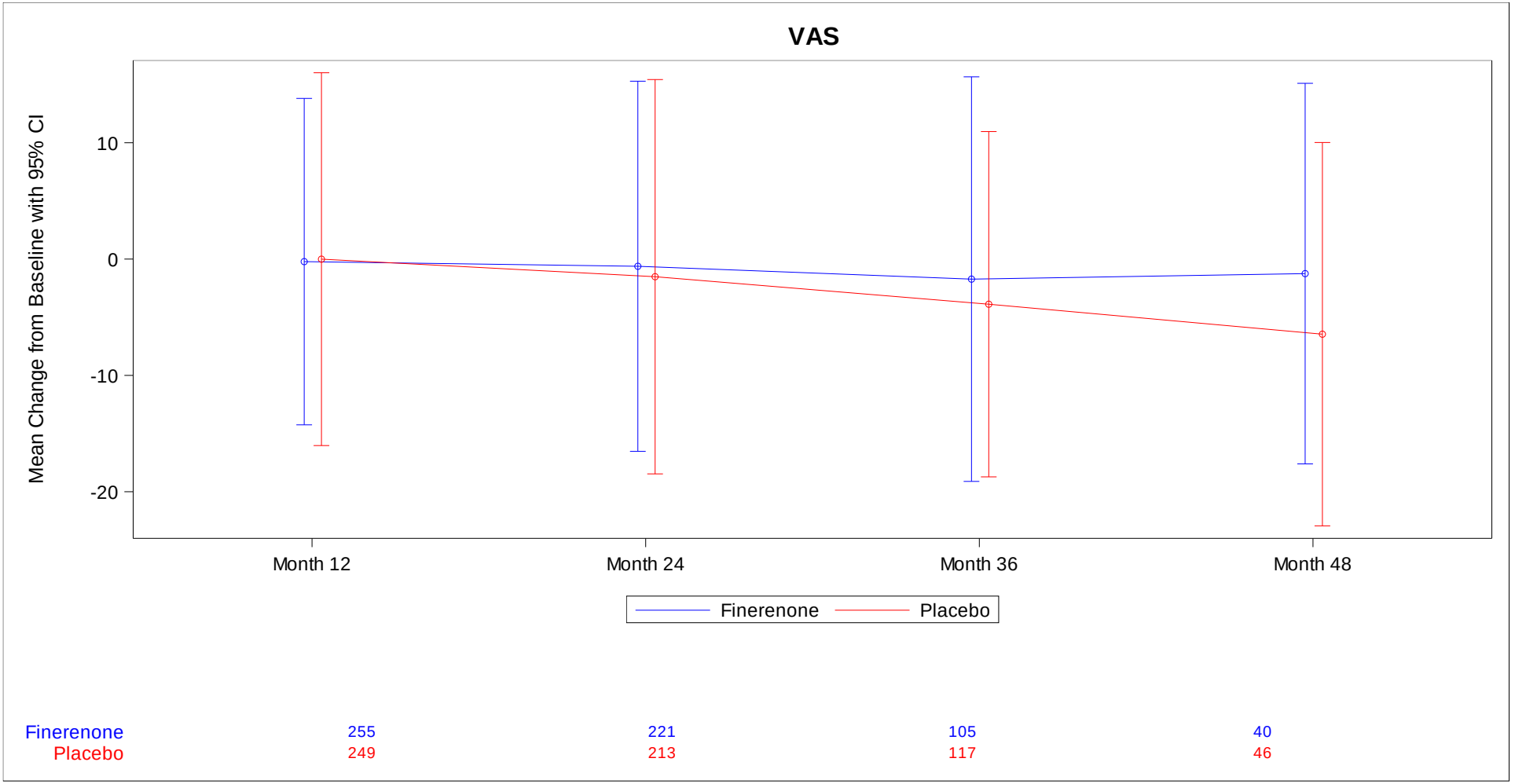
n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

Timepoint	Finerenone (N=290) N	Finerenone (N=290) LSMean (SE)	Placebo (N=281) N	Placebo (N=281) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	255	-0.26 (1.56)	249	0.68 (1.56)	-0.94 (-3.35, 1.47)	0.4457	-0.04 (-0.21, 0.14)	0.6718

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of change from baseline of EQ5D-VAS over time
Full Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	236/ 289 (81.66)	242/ 281 (86.12)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.72 (0.46, 1.13)	
p-value	0.1490	
Risk Ratio (95% CI)	0.95 (0.88, 1.02)	
p-value	0.1479	
Risk Difference (95% CI)	-0.04 (-0.10, 0.02)	
p-value	0.1465	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	234/ 289 (80.97)	242/ 281 (86.12)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.69 (0.44, 1.07)	
p-value	0.0987	
Risk Ratio (95% CI)	0.94 (0.87, 1.01)	
p-value	0.0976	
Risk Difference (95% CI)	-0.05 (-0.11, 0.01)	
p-value	0.0961	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	123/ 289 (42.56)	112/ 281 (39.86)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.12 (0.80, 1.56)	
p-value	0.5123	
Risk Ratio (95% CI)	1.07 (0.88, 1.30)	
p-value	0.5126	
Risk Difference (95% CI)	0.03 (-0.05, 0.11)	
p-value	0.5120	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	121/ 289 (41.87)	112/ 281 (39.86)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.09 (0.78, 1.52)	
p-value	0.6254	
Risk Ratio (95% CI)	1.05 (0.86, 1.28)	
p-value	0.6256	
Risk Difference (95% CI)	0.02 (-0.06, 0.10)	
p-value	0.6253	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	69/ 289 (23.88)	72/ 281 (25.62)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.91 (0.62, 1.33)	
p-value	0.6289	
Risk Ratio (95% CI)	0.93 (0.70, 1.24)	
p-value	0.6289	
Risk Difference (95% CI)	-0.02 (-0.09, 0.05)	
p-value	0.6289	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	68/ 289 (23.53)	70/ 281 (24.91)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.93 (0.63, 1.36)	
p-value	0.7003	
Risk Ratio (95% CI)	0.94 (0.71, 1.26)	
p-value	0.7003	
Risk Difference (95% CI)	-0.01 (-0.08, 0.06)	
p-value	0.7003	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	11/ 289 (3.81)	14/ 281 (4.98)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.75 (0.34, 1.69)	
p-value	0.4943	
Risk Ratio (95% CI)	0.76 (0.35, 1.65)	
p-value	0.4945	
Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
p-value	0.4937	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	11/ 289 (3.81)	14/ 281 (4.98)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.75 (0.34, 1.69)	
p-value	0.4943	
Risk Ratio (95% CI)	0.76 (0.35, 1.65)	
p-value	0.4945	
Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
p-value	0.4937	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	10/ 289 (3.46)	9/ 281 (3.20)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.08 (0.43, 2.71)	
p-value	0.8642	
Risk Ratio (95% CI)	1.08 (0.45, 2.62)	
p-value	0.8642	
Risk Difference (95% CI)	0.00 (-0.03, 0.03)	
p-value	0.8640	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Serious)
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	5/ 289 (1.73)	8/ 281 (2.85)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.60 (0.19, 1.86)	
p-value	0.3767	
Risk Ratio (95% CI)	0.61 (0.20, 1.84)	
p-value	0.3771	
Risk Difference (95% CI)	-0.01 (-0.04, 0.01)	
p-value	0.3731	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Severe)
Safety Analysis Set

	Finerenone (N=289)	Placebo (N=281)
Number of subjects with event, n/N (%)	5/ 289 (1.73)	6/ 281 (2.14)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.81 (0.24, 2.67)	
p-value	0.7257	
Risk Ratio (95% CI)	0.81 (0.25, 2.62)	
p-value	0.7257	
Risk Difference (95% CI)	-0.00 (-0.03, 0.02)	
p-value	0.7256	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	41/ 289 (14.19)	34/ 281 (12.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.74, 1.96)	
	p-value	0.4615	
	Risk Ratio (95% CI)	1.17 (0.77, 1.79)	
	p-value	0.4619	
	Risk Difference (95% CI)	0.02 (-0.03, 0.08)	
	p-value	0.4605	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	28/ 289 (9.69)	23/ 281 (8.19)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.68, 2.14)	
	p-value	0.5300	
	Risk Ratio (95% CI)	1.18 (0.70, 2.00)	
	p-value	0.5302	
	Risk Difference (95% CI)	0.02 (-0.03, 0.06)	
	p-value	0.5289	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	77/ 289 (26.64)	71/ 281 (25.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.74, 1.56)	
	p-value	0.7078	
	Risk Ratio (95% CI)	1.05 (0.80, 1.39)	
	p-value	0.7079	
	Risk Difference (95% CI)	0.01 (-0.06, 0.09)	
	p-value	0.7077	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	12/ 289 (4.15)	19/ 281 (6.76)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.60 (0.28, 1.25)	
	p-value	0.1737	
	Risk Ratio (95% CI)	0.61 (0.30, 1.24)	
	p-value	0.1745	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.01)	
	p-value	0.1703	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders; PT: Cardiac failure chronic	Number of subjects with event, n/N (%)	12/ 289 (4.15)	7/ 281 (2.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.70 (0.66, 4.37)	
	p-value	0.2744	
	Risk Ratio (95% CI)	1.67 (0.67, 4.17)	
	p-value	0.2751	
	Risk Difference (95% CI)	0.02 (-0.01, 0.05)	
	p-value	0.2672	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	10/ 289 (3.46)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.34, 1.89)	
	p-value	0.6162	
	Risk Ratio (95% CI)	0.81 (0.36, 1.85)	
	p-value	0.6163	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.6160	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Endocrine disorders	Number of subjects with event, n/N (%)	10/ 289 (3.46)	5/ 281 (1.78)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.98 (0.67, 5.86)	
	p-value	0.2183	
	Risk Ratio (95% CI)	1.94 (0.67, 5.62)	
	p-value	0.2192	
	Risk Difference (95% CI)	0.02 (-0.01, 0.04)	
	p-value	0.2074	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Eye disorders	Number of subjects with event, n/N (%)	35/ 289 (12.11)	25/ 281 (8.90)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.41 (0.82, 2.43)	
	p-value	0.2129	
	Risk Ratio (95% CI)	1.36 (0.84, 2.21)	
	p-value	0.2138	
	Risk Difference (95% CI)	0.03 (-0.02, 0.08)	
	p-value	0.2098	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Eye disorders; PT: Cataract	Number of subjects with event, n/N (%)	18/ 289 (6.23)	8/ 281 (2.85)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.27 (0.97, 5.30)	
	p-value	0.0591	
	Risk Ratio (95% CI)	2.19 (0.97, 4.95)	
	p-value	0.0602	
	Risk Difference (95% CI)	0.03 (-0.00, 0.07)	
	p-value	0.0511	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Eye disorders; PT: Diabetic retinopathy	Number of subjects with event, n/N (%)	11/ 289 (3.81)	5/ 281 (1.78)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.18 (0.75, 6.37)	
	p-value	0.1525	
	Risk Ratio (95% CI)	2.14 (0.75, 6.08)	
	p-value	0.1535	
	Risk Difference (95% CI)	0.02 (-0.01, 0.05)	
	p-value	0.1403	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	75/ 289 (25.95)	72/ 281 (25.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.70, 1.48)	
	p-value	0.9285	
	Risk Ratio (95% CI)	1.01 (0.77, 1.34)	
	p-value	0.9285	
	Risk Difference (95% CI)	0.00 (-0.07, 0.08)	
	p-value	0.9285	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Abdominal pain	Number of subjects with event, n/N (%)	10/ 289 (3.46)	4/ 281 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.48 (0.77, 8.01)	
	p-value	0.1282	
	Risk Ratio (95% CI)	2.43 (0.77, 7.66)	
	p-value	0.1294	
	Risk Difference (95% CI)	0.02 (-0.00, 0.05)	
	p-value	0.1134	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Constipation	Number of subjects with event, n/N (%)	13/ 289 (4.50)	15/ 281 (5.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.39, 1.79)	
	p-value	0.6432	
	Risk Ratio (95% CI)	0.84 (0.41, 1.74)	
	p-value	0.6432	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.03)	
	p-value	0.6431	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	11/ 289 (3.81)	15/ 281 (5.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.70 (0.32, 1.56)	
	p-value	0.3830	
	Risk Ratio (95% CI)	0.71 (0.33, 1.53)	
	p-value	0.3834	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.02)	
	p-value	0.3816	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Gastrooesophageal reflux disease	Number of subjects with event, n/N (%)	12/ 289 (4.15)	3/ 281 (1.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	4.01 (1.12, 14.38)	
	p-value	0.0328	
	Risk Ratio (95% CI)	3.89 (1.11, 13.64)	
	p-value	0.0338	
	Risk Difference (95% CI)	0.03 (0.00, 0.06)	
	p-value	0.0198	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	15/ 289 (5.19)	13/ 281 (4.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.53, 2.42)	
	p-value	0.7556	
	Risk Ratio (95% CI)	1.12 (0.54, 2.31)	
	p-value	0.7556	
	Risk Difference (95% CI)	0.01 (-0.03, 0.04)	
	p-value	0.7552	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	58/ 289 (20.07)	59/ 281 (21.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.94 (0.63, 1.42)	
	p-value	0.7841	
	Risk Ratio (95% CI)	0.96 (0.69, 1.32)	
	p-value	0.7841	
	Risk Difference (95% CI)	-0.01 (-0.08, 0.06)	
	p-value	0.7841	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions; PT: Chest pain	Number of subjects with event, n/N (%)	12/ 289 (4.15)	14/ 281 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.83 (0.38, 1.82)	
	p-value	0.6354	
	Risk Ratio (95% CI)	0.83 (0.39, 1.77)	
	p-value	0.6354	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.03)	
	p-value	0.6353	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	19/ 289 (6.57)	24/ 281 (8.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.75 (0.40, 1.41)	
	p-value	0.3754	
	Risk Ratio (95% CI)	0.77 (0.43, 1.37)	
	p-value	0.3757	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.02)	
	p-value	0.3746	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	24/ 289 (8.30)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.32 (0.70, 2.50)	
	p-value	0.3869	
	Risk Ratio (95% CI)	1.30 (0.72, 2.34)	
	p-value	0.3874	
	Risk Difference (95% CI)	0.02 (-0.02, 0.06)	
	p-value	0.3846	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	131/ 289 (45.33)	139/ 281 (49.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.61, 1.18)	
	p-value	0.3228	
	Risk Ratio (95% CI)	0.92 (0.77, 1.09)	
	p-value	0.3229	
	Risk Difference (95% CI)	-0.04 (-0.12, 0.04)	
	p-value	0.3222	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Bronchitis	Number of subjects with event, n/N (%)	14/ 289 (4.84)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.52, 2.51)	
	p-value	0.7429	
	Risk Ratio (95% CI)	1.13 (0.53, 2.41)	
	p-value	0.7429	
	Risk Difference (95% CI)	0.01 (-0.03, 0.04)	
	p-value	0.7425	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	13/ 289 (4.50)	9/ 281 (3.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.42 (0.60, 3.39)	
	p-value	0.4243	
	Risk Ratio (95% CI)	1.40 (0.61, 3.23)	
	p-value	0.4247	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.4208	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	19/ 289 (6.57)	20/ 281 (7.12)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.92 (0.48, 1.76)	
	p-value	0.7974	
	Risk Ratio (95% CI)	0.92 (0.50, 1.69)	
	p-value	0.7974	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.04)	
	p-value	0.7975	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	20/ 289 (6.92)	28/ 281 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.37, 1.22)	
	p-value	0.1930	
	Risk Ratio (95% CI)	0.69 (0.40, 1.20)	
	p-value	0.1938	
	Risk Difference (95% CI)	-0.03 (-0.08, 0.02)	
	p-value	0.1911	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Upper respiratory tract infection	Number of subjects with event, n/N (%)	14/ 289 (4.84)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.56, 2.80)	
	p-value	0.5886	
	Risk Ratio (95% CI)	1.24 (0.57, 2.68)	
	p-value	0.5887	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.5873	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	19/ 289 (6.57)	28/ 281 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.64 (0.35, 1.17)	
	p-value	0.1439	
	Risk Ratio (95% CI)	0.66 (0.38, 1.15)	
	p-value	0.1448	
	Risk Difference (95% CI)	-0.03 (-0.08, 0.01)	
	p-value	0.1416	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	41/ 289 (14.19)	45/ 281 (16.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.55, 1.37)	
	p-value	0.5425	
	Risk Ratio (95% CI)	0.89 (0.60, 1.31)	
	p-value	0.5426	
	Risk Difference (95% CI)	-0.02 (-0.08, 0.04)	
	p-value	0.5424	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations	Number of subjects with event, n/N (%)	75/ 289 (25.95)	63/ 281 (22.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.21 (0.83, 1.78)	
	p-value	0.3254	
	Risk Ratio (95% CI)	1.16 (0.86, 1.55)	
	p-value	0.3261	
	Risk Difference (95% CI)	0.04 (-0.03, 0.11)	
	p-value	0.3243	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Blood creatine phosphokinase increased	Number of subjects with event, n/N (%)	11/ 289 (3.81)	3/ 281 (1.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	3.67 (1.01, 13.29)	
	p-value	0.0479	
	Risk Ratio (95% CI)	3.57 (1.01, 12.64)	
	p-value	0.0491	
	Risk Difference (95% CI)	0.03 (0.00, 0.05)	
	p-value	0.0326	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: C-reactive protein increased	Number of subjects with event, n/N (%)	10/ 289 (3.46)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.34, 1.89)	
	p-value	0.6162	
	Risk Ratio (95% CI)	0.81 (0.36, 1.85)	
	p-value	0.6163	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.6160	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Gamma-glutamyltransferase increased	Number of subjects with event, n/N (%)	10/ 289 (3.46)	4/ 281 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.48 (0.77, 8.01)	
	p-value	0.1282	
	Risk Ratio (95% CI)	2.43 (0.77, 7.66)	
	p-value	0.1294	
	Risk Difference (95% CI)	0.02 (-0.00, 0.05)	
	p-value	0.1134	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	18/ 289 (6.23)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.80 (0.82, 3.97)	
	p-value	0.1453	
	Risk Ratio (95% CI)	1.75 (0.82, 3.73)	
	p-value	0.1464	
	Risk Difference (95% CI)	0.03 (-0.01, 0.06)	
	p-value	0.1382	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	103/ 289 (35.64)	91/ 281 (32.38)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.82, 1.64)	
	p-value	0.4123	
	Risk Ratio (95% CI)	1.10 (0.88, 1.38)	
	p-value	0.4127	
	Risk Difference (95% CI)	0.03 (-0.05, 0.11)	
	p-value	0.4117	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Diabetes mellitus	Number of subjects with event, n/N (%)	8/ 289 (2.77)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.64 (0.26, 1.59)	
	p-value	0.3334	
	Risk Ratio (95% CI)	0.65 (0.27, 1.56)	
	p-value	0.3339	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.02)	
	p-value	0.3308	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Diabetes mellitus inadequate control	Number of subjects with event, n/N (%)	10/ 289 (3.46)	4/ 281 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.48 (0.77, 8.01)	
	p-value	0.1282	
	Risk Ratio (95% CI)	2.43 (0.77, 7.66)	
	p-value	0.1294	
	Risk Difference (95% CI)	0.02 (-0.00, 0.05)	
	p-value	0.1134	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Gout	Number of subjects with event, n/N (%)	10/ 289 (3.46)	7/ 281 (2.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.40 (0.53, 3.74)	
	p-value	0.4984	
	Risk Ratio (95% CI)	1.39 (0.54, 3.60)	
	p-value	0.4986	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.4954	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia	Number of subjects with event, n/N (%)	15/ 289 (5.19)	8/ 281 (2.85)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.87 (0.78, 4.48)	
	p-value	0.1612	
	Risk Ratio (95% CI)	1.82 (0.79, 4.23)	
	p-value	0.1622	
	Risk Difference (95% CI)	0.02 (-0.01, 0.06)	
	p-value	0.1528	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	28/ 289 (9.69)	14/ 281 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.05 (1.05, 3.97)	
	p-value	0.0346	
	Risk Ratio (95% CI)	1.94 (1.05, 3.62)	
	p-value	0.0356	
	Risk Difference (95% CI)	0.05 (0.00, 0.09)	
	p-value	0.0302	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hyperuricaemia	Number of subjects with event, n/N (%)	15/ 289 (5.19)	16/ 281 (5.69)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.44, 1.87)	
	p-value	0.7910	
	Risk Ratio (95% CI)	0.91 (0.46, 1.81)	
	p-value	0.7910	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.03)	
	p-value	0.7911	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hypoglycaemia	Number of subjects with event, n/N (%)	17/ 289 (5.88)	16/ 281 (5.69)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.51, 2.09)	
	p-value	0.9233	
	Risk Ratio (95% CI)	1.03 (0.53, 2.00)	
	p-value	0.9233	
	Risk Difference (95% CI)	0.00 (-0.04, 0.04)	
	p-value	0.9233	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hypokalaemia	Number of subjects with event, n/N (%)	7/ 289 (2.42)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.25, 1.79)	
	p-value	0.4279	
	Risk Ratio (95% CI)	0.68 (0.26, 1.76)	
	p-value	0.4282	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.4261	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	65/ 289 (22.49)	72/ 281 (25.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.57, 1.24)	
	p-value	0.3820	
	Risk Ratio (95% CI)	0.88 (0.66, 1.18)	
	p-value	0.3822	
	Risk Difference (95% CI)	-0.03 (-0.10, 0.04)	
	p-value	0.3817	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	19/ 289 (6.57)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.73 (0.81, 3.70)	
	p-value	0.1595	
	Risk Ratio (95% CI)	1.68 (0.81, 3.46)	
	p-value	0.1606	
	Risk Difference (95% CI)	0.03 (-0.01, 0.06)	
	p-value	0.1530	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	18/ 289 (6.23)	16/ 281 (5.69)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.10 (0.55, 2.20)	
	p-value	0.7877	
	Risk Ratio (95% CI)	1.09 (0.57, 2.10)	
	p-value	0.7878	
	Risk Difference (95% CI)	0.01 (-0.03, 0.04)	
	p-value	0.7875	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders; PT: Osteoarthritis	Number of subjects with event, n/N (%)	7/ 289 (2.42)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.61 (0.23, 1.59)	
	p-value	0.3129	
	Risk Ratio (95% CI)	0.62 (0.24, 1.57)	
	p-value	0.3134	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.01)	
	p-value	0.3095	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity	Number of subjects with event, n/N (%)	11/ 289 (3.81)	9/ 281 (3.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.49, 2.93)	
	p-value	0.6958	
	Risk Ratio (95% CI)	1.19 (0.50, 2.82)	
	p-value	0.6959	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.6951	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	21/ 289 (7.27)	22/ 281 (7.83)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.92 (0.50, 1.72)	
	p-value	0.7993	
	Risk Ratio (95% CI)	0.93 (0.52, 1.65)	
	p-value	0.7993	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.04)	
	p-value	0.7993	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	55/ 289 (19.03)	65/ 281 (23.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.52, 1.17)	
	p-value	0.2305	
	Risk Ratio (95% CI)	0.82 (0.60, 1.13)	
	p-value	0.2311	
	Risk Difference (95% CI)	-0.04 (-0.11, 0.03)	
	p-value	0.2298	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders; PT: Diabetic neuropathy	Number of subjects with event, n/N (%)	10/ 289 (3.46)	9/ 281 (3.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.43, 2.71)	
	p-value	0.8642	
	Risk Ratio (95% CI)	1.08 (0.45, 2.62)	
	p-value	0.8642	
	Risk Difference (95% CI)	0.00 (-0.03, 0.03)	
	p-value	0.8640	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	5/ 289 (1.73)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.26 (0.09, 0.70)	
	p-value	0.0081	
	Risk Ratio (95% CI)	0.27 (0.10, 0.72)	
	p-value	0.0086	
	Risk Difference (95% CI)	-0.05 (-0.08, -0.01)	
	p-value	0.0046	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders; PT: Headache	Number of subjects with event, n/N (%)	15/ 289 (5.19)	7/ 281 (2.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.14 (0.86, 5.34)	
	p-value	0.1017	
	Risk Ratio (95% CI)	2.08 (0.86, 5.03)	
	p-value	0.1028	
	Risk Difference (95% CI)	0.03 (-0.00, 0.06)	
	p-value	0.0921	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	16/ 289 (5.54)	23/ 281 (8.19)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.66 (0.34, 1.27)	
	p-value	0.2132	
	Risk Ratio (95% CI)	0.68 (0.37, 1.25)	
	p-value	0.2139	
	Risk Difference (95% CI)	-0.03 (-0.07, 0.02)	
	p-value	0.2110	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	54/ 289 (18.69)	65/ 281 (23.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.76 (0.51, 1.15)	
	p-value	0.1923	
	Risk Ratio (95% CI)	0.81 (0.59, 1.11)	
	p-value	0.1929	
	Risk Difference (95% CI)	-0.04 (-0.11, 0.02)	
	p-value	0.1914	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	22/ 289 (7.61)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.63, 2.30)	
	p-value	0.5733	
	Risk Ratio (95% CI)	1.19 (0.65, 2.17)	
	p-value	0.5734	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.5723	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders; PT: Renal cyst	Number of subjects with event, n/N (%)	7/ 289 (2.42)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.25, 1.79)	
	p-value	0.4279	
	Risk Ratio (95% CI)	0.68 (0.26, 1.76)	
	p-value	0.4282	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.4261	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	15/ 289 (5.19)	16/ 281 (5.69)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.44, 1.87)	
	p-value	0.7910	
	Risk Ratio (95% CI)	0.91 (0.46, 1.81)	
	p-value	0.7910	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.03)	
	p-value	0.7911	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	64/ 289 (22.15)	68/ 281 (24.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.60, 1.32)	
	p-value	0.5612	
	Risk Ratio (95% CI)	0.92 (0.68, 1.23)	
	p-value	0.5613	
	Risk Difference (95% CI)	-0.02 (-0.09, 0.05)	
	p-value	0.5612	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	11/ 289 (3.81)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.45, 2.57)	
	p-value	0.8754	
	Risk Ratio (95% CI)	1.07 (0.46, 2.48)	
	p-value	0.8754	
	Risk Difference (95% CI)	0.00 (-0.03, 0.03)	
	p-value	0.8753	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough	Number of subjects with event, n/N (%)	12/ 289 (4.15)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.06 (0.46, 2.45)	
	p-value	0.8854	
	Risk Ratio (95% CI)	1.06 (0.48, 2.36)	
	p-value	0.8854	
	Risk Difference (95% CI)	0.00 (-0.03, 0.03)	
	p-value	0.8853	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	13/ 289 (4.50)	16/ 281 (5.69)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.37, 1.65)	
	p-value	0.5170	
	Risk Ratio (95% CI)	0.79 (0.39, 1.61)	
	p-value	0.5171	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.5165	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	46/ 289 (15.92)	39/ 281 (13.88)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.74, 1.86)	
	p-value	0.4950	
	Risk Ratio (95% CI)	1.15 (0.77, 1.70)	
	p-value	0.4953	
	Risk Difference (95% CI)	0.02 (-0.04, 0.08)	
	p-value	0.4942	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Skin and subcutaneous tissue disorders; PT: Skin ulcer	Number of subjects with event, n/N (%)	15/ 289 (5.19)	8/ 281 (2.85)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.87 (0.78, 4.48)	
	p-value	0.1612	
	Risk Ratio (95% CI)	1.82 (0.79, 4.23)	
	p-value	0.1622	
	Risk Difference (95% CI)	0.02 (-0.01, 0.06)	
	p-value	0.1528	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	21/ 289 (7.27)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.60, 2.20)	
	p-value	0.6842	
	Risk Ratio (95% CI)	1.13 (0.62, 2.08)	
	p-value	0.6843	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.6838	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	66/ 289 (22.84)	74/ 281 (26.33)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.83 (0.57, 1.21)	
	p-value	0.3325	
	Risk Ratio (95% CI)	0.87 (0.65, 1.16)	
	p-value	0.3328	
	Risk Difference (95% CI)	-0.03 (-0.11, 0.04)	
	p-value	0.3321	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders; PT: Hypertension	Number of subjects with event, n/N (%)	22/ 289 (7.61)	30/ 281 (10.68)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.39, 1.23)	
	p-value	0.2060	
	Risk Ratio (95% CI)	0.71 (0.42, 1.21)	
	p-value	0.2068	
	Risk Difference (95% CI)	-0.03 (-0.08, 0.02)	
	p-value	0.2044	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	18/ 289 (6.23)	13/ 281 (4.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.37 (0.66, 2.85)	
	p-value	0.4008	
	Risk Ratio (95% CI)	1.35 (0.67, 2.70)	
	p-value	0.4012	
	Risk Difference (95% CI)	0.02 (-0.02, 0.05)	
	p-value	0.3979	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders; PT: Peripheral arterial occlusive disease	Number of subjects with event, n/N (%)	8/ 289 (2.77)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.30, 1.98)	
	p-value	0.5904	
	Risk Ratio (95% CI)	0.78 (0.31, 1.94)	
	p-value	0.5905	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.5900	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	13/ 289 (4.50)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (0.55, 2.96)	
	p-value	0.5696	
	Risk Ratio (95% CI)	1.26 (0.56, 2.84)	
	p-value	0.5698	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.5680	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	12/ 289 (4.15)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.43, 2.20)	
	p-value	0.9440	
	Risk Ratio (95% CI)	0.97 (0.44, 2.13)	
	p-value	0.9440	
	Risk Difference (95% CI)	-0.00 (-0.03, 0.03)	
	p-value	0.9440	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	9/ 289 (3.11)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.79 (0.32, 1.93)	
	p-value	0.6044	
	Risk Ratio (95% CI)	0.80 (0.33, 1.89)	
	p-value	0.6045	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.6041	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	49/ 289 (16.96)	46/ 281 (16.37)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.67, 1.62)	
	p-value	0.8514	
	Risk Ratio (95% CI)	1.04 (0.72, 1.50)	
	p-value	0.8514	
	Risk Difference (95% CI)	0.01 (-0.06, 0.07)	
	p-value	0.8514	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	12/ 289 (4.15)	15/ 281 (5.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.35, 1.67)	
	p-value	0.5063	
	Risk Ratio (95% CI)	0.78 (0.37, 1.63)	
	p-value	0.5065	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.5058	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	9/ 289 (3.11)	12/ 281 (4.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.72 (0.30, 1.74)	
	p-value	0.4655	
	Risk Ratio (95% CI)	0.73 (0.31, 1.70)	
	p-value	0.4658	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.4645	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	26/ 289 (9.00)	15/ 281 (5.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.75 (0.91, 3.38)	
	p-value	0.0945	
	Risk Ratio (95% CI)	1.69 (0.91, 3.11)	
	p-value	0.0956	
	Risk Difference (95% CI)	0.04 (-0.01, 0.08)	
	p-value	0.0891	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	9/ 289 (3.11)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.79 (0.32, 1.93)	
	p-value	0.6044	
	Risk Ratio (95% CI)	0.80 (0.33, 1.89)	
	p-value	0.6045	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.6041	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	10/ 289 (3.46)	6/ 281 (2.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.64 (0.59, 4.58)	
	p-value	0.3429	
	Risk Ratio (95% CI)	1.62 (0.60, 4.40)	
	p-value	0.3434	
	Risk Difference (95% CI)	0.01 (-0.01, 0.04)	
	p-value	0.3364	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	13/ 289 (4.50)	9/ 281 (3.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.42 (0.60, 3.39)	
	p-value	0.4243	
	Risk Ratio (95% CI)	1.40 (0.61, 3.23)	
	p-value	0.4247	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.4208	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	14/ 289 (4.84)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.74 (0.36, 1.53)	
	p-value	0.4196	
	Risk Ratio (95% CI)	0.76 (0.38, 1.49)	
	p-value	0.4199	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.02)	
	p-value	0.4187	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	10/ 289 (3.46)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.88 (0.37, 2.11)	
	p-value	0.7735	
	Risk Ratio (95% CI)	0.88 (0.38, 2.05)	
	p-value	0.7736	
	Risk Difference (95% CI)	-0.00 (-0.04, 0.03)	
	p-value	0.7736	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	21/ 289 (7.27)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.60, 2.20)	
	p-value	0.6842	
	Risk Ratio (95% CI)	1.13 (0.62, 2.08)	
	p-value	0.6843	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.6838	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	11/ 289 (3.81)	5/ 281 (1.78)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.18 (0.75, 6.37)	
	p-value	0.1525	
	Risk Ratio (95% CI)	2.14 (0.75, 6.08)	
	p-value	0.1535	
	Risk Difference (95% CI)	0.02 (-0.01, 0.05)	
	p-value	0.1403	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	6/ 289 (2.08)	18/ 281 (6.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.31 (0.12, 0.79)	
	p-value	0.0144	
	Risk Ratio (95% CI)	0.32 (0.13, 0.80)	
	p-value	0.0152	
	Risk Difference (95% CI)	-0.04 (-0.08, -0.01)	
	p-value	0.0102	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	8/ 289 (2.77)	10/ 281 (3.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.30, 1.98)	
	p-value	0.5904	
	Risk Ratio (95% CI)	0.78 (0.31, 1.94)	
	p-value	0.5905	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.5900	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	11/ 289 (3.81)	7/ 281 (2.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.55 (0.59, 4.05)	
	p-value	0.3728	
	Risk Ratio (95% CI)	1.53 (0.60, 3.89)	
	p-value	0.3733	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.3677	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	23/ 289 (7.96)	27/ 281 (9.61)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.81 (0.45, 1.46)	
	p-value	0.4869	
	Risk Ratio (95% CI)	0.83 (0.49, 1.41)	
	p-value	0.4871	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.03)	
	p-value	0.4866	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	16/ 289 (5.54)	11/ 281 (3.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.44 (0.66, 3.16)	
	p-value	0.3645	
	Risk Ratio (95% CI)	1.41 (0.67, 2.99)	
	p-value	0.3650	
	Risk Difference (95% CI)	0.02 (-0.02, 0.05)	
	p-value	0.3607	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	10/ 289 (3.46)	13/ 281 (4.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.74 (0.32, 1.71)	
	p-value	0.4808	
	Risk Ratio (95% CI)	0.75 (0.33, 1.68)	
	p-value	0.4811	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.4800	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	10/ 289 (3.46)	15/ 281 (5.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.64 (0.28, 1.44)	
	p-value	0.2773	
	Risk Ratio (95% CI)	0.65 (0.30, 1.42)	
	p-value	0.2779	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.01)	
	p-value	0.2746	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	0/ 289 (0.00)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders; PT: Coronary artery disease	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Cardiac disorders; PT: Palpitations	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Ear and labyrinth disorders; PT: Vertigo	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	2/ 289 (0.69)	6/ 281 (2.14)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Abdominal distension	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Abdominal pain	Number of subjects with event, n/N (%)	1/ 289 (0.35)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Ascites	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Constipation Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Diabetic gastroenteropathy	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	0/ 289 (0.00)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	1/ 289 (0.35)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions; PT: Fatigue	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: General disorders and administration site conditions; PT: Swelling	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Infections and infestations; PT: Onychomycosis	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations	Number of subjects with event, n/N (%)	4/ 289 (1.38)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Blood potassium increased Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Blood pressure increased Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Gamma-glutamyltransferase increased	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	2/ 289 (0.69)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	2/ 289 (0.69)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	1/ 289 (0.35)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Metabolism and nutrition disorders; PT: Hyponatraemia	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Colon cancer	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	1/ 289 (0.35)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	0/ 289 (0.00)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Nervous system disorders; PT: Somnolence	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	0/ 289 (0.00)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Skin and subcutaneous tissue disorders; PT: Dermatitis allergic	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Skin and subcutaneous tissue disorders; PT: Hyperhidrosis	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Surgical and medical procedures; PT: Internal fixation of fracture	Number of subjects with event, n/N (%)	1/ 289 (0.35)	0/ 281 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	0/ 289 (0.00)	2/ 281 (0.71)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders; PT: Arterial thrombosis	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=289)	Placebo (N=281)
SOC: Vascular disorders; PT: Flushing	Number of subjects with event, n/N (%)	0/ 289 (0.00)	1/ 281 (0.36)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline
Full Analysis Set

Standard drug grouping	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	289 (99.66 %)	281 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	204 (70.34 %)	202 (71.89 %)
Loop diuretics	111 (38.28 %)	109 (38.79 %)
Thiazide diuretics	41 (14.14 %)	49 (17.44 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	13 (4.48 %)	15 (5.34 %)
Potassium lowering (incl.binders)	2 (0.69 %)	0 (0.00 %)
Alpha blocking agents	48 (16.55 %)	42 (14.95 %)
Calcium channel blockers	136 (46.90 %)	128 (45.55 %)
Centrally acting antihypertensivs	30 (10.34 %)	23 (8.19 %)
Strong CYP3A4 inhibitors	3 (1.03 %)	2 (0.71 %)
Moderate CYP3A4 inhibitors	5 (1.72 %)	5 (1.78 %)
Weak CYP3A4 inhibitors	182 (62.76 %)	168 (59.79 %)
Unclassified CYP3A4 inhibitors	6 (2.07 %)	4 (1.42 %)
Strong CYP3A4 inducers	1 (0.34 %)	0 (0.00 %)
Moderate CYP3A4 inducers	0 (0.00 %)	0 (0.00 %)
Weak CYP3A4 inducers	0 (0.00 %)	9 (3.20 %)
Unclassified CYP3A4 inducers	0 (0.00 %)	0 (0.00 %)
Acetylsalycylic acid and its salts	173 (59.66 %)	170 (60.50 %)
Statins	200 (68.97 %)	214 (76.16 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	185 (63.79 %)	178 (63.35 %)
Glycosurics as SGLT-2 inhibitors	18 (6.21 %)	14 (4.98 %)
Anticoagulants	42 (14.48 %)	51 (18.15 %)
Injectable glucagon-like peptide	17 (5.86 %)	7 (2.49 %)
Antiarrhythmic drugs	24 (8.28 %)	27 (9.61 %)
Biguanides	169 (58.28 %)	162 (57.65 %)
Sulfonylureas	81 (27.93 %)	75 (26.69 %)
Combinations of oral blood glucose lowering drugs	7 (2.41 %)	2 (0.71 %)
Combinations of various lipid modifying agents	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	20 (6.90 %)	15 (5.34 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	59 (98.33 %)	55 (100.00 %)
	Coronary Artery Disease (PBMQ)	Yes	203 (99.51 %)	215 (100.00 %)
	Hyperlipidemia (MLG)	Yes	89 (98.89 %)	100 (100.00 %)
	Hypertension (MLG)	Yes	281 (99.65 %)	272 (100.00 %)
	Region	Western Europe, Oceania and Others	33 (100.00 %)	39 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	44 (73.33 %)	47 (85.45 %)
	Coronary Artery Disease (PBMQ)	Yes	147 (72.06 %)	156 (72.56 %)
	Hyperlipidemia (MLG)	Yes	66 (73.33 %)	75 (75.00 %)
	Hypertension (MLG)	Yes	201 (71.28 %)	196 (72.06 %)
	Region	Western Europe, Oceania and Others	22 (66.67 %)	27 (69.23 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	36 (60.00 %)	31 (56.36 %)
	Coronary Artery Disease (PBMQ)	Yes	73 (35.78 %)	89 (41.40 %)
	Hyperlipidemia (MLG)	Yes	48 (53.33 %)	59 (59.00 %)
	Hypertension (MLG)	Yes	109 (38.65 %)	104 (38.24 %)
	Region	Western Europe, Oceania and Others	24 (72.73 %)	27 (69.23 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	13 (21.67 %)	8 (14.55 %)
	Coronary Artery Disease (PBMQ)	Yes	25 (12.25 %)	35 (16.28 %)
	Hyperlipidemia (MLG)	Yes	15 (16.67 %)	20 (20.00 %)
	Hypertension (MLG)	Yes	39 (13.83 %)	48 (17.65 %)
	Region	Western Europe, Oceania and Others	12 (36.36 %)	9 (23.08 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (3.33 %)	5 (9.09 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (3.43 %)	9 (4.19 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	13 (13.00 %)
	Hypertension (MLG)	Yes	12 (4.26 %)	15 (5.51 %)
	Region	Western Europe, Oceania and Others	1 (3.03 %)	5 (12.82 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.49 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	1 (1.11 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	2 (0.71 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (20.00 %)	10 (18.18 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	35 (17.16 %)	34 (15.81 %)
	Hyperlipidemia (MLG)	Yes	23 (25.56 %)	21 (21.00 %)
	Hypertension (MLG)	Yes	46 (16.31 %)	40 (14.71 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	11 (28.21 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	31 (51.67 %)	19 (34.55 %)
	Coronary Artery Disease (PBMQ)	Yes	96 (47.06 %)	99 (46.05 %)
	Hyperlipidemia (MLG)	Yes	41 (45.56 %)	40 (40.00 %)
	Hypertension (MLG)	Yes	134 (47.52 %)	125 (45.96 %)
	Region	Western Europe, Oceania and Others	20 (60.61 %)	16 (41.03 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	23 (11.27 %)	15 (6.98 %)
	Hyperlipidemia (MLG)	Yes	8 (8.89 %)	7 (7.00 %)
	Hypertension (MLG)	Yes	28 (9.93 %)	23 (8.46 %)
	Region	Western Europe, Oceania and Others	1 (3.03 %)	2 (5.13 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	1 (1.82 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (1.47 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	1 (1.00 %)
	Hypertension (MLG)	Yes	3 (1.06 %)	2 (0.74 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	1 (2.56 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (5.00 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (1.96 %)	3 (1.40 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	2 (2.00 %)
	Hypertension (MLG)	Yes	5 (1.77 %)	5 (1.84 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	1 (2.56 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	44 (73.33 %)	28 (50.91 %)
	Coronary Artery Disease (PBMQ)	Yes	139 (68.14 %)	132 (61.40 %)
	Hyperlipidemia (MLG)	Yes	58 (64.44 %)	65 (65.00 %)
	Hypertension (MLG)	Yes	179 (63.48 %)	164 (60.29 %)
	Region	Western Europe, Oceania and Others	26 (78.79 %)	21 (53.85 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	1 (1.82 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (1.47 %)	3 (1.40 %)
	Hyperlipidemia (MLG)	Yes	5 (5.56 %)	2 (2.00 %)
	Hypertension (MLG)	Yes	6 (2.13 %)	4 (1.47 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	1 (2.56 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	1 (0.35 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	3 (5.45 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	6 (2.79 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	7 (7.00 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	0 (0.00 %)	8 (2.94 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	2 (5.13 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	28 (46.67 %)	20 (36.36 %)
	Coronary Artery Disease (PBMQ)	Yes	134 (65.69 %)	137 (63.72 %)
	Hyperlipidemia (MLG)	Yes	56 (62.22 %)	60 (60.00 %)
	Hypertension (MLG)	Yes	168 (59.57 %)	164 (60.29 %)
	Region	Western Europe, Oceania and Others	19 (57.58 %)	18 (46.15 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	45 (75.00 %)	47 (85.45 %)
	Coronary Artery Disease (PBMQ)	Yes	151 (74.02 %)	173 (80.47 %)
	Hyperlipidemia (MLG)	Yes	76 (84.44 %)	86 (86.00 %)
	Hypertension (MLG)	Yes	196 (69.50 %)	208 (76.47 %)
	Region	Western Europe, Oceania and Others	29 (87.88 %)	36 (92.31 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	37 (61.67 %)	35 (63.64 %)
	Coronary Artery Disease (PBMQ)	Yes	128 (62.75 %)	136 (63.26 %)
	Hyperlipidemia (MLG)	Yes	63 (70.00 %)	70 (70.00 %)
	Hypertension (MLG)	Yes	181 (64.18 %)	171 (62.87 %)
	Region	Western Europe, Oceania and Others	24 (72.73 %)	30 (76.92 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	4 (7.27 %)
	Coronary Artery Disease (PBMQ)	Yes	14 (6.86 %)	9 (4.19 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	7 (7.00 %)
	Hypertension (MLG)	Yes	18 (6.38 %)	14 (5.15 %)
	Region	Western Europe, Oceania and Others	3 (9.09 %)	4 (10.26 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	37 (61.67 %)	39 (70.91 %)
	Coronary Artery Disease (PBMQ)	Yes	31 (15.20 %)	42 (19.53 %)
	Hyperlipidemia (MLG)	Yes	20 (22.22 %)	26 (26.00 %)
	Hypertension (MLG)	Yes	40 (14.18 %)	47 (17.28 %)
	Region	Western Europe, Oceania and Others	12 (36.36 %)	22 (56.41 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	11 (5.39 %)	7 (3.26 %)
	Hyperlipidemia (MLG)	Yes	10 (11.11 %)	3 (3.00 %)
	Hypertension (MLG)	Yes	16 (5.67 %)	7 (2.57 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	2 (5.13 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	21 (35.00 %)	19 (34.55 %)
	Coronary Artery Disease (PBMQ)	Yes	17 (8.33 %)	21 (9.77 %)
	Hyperlipidemia (MLG)	Yes	8 (8.89 %)	13 (13.00 %)
	Hypertension (MLG)	Yes	23 (8.16 %)	26 (9.56 %)
	Region	Western Europe, Oceania and Others	6 (18.18 %)	7 (17.95 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	35 (58.33 %)	27 (49.09 %)
	Coronary Artery Disease (PBMQ)	Yes	118 (57.84 %)	121 (56.28 %)
	Hyperlipidemia (MLG)	Yes	45 (50.00 %)	50 (50.00 %)
	Hypertension (MLG)	Yes	165 (58.51 %)	159 (58.46 %)
	Region	Western Europe, Oceania and Others	20 (60.61 %)	21 (53.85 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	20 (33.33 %)	10 (18.18 %)
	Coronary Artery Disease (PBMQ)	Yes	53 (25.98 %)	65 (30.23 %)
	Hyperlipidemia (MLG)	Yes	17 (18.89 %)	25 (25.00 %)
	Hypertension (MLG)	Yes	78 (27.66 %)	72 (26.47 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	2 (5.13 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	1 (1.82 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (1.47 %)	2 (0.93 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	1 (1.00 %)
	Hypertension (MLG)	Yes	7 (2.48 %)	2 (0.74 %)
	Region	Western Europe, Oceania and Others	1 (3.03 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	15 (7.35 %)	13 (6.05 %)
	Hyperlipidemia (MLG)	Yes	7 (7.78 %)	10 (10.00 %)
	Hypertension (MLG)	Yes	19 (6.74 %)	14 (5.15 %)
	Region	Western Europe, Oceania and Others	6 (18.18 %)	5 (12.82 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period
Full Analysis Set

Standard drug grouping	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	289 (99.66 %)	281 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	1 (0.34 %)	1 (0.36 %)
Beta-Blocker	227 (78.28 %)	221 (78.65 %)
Loop diuretics	150 (51.72 %)	157 (55.87 %)
Thiazide diuretics	59 (20.34 %)	70 (24.91 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	33 (11.38 %)	50 (17.79 %)
Potassium lowering (incl.binders)	14 (4.83 %)	6 (2.14 %)
Alpha blocking agents	103 (35.52 %)	102 (36.30 %)
Calcium channel blockers	161 (55.52 %)	162 (57.65 %)
Centrally acting antihypertensivs	41 (14.14 %)	40 (14.23 %)
Strong CYP3A4 inhibitors	15 (5.17 %)	13 (4.63 %)
Moderate CYP3A4 inhibitors	40 (13.79 %)	46 (16.37 %)
Weak CYP3A4 inhibitors	204 (70.34 %)	212 (75.44 %)
Unclassified CYP3A4 inhibitors	16 (5.52 %)	19 (6.76 %)
Strong CYP3A4 inducers	5 (1.72 %)	2 (0.71 %)
Moderate CYP3A4 inducers	13 (4.48 %)	25 (8.90 %)
Weak CYP3A4 inducers	15 (5.17 %)	19 (6.76 %)
Unclassified CYP3A4 inducers	13 (4.48 %)	8 (2.85 %)
Acetylsalycylic acid and its salts	203 (70.00 %)	194 (69.04 %)
Statins	220 (75.86 %)	232 (82.56 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	200 (68.97 %)	200 (71.17 %)
Glycosurics as SGLT-2 inhibitors	40 (13.79 %)	40 (14.23 %)
Anticoagulants	65 (22.41 %)	72 (25.62 %)
Injectable glucagon-like peptide	36 (12.41 %)	25 (8.90 %)
Antiarrhythmic drugs	41 (14.14 %)	46 (16.37 %)
Biguanides	179 (61.72 %)	176 (62.63 %)
Sulfonylureas	95 (32.76 %)	85 (30.25 %)
Combinations of oral blood glucose lowering drugs	8 (2.76 %)	3 (1.07 %)
Combinations of various lipid modifying agents	0 (0.00 %)	1 (0.36 %)
Other lipid modifying agents	33 (11.38 %)	24 (8.54 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	60 (100.00 %)	55 (100.00 %)
	Coronary Artery Disease (PBMQ)	Yes	204 (100.00 %)	215 (100.00 %)
	Hyperlipidemia (MLG)	Yes	90 (100.00 %)	100 (100.00 %)
	Hypertension (MLG)	Yes	281 (99.65 %)	272 (100.00 %)
	Region	Western Europe, Oceania and Others	33 (100.00 %)	39 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.49 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	1 (0.35 %)	1 (0.37 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	53 (88.33 %)	51 (92.73 %)
	Coronary Artery Disease (PBMQ)	Yes	164 (80.39 %)	170 (79.07 %)
	Hyperlipidemia (MLG)	Yes	75 (83.33 %)	83 (83.00 %)
	Hypertension (MLG)	Yes	223 (79.08 %)	214 (78.68 %)
	Region	Western Europe, Oceania and Others	24 (72.73 %)	32 (82.05 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	48 (80.00 %)	42 (76.36 %)
	Coronary Artery Disease (PBMQ)	Yes	100 (49.02 %)	129 (60.00 %)
	Hyperlipidemia (MLG)	Yes	64 (71.11 %)	76 (76.00 %)
	Hypertension (MLG)	Yes	146 (51.77 %)	151 (55.51 %)
	Region	Western Europe, Oceania and Others	29 (87.88 %)	33 (84.62 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	17 (28.33 %)	13 (23.64 %)
	Coronary Artery Disease (PBMQ)	Yes	37 (18.14 %)	54 (25.12 %)
	Hyperlipidemia (MLG)	Yes	23 (25.56 %)	30 (30.00 %)
	Hypertension (MLG)	Yes	57 (20.21 %)	69 (25.37 %)
	Region	Western Europe, Oceania and Others	13 (39.39 %)	10 (25.64 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (20.00 %)	16 (29.09 %)
	Coronary Artery Disease (PBMQ)	Yes	21 (10.29 %)	37 (17.21 %)
	Hyperlipidemia (MLG)	Yes	18 (20.00 %)	36 (36.00 %)
	Hypertension (MLG)	Yes	31 (10.99 %)	50 (18.38 %)
	Region	Western Europe, Oceania and Others	5 (15.15 %)	12 (30.77 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	6 (2.79 %)
	Hyperlipidemia (MLG)	Yes	12 (13.33 %)	3 (3.00 %)
	Hypertension (MLG)	Yes	14 (4.96 %)	6 (2.21 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	1 (2.56 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	22 (36.67 %)	22 (40.00 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

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Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	74 (36.27 %)	81 (37.67 %)
	Hyperlipidemia (MLG)	Yes	43 (47.78 %)	46 (46.00 %)
	Hypertension (MLG)	Yes	100 (35.46 %)	98 (36.03 %)
	Region	Western Europe, Oceania and Others	11 (33.33 %)	22 (56.41 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	37 (61.67 %)	26 (47.27 %)
	Coronary Artery Disease (PBMQ)	Yes	113 (55.39 %)	127 (59.07 %)
	Hyperlipidemia (MLG)	Yes	51 (56.67 %)	55 (55.00 %)
	Hypertension (MLG)	Yes	159 (56.38 %)	159 (58.46 %)
	Region	Western Europe, Oceania and Others	20 (60.61 %)	21 (53.85 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	9 (15.00 %)	4 (7.27 %)
	Coronary Artery Disease (PBMQ)	Yes	28 (13.73 %)	30 (13.95 %)
	Hyperlipidemia (MLG)	Yes	10 (11.11 %)	12 (12.00 %)
	Hypertension (MLG)	Yes	39 (13.83 %)	40 (14.71 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	3 (7.69 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	5 (9.09 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (3.43 %)	8 (3.72 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	6 (6.00 %)
	Hypertension (MLG)	Yes	14 (4.96 %)	13 (4.78 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	6 (15.38 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	13 (21.67 %)	10 (18.18 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (14.71 %)	31 (14.42 %)
	Hyperlipidemia (MLG)	Yes	12 (13.33 %)	22 (22.00 %)
	Hypertension (MLG)	Yes	38 (13.48 %)	45 (16.54 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	11 (28.21 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	49 (81.67 %)	40 (72.73 %)
	Coronary Artery Disease (PBMQ)	Yes	154 (75.49 %)	167 (77.67 %)
	Hyperlipidemia (MLG)	Yes	68 (75.56 %)	81 (81.00 %)
	Hypertension (MLG)	Yes	201 (71.28 %)	206 (75.74 %)
	Region	Western Europe, Oceania and Others	27 (81.82 %)	31 (79.49 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	8 (14.55 %)
	Coronary Artery Disease (PBMQ)	Yes	11 (5.39 %)	14 (6.51 %)
	Hyperlipidemia (MLG)	Yes	10 (11.11 %)	11 (11.00 %)
	Hypertension (MLG)	Yes	15 (5.32 %)	19 (6.99 %)
	Region	Western Europe, Oceania and Others	4 (12.12 %)	10 (25.64 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (1.96 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	5 (1.77 %)	2 (0.74 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (10.00 %)	6 (10.91 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (4.41 %)	20 (9.30 %)
	Hyperlipidemia (MLG)	Yes	6 (6.67 %)	11 (11.00 %)
	Hypertension (MLG)	Yes	13 (4.61 %)	25 (9.19 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	2 (5.13 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	7 (12.73 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	15 (6.98 %)
	Hyperlipidemia (MLG)	Yes	7 (7.78 %)	12 (12.00 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	14 (4.96 %)	18 (6.62 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	5 (12.82 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	6 (2.79 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	3 (3.00 %)
	Hypertension (MLG)	Yes	12 (4.26 %)	8 (2.94 %)
	Region	Western Europe, Oceania and Others	4 (12.12 %)	2 (5.13 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	34 (56.67 %)	29 (52.73 %)
	Coronary Artery Disease (PBMQ)	Yes	152 (74.51 %)	157 (73.02 %)
	Hyperlipidemia (MLG)	Yes	67 (74.44 %)	72 (72.00 %)
	Hypertension (MLG)	Yes	197 (69.86 %)	187 (68.75 %)
	Region	Western Europe, Oceania and Others	21 (63.64 %)	24 (61.54 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	52 (86.67 %)	51 (92.73 %)
	Coronary Artery Disease (PBMQ)	Yes	162 (79.41 %)	187 (86.98 %)
	Hyperlipidemia (MLG)	Yes	83 (92.22 %)	91 (91.00 %)
	Hypertension (MLG)	Yes	215 (76.24 %)	226 (83.09 %)
	Region	Western Europe, Oceania and Others	31 (93.94 %)	38 (97.44 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	39 (65.00 %)	41 (74.55 %)
	Coronary Artery Disease (PBMQ)	Yes	140 (68.63 %)	153 (71.16 %)
	Hyperlipidemia (MLG)	Yes	68 (75.56 %)	81 (81.00 %)
	Hypertension (MLG)	Yes	196 (69.50 %)	193 (70.96 %)
	Region	Western Europe, Oceania and Others	26 (78.79 %)	33 (84.62 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (10.00 %)	11 (20.00 %)
	Coronary Artery Disease (PBMQ)	Yes	31 (15.20 %)	26 (12.09 %)
	Hyperlipidemia (MLG)	Yes	20 (22.22 %)	24 (24.00 %)
	Hypertension (MLG)	Yes	39 (13.83 %)	40 (14.71 %)
	Region	Western Europe, Oceania and Others	10 (30.30 %)	13 (33.33 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	46 (76.67 %)	44 (80.00 %)
	Coronary Artery Disease (PBMQ)	Yes	45 (22.06 %)	59 (27.44 %)
	Hyperlipidemia (MLG)	Yes	30 (33.33 %)	38 (38.00 %)
	Hypertension (MLG)	Yes	62 (21.99 %)	68 (25.00 %)
	Region	Western Europe, Oceania and Others	14 (42.42 %)	27 (69.23 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (13.33 %)	6 (10.91 %)
	Coronary Artery Disease (PBMQ)	Yes	25 (12.25 %)	16 (7.44 %)
	Hyperlipidemia (MLG)	Yes	21 (23.33 %)	15 (15.00 %)
	Hypertension (MLG)	Yes	34 (12.06 %)	25 (9.19 %)
	Region	Western Europe, Oceania and Others	10 (30.30 %)	5 (12.82 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	30 (50.00 %)	25 (45.45 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (14.71 %)	38 (17.67 %)
	Hyperlipidemia (MLG)	Yes	15 (16.67 %)	25 (25.00 %)
	Hypertension (MLG)	Yes	39 (13.83 %)	45 (16.54 %)
	Region	Western Europe, Oceania and Others	9 (27.27 %)	14 (35.90 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	38 (63.33 %)	32 (58.18 %)
	Coronary Artery Disease (PBMQ)	Yes	125 (61.27 %)	134 (62.33 %)
	Hyperlipidemia (MLG)	Yes	49 (54.44 %)	58 (58.00 %)
	Hypertension (MLG)	Yes	175 (62.06 %)	173 (63.60 %)
	Region	Western Europe, Oceania and Others	22 (66.67 %)	23 (58.97 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	23 (38.33 %)	12 (21.82 %)
	Coronary Artery Disease (PBMQ)	Yes	61 (29.90 %)	69 (32.09 %)
	Hyperlipidemia (MLG)	Yes	24 (26.67 %)	30 (30.00 %)
	Hypertension (MLG)	Yes	92 (32.62 %)	82 (30.15 %)
	Region	Western Europe, Oceania and Others	9 (27.27 %)	3 (7.69 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	1 (1.82 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (1.96 %)	3 (1.40 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	1 (1.00 %)
	Hypertension (MLG)	Yes	8 (2.84 %)	3 (1.10 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	1 (1.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	1 (0.37 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	22 (10.78 %)	18 (8.37 %)
	Hyperlipidemia (MLG)	Yes	15 (16.67 %)	13 (13.00 %)
	Hypertension (MLG)	Yes	32 (11.35 %)	23 (8.46 %)
	Region	Western Europe, Oceania and Others	9 (27.27 %)	7 (17.95 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug
Full Analysis Set

Standard drug grouping	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	103 (35.52 %)	121 (43.06 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	1 (0.34 %)	1 (0.36 %)
Beta-Blocker	92 (31.72 %)	105 (37.37 %)
Loop diuretics	91 (31.38 %)	112 (39.86 %)
Thiazide diuretics	22 (7.59 %)	30 (10.68 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	25 (8.62 %)	39 (13.88 %)
Potassium lowering (incl.binders)	13 (4.48 %)	6 (2.14 %)
Alpha blocking agents	68 (23.45 %)	76 (27.05 %)
Calcium channel blockers	75 (25.86 %)	80 (28.47 %)
Centrally acting antihypertensivs	16 (5.52 %)	21 (7.47 %)
Strong CYP3A4 inhibitors	14 (4.83 %)	11 (3.91 %)
Moderate CYP3A4 inhibitors	36 (12.41 %)	44 (15.66 %)
Weak CYP3A4 inhibitors	99 (34.14 %)	113 (40.21 %)
Unclassified CYP3A4 inhibitors	11 (3.79 %)	16 (5.69 %)
Strong CYP3A4 inducers	4 (1.38 %)	2 (0.71 %)
Moderate CYP3A4 inducers	13 (4.48 %)	25 (8.90 %)
Weak CYP3A4 inducers	15 (5.17 %)	13 (4.63 %)
Unclassified CYP3A4 inducers	13 (4.48 %)	8 (2.85 %)
Acetylsalycylic acid and its salts	62 (21.38 %)	50 (17.79 %)
Statins	79 (27.24 %)	86 (30.60 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	110 (37.93 %)	123 (43.77 %)
Glycosurics as SGLT-2 inhibitors	26 (8.97 %)	27 (9.61 %)
Anticoagulants	41 (14.14 %)	47 (16.73 %)
Injectable glucagon-like peptide	24 (8.28 %)	21 (7.47 %)
Antiarrhythmic drugs	24 (8.28 %)	28 (9.96 %)
Biguanides	52 (17.93 %)	58 (20.64 %)
Sulfonylureas	34 (11.72 %)	30 (10.68 %)
Combinations of oral blood glucose lowering drugs	3 (1.03 %)	1 (0.36 %)
Combinations of various lipid modifying agents	0 (0.00 %)	1 (0.36 %)
Other lipid modifying agents	20 (6.90 %)	15 (5.34 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	24 (40.00 %)	27 (49.09 %)
	Coronary Artery Disease (PBMQ)	Yes	80 (39.22 %)	101 (46.98 %)
	Hyperlipidemia (MLG)	Yes	44 (48.89 %)	53 (53.00 %)
	Hypertension (MLG)	Yes	102 (36.17 %)	117 (43.01 %)
	Region	Western Europe, Oceania and Others	14 (42.42 %)	22 (56.41 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.49 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	1 (0.35 %)	1 (0.37 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	31 (51.67 %)	32 (58.18 %)
	Coronary Artery Disease (PBMQ)	Yes	64 (31.37 %)	85 (39.53 %)
	Hyperlipidemia (MLG)	Yes	36 (40.00 %)	53 (53.00 %)
	Hypertension (MLG)	Yes	91 (32.27 %)	103 (37.87 %)
	Region	Western Europe, Oceania and Others	11 (33.33 %)	25 (64.10 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	31 (51.67 %)	34 (61.82 %)
	Coronary Artery Disease (PBMQ)	Yes	60 (29.41 %)	93 (43.26 %)
	Hyperlipidemia (MLG)	Yes	42 (46.67 %)	60 (60.00 %)
	Hypertension (MLG)	Yes	88 (31.21 %)	109 (40.07 %)
	Region	Western Europe, Oceania and Others	20 (60.61 %)	29 (74.36 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	6 (10.91 %)
	Coronary Artery Disease (PBMQ)	Yes	15 (7.35 %)	26 (12.09 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	14 (14.00 %)
	Hypertension (MLG)	Yes	22 (7.80 %)	30 (11.03 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	5 (12.82 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	11 (18.33 %)	12 (21.82 %)
	Coronary Artery Disease (PBMQ)	Yes	18 (8.82 %)	31 (14.42 %)
	Hyperlipidemia (MLG)	Yes	13 (14.44 %)	27 (27.00 %)
	Hypertension (MLG)	Yes	24 (8.51 %)	39 (14.34 %)
	Region	Western Europe, Oceania and Others	5 (15.15 %)	9 (23.08 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (5.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	6 (2.79 %)
	Hyperlipidemia (MLG)	Yes	11 (12.22 %)	3 (3.00 %)
	Hypertension (MLG)	Yes	13 (4.61 %)	6 (2.21 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	1 (2.56 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	16 (26.67 %)	15 (27.27 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
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BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	49 (24.02 %)	58 (26.98 %)
	Hyperlipidemia (MLG)	Yes	27 (30.00 %)	32 (32.00 %)
	Hypertension (MLG)	Yes	66 (23.40 %)	74 (27.21 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	15 (38.46 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	16 (26.67 %)	15 (27.27 %)
	Coronary Artery Disease (PBMQ)	Yes	49 (24.02 %)	65 (30.23 %)
	Hyperlipidemia (MLG)	Yes	33 (36.67 %)	32 (32.00 %)
	Hypertension (MLG)	Yes	73 (25.89 %)	80 (29.41 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	10 (25.64 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	5 (8.33 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (4.41 %)	18 (8.37 %)
	Hyperlipidemia (MLG)	Yes	4 (4.44 %)	6 (6.00 %)
	Hypertension (MLG)	Yes	15 (5.32 %)	21 (7.72 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	2 (5.13 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	4 (7.27 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (2.94 %)	7 (3.26 %)
	Hyperlipidemia (MLG)	Yes	8 (8.89 %)	5 (5.00 %)
	Hypertension (MLG)	Yes	13 (4.61 %)	11 (4.04 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	5 (12.82 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	10 (16.67 %)	10 (18.18 %)
	Coronary Artery Disease (PBMQ)	Yes	27 (13.24 %)	30 (13.95 %)
	Hyperlipidemia (MLG)	Yes	11 (12.22 %)	20 (20.00 %)
	Hypertension (MLG)	Yes	34 (12.06 %)	43 (15.81 %)
	Region	Western Europe, Oceania and Others	7 (21.21 %)	10 (25.64 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	25 (41.67 %)	27 (49.09 %)
	Coronary Artery Disease (PBMQ)	Yes	70 (34.31 %)	91 (42.33 %)
	Hyperlipidemia (MLG)	Yes	43 (47.78 %)	49 (49.00 %)
	Hypertension (MLG)	Yes	97 (34.40 %)	111 (40.81 %)
	Region	Western Europe, Oceania and Others	16 (48.48 %)	21 (53.85 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (5.00 %)	8 (14.55 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (3.92 %)	12 (5.58 %)
	Hyperlipidemia (MLG)	Yes	6 (6.67 %)	10 (10.00 %)
	Hypertension (MLG)	Yes	10 (3.55 %)	16 (5.88 %)
	Region	Western Europe, Oceania and Others	4 (12.12 %)	10 (25.64 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (1.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (1.96 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	2 (2.22 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	4 (1.42 %)	2 (0.74 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (10.00 %)	6 (10.91 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (4.41 %)	20 (9.30 %)
	Hyperlipidemia (MLG)	Yes	6 (6.67 %)	11 (11.00 %)
	Hypertension (MLG)	Yes	13 (4.61 %)	25 (9.19 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	2 (5.13 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (11.67 %)	7 (12.73 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	11 (5.12 %)
	Hyperlipidemia (MLG)	Yes	7 (7.78 %)	8 (8.00 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	14 (4.96 %)	13 (4.78 %)
	Region	Western Europe, Oceania and Others	2 (6.06 %)	5 (12.82 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	2 (3.64 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (4.90 %)	6 (2.79 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	3 (3.00 %)
	Hypertension (MLG)	Yes	12 (4.26 %)	8 (2.94 %)
	Region	Western Europe, Oceania and Others	4 (12.12 %)	2 (5.13 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (20.00 %)	13 (23.64 %)
	Coronary Artery Disease (PBMQ)	Yes	42 (20.59 %)	41 (19.07 %)
	Hyperlipidemia (MLG)	Yes	22 (24.44 %)	20 (20.00 %)
	Hypertension (MLG)	Yes	61 (21.63 %)	49 (18.01 %)
	Region	Western Europe, Oceania and Others	5 (15.15 %)	6 (15.38 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	23 (38.33 %)	23 (41.82 %)
	Coronary Artery Disease (PBMQ)	Yes	52 (25.49 %)	69 (32.09 %)
	Hyperlipidemia (MLG)	Yes	34 (37.78 %)	36 (36.00 %)
	Hypertension (MLG)	Yes	76 (26.95 %)	86 (31.62 %)
	Region	Western Europe, Oceania and Others	14 (42.42 %)	15 (38.46 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	25 (41.67 %)	26 (47.27 %)
	Coronary Artery Disease (PBMQ)	Yes	74 (36.27 %)	93 (43.26 %)
	Hyperlipidemia (MLG)	Yes	43 (47.78 %)	58 (58.00 %)
	Hypertension (MLG)	Yes	109 (38.65 %)	121 (44.49 %)
	Region	Western Europe, Oceania and Others	17 (51.52 %)	23 (58.97 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	5 (8.33 %)	7 (12.73 %)
	Coronary Artery Disease (PBMQ)	Yes	20 (9.80 %)	18 (8.37 %)
	Hyperlipidemia (MLG)	Yes	12 (13.33 %)	18 (18.00 %)
	Hypertension (MLG)	Yes	25 (8.87 %)	27 (9.93 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	10 (25.64 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	25 (41.67 %)	23 (41.82 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (14.71 %)	39 (18.14 %)
	Hyperlipidemia (MLG)	Yes	20 (22.22 %)	27 (27.00 %)
	Hypertension (MLG)	Yes	38 (13.48 %)	43 (15.81 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	17 (43.59 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	5 (9.09 %)
	Coronary Artery Disease (PBMQ)	Yes	18 (8.82 %)	12 (5.58 %)
	Hyperlipidemia (MLG)	Yes	14 (15.56 %)	14 (14.00 %)
	Hypertension (MLG)	Yes	23 (8.16 %)	21 (7.72 %)
	Region	Western Europe, Oceania and Others	6 (18.18 %)	4 (10.26 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=290)	Placebo (N=281)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	15 (25.00 %)	15 (27.27 %)
	Coronary Artery Disease (PBMQ)	Yes	18 (8.82 %)	23 (10.70 %)
	Hyperlipidemia (MLG)	Yes	8 (8.89 %)	18 (18.00 %)
	Hypertension (MLG)	Yes	23 (8.16 %)	28 (10.29 %)
	Region	Western Europe, Oceania and Others	5 (15.15 %)	12 (30.77 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	16 (26.67 %)	15 (27.27 %)
	Coronary Artery Disease (PBMQ)	Yes	37 (18.14 %)	48 (22.33 %)
	Hyperlipidemia (MLG)	Yes	22 (24.44 %)	28 (28.00 %)
	Hypertension (MLG)	Yes	51 (18.09 %)	57 (20.96 %)
	Region	Western Europe, Oceania and Others	8 (24.24 %)	12 (30.77 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (13.33 %)	6 (10.91 %)
	Coronary Artery Disease (PBMQ)	Yes	22 (10.78 %)	20 (9.30 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	13 (13.00 %)
	Hypertension (MLG)	Yes	33 (11.70 %)	30 (11.03 %)
	Region	Western Europe, Oceania and Others	3 (9.09 %)	1 (2.56 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.49 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	1 (1.11 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	3 (1.06 %)	1 (0.37 %)
	Region	Western Europe, Oceania and Others	1 (3.03 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	1 (0.47 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	1 (1.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	1 (0.37 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (6.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	12 (5.88 %)	10 (4.65 %)
	Hyperlipidemia (MLG)	Yes	9 (10.00 %)	7 (7.00 %)
	Hypertension (MLG)	Yes	19 (6.74 %)	14 (5.15 %)
	Region	Western Europe, Oceania and Others	6 (18.18 %)	3 (7.69 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	289	135.70 (13.60)	134.67	100.00, 180.67	-	-	-	-
	Placebo	281	134.97 (13.88)	134.67	98.00, 181.67	-	-	-	-
Month 1	Finerenone	282	133.08 (14.00)	134.00	91.33, 169.67	282	-2.79 (12.57)	-1.00	-51.00, 28.33
	Placebo	276	135.04 (14.41)	134.00	92.33, 197.00	276	0.04 (12.05)	0.00	-42.00, 64.67
Month 4	Finerenone	273	133.00 (14.22)	133.33	83.00, 173.33	273	-2.84 (14.56)	-1.33	-59.33, 40.00
	Placebo	273	135.09 (16.02)	135.00	80.33, 185.67	273	0.06 (14.07)	-0.33	-51.67, 51.67
Month 8	Finerenone	260	133.14 (14.77)	132.67	83.00, 196.67	260	-2.60 (15.98)	-1.67	-60.67, 58.00
	Placebo	258	136.20 (15.04)	135.50	100.00, 182.67	258	1.22 (15.30)	0.67	-45.00, 54.33
Month 12	Finerenone	258	133.07 (14.05)	133.33	90.67, 181.33	258	-2.58 (14.96)	-1.67	-53.33, 47.00
	Placebo	255	135.27 (14.73)	135.33	89.67, 182.00	255	0.16 (14.35)	0.33	-56.67, 54.00
Month 16	Finerenone	253	132.45 (14.59)	131.67	98.00, 183.67	253	-3.02 (16.53)	-1.67	-51.67, 55.33
	Placebo	246	134.72 (16.06)	134.00	91.33, 199.00	246	-0.34 (15.60)	-0.67	-66.67, 51.33
Month 20	Finerenone	241	132.60 (15.03)	132.67	94.33, 179.33	241	-2.99 (16.56)	-2.00	-54.00, 45.67
	Placebo	234	134.75 (16.96)	134.00	90.67, 193.67	234	-0.14 (16.89)	0.00	-90.00, 57.67
Month 24	Finerenone	223	133.52 (15.15)	133.33	96.67, 199.67	223	-1.88 (16.60)	-1.33	-48.67, 68.33
	Placebo	220	132.22 (15.61)	131.33	79.33, 179.67	220	-2.64 (16.70)	-2.67	-76.67, 45.67
Month 28	Finerenone	188	132.31 (14.15)	130.83	96.00, 174.67	188	-3.70 (15.70)	-1.67	-54.67, 37.67
	Placebo	186	134.36 (15.95)	132.33	88.67, 182.67	186	-0.09 (17.38)	0.00	-85.00, 52.67
Month 32	Finerenone	143	134.15 (13.86)	133.00	90.00, 177.00	143	-1.76 (16.25)	-1.67	-60.33, 38.00
	Placebo	143	134.81 (15.43)	132.33	92.00, 186.00	143	0.14 (16.77)	0.00	-80.00, 43.67
Month 36	Finerenone	107	134.02 (15.19)	132.67	98.00, 189.00	107	-2.23 (15.54)	-0.67	-39.33, 57.67
	Placebo	118	134.82 (15.93)	134.50	90.67, 203.00	118	0.55 (18.13)	-0.83	-83.33, 70.67
Month 40	Finerenone	90	133.79 (14.68)	134.17	94.33, 198.67	90	-1.98 (18.22)	-1.67	-54.00, 57.33
	Placebo	106	134.91 (16.37)	133.67	98.33, 198.00	106	1.18 (17.01)	0.00	-35.00, 62.00
Month 44	Finerenone	64	133.62 (15.61)	132.67	107.00, 205.67	64	-0.83 (19.74)	-3.00	-43.33, 64.33
	Placebo	66	135.52 (16.15)	134.67	96.67, 181.67	66	0.92 (15.09)	-1.67	-31.00, 46.00
Month 48	Finerenone	40	134.40 (15.45)	132.50	107.33, 190.00	40	1.55 (17.17)	1.17	-48.67, 48.67
	Placebo	46	134.50 (18.11)	132.50	106.33, 210.00	46	-0.14 (19.05)	-2.67	-41.67, 64.33
Month 52	Finerenone	23	130.72 (17.06)	128.00	101.00, 180.00	23	0.46 (22.46)	-4.00	-44.00, 40.67
	Placebo	21	139.76 (16.06)	140.00	107.00, 175.00	21	2.95 (19.70)	-0.33	-34.00, 54.33
Month 56	Finerenone	11	129.76 (14.73)	128.33	106.33, 149.00	11	0.97 (23.99)	-1.67	-31.33, 47.67
	Placebo	8	135.33 (8.05)	137.33	120.67, 144.00	8	8.00 (15.34)	9.83	-20.33, 28.00
Month 60	Finerenone	0	NE (NE)	NE	NE, NE	0	NE (NE)	NE	NE, NE
	Placebo	1	106.67 (NE)	106.67	106.67, 106.67	1	-14.33 (NE)	-14.33	-14.33, -14.33
Premature discontinuation	Finerenone	7	125.38 (15.82)	130.67	98.67, 146.00	7	-7.00 (7.85)	-3.33	-21.00, 0.00
	Placebo	13	131.62 (15.49)	129.00	108.67, 157.67	13	-0.72 (15.50)	-1.33	-22.00, 23.00
End of Study Visit	Finerenone	208	134.00 (12.40)	133.33	104.33, 182.33	208	-1.34 (13.46)	-0.33	-37.33, 41.67
	Placebo	215	136.21 (16.46)	135.00	86.67, 204.67	215	0.67 (18.87)	0.33	-95.00, 59.00
Post Treatment Visit	Finerenone	10	128.33 (18.40)	131.67	103.33, 155.00	10	-8.70 (16.78)	-2.50	-41.33, 11.67
	Placebo	10	134.83 (13.49)	133.83	106.67, 157.33	10	3.30 (18.24)	6.33	-22.00, 27.33

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	281	135.72 (13.46)	134.67	100.00, 180.67	-	-	-	-
	Placebo	272	135.16 (13.80)	134.83	98.00, 181.67	-	-	-	-
Month 1	Finerenone	274	133.16 (14.06)	134.00	91.33, 169.67	274	-2.73 (12.64)	-1.00	-51.00, 28.33
	Placebo	267	135.12 (14.40)	134.00	92.33, 197.00	267	-0.07 (12.16)	-0.67	-42.00, 64.67
Month 4	Finerenone	265	133.06 (14.27)	133.33	83.00, 173.33	265	-2.80 (14.64)	-1.33	-59.33, 40.00
	Placebo	264	135.06 (16.08)	134.83	80.33, 185.67	264	-0.17 (14.12)	-0.67	-51.67, 51.67
Month 8	Finerenone	253	133.23 (14.92)	132.67	83.00, 196.67	253	-2.60 (15.76)	-1.67	-60.67, 58.00
	Placebo	249	136.35 (15.18)	135.33	100.00, 182.67	249	1.15 (15.40)	0.67	-45.00, 54.33
Month 12	Finerenone	251	133.40 (14.01)	133.33	90.67, 181.33	251	-2.34 (14.67)	-1.67	-47.00, 47.00
	Placebo	247	135.63 (14.59)	135.33	89.67, 182.00	247	0.31 (14.39)	0.33	-56.67, 54.00
Month 16	Finerenone	246	132.65 (14.71)	131.83	98.00, 183.67	246	-2.90 (16.58)	-1.67	-51.67, 55.33
	Placebo	238	135.04 (16.00)	134.17	91.33, 199.00	238	-0.24 (15.79)	-0.67	-66.67, 51.33
Month 20	Finerenone	235	132.88 (15.08)	133.00	94.33, 179.33	235	-2.77 (16.46)	-2.00	-54.00, 45.67
	Placebo	227	134.79 (17.07)	134.00	90.67, 193.67	227	-0.30 (16.85)	0.00	-90.00, 57.67
Month 24	Finerenone	218	133.81 (15.13)	133.50	96.67, 199.67	218	-1.82 (16.70)	-1.33	-48.67, 68.33
	Placebo	213	132.46 (15.58)	131.33	79.33, 179.67	213	-2.62 (16.66)	-2.67	-76.67, 45.67
Month 28	Finerenone	184	132.51 (14.02)	131.00	96.00, 174.67	184	-3.74 (15.76)	-1.67	-54.67, 37.67
	Placebo	180	134.28 (16.05)	132.00	88.67, 182.67	180	-0.28 (17.16)	0.00	-85.00, 50.33
Month 32	Finerenone	140	134.43 (13.84)	133.17	90.00, 177.00	140	-1.65 (16.30)	-1.67	-60.33, 38.00
	Placebo	139	134.90 (15.62)	132.33	92.00, 186.00	139	0.35 (16.85)	0.00	-80.00, 43.67
Month 36	Finerenone	105	134.31 (15.16)	132.67	98.00, 189.00	105	-2.14 (15.59)	-0.67	-39.33, 57.67
	Placebo	114	134.80 (16.18)	134.33	90.67, 203.00	114	0.68 (18.35)	-0.50	-83.33, 70.67
Month 40	Finerenone	88	133.99 (14.65)	134.17	94.33, 198.67	88	-2.00 (18.20)	-1.67	-54.00, 57.33
	Placebo	102	134.59 (16.34)	133.00	98.33, 198.00	102	1.06 (17.24)	0.00	-35.00, 62.00
Month 44	Finerenone	62	133.90 (15.68)	132.67	107.00, 205.67	62	-0.83 (19.86)	-3.00	-43.33, 64.33
	Placebo	62	135.93 (16.17)	134.67	96.67, 181.67	62	1.61 (14.99)	1.33	-30.33, 46.00
Month 48	Finerenone	39	134.47 (15.65)	132.67	107.33, 190.00	39	1.29 (17.31)	0.00	-48.67, 48.67
	Placebo	42	134.17 (18.37)	131.83	106.33, 210.00	42	-0.06 (19.07)	-2.67	-41.67, 64.33
Month 52	Finerenone	21	131.75 (17.47)	129.00	101.00, 180.00	21	1.06 (23.21)	-4.00	-44.00, 40.67
	Placebo	20	139.55 (16.45)	138.33	107.00, 175.00	20	1.70 (19.34)	-1.83	-34.00, 54.33
Month 56	Finerenone	10	131.23 (14.64)	130.67	106.33, 149.00	10	1.57 (25.20)	0.17	-31.33, 47.67
	Placebo	7	134.10 (7.83)	136.67	120.67, 142.67	7	5.14 (14.08)	8.33	-20.33, 20.33
Month 60	Finerenone	0	()		,	0			
	Placebo	1	106.67 (NE)	106.67	106.67, 106.67	1	-14.33 (NE)	-14.33	-14.33, -14.33
Premature discontinuation	Finerenone	7	125.38 (15.82)	130.67	98.67, 146.00	7	-7.00 (7.85)	-3.33	-21.00, 0.00
	Placebo	13	131.62 (15.49)	129.00	108.67, 157.67	13	-0.72 (15.50)	-1.33	-22.00, 23.00
End of Study Visit	Finerenone	205	134.11 (12.43)	133.33	104.33, 182.33	205	-1.46 (13.46)	-0.33	-37.33, 41.67
	Placebo	208	136.39 (16.59)	135.00	86.67, 204.67	208	0.70 (18.74)	0.33	-95.00, 59.00
Post Treatment Visit	Finerenone	10	128.33 (18.40)	131.67	103.33, 155.00	10	-8.70 (16.78)	-2.50	-41.33, 11.67

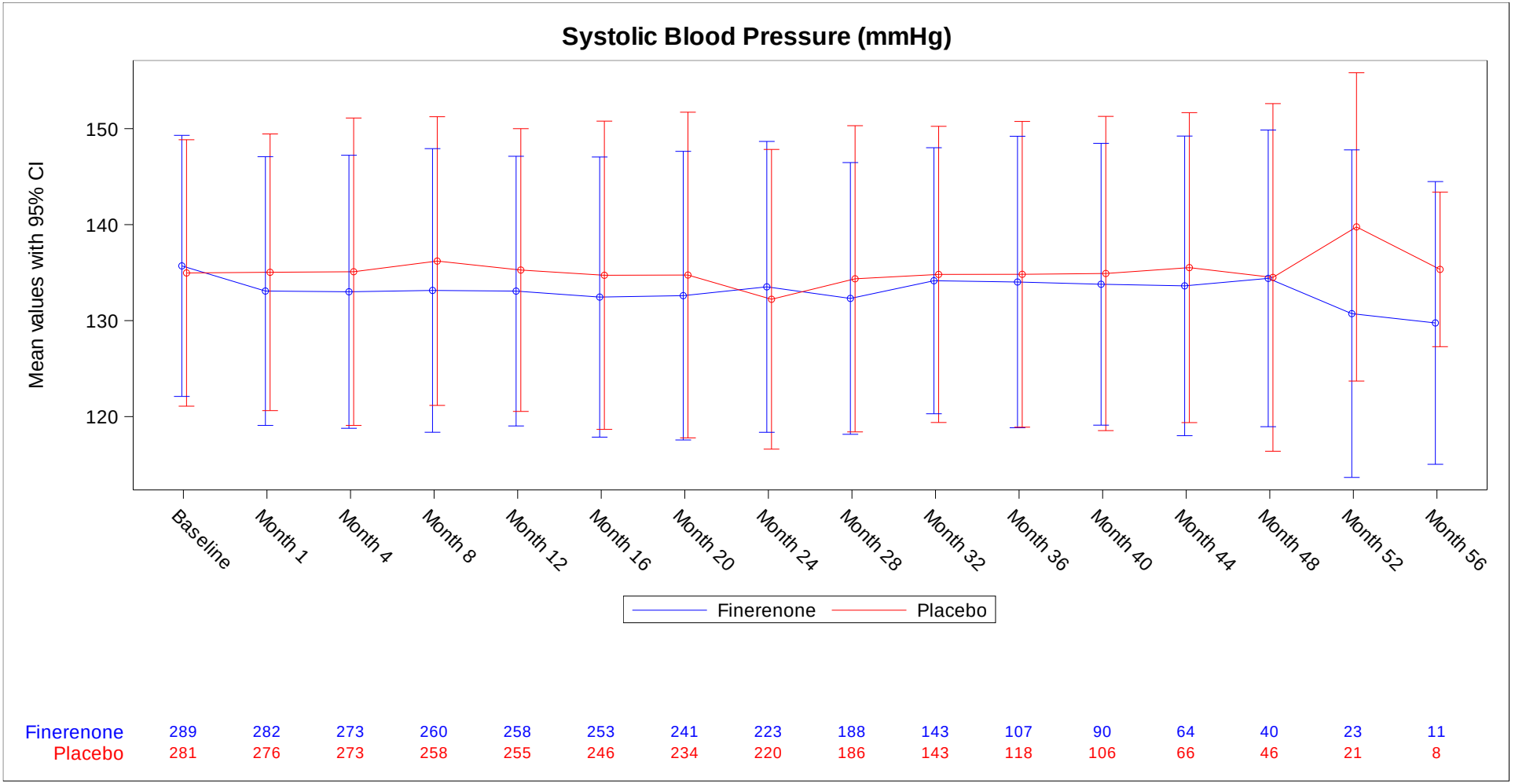
N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
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FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Post Treatment Visit	Placebo	10	134.83 (13.49)	133.83	106.67, 157.33	10	3.30 (18.24)	6.33	-22.00, 27.33

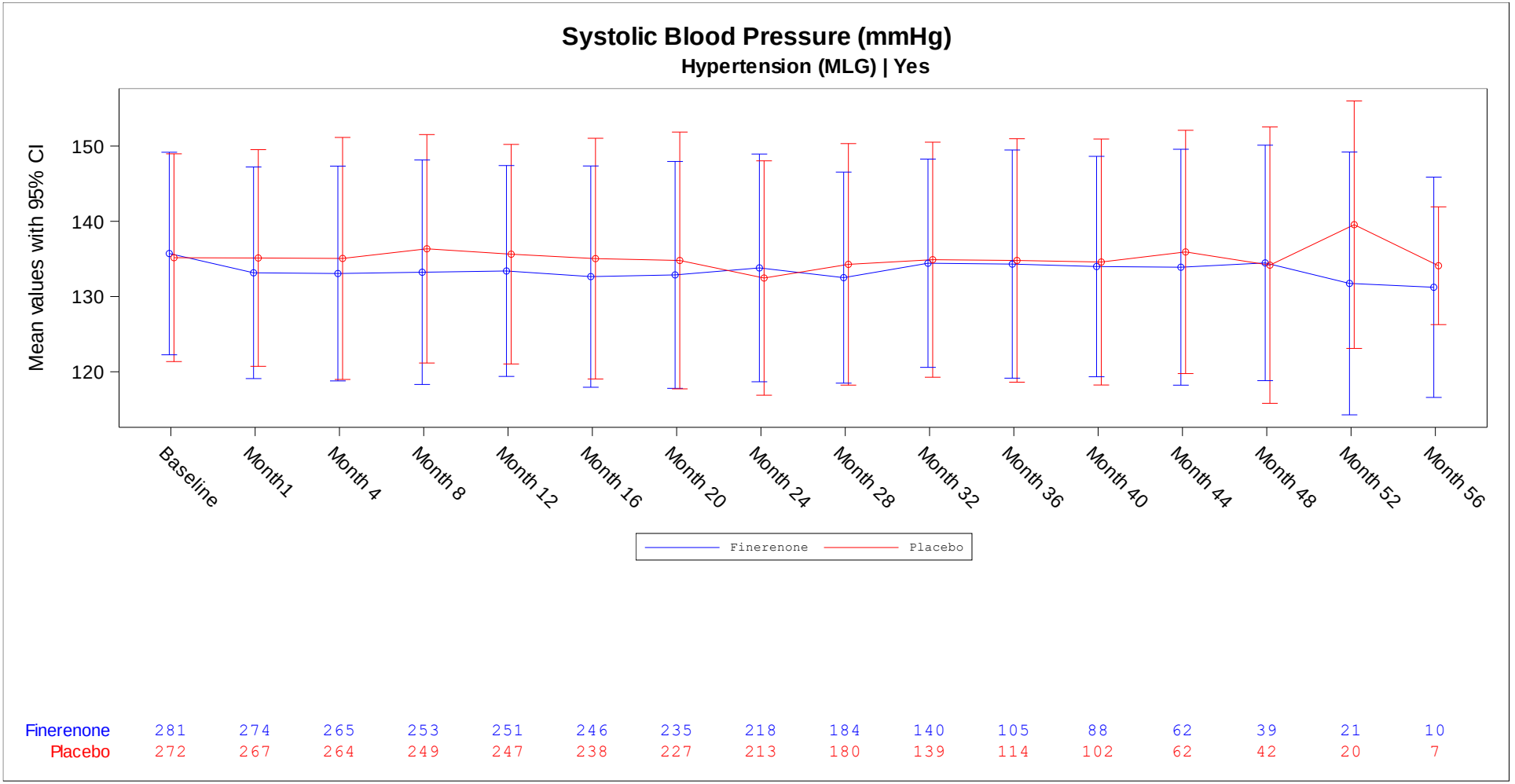
N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Systolic Blood Pressure (mmHg) over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	289	77.60 (9.72)	79.00	51.33, 105.00	-	-	-	-
	Placebo	281	75.95 (10.46)	76.67	45.00, 103.67	-	-	-	-
Month 1	Finerenone	282	75.96 (9.80)	76.67	50.00, 102.33	282	-1.60 (7.53)	-0.67	-27.67, 18.00
	Placebo	276	76.21 (10.11)	77.67	44.00, 102.33	276	0.29 (7.80)	0.00	-40.67, 36.33
Month 4	Finerenone	273	76.04 (9.67)	77.67	47.67, 100.67	273	-1.67 (7.96)	-1.00	-30.67, 24.33
	Placebo	273	75.94 (10.20)	77.00	43.33, 103.67	273	-0.02 (8.12)	0.33	-41.67, 25.33
Month 8	Finerenone	260	76.53 (10.24)	78.50	41.67, 102.67	260	-1.07 (8.49)	-0.67	-42.33, 22.00
	Placebo	258	75.85 (10.33)	76.67	46.00, 102.00	258	-0.11 (8.84)	0.00	-40.00, 25.33
Month 12	Finerenone	258	76.01 (9.79)	77.83	46.33, 114.67	258	-1.57 (8.98)	-1.67	-26.00, 30.00
	Placebo	255	75.30 (10.24)	76.67	46.00, 102.67	255	-0.76 (8.66)	-1.00	-30.00, 30.00
Month 16	Finerenone	253	75.49 (10.13)	77.33	50.33, 103.67	253	-2.01 (8.91)	-1.67	-29.33, 26.00
	Placebo	246	75.22 (10.61)	76.67	41.67, 106.33	246	-0.74 (8.98)	-0.33	-29.67, 31.00
Month 20	Finerenone	241	75.79 (10.06)	77.67	42.33, 102.67	241	-1.94 (9.18)	-1.33	-28.00, 25.67
	Placebo	234	76.00 (10.60)	77.33	43.33, 105.67	234	-0.05 (8.85)	0.33	-30.00, 24.67
Month 24	Finerenone	223	76.14 (10.67)	78.33	46.00, 110.67	223	-1.51 (9.68)	-1.67	-27.67, 40.67
	Placebo	220	74.96 (10.79)	76.50	40.67, 102.00	220	-1.12 (9.57)	-1.00	-31.00, 29.67
Month 28	Finerenone	188	75.70 (10.01)	77.33	51.00, 99.67	188	-2.40 (9.00)	-1.50	-32.67, 19.00
	Placebo	186	75.60 (10.08)	77.33	34.33, 102.33	186	-0.06 (9.74)	0.17	-31.67, 37.00
Month 32	Finerenone	143	75.98 (9.83)	76.67	51.00, 109.33	143	-1.47 (9.29)	-1.33	-34.67, 25.67
	Placebo	143	75.88 (9.56)	78.00	50.67, 97.33	143	0.06 (8.58)	0.00	-23.33, 20.67
Month 36	Finerenone	107	75.84 (10.04)	78.00	52.67, 99.00	107	-2.63 (8.63)	-2.67	-32.00, 22.67
	Placebo	118	76.40 (9.64)	78.67	48.67, 95.67	118	1.02 (9.45)	0.67	-31.67, 37.67
Month 40	Finerenone	90	76.74 (9.44)	78.50	55.33, 101.67	90	-1.10 (9.04)	-1.67	-20.00, 29.00
	Placebo	106	76.25 (10.23)	77.00	40.00, 103.67	106	0.81 (10.02)	0.67	-21.33, 32.00
Month 44	Finerenone	64	75.52 (11.14)	76.83	50.33, 96.33	64	-2.18 (9.34)	-3.50	-21.33, 26.33
	Placebo	66	76.00 (11.50)	78.50	43.33, 97.67	66	0.13 (10.54)	0.00	-24.00, 30.33
Month 48	Finerenone	40	76.64 (9.14)	78.67	58.33, 95.33	40	-0.62 (8.63)	-0.50	-21.67, 18.00
	Placebo	46	75.31 (10.52)	77.00	49.33, 92.33	46	-0.09 (11.01)	0.00	-21.00, 24.67
Month 52	Finerenone	23	72.88 (10.87)	72.00	58.33, 100.00	23	-2.00 (11.82)	-6.67	-17.67, 22.33
	Placebo	21	78.29 (9.67)	80.00	61.33, 100.00	21	0.27 (9.42)	0.00	-17.00, 20.00
Month 56	Finerenone	11	74.27 (8.90)	76.00	59.33, 86.33	11	0.73 (14.20)	2.33	-19.67, 30.33
	Placebo	8	77.37 (5.25)	76.17	71.67, 83.33	8	6.17 (6.06)	5.83	-2.00, 14.33
Month 60	Finerenone	0	NE (NE)	NE	NE, NE	0	NE (NE)	NE	NE, NE
	Placebo	1	57.00 (NE)	57.00	57.00, 57.00	1	-0.67 (NE)	-0.67	-0.67, -0.67
Premature discontinuation	Finerenone	7	70.90 (11.05)	75.33	51.33, 82.67	7	-0.86 (6.06)	-2.67	-6.67, 7.67
	Placebo	13	71.85 (9.77)	70.67	58.00, 97.67	13	-2.82 (6.96)	-2.00	-16.00, 7.67
End of Study Visit	Finerenone	208	77.71 (9.72)	79.33	40.67, 99.33	208	-0.46 (9.35)	-0.33	-30.00, 23.00
	Placebo	215	76.94 (11.20)	77.67	42.67, 137.33	215	0.50 (10.71)	0.00	-31.67, 48.67
Post Treatment Visit	Finerenone	10	74.03 (11.94)	77.67	50.67, 91.67	10	-1.97 (9.71)	-0.33	-17.33, 12.33
	Placebo	10	74.47 (9.58)	72.83	60.00, 93.33	10	-2.67 (11.56)	-4.00	-19.33, 13.33

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	281	77.70 (9.75)	79.33	51.33, 105.00	-	-	-	-
	Placebo	272	76.08 (10.48)	76.67	45.00, 103.67	-	-	-	-
Month 1	Finerenone	274	76.05 (9.86)	76.83	50.00, 102.33	274	-1.61 (7.57)	-0.67	-27.67, 18.00
	Placebo	267	76.30 (10.10)	77.67	44.00, 102.33	267	0.24 (7.77)	0.00	-40.67, 36.33
Month 4	Finerenone	265	76.21 (9.69)	77.67	47.67, 100.67	265	-1.61 (8.03)	-0.67	-30.67, 24.33
	Placebo	264	76.04 (10.25)	77.17	43.33, 103.67	264	-0.05 (8.18)	0.33	-41.67, 25.33
Month 8	Finerenone	253	76.69 (10.21)	78.67	41.67, 102.67	253	-1.02 (8.34)	-0.67	-42.33, 22.00
	Placebo	249	75.96 (10.35)	76.67	46.00, 102.00	249	-0.14 (8.90)	0.00	-40.00, 25.33
Month 12	Finerenone	251	76.24 (9.76)	78.00	46.33, 114.67	251	-1.46 (8.96)	-1.67	-26.00, 30.00
	Placebo	247	75.49 (10.22)	76.67	46.00, 102.67	247	-0.72 (8.70)	-1.00	-30.00, 30.00
Month 16	Finerenone	246	75.59 (10.19)	77.50	50.33, 103.67	246	-2.02 (8.91)	-1.83	-29.33, 26.00
	Placebo	238	75.50 (10.49)	77.17	41.67, 106.33	238	-0.60 (9.04)	-0.17	-29.67, 31.00
Month 20	Finerenone	235	75.94 (10.07)	78.00	42.33, 102.67	235	-1.93 (9.10)	-1.33	-28.00, 25.67
	Placebo	227	76.13 (10.53)	77.67	43.33, 105.67	227	-0.07 (8.78)	0.33	-30.00, 22.67
Month 24	Finerenone	218	76.40 (10.61)	78.33	46.00, 110.67	218	-1.45 (9.74)	-1.17	-27.67, 40.67
	Placebo	213	75.17 (10.76)	76.67	40.67, 102.00	213	-1.08 (9.57)	-1.00	-31.00, 29.67
Month 28	Finerenone	184	75.92 (9.90)	77.33	51.00, 99.67	184	-2.41 (9.03)	-1.17	-32.67, 19.00
	Placebo	180	75.69 (10.10)	77.33	34.33, 102.33	180	-0.07 (9.71)	0.33	-31.67, 37.00
Month 32	Finerenone	140	76.12 (9.73)	76.67	51.00, 109.33	140	-1.51 (9.29)	-1.33	-34.67, 25.67
	Placebo	139	76.07 (9.42)	78.00	52.00, 97.33	139	0.14 (8.57)	0.00	-23.33, 20.67
Month 36	Finerenone	105	75.88 (10.08)	78.00	52.67, 99.00	105	-2.74 (8.64)	-2.67	-32.00, 22.67
	Placebo	114	76.44 (9.57)	78.50	48.67, 95.67	114	0.94 (9.50)	0.33	-31.67, 37.67
Month 40	Finerenone	88	76.93 (9.43)	78.67	55.33, 101.67	88	-1.06 (9.11)	-1.67	-20.00, 29.00
	Placebo	102	76.29 (10.17)	76.83	40.00, 103.67	102	0.72 (10.05)	0.67	-21.33, 32.00
Month 44	Finerenone	62	75.61 (11.19)	76.83	50.33, 96.33	62	-2.30 (9.34)	-3.50	-21.33, 26.33
	Placebo	62	76.52 (11.08)	79.33	54.67, 97.67	62	0.40 (10.51)	0.00	-24.00, 30.33
Month 48	Finerenone	39	76.51 (9.23)	78.33	58.33, 95.33	39	-0.90 (8.56)	-0.67	-21.67, 18.00
	Placebo	42	75.67 (10.04)	77.33	51.00, 92.33	42	-0.05 (10.93)	0.00	-21.00, 24.67
Month 52	Finerenone	21	73.56 (11.16)	72.33	58.33, 100.00	21	-1.71 (12.35)	-6.67	-17.67, 22.33
	Placebo	20	78.00 (9.83)	78.33	61.33, 100.00	20	-0.45 (9.05)	-0.17	-17.00, 20.00
Month 56	Finerenone	10	74.03 (9.34)	74.33	59.33, 86.33	10	0.30 (14.89)	0.83	-19.67, 30.33
	Placebo	7	76.57 (5.11)	74.00	71.67, 83.33	7	5.10 (5.67)	3.33	-2.00, 14.33
Month 60	Finerenone	0	()		,	0			
	Placebo	1	57.00 (NE)	57.00	57.00, 57.00	1	-0.67 (NE)	-0.67	-0.67, -0.67
Premature discontinuation	Finerenone	7	70.90 (11.05)	75.33	51.33, 82.67	7	-0.86 (6.06)	-2.67	-6.67, 7.67
	Placebo	13	71.85 (9.77)	70.67	58.00, 97.67	13	-2.82 (6.96)	-2.00	-16.00, 7.67
End of Study Visit	Finerenone	205	77.83 (9.70)	79.33	40.67, 99.33	205	-0.47 (9.39)	-0.33	-30.00, 23.00
	Placebo	208	77.11 (11.04)	77.83	49.33, 137.33	208	0.56 (10.54)	0.00	-31.67, 48.67
Post Treatment Visit	Finerenone	10	74.03 (11.94)	77.67	50.67, 91.67	10	-1.97 (9.71)	-0.33	-17.33, 12.33

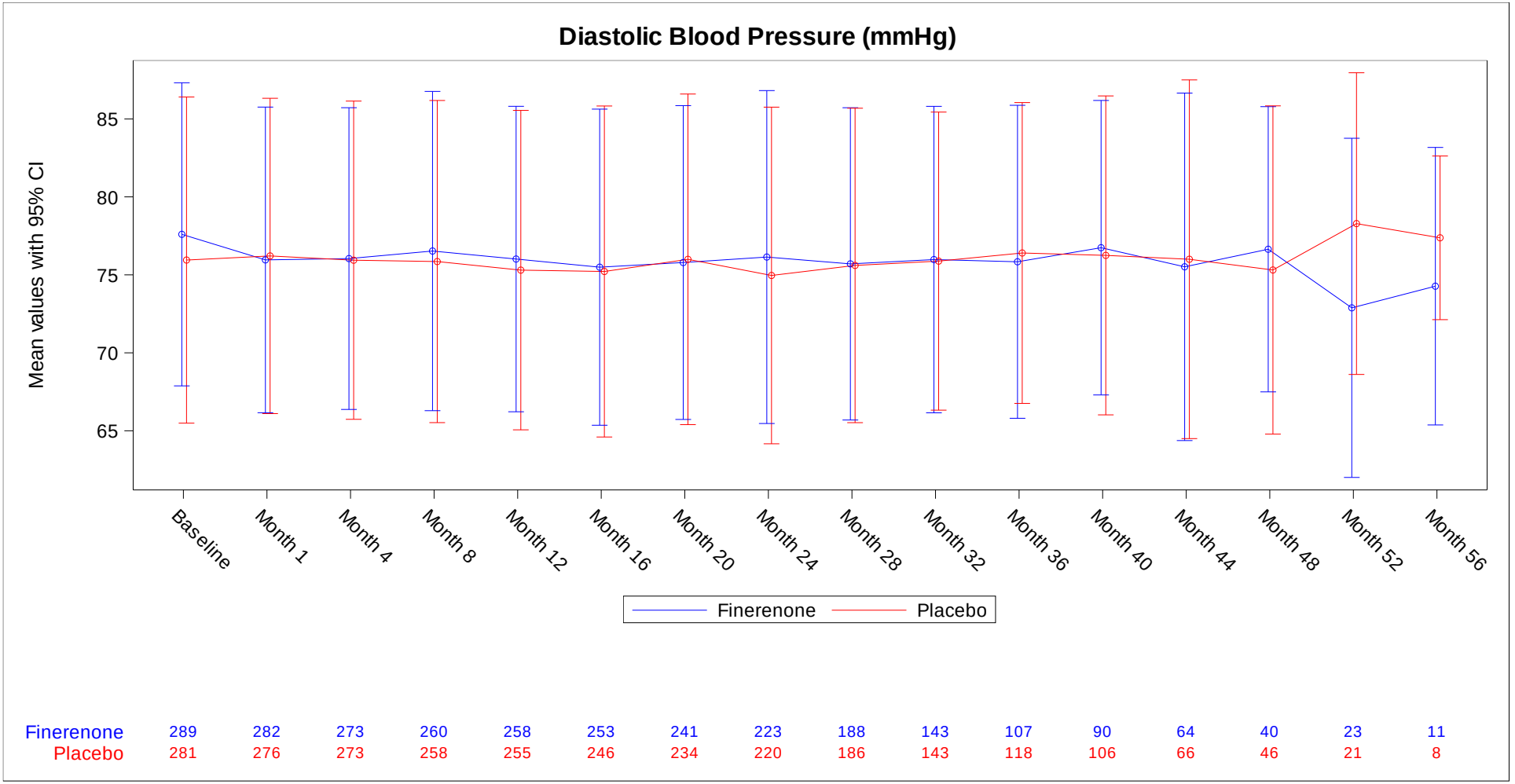
N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Post Treatment Visit	Placebo	10	74.47 (9.58)	72.83	60.00, 93.33	10	-2.67 (11.56)	-4.00	-19.33, 13.33

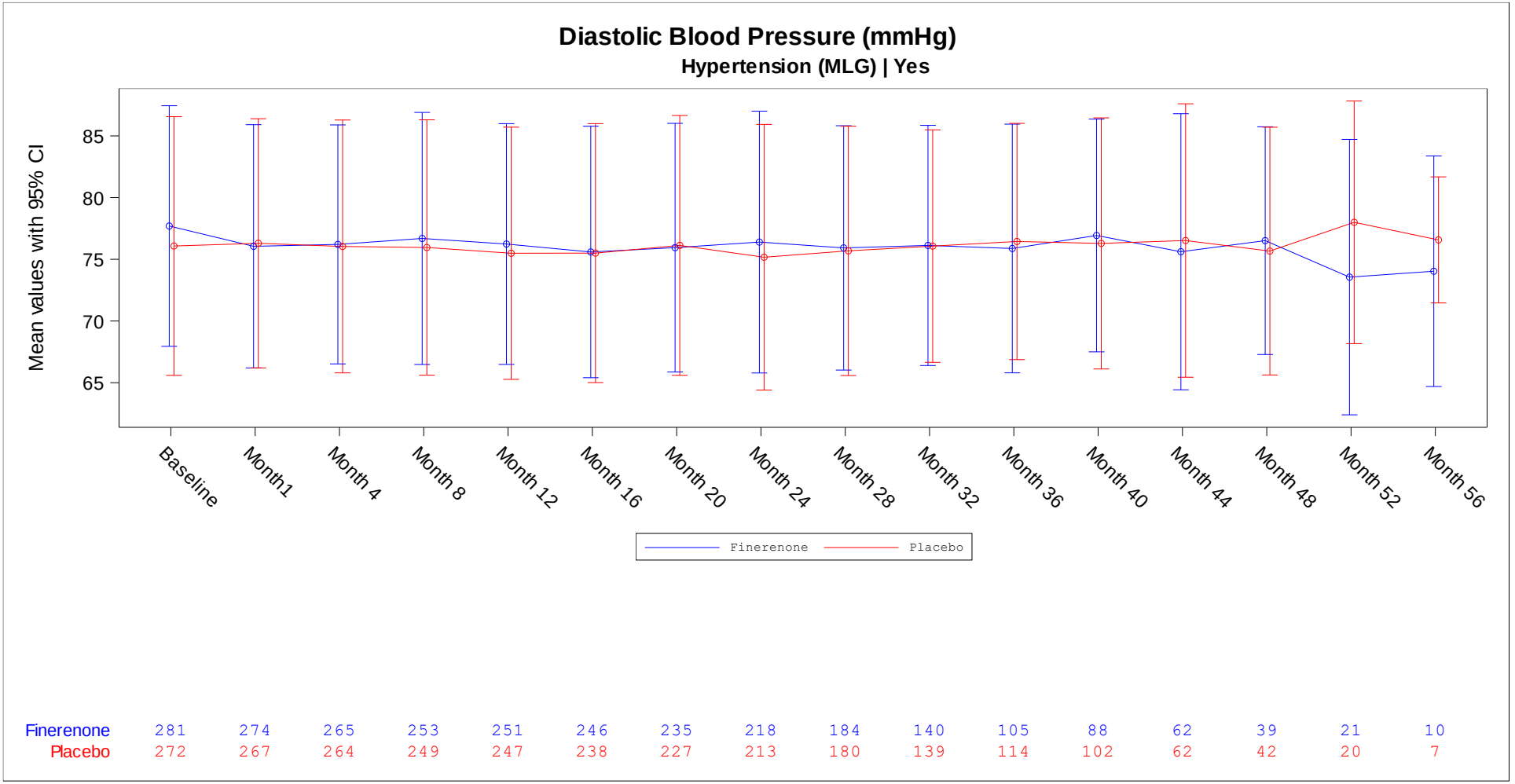
N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Hemoglobin A1C (%) in Blood over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	288	8.04 (1.48)	7.80	5.30, 14.50	-	-	-	-
	Placebo	279	7.91 (1.33)	7.80	5.30, 11.50	-	-	-	-
Month 1	Finerenone	1	6.60 (NE)	6.60	6.60, 6.60	1	-0.30 (NE)	-0.30	-0.30, -0.30
	Placebo	2	7.35 (0.21)	7.35	7.20, 7.50	2	-0.45 (0.07)	-0.45	-0.50, -0.40
Month 4	Finerenone	266	8.05 (1.60)	7.80	5.20, 14.60	266	0.02 (0.99)	0.00	-3.60, 3.70
	Placebo	267	7.95 (1.42)	7.80	5.20, 13.20	265	0.07 (0.93)	0.00	-2.40, 4.80
Month 8	Finerenone	253	8.07 (1.53)	7.90	5.10, 14.80	253	0.03 (1.07)	0.00	-3.30, 3.40
	Placebo	253	8.09 (1.45)	7.90	5.30, 14.60	251	0.18 (1.12)	0.10	-2.90, 8.10
Month 12	Finerenone	254	8.03 (1.44)	7.85	5.30, 12.50	254	0.05 (1.07)	0.10	-4.90, 2.80
	Placebo	252	8.06 (1.54)	7.80	4.90, 14.40	250	0.16 (1.07)	0.15	-3.00, 6.10
Month 16	Finerenone	249	8.10 (1.59)	7.90	5.20, 16.90	249	0.09 (1.15)	0.00	-3.50, 3.50
	Placebo	239	8.07 (1.55)	7.70	5.10, 12.70	238	0.17 (1.28)	0.05	-5.20, 5.10
Month 20	Finerenone	240	8.17 (1.63)	8.00	4.70, 15.50	240	0.18 (1.26)	0.15	-4.40, 4.10
	Placebo	227	8.17 (1.67)	8.00	5.30, 14.70	225	0.27 (1.39)	0.10	-3.90, 8.20
Month 24	Finerenone	219	8.19 (1.55)	8.00	5.40, 13.40	219	0.21 (1.38)	0.20	-4.70, 4.20
	Placebo	214	8.08 (1.64)	7.80	4.80, 14.20	212	0.17 (1.31)	0.10	-4.20, 6.10
Month 28	Finerenone	184	8.06 (1.55)	7.80	5.20, 13.60	184	0.15 (1.32)	0.20	-4.70, 3.30
	Placebo	181	7.98 (1.60)	7.60	5.40, 13.40	179	0.12 (1.38)	0.00	-3.90, 6.50
Month 32	Finerenone	140	8.09 (1.54)	7.85	5.40, 13.30	140	0.13 (1.32)	0.00	-3.90, 5.00
	Placebo	138	7.90 (1.56)	7.60	5.10, 12.20	137	0.08 (1.28)	0.00	-3.80, 3.30
Month 36	Finerenone	99	8.05 (1.71)	7.70	5.20, 14.20	99	0.15 (1.47)	0.10	-4.80, 5.50
	Placebo	116	7.99 (1.74)	7.60	5.10, 13.20	116	0.18 (1.38)	0.00	-4.10, 4.30
Month 40	Finerenone	86	8.37 (1.71)	8.00	5.30, 14.00	86	0.60 (1.67)	0.40	-3.30, 6.80
	Placebo	102	7.94 (1.68)	7.70	4.80, 12.80	101	0.10 (1.46)	-0.10	-4.00, 5.10
Month 44	Finerenone	63	8.33 (1.61)	7.80	5.50, 13.80	63	0.48 (1.52)	0.50	-2.40, 5.10
	Placebo	66	8.09 (1.69)	7.95	4.70, 12.30	66	0.20 (1.53)	-0.20	-3.60, 4.20
Month 48	Finerenone	39	8.15 (1.60)	7.80	5.40, 12.50	39	0.48 (1.53)	0.10	-3.60, 3.40
	Placebo	45	8.02 (1.69)	7.90	4.40, 12.00	45	0.17 (1.43)	0.10	-3.90, 3.60
Month 52	Finerenone	22	7.84 (1.26)	7.45	6.10, 11.30	22	0.13 (1.50)	0.20	-3.30, 2.70
	Placebo	21	7.75 (2.38)	7.30	4.70, 14.60	21	-0.02 (2.35)	-0.40	-4.00, 8.40
Month 56	Finerenone	11	7.66 (1.43)	7.30	5.50, 10.20	11	0.02 (1.78)	0.30	-4.00, 2.40
	Placebo	8	7.20 (1.93)	7.20	5.00, 11.10	8	-0.38 (0.90)	-0.25	-1.60, 0.80
Month 60	Finerenone	0	NE (NE)	NE	NE, NE	0	NE (NE)	NE	NE, NE
	Placebo	1	5.60 (NE)	5.60	5.60, 5.60	1	-1.40 (NE)	-1.40	-1.40, -1.40
Last treatment-emergent	Finerenone	283	8.25 (1.63)	8.00	5.30, 16.90	283	0.19 (1.39)	0.10	-4.40, 4.10
	Placebo	279	8.03 (1.64)	7.80	4.60, 13.70	277	0.14 (1.45)	0.00	-5.30, 6.70
Premature discontinuation	Finerenone	7	8.63 (1.28)	9.20	6.60, 10.20	7	0.29 (1.43)	0.10	-1.90, 2.40
	Placebo	13	7.52 (0.84)	7.60	5.80, 8.90	13	0.44 (1.14)	0.10	-2.10, 2.70
End of Study Visit	Finerenone	197	8.15 (1.69)	7.90	5.30, 15.80	197	0.16 (1.57)	0.10	-4.40, 6.00
	Placebo	207	7.98 (1.63)	7.80	4.60, 13.70	207	0.11 (1.44)	-0.10	-5.30, 5.60

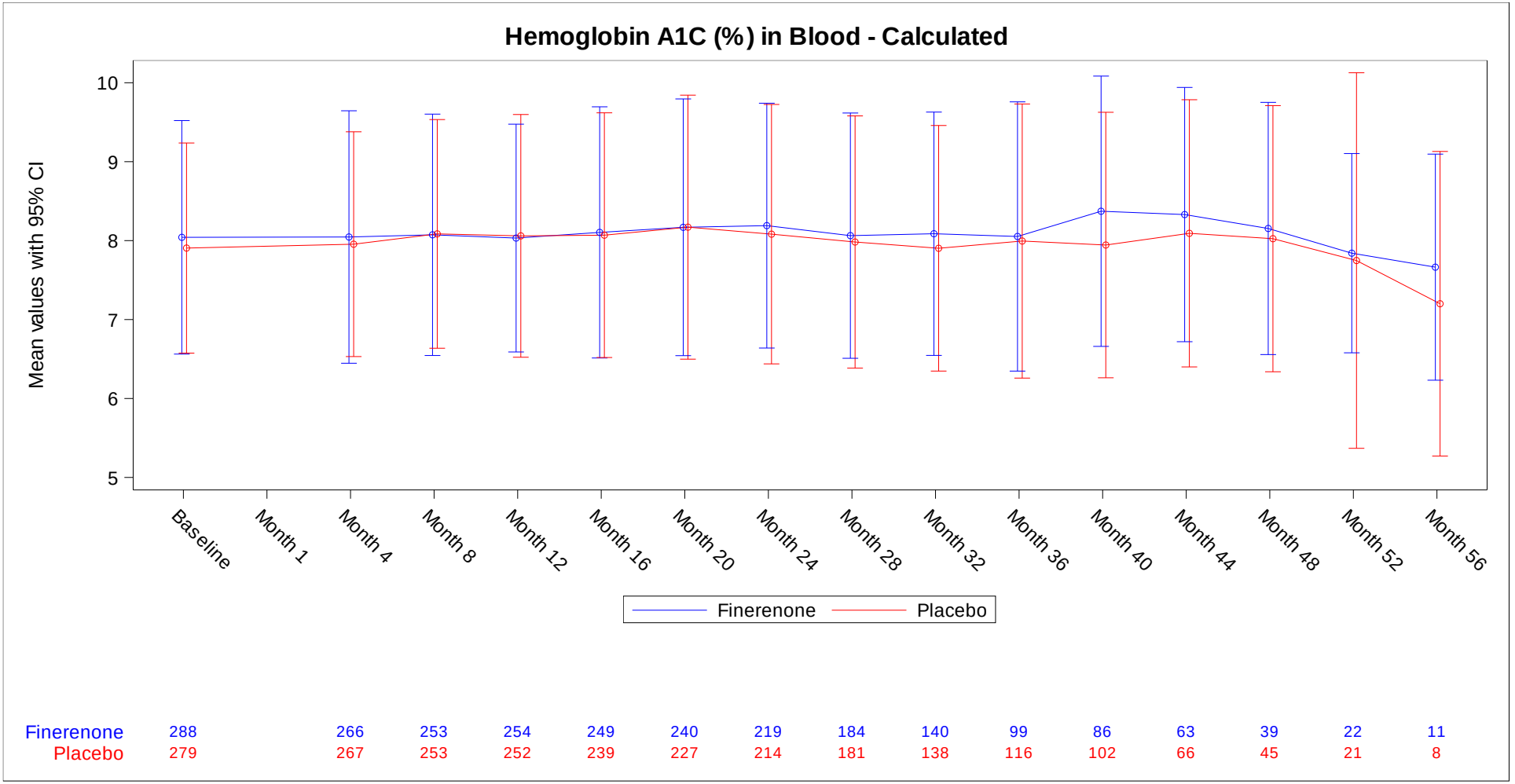
N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Hemoglobin A1C (%) in Blood over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Post Treatment Visit	Finerenone	9	7.79 (1.97)	7.50	5.00, 12.10	9	0.37 (1.91)	-0.20	-1.30, 5.20
	Placebo	8	7.80 (2.50)	7.15	5.80, 13.80	8	1.01 (1.98)	0.30	-0.60, 5.70

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Hemoglobin A1C (%) in Blood over time
Safety Analysis Set



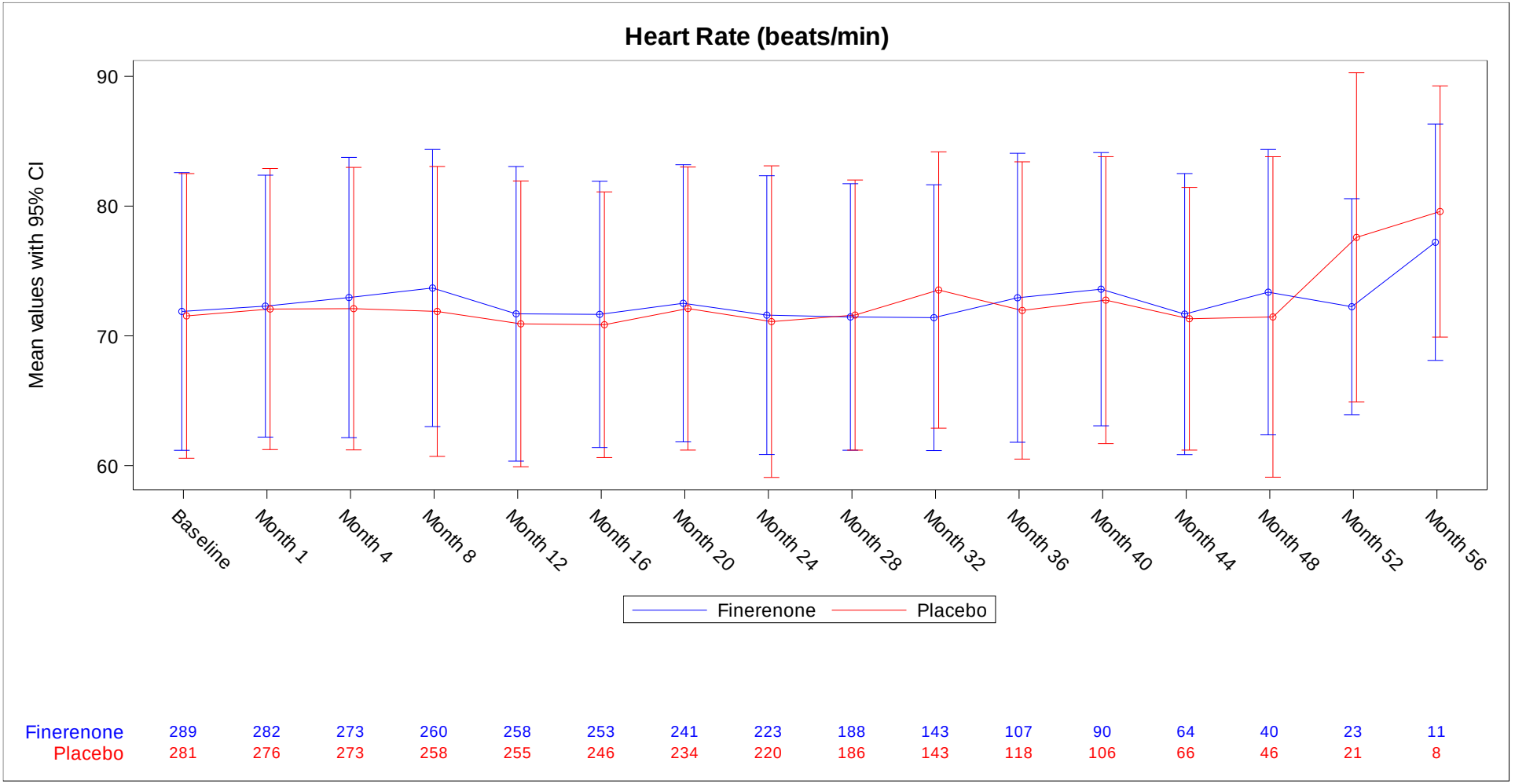
Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Heart Rate over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	289	71.88 (10.70)	71.67	45.33, 115.00	-	-	-	-
	Placebo	281	71.54 (10.97)	70.67	41.00, 104.67	-	-	-	-
Month 1	Finerenone	282	72.29 (10.09)	72.50	45.67, 114.00	282	0.62 (7.74)	0.67	-25.00, 32.33
	Placebo	276	72.07 (10.83)	71.33	47.33, 113.33	276	0.55 (7.98)	0.00	-27.33, 39.00
Month 4	Finerenone	273	72.95 (10.80)	73.00	46.33, 141.33	273	1.42 (10.28)	1.67	-49.00, 85.67
	Placebo	273	72.10 (10.89)	71.00	46.33, 104.00	273	0.68 (8.46)	0.00	-27.33, 33.00
Month 8	Finerenone	260	73.69 (10.68)	72.83	49.00, 123.67	260	2.34 (9.58)	1.67	-26.00, 68.00
	Placebo	258	71.88 (11.17)	71.00	45.33, 116.33	258	0.48 (9.58)	0.00	-33.00, 44.33
Month 12	Finerenone	258	71.70 (11.35)	70.67	33.33, 111.00	258	0.26 (9.49)	0.33	-55.00, 32.00
	Placebo	255	70.93 (11.01)	70.33	42.00, 100.33	255	-0.28 (10.55)	-0.33	-36.00, 37.33
Month 16	Finerenone	253	71.66 (10.26)	70.33	42.33, 100.00	253	0.25 (9.32)	0.00	-35.67, 34.00
	Placebo	246	70.86 (10.24)	71.00	45.67, 97.33	246	-0.39 (10.19)	-0.67	-47.33, 27.33
Month 20	Finerenone	241	72.51 (10.68)	71.67	48.67, 112.00	241	1.15 (9.72)	1.00	-35.00, 39.00
	Placebo	234	72.10 (10.91)	71.67	45.33, 114.67	234	0.68 (10.58)	0.17	-47.00, 30.00
Month 24	Finerenone	223	71.60 (10.74)	70.67	48.33, 112.00	223	0.39 (9.81)	0.00	-43.00, 34.00
	Placebo	220	71.10 (12.01)	69.00	50.00, 119.00	220	-0.42 (11.89)	-0.33	-36.00, 42.33
Month 28	Finerenone	188	71.46 (10.27)	70.33	50.67, 102.00	188	0.41 (9.81)	0.17	-26.67, 34.67
	Placebo	186	71.60 (10.41)	71.33	44.00, 110.33	186	0.32 (11.17)	-0.50	-32.33, 33.00
Month 32	Finerenone	143	71.40 (10.24)	71.33	42.67, 110.33	143	0.13 (10.30)	0.00	-29.33, 28.67
	Placebo	143	73.53 (10.65)	72.00	54.00, 110.00	143	1.82 (10.81)	1.00	-28.00, 50.33
Month 36	Finerenone	107	72.93 (11.13)	72.00	53.67, 118.00	107	1.81 (12.79)	1.00	-27.00, 59.67
	Placebo	118	71.96 (11.45)	70.17	49.00, 100.00	118	0.54 (11.48)	0.33	-34.33, 31.67
Month 40	Finerenone	90	73.60 (10.53)	73.50	55.00, 103.33	90	2.84 (10.15)	2.67	-21.33, 26.00
	Placebo	106	72.75 (11.05)	73.33	49.33, 98.00	106	1.39 (10.89)	0.33	-30.33, 29.00
Month 44	Finerenone	64	71.68 (10.83)	70.83	49.33, 94.00	64	1.33 (9.66)	0.83	-13.33, 31.00
	Placebo	66	71.32 (10.12)	72.50	50.00, 90.33	66	-0.40 (10.97)	0.00	-32.67, 32.00
Month 48	Finerenone	40	73.37 (11.00)	72.50	56.00, 97.67	40	1.90 (10.47)	2.00	-21.33, 28.00
	Placebo	46	71.46 (12.35)	71.33	48.00, 112.33	46	1.59 (13.70)	2.00	-28.33, 52.00
Month 52	Finerenone	23	72.25 (8.32)	72.00	60.33, 85.67	23	1.10 (10.17)	-0.67	-12.33, 24.33
	Placebo	21	77.59 (12.69)	76.67	60.33, 114.00	21	6.16 (13.87)	7.00	-24.33, 33.00
Month 56	Finerenone	11	77.21 (9.10)	75.67	59.00, 89.00	11	5.48 (12.34)	4.33	-15.33, 23.67
	Placebo	8	79.58 (9.68)	82.67	63.00, 91.67	8	11.50 (10.09)	11.67	-0.67, 31.33
Month 60	Finerenone	0	NE (NE)	NE	NE, NE	0	NE (NE)	NE	NE, NE
	Placebo	1	65.33 (NE)	65.33	65.33, 65.33	1	-17.00 (NE)	-17.00	-17.00, -17.00
Premature discontinuation	Finerenone	7	64.33 (10.96)	64.67	51.00, 79.00	7	-3.14 (10.60)	0.00	-21.00, 13.33
	Placebo	13	73.05 (10.75)	74.00	59.00, 89.33	13	-0.74 (8.42)	-2.67	-11.67, 19.67
End of Study Visit	Finerenone	208	72.87 (10.07)	72.00	48.67, 113.00	208	1.49 (10.92)	0.17	-34.00, 52.00
	Placebo	215	73.57 (11.25)	71.67	46.67, 112.00	215	2.32 (11.51)	1.33	-27.33, 40.00
Post Treatment Visit	Finerenone	10	68.73 (14.16)	64.83	54.67, 103.33	10	-3.20 (7.98)	-1.83	-17.33, 6.67
	Placebo	10	70.70 (10.29)	73.50	53.33, 84.67	10	2.03 (6.92)	-0.33	-4.67, 18.33

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Heart Rate over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 17530 - Datacut: 19APR2021
FIGARO-DKD HF-subpopulation - Finerenone vs. Placebo
Summary of medical history of interest
Full Analysis Set

	Finerenone (N=290)	Placebo (N=281)
	n (%)	n (%)
Atrial Fibrillation And Atrial Flutter (PBMQ)	60 (20.69)	55 (19.57)
Hyperlipidemia (MLG)	90 (31.03)	100 (35.59)
Type 2 Diabetes Mellitus (PT)	290 (100.00)	281 (100.00)
Chronic Kidney Disease (PT)	290 (100.00)	281 (100.00)
Hypertension (MLG)	282 (97.24)	272 (96.80)
Ischaemic Stroke/Transitory Ischaemic Attack (PBMQ)	55 (18.97)	50 (17.79)
Cardiac Failure (MLG)	290 (100.00)	281 (100.00)
Carotid Endarterectomy (PT)	6 (2.07)	7 (2.49)
Coronary Artery Bypass Graft (PBMQ)	40 (13.79)	45 (16.01)
Myocardial Infarction (MLG)	95 (32.76)	98 (34.88)
Percutaneous Coronary Intervention (PBMQ)	30 (10.34)	29 (10.32)
Coronary Artery Disease (PBMQ)	204 (70.34)	215 (76.51)
Peripheral Arterial Disease (PBMQ)	71 (24.48)	68 (24.20)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Disposition: End of treatment
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
	n (%)	n (%)
Full analysis set	195 (100.00)	241 (100.00)
Treated	195 (100.00)	241 (100.00)
Completed study	195 (100.00)	241 (100.00)
Completed	126 (64.62)	148 (61.41)
Not completed	69 (35.38)	93 (38.59)
ADVERSE EVENT / OUTCOME EVENT	26 (13.33)	25 (10.37)
DEATH	17 (8.72)	29 (12.03)
DETERIORATION OF GENERAL CONDITIONS	0 (0.00)	1 (0.41)
LOGISTICAL DIFFICULTIES	1 (0.51)	2 (0.83)
NON-COMPLIANCE WITH STUDY DRUG	5 (2.56)	2 (0.83)
PHYSICIAN DECISION	9 (4.62)	13 (5.39)
PROTOCOL DEVIATION	0 (0.00)	1 (0.41)
SPONSOR DECISION	1 (0.51)	1 (0.41)
SWITCHING TO OTHER THERAPY	0 (0.00)	1 (0.41)
WITHDRAWAL BY SUBJECT	10 (5.13)	18 (7.47)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=195)	Placebo (N=241)
Sex, n (%)	Male	120 (61.54)	160 (66.39)
	Female	75 (38.46)	81 (33.61)
Age	n (missing)	195 (0)	241 (0)
	Mean (SD)	66.4 (8.77)	66.2 (8.52)
	Geo.Mean (SD)	65.8 (1.15)	65.6 (1.14)
	Median	66.0	67.0
	Q1, Q3	61.0, 73.0	61.0, 72.0
	Min, Max	42.0, 86.0	42.0, 89.0
Age group (years), n (%)	< 65 years	83 (42.56)	95 (39.42)
	65 - < 75 years	74 (37.95)	110 (45.64)
	75 - < 85 years	36 (18.46)	33 (13.69)
	>= 85 years	2 (1.03)	3 (1.24)
Pooled Race Group 01, n (%)	White	156 (80.00)	187 (77.59)
	Black	9 (4.62)	19 (7.88)
	Asian	23 (11.79)	27 (11.20)
	Other	7 (3.59)	8 (3.32)
Region (pooled region for subgroup analysis), n (%)	Western Europe, Oceania and Others	37 (18.97)	46 (19.09)
	Eastern Europe	78 (40.00)	97 (40.25)
	Asia	38 (19.49)	33 (13.69)
	North America	37 (18.97)	46 (19.09)
	Latin America	5 (2.56)	19 (7.88)
Baseline Body Mass Index (kg/m2)	n (missing)	194 (1)	241 (0)
	Mean (SD)	33.7 (6.60)	32.7 (6.44)
	Geo.Mean (SD)	33.1 (1.21)	32.2 (1.21)
	Median	32.6	32.0
	Q1, Q3	28.6, 37.1	28.4, 35.6
	Min, Max	23.3, 55.8	19.5, 53.7
Baseline BMI (kg/m2) category 2, n (%)	< 30 kg/m2	63 (32.31)	89 (36.93)
	>= 30 kg/m2	131 (67.18)	152 (63.07)
	Missing	1 (0.51)	0 (0.00)
Smoking History, n (%)	Never	109 (55.90)	113 (46.89)
	Former	64 (32.82)	95 (39.42)
	Current	22 (11.28)	33 (13.69)
Alcohol Use, n (%)	Abstinent	130 (66.67)	166 (68.88)
	Light	53 (27.18)	61 (25.31)
	Moderate	11 (5.64)	13 (5.39)
	Heavy	1 (0.51)	1 (0.41)
Baseline eGFR (mL/min/1.73m2)	n (missing)	195 (0)	241 (0)
	Mean (SD)	42.5 (12.90)	42.1 (12.49)
	Geo.Mean (SD)	40.8 (1.33)	40.3 (1.34)
	Median	40.6	40.5
	Q1, Q3	33.8, 48.3	32.6, 49.0
	Min, Max	18.3, 107.2	20.0, 84.6
Baseline eGFR (mL/min/1.73 m2) category, n (%)	< 60 mL/min/1.73m2	175 (89.74)	220 (91.29)
	>= 60 mL/min/1.73m2	20 (10.26)	21 (8.71)
Baseline potassium (mmol/L)	n (missing)	195 (0)	241 (0)
	Mean (SD)	4.3 (0.48)	4.4 (0.53)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=195)	Placebo (N=241)
Baseline potassium (mmol/L)	Geo.Mean (SD)	4.3 (1.12)	4.4 (1.13)
	Median	4.3	4.4
	Q1, Q3	4.1, 4.7	4.1, 4.7
	Min, Max	2.8, 5.6	2.6, 6.6
Baseline serum potassium (mmol/L) category, n (%)	<= 4.5 mmol/L	131 (67.18)	145 (60.17)
	> 4.5 mmol/L	64 (32.82)	96 (39.83)
Baseline UACR (mg/g)	n (missing)	195 (0)	241 (0)
	Mean (SD)	1220.3 (1135.35)	1274.0 (1165.44)
	Geo.Mean (SD)	771.8 (2.94)	856.1 (2.66)
	Median	808.1	910.3
	Q1, Q3	398.3, 1783.3	496.3, 1594.3
	Min, Max	5.9, 6381.0	27.6, 6620.0
Baseline albuminuria (mg/g) category, n (%)	Normalbuminuria (UACR < 30 mg/g)	2 (1.03)	1 (0.41)
	High albuminuria (30 mg/g - < 300 mg/g)	27 (13.85)	20 (8.30)
	Very high albuminuria (>= 300 mg/g)	166 (85.13)	220 (91.29)
Baseline Hemoglobin A1C (%)	n (missing)	195 (0)	240 (1)
	Mean (SD)	7.9 (1.31)	7.8 (1.33)
	Geo.Mean (SD)	7.8 (1.18)	7.7 (1.18)
	Median	7.8	7.6
	Q1, Q3	6.9, 8.8	6.7, 8.7
	Min, Max	5.6, 11.4	5.4, 11.8
Baseline Diastolic Blood Pressure (mmHg)	n (missing)	195 (0)	241 (0)
	Mean (SD)	76.4 (9.64)	75.4 (9.51)
	Geo.Mean (SD)	75.8 (1.14)	74.7 (1.14)
	Median	78.0	76.3
	Q1, Q3	70.0, 83.0	69.3, 82.0
	Min, Max	43.3, 97.7	52.0, 98.0
Baseline Systolic Blood Pressure (mmHg)	n (missing)	195 (0)	241 (0)
	Mean (SD)	138.0 (13.56)	138.0 (15.14)
	Geo.Mean (SD)	137.3 (1.11)	137.2 (1.12)
	Median	137.7	139.3
	Q1, Q3	130.0, 148.7	128.7, 146.7
	Min, Max	97.7, 173.0	90.0, 180.7

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=195)	Placebo (N=241)
Observation Duration of All-Cause Mortality in months	Number of patients in analysis	195	241
	Mean (SD)	31.8 (10.73)	30.6 (10.10)
	Median	31.6	30.6
	Min, Max	6.3, 51.1	1.0, 52.0
Observation Duration of CV death and HHF in months	Number of patients in analysis	195	241
	Mean (SD)	29.5 (12.09)	27.9 (11.48)
	Median	29.2	27.8
	Min, Max	0.8, 51.1	0.3, 52.0
Observation Duration of CV death or non-fatal CV event in months	Number of patients in analysis	195	241
	Mean (SD)	29.1 (12.32)	26.7 (12.01)
	Median	28.1	26.4
	Min, Max	0.8, 51.1	0.3, 52.0
Observation Duration of Cardiovascular Death in months	Number of patients in analysis	195	241
	Mean (SD)	31.8 (10.73)	30.6 (10.10)
	Median	31.6	30.6
	Min, Max	6.3, 51.1	1.0, 52.0
Observation Duration of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis in months	Number of patients in analysis	195	241
	Mean (SD)	28.1 (11.87)	27.7 (10.91)
	Median	27.6	27.1
	Min, Max	1.2, 51.1	0.0, 50.1
Observation Duration of New onset of atrial fibrillation in months	Number of patients in analysis	147	192
	Mean (SD)	31.7 (10.48)	29.4 (10.29)
	Median	31.6	28.9
	Min, Max	6.6, 49.5	1.0, 52.0
Observation Duration of Time to Heart Failure Hospitalization in months	Number of patients in analysis	195	241
	Mean (SD)	29.5 (12.09)	27.9 (11.48)
	Median	29.2	27.8
	Min, Max	0.8, 51.1	0.3, 52.0
Observation Duration of Time to all-cause hospitalization in months	Number of patients in analysis	195	241
	Mean (SD)	21.2 (13.13)	20.2 (13.11)
	Median	21.1	20.1
	Min, Max	0.0, 48.3	0.2, 52.0
Observation Duration of Time to first CV hospitalization in months	Number of patients in analysis	195	241
	Mean (SD)	26.4 (13.07)	25.1 (12.51)
	Median	26.6	24.8
	Min, Max	0.8, 49.5	0.2, 52.0
Observation Duration of Time to first myocardial infarction (combined fatal and non-fatal) in months	Number of patients in analysis	195	241
	Mean (SD)	31.5 (11.00)	29.8 (10.77)
	Median	31.6	29.7
	Min, Max	2.7, 51.1	0.9, 52.0
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Number of patients in analysis	195	241
	Mean (SD)	21.2 (13.13)	20.2 (13.11)

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=195)	Placebo (N=241)
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Median	21.1	20.1
	Min, Max	0.0, 48.3	0.2, 52.0
Observation Duration of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) in months	Number of patients in analysis	195	241
	Mean (SD)	26.4 (13.05)	25.1 (12.51)
	Median	26.6	24.6
	Min, Max	0.8, 49.5	0.2, 52.0
Observation Duration of Time to first stroke (combined fatal and non-fatal) in months	Number of patients in analysis	195	241
	Mean (SD)	31.3 (11.00)	29.9 (10.51)
	Median	31.4	29.7
	Min, Max	5.3, 51.1	1.0, 52.0
Observation Duration of Time to initiation of dialysis or renal transplantation in months	Number of patients in analysis	195	241
	Mean (SD)	31.0 (10.63)	29.8 (10.22)
	Median	31.0	29.3
	Min, Max	6.3, 51.1	1.0, 52.0
Observation Duration of Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks in months	Number of patients in analysis	195	241
	Mean (SD)	28.0 (11.95)	27.8 (10.88)
	Median	27.6	27.4
	Min, Max	1.2, 51.1	0.0, 50.1
Observation Duration of VAS in months	Number of patients in analysis	194	240
	Mean (SD)	27.7 (13.21)	27.2 (12.21)
	Median	26.6	25.3
	Min, Max	0.0, 51.1	0.0, 50.1
Study Duration in months	Number of patients in analysis	195	241
	Mean (SD)	32.4 (10.76)	31.2 (10.10)
	Median	32.7	31.1
	Min, Max	6.3, 52.0	1.0, 52.0
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks in months	Number of patients in analysis	195	241
	Mean (SD)	28.3 (12.05)	27.9 (10.91)
	Median	27.9	26.9
	Min, Max	1.2, 51.1	0.0, 50.1

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Observation duration for Safety endpoints
Safety Analysis Set

Endpoint		Finerenone (N=195)	Placebo (N=241)
Observation Duration of Treatment Duration in months	Number of patients in analysis	195	241
	Mean (SD)	25.3 (12.86)	25.2 (12.01)
	Median	24.8	24.9
	Min, Max	0.5, 51.0	0.6, 50.1

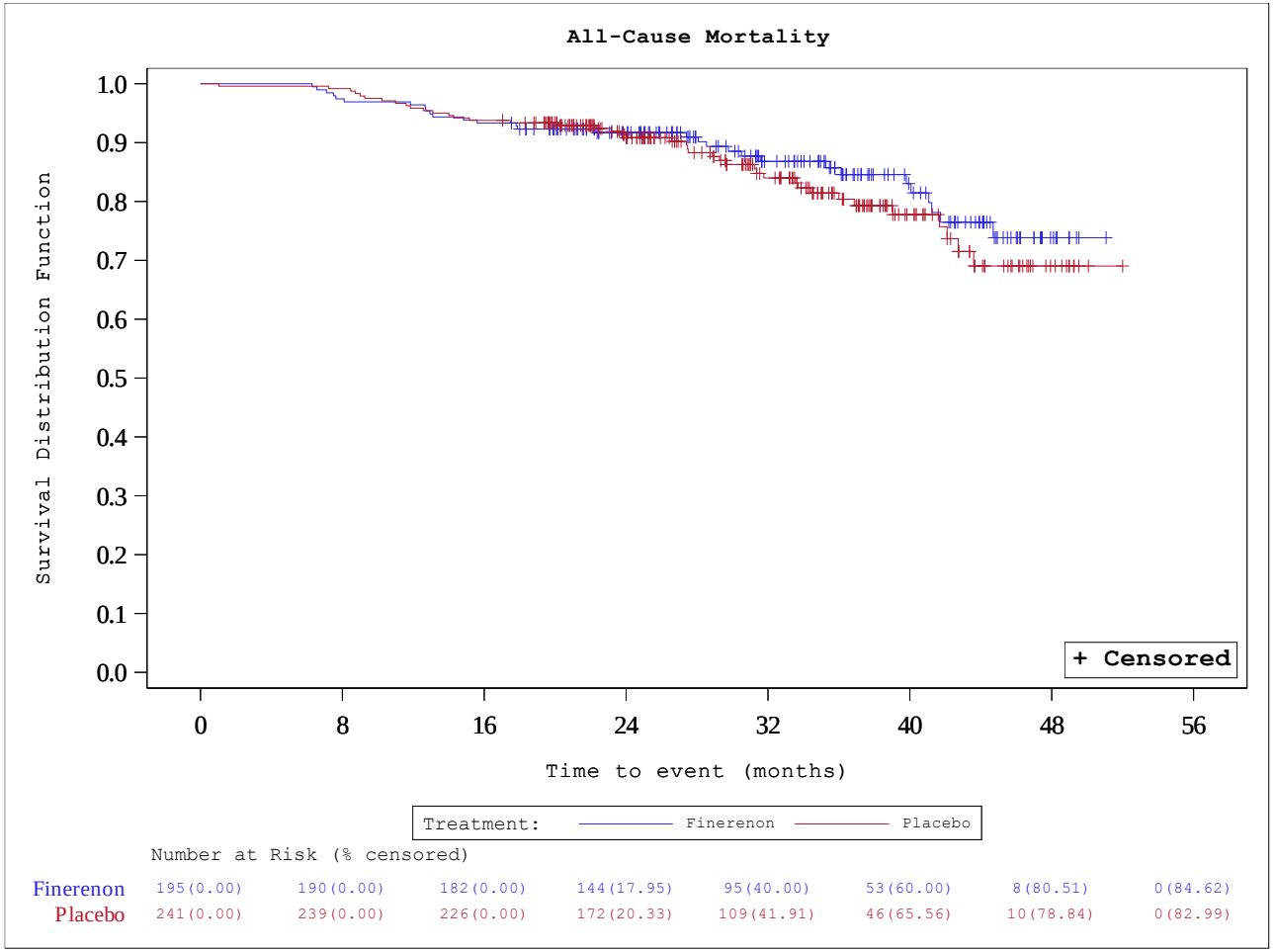
Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
All-cause mortality
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	30/ 195 (15.38)	41/ 241 (17.01)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	44.7 (40.1, NE)	42.1 (34.4, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.87 (0.53, 1.44)	
p-value	0.5933	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.82 (0.51, 1.32)	
p-value	0.4213	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of All-cause mortality
Full Analysis Set



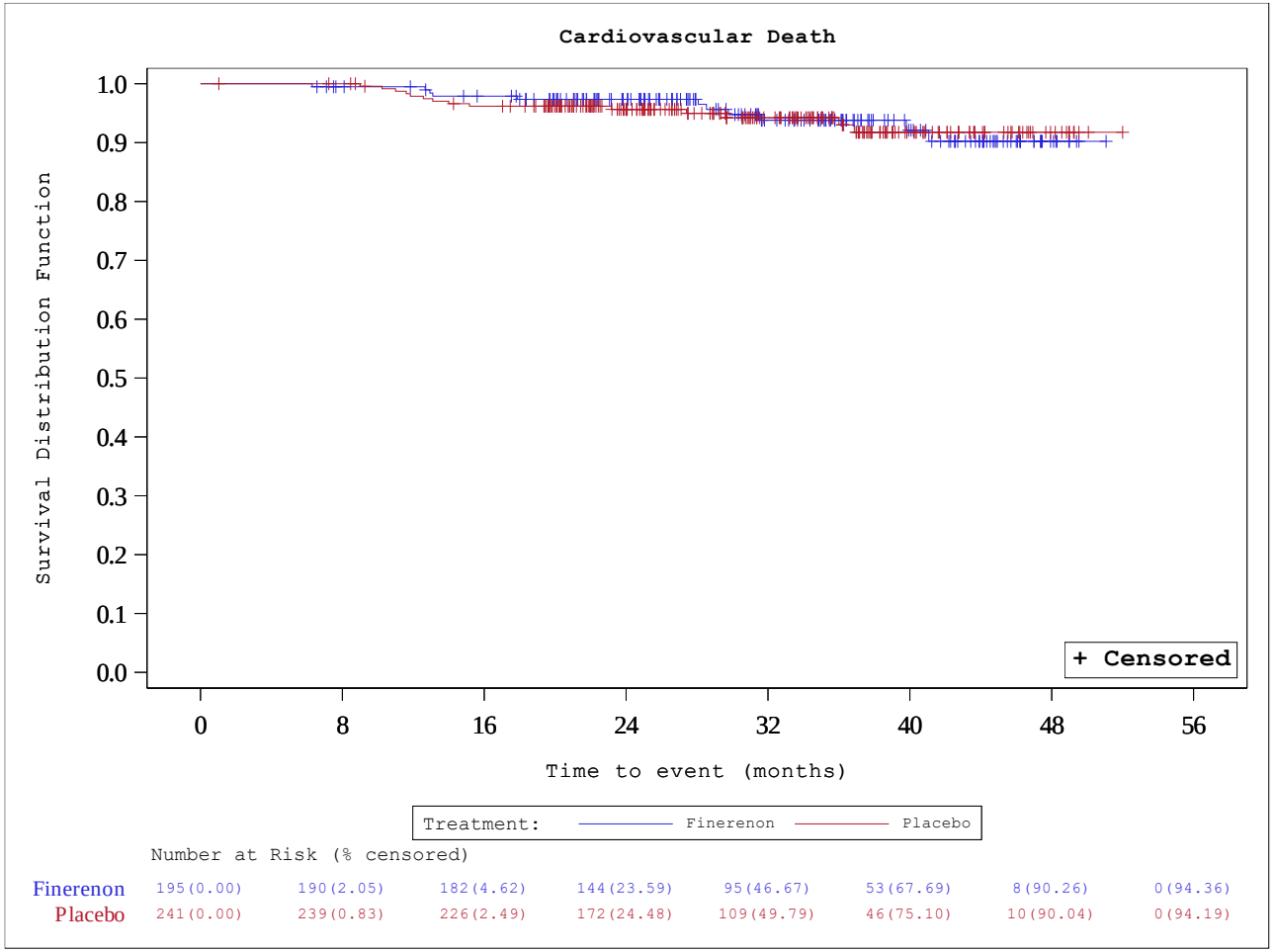
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
CV death
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	11/ 195 (5.64)	14/ 241 (5.81)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.37, 2.04)	
p-value	0.7396	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.42, 2.02)	
p-value	0.8290	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of CV death
Full Analysis Set



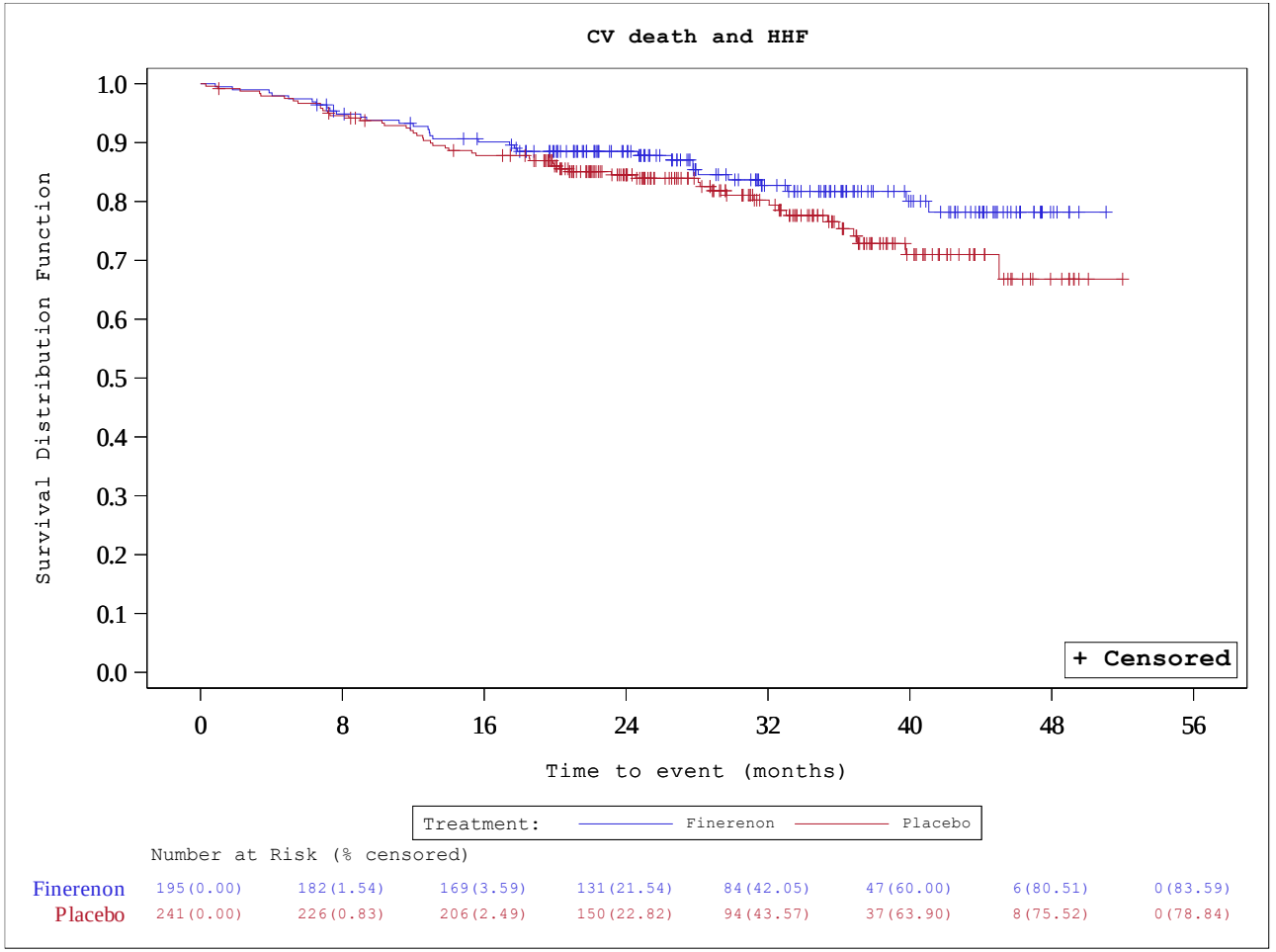
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	32/ 195 (16.41)	51/ 241 (21.16)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (33.1, NE)	36.8 (29.7, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.71 (0.45, 1.12)	
p-value	0.1385	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.73 (0.47, 1.14)	
p-value	0.1633	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; HHF=hospitalization for heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite endpoint of CV death and HF hospitalization
Full Analysis Set



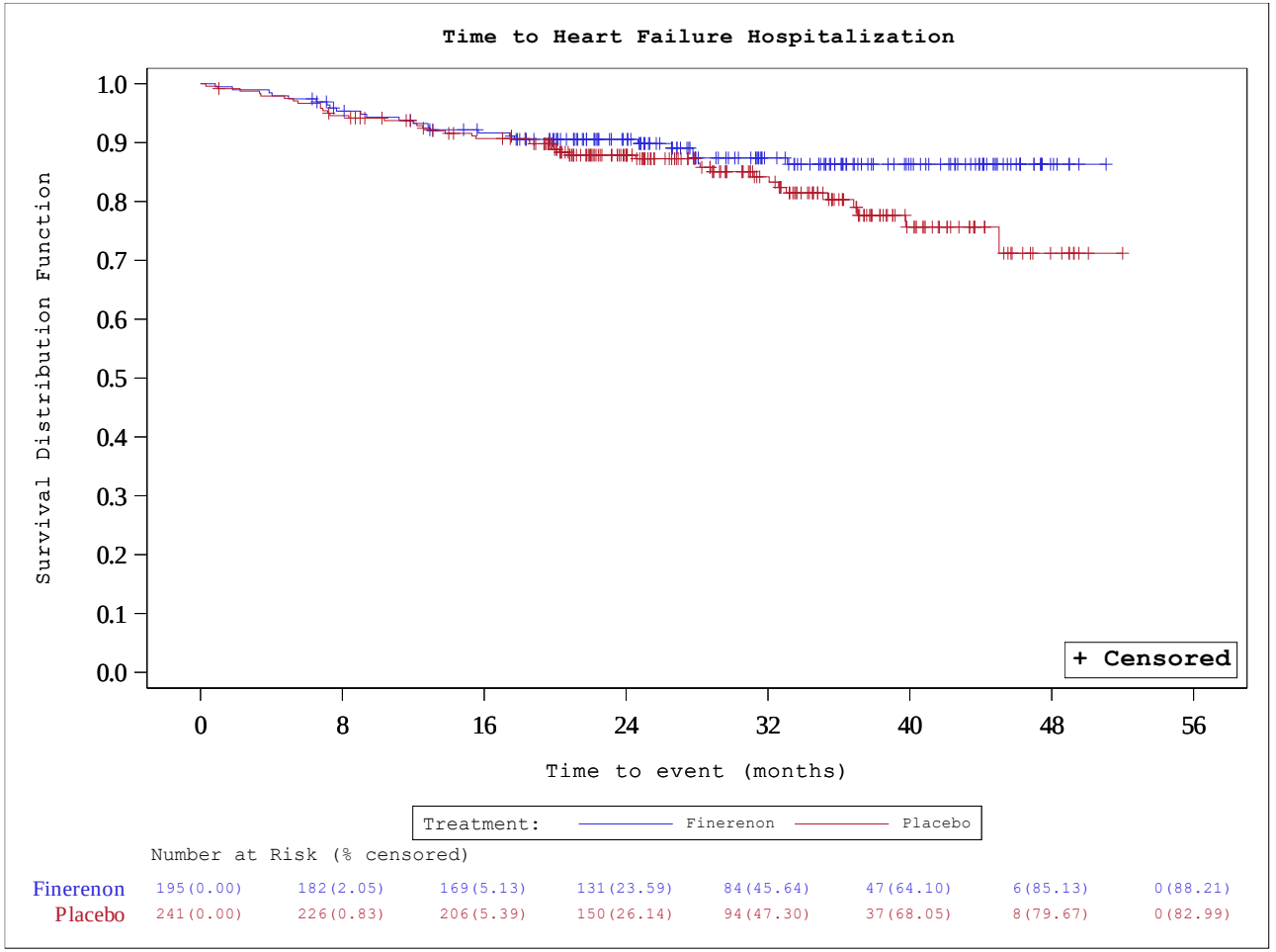
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to Heart Failure Hospitalization
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	23/ 195 (11.79)	41/ 241 (17.01)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	45.0 (33.0, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.67 (0.40, 1.13)	
p-value	0.1288	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.66 (0.40, 1.10)	
p-value	0.1087	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



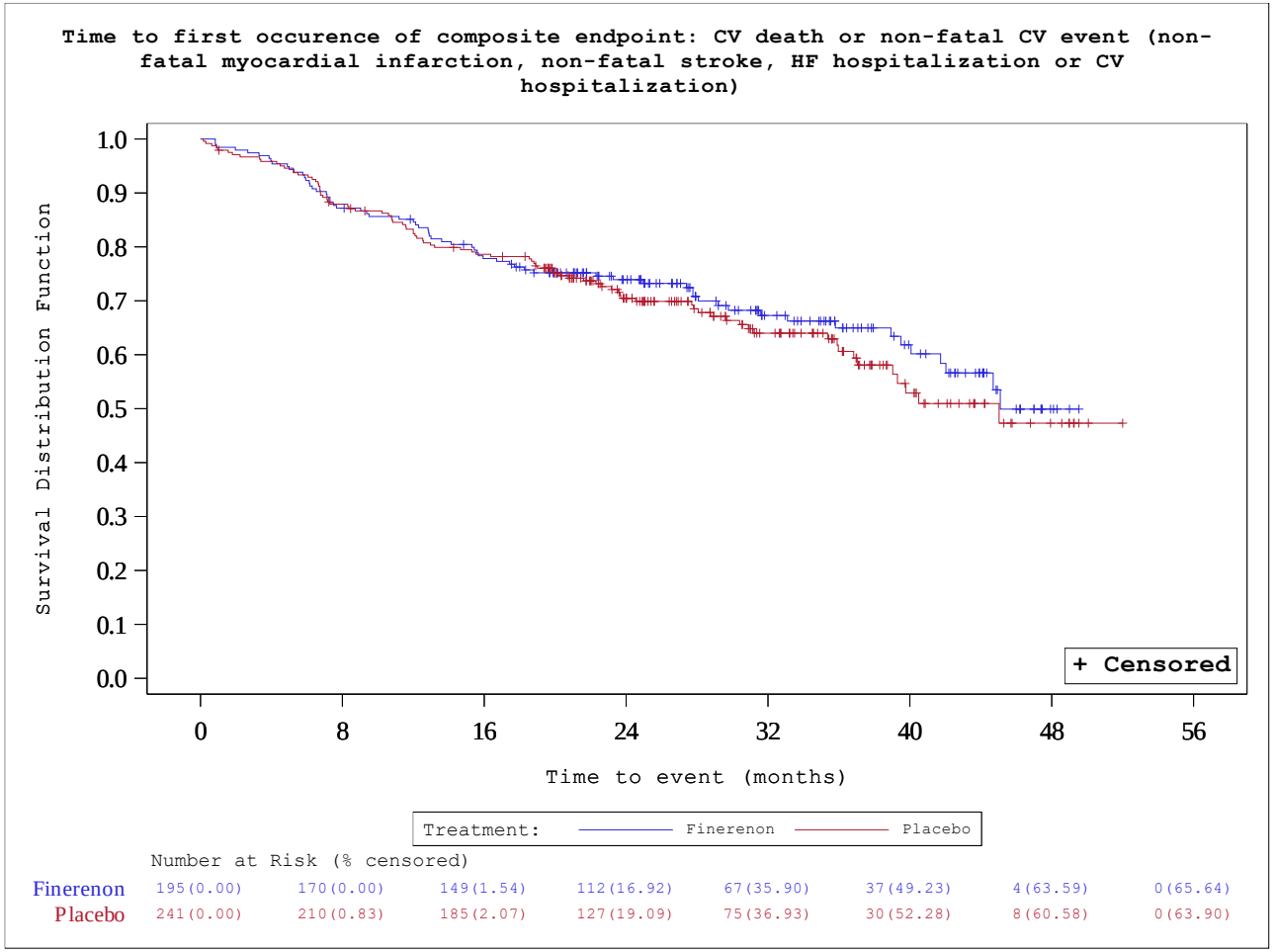
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	67/ 195 (34.36)	87/ 241 (36.10)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	22.3 (13.6, 29.8)	20.2 (13.0, 27.7)
Median (95% CI)	45.1 (41.7, NE)	45.0 (37.0, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.62, 1.20)	
p-value	0.3827	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.65, 1.23)	
p-value	0.4937	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set



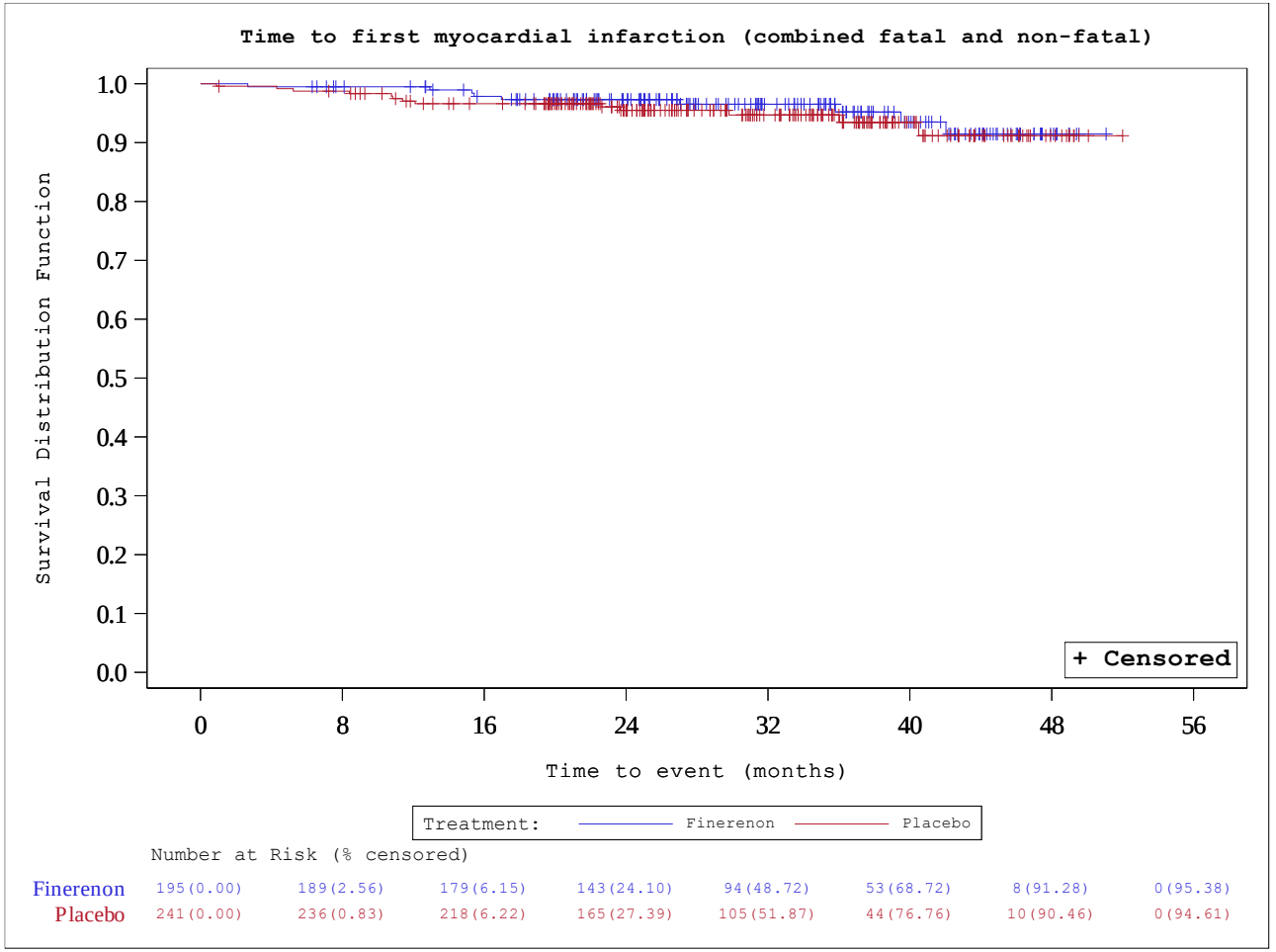
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	9/ 195 (4.62)	13/ 241 (5.39)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.74 (0.30, 1.80)	
p-value	0.5065	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.78 (0.33, 1.82)	
p-value	0.5575	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



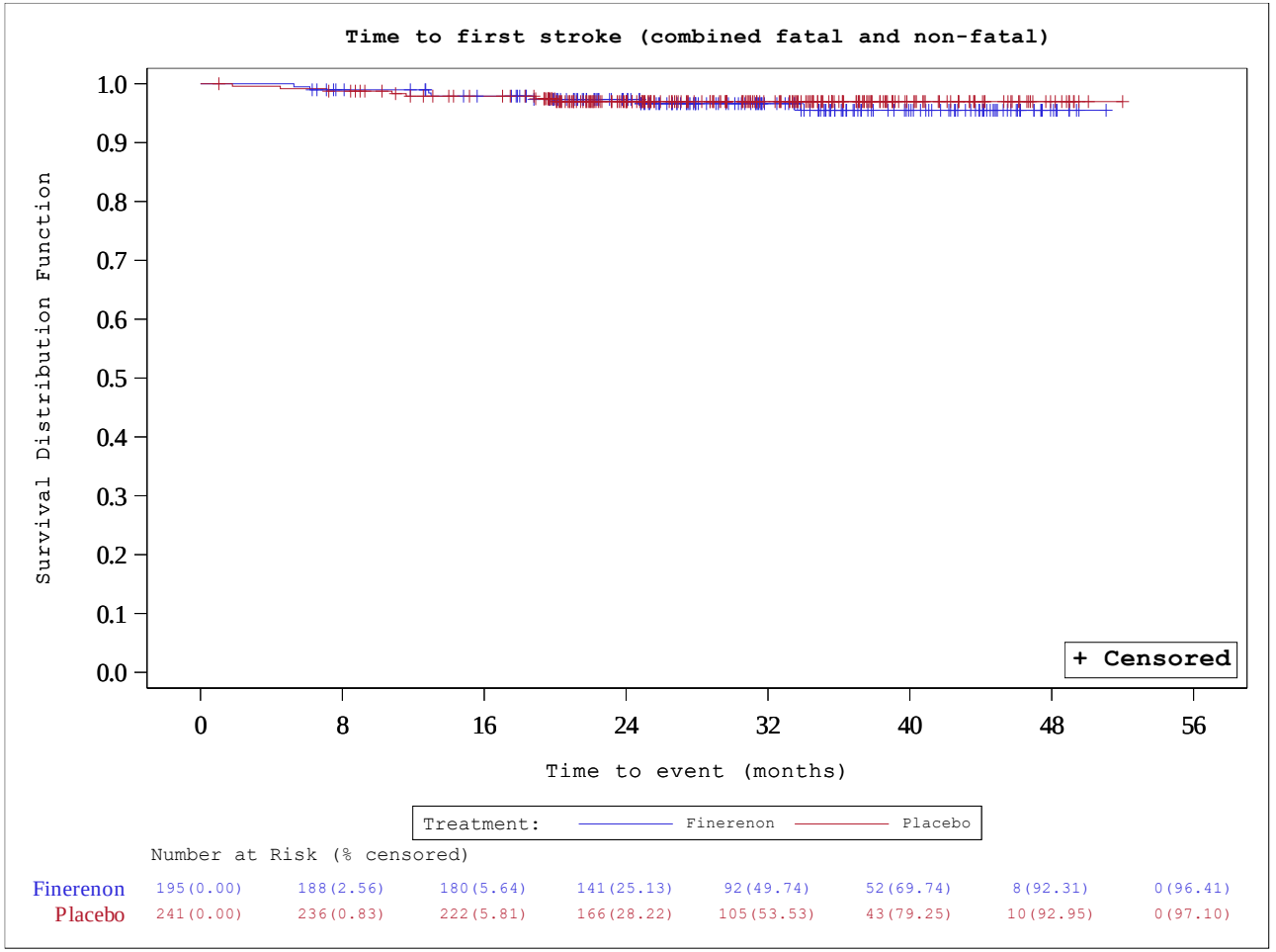
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	7/ 195 (3.59)	7/ 241 (2.90)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.12 (0.38, 3.34)	
p-value	0.8400	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.22 (0.43, 3.47)	
p-value	0.7119	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first stroke (combined fatal and non-fatal)
Full Analysis Set



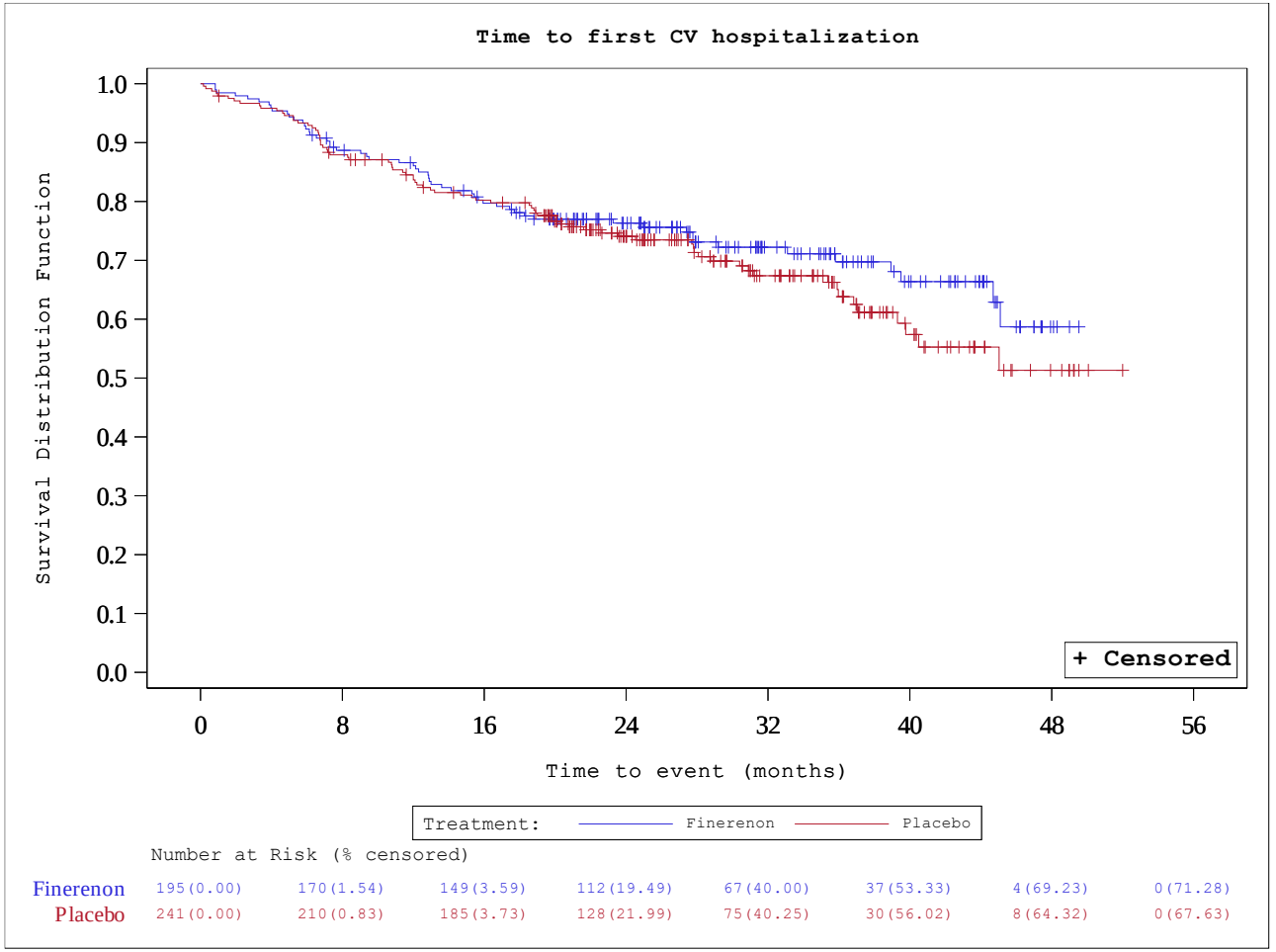
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first CV hospitalization
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	56/ 195 (28.72)	78/ 241 (32.37)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	27.4 (15.4, 39.5)	22.6 (15.5, 30.4)
Median (95% CI)	NE (45.1, NE)	NE (39.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.80 (0.56, 1.15)	
p-value	0.2204	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.60, 1.19)	
p-value	0.3319	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first CV hospitalization
Full Analysis Set



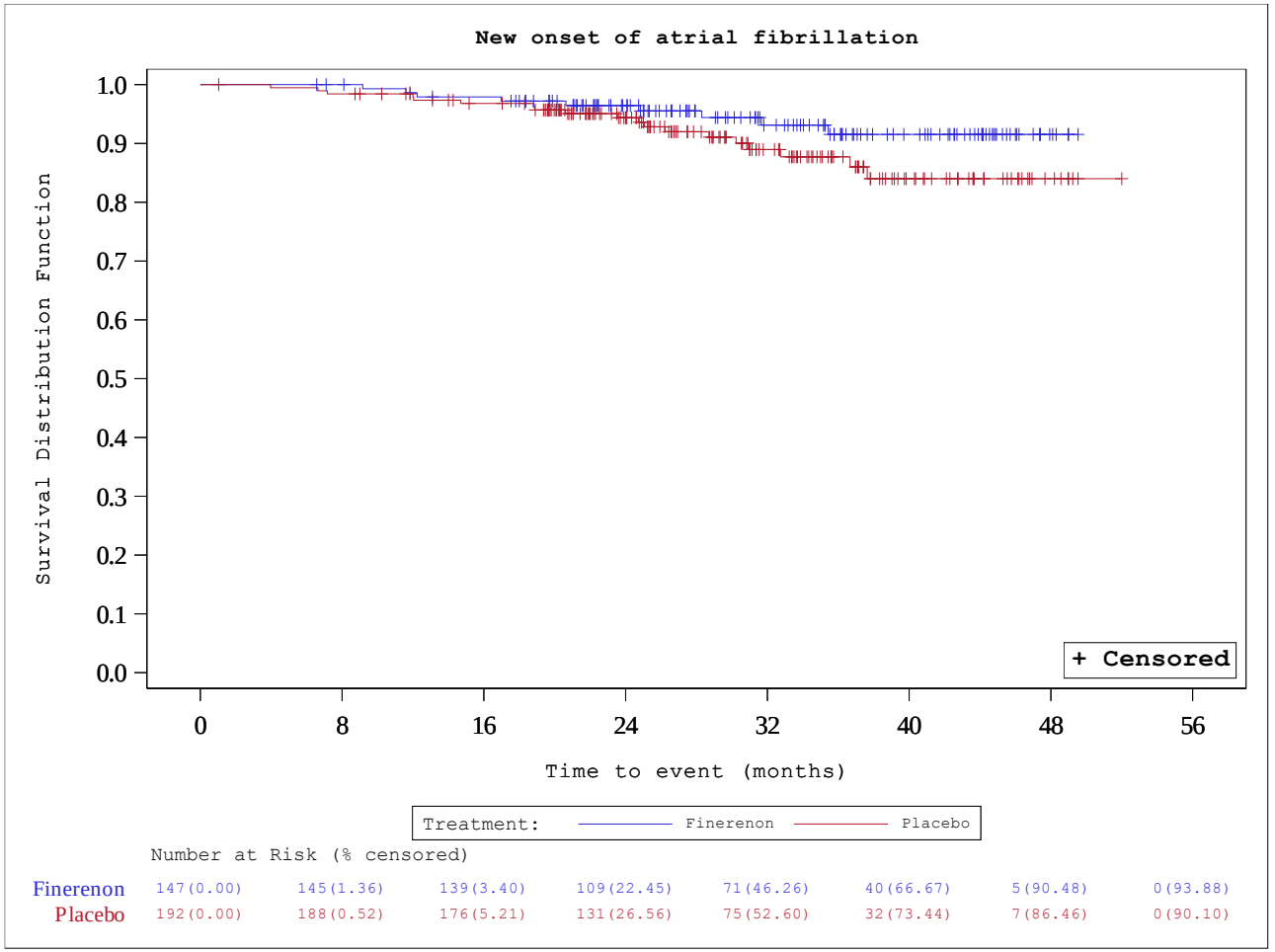
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to new onset of atrial fibrillation
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	9/ 147 (6.12)	19/ 192 (9.90)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (37.6, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.65 (0.29, 1.43)	
p-value	0.2782	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.56 (0.25, 1.24)	
p-value	0.1487	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to new onset of atrial fibrillation
Full Analysis Set



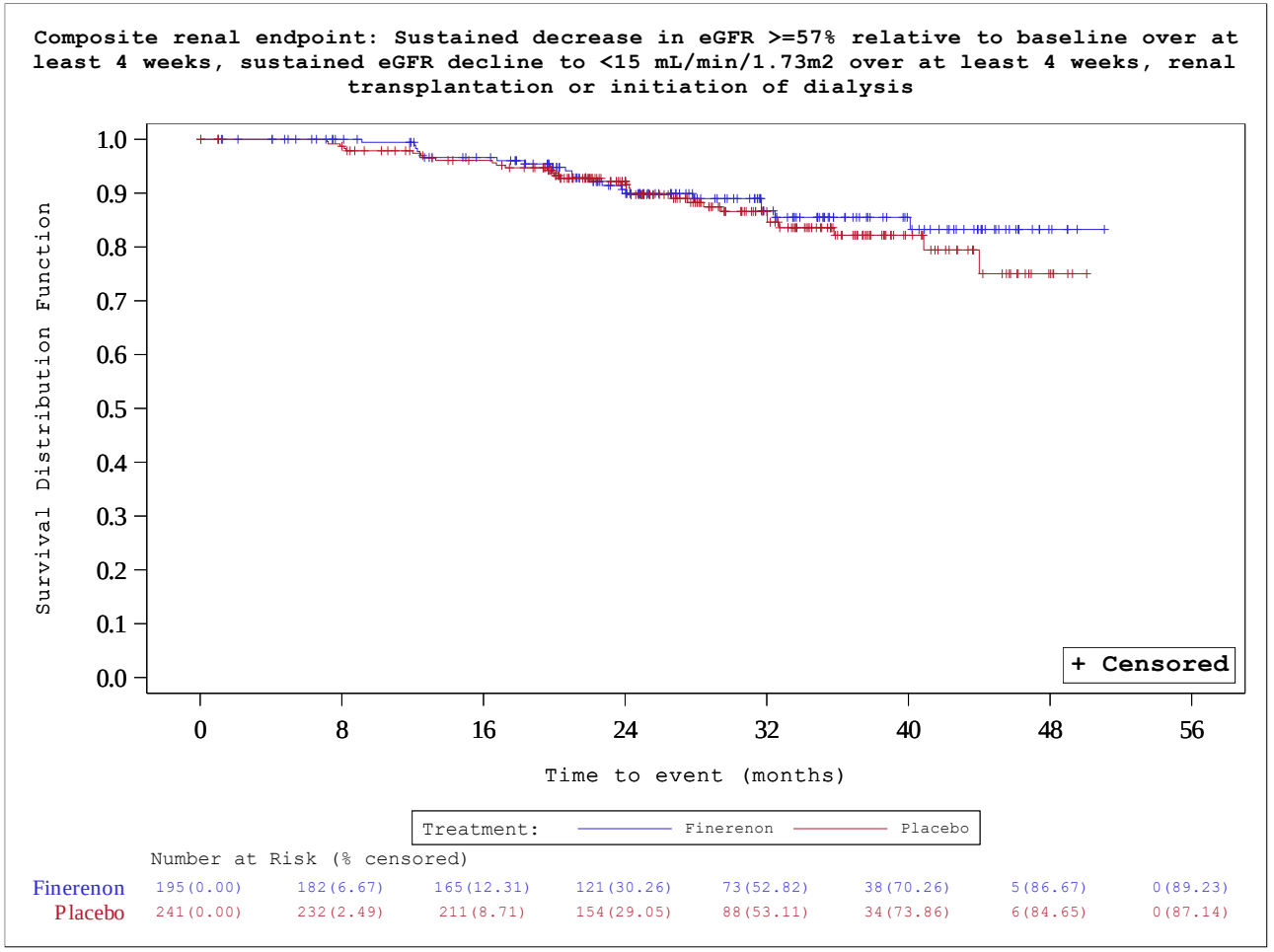
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	21/ 195 (10.77)	31/ 241 (12.86)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (40.1, NE)	NE (35.8, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.50, 1.60)	
p-value	0.7060	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.82 (0.47, 1.44)	
p-value	0.4941	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



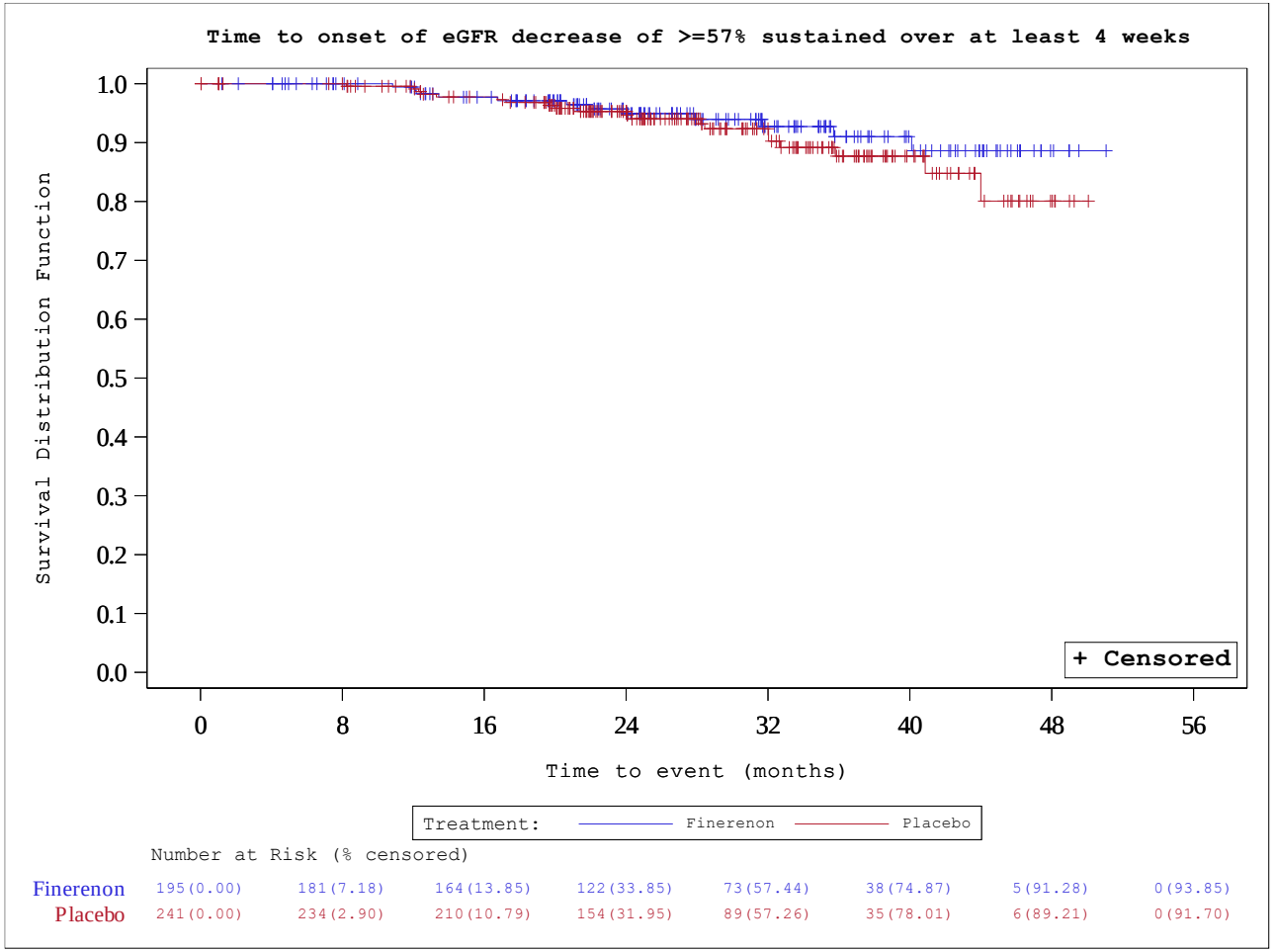
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	12/ 195 (6.15)	20/ 241 (8.30)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (40.9, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.85 (0.40, 1.82)	
p-value	0.6763	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.72 (0.35, 1.48)	
p-value	0.3684	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set



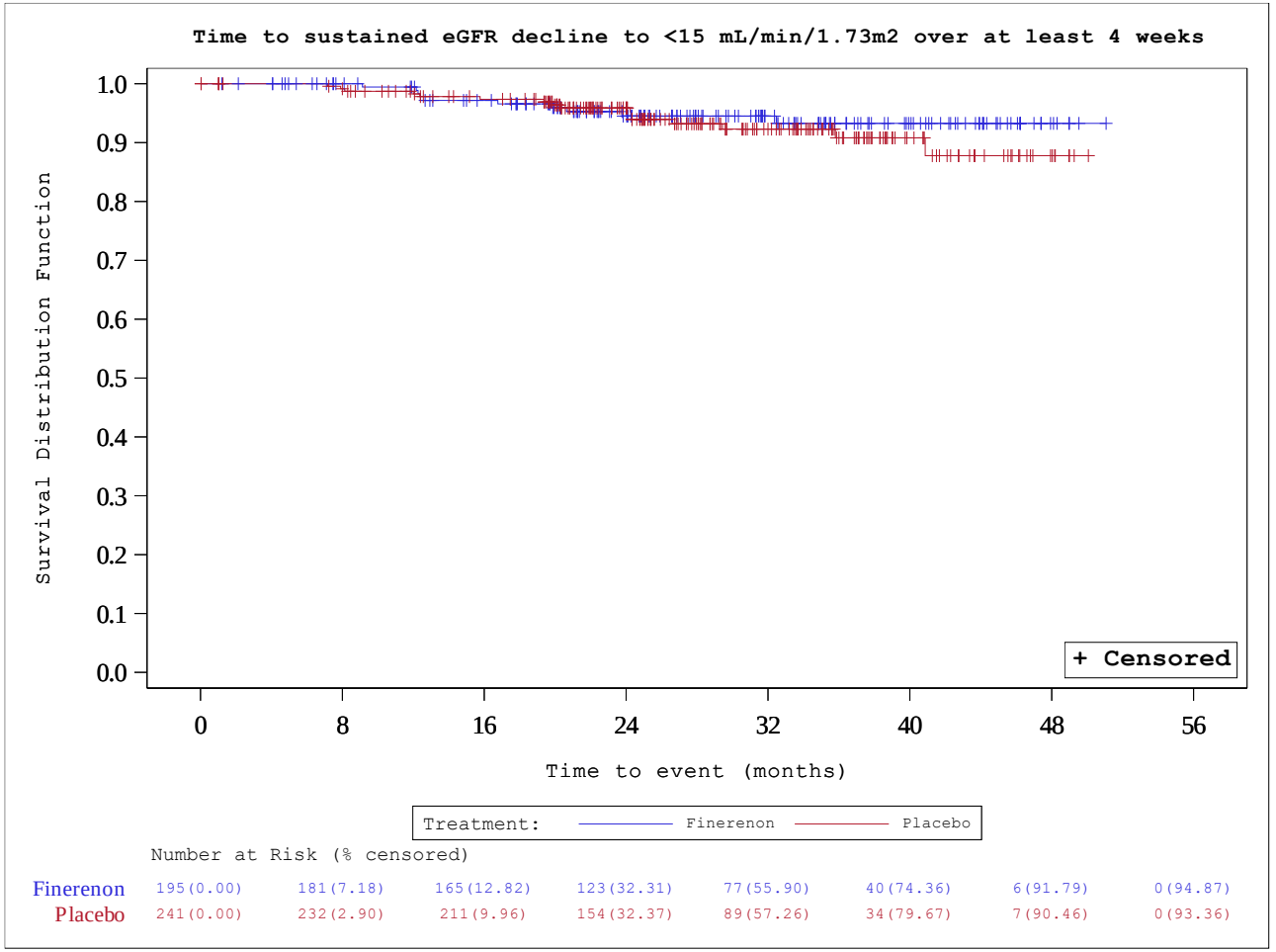
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	10/ 195 (5.13)	16/ 241 (6.64)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.38, 1.94)	
p-value	0.7177	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.77 (0.35, 1.70)	
p-value	0.5134	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



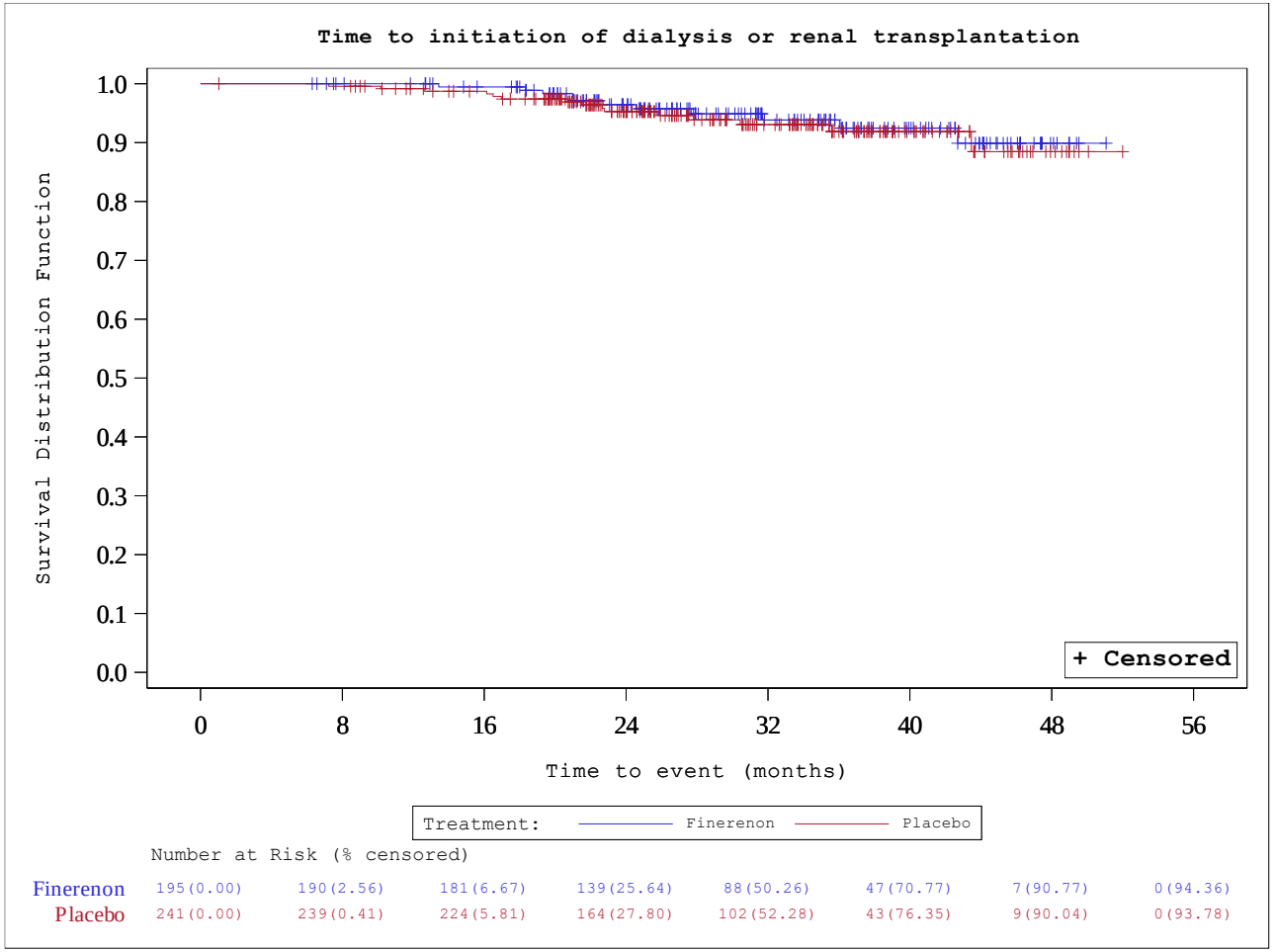
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	11/ 195 (5.64)	15/ 241 (6.22)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.38, 1.86)	
p-value	0.6693	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.39, 1.84)	
p-value	0.6704	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



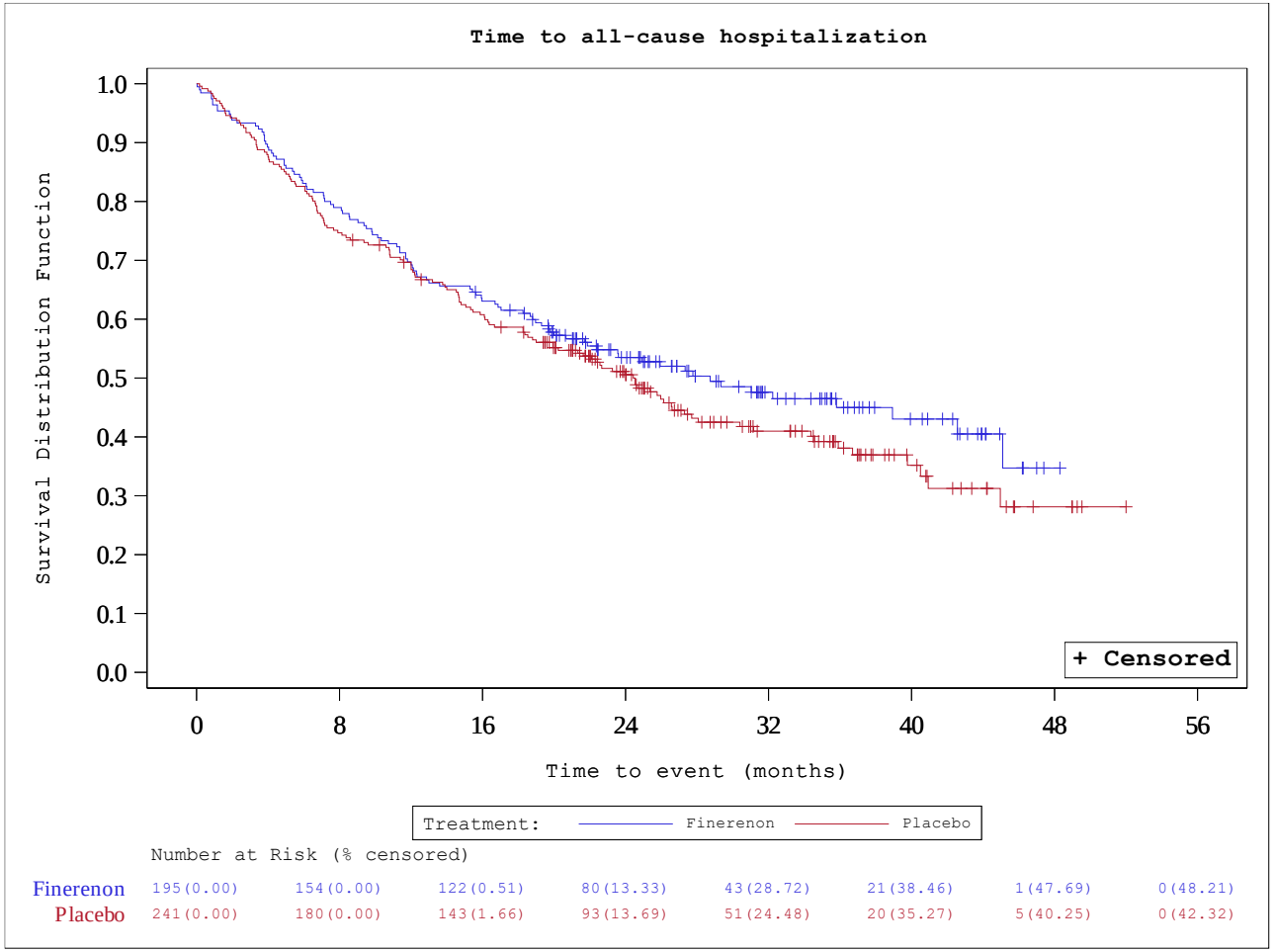
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first all-cause hospitalization
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	101/ 195 (51.79)	139/ 241 (57.68)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.8 (7.1, 12.1)	7.9 (6.5, 12.0)
Median (95% CI)	28.7 (20.0, 42.6)	24.4 (18.8, 27.7)
75%-ile (95% CI)	NE (45.1, NE)	NE (40.9, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.81 (0.62, 1.05)	
p-value	0.1136	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.86 (0.66, 1.11)	
p-value	0.2397	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



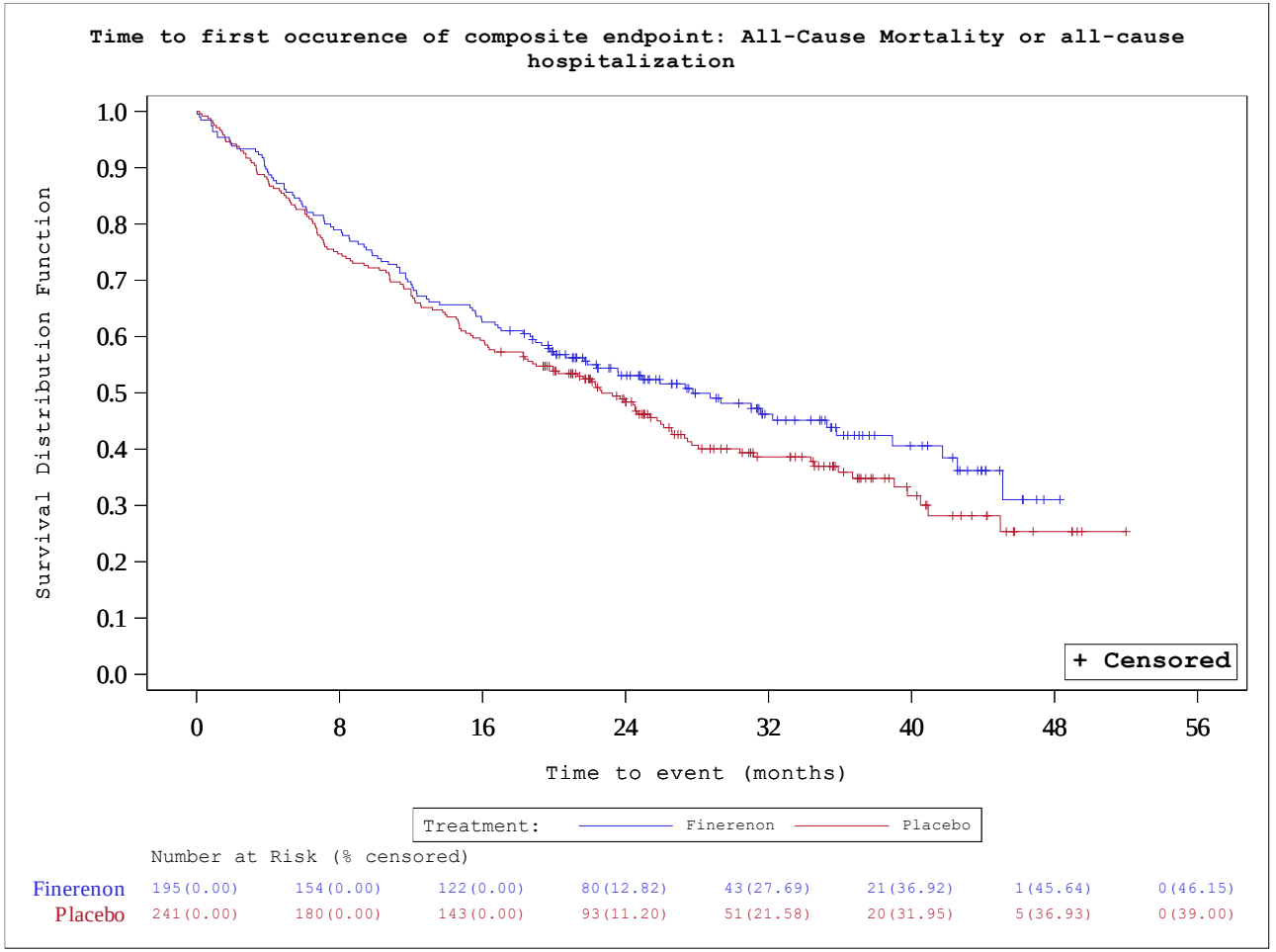
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	105/ 195 (53.85)	147/ 241 (61.00)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.8 (7.1, 12.1)	7.9 (6.5, 11.4)
Median (95% CI)	27.8 (20.0, 38.9)	22.7 (18.3, 26.6)
75%-ile (95% CI)	NE (45.1, NE)	NE (39.8, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.79 (0.61, 1.03)	
p-value	0.0797	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.65, 1.08)	
p-value	0.1740	

Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Event counts per component of composite efficacy endpoints
Full Analysis Set

Endpoint	Finerenone (N=195) n (%)	Placebo (N=241) n (%)
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)	67 (34.36 %)	87 (36.10 %)
CV hospitalization	56 (28.72 %)	75 (31.12 %)
Cardiovascular Death	10 (5.13 %)	9 (3.73 %)
Non-fatal MI	1 (0.51 %)	1 (0.41 %)
Non-fatal Stroke	0 (0.00 %)	2 (0.83 %)
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis	21 (10.77 %)	31 (12.86 %)
Renal transplantation or initiation of dialysis	5 (2.56 %)	5 (2.07 %)
Sustained decrease in eGFR <15	10 (5.13 %)	13 (5.39 %)
Sustained decrease in eGFR >=57%	6 (3.08 %)	13 (5.39 %)
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization	105 (53.85 %)	147 (61.00 %)
All-cause hospitalization	101 (51.79 %)	139 (57.68 %)
Cardiovascular Death	3 (1.54 %)	7 (2.90 %)
Non-Cardiovascular Death	1 (0.51 %)	1 (0.41 %)
CV death and HHF	32 (16.41 %)	51 (21.16 %)
Cardiovascular Death	9 (4.62 %)	10 (4.15 %)
Hospitalization due to Heart Failure	23 (11.79 %)	41 (17.01 %)

n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with reponse, n/N (%)	43/ 181 (23.76)	43/ 222 (19.37)
Number of imputed values	11	11
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.31 (0.80, 2.16)	
p-value	0.2852	
Risk Ratio (95% CI)	1.12 (0.83, 1.51)	
p-value	0.4752	
Risk Difference (95% CI)	0.06 (-0.02, 0.14)	
p-value	0.1322	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.30 (0.80, 2.09)	
p-value	0.2856	
Risk Ratio (95% CI)	1.23 (0.84, 1.78)	
p-value	0.2851	
Risk Difference (95% CI)	0.04 (-0.04, 0.12)	
p-value	0.2879	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with reponse, n/N (%)	32/ 181 (17.68)	47/ 222 (21.17)
Number of imputed values	11	11
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.84 (0.50, 1.41)	
p-value	0.5137	
Risk Ratio (95% CI)	0.87 (0.58, 1.30)	
p-value	0.4919	
Risk Difference (95% CI)	-0.03 (-0.12, 0.07)	
p-value	0.5886	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.80 (0.49, 1.32)	
p-value	0.3804	
Risk Ratio (95% CI)	0.84 (0.56, 1.25)	
p-value	0.3820	
Risk Difference (95% CI)	-0.03 (-0.11, 0.04)	
p-value	0.3760	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
EQ5D-VAS: Completion rates
Full Analysis Set

	Finerenone (N=195)		Placebo (N=241)	
Timepoint	n/ N	Completion	n/ N	Completion
Baseline	193 /195	98.97 %	235 /241	97.51 %
Month 12	171 /188	90.96 %	215 /231	93.07 %
Month 24	122 /144	84.72 %	146 /172	84.88 %
Month 36	54 /74	72.97 %	61 /78	78.21 %
Month 48	3 /8	37.50 %	5 /10	50.00 %

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

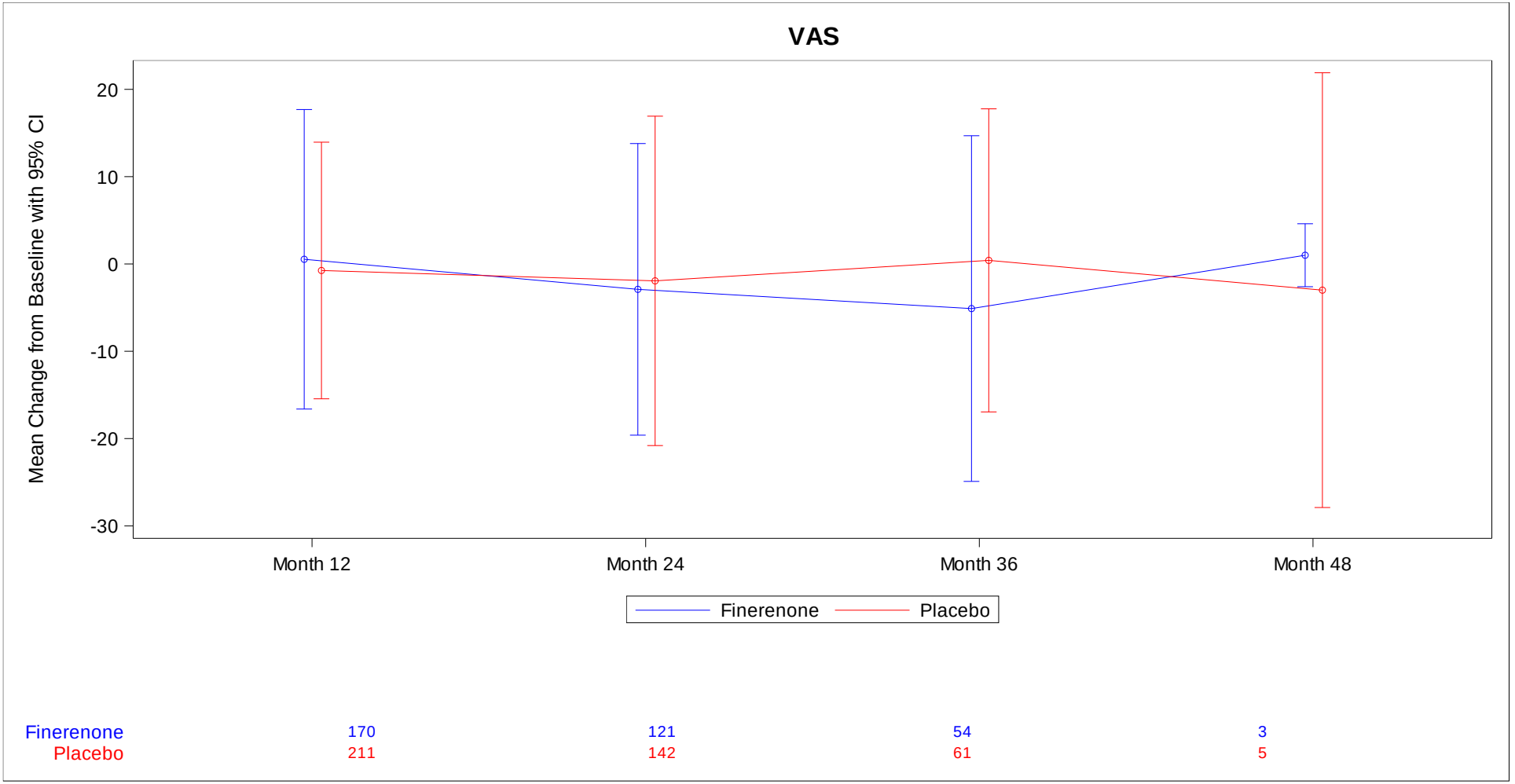
	Finerenone (N=195)				Placebo (N=241)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	193	67.13 (17.08)	-	-	235	65.82 (17.31)	-	-
Month 12	171	68.61 (18.75)	170	0.54 (17.15)	215	65.46 (18.40)	211	-0.75 (14.70)
Month 24	122	66.32 (18.72)	121	-2.91 (16.70)	146	64.91 (19.08)	142	-1.94 (18.87)
Month 36	54	66.69 (19.52)	54	-5.11 (19.80)	61	64.85 (16.29)	61	0.41 (17.36)
Month 48	3	80.00 (13.23)	3	1.00 (3.61)	5	74.00 (18.17)	5	-3.00 (24.90)
Premature discontinuation	11	67.27 (16.18)	11	-2.27 (17.66)	12	62.17 (20.25)	11	-2.09 (25.16)
End of Study Visit	137	64.82 (17.08)	136	-2.68 (16.77)	174	64.05 (18.52)	170	-0.66 (15.75)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

Timepoint	Finerenone (N=195) N	Finerenone (N=195) LSMean (SE)	Placebo (N=241) N	Placebo (N=241) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	170	5.58 (2.33)	211	3.90 (2.27)	1.68 (-1.33, 4.68)	0.2736	0.05 (-0.15, 0.25)	0.6102

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	167/ 195 (85.64)	211/ 241 (87.55)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.85 (0.49, 1.48)	
p-value	0.5594	
Risk Ratio (95% CI)	0.98 (0.91, 1.05)	
p-value	0.5622	
Risk Difference (95% CI)	-0.02 (-0.08, 0.05)	
p-value	0.5615	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	167/ 195 (85.64)	211/ 241 (87.55)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.85 (0.49, 1.48)	
p-value	0.5594	
Risk Ratio (95% CI)	0.98 (0.91, 1.05)	
p-value	0.5622	
Risk Difference (95% CI)	-0.02 (-0.08, 0.05)	
p-value	0.5615	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	81/ 195 (41.54)	121/ 241 (50.21)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.70 (0.48, 1.03)	
p-value	0.0715	
Risk Ratio (95% CI)	0.83 (0.67, 1.02)	
p-value	0.0750	
Risk Difference (95% CI)	-0.09 (-0.18, 0.01)	
p-value	0.0696	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	80/ 195 (41.03)	120/ 241 (49.79)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.70 (0.48, 1.03)	
p-value	0.0681	
Risk Ratio (95% CI)	0.82 (0.67, 1.02)	
p-value	0.0716	
Risk Difference (95% CI)	-0.09 (-0.18, 0.01)	
p-value	0.0662	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	55/ 195 (28.21)	72/ 241 (29.88)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.92 (0.61, 1.40)	
p-value	0.7027	
Risk Ratio (95% CI)	0.94 (0.70, 1.27)	
p-value	0.7031	
Risk Difference (95% CI)	-0.02 (-0.10, 0.07)	
p-value	0.7021	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	53/ 195 (27.18)	71/ 241 (29.46)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.89 (0.59, 1.36)	
p-value	0.5997	
Risk Ratio (95% CI)	0.92 (0.68, 1.25)	
p-value	0.6004	
Risk Difference (95% CI)	-0.02 (-0.11, 0.06)	
p-value	0.5986	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	19/ 195 (9.74)	15/ 241 (6.22)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.63 (0.80, 3.29)	
p-value	0.1763	
Risk Ratio (95% CI)	1.57 (0.82, 3.00)	
p-value	0.1766	
Risk Difference (95% CI)	0.04 (-0.02, 0.09)	
p-value	0.1813	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	18/ 195 (9.23)	15/ 241 (6.22)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.53 (0.75, 3.13)	
p-value	0.2407	
Risk Ratio (95% CI)	1.48 (0.77, 2.87)	
p-value	0.2409	
Risk Difference (95% CI)	0.03 (-0.02, 0.08)	
p-value	0.2461	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	9/ 195 (4.62)	11/ 241 (4.56)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.01 (0.41, 2.49)	
p-value	0.9798	
Risk Ratio (95% CI)	1.01 (0.43, 2.39)	
p-value	0.9798	
Risk Difference (95% CI)	0.00 (-0.04, 0.04)	
p-value	0.9798	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Serious)
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	8/ 195 (4.10)	7/ 241 (2.90)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.43 (0.51, 4.02)	
p-value	0.4971	
Risk Ratio (95% CI)	1.41 (0.52, 3.83)	
p-value	0.4971	
Risk Difference (95% CI)	0.01 (-0.02, 0.05)	
p-value	0.5022	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Severe)
Safety Analysis Set

	Finerenone (N=195)	Placebo (N=241)
Number of subjects with event, n/N (%)	7/ 195 (3.59)	7/ 241 (2.90)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.24 (0.43, 3.61)	
p-value	0.6871	
Risk Ratio (95% CI)	1.24 (0.44, 3.46)	
p-value	0.6871	
Risk Difference (95% CI)	0.01 (-0.03, 0.04)	
p-value	0.6897	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	38/ 195 (19.49)	49/ 241 (20.33)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.59, 1.52)	
	p-value	0.8263	
	Risk Ratio (95% CI)	0.96 (0.66, 1.40)	
	p-value	0.8264	
	Risk Difference (95% CI)	-0.01 (-0.08, 0.07)	
	p-value	0.8260	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	24/ 195 (12.31)	31/ 241 (12.86)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.54, 1.68)	
	p-value	0.8621	
	Risk Ratio (95% CI)	0.96 (0.58, 1.57)	
	p-value	0.8622	
	Risk Difference (95% CI)	-0.01 (-0.07, 0.06)	
	p-value	0.8619	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	44/ 195 (22.56)	81/ 241 (33.61)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.58 (0.37, 0.88)	
	p-value	0.0116	
	Risk Ratio (95% CI)	0.67 (0.49, 0.92)	
	p-value	0.0131	
	Risk Difference (95% CI)	-0.11 (-0.19, -0.03)	
	p-value	0.0097	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders; PT: Bradycardia	Number of subjects with event, n/N (%)	2/ 195 (1.03)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.24 (0.05, 1.11)	
	p-value	0.0671	
	Risk Ratio (95% CI)	0.25 (0.05, 1.11)	
	p-value	0.0690	
	Risk Difference (95% CI)	-0.03 (-0.06, -0.00)	
	p-value	0.0340	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	11/ 195 (5.64)	24/ 241 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.54 (0.26, 1.13)	
	p-value	0.1033	
	Risk Ratio (95% CI)	0.57 (0.28, 1.13)	
	p-value	0.1055	
	Risk Difference (95% CI)	-0.04 (-0.09, 0.01)	
	p-value	0.0891	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	12/ 195 (6.15)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.55, 2.85)	
	p-value	0.5935	
	Risk Ratio (95% CI)	1.24 (0.57, 2.69)	
	p-value	0.5934	
	Risk Difference (95% CI)	0.01 (-0.03, 0.06)	
	p-value	0.5966	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Endocrine disorders	Number of subjects with event, n/N (%)	5/ 195 (2.56)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.43 (0.15, 1.21)	
	p-value	0.1082	
	Risk Ratio (95% CI)	0.44 (0.16, 1.20)	
	p-value	0.1102	
	Risk Difference (95% CI)	-0.03 (-0.07, 0.00)	
	p-value	0.0851	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Eye disorders	Number of subjects with event, n/N (%)	23/ 195 (11.79)	39/ 241 (16.18)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.40, 1.21)	
	p-value	0.1938	
	Risk Ratio (95% CI)	0.73 (0.45, 1.18)	
	p-value	0.1961	
	Risk Difference (95% CI)	-0.04 (-0.11, 0.02)	
	p-value	0.1851	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Eye disorders; PT: Cataract	Number of subjects with event, n/N (%)	7/ 195 (3.59)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.27, 1.84)	
	p-value	0.4817	
	Risk Ratio (95% CI)	0.72 (0.29, 1.80)	
	p-value	0.4823	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.4723	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Eye disorders; PT: Diabetic retinopathy	Number of subjects with event, n/N (%)	5/ 195 (2.56)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.46 (0.16, 1.32)	
	p-value	0.1486	
	Risk Ratio (95% CI)	0.48 (0.17, 1.31)	
	p-value	0.1506	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.01)	
	p-value	0.1248	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	59/ 195 (30.26)	61/ 241 (25.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (0.84, 1.95)	
	p-value	0.2508	
	Risk Ratio (95% CI)	1.20 (0.88, 1.62)	
	p-value	0.2500	
	Risk Difference (95% CI)	0.05 (-0.04, 0.13)	
	p-value	0.2524	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders; PT: Constipation	Number of subjects with event, n/N (%)	8/ 195 (4.10)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.75 (0.30, 1.85)	
	p-value	0.5324	
	Risk Ratio (95% CI)	0.76 (0.32, 1.80)	
	p-value	0.5329	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.03)	
	p-value	0.5253	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	13/ 195 (6.67)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.53, 2.53)	
	p-value	0.7120	
	Risk Ratio (95% CI)	1.15 (0.55, 2.38)	
	p-value	0.7120	
	Risk Difference (95% CI)	0.01 (-0.04, 0.05)	
	p-value	0.7137	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	8/ 195 (4.10)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.99 (0.38, 2.55)	
	p-value	0.9805	
	Risk Ratio (95% CI)	0.99 (0.40, 2.46)	
	p-value	0.9805	
	Risk Difference (95% CI)	-0.00 (-0.04, 0.04)	
	p-value	0.9805	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	44/ 195 (22.56)	66/ 241 (27.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.50, 1.20)	
	p-value	0.2497	
	Risk Ratio (95% CI)	0.82 (0.59, 1.15)	
	p-value	0.2521	
	Risk Difference (95% CI)	-0.05 (-0.13, 0.03)	
	p-value	0.2451	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	16/ 195 (8.21)	28/ 241 (11.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.68 (0.36, 1.30)	
	p-value	0.2416	
	Risk Ratio (95% CI)	0.71 (0.39, 1.27)	
	p-value	0.2435	
	Risk Difference (95% CI)	-0.03 (-0.09, 0.02)	
	p-value	0.2311	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	16/ 195 (8.21)	22/ 241 (9.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.45, 1.75)	
	p-value	0.7340	
	Risk Ratio (95% CI)	0.90 (0.49, 1.66)	
	p-value	0.7342	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.04)	
	p-value	0.7326	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Hepatobiliary disorders; PT: Hepatic steatosis	Number of subjects with event, n/N (%)	3/ 195 (1.54)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.33 (0.09, 1.19)	
	p-value	0.0894	
	Risk Ratio (95% CI)	0.34 (0.10, 1.19)	
	p-value	0.0914	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.00)	
	p-value	0.0598	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	91/ 195 (46.67)	114/ 241 (47.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.67, 1.42)	
	p-value	0.8947	
	Risk Ratio (95% CI)	0.99 (0.81, 1.21)	
	p-value	0.8948	
	Risk Difference (95% CI)	-0.01 (-0.10, 0.09)	
	p-value	0.8947	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Bronchitis	Number of subjects with event, n/N (%)	11/ 195 (5.64)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.43, 2.19)	
	p-value	0.9402	
	Risk Ratio (95% CI)	0.97 (0.45, 2.09)	
	p-value	0.9402	
	Risk Difference (95% CI)	-0.00 (-0.05, 0.04)	
	p-value	0.9401	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	7/ 195 (3.59)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.32, 2.30)	
	p-value	0.7643	
	Risk Ratio (95% CI)	0.87 (0.34, 2.23)	
	p-value	0.7644	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.03)	
	p-value	0.7624	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	16/ 195 (8.21)	22/ 241 (9.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.45, 1.75)	
	p-value	0.7340	
	Risk Ratio (95% CI)	0.90 (0.49, 1.66)	
	p-value	0.7342	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.04)	
	p-value	0.7326	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	16/ 195 (8.21)	36/ 241 (14.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.51 (0.27, 0.95)	
	p-value	0.0334	
	Risk Ratio (95% CI)	0.55 (0.31, 0.96)	
	p-value	0.0353	
	Risk Difference (95% CI)	-0.07 (-0.13, -0.01)	
	p-value	0.0259	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Upper respiratory tract infection	Number of subjects with event, n/N (%)	14/ 195 (7.18)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.58, 2.70)	
	p-value	0.5624	
	Risk Ratio (95% CI)	1.24 (0.60, 2.53)	
	p-value	0.5623	
	Risk Difference (95% CI)	0.01 (-0.03, 0.06)	
	p-value	0.5656	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	19/ 195 (9.74)	15/ 241 (6.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.63 (0.80, 3.29)	
	p-value	0.1763	
	Risk Ratio (95% CI)	1.57 (0.82, 3.00)	
	p-value	0.1766	
	Risk Difference (95% CI)	0.04 (-0.02, 0.09)	
	p-value	0.1813	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	39/ 195 (20.00)	63/ 241 (26.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.45, 1.11)	
	p-value	0.1330	
	Risk Ratio (95% CI)	0.77 (0.54, 1.09)	
	p-value	0.1359	
	Risk Difference (95% CI)	-0.06 (-0.14, 0.02)	
	p-value	0.1273	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Investigations	Number of subjects with event, n/N (%)	49/ 195 (25.13)	69/ 241 (28.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.55, 1.28)	
	p-value	0.4134	
	Risk Ratio (95% CI)	0.88 (0.64, 1.20)	
	p-value	0.4150	
	Risk Difference (95% CI)	-0.04 (-0.12, 0.05)	
	p-value	0.4107	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Investigations; PT: Blood pressure increased	Number of subjects with event, n/N (%)	4/ 195 (2.05)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.37 (0.12, 1.15)	
	p-value	0.0843	
	Risk Ratio (95% CI)	0.38 (0.13, 1.15)	
	p-value	0.0863	
	Risk Difference (95% CI)	-0.03 (-0.07, 0.00)	
	p-value	0.0595	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	13/ 195 (6.67)	19/ 241 (7.88)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.83 (0.40, 1.74)	
	p-value	0.6284	
	Risk Ratio (95% CI)	0.85 (0.43, 1.67)	
	p-value	0.6287	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.04)	
	p-value	0.6251	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	79/ 195 (40.51)	98/ 241 (40.66)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.99 (0.68, 1.46)	
	p-value	0.9745	
	Risk Ratio (95% CI)	1.00 (0.79, 1.25)	
	p-value	0.9745	
	Risk Difference (95% CI)	-0.00 (-0.09, 0.09)	
	p-value	0.9745	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Diabetes mellitus	Number of subjects with event, n/N (%)	7/ 195 (3.59)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.27, 1.84)	
	p-value	0.4817	
	Risk Ratio (95% CI)	0.72 (0.29, 1.80)	
	p-value	0.4823	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.4723	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia	Number of subjects with event, n/N (%)	7/ 195 (3.59)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.30, 2.05)	
	p-value	0.6119	
	Risk Ratio (95% CI)	0.79 (0.31, 1.99)	
	p-value	0.6122	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.03)	
	p-value	0.6066	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	38/ 195 (19.49)	24/ 241 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.19 (1.26, 3.80)	
	p-value	0.0053	
	Risk Ratio (95% CI)	1.96 (1.22, 3.15)	
	p-value	0.0056	
	Risk Difference (95% CI)	0.10 (0.03, 0.16)	
	p-value	0.0055	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hyperuricaemia	Number of subjects with event, n/N (%)	11/ 195 (5.64)	17/ 241 (7.05)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.79 (0.36, 1.72)	
	p-value	0.5504	
	Risk Ratio (95% CI)	0.80 (0.38, 1.67)	
	p-value	0.5509	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.03)	
	p-value	0.5450	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hypoglycaemia	Number of subjects with event, n/N (%)	11/ 195 (5.64)	16/ 241 (6.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.38, 1.86)	
	p-value	0.6676	
	Risk Ratio (95% CI)	0.85 (0.40, 1.79)	
	p-value	0.6679	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.04)	
	p-value	0.6647	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hypokalaemia	Number of subjects with event, n/N (%)	2/ 195 (1.03)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.22 (0.05, 0.99)	
	p-value	0.0484	
	Risk Ratio (95% CI)	0.22 (0.05, 1.00)	
	p-value	0.0503	
	Risk Difference (95% CI)	-0.04 (-0.07, -0.01)	
	p-value	0.0204	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	47/ 195 (24.10)	65/ 241 (26.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.56, 1.33)	
	p-value	0.4957	
	Risk Ratio (95% CI)	0.89 (0.65, 1.24)	
	p-value	0.4968	
	Risk Difference (95% CI)	-0.03 (-0.11, 0.05)	
	p-value	0.4936	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	11/ 195 (5.64)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.38 (0.57, 3.32)	
	p-value	0.4712	
	Risk Ratio (95% CI)	1.36 (0.59, 3.13)	
	p-value	0.4712	
	Risk Difference (95% CI)	0.01 (-0.03, 0.06)	
	p-value	0.4760	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	11/ 195 (5.64)	17/ 241 (7.05)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.79 (0.36, 1.72)	
	p-value	0.5504	
	Risk Ratio (95% CI)	0.80 (0.38, 1.67)	
	p-value	0.5509	
	Risk Difference (95% CI)	-0.01 (-0.06, 0.03)	
	p-value	0.5450	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity	Number of subjects with event, n/N (%)	5/ 195 (2.56)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.55 (0.19, 1.61)	
	p-value	0.2758	
	Risk Ratio (95% CI)	0.56 (0.20, 1.59)	
	p-value	0.2772	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.01)	
	p-value	0.2551	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	18/ 195 (9.23)	20/ 241 (8.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.12 (0.58, 2.19)	
	p-value	0.7317	
	Risk Ratio (95% CI)	1.11 (0.61, 2.04)	
	p-value	0.7316	
	Risk Difference (95% CI)	0.01 (-0.04, 0.06)	
	p-value	0.7328	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	38/ 195 (19.49)	63/ 241 (26.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.68 (0.43, 1.08)	
	p-value	0.1025	
	Risk Ratio (95% CI)	0.75 (0.52, 1.06)	
	p-value	0.1054	
	Risk Difference (95% CI)	-0.07 (-0.15, 0.01)	
	p-value	0.0968	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Nervous system disorders; PT: Syncope	Number of subjects with event, n/N (%)	4/ 195 (2.05)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.40 (0.13, 1.26)	
	p-value	0.1173	
	Risk Ratio (95% CI)	0.41 (0.13, 1.26)	
	p-value	0.1193	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.00)	
	p-value	0.0906	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	18/ 195 (9.23)	26/ 241 (10.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.45, 1.58)	
	p-value	0.5917	
	Risk Ratio (95% CI)	0.86 (0.48, 1.51)	
	p-value	0.5922	
	Risk Difference (95% CI)	-0.02 (-0.07, 0.04)	
	p-value	0.5885	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Psychiatric disorders; PT: Insomnia	Number of subjects with event, n/N (%)	6/ 195 (3.08)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.66 (0.24, 1.83)	
	p-value	0.4279	
	Risk Ratio (95% CI)	0.67 (0.25, 1.79)	
	p-value	0.4287	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.4155	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	47/ 195 (24.10)	65/ 241 (26.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.86 (0.56, 1.33)	
	p-value	0.4957	
	Risk Ratio (95% CI)	0.89 (0.65, 1.24)	
	p-value	0.4968	
	Risk Difference (95% CI)	-0.03 (-0.11, 0.05)	
	p-value	0.4936	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	20/ 195 (10.26)	24/ 241 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.55, 1.93)	
	p-value	0.9182	
	Risk Ratio (95% CI)	1.03 (0.59, 1.81)	
	p-value	0.9182	
	Risk Difference (95% CI)	0.00 (-0.05, 0.06)	
	p-value	0.9183	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Chronic kidney disease	Number of subjects with event, n/N (%)	4/ 195 (2.05)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.48 (0.15, 1.57)	
	p-value	0.2259	
	Risk Ratio (95% CI)	0.49 (0.16, 1.55)	
	p-value	0.2275	
	Risk Difference (95% CI)	-0.02 (-0.05, 0.01)	
	p-value	0.2000	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	12/ 195 (6.15)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.55, 2.85)	
	p-value	0.5935	
	Risk Ratio (95% CI)	1.24 (0.57, 2.69)	
	p-value	0.5934	
	Risk Difference (95% CI)	0.01 (-0.03, 0.06)	
	p-value	0.5966	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	10/ 195 (5.13)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.51, 3.06)	
	p-value	0.6278	
	Risk Ratio (95% CI)	1.24 (0.53, 2.91)	
	p-value	0.6277	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.6307	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	46/ 195 (23.59)	67/ 241 (27.80)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.52, 1.24)	
	p-value	0.3188	
	Risk Ratio (95% CI)	0.85 (0.61, 1.17)	
	p-value	0.3209	
	Risk Difference (95% CI)	-0.04 (-0.12, 0.04)	
	p-value	0.3151	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	13/ 195 (6.67)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.36 (0.61, 3.06)	
	p-value	0.4526	
	Risk Ratio (95% CI)	1.34 (0.63, 2.87)	
	p-value	0.4526	
	Risk Difference (95% CI)	0.02 (-0.03, 0.06)	
	p-value	0.4573	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	16/ 195 (8.21)	19/ 241 (7.88)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.52, 2.09)	
	p-value	0.9023	
	Risk Ratio (95% CI)	1.04 (0.55, 1.97)	
	p-value	0.9023	
	Risk Difference (95% CI)	0.00 (-0.05, 0.05)	
	p-value	0.9025	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	36/ 195 (18.46)	47/ 241 (19.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.58, 1.51)	
	p-value	0.7832	
	Risk Ratio (95% CI)	0.95 (0.64, 1.40)	
	p-value	0.7834	
	Risk Difference (95% CI)	-0.01 (-0.08, 0.06)	
	p-value	0.7827	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Skin and subcutaneous tissue disorders; PT: Skin ulcer	Number of subjects with event, n/N (%)	8/ 195 (4.10)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.28, 1.69)	
	p-value	0.4205	
	Risk Ratio (95% CI)	0.71 (0.30, 1.65)	
	p-value	0.4214	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.02)	
	p-value	0.4099	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	12/ 195 (6.15)	23/ 241 (9.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.62 (0.30, 1.28)	
	p-value	0.1986	
	Risk Ratio (95% CI)	0.64 (0.33, 1.26)	
	p-value	0.2006	
	Risk Difference (95% CI)	-0.03 (-0.08, 0.02)	
	p-value	0.1851	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	52/ 195 (26.67)	65/ 241 (26.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.64, 1.51)	
	p-value	0.9432	
	Risk Ratio (95% CI)	0.99 (0.72, 1.35)	
	p-value	0.9432	
	Risk Difference (95% CI)	-0.00 (-0.09, 0.08)	
	p-value	0.9431	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Vascular disorders; PT: Hypertension	Number of subjects with event, n/N (%)	18/ 195 (9.23)	26/ 241 (10.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.45, 1.58)	
	p-value	0.5917	
	Risk Ratio (95% CI)	0.86 (0.48, 1.51)	
	p-value	0.5922	
	Risk Difference (95% CI)	-0.02 (-0.07, 0.04)	
	p-value	0.5885	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	16/ 195 (8.21)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.06 (0.92, 4.66)	
	p-value	0.0808	
	Risk Ratio (95% CI)	1.98 (0.92, 4.26)	
	p-value	0.0815	
	Risk Difference (95% CI)	0.04 (-0.01, 0.09)	
	p-value	0.0841	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Vascular disorders; PT: Peripheral arterial occlusive disease	Number of subjects with event, n/N (%)	3/ 195 (1.54)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.36 (0.10, 1.33)	
	p-value	0.1257	
	Risk Ratio (95% CI)	0.37 (0.10, 1.33)	
	p-value	0.1276	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.00)	
	p-value	0.0938	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	4/ 195 (2.05)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.44 (0.14, 1.40)	
	p-value	0.1631	
	Risk Ratio (95% CI)	0.45 (0.15, 1.39)	
	p-value	0.1649	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.01)	
	p-value	0.1358	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	15/ 195 (7.69)	7/ 241 (2.90)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.79 (1.11, 6.98)	
	p-value	0.0287	
	Risk Ratio (95% CI)	2.65 (1.10, 6.37)	
	p-value	0.0295	
	Risk Difference (95% CI)	0.05 (0.00, 0.09)	
	p-value	0.0291	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	11/ 195 (5.64)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.46, 2.40)	
	p-value	0.9105	
	Risk Ratio (95% CI)	1.05 (0.48, 2.28)	
	p-value	0.9105	
	Risk Difference (95% CI)	0.00 (-0.04, 0.05)	
	p-value	0.9107	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	36/ 195 (18.46)	46/ 241 (19.09)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.59, 1.56)	
	p-value	0.8680	
	Risk Ratio (95% CI)	0.97 (0.65, 1.43)	
	p-value	0.8681	
	Risk Difference (95% CI)	-0.01 (-0.08, 0.07)	
	p-value	0.8678	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	11/ 195 (5.64)	27/ 241 (11.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.47 (0.23, 0.98)	
	p-value	0.0444	
	Risk Ratio (95% CI)	0.50 (0.26, 0.99)	
	p-value	0.0464	
	Risk Difference (95% CI)	-0.06 (-0.11, -0.00)	
	p-value	0.0337	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	16/ 195 (8.21)	9/ 241 (3.73)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.30 (1.00, 5.34)	
	p-value	0.0513	
	Risk Ratio (95% CI)	2.20 (0.99, 4.86)	
	p-value	0.0522	
	Risk Difference (95% CI)	0.04 (-0.00, 0.09)	
	p-value	0.0533	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	15/ 195 (7.69)	31/ 241 (12.86)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.56 (0.30, 1.08)	
	p-value	0.0836	
	Risk Ratio (95% CI)	0.60 (0.33, 1.08)	
	p-value	0.0859	
	Risk Difference (95% CI)	-0.05 (-0.11, 0.00)	
	p-value	0.0726	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	10/ 195 (5.13)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.51, 3.06)	
	p-value	0.6278	
	Risk Ratio (95% CI)	1.24 (0.53, 2.91)	
	p-value	0.6277	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.6307	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	10/ 195 (5.13)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.41, 2.21)	
	p-value	0.9017	
	Risk Ratio (95% CI)	0.95 (0.43, 2.12)	
	p-value	0.9017	
	Risk Difference (95% CI)	-0.00 (-0.04, 0.04)	
	p-value	0.9014	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	11/ 195 (5.64)	26/ 241 (10.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.49 (0.24, 1.03)	
	p-value	0.0592	
	Risk Ratio (95% CI)	0.52 (0.27, 1.03)	
	p-value	0.0613	
	Risk Difference (95% CI)	-0.05 (-0.10, -0.00)	
	p-value	0.0471	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	6/ 195 (3.08)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.61 (0.22, 1.64)	
	p-value	0.3253	
	Risk Ratio (95% CI)	0.62 (0.24, 1.62)	
	p-value	0.3266	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.02)	
	p-value	0.3087	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	13/ 195 (6.67)	16/ 241 (6.64)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.47, 2.14)	
	p-value	0.9908	
	Risk Ratio (95% CI)	1.00 (0.50, 2.04)	
	p-value	0.9908	
	Risk Difference (95% CI)	0.00 (-0.05, 0.05)	
	p-value	0.9908	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	7/ 195 (3.59)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.30, 2.05)	
	p-value	0.6119	
	Risk Ratio (95% CI)	0.79 (0.31, 1.99)	
	p-value	0.6122	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.03)	
	p-value	0.6066	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	4/ 195 (2.05)	13/ 241 (5.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.37 (0.12, 1.15)	
	p-value	0.0843	
	Risk Ratio (95% CI)	0.38 (0.13, 1.15)	
	p-value	0.0863	
	Risk Difference (95% CI)	-0.03 (-0.07, 0.00)	
	p-value	0.0595	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	6/ 195 (3.08)	10/ 241 (4.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.73 (0.26, 2.05)	
	p-value	0.5551	
	Risk Ratio (95% CI)	0.74 (0.27, 2.00)	
	p-value	0.5556	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.5475	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	18/ 195 (9.23)	27/ 241 (11.20)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.81 (0.43, 1.51)	
	p-value	0.5015	
	Risk Ratio (95% CI)	0.82 (0.47, 1.45)	
	p-value	0.5022	
	Risk Difference (95% CI)	-0.02 (-0.08, 0.04)	
	p-value	0.4968	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	5/ 195 (2.56)	14/ 241 (5.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.43 (0.15, 1.21)	
	p-value	0.1082	
	Risk Ratio (95% CI)	0.44 (0.16, 1.20)	
	p-value	0.1102	
	Risk Difference (95% CI)	-0.03 (-0.07, 0.00)	
	p-value	0.0851	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	11/ 195 (5.64)	9/ 241 (3.73)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.54 (0.63, 3.80)	
	p-value	0.3473	
	Risk Ratio (95% CI)	1.51 (0.64, 3.57)	
	p-value	0.3475	
	Risk Difference (95% CI)	0.02 (-0.02, 0.06)	
	p-value	0.3534	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	9/ 195 (4.62)	11/ 241 (4.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.41, 2.49)	
	p-value	0.9798	
	Risk Ratio (95% CI)	1.01 (0.43, 2.39)	
	p-value	0.9798	
	Risk Difference (95% CI)	0.00 (-0.04, 0.04)	
	p-value	0.9798	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	11/ 195 (5.64)	24/ 241 (9.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.54 (0.26, 1.13)	
	p-value	0.1033	
	Risk Ratio (95% CI)	0.57 (0.28, 1.13)	
	p-value	0.1055	
	Risk Difference (95% CI)	-0.04 (-0.09, 0.01)	
	p-value	0.0891	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	5/ 195 (2.56)	12/ 241 (4.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.50 (0.17, 1.45)	
	p-value	0.2032	
	Risk Ratio (95% CI)	0.51 (0.18, 1.44)	
	p-value	0.2049	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.01)	
	p-value	0.1800	

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Blood and lymphatic system disorders; PT: Pancytopenia	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	2/ 195 (1.03)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Gastrointestinal disorders; PT: Vomiting	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	3/ 195 (1.54)	2/ 241 (0.83)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Localised infection	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Infections and infestations; PT: Urosepsis	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Injury, poisoning and procedural complications; PT: Road traffic accident	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Investigations	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=195)	Placebo (N=241)
SOC: Investigations; PT: Blood potassium increased Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	2/ 195 (1.03)	4/ 241 (1.66)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	2/ 195 (1.03)	4/ 241 (1.66)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	1/ 195 (0.51)	3/ 241 (1.24)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Adenocarcinoma of colon	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Bladder cancer	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lung neoplasm malignant	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Small cell lung cancer	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	4/ 195 (2.05)	2/ 241 (0.83)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: End stage renal disease	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Renal failure	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	3/ 195 (1.54)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	1/ 195 (0.51)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	0/ 195 (0.00)	1/ 241 (0.41)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Respiratory failure	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=195)	Placebo (N=241)
SOC: Surgical and medical procedures; PT: Pancreaticosplenectomy	Number of subjects with event, n/N (%)	1/ 195 (0.51)	0/ 241 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline
Full Analysis Set

Standard drug grouping	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	195 (100.00 %)	241 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	142 (72.82 %)	188 (78.01 %)
Loop diuretics	114 (58.46 %)	129 (53.53 %)
Thiazide diuretics	17 (8.72 %)	26 (10.79 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	15 (7.69 %)	16 (6.64 %)
Potassium lowering (incl.binders)	4 (2.05 %)	8 (3.32 %)
Alpha blocking agents	51 (26.15 %)	63 (26.14 %)
Calcium channel blockers	114 (58.46 %)	138 (57.26 %)
Centrally acting antihypertensivs	19 (9.74 %)	33 (13.69 %)
Strong CYP3A4 inhibitors	3 (1.54 %)	2 (0.83 %)
Moderate CYP3A4 inhibitors	4 (2.05 %)	3 (1.24 %)
Weak CYP3A4 inhibitors	125 (64.10 %)	156 (64.73 %)
Unclassified CYP3A4 inhibitors	4 (2.05 %)	2 (0.83 %)
Strong CYP3A4 inducers	1 (0.51 %)	1 (0.41 %)
Moderate CYP3A4 inducers	0 (0.00 %)	1 (0.41 %)
Weak CYP3A4 inducers	5 (2.56 %)	7 (2.90 %)
Unclassified CYP3A4 inducers	3 (1.54 %)	3 (1.24 %)
Acetylsalycylic acid and its salts	111 (56.92 %)	135 (56.02 %)
Statins	152 (77.95 %)	197 (81.74 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	135 (69.23 %)	176 (73.03 %)
Glycosurics as SGLT-2 inhibitors	7 (3.59 %)	7 (2.90 %)
Anticoagulants	38 (19.49 %)	42 (17.43 %)
Injectable glucagon-like peptide	9 (4.62 %)	7 (2.90 %)
Antiarrhythmic drugs	13 (6.67 %)	19 (7.88 %)
Biguanides	71 (36.41 %)	83 (34.44 %)
Sulfonylureas	47 (24.10 %)	52 (21.58 %)
Combinations of oral blood glucose lowering drugs	4 (2.05 %)	4 (1.66 %)
Combinations of various lipid modifying agents	1 (0.51 %)	0 (0.00 %)
Other lipid modifying agents	18 (9.23 %)	16 (6.64 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	48 (100.00 %)	49 (100.00 %)
	Coronary Artery Disease (PBMQ)	Yes	140 (100.00 %)	169 (100.00 %)
	Hyperlipidemia (MLG)	Yes	82 (100.00 %)	101 (100.00 %)
	Hypertension (MLG)	Yes	191 (100.00 %)	236 (100.00 %)
	Region	Western Europe, Oceania and Others	37 (100.00 %)	46 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	38 (79.17 %)	43 (87.76 %)
	Coronary Artery Disease (PBMQ)	Yes	106 (75.71 %)	139 (82.25 %)
	Hyperlipidemia (MLG)	Yes	63 (76.83 %)	86 (85.15 %)
	Hypertension (MLG)	Yes	139 (72.77 %)	185 (78.39 %)
	Region	Western Europe, Oceania and Others	26 (70.27 %)	37 (80.43 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	36 (75.00 %)	31 (63.27 %)
	Coronary Artery Disease (PBMQ)	Yes	75 (53.57 %)	81 (47.93 %)
	Hyperlipidemia (MLG)	Yes	57 (69.51 %)	61 (60.40 %)
	Hypertension (MLG)	Yes	111 (58.12 %)	127 (53.81 %)
	Region	Western Europe, Oceania and Others	31 (83.78 %)	37 (80.43 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (4.17 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	12 (8.57 %)	16 (9.47 %)
	Hyperlipidemia (MLG)	Yes	10 (12.20 %)	13 (12.87 %)
	Hypertension (MLG)	Yes	16 (8.38 %)	25 (10.59 %)
	Region	Western Europe, Oceania and Others	4 (10.81 %)	12 (26.09 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (14.58 %)	5 (10.20 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (5.71 %)	11 (6.51 %)
	Hyperlipidemia (MLG)	Yes	10 (12.20 %)	11 (10.89 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	16 (6.78 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	3 (6.52 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	3 (6.12 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (1.43 %)	4 (2.37 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	3 (1.57 %)	8 (3.39 %)
	Region	Western Europe, Oceania and Others	1 (2.70 %)	4 (8.70 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	23 (47.92 %)	15 (30.61 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	34 (24.29 %)	38 (22.49 %)
	Hyperlipidemia (MLG)	Yes	25 (30.49 %)	28 (27.72 %)
	Hypertension (MLG)	Yes	51 (26.70 %)	62 (26.27 %)
	Region	Western Europe, Oceania and Others	11 (29.73 %)	20 (43.48 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	22 (45.83 %)	27 (55.10 %)
	Coronary Artery Disease (PBMQ)	Yes	86 (61.43 %)	91 (53.85 %)
	Hyperlipidemia (MLG)	Yes	50 (60.98 %)	56 (55.45 %)
	Hypertension (MLG)	Yes	113 (59.16 %)	135 (57.20 %)
	Region	Western Europe, Oceania and Others	23 (62.16 %)	29 (63.04 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	6 (12.24 %)
	Coronary Artery Disease (PBMQ)	Yes	16 (11.43 %)	21 (12.43 %)
	Hyperlipidemia (MLG)	Yes	8 (9.76 %)	12 (11.88 %)
	Hypertension (MLG)	Yes	19 (9.95 %)	33 (13.98 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	8 (17.39 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (1.43 %)	1 (0.59 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	2 (1.98 %)
	Hypertension (MLG)	Yes	3 (1.57 %)	2 (0.85 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	2 (4.35 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (2.14 %)	1 (0.59 %)
	Hyperlipidemia (MLG)	Yes	3 (3.66 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	4 (2.09 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	1 (2.17 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	28 (58.33 %)	36 (73.47 %)
	Coronary Artery Disease (PBMQ)	Yes	99 (70.71 %)	114 (67.46 %)
	Hyperlipidemia (MLG)	Yes	52 (63.41 %)	67 (66.34 %)
	Hypertension (MLG)	Yes	124 (64.92 %)	154 (65.25 %)
	Region	Western Europe, Oceania and Others	22 (59.46 %)	27 (58.70 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (4.17 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	3 (2.14 %)	2 (1.18 %)
	Hyperlipidemia (MLG)	Yes	3 (3.66 %)	2 (1.98 %)
	Hypertension (MLG)	Yes	4 (2.09 %)	2 (0.85 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	1 (0.59 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	1 (0.99 %)
	Hypertension (MLG)	Yes	1 (0.52 %)	1 (0.42 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	1 (0.59 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	1 (0.42 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (4.17 %)	3 (6.12 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (1.43 %)	5 (2.96 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	5 (4.95 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	5 (2.62 %)	7 (2.97 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.71 %)	1 (0.59 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	1 (0.99 %)
	Hypertension (MLG)	Yes	3 (1.57 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	1 (2.70 %)	1 (2.17 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (25.00 %)	14 (28.57 %)
	Coronary Artery Disease (PBMQ)	Yes	92 (65.71 %)	96 (56.80 %)
	Hyperlipidemia (MLG)	Yes	50 (60.98 %)	60 (59.41 %)
	Hypertension (MLG)	Yes	110 (57.59 %)	131 (55.51 %)
	Region	Western Europe, Oceania and Others	20 (54.05 %)	29 (63.04 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	36 (75.00 %)	43 (87.76 %)
	Coronary Artery Disease (PBMQ)	Yes	113 (80.71 %)	137 (81.07 %)
	Hyperlipidemia (MLG)	Yes	72 (87.80 %)	94 (93.07 %)
	Hypertension (MLG)	Yes	148 (77.49 %)	195 (82.63 %)
	Region	Western Europe, Oceania and Others	29 (78.38 %)	43 (93.48 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	29 (60.42 %)	31 (63.27 %)
	Coronary Artery Disease (PBMQ)	Yes	97 (69.29 %)	118 (69.82 %)
	Hyperlipidemia (MLG)	Yes	61 (74.39 %)	69 (68.32 %)
	Hypertension (MLG)	Yes	133 (69.63 %)	172 (72.88 %)
	Region	Western Europe, Oceania and Others	24 (64.86 %)	40 (86.96 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (4.29 %)	6 (3.55 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	3 (2.97 %)
	Hypertension (MLG)	Yes	6 (3.14 %)	7 (2.97 %)
	Region	Western Europe, Oceania and Others	1 (2.70 %)	3 (6.52 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	33 (68.75 %)	35 (71.43 %)
	Coronary Artery Disease (PBMQ)	Yes	22 (15.71 %)	31 (18.34 %)
	Hyperlipidemia (MLG)	Yes	18 (21.95 %)	26 (25.74 %)
	Hypertension (MLG)	Yes	37 (19.37 %)	42 (17.80 %)
	Region	Western Europe, Oceania and Others	11 (29.73 %)	14 (30.43 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	2 (4.17 %)	3 (6.12 %)
	Coronary Artery Disease (PBMQ)	Yes	5 (3.57 %)	5 (2.96 %)
	Hyperlipidemia (MLG)	Yes	5 (6.10 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	9 (4.71 %)	7 (2.97 %)
	Region	Western Europe, Oceania and Others	2 (5.41 %)	2 (4.35 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication ongoing at baseline - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (25.00 %)	10 (20.41 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (4.29 %)	16 (9.47 %)
	Hyperlipidemia (MLG)	Yes	4 (4.88 %)	10 (9.90 %)
	Hypertension (MLG)	Yes	12 (6.28 %)	17 (7.20 %)
	Region	Western Europe, Oceania and Others	2 (5.41 %)	4 (8.70 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	22 (45.83 %)	18 (36.73 %)
	Coronary Artery Disease (PBMQ)	Yes	49 (35.00 %)	62 (36.69 %)
	Hyperlipidemia (MLG)	Yes	32 (39.02 %)	29 (28.71 %)
	Hypertension (MLG)	Yes	69 (36.13 %)	81 (34.32 %)
	Region	Western Europe, Oceania and Others	17 (45.95 %)	16 (34.78 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (25.00 %)	10 (20.41 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (21.43 %)	39 (23.08 %)
	Hyperlipidemia (MLG)	Yes	18 (21.95 %)	24 (23.76 %)
	Hypertension (MLG)	Yes	46 (24.08 %)	51 (21.61 %)
	Region	Western Europe, Oceania and Others	7 (18.92 %)	5 (10.87 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (2.86 %)	4 (2.37 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	2 (1.98 %)
	Hypertension (MLG)	Yes	4 (2.09 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	5 (10.42 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	13 (9.29 %)	11 (6.51 %)
	Hyperlipidemia (MLG)	Yes	13 (15.85 %)	9 (8.91 %)
	Hypertension (MLG)	Yes	18 (9.42 %)	15 (6.36 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	3 (6.52 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Ongoing at baseline means starting before or on the day of randomization and ending at least one day after the day of randomization.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period
Full Analysis Set

Standard drug grouping	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	195 (100.00 %)	241 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	1 (0.51 %)	4 (1.66 %)
Beta-Blocker	150 (76.92 %)	207 (85.89 %)
Loop diuretics	132 (67.69 %)	163 (67.63 %)
Thiazide diuretics	26 (13.33 %)	44 (18.26 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	25 (12.82 %)	43 (17.84 %)
Potassium lowering (incl.binders)	22 (11.28 %)	17 (7.05 %)
Alpha blocking agents	80 (41.03 %)	110 (45.64 %)
Calcium channel blockers	132 (67.69 %)	172 (71.37 %)
Centrally acting antihypertensivs	30 (15.38 %)	63 (26.14 %)
Strong CYP3A4 inhibitors	14 (7.18 %)	18 (7.47 %)
Moderate CYP3A4 inhibitors	31 (15.90 %)	34 (14.11 %)
Weak CYP3A4 inhibitors	142 (72.82 %)	188 (78.01 %)
Unclassified CYP3A4 inhibitors	13 (6.67 %)	14 (5.81 %)
Strong CYP3A4 inducers	3 (1.54 %)	4 (1.66 %)
Moderate CYP3A4 inducers	14 (7.18 %)	23 (9.54 %)
Weak CYP3A4 inducers	30 (15.38 %)	22 (9.13 %)
Unclassified CYP3A4 inducers	11 (5.64 %)	14 (5.81 %)
Acetylsalycylic acid and its salts	127 (65.13 %)	154 (63.90 %)
Statins	159 (81.54 %)	210 (87.14 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	151 (77.44 %)	193 (80.08 %)
Glycosurics as SGLT-2 inhibitors	15 (7.69 %)	17 (7.05 %)
Anticoagulants	47 (24.10 %)	69 (28.63 %)
Injectable glucagon-like peptide	17 (8.72 %)	20 (8.30 %)
Antiarrhythmic drugs	23 (11.79 %)	35 (14.52 %)
Biguanides	76 (38.97 %)	91 (37.76 %)
Sulfonylureas	54 (27.69 %)	58 (24.07 %)
Combinations of oral blood glucose lowering drugs	4 (2.05 %)	5 (2.07 %)
Combinations of various lipid modifying agents	2 (1.03 %)	0 (0.00 %)
Other lipid modifying agents	28 (14.36 %)	23 (9.54 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	48 (100.00 %)	49 (100.00 %)
	Coronary Artery Disease (PBMQ)	Yes	140 (100.00 %)	169 (100.00 %)
	Hyperlipidemia (MLG)	Yes	82 (100.00 %)	101 (100.00 %)
	Hypertension (MLG)	Yes	191 (100.00 %)	236 (100.00 %)
	Region	Western Europe, Oceania and Others	37 (100.00 %)	46 (100.00 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.71 %)	4 (2.37 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	4 (3.96 %)
	Hypertension (MLG)	Yes	1 (0.52 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	39 (81.25 %)	46 (93.88 %)
	Coronary Artery Disease (PBMQ)	Yes	111 (79.29 %)	148 (87.57 %)
	Hyperlipidemia (MLG)	Yes	67 (81.71 %)	93 (92.08 %)
	Hypertension (MLG)	Yes	147 (76.96 %)	204 (86.44 %)
	Region	Western Europe, Oceania and Others	29 (78.38 %)	42 (91.30 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	39 (81.25 %)	35 (71.43 %)
	Coronary Artery Disease (PBMQ)	Yes	88 (62.86 %)	109 (64.50 %)
	Hyperlipidemia (MLG)	Yes	64 (78.05 %)	74 (73.27 %)
	Hypertension (MLG)	Yes	129 (67.54 %)	159 (67.37 %)
	Region	Western Europe, Oceania and Others	32 (86.49 %)	40 (86.96 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	8 (16.33 %)
	Coronary Artery Disease (PBMQ)	Yes	18 (12.86 %)	27 (15.98 %)
	Hyperlipidemia (MLG)	Yes	14 (17.07 %)	23 (22.77 %)
	Hypertension (MLG)	Yes	25 (13.09 %)	42 (17.80 %)
	Region	Western Europe, Oceania and Others	9 (24.32 %)	17 (36.96 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	9 (18.75 %)	11 (22.45 %)
	Coronary Artery Disease (PBMQ)	Yes	16 (11.43 %)	33 (19.53 %)
	Hyperlipidemia (MLG)	Yes	17 (20.73 %)	24 (23.76 %)
	Hypertension (MLG)	Yes	24 (12.57 %)	42 (17.80 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	11 (23.91 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	5 (10.20 %)
	Coronary Artery Disease (PBMQ)	Yes	15 (10.71 %)	11 (6.51 %)
	Hyperlipidemia (MLG)	Yes	11 (13.41 %)	10 (9.90 %)
	Hypertension (MLG)	Yes	21 (10.99 %)	17 (7.20 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	7 (15.22 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	31 (64.58 %)	27 (55.10 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	52 (37.14 %)	76 (44.97 %)
	Hyperlipidemia (MLG)	Yes	41 (50.00 %)	49 (48.51 %)
	Hypertension (MLG)	Yes	80 (41.88 %)	108 (45.76 %)
	Region	Western Europe, Oceania and Others	18 (48.65 %)	30 (65.22 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	29 (60.42 %)	39 (79.59 %)
	Coronary Artery Disease (PBMQ)	Yes	93 (66.43 %)	116 (68.64 %)
	Hyperlipidemia (MLG)	Yes	60 (73.17 %)	73 (72.28 %)
	Hypertension (MLG)	Yes	131 (68.59 %)	168 (71.19 %)
	Region	Western Europe, Oceania and Others	28 (75.68 %)	38 (82.61 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	5 (10.42 %)	12 (24.49 %)
	Coronary Artery Disease (PBMQ)	Yes	22 (15.71 %)	40 (23.67 %)
	Hyperlipidemia (MLG)	Yes	14 (17.07 %)	20 (19.80 %)
	Hypertension (MLG)	Yes	30 (15.71 %)	63 (26.69 %)
	Region	Western Europe, Oceania and Others	8 (21.62 %)	14 (30.43 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (25.00 %)	8 (16.33 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (5.71 %)	12 (7.10 %)
	Hyperlipidemia (MLG)	Yes	9 (10.98 %)	8 (7.92 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	18 (7.63 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	5 (10.87 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	11 (22.92 %)	11 (22.45 %)
	Coronary Artery Disease (PBMQ)	Yes	22 (15.71 %)	23 (13.61 %)
	Hyperlipidemia (MLG)	Yes	18 (21.95 %)	16 (15.84 %)
	Hypertension (MLG)	Yes	30 (15.71 %)	32 (13.56 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	11 (23.91 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	32 (66.67 %)	39 (79.59 %)
	Coronary Artery Disease (PBMQ)	Yes	107 (76.43 %)	134 (79.29 %)
	Hyperlipidemia (MLG)	Yes	61 (74.39 %)	81 (80.20 %)
	Hypertension (MLG)	Yes	141 (73.82 %)	184 (77.97 %)
	Region	Western Europe, Oceania and Others	29 (78.38 %)	37 (80.43 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (14.58 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (6.43 %)	10 (5.92 %)
	Hyperlipidemia (MLG)	Yes	9 (10.98 %)	8 (7.92 %)
	Hypertension (MLG)	Yes	13 (6.81 %)	13 (5.51 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	2 (4.35 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	2 (4.08 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (1.43 %)	3 (1.78 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	2 (1.98 %)
	Hypertension (MLG)	Yes	3 (1.57 %)	4 (1.69 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	1 (2.17 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (7.14 %)	16 (9.47 %)
	Hyperlipidemia (MLG)	Yes	9 (10.98 %)	13 (12.87 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	23 (9.75 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	7 (15.22 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	10 (20.83 %)	6 (12.24 %)
	Coronary Artery Disease (PBMQ)	Yes	20 (14.29 %)	17 (10.06 %)
	Hyperlipidemia (MLG)	Yes	19 (23.17 %)	14 (13.86 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	29 (15.18 %)	22 (9.32 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	3 (6.52 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	6 (4.29 %)	8 (4.73 %)
	Hyperlipidemia (MLG)	Yes	4 (4.88 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	11 (5.76 %)	13 (5.51 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	7 (15.22 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	17 (35.42 %)	19 (38.78 %)
	Coronary Artery Disease (PBMQ)	Yes	101 (72.14 %)	112 (66.27 %)
	Hyperlipidemia (MLG)	Yes	59 (71.95 %)	67 (66.34 %)
	Hypertension (MLG)	Yes	125 (65.45 %)	150 (63.56 %)
	Region	Western Europe, Oceania and Others	23 (62.16 %)	30 (65.22 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	40 (83.33 %)	44 (89.80 %)
	Coronary Artery Disease (PBMQ)	Yes	119 (85.00 %)	148 (87.57 %)
	Hyperlipidemia (MLG)	Yes	73 (89.02 %)	98 (97.03 %)
	Hypertension (MLG)	Yes	155 (81.15 %)	207 (87.71 %)
	Region	Western Europe, Oceania and Others	31 (83.78 %)	44 (95.65 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	36 (75.00 %)	34 (69.39 %)
	Coronary Artery Disease (PBMQ)	Yes	109 (77.86 %)	133 (78.70 %)
	Hyperlipidemia (MLG)	Yes	69 (84.15 %)	77 (76.24 %)
	Hypertension (MLG)	Yes	147 (76.96 %)	189 (80.08 %)
	Region	Western Europe, Oceania and Others	27 (72.97 %)	41 (89.13 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	7 (14.58 %)	2 (4.08 %)
	Coronary Artery Disease (PBMQ)	Yes	13 (9.29 %)	13 (7.69 %)
	Hyperlipidemia (MLG)	Yes	4 (4.88 %)	9 (8.91 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	16 (6.78 %)
	Region	Western Europe, Oceania and Others	4 (10.81 %)	4 (8.70 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	34 (70.83 %)	41 (83.67 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (21.43 %)	50 (29.59 %)
	Hyperlipidemia (MLG)	Yes	21 (25.61 %)	38 (37.62 %)
	Hypertension (MLG)	Yes	46 (24.08 %)	67 (28.39 %)
	Region	Western Europe, Oceania and Others	15 (40.54 %)	23 (50.00 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (16.67 %)	6 (12.24 %)
	Coronary Artery Disease (PBMQ)	Yes	11 (7.86 %)	13 (7.69 %)
	Hyperlipidemia (MLG)	Yes	11 (13.41 %)	13 (12.87 %)
	Hypertension (MLG)	Yes	17 (8.90 %)	20 (8.47 %)
	Region	Western Europe, Oceania and Others	2 (5.41 %)	7 (15.22 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication taken within the treatment period - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	18 (37.50 %)	15 (30.61 %)
	Coronary Artery Disease (PBMQ)	Yes	14 (10.00 %)	27 (15.98 %)
	Hyperlipidemia (MLG)	Yes	7 (8.54 %)	17 (16.83 %)
	Hypertension (MLG)	Yes	22 (11.52 %)	32 (13.56 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	8 (17.39 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	24 (50.00 %)	19 (38.78 %)
	Coronary Artery Disease (PBMQ)	Yes	51 (36.43 %)	69 (40.83 %)
	Hyperlipidemia (MLG)	Yes	34 (41.46 %)	34 (33.66 %)
	Hypertension (MLG)	Yes	74 (38.74 %)	89 (37.71 %)
	Region	Western Europe, Oceania and Others	18 (48.65 %)	17 (36.96 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	15 (31.25 %)	11 (22.45 %)
	Coronary Artery Disease (PBMQ)	Yes	36 (25.71 %)	42 (24.85 %)
	Hyperlipidemia (MLG)	Yes	20 (24.39 %)	27 (26.73 %)
	Hypertension (MLG)	Yes	53 (27.75 %)	57 (24.15 %)
	Region	Western Europe, Oceania and Others	8 (21.62 %)	5 (10.87 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	4 (2.86 %)	5 (2.96 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	3 (2.97 %)
	Hypertension (MLG)	Yes	4 (2.09 %)	4 (1.69 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.71 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	1 (0.52 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (16.67 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	20 (14.29 %)	18 (10.65 %)
	Hyperlipidemia (MLG)	Yes	18 (21.95 %)	15 (14.85 %)
	Hypertension (MLG)	Yes	28 (14.66 %)	21 (8.90 %)
	Region	Western Europe, Oceania and Others	8 (21.62 %)	4 (8.70 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug
Full Analysis Set

Standard drug grouping	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	70 (35.90 %)	103 (42.74 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	1 (0.51 %)	4 (1.66 %)
Beta-Blocker	62 (31.79 %)	99 (41.08 %)
Loop diuretics	85 (43.59 %)	116 (48.13 %)
Thiazide diuretics	12 (6.15 %)	23 (9.54 %)
Digoxin	NA	NA
Nitrate	NA	NA
Potassium supplements	16 (8.21 %)	34 (14.11 %)
Potassium lowering (incl.binders)	20 (10.26 %)	12 (4.98 %)
Alpha blocking agents	53 (27.18 %)	80 (33.20 %)
Calcium channel blockers	60 (30.77 %)	102 (42.32 %)
Centrally acting antihypertensivs	21 (10.77 %)	35 (14.52 %)
Strong CYP3A4 inhibitors	13 (6.67 %)	16 (6.64 %)
Moderate CYP3A4 inhibitors	29 (14.87 %)	31 (12.86 %)
Weak CYP3A4 inhibitors	64 (32.82 %)	102 (42.32 %)
Unclassified CYP3A4 inhibitors	10 (5.13 %)	12 (4.98 %)
Strong CYP3A4 inducers	2 (1.03 %)	3 (1.24 %)
Moderate CYP3A4 inducers	14 (7.18 %)	22 (9.13 %)
Weak CYP3A4 inducers	26 (13.33 %)	17 (7.05 %)
Unclassified CYP3A4 inducers	10 (5.13 %)	12 (4.98 %)
Acetylsalycylic acid and its salts	40 (20.51 %)	57 (23.65 %)
Statins	53 (27.18 %)	74 (30.71 %)
MRA	NA	NA
OATP substrates	NA	NA
Insulin and insulin analogues	93 (47.69 %)	117 (48.55 %)
Glycosurics as SGLT-2 inhibitors	8 (4.10 %)	12 (4.98 %)
Anticoagulants	24 (12.31 %)	41 (17.01 %)
Injectable glucagon-like peptide	10 (5.13 %)	15 (6.22 %)
Antiarrhythmic drugs	14 (7.18 %)	23 (9.54 %)
Biguanides	24 (12.31 %)	31 (12.86 %)
Sulfonylureas	15 (7.69 %)	23 (9.54 %)
Combinations of oral blood glucose lowering drugs	0 (0.00 %)	2 (0.83 %)
Combinations of various lipid modifying agents	1 (0.51 %)	0 (0.00 %)
Other lipid modifying agents	12 (6.15 %)	10 (4.15 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group.
Medications taken within the treatment period are included in this table, if started after start of study drug.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Patients with medical history of interest and patients in Western Europe, Oceania and Others
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
ACEIs or ARBs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	21 (43.75 %)	17 (34.69 %)
	Coronary Artery Disease (PBMQ)	Yes	51 (36.43 %)	81 (47.93 %)
	Hyperlipidemia (MLG)	Yes	33 (40.24 %)	50 (49.50 %)
	Hypertension (MLG)	Yes	67 (35.08 %)	101 (42.80 %)
	Region	Western Europe, Oceania and Others	19 (51.35 %)	20 (43.48 %)
Angiotensin receptor neprilysin inhibitors (ARNIs)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.71 %)	4 (2.37 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	4 (3.96 %)
	Hypertension (MLG)	Yes	1 (0.52 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Beta-Blocker	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	17 (35.42 %)	19 (38.78 %)
	Coronary Artery Disease (PBMQ)	Yes	43 (30.71 %)	70 (41.42 %)
	Hyperlipidemia (MLG)	Yes	29 (35.37 %)	45 (44.55 %)
	Hypertension (MLG)	Yes	61 (31.94 %)	96 (40.68 %)
	Region	Western Europe, Oceania and Others	17 (45.95 %)	25 (54.35 %)
Loop diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	24 (50.00 %)	23 (46.94 %)
	Coronary Artery Disease (PBMQ)	Yes	58 (41.43 %)	83 (49.11 %)
	Hyperlipidemia (MLG)	Yes	41 (50.00 %)	55 (54.46 %)
	Hypertension (MLG)	Yes	83 (43.46 %)	112 (47.46 %)
	Region	Western Europe, Oceania and Others	23 (62.16 %)	35 (76.09 %)
Thiazide diuretics	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	9 (6.43 %)	15 (8.88 %)
	Hyperlipidemia (MLG)	Yes	6 (7.32 %)	12 (11.88 %)
	Hypertension (MLG)	Yes	12 (6.28 %)	22 (9.32 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	7 (15.22 %)
Digoxin	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Nitrate	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Potassium supplements	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	8 (16.33 %)
	Coronary Artery Disease (PBMQ)	Yes	12 (8.57 %)	27 (15.98 %)
	Hyperlipidemia (MLG)	Yes	11 (13.41 %)	18 (17.82 %)
	Hypertension (MLG)	Yes	15 (7.85 %)	33 (13.98 %)
	Region	Western Europe, Oceania and Others	1 (2.70 %)	10 (21.74 %)
Potassium lowering (incl.binders)	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	2 (4.08 %)
	Coronary Artery Disease (PBMQ)	Yes	15 (10.71 %)	7 (4.14 %)
	Hyperlipidemia (MLG)	Yes	11 (13.41 %)	7 (6.93 %)
	Hypertension (MLG)	Yes	19 (9.95 %)	12 (5.08 %)
	Region	Western Europe, Oceania and Others	2 (5.41 %)	6 (13.04 %)
Alpha blocking agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	16 (33.33 %)	19 (38.78 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table, if started after start of study drug.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Alpha blocking agents	Coronary Artery Disease (PBMQ)	Yes	35 (25.00 %)	56 (33.14 %)
	Hyperlipidemia (MLG)	Yes	28 (34.15 %)	37 (36.63 %)
	Hypertension (MLG)	Yes	53 (27.75 %)	79 (33.47 %)
	Region	Western Europe, Oceania and Others	14 (37.84 %)	24 (52.17 %)
Calcium channel blockers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	17 (35.42 %)	25 (51.02 %)
	Coronary Artery Disease (PBMQ)	Yes	36 (25.71 %)	71 (42.01 %)
	Hyperlipidemia (MLG)	Yes	29 (35.37 %)	44 (43.56 %)
	Hypertension (MLG)	Yes	60 (31.41 %)	101 (42.80 %)
	Region	Western Europe, Oceania and Others	16 (43.24 %)	28 (60.87 %)
Centrally acting antihypertensivs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	4 (8.33 %)	7 (14.29 %)
	Coronary Artery Disease (PBMQ)	Yes	13 (9.29 %)	23 (13.61 %)
	Hyperlipidemia (MLG)	Yes	11 (13.41 %)	11 (10.89 %)
	Hypertension (MLG)	Yes	21 (10.99 %)	35 (14.83 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	7 (15.22 %)
Strong CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	11 (22.92 %)	7 (14.29 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (5.00 %)	11 (6.51 %)
	Hyperlipidemia (MLG)	Yes	9 (10.98 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	13 (6.81 %)	16 (6.78 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	3 (6.52 %)
Moderate CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	9 (18.75 %)	10 (20.41 %)
	Coronary Artery Disease (PBMQ)	Yes	21 (15.00 %)	22 (13.02 %)
	Hyperlipidemia (MLG)	Yes	16 (19.51 %)	16 (15.84 %)
	Hypertension (MLG)	Yes	28 (14.66 %)	29 (12.29 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	10 (21.74 %)
Weak CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	14 (29.17 %)	22 (44.90 %)
	Coronary Artery Disease (PBMQ)	Yes	43 (30.71 %)	81 (47.93 %)
	Hyperlipidemia (MLG)	Yes	30 (36.59 %)	47 (46.53 %)
	Hypertension (MLG)	Yes	64 (33.51 %)	100 (42.37 %)
	Region	Western Europe, Oceania and Others	14 (37.84 %)	25 (54.35 %)
Unclassified CYP3A4 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (12.50 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (5.00 %)	8 (4.73 %)
	Hyperlipidemia (MLG)	Yes	7 (8.54 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	10 (5.24 %)	11 (4.66 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	2 (4.35 %)
Strong CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	2 (4.08 %)
	Coronary Artery Disease (PBMQ)	Yes	2 (1.43 %)	2 (1.18 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	1 (0.99 %)
	Hypertension (MLG)	Yes	2 (1.05 %)	3 (1.27 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	1 (2.17 %)
Moderate CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	1 (2.08 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (7.14 %)	15 (8.88 %)
	Hyperlipidemia (MLG)	Yes	9 (10.98 %)	13 (12.87 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	22 (9.32 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	7 (15.22 %)
Weak CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	8 (16.67 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	19 (13.57 %)	14 (8.28 %)
	Hyperlipidemia (MLG)	Yes	18 (21.95 %)	9 (8.91 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
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Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Weak CYP3A4 inducers	Hypertension (MLG)	Yes	25 (13.09 %)	17 (7.20 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	3 (6.52 %)
Unclassified CYP3A4 inducers	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	4 (8.16 %)
	Coronary Artery Disease (PBMQ)	Yes	5 (3.57 %)	7 (4.14 %)
	Hyperlipidemia (MLG)	Yes	3 (3.66 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	10 (5.24 %)	11 (4.66 %)
	Region	Western Europe, Oceania and Others	6 (16.22 %)	7 (15.22 %)
Acetylsalycylic acid and its salts	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	9 (18.75 %)	9 (18.37 %)
	Coronary Artery Disease (PBMQ)	Yes	30 (21.43 %)	44 (26.04 %)
	Hyperlipidemia (MLG)	Yes	20 (24.39 %)	25 (24.75 %)
	Hypertension (MLG)	Yes	39 (20.42 %)	57 (24.15 %)
	Region	Western Europe, Oceania and Others	8 (21.62 %)	7 (15.22 %)
Statins	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	14 (29.17 %)	13 (26.53 %)
	Coronary Artery Disease (PBMQ)	Yes	41 (29.29 %)	57 (33.73 %)
	Hyperlipidemia (MLG)	Yes	27 (32.93 %)	41 (40.59 %)
	Hypertension (MLG)	Yes	52 (27.23 %)	73 (30.93 %)
	Region	Western Europe, Oceania and Others	11 (29.73 %)	21 (45.65 %)
MRA	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
OATP substrates	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	NA	NA
	Coronary Artery Disease (PBMQ)	Yes	NA	NA
	Hyperlipidemia (MLG)	Yes	NA	NA
	Hypertension (MLG)	Yes	NA	NA
	Region	Western Europe, Oceania and Others	NA	NA
Insulin and insulin analogues	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	24 (50.00 %)	21 (42.86 %)
	Coronary Artery Disease (PBMQ)	Yes	64 (45.71 %)	84 (49.70 %)
	Hyperlipidemia (MLG)	Yes	47 (57.32 %)	53 (52.48 %)
	Hypertension (MLG)	Yes	91 (47.64 %)	114 (48.31 %)
	Region	Western Europe, Oceania and Others	21 (56.76 %)	30 (65.22 %)
Glycosurics as SGLT-2 inhibitors	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	1 (2.04 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (5.00 %)	8 (4.73 %)
	Hyperlipidemia (MLG)	Yes	2 (2.44 %)	6 (5.94 %)
	Hypertension (MLG)	Yes	8 (4.19 %)	11 (4.66 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	2 (4.35 %)
Anticoagulants	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	14 (29.17 %)	16 (32.65 %)
	Coronary Artery Disease (PBMQ)	Yes	15 (10.71 %)	29 (17.16 %)
	Hyperlipidemia (MLG)	Yes	8 (9.76 %)	23 (22.77 %)
	Hypertension (MLG)	Yes	24 (12.57 %)	39 (16.53 %)
	Region	Western Europe, Oceania and Others	11 (29.73 %)	13 (28.26 %)
Injectable glucagon-like peptide	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (12.50 %)	5 (10.20 %)
	Coronary Artery Disease (PBMQ)	Yes	7 (5.00 %)	8 (4.73 %)
	Hyperlipidemia (MLG)	Yes	8 (9.76 %)	9 (8.91 %)
	Hypertension (MLG)	Yes	10 (5.24 %)	15 (6.36 %)
	Region	Western Europe, Oceania and Others	1 (2.70 %)	5 (10.87 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
Medications taken within the treatment period are included in this table, if started after start of study drug.
Post-hoc defined using following ATC codes: Anticoagulants (B01AA, B01AE, B01AF), Antiarrhythmic drugs (C01AA, C01BC, C01BD)
Biguanides (A10BA), Sulfonylureas (A10BB), Combinations of oral blood glucose lowering drugs (A10BD)
Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Concomitant medication that started after start of study drug - Subgroup analysis
Full Analysis Set

Standard drug grouping	Subgroup	Subgroup Level	Finerenone (N=195)	Placebo (N=241)
Antiarrhythmic drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	10 (20.83 %)	8 (16.33 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (5.71 %)	18 (10.65 %)
	Hyperlipidemia (MLG)	Yes	5 (6.10 %)	9 (8.91 %)
	Hypertension (MLG)	Yes	14 (7.33 %)	20 (8.47 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	6 (13.04 %)
Biguanides	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	12 (25.00 %)	8 (16.33 %)
	Coronary Artery Disease (PBMQ)	Yes	11 (7.86 %)	24 (14.20 %)
	Hyperlipidemia (MLG)	Yes	14 (17.07 %)	15 (14.85 %)
	Hypertension (MLG)	Yes	24 (12.57 %)	31 (13.14 %)
	Region	Western Europe, Oceania and Others	5 (13.51 %)	10 (21.74 %)
Sulfonylureas	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	6 (12.50 %)	3 (6.12 %)
	Coronary Artery Disease (PBMQ)	Yes	10 (7.14 %)	14 (8.28 %)
	Hyperlipidemia (MLG)	Yes	6 (7.32 %)	11 (10.89 %)
	Hypertension (MLG)	Yes	15 (7.85 %)	22 (9.32 %)
	Region	Western Europe, Oceania and Others	4 (10.81 %)	2 (4.35 %)
Combinations of oral blood glucose lowering drugs	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	0 (0.00 %)	2 (1.18 %)
	Hyperlipidemia (MLG)	Yes	0 (0.00 %)	1 (0.99 %)
	Hypertension (MLG)	Yes	0 (0.00 %)	2 (0.85 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Combinations of various lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	0 (0.00 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	1 (0.71 %)	0 (0.00 %)
	Hyperlipidemia (MLG)	Yes	1 (1.22 %)	0 (0.00 %)
	Hypertension (MLG)	Yes	1 (0.52 %)	0 (0.00 %)
	Region	Western Europe, Oceania and Others	0 (0.00 %)	0 (0.00 %)
Other lipid modifying agents	Atrial Fibrillation And Atrial Flutter (PBMQ)	Yes	3 (6.25 %)	0 (0.00 %)
	Coronary Artery Disease (PBMQ)	Yes	8 (5.71 %)	8 (4.73 %)
	Hyperlipidemia (MLG)	Yes	7 (8.54 %)	8 (7.92 %)
	Hypertension (MLG)	Yes	12 (6.28 %)	9 (3.81 %)
	Region	Western Europe, Oceania and Others	3 (8.11 %)	1 (2.17 %)

Digoxin, MRA, Nitrate, OATP substrates were a medication group of interest in FINEARTS-HF, but not in FIDELIO-DKD and FIGARO-DKD.
A subject is counted only once within each Standard Drug Group. Subgroups of medical history of interest were defined as in FINEARTS-HF study protocol.
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Combinations of various lipid modifying agents (C10BA), Other lipid modifying agents (C10AX), Injectable glucagon-like peptide (A10BJ)

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	195	138.01 (13.56)	137.67	97.67, 173.00	-	-	-	-
	Placebo	241	138.02 (15.14)	139.33	90.00, 180.67	-	-	-	-
Month 1	Finerenone	193	134.54 (14.23)	135.00	102.00, 208.33	193	-3.43 (14.31)	-2.67	-46.00, 58.33
	Placebo	238	138.42 (15.17)	138.67	101.33, 186.67	238	0.18 (14.86)	0.00	-50.00, 66.00
Month 4	Finerenone	187	133.97 (14.30)	134.00	91.33, 188.67	187	-3.95 (15.74)	-4.33	-49.33, 42.33
	Placebo	233	139.13 (16.42)	139.00	96.00, 192.67	233	1.27 (15.09)	0.00	-47.00, 55.00
Month 8	Finerenone	177	134.68 (13.89)	135.00	89.00, 194.67	177	-3.12 (16.22)	-4.33	-73.67, 47.67
	Placebo	227	138.41 (17.01)	138.67	98.00, 202.00	227	0.13 (16.52)	-0.33	-47.67, 59.67
Month 12	Finerenone	174	136.22 (16.84)	137.83	88.33, 172.33	174	-1.52 (17.82)	-0.33	-57.00, 51.33
	Placebo	221	138.85 (18.49)	136.67	96.67, 210.00	221	0.54 (17.05)	-1.00	-49.00, 67.67
Month 16	Finerenone	163	135.19 (15.04)	136.33	95.00, 175.67	163	-2.16 (15.64)	-2.00	-44.00, 59.33
	Placebo	207	138.35 (17.19)	138.00	88.00, 209.33	207	-0.06 (16.64)	0.00	-51.33, 49.33
Month 20	Finerenone	145	135.45 (15.80)	136.00	99.00, 182.33	145	-2.02 (17.06)	-1.00	-53.33, 37.67
	Placebo	191	137.55 (17.16)	137.33	79.33, 194.67	191	-0.64 (18.00)	0.00	-62.00, 50.00
Month 24	Finerenone	123	135.09 (15.33)	135.33	90.67, 172.00	123	-2.10 (15.69)	-2.00	-58.00, 41.67
	Placebo	151	137.32 (17.90)	136.33	88.33, 226.67	151	-0.63 (18.43)	-1.67	-39.00, 60.67
Month 28	Finerenone	98	132.46 (14.28)	132.50	99.67, 176.67	98	-4.48 (15.51)	-4.17	-47.00, 30.67
	Placebo	116	136.93 (17.84)	136.67	98.00, 218.67	116	-0.93 (19.37)	1.33	-56.67, 74.00
Month 32	Finerenone	76	135.18 (15.60)	135.67	101.00, 174.00	76	-1.82 (18.20)	-2.50	-37.67, 48.00
	Placebo	89	137.48 (17.56)	138.00	100.67, 190.67	89	0.23 (17.66)	-0.33	-41.33, 58.00
Month 36	Finerenone	54	130.19 (16.19)	132.17	102.00, 177.33	54	-5.65 (18.18)	-4.50	-43.33, 40.67
	Placebo	63	138.52 (19.53)	135.33	98.00, 200.00	63	0.52 (19.22)	0.00	-40.00, 59.67
Month 40	Finerenone	39	134.03 (14.15)	136.00	101.67, 178.33	39	-0.98 (17.20)	-1.67	-37.33, 41.33
	Placebo	35	138.65 (16.46)	137.33	106.67, 171.00	35	0.62 (19.19)	-1.67	-29.67, 46.67
Month 44	Finerenone	23	134.32 (18.20)	137.33	90.33, 170.00	23	1.06 (22.25)	7.00	-63.67, 30.67
	Placebo	20	133.58 (15.99)	134.83	108.67, 164.67	20	-3.02 (16.03)	-3.17	-37.33, 25.33
Month 48	Finerenone	3	144.56 (25.46)	141.67	120.67, 171.33	3	7.33 (17.57)	4.00	-8.33, 26.33
	Placebo	5	131.53 (7.64)	132.67	121.67, 142.33	5	2.07 (6.07)	-0.33	-4.67, 10.67
Premature discontinuation	Finerenone	11	146.76 (22.30)	144.33	114.33, 180.33	11	9.52 (26.51)	13.00	-31.67, 58.00
	Placebo	12	147.83 (23.34)	147.33	121.67, 200.00	12	9.14 (17.35)	15.83	-20.00, 30.00
End of Study Visit	Finerenone	139	137.86 (17.84)	137.33	87.67, 195.00	139	1.19 (20.53)	0.33	-66.33, 76.00
	Placebo	177	137.70 (16.10)	136.33	101.67, 202.33	177	-0.54 (17.77)	-1.33	-46.67, 55.33
Post Treatment Visit	Finerenone	8	128.92 (18.92)	124.67	106.00, 166.00	8	-7.33 (21.08)	-11.33	-28.00, 32.33
	Placebo	7	154.38 (23.31)	142.00	127.33, 193.00	7	4.00 (13.51)	0.33	-12.67, 23.33

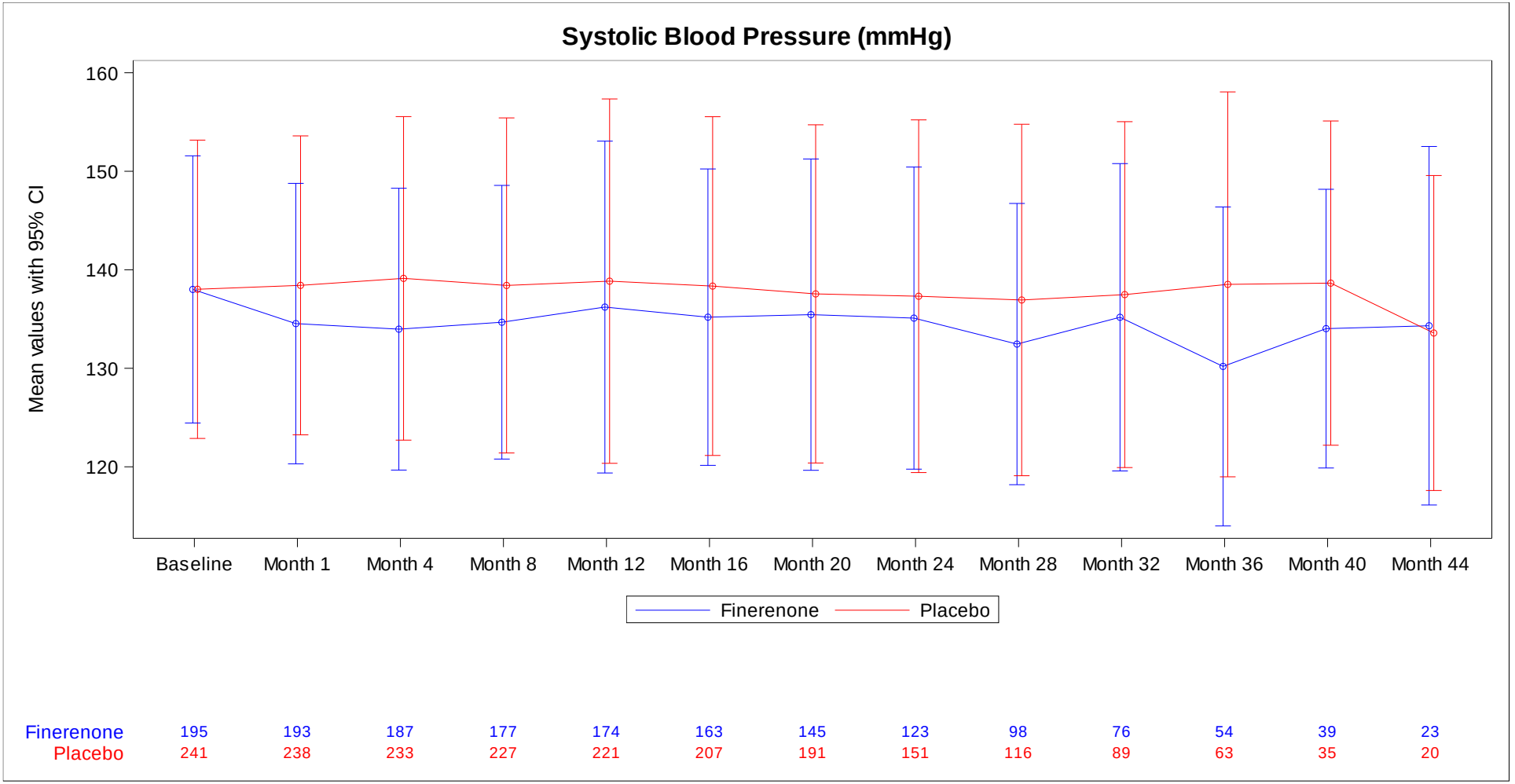
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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	191	138.21 (13.26)	137.67	97.67, 173.00	-	-	-	-
	Placebo	236	138.16 (15.03)	139.33	90.00, 180.67	-	-	-	-
Month 1	Finerenone	189	134.75 (14.22)	135.33	102.00, 208.33	189	-3.41 (14.32)	-2.67	-46.00, 58.33
	Placebo	233	138.39 (15.17)	138.67	101.33, 186.67	233	0.02 (14.86)	0.00	-50.00, 66.00
Month 4	Finerenone	183	134.17 (14.28)	134.00	91.33, 188.67	183	-3.96 (15.85)	-4.33	-49.33, 42.33
	Placebo	228	138.99 (16.29)	138.67	96.00, 192.67	228	0.99 (14.97)	-0.33	-47.00, 55.00
Month 8	Finerenone	175	135.02 (13.57)	135.00	89.00, 194.67	175	-3.12 (16.31)	-4.33	-73.67, 47.67
	Placebo	223	138.43 (17.01)	138.67	98.00, 202.00	223	-0.02 (16.62)	-0.67	-47.67, 59.67
Month 12	Finerenone	172	136.55 (16.65)	138.00	88.33, 172.33	172	-1.54 (17.91)	-0.33	-57.00, 51.33
	Placebo	217	139.05 (18.51)	138.00	96.67, 210.00	217	0.57 (17.12)	-1.00	-49.00, 67.67
Month 16	Finerenone	161	135.35 (14.89)	136.33	95.00, 175.67	161	-2.36 (15.57)	-2.00	-44.00, 59.33
	Placebo	203	138.41 (17.22)	138.00	88.00, 209.33	203	-0.19 (16.75)	0.00	-51.33, 49.33
Month 20	Finerenone	143	135.70 (15.74)	136.33	99.00, 182.33	143	-2.18 (17.12)	-1.00	-53.33, 37.67
	Placebo	188	137.79 (17.15)	137.67	79.33, 194.67	188	-0.70 (18.12)	0.00	-62.00, 50.00
Month 24	Finerenone	121	135.50 (15.13)	135.33	90.67, 172.00	121	-2.18 (15.78)	-2.00	-58.00, 41.67
	Placebo	148	137.50 (17.99)	136.50	88.33, 226.67	148	-0.82 (18.47)	-1.67	-39.00, 60.67
Month 28	Finerenone	96	132.91 (14.06)	132.83	99.67, 176.67	96	-4.64 (15.61)	-5.33	-47.00, 30.67
	Placebo	113	137.30 (17.80)	136.67	98.00, 218.67	113	-1.04 (19.51)	1.33	-56.67, 74.00
Month 32	Finerenone	75	135.45 (15.52)	135.67	101.00, 174.00	75	-1.81 (18.32)	-2.67	-37.67, 48.00
	Placebo	88	137.72 (17.51)	138.17	100.67, 190.67	88	0.08 (17.70)	-0.33	-41.33, 58.00
Month 36	Finerenone	53	130.48 (16.20)	132.33	102.00, 177.33	53	-5.71 (18.35)	-4.67	-43.33, 40.67
	Placebo	62	138.73 (19.62)	136.33	98.00, 200.00	62	0.16 (19.16)	0.00	-40.00, 59.67
Month 40	Finerenone	39	134.03 (14.15)	136.00	101.67, 178.33	39	-0.98 (17.20)	-1.67	-37.33, 41.33
	Placebo	35	138.65 (16.46)	137.33	106.67, 171.00	35	0.62 (19.19)	-1.67	-29.67, 46.67
Month 44	Finerenone	23	134.32 (18.20)	137.33	90.33, 170.00	23	1.06 (22.25)	7.00	-63.67, 30.67
	Placebo	20	133.58 (15.99)	134.83	108.67, 164.67	20	-3.02 (16.03)	-3.17	-37.33, 25.33
Month 48	Finerenone	3	144.56 (25.46)	141.67	120.67, 171.33	3	7.33 (17.57)	4.00	-8.33, 26.33
	Placebo	5	131.53 (7.64)	132.67	121.67, 142.33	5	2.07 (6.07)	-0.33	-4.67, 10.67
Premature discontinuation	Finerenone	10	150.00 (20.60)	147.83	121.67, 180.33	10	13.63 (23.95)	14.17	-15.00, 58.00
	Placebo	11	149.97 (23.22)	150.00	121.67, 200.00	11	10.91 (17.03)	16.67	-20.00, 30.00
End of Study Visit	Finerenone	138	137.98 (17.85)	137.33	87.67, 195.00	138	1.03 (20.52)	0.17	-66.33, 76.00
	Placebo	174	137.61 (15.97)	136.33	101.67, 202.33	174	-0.82 (17.79)	-1.50	-46.67, 55.33
Post Treatment Visit	Finerenone	8	128.92 (18.92)	124.67	106.00, 166.00	8	-7.33 (21.08)	-11.33	-28.00, 32.33
	Placebo	7	154.38 (23.31)	142.00	127.33, 193.00	7	4.00 (13.51)	0.33	-12.67, 23.33

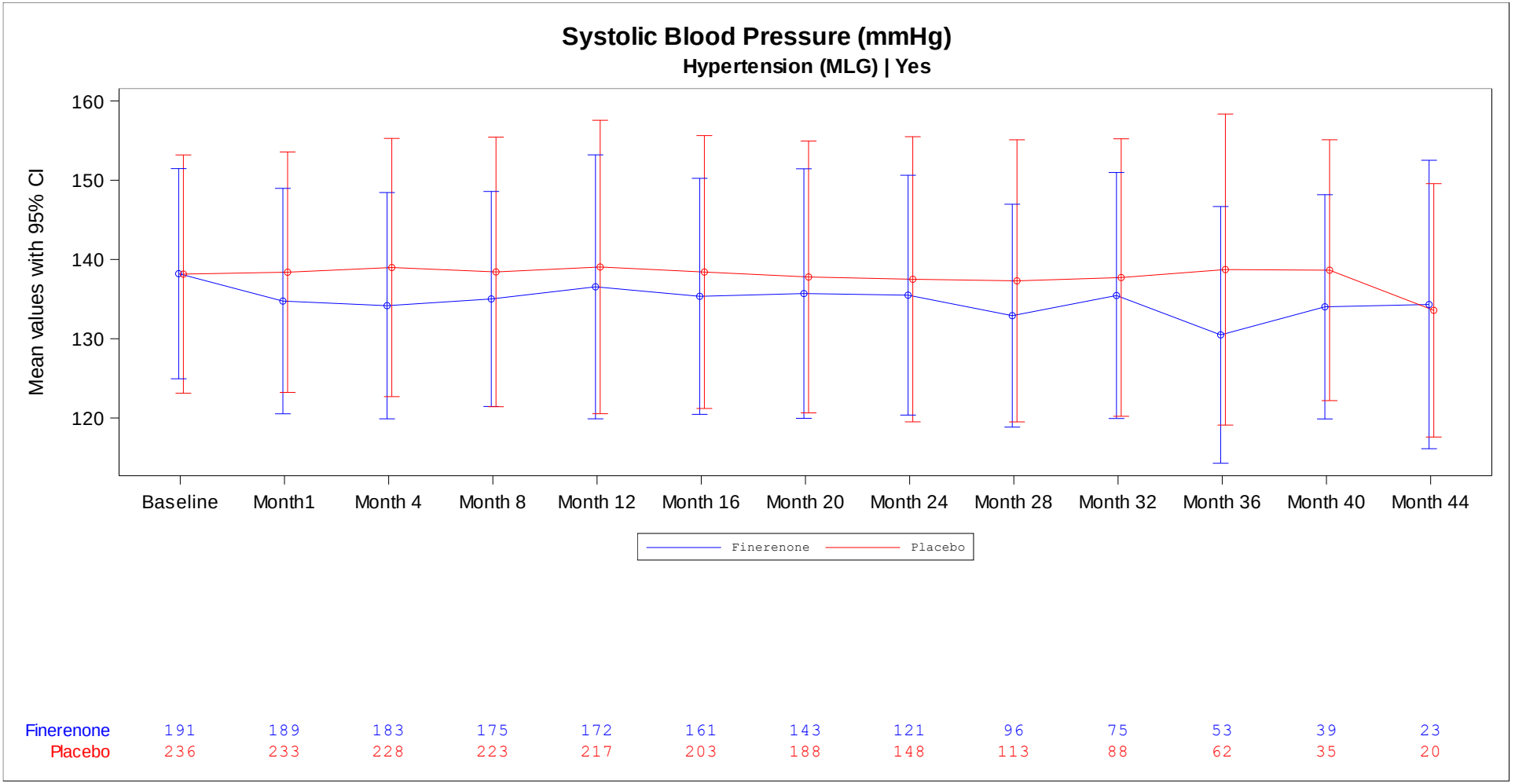
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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Systolic Blood Pressure (mmHg) over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Systolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	195	76.41 (9.64)	78.00	43.33, 97.67	-	-	-	-
	Placebo	241	75.37 (9.51)	76.33	52.00, 98.00	-	-	-	-
Month 1	Finerenone	193	75.13 (10.36)	75.67	44.00, 101.00	193	-1.35 (7.36)	-1.33	-22.00, 25.33
	Placebo	238	75.22 (10.57)	76.67	46.33, 108.00	238	-0.17 (7.73)	0.00	-19.33, 21.67
Month 4	Finerenone	187	74.60 (10.06)	75.33	50.67, 96.33	187	-1.81 (8.81)	-2.33	-25.00, 24.00
	Placebo	233	75.27 (10.82)	76.00	43.67, 106.67	233	-0.05 (8.68)	-0.67	-23.67, 30.00
Month 8	Finerenone	177	75.50 (10.51)	77.33	48.67, 96.33	177	-0.99 (9.29)	-0.67	-28.00, 29.00
	Placebo	227	75.31 (10.71)	77.33	44.00, 106.33	227	-0.01 (8.64)	-1.00	-22.33, 30.67
Month 12	Finerenone	174	75.25 (10.68)	76.00	48.67, 100.00	174	-1.40 (9.68)	-1.67	-28.67, 26.67
	Placebo	221	74.92 (10.66)	76.67	47.33, 103.33	221	-0.44 (9.06)	-0.67	-27.00, 32.67
Month 16	Finerenone	163	75.47 (10.77)	76.33	46.67, 108.67	163	-1.31 (9.59)	-1.33	-31.00, 43.00
	Placebo	207	74.41 (10.91)	75.33	46.00, 105.00	207	-1.12 (9.33)	-1.33	-28.00, 28.33
Month 20	Finerenone	145	75.37 (11.08)	75.67	49.00, 107.00	145	-1.16 (9.56)	-1.00	-26.33, 30.33
	Placebo	191	74.20 (11.12)	75.33	40.00, 100.00	191	-1.48 (9.59)	-0.33	-27.67, 19.00
Month 24	Finerenone	123	74.62 (11.26)	75.00	49.67, 103.00	123	-1.41 (9.84)	-2.00	-35.33, 23.00
	Placebo	151	74.87 (10.70)	75.67	47.33, 110.67	151	0.03 (10.23)	0.00	-23.67, 26.67
Month 28	Finerenone	98	72.88 (10.87)	73.67	49.00, 96.00	98	-2.93 (9.49)	-2.17	-35.33, 17.33
	Placebo	116	74.51 (10.94)	76.00	50.00, 98.67	116	-0.55 (9.74)	0.00	-29.67, 43.00
Month 32	Finerenone	76	73.71 (10.29)	73.33	51.00, 99.67	76	-1.41 (9.35)	-1.83	-23.67, 25.67
	Placebo	89	74.00 (11.04)	74.67	46.67, 94.67	89	-1.35 (9.38)	-2.00	-20.00, 22.00
Month 36	Finerenone	54	70.77 (10.19)	71.00	50.33, 100.67	54	-2.50 (10.02)	-3.00	-25.33, 26.00
	Placebo	63	73.43 (9.04)	75.00	48.00, 96.00	63	-1.46 (9.12)	-2.00	-17.67, 22.33
Month 40	Finerenone	39	72.72 (12.78)	71.33	45.67, 93.33	39	0.08 (10.90)	0.00	-18.67, 36.33
	Placebo	35	73.08 (10.13)	71.67	57.67, 107.67	35	-1.75 (12.01)	-1.67	-26.67, 34.00
Month 44	Finerenone	23	67.09 (9.37)	65.33	52.33, 92.00	23	-2.12 (12.68)	-3.67	-27.00, 27.33
	Placebo	20	70.12 (8.42)	69.17	53.33, 86.67	20	-4.08 (8.30)	-3.67	-18.33, 10.00
Month 48	Finerenone	3	61.22 (6.74)	57.33	57.33, 69.00	3	-0.22 (6.53)	-1.00	-6.33, 6.67
	Placebo	5	71.80 (14.02)	70.33	57.33, 91.33	5	-1.27 (8.88)	-0.67	-14.67, 9.00
Premature discontinuation	Finerenone	11	78.82 (12.85)	81.00	50.33, 95.00	11	4.45 (8.96)	6.67	-8.00, 18.00
	Placebo	12	74.44 (7.72)	74.33	62.00, 84.00	12	3.00 (11.56)	4.17	-17.33, 25.00
End of Study Visit	Finerenone	139	75.71 (10.15)	76.67	48.33, 101.33	139	-0.15 (10.13)	-1.67	-26.67, 26.00
	Placebo	177	74.78 (10.70)	75.67	46.67, 106.00	177	-1.16 (9.34)	-1.00	-28.00, 30.67
Post Treatment Visit	Finerenone	8	69.92 (12.53)	72.67	50.67, 89.00	8	-0.58 (9.81)	0.17	-13.33, 16.67
	Placebo	7	70.48 (16.43)	64.00	55.00, 100.33	7	-4.62 (13.21)	-5.67	-18.00, 19.33

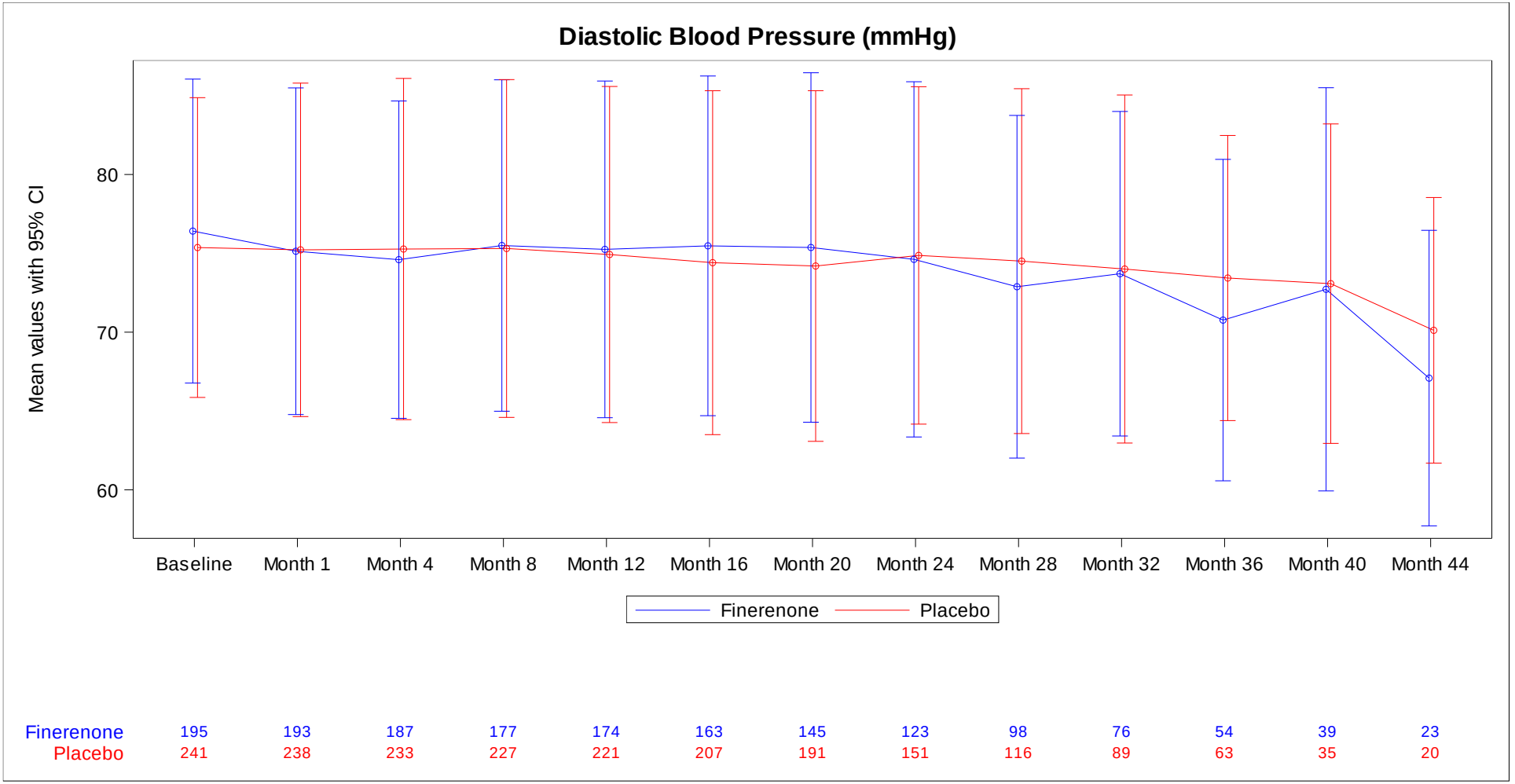
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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	191	76.64 (9.48)	78.00	43.33, 97.67	-	-	-	-
	Placebo	236	75.45 (9.54)	76.67	52.00, 98.00	-	-	-	-
Month 1	Finerenone	189	75.23 (10.40)	75.67	44.00, 101.00	189	-1.48 (7.34)	-1.33	-22.00, 25.33
	Placebo	233	75.21 (10.64)	76.67	46.33, 108.00	233	-0.27 (7.76)	0.00	-19.33, 21.67
Month 4	Finerenone	183	74.75 (10.05)	75.33	50.67, 96.33	183	-1.90 (8.88)	-2.67	-25.00, 24.00
	Placebo	228	75.21 (10.84)	76.00	43.67, 106.67	228	-0.20 (8.55)	-0.67	-23.67, 30.00
Month 8	Finerenone	175	75.63 (10.46)	78.00	48.67, 96.33	175	-0.95 (9.32)	-0.67	-28.00, 29.00
	Placebo	223	75.35 (10.77)	77.33	44.00, 106.33	223	-0.08 (8.68)	-1.00	-22.33, 30.67
Month 12	Finerenone	172	75.36 (10.64)	76.00	48.67, 100.00	172	-1.39 (9.73)	-1.67	-28.67, 26.67
	Placebo	217	75.06 (10.70)	77.33	47.33, 103.33	217	-0.42 (9.13)	-0.67	-27.00, 32.67
Month 16	Finerenone	161	75.60 (10.71)	76.33	46.67, 108.67	161	-1.29 (9.65)	-1.33	-31.00, 43.00
	Placebo	203	74.50 (10.99)	75.67	46.00, 105.00	203	-1.16 (9.41)	-1.33	-28.00, 28.33
Month 20	Finerenone	143	75.47 (11.10)	76.00	49.00, 107.00	143	-1.17 (9.60)	-1.00	-26.33, 30.33
	Placebo	188	74.26 (11.15)	75.50	40.00, 100.00	188	-1.56 (9.63)	-0.50	-27.67, 19.00
Month 24	Finerenone	121	74.76 (11.30)	75.00	49.67, 103.00	121	-1.40 (9.82)	-2.00	-35.33, 23.00
	Placebo	148	74.91 (10.76)	75.67	47.33, 110.67	148	-0.08 (10.30)	0.00	-23.67, 26.67
Month 28	Finerenone	96	73.04 (10.90)	73.83	49.00, 96.00	96	-2.93 (9.53)	-2.17	-35.33, 17.33
	Placebo	113	74.73 (10.98)	77.33	50.00, 98.67	113	-0.53 (9.80)	0.00	-29.67, 43.00
Month 32	Finerenone	75	73.78 (10.34)	73.33	51.00, 99.67	75	-1.26 (9.32)	-1.67	-23.67, 25.67
	Placebo	88	74.13 (11.04)	75.00	46.67, 94.67	88	-1.38 (9.43)	-2.17	-20.00, 22.00
Month 36	Finerenone	53	70.68 (10.27)	71.00	50.33, 100.67	53	-2.45 (10.11)	-3.00	-25.33, 26.00
	Placebo	62	73.40 (9.11)	75.00	48.00, 96.00	62	-1.70 (8.98)	-2.17	-17.67, 22.33
Month 40	Finerenone	39	72.72 (12.78)	71.33	45.67, 93.33	39	0.08 (10.90)	0.00	-18.67, 36.33
	Placebo	35	73.08 (10.13)	71.67	57.67, 107.67	35	-1.75 (12.01)	-1.67	-26.67, 34.00
Month 44	Finerenone	23	67.09 (9.37)	65.33	52.33, 92.00	23	-2.12 (12.68)	-3.67	-27.00, 27.33
	Placebo	20	70.12 (8.42)	69.17	53.33, 86.67	20	-4.08 (8.30)	-3.67	-18.33, 10.00
Month 48	Finerenone	3	61.22 (6.74)	57.33	57.33, 69.00	3	-0.22 (6.53)	-1.00	-6.33, 6.67
	Placebo	5	71.80 (14.02)	70.33	57.33, 91.33	5	-1.27 (8.88)	-0.67	-14.67, 9.00
Premature discontinuation	Finerenone	10	81.67 (9.18)	81.83	69.67, 95.00	10	5.40 (8.84)	7.33	-8.00, 18.00
	Placebo	11	74.88 (7.95)	75.33	62.00, 84.00	11	2.97 (12.12)	5.00	-17.33, 25.00
End of Study Visit	Finerenone	138	75.74 (10.18)	76.67	48.33, 101.33	138	-0.27 (10.07)	-1.67	-26.67, 26.00
	Placebo	174	74.86 (10.76)	76.17	46.67, 106.00	174	-1.19 (9.36)	-1.17	-28.00, 30.67
Post Treatment Visit	Finerenone	8	69.92 (12.53)	72.67	50.67, 89.00	8	-0.58 (9.81)	0.17	-13.33, 16.67
	Placebo	7	70.48 (16.43)	64.00	55.00, 100.33	7	-4.62 (13.21)	-5.67	-18.00, 19.33

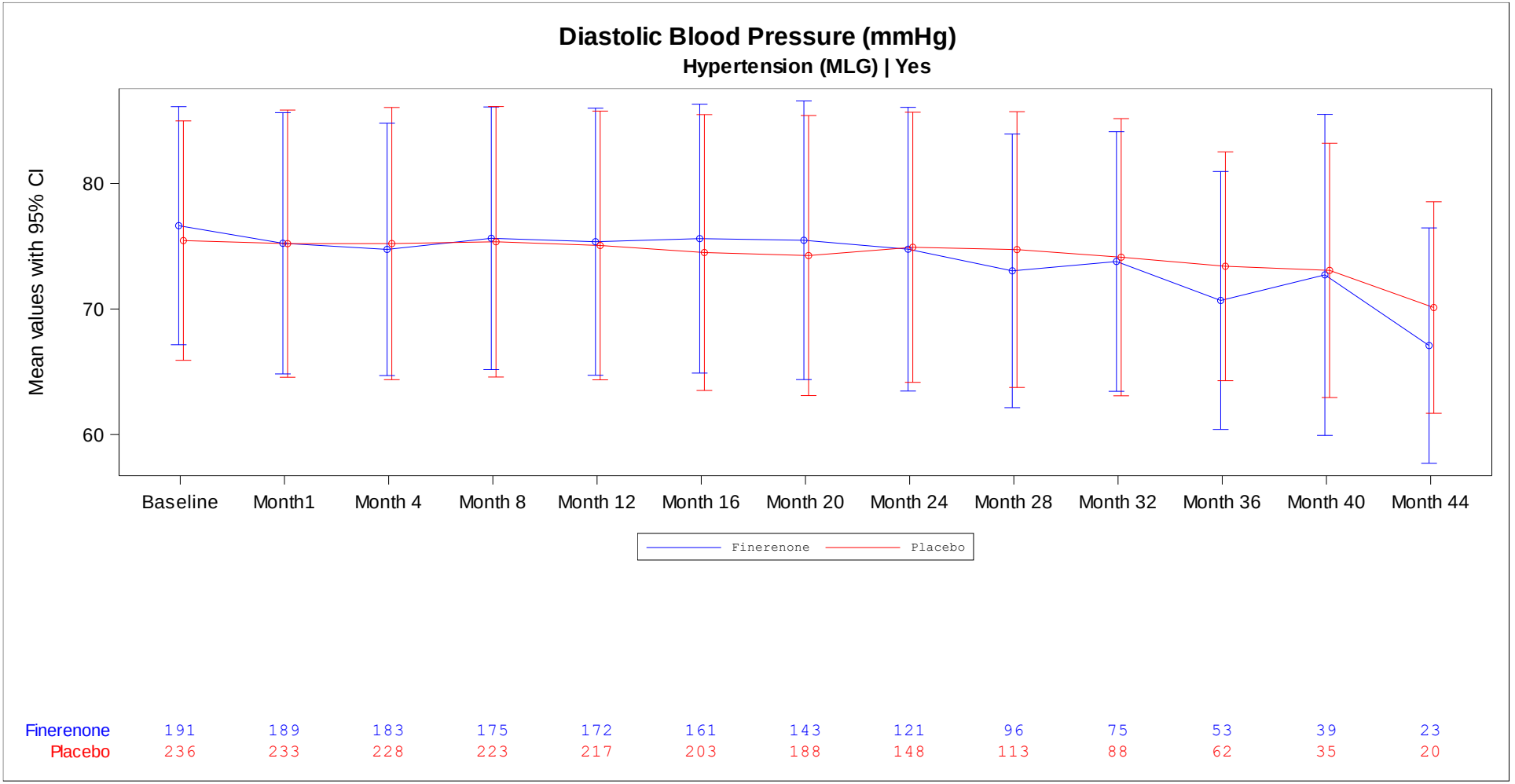
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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time
Safety Analysis Set



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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Diastolic Blood Pressure (mmHg) over time - Patients with hypertension in medical history
Safety Analysis Set



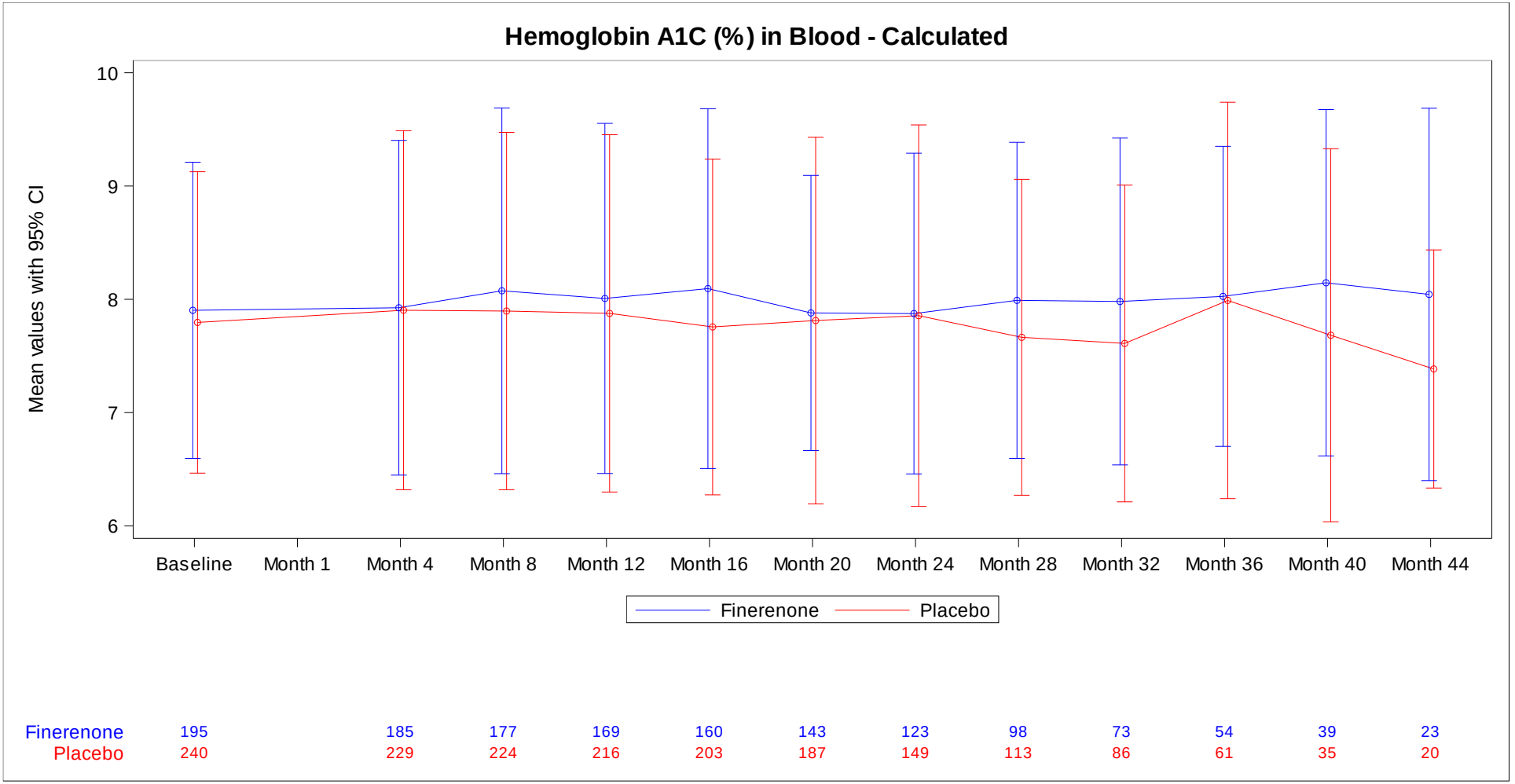
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BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Hemoglobin A1C (%) in Blood over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	195	7.90 (1.31)	7.80	5.60, 11.40	-	-	-	-
	Placebo	240	7.80 (1.33)	7.60	5.40, 11.80	-	-	-	-
Month 1	Finerenone	0	NE (NE)	NE	NE, NE	0	NE (NE)	NE	NE, NE
	Placebo	3	6.67 (0.42)	6.80	6.20, 7.00	3	-0.13 (0.40)	0.10	-0.60, 0.10
Month 4	Finerenone	185	7.93 (1.48)	7.70	5.40, 13.40	185	0.06 (1.04)	0.00	-2.20, 5.10
	Placebo	229	7.90 (1.58)	7.60	5.10, 13.70	229	0.11 (1.06)	0.10	-4.80, 5.30
Month 8	Finerenone	177	8.08 (1.61)	7.80	5.50, 14.30	177	0.17 (1.20)	0.10	-4.60, 4.80
	Placebo	224	7.90 (1.58)	7.70	5.10, 14.10	224	0.10 (1.24)	0.10	-4.20, 5.70
Month 12	Finerenone	169	8.01 (1.55)	7.80	4.80, 14.60	169	0.11 (1.31)	0.10	-5.70, 5.70
	Placebo	216	7.88 (1.58)	7.60	4.60, 14.30	216	0.07 (1.30)	0.00	-4.10, 5.90
Month 16	Finerenone	160	8.09 (1.59)	7.90	5.30, 14.30	160	0.21 (1.32)	0.05	-3.50, 5.40
	Placebo	203	7.76 (1.48)	7.60	5.10, 13.00	203	-0.07 (1.23)	0.00	-4.10, 3.20
Month 20	Finerenone	143	7.88 (1.21)	7.90	5.50, 12.90	143	0.07 (1.03)	0.10	-3.00, 2.70
	Placebo	187	7.81 (1.62)	7.50	5.20, 14.80	187	-0.01 (1.46)	-0.10	-4.70, 6.40
Month 24	Finerenone	123	7.87 (1.42)	7.60	5.30, 12.40	123	-0.01 (1.44)	-0.10	-5.40, 5.10
	Placebo	149	7.86 (1.68)	7.60	5.10, 14.80	149	0.07 (1.52)	0.10	-4.90, 6.40
Month 28	Finerenone	98	7.99 (1.39)	7.80	5.30, 13.60	98	0.07 (1.27)	-0.10	-2.10, 4.10
	Placebo	113	7.66 (1.39)	7.60	5.20, 13.60	113	-0.22 (1.44)	-0.10	-4.70, 5.20
Month 32	Finerenone	73	7.98 (1.44)	7.80	5.10, 11.90	73	0.23 (1.21)	0.10	-2.40, 4.70
	Placebo	86	7.61 (1.40)	7.50	4.70, 11.50	86	-0.21 (1.33)	-0.30	-4.00, 4.00
Month 36	Finerenone	54	8.03 (1.32)	7.80	6.00, 10.90	54	0.04 (1.32)	0.10	-3.20, 4.30
	Placebo	61	7.99 (1.75)	7.70	5.40, 12.50	61	0.19 (1.61)	-0.10	-2.50, 5.50
Month 40	Finerenone	39	8.15 (1.53)	7.80	5.00, 11.60	39	0.18 (1.27)	0.20	-2.20, 3.80
	Placebo	35	7.68 (1.65)	7.50	4.70, 12.60	35	-0.09 (1.54)	0.10	-4.30, 4.50
Month 44	Finerenone	23	8.04 (1.64)	7.90	6.20, 12.50	23	0.47 (1.64)	0.10	-1.80, 5.80
	Placebo	20	7.39 (1.05)	7.40	5.70, 9.70	20	-0.36 (1.31)	-0.25	-3.40, 1.40
Month 48	Finerenone	3	8.33 (0.86)	8.50	7.40, 9.10	3	0.83 (0.75)	0.80	0.10, 1.60
	Placebo	4	6.70 (0.91)	6.85	5.60, 7.50	4	-0.78 (1.06)	-1.25	-1.40, 0.80
Last treatment-emergent	Finerenone	194	8.19 (1.67)	7.90	5.30, 14.20	194	0.29 (1.26)	0.10	-3.10, 4.70
	Placebo	238	7.76 (1.46)	7.65	4.90, 13.60	238	-0.03 (1.44)	0.00	-5.60, 4.70
Premature discontinuation	Finerenone	11	8.39 (2.70)	7.80	5.90, 14.50	11	0.04 (1.82)	-0.40	-2.20, 4.70
	Placebo	12	6.94 (1.08)	6.55	5.80, 8.60	12	-0.22 (1.05)	-0.20	-1.60, 2.40
End of Study Visit	Finerenone	138	8.19 (1.53)	8.05	5.50, 13.20	138	0.19 (1.29)	0.20	-3.10, 4.70
	Placebo	175	7.82 (1.57)	7.60	4.90, 13.60	175	0.02 (1.59)	-0.10	-5.60, 4.70
Post Treatment Visit	Finerenone	6	9.15 (2.58)	8.40	6.30, 12.70	6	0.55 (2.09)	-0.15	-1.40, 4.40
	Placebo	6	8.62 (1.40)	8.25	6.80, 10.60	6	1.15 (1.28)	0.85	-0.50, 2.70

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Hemoglobin A1C (%) in Blood over time
Safety Analysis Set



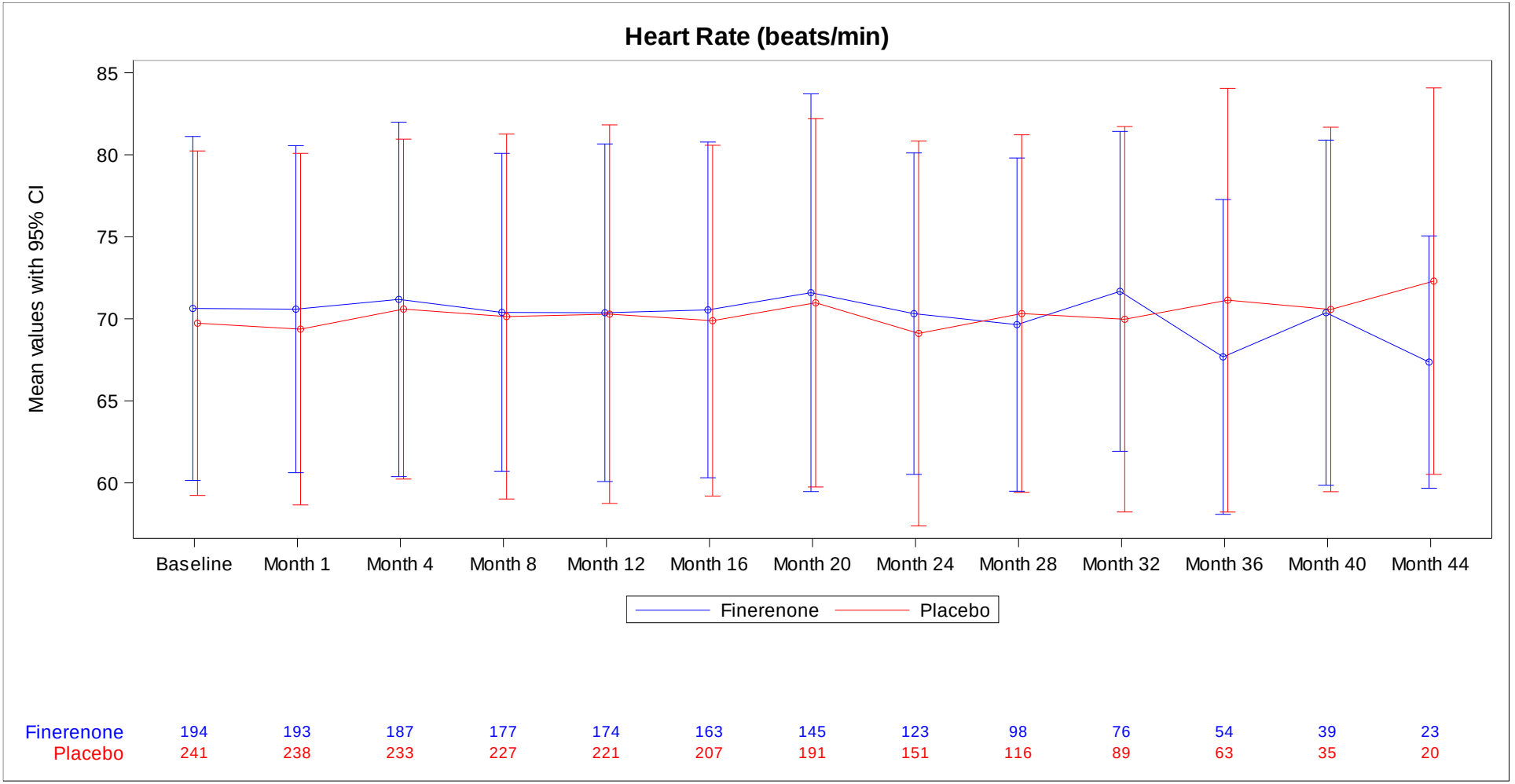
Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Mean values and absolute change from Baseline in Heart Rate over time
Safety Analysis Set

		Value at timepoint				Change from Baseline			
Timepoint	Treatment	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline	Finerenone	194	70.63 (10.48)	70.67	46.67, 112.00	-	-	-	-
	Placebo	241	69.73 (10.50)	69.67	42.33, 102.67	-	-	-	-
Month 1	Finerenone	193	70.59 (9.97)	70.33	39.33, 104.33	192	-0.01 (8.24)	-0.33	-32.00, 29.33
	Placebo	238	69.37 (10.72)	68.83	40.67, 103.00	238	-0.37 (6.85)	-0.67	-42.00, 23.33
Month 4	Finerenone	187	71.19 (10.80)	70.00	49.33, 109.33	186	0.46 (8.28)	-0.17	-34.00, 28.00
	Placebo	233	70.59 (10.36)	70.67	38.67, 100.00	233	0.93 (8.94)	0.67	-41.33, 28.33
Month 8	Finerenone	177	70.39 (9.70)	70.00	48.00, 107.33	177	-0.25 (8.70)	-1.00	-38.00, 21.00
	Placebo	227	70.14 (11.12)	69.67	38.00, 101.00	227	0.50 (9.27)	0.67	-38.33, 30.00
Month 12	Finerenone	174	70.37 (10.29)	70.17	48.33, 97.67	174	-0.07 (10.27)	0.17	-60.00, 32.67
	Placebo	221	70.29 (11.54)	68.67	41.33, 122.67	221	0.75 (10.92)	0.67	-38.33, 62.33
Month 16	Finerenone	163	70.54 (10.23)	70.00	48.00, 100.33	162	-0.01 (8.64)	0.00	-22.67, 33.67
	Placebo	207	69.89 (10.69)	70.00	44.00, 99.33	207	0.22 (9.82)	0.67	-40.33, 30.00
Month 20	Finerenone	145	71.59 (12.12)	70.67	44.67, 144.67	144	0.92 (10.95)	-0.17	-56.33, 63.00
	Placebo	191	70.98 (11.23)	70.00	41.33, 108.67	191	1.28 (11.22)	2.00	-41.67, 34.33
Month 24	Finerenone	123	70.31 (9.80)	69.67	44.33, 106.33	122	0.05 (9.53)	1.17	-56.00, 20.67
	Placebo	151	69.11 (11.73)	68.33	42.00, 109.00	151	0.58 (11.37)	0.00	-40.33, 32.33
Month 28	Finerenone	98	69.65 (10.16)	68.50	45.33, 100.00	97	-0.63 (9.92)	0.00	-52.67, 16.33
	Placebo	116	70.32 (10.90)	69.00	42.00, 95.00	116	2.16 (10.33)	1.50	-24.67, 29.67
Month 32	Finerenone	76	71.68 (9.75)	72.33	49.00, 96.67	75	0.86 (10.47)	1.33	-31.00, 36.67
	Placebo	89	69.97 (11.75)	70.67	41.00, 100.33	89	2.21 (11.26)	0.33	-25.67, 36.00
Month 36	Finerenone	54	67.68 (9.60)	67.33	50.67, 95.33	53	-1.48 (12.66)	-2.33	-53.33, 27.67
	Placebo	63	71.14 (12.92)	70.67	44.33, 98.67	63	3.87 (11.46)	2.67	-25.67, 34.33
Month 40	Finerenone	39	70.38 (10.52)	71.00	53.00, 105.67	39	2.89 (10.57)	3.00	-17.00, 26.00
	Placebo	35	70.57 (11.11)	70.67	44.00, 94.67	35	3.13 (10.40)	3.00	-19.00, 30.33
Month 44	Finerenone	23	67.36 (7.69)	64.67	53.67, 82.00	23	1.20 (10.45)	-1.33	-15.33, 20.33
	Placebo	20	72.30 (11.78)	71.67	54.33, 109.33	20	3.60 (14.05)	0.67	-15.67, 45.00
Month 48	Finerenone	3	62.33 (2.67)	62.33	59.67, 65.00	3	1.22 (5.58)	-2.00	-2.00, 7.67
	Placebo	5	70.67 (9.17)	68.00	63.67, 86.67	5	-2.13 (16.77)	-11.00	-17.67, 22.33
Premature discontinuation	Finerenone	11	64.15 (10.42)	61.33	51.67, 87.67	11	-1.79 (4.03)	-3.33	-7.00, 4.67
	Placebo	12	64.17 (10.89)	65.50	49.33, 92.67	12	-2.67 (9.64)	-0.83	-21.67, 8.00
End of Study Visit	Finerenone	139	71.70 (10.79)	71.00	49.00, 105.00	138	2.23 (8.94)	0.83	-15.33, 26.67
	Placebo	177	69.83 (11.34)	69.00	41.33, 99.67	177	0.58 (10.94)	0.67	-27.33, 33.00
Post Treatment Visit	Finerenone	8	66.75 (9.99)	69.50	46.00, 77.33	8	-0.71 (7.45)	-0.83	-14.67, 9.33
	Placebo	7	72.19 (19.72)	69.00	48.00, 102.67	7	1.86 (14.85)	1.00	-23.00, 23.00

N=Number of subjects included in the analysis, NE: Not estimable, Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Graphical summary of mean values of Heart Rate over time
Safety Analysis Set



Only visits with N>=5 patients in each treatment group are displayed.

BayerVital
Study 16244 - Datacut: 29JUL2020
FIDELIO-DKD HF-subpopulation - Finerenone vs. Placebo
Summary of medical history of interest
Full Analysis Set

	Finerenone (N=195)	Placebo (N=241)
	n (%)	n (%)
Atrial Fibrillation And Atrial Flutter (PBMQ)	48 (24.62)	49 (20.33)
Hyperlipidemia (MLG)	82 (42.05)	101 (41.91)
Type 2 Diabetes Mellitus (PT)	195 (100.00)	241 (100.00)
Chronic Kidney Disease (PT)	195 (100.00)	241 (100.00)
Hypertension (MLG)	191 (97.95)	236 (97.93)
Ischaemic Stroke/Transitory Ischaemic Attack (PBMQ)	38 (19.49)	56 (23.24)
Cardiac Failure (MLG)	195 (100.00)	241 (100.00)
Carotid Endarterectomy (PT)	3 (1.54)	5 (2.07)
Coronary Artery Bypass Graft (PBMQ)	30 (15.38)	34 (14.11)
Myocardial Infarction (MLG)	55 (28.21)	67 (27.80)
Percutaneous Coronary Intervention (PBMQ)	27 (13.85)	22 (9.13)
Coronary Artery Disease (PBMQ)	140 (71.79)	169 (70.12)
Peripheral Arterial Disease (PBMQ)	60 (30.77)	69 (28.63)

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Demographic and Baseline Characteristics
Full Analysis Set

Endpoint		Finerenone (N=3488)	Placebo (N=3520)
Sex, n (%)	Male	1950 (55.91)	1949 (55.37)
	Female	1538 (44.09)	1571 (44.63)
Age	n (missing)	3488 (0)	3520 (0)
	Mean (SD)	71.1 (9.76)	71.2 (9.76)
	Geo.Mean (SD)	70.3 (1.16)	70.5 (1.16)
	Median	72.0	72.0
	Q1, Q3	65.0, 78.0	65.0, 78.0
	Min, Max	35.0, 96.0	33.0, 97.0
Age group (years), n (%)	< 65 years	854 (24.48)	821 (23.32)
	65 - < 75 years	1266 (36.30)	1347 (38.27)
	75 - < 85 years	1139 (32.65)	1105 (31.39)
	>= 85 years	229 (6.57)	247 (7.02)
Pooled Race Group 01, n (%)	White	2785 (79.85)	2795 (79.40)
	Black	73 (2.09)	69 (1.96)
	Asian	530 (15.19)	544 (15.45)
	Other	100 (2.87)	112 (3.18)
Region (pooled region for subgroup analysis), n (%)	Western Europe, Oceania and Others	694 (19.90)	717 (20.37)
	Eastern Europe	1580 (45.30)	1569 (44.57)
	Asia	555 (15.91)	553 (15.71)
	North America	318 (9.12)	317 (9.01)
	Latin America	341 (9.78)	364 (10.34)
Baseline Body Mass Index (kg/m2)	n (missing)	3479 (9)	3514 (6)
	Mean (SD)	30.4 (6.28)	30.4 (6.20)
	Geo.Mean (SD)	29.7 (1.23)	29.8 (1.22)
	Median	29.5	29.6
	Q1, Q3	25.9, 34.0	25.9, 34.0
	Min, Max	15.2, 65.1	13.5, 53.7
Baseline BMI (kg/m2) category 2, n (%)	< 30 kg/m2	1817 (52.09)	1837 (52.19)
	>= 30 kg/m2	1662 (47.65)	1677 (47.64)
	Missing	9 (0.26)	6 (0.17)
Smoking History, n (%)	Never	2101 (60.24)	2139 (60.77)
	Former	1065 (30.53)	1059 (30.09)
	Current	322 (9.23)	322 (9.15)
Alcohol Use, n (%)	Abstinent	2421 (69.41)	2413 (68.55)
	Light	958 (27.47)	954 (27.10)
	Moderate	107 (3.07)	149 (4.23)
	Heavy	2 (0.06)	4 (0.11)
Baseline eGFR (mL/min/1.73m2)	n (missing)	3488 (0)	3519 (1)
	Mean (SD)	61.0 (19.81)	60.9 (20.43)
	Geo.Mean (SD)	57.7 (1.41)	57.3 (1.43)
	Median	59.8	59.3
	Q1, Q3	45.5, 75.3	44.6, 76.6
	Min, Max	18.3, 137.1	4.3, 133.2
Baseline eGFR (mL/min/1.73 m2) category, n (%)	< 60 mL/min/1.73m2	1758 (50.40)	1798 (51.08)
	>= 60 mL/min/1.73m2	1730 (49.60)	1721 (48.89)
	Missing	0 (0.00)	1 (0.03)
Baseline potassium (mmol/L)	n (missing)	3488 (0)	3519 (1)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

Endpoint		Finerenone (N=3488)	Placebo (N=3520)
Baseline potassium (mmol/L)	Mean (SD)	4.4 (0.48)	4.4 (0.47)
	Geo.Mean (SD)	4.4 (1.12)	4.3 (1.11)
	Median	4.4	4.4
	Q1, Q3	4.1, 4.7	4.1, 4.7
	Min, Max	2.6, 7.3	2.6, 7.3
Baseline serum potassium (mmol/L) category, n (%)	<= 4.5 mmol/L	2284 (65.48)	2285 (64.91)
	> 4.5 mmol/L	1204 (34.52)	1234 (35.06)
	Missing	0 (0.00)	1 (0.03)
Baseline UACR (mg/g)	n (missing)	3386 (102)	3418 (102)
	Mean (SD)	259.0 (720.37)	271.4 (731.48)
	Geo.Mean (SD)	37.0 (6.92)	38.6 (7.06)
	Median	25.0	27.0
	Q1, Q3	8.0, 142.8	8.0, 151.0
	Min, Max	0.8, 10135.0	1.0, 11451.0
Baseline albuminuria (mg/g) category, n (%)	Normalbuminuria (UACR < 30 mg/g)	1779 (51.00)	1758 (49.94)
	High albuminuria (30 mg/g - < 300 mg/g)	1009 (28.93)	1033 (29.35)
	Very high albuminuria (>= 300 mg/g)	598 (17.14)	627 (17.81)
	Missing	102 (2.92)	102 (2.90)
Baseline Hemoglobin A1C (%)	n (missing)	3436 (52)	3455 (65)
	Mean (SD)	6.7 (1.36)	6.6 (1.29)
	Geo.Mean (SD)	6.5 (1.20)	6.5 (1.19)
	Median	6.2	6.2
	Q1, Q3	5.7, 7.2	5.7, 7.2
	Min, Max	3.7, 14.5	3.9, 13.7
Baseline Diastolic Blood Pressure (mmHg)	n (missing)	3487 (1)	3519 (1)
	Mean (SD)	75.8 (10.21)	75.4 (10.36)
	Geo.Mean (SD)	75.1 (1.15)	74.7 (1.15)
	Median	76.5	75.5
	Q1, Q3	69.3, 82.5	69.0, 82.5
	Min, Max	38.5, 122.5	38.0, 119.0
Baseline Systolic Blood Pressure (mmHg)	n (missing)	3487 (1)	3519 (1)
	Mean (SD)	130.5 (15.32)	130.4 (15.39)
	Geo.Mean (SD)	129.6 (1.13)	129.4 (1.13)
	Median	131.0	130.0
	Q1, Q3	120.3, 140.5	120.0, 140.3
	Min, Max	80.5, 180.7	74.0, 181.7

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Geo.: Geometric, Min: Minimum, Max = Maximum.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=3488)	Placebo (N=3520)
Observation Duration of All-Cause Mortality in months	Number of patients in analysis	3488	3520
	Mean (SD)	30.4 (10.13)	30.2 (10.08)
	Median	32.7	32.3
	Min, Max	0.0, 59.9	0.1, 61.4
Observation Duration of CV death and HHF in months	Number of patients in analysis	3488	3520
	Mean (SD)	28.1 (11.71)	27.6 (11.95)
	Median	30.9	30.2
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of CV death or non-fatal CV event in months	Number of patients in analysis	3488	3520
	Mean (SD)	27.4 (12.05)	27.0 (12.13)
	Median	30.1	29.7
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Cardiovascular Death in months	Number of patients in analysis	3488	3520
	Mean (SD)	30.2 (10.24)	30.1 (10.15)
	Median	32.6	32.2
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis in months	Number of patients in analysis	3488	3520
	Mean (SD)	27.0 (12.37)	27.0 (12.35)
	Median	30.0	29.6
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of New onset of atrial fibrillation in months	Number of patients in analysis	1732	1791
	Mean (SD)	30.2 (10.80)	30.0 (10.76)
	Median	32.7	32.1
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to Heart Failure Hospitalization in months	Number of patients in analysis	3488	3520
	Mean (SD)	28.1 (11.71)	27.6 (11.95)
	Median	30.9	30.2
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to all-cause hospitalization in months	Number of patients in analysis	3488	3520
	Mean (SD)	21.9 (13.41)	21.3 (13.48)
	Median	22.4	21.8
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to first CV hospitalization in months	Number of patients in analysis	3488	3520
	Mean (SD)	26.2 (12.39)	25.5 (12.65)
	Median	28.9	28.1
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to first myocardial infarction (combined fatal and non-fatal) in months	Number of patients in analysis	3488	3520
	Mean (SD)	29.8 (10.59)	29.7 (10.35)
	Median	32.2	32.0
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Number of patients in analysis	3488	3520
	Mean (SD)	22.0 (13.42)	21.3 (13.48)

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Observation duration for Efficacy endpoints
Full Analysis Set

Endpoint		Finerenone (N=3488)	Placebo (N=3520)
Observation Duration of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization in months	Median	22.7	21.9
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) in months	Number of patients in analysis	3488	3520
	Mean (SD)	26.0 (12.52)	25.4 (12.69)
	Median	28.7	28.0
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to first stroke (combined fatal and non-fatal) in months	Number of patients in analysis	3488	3520
	Mean (SD)	29.7 (10.52)	29.7 (10.39)
	Median	32.0	31.9
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to initiation of dialysis or renal transplantation in months	Number of patients in analysis	3488	3520
	Mean (SD)	27.5 (12.39)	27.3 (12.32)
	Median	30.5	30.0
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks in months	Number of patients in analysis	3488	3520
	Mean (SD)	27.0 (12.37)	27.0 (12.34)
	Median	30.0	29.6
	Min, Max	0.0, 59.9	0.0, 61.4
Observation Duration of VAS in months	Number of patients in analysis	3483	3510
	Mean (SD)	26.8 (12.69)	26.7 (12.73)
	Median	30.1	29.8
	Min, Max	0.0, 59.9	0.0, 61.4
Study Duration in months	Number of patients in analysis	3488	3520
	Mean (SD)	30.9 (10.39)	30.7 (10.33)
	Median	33.2	33.0
	Min, Max	0.0, 60.9	0.0, 62.3
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks in months	Number of patients in analysis	3488	3520
	Mean (SD)	27.1 (12.38)	27.1 (12.33)
	Median	30.1	29.7
	Min, Max	0.0, 59.9	0.0, 61.4

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period is defined as time from randomization to the date of the last available date of data collection (e.g. date of lost to follow-up, date of data cut-off, date of respective event).
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Observation duration for Safety endpoints
Safety Analysis Set

Endpoint		Finerenone (N=3477)	Placebo (N=3515)
Observation Duration of Treatment Duration in months	Number of patients in analysis	3477	3515
	Mean (SD)	25.6 (12.76)	25.9 (12.66)
	Median	28.2	28.2
	Min, Max	0.0, 59.9	0.0, 61.3

Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
All-cause mortality
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	562/ 3488 (16.11)	608/ 3520 (17.27)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	50.2 (44.4, NE)	43.8 (42.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.83, 1.04)	
p-value	0.2146	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.82, 1.04)	
p-value	0.1758	

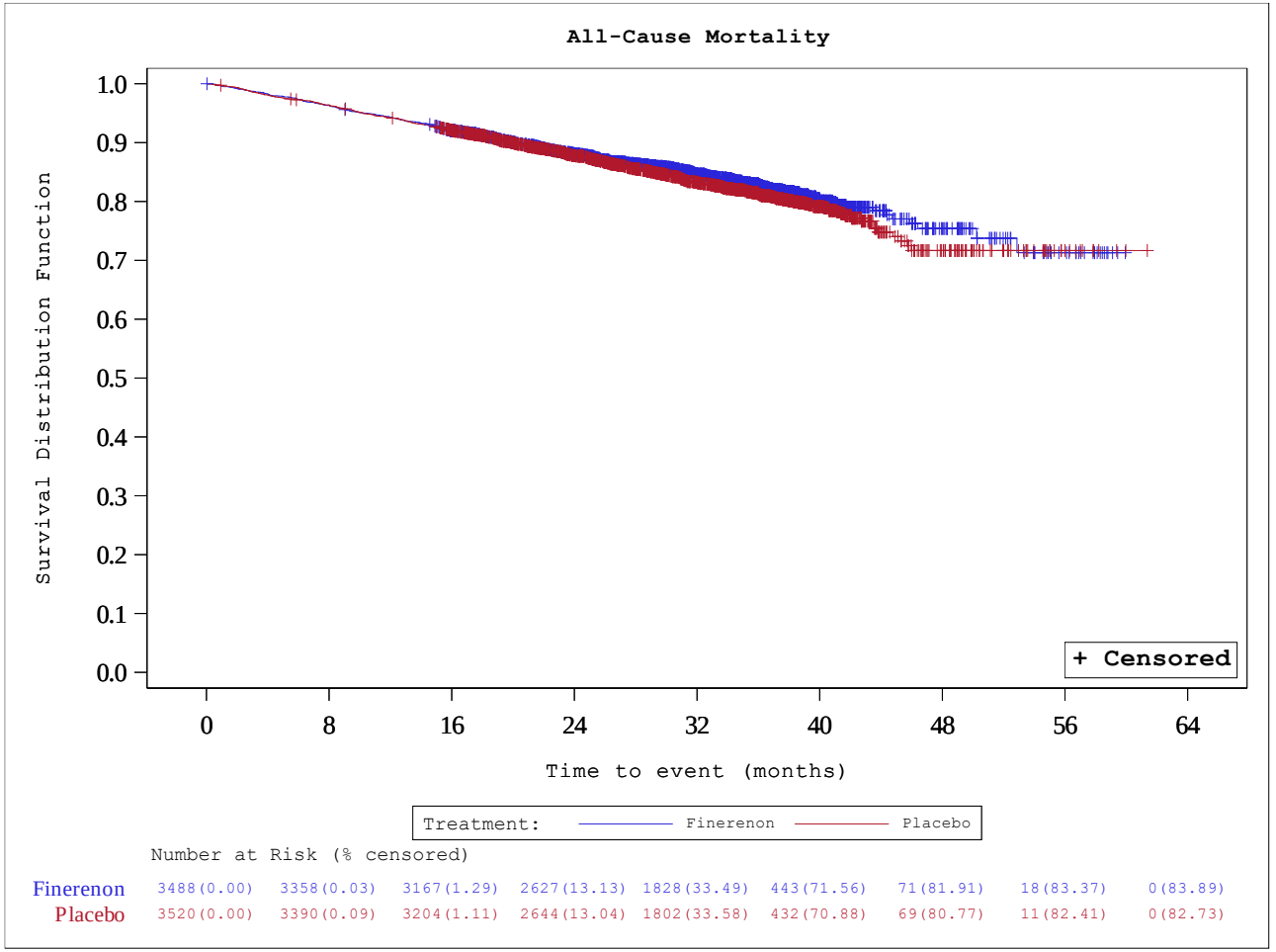
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
All-cause mortality - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5010
Male	334/ 1950 (17.13)	NE (NE, NE)	364/ 1949 (18.68)	NE (NE, NE)	0.89 (0.77, 1.03)	0.1296	
Female	228/ 1538 (14.82)	NE (NE, NE)	244/ 1571 (15.53)	NE (NE, NE)	0.97 (0.81, 1.16)	0.7245	
Region							0.4308
Western Europe, Oceania and Others	123/ 694 (17.72)	NE (52.9, NE)	129/ 717 (17.99)	NE (NE, NE)	0.98 (0.76, 1.25)	0.8441	
Eastern Europe	246/ 1580 (15.57)	NE (NE, NE)	250/ 1569 (15.93)	NE (NE, NE)	0.99 (0.83, 1.18)	0.9127	
Asia	78/ 555 (14.05)	NE (NE, NE)	94/ 553 (17.00)	NE (NE, NE)	0.80 (0.59, 1.08)	0.1500	
North America	52/ 318 (16.35)	NE (NE, NE)	68/ 317 (21.45)	NE (NE, NE)	0.70 (0.49, 1.01)	0.0556	
Latin America	63/ 341 (18.48)	NE (NE, NE)	67/ 364 (18.41)	NE (NE, NE)	1.05 (0.74, 1.48)	0.7927	
Age group (years)							0.1871
<= median in FAS	240/ 1830 (13.11)	NE (NE, NE)	237/ 1835 (12.92)	NE (NE, NE)	1.02 (0.85, 1.22)	0.8539	
> median in FAS	322/ 1658 (19.42)	NE (50.2, NE)	371/ 1685 (22.02)	NE (46.0, NE)	0.87 (0.75, 1.01)	0.0594	
Study							0.8983
FINEARTS-HF	491/ 3003 (16.35)	NE (NE, NE)	522/ 2998 (17.41)	NE (NE, NE)	0.94 (0.83, 1.06)	0.2890	
FIGARO-DKD	41/ 290 (14.14)	NE (NE, NE)	45/ 281 (16.01)	NE (NE, NE)	0.87 (0.57, 1.33)	0.5317	
FIDELIO-DKD	30/ 195 (15.38)	NE (NE, NE)	41/ 241 (17.01)	NE (NE, NE)	0.82 (0.51, 1.32)	0.4213	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of All-cause mortality
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
CV death
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	273/ 3488 (7.83)	299/ 3520 (8.49)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.92 (0.78, 1.09)	
p-value	0.3435	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.91 (0.78, 1.08)	
p-value	0.2803	

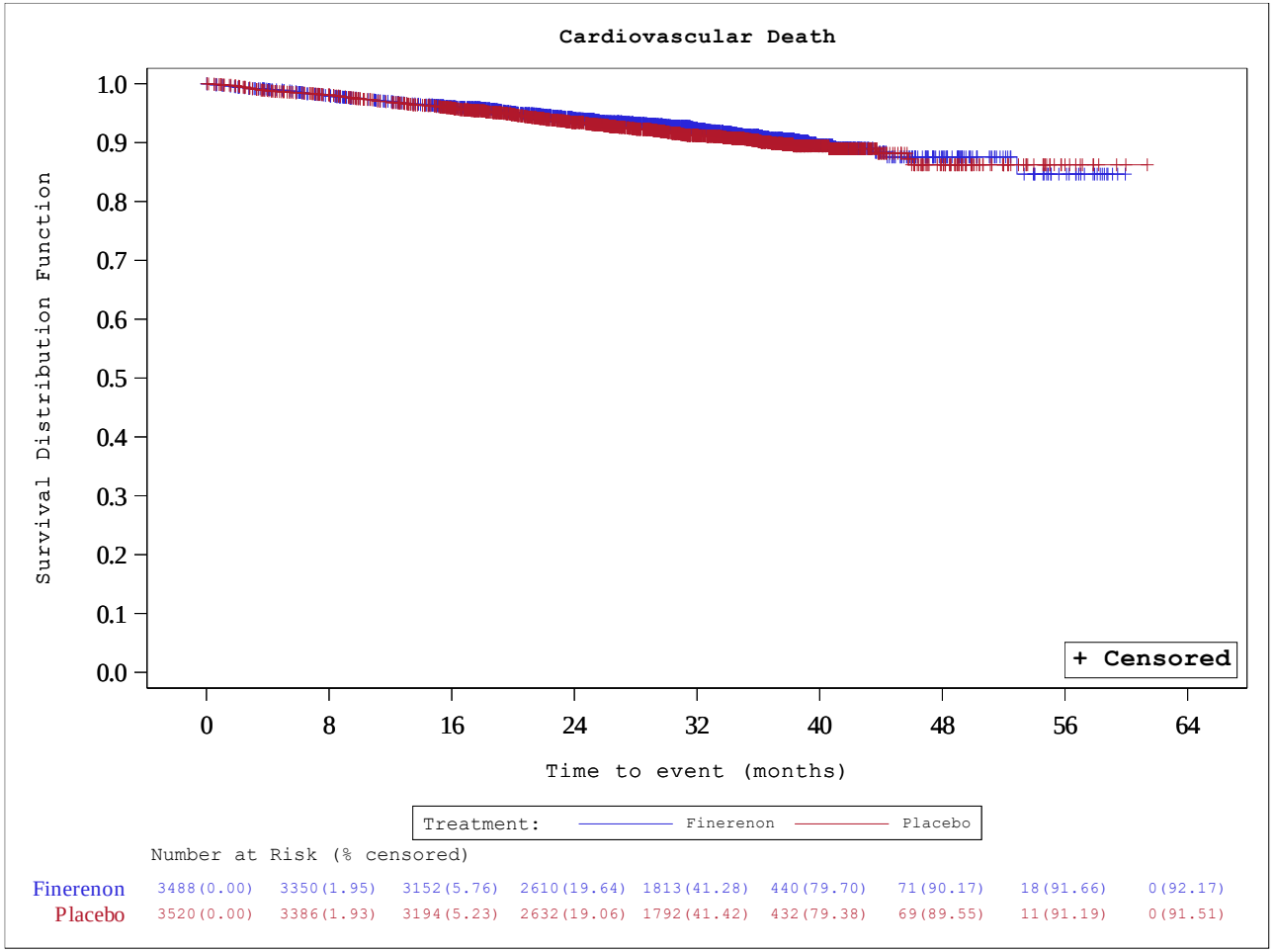
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
CV death - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.7138
Male	169/ 1950 (8.67)	NE (NE, NE)	176/ 1949 (9.03)	NE (NE, NE)	0.93 (0.75, 1.15)	0.5141	
Female	104/ 1538 (6.76)	NE (NE, NE)	123/ 1571 (7.83)	NE (NE, NE)	0.88 (0.67, 1.14)	0.3157	
Region							0.6393
Western Europe, Oceania and Others	59/ 694 (8.50)	NE (52.9, NE)	58/ 717 (8.09)	NE (NE, NE)	1.04 (0.73, 1.50)	0.8202	
Eastern Europe	126/ 1580 (7.97)	NE (NE, NE)	133/ 1569 (8.48)	NE (NE, NE)	0.95 (0.75, 1.21)	0.6871	
Asia	42/ 555 (7.57)	NE (NE, NE)	44/ 553 (7.96)	NE (NE, NE)	0.93 (0.61, 1.43)	0.7490	
North America	19/ 318 (5.97)	NE (NE, NE)	21/ 317 (6.62)	NE (NE, NE)	0.85 (0.46, 1.59)	0.6155	
Latin America	27/ 341 (7.92)	NE (NE, NE)	43/ 364 (11.81)	NE (NE, NE)	0.69 (0.43, 1.12)	0.1328	
Age group (years)							0.8513
<= median in FAS	124/ 1830 (6.78)	NE (NE, NE)	138/ 1835 (7.52)	NE (NE, NE)	0.90 (0.70, 1.14)	0.3729	
> median in FAS	149/ 1658 (8.99)	NE (52.9, NE)	161/ 1685 (9.55)	NE (NE, NE)	0.93 (0.74, 1.16)	0.5016	
Study							0.8359
FINEARTS-HF	242/ 3003 (8.06)	NE (NE, NE)	260/ 2998 (8.67)	NE (NE, NE)	0.93 (0.78, 1.10)	0.3993	
FIGARO-DKD	20/ 290 (6.90)	NE (NE, NE)	25/ 281 (8.90)	NE (NE, NE)	0.77 (0.43, 1.39)	0.3827	
FIDELIO-DKD	11/ 195 (5.64)	NE (NE, NE)	14/ 241 (5.81)	NE (NE, NE)	0.92 (0.42, 2.02)	0.8290	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of CV death
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	677/ 3488 (19.41)	775/ 3520 (22.02)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	42.2 (39.8, NE)	37.5 (34.3, 43.8)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.87 (0.78, 0.96)	
p-value	0.0078	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.87 (0.78, 0.96)	
p-value	0.0060	

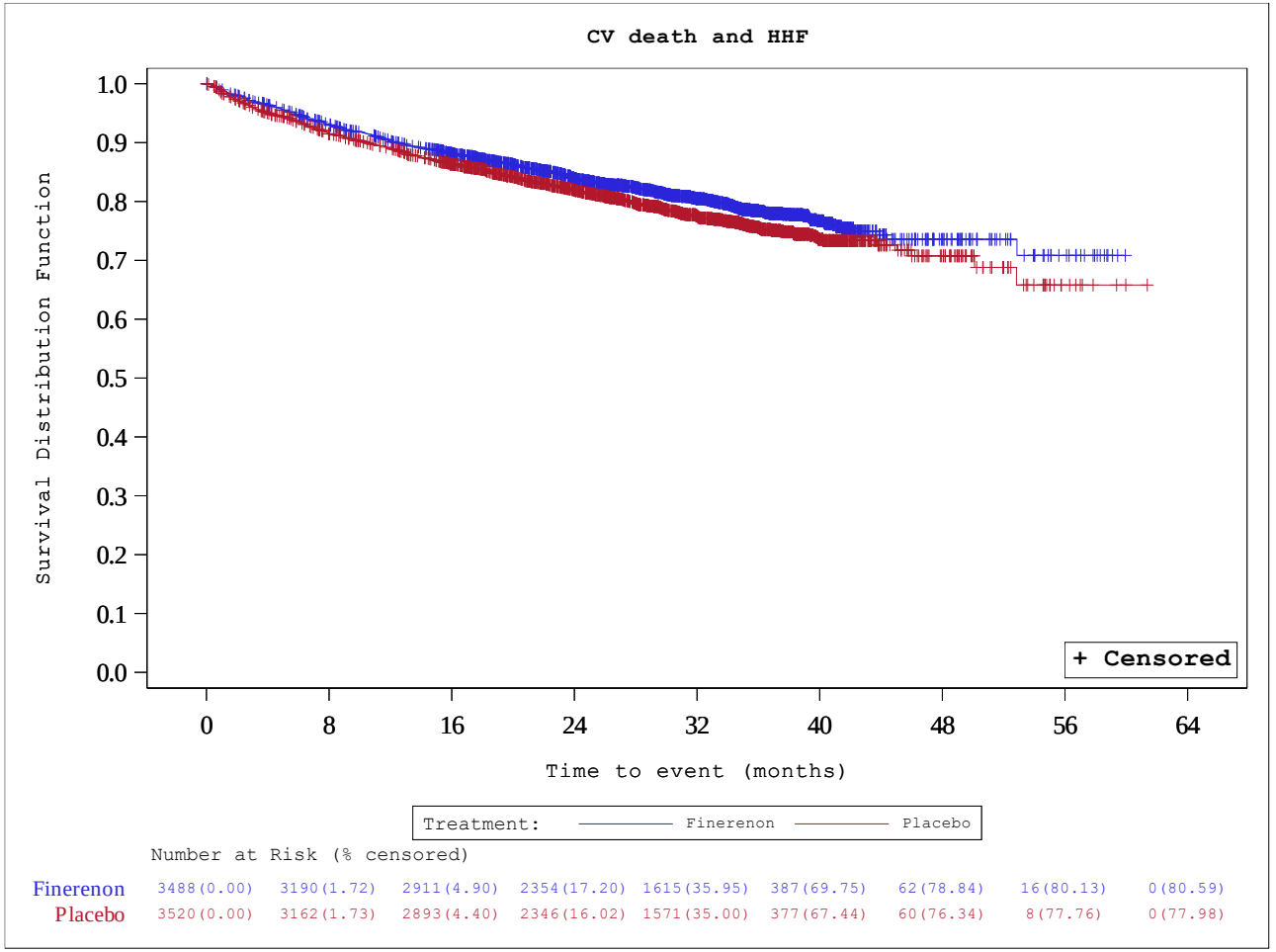
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; HHF=hospitalization for heart failure
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Composite endpoint of CV death and HF hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.9579
Male	393/ 1950 (20.15)	NE (NE, NE)	440/ 1949 (22.58)	NE (NE, NE)	0.86 (0.75, 0.99)	0.0360	
Female	284/ 1538 (18.47)	NE (NE, NE)	335/ 1571 (21.32)	NE (NE, NE)	0.87 (0.74, 1.01)	0.0717	
Region							0.4353
Western Europe, Oceania and Others	180/ 694 (25.94)	52.9 (52.9, NE)	198/ 717 (27.62)	NE (45.0, NE)	0.93 (0.76, 1.14)	0.4868	
Eastern Europe	231/ 1580 (14.62)	NE (NE, NE)	274/ 1569 (17.46)	NE (NE, NE)	0.84 (0.70, 1.00)	0.0431	
Asia	125/ 555 (22.52)	NE (NE, NE)	132/ 553 (23.87)	NE (52.8, NE)	0.93 (0.73, 1.19)	0.5499	
North America	79/ 318 (24.84)	NE (NE, NE)	78/ 317 (24.61)	NE (50.1, NE)	0.95 (0.70, 1.31)	0.7680	
Latin America	62/ 341 (18.18)	NE (NE, NE)	93/ 364 (25.55)	NE (NE, NE)	0.68 (0.49, 0.94)	0.0185	
Age group (years)							0.1417
<= median in FAS	299/ 1830 (16.34)	NE (NE, NE)	368/ 1835 (20.05)	NE (NE, NE)	0.80 (0.69, 0.93)	0.0039	
> median in FAS	378/ 1658 (22.80)	NE (52.9, NE)	407/ 1685 (24.15)	NE (52.8, NE)	0.93 (0.81, 1.07)	0.3257	
Study							0.4877
FINEARTS-HF	599/ 3003 (19.95)	NE (NE, NE)	664/ 2998 (22.15)	NE (NE, NE)	0.89 (0.79, 0.99)	0.0335	
FIGARO-DKD	46/ 290 (15.86)	NE (NE, NE)	60/ 281 (21.35)	NE (NE, NE)	0.73 (0.50, 1.07)	0.1090	
FIDELIO-DKD	32/ 195 (16.41)	NE (NE, NE)	51/ 241 (21.16)	NE (NE, NE)	0.73 (0.47, 1.14)	0.1633	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
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CV=cardiovascular; HHF=hospitalization for heart failure;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite endpoint of CV death and HF hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to Heart Failure Hospitalization
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	502/ 3488 (14.39)	597/ 3520 (16.96)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	52.8 (50.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.84 (0.74, 0.94)	
p-value	0.0031	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.83 (0.74, 0.94)	
p-value	0.0027	

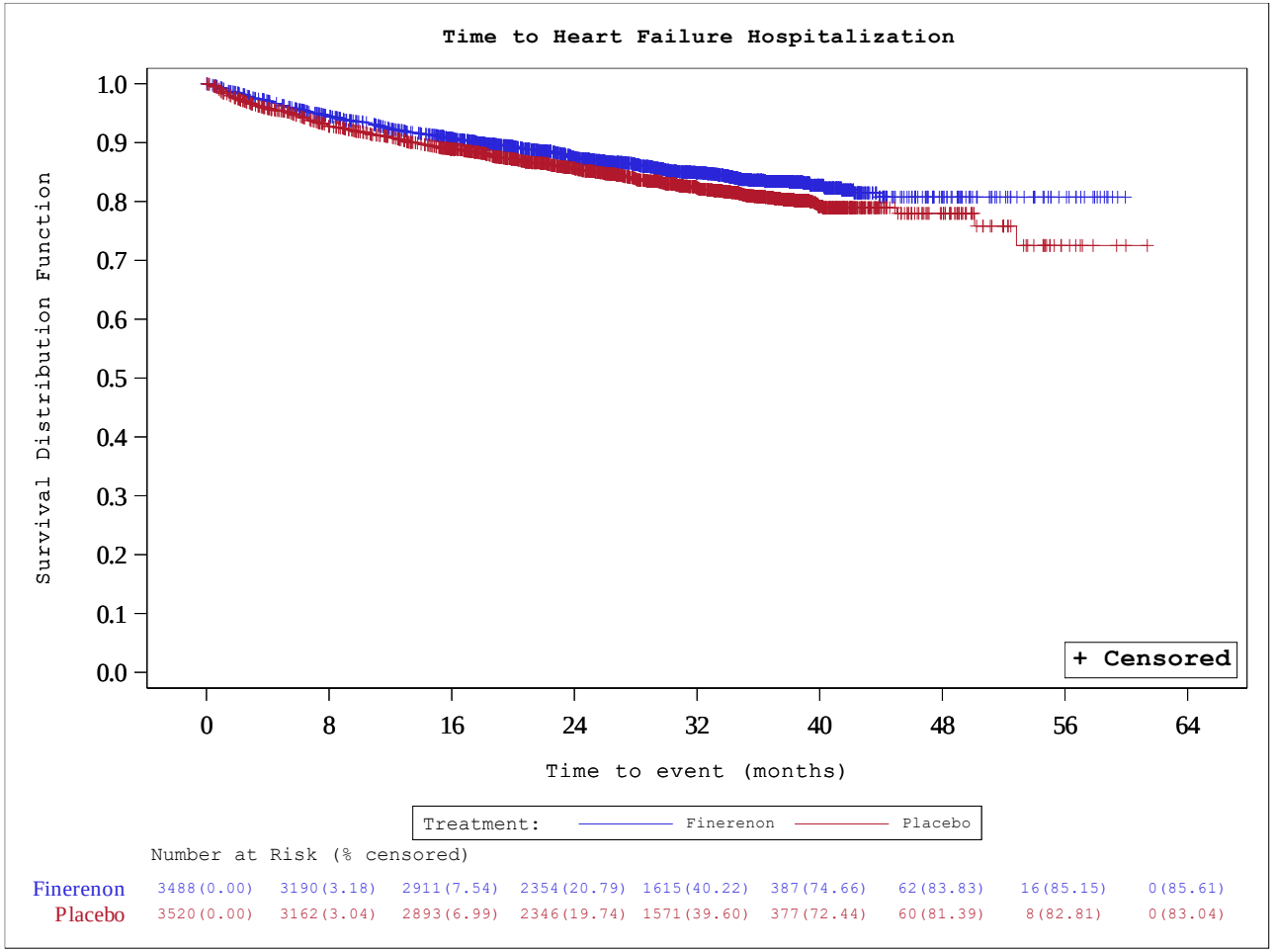
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Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to Heart Failure Hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.4469
Male	282/ 1950 (14.46)	NE (NE, NE)	341/ 1949 (17.50)	NE (NE, NE)	0.80 (0.69, 0.94)	0.0067	
Female	220/ 1538 (14.30)	NE (NE, NE)	256/ 1571 (16.30)	NE (NE, NE)	0.88 (0.73, 1.05)	0.1490	
Region							0.4026
Western Europe, Oceania and Others	150/ 694 (21.61)	NE (NE, NE)	173/ 717 (24.13)	NE (NE, NE)	0.89 (0.71, 1.10)	0.2843	
Eastern Europe	139/ 1580 (8.80)	NE (NE, NE)	186/ 1569 (11.85)	NE (NE, NE)	0.74 (0.60, 0.92)	0.0075	
Asia	100/ 555 (18.02)	NE (NE, NE)	107/ 553 (19.35)	NE (52.8, NE)	0.92 (0.70, 1.21)	0.5386	
North America	70/ 318 (22.01)	NE (NE, NE)	67/ 317 (21.14)	NE (50.1, NE)	0.99 (0.70, 1.38)	0.9358	
Latin America	43/ 341 (12.61)	NE (NE, NE)	64/ 364 (17.58)	NE (NE, NE)	0.67 (0.45, 0.99)	0.0427	
Age group (years)							0.0475
<= median in FAS	207/ 1830 (11.31)	NE (NE, NE)	279/ 1835 (15.20)	NE (NE, NE)	0.73 (0.61, 0.88)	0.0007	
> median in FAS	295/ 1658 (17.79)	NE (NE, NE)	318/ 1685 (18.87)	NE (52.8, NE)	0.93 (0.79, 1.09)	0.3742	
Study							0.3746
FINEARTS-HF	450/ 3003 (14.99)	NE (NE, NE)	514/ 2998 (17.14)	NE (NE, NE)	0.86 (0.76, 0.98)	0.0206	
FIGARO-DKD	29/ 290 (10.00)	NE (NE, NE)	42/ 281 (14.95)	NE (NE, NE)	0.66 (0.41, 1.06)	0.0819	
FIDELIO-DKD	23/ 195 (11.79)	NE (NE, NE)	41/ 241 (17.01)	NE (NE, NE)	0.66 (0.40, 1.10)	0.1087	

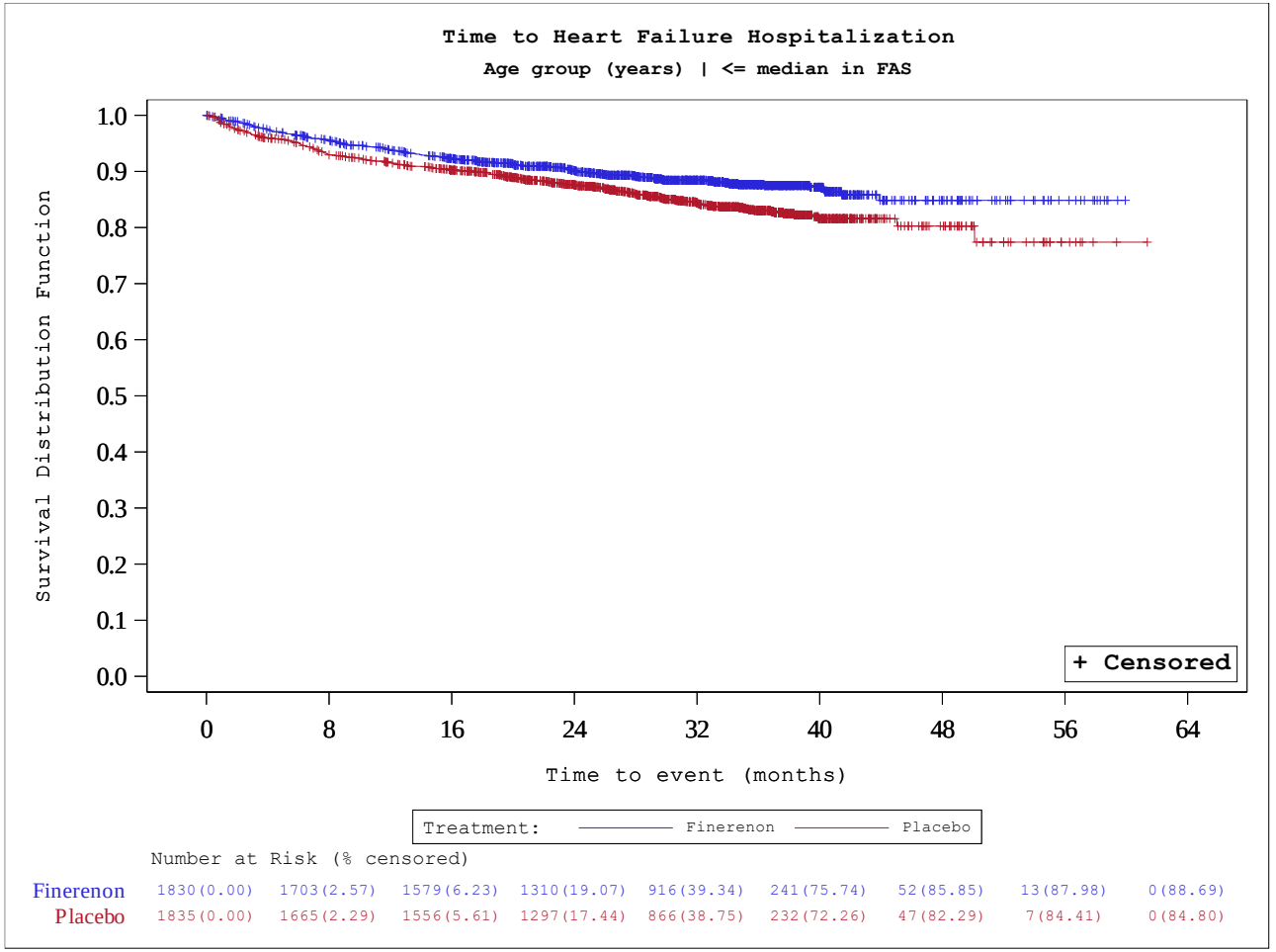
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



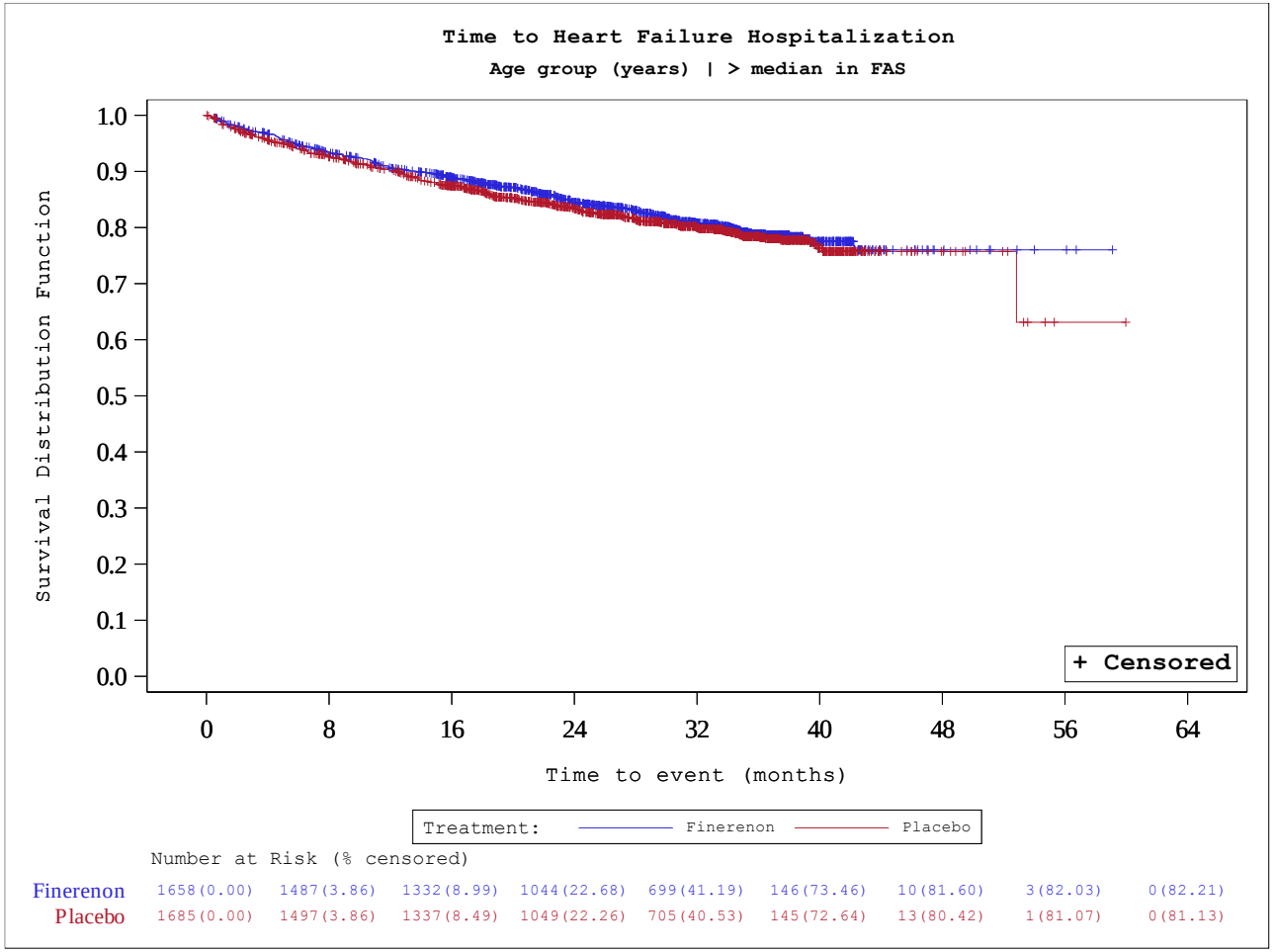
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to Heart Failure Hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	1044/ 3488 (29.93)	1158/ 3520 (32.90)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	23.8 (21.5, 25.4)	20.8 (19.1, 22.9)
Median (95% CI)	NE (52.7, NE)	52.8 (49.6, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.82, 0.97)	
p-value	0.0085	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.89 (0.82, 0.97)	
p-value	0.0065	

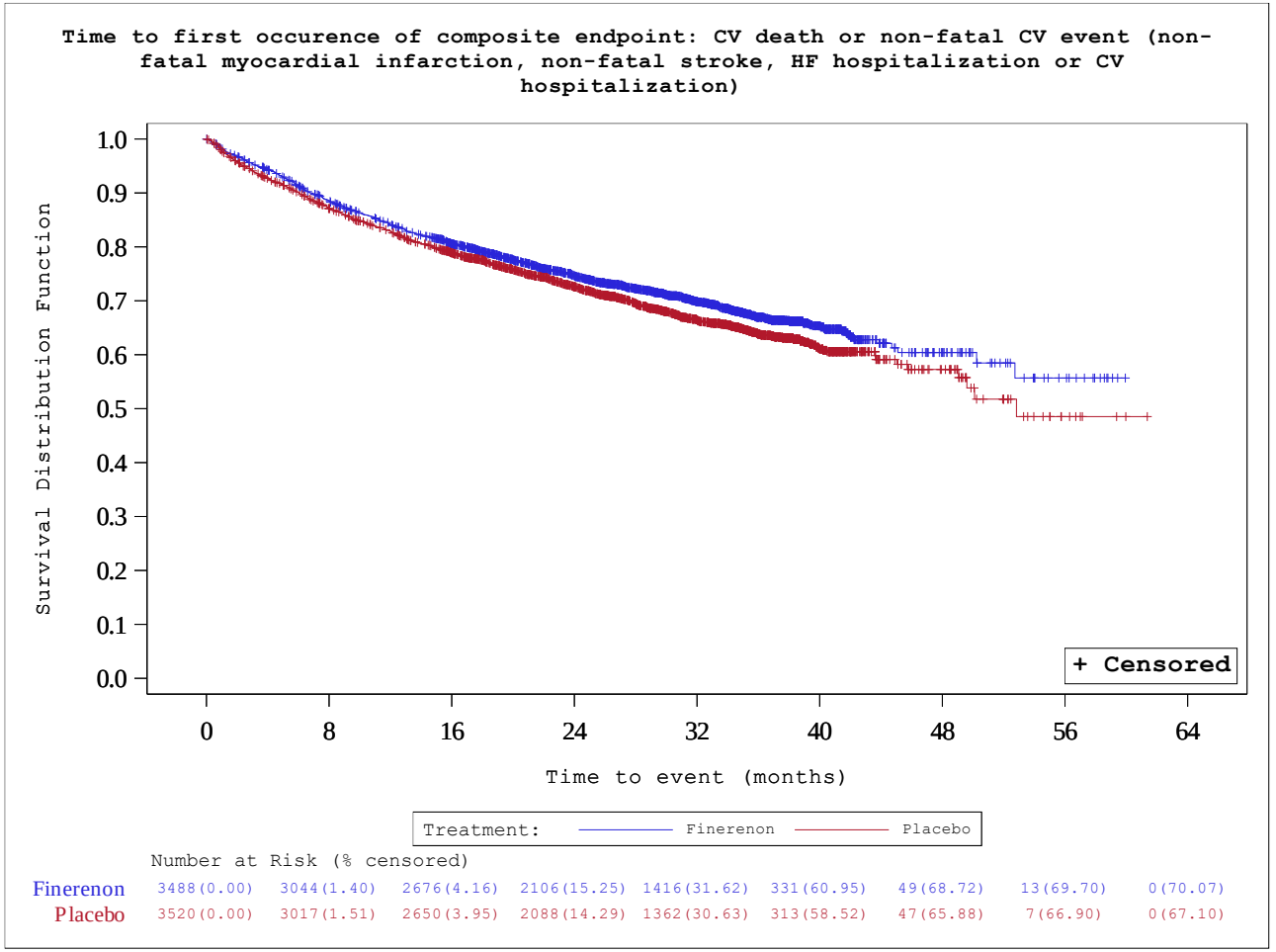
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.7128
Male	618/ 1950 (31.69)	NE (52.7, NE)	663/ 1949 (34.02)	52.8 (50.1, NE)	0.90 (0.81, 1.01)	0.0721	
Female	426/ 1538 (27.70)	NE (50.2, NE)	495/ 1571 (31.51)	NE (49.1, NE)	0.87 (0.77, 0.99)	0.0373	
Region							0.0530
Western Europe, Oceania and Others	244/ 694 (35.16)	52.7 (42.2, NE)	271/ 717 (37.80)	45.0 (40.5, NE)	0.93 (0.78, 1.11)	0.4264	
Eastern Europe	406/ 1580 (25.70)	NE (NE, NE)	436/ 1569 (27.79)	NE (NE, NE)	0.91 (0.80, 1.05)	0.1880	
Asia	190/ 555 (34.23)	NE (42.0, NE)	216/ 553 (39.06)	43.6 (39.3, NE)	0.85 (0.70, 1.03)	0.1008	
North America	125/ 318 (39.31)	41.9 (36.7, NE)	110/ 317 (34.70)	49.6 (39.0, NE)	1.11 (0.86, 1.44)	0.4123	
Latin America	79/ 341 (23.17)	NE (NE, NE)	125/ 364 (34.34)	NE (38.3, NE)	0.62 (0.47, 0.83)	0.0010	
Age group (years)							0.2094
<= median in FAS	514/ 1830 (28.09)	NE (NE, NE)	594/ 1835 (32.37)	NE (49.6, NE)	0.85 (0.75, 0.95)	0.0054	
> median in FAS	530/ 1658 (31.97)	52.7 (50.2, NE)	564/ 1685 (33.47)	49.1 (45.8, NE)	0.94 (0.84, 1.06)	0.3109	
Study							0.1773
FINEARTS-HF	885/ 3003 (29.47)	NE (NE, NE)	951/ 2998 (31.72)	NE (NE, NE)	0.92 (0.84, 1.00)	0.0591	
FIGARO-DKD	92/ 290 (31.72)	NE (52.7, NE)	120/ 281 (42.70)	49.6 (39.9, NE)	0.70 (0.53, 0.91)	0.0086	
FIDELIO-DKD	67/ 195 (34.36)	45.1 (41.7, NE)	87/ 241 (36.10)	45.0 (37.0, NE)	0.89 (0.65, 1.23)	0.4937	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: CV death or non-fatal CV event (non-fatal myocardial infarction, non-fatal stroke, HF hospitalization or CV hospitalization)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	120/ 3488 (3.44)	111/ 3520 (3.15)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.10 (0.85, 1.43)	
p-value	0.4624	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.09 (0.84, 1.41)	
p-value	0.5193	

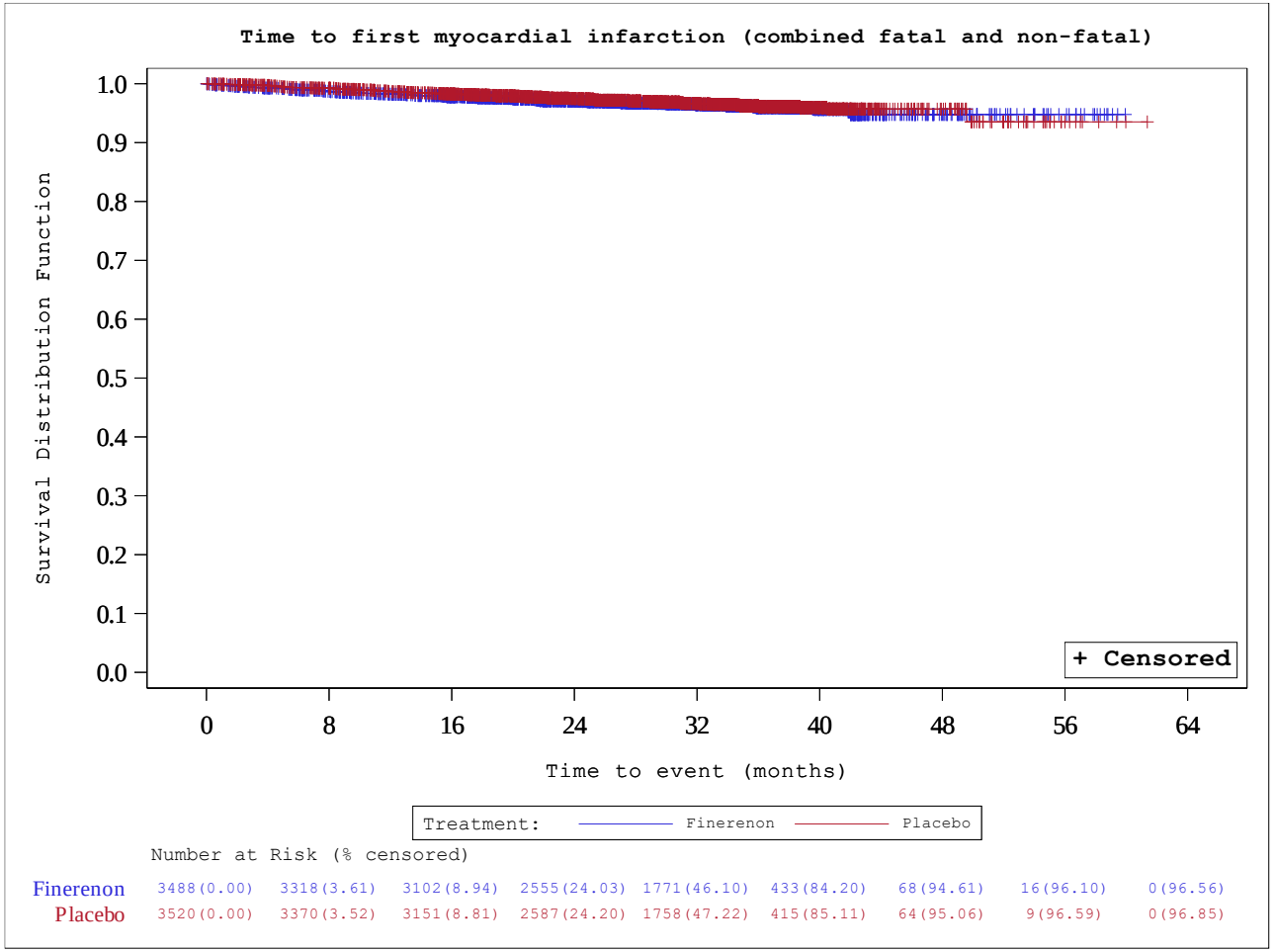
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first myocardial infarction (combined fatal and non-fatal) - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.3540
Male	84/ 1950 (4.31)	NE (NE, NE)	70/ 1949 (3.59)	NE (NE, NE)	1.18 (0.86, 1.63)	0.2949	
Female	36/ 1538 (2.34)	NE (NE, NE)	41/ 1571 (2.61)	NE (NE, NE)	0.91 (0.58, 1.43)	0.6947	
Region							0.8166
Western Europe, Oceania and Others	34/ 694 (4.90)	NE (NE, NE)	31/ 717 (4.32)	NE (NE, NE)	1.18 (0.73, 1.92)	0.5009	
Eastern Europe	33/ 1580 (2.09)	NE (NE, NE)	32/ 1569 (2.04)	NE (NE, NE)	1.03 (0.63, 1.68)	0.9025	
Asia	19/ 555 (3.42)	NE (NE, NE)	12/ 553 (2.17)	NE (NE, NE)	1.51 (0.73, 3.12)	0.2634	
North America	24/ 318 (7.55)	NE (NE, NE)	23/ 317 (7.26)	NE (NE, NE)	1.02 (0.58, 1.81)	0.9411	
Latin America	10/ 341 (2.93)	NE (NE, NE)	13/ 364 (3.57)	NE (NE, NE)	0.84 (0.37, 1.93)	0.6792	
Age group (years)							0.0492
<= median in FAS	58/ 1830 (3.17)	NE (NE, NE)	68/ 1835 (3.71)	NE (NE, NE)	0.85 (0.60, 1.21)	0.3789	
> median in FAS	62/ 1658 (3.74)	NE (NE, NE)	43/ 1685 (2.55)	NE (NE, NE)	1.44 (0.97, 2.12)	0.0673	
Study							0.3403
FINEARTS-HF	99/ 3003 (3.30)	NE (NE, NE)	82/ 2998 (2.74)	NE (NE, NE)	1.21 (0.90, 1.62)	0.2010	
FIGARO-DKD	12/ 290 (4.14)	NE (NE, NE)	16/ 281 (5.69)	NE (NE, NE)	0.71 (0.34, 1.51)	0.3770	
FIDELIO-DKD	9/ 195 (4.62)	NE (NE, NE)	13/ 241 (5.39)	NE (NE, NE)	0.78 (0.33, 1.82)	0.5575	

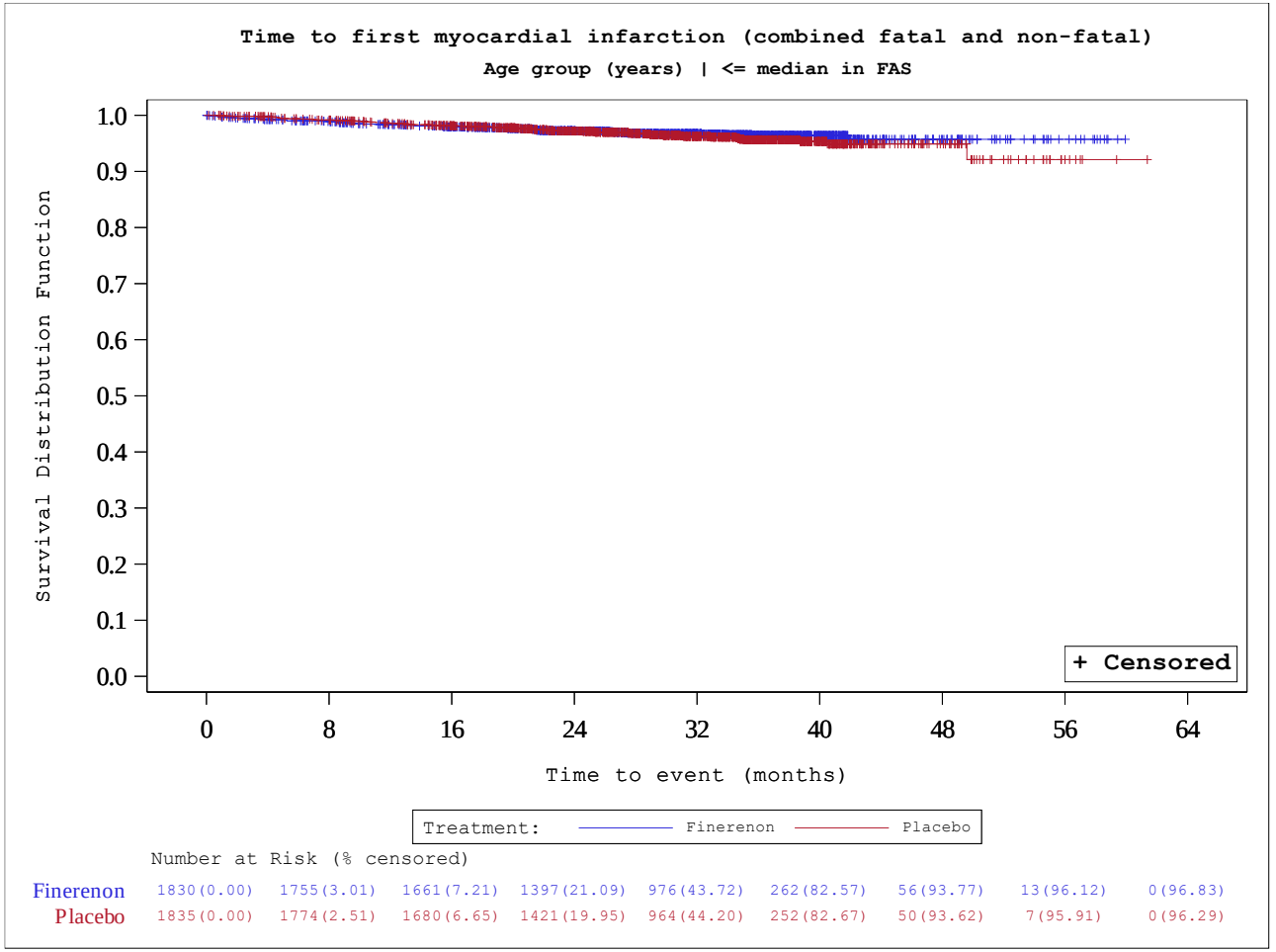
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Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



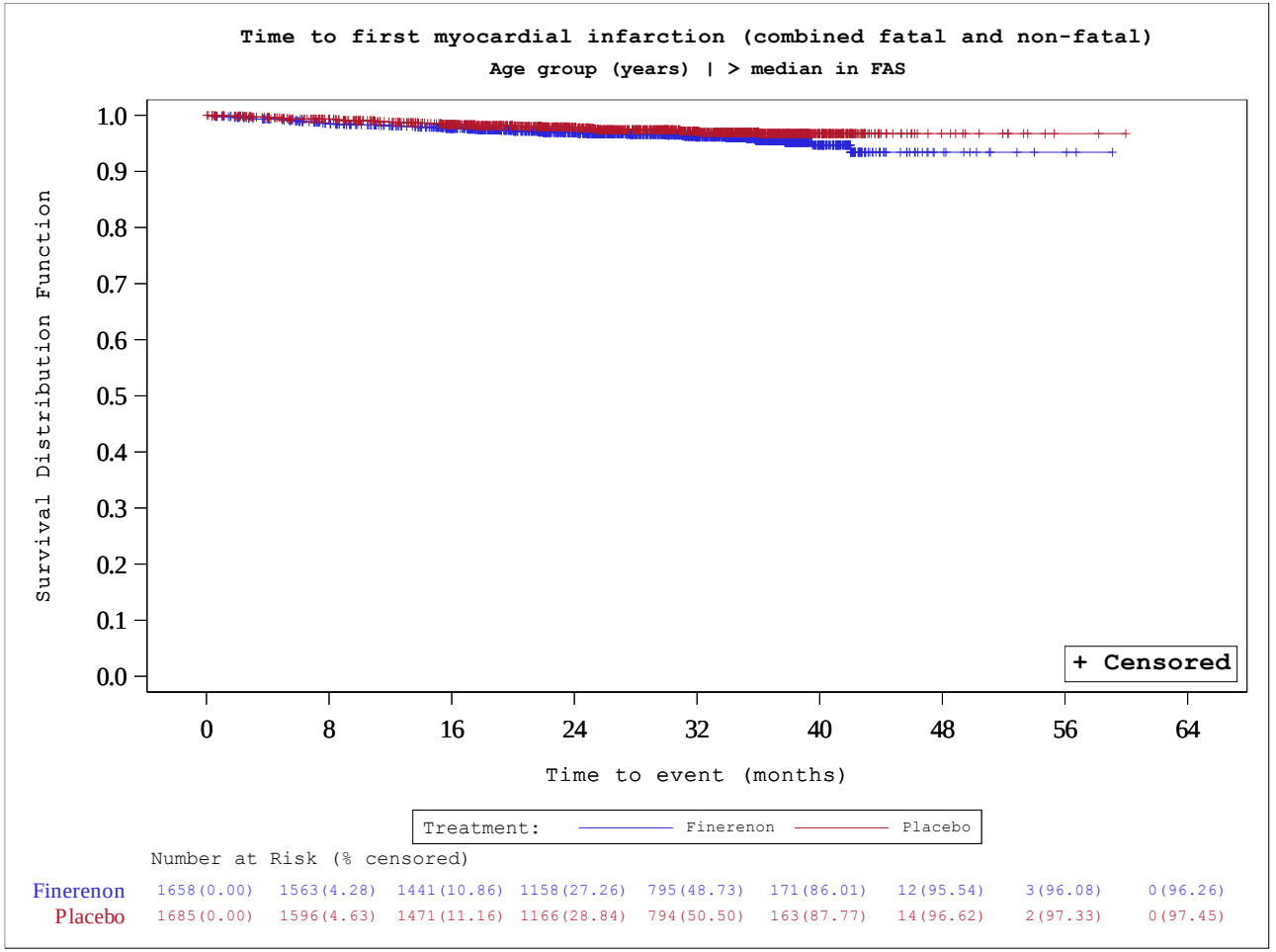
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first myocardial infarction (combined fatal and non-fatal)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal)
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	137/ 3488 (3.93)	122/ 3520 (3.47)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.13 (0.89, 1.45)	
p-value	0.3154	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.13 (0.89, 1.45)	
p-value	0.3178	

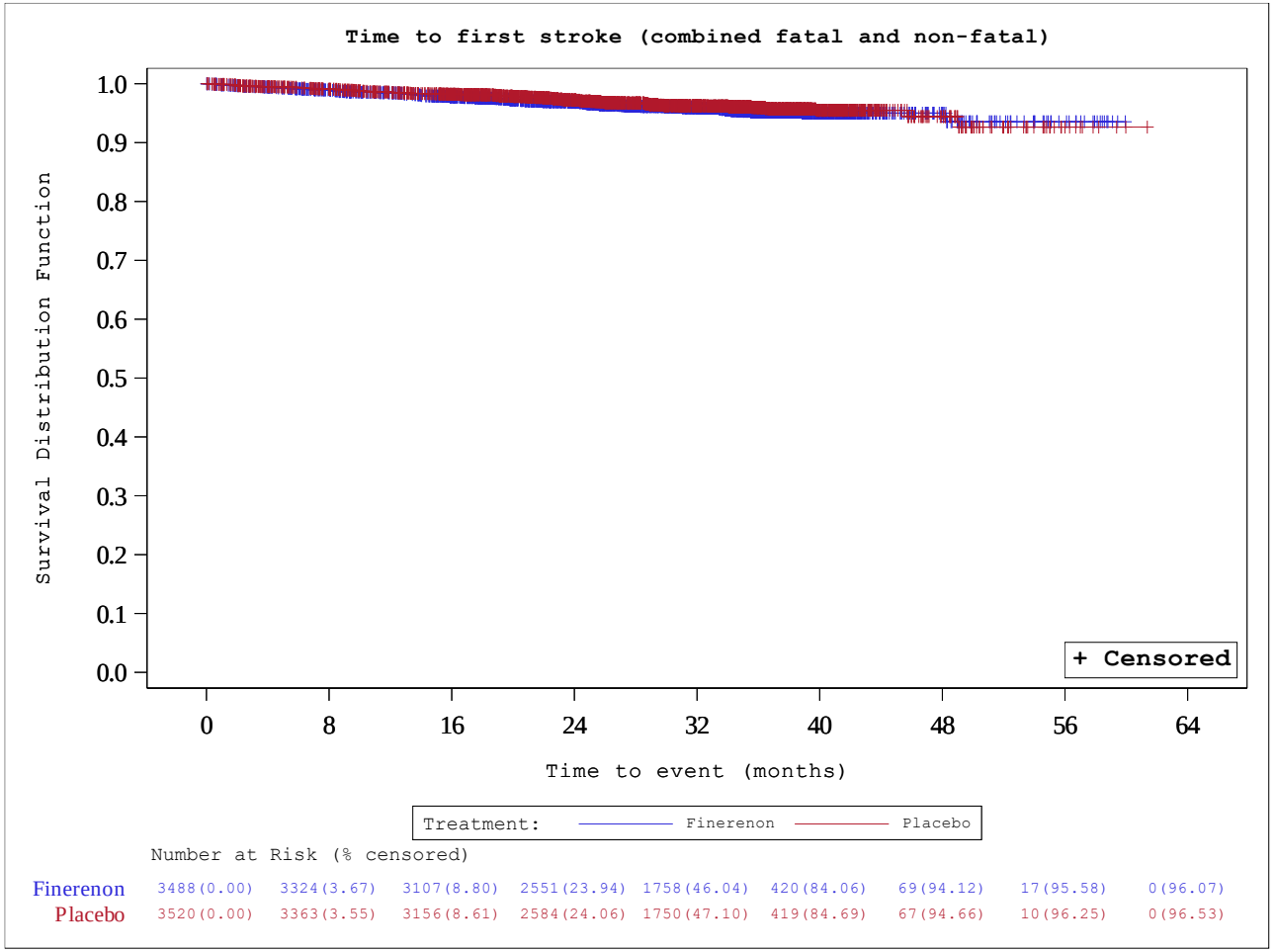
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
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Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first stroke (combined fatal and non-fatal) - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.1259
Male	80/ 1950 (4.10)	NE (NE, NE)	58/ 1949 (2.98)	NE (NE, NE)	1.36 (0.97, 1.91)	0.0717	
Female	57/ 1538 (3.71)	NE (NE, NE)	64/ 1571 (4.07)	NE (NE, NE)	0.93 (0.65, 1.33)	0.6838	
Region							0.4089
Western Europe, Oceania and Others	22/ 694 (3.17)	NE (NE, NE)	30/ 717 (4.18)	NE (NE, NE)	0.77 (0.44, 1.33)	0.3421	
Eastern Europe	67/ 1580 (4.24)	NE (NE, NE)	48/ 1569 (3.06)	NE (NE, NE)	1.40 (0.97, 2.03)	0.0718	
Asia	31/ 555 (5.59)	NE (NE, NE)	28/ 553 (5.06)	NE (NE, NE)	1.10 (0.66, 1.84)	0.7120	
North America	8/ 318 (2.52)	NE (NE, NE)	5/ 317 (1.58)	NE (NE, NE)	1.44 (0.47, 4.41)	0.5200	
Latin America	9/ 341 (2.64)	NE (NE, NE)	11/ 364 (3.02)	NE (NE, NE)	0.86 (0.35, 2.09)	0.7405	
Age group (years)							0.1734
<= median in FAS	78/ 1830 (4.26)	NE (NE, NE)	59/ 1835 (3.22)	NE (NE, NE)	1.33 (0.95, 1.87)	0.0948	
> median in FAS	59/ 1658 (3.56)	NE (NE, NE)	63/ 1685 (3.74)	NE (NE, NE)	0.95 (0.67, 1.36)	0.7876	
Study							0.8427
FINEARTS-HF	118/ 3003 (3.93)	NE (NE, NE)	107/ 2998 (3.57)	NE (NE, NE)	1.10 (0.85, 1.43)	0.4589	
FIGARO-DKD	12/ 290 (4.14)	NE (NE, NE)	8/ 281 (2.85)	NE (NE, NE)	1.44 (0.59, 3.52)	0.4225	
FIDELIO-DKD	7/ 195 (3.59)	NE (NE, NE)	7/ 241 (2.90)	NE (NE, NE)	1.22 (0.43, 3.47)	0.7119	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first stroke (combined fatal and non-fatal)
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first CV hospitalization
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	892/ 3488 (25.57)	1003/ 3520 (28.49)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	29.2 (26.2, 32.3)	24.6 (22.6, 27.5)
Median (95% CI)	NE (NE, NE)	NE (52.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.88 (0.80, 0.96)	
p-value	0.0056	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.88 (0.80, 0.96)	
p-value	0.0042	

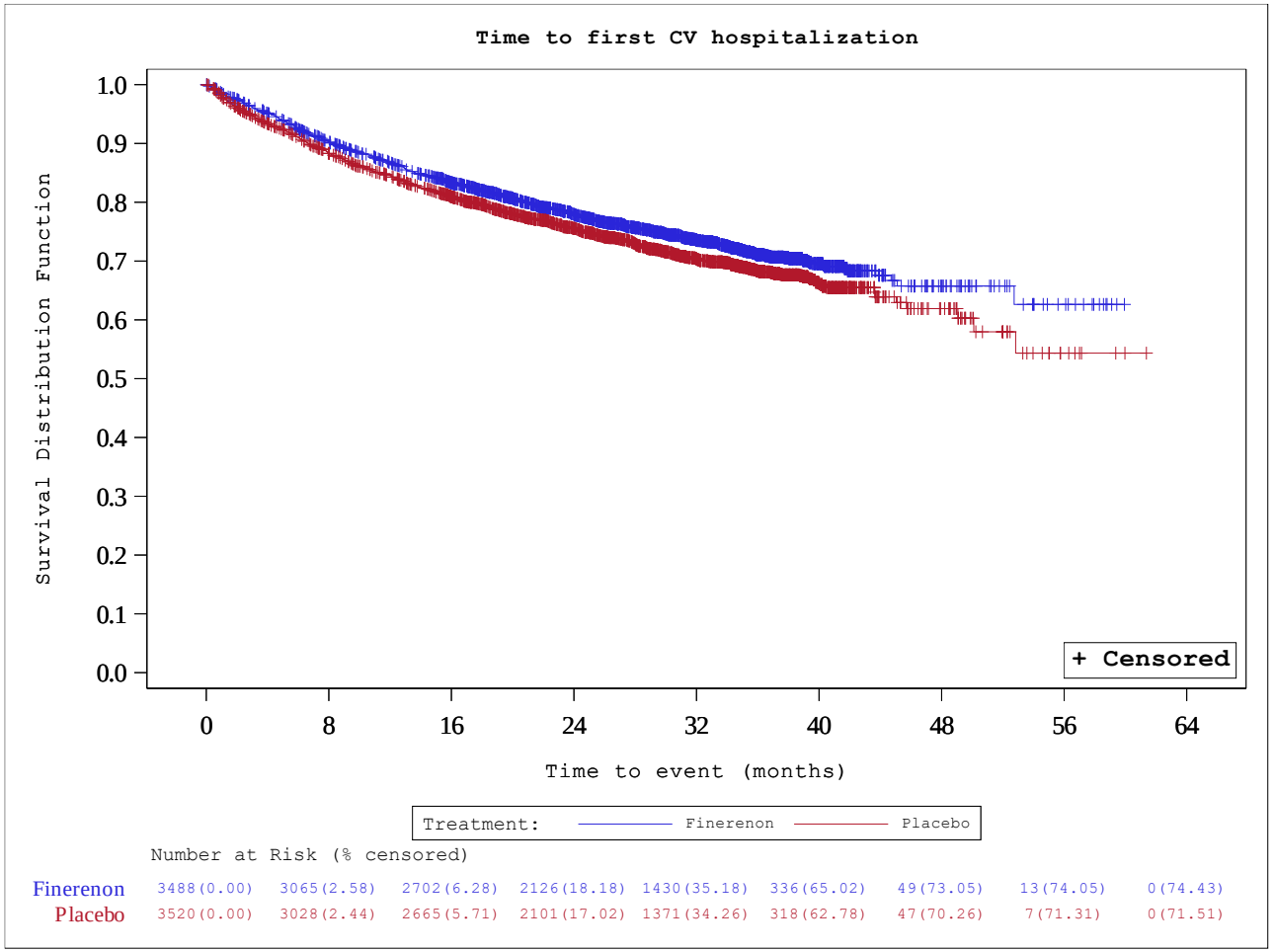
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
CV=cardiovascular; Urgent HF visits per investigator not included as events in dossier analyses of CV hospitalization for FINEARTS-HF.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first CV hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.7249
Male	525/ 1950 (26.92)	NE (NE, NE)	571/ 1949 (29.30)	NE (50.1, NE)	0.89 (0.79, 1.00)	0.0563	
Female	367/ 1538 (23.86)	NE (NE, NE)	432/ 1571 (27.50)	NE (NE, NE)	0.86 (0.75, 0.98)	0.0292	
Region							0.1939
Western Europe, Oceania and Others	219/ 694 (31.56)	52.7 (52.7, NE)	248/ 717 (34.59)	45.0 (43.7, NE)	0.91 (0.76, 1.09)	0.3114	
Eastern Europe	334/ 1580 (21.14)	NE (NE, NE)	367/ 1569 (23.39)	NE (NE, NE)	0.89 (0.77, 1.03)	0.1283	
Asia	161/ 555 (29.01)	NE (NE, NE)	188/ 553 (34.00)	52.8 (43.6, NE)	0.82 (0.67, 1.01)	0.0675	
North America	111/ 318 (34.91)	44.7 (41.9, NE)	99/ 317 (31.23)	50.1 (39.6, NE)	1.09 (0.83, 1.44)	0.5167	
Latin America	67/ 341 (19.65)	NE (NE, NE)	101/ 364 (27.75)	NE (NE, NE)	0.66 (0.49, 0.90)	0.0091	
Age group (years)							0.2416
<= median in FAS	439/ 1830 (23.99)	NE (NE, NE)	516/ 1835 (28.12)	NE (NE, NE)	0.83 (0.73, 0.94)	0.0045	
> median in FAS	453/ 1658 (27.32)	NE (52.7, NE)	487/ 1685 (28.90)	52.8 (49.1, NE)	0.93 (0.82, 1.05)	0.2434	
Study							0.2842
FINEARTS-HF	754/ 3003 (25.11)	NE (NE, NE)	819/ 2998 (27.32)	NE (NE, NE)	0.90 (0.82, 1.00)	0.0417	
FIGARO-DKD	82/ 290 (28.28)	NE (NE, NE)	106/ 281 (37.72)	NE (49.1, NE)	0.71 (0.53, 0.94)	0.0170	
FIDELIO-DKD	56/ 195 (28.72)	NE (45.1, NE)	78/ 241 (32.37)	NE (39.8, NE)	0.84 (0.60, 1.19)	0.3319	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
CV=cardiovascular;Urgent HF visits per investigator not included as events in dossier analyses of CV hospitalization for FINEARTS-HF.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first CV hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to new onset of atrial fibrillation
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	100/ 1732 (5.77)	134/ 1791 (7.48)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.77 (0.59, 0.99)	
p-value	0.0433	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.77 (0.59, 0.99)	
p-value	0.0436	

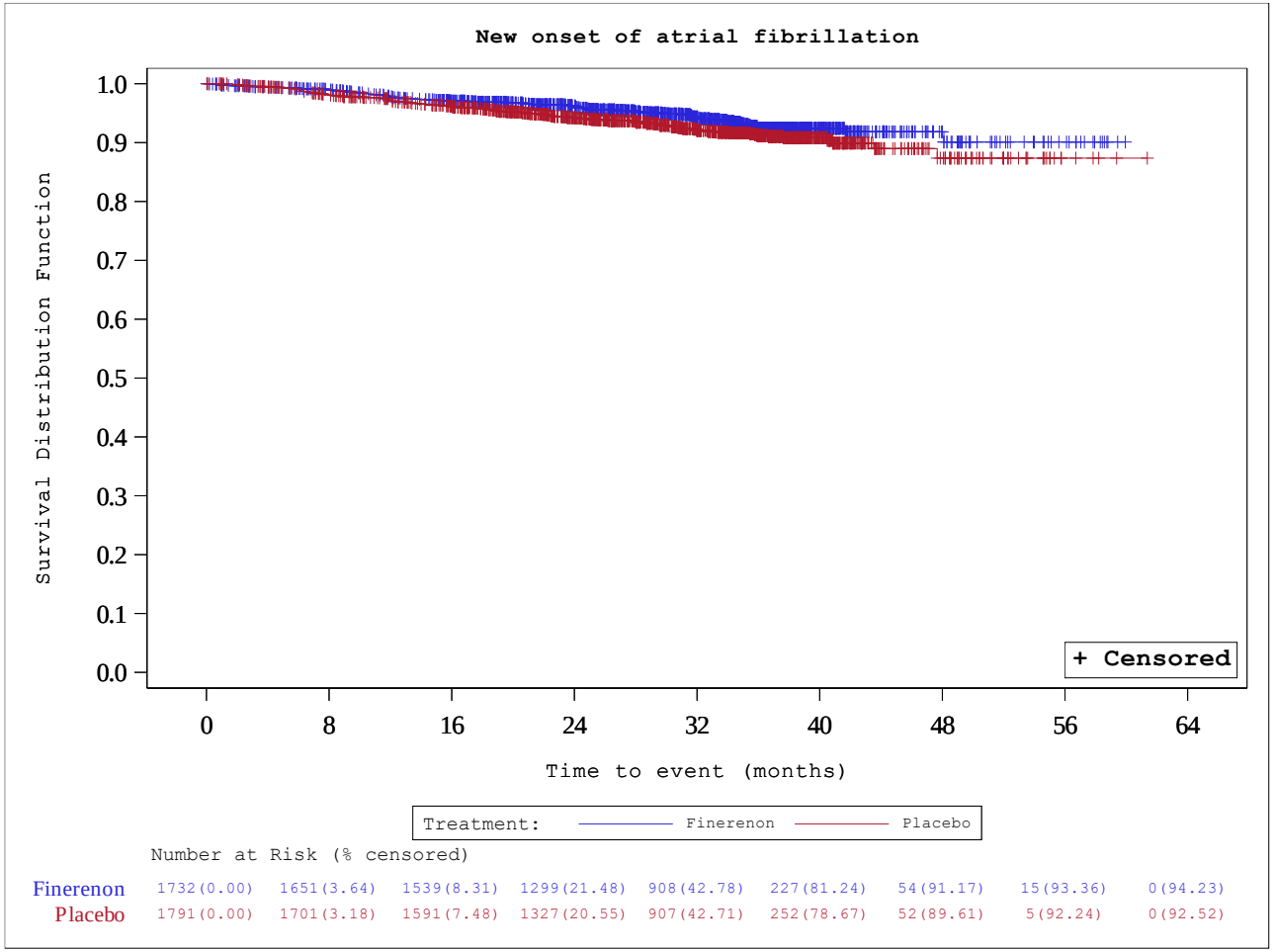
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Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to new onset of atrial fibrillation - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.3107
Male	55/ 993 (5.54)	NE (NE, NE)	80/ 1014 (7.89)	NE (NE, NE)	0.68 (0.49, 0.96)	0.0295	
Female	45/ 739 (6.09)	NE (NE, NE)	54/ 777 (6.95)	NE (NE, NE)	0.89 (0.60, 1.32)	0.5660	
Region							0.4701
Western Europe, Oceania and Others	22/ 243 (9.05)	NE (NE, NE)	38/ 252 (15.08)	NE (NE, NE)	0.60 (0.36, 1.02)	0.0578	
Eastern Europe	49/ 822 (5.96)	NE (NE, NE)	50/ 825 (6.06)	NE (NE, NE)	1.01 (0.68, 1.49)	0.9708	
Asia	11/ 281 (3.91)	NE (NE, NE)	16/ 285 (5.61)	NE (NE, NE)	0.71 (0.33, 1.52)	0.3734	
North America	12/ 171 (7.02)	NE (NE, NE)	15/ 168 (8.93)	NE (NE, NE)	0.72 (0.34, 1.54)	0.3965	
Latin America	6/ 215 (2.79)	NE (NE, NE)	15/ 261 (5.75)	NE (NE, NE)	0.46 (0.18, 1.18)	0.0985	
Age group (years)							0.9818
<= median in FAS	53/ 1109 (4.78)	NE (NE, NE)	69/ 1123 (6.14)	NE (NE, NE)	0.77 (0.54, 1.10)	0.1532	
> median in FAS	47/ 623 (7.54)	NE (NE, NE)	65/ 668 (9.73)	NE (47.7, NE)	0.78 (0.54, 1.14)	0.1929	
Study							0.6721
FINEARTS-HF	76/ 1355 (5.61)	NE (NE, NE)	99/ 1373 (7.21)	NE (NE, NE)	0.78 (0.58, 1.05)	0.0973	
FIGARO-DKD	15/ 230 (6.52)	NE (NE, NE)	16/ 226 (7.08)	NE (NE, NE)	0.92 (0.45, 1.86)	0.8139	
FIDELIO-DKD	9/ 147 (6.12)	NE (NE, NE)	19/ 192 (9.90)	NE (NE, NE)	0.56 (0.25, 1.24)	0.1487	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to new onset of atrial fibrillation
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	67/ 3488 (1.92)	68/ 3520 (1.93)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	57.8 (56.8, NE)
Median (95% CI)	NE (NE, NE)	NE (56.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (57.8, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.07 (0.76, 1.51)	
p-value	0.6924	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.05 (0.75, 1.47)	
p-value	0.7755	

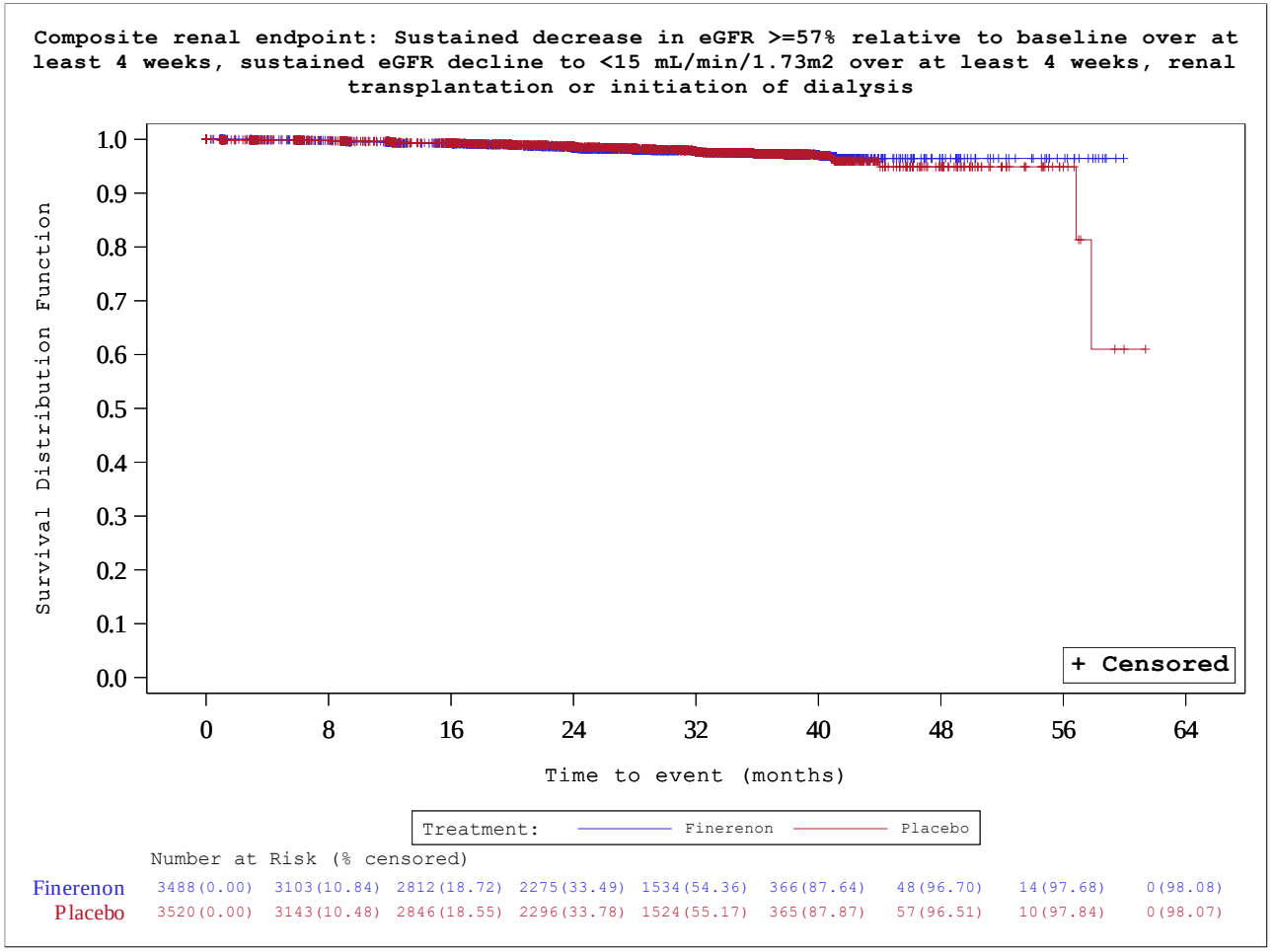
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.0195
Male	48/ 1950 (2.46)	NE (NE, NE)	36/ 1949 (1.85)	NE (56.8, NE)	1.45 (0.94, 2.23)	0.0925	
Female	19/ 1538 (1.24)	NE (NE, NE)	32/ 1571 (2.04)	57.8 (57.8, NE)	0.63 (0.35, 1.11)	0.1032	
Region							0.3632
Western Europe, Oceania and Others	15/ 694 (2.16)	NE (NE, NE)	14/ 717 (1.95)	NE (NE, NE)	1.28 (0.62, 2.67)	0.5017	
Eastern Europe	17/ 1580 (1.08)	NE (NE, NE)	24/ 1569 (1.53)	NE (NE, NE)	0.80 (0.43, 1.50)	0.4929	
Asia	15/ 555 (2.70)	NE (NE, NE)	13/ 553 (2.35)	56.8 (56.8, NE)	1.00 (0.47, 2.10)	0.9952	
North America	9/ 318 (2.83)	NE (NE, NE)	11/ 317 (3.47)	NE (57.8, NE)	0.82 (0.34, 1.99)	0.6531	
Latin America	11/ 341 (3.23)	NE (NE, NE)	6/ 364 (1.65)	NE (NE, NE)	2.60 (0.92, 7.36)	0.0644	
Age group (years)							0.8259
<= median in FAS	41/ 1830 (2.24)	NE (NE, NE)	44/ 1835 (2.40)	NE (57.8, NE)	1.04 (0.68, 1.59)	0.8651	
> median in FAS	26/ 1658 (1.57)	NE (NE, NE)	24/ 1685 (1.42)	56.8 (56.8, NE)	1.13 (0.64, 1.98)	0.6761	
Study							0.3841
FINEARTS-HF	41/ 3003 (1.37)	NE (NE, NE)	31/ 2998 (1.03)	NE (NE, NE)	1.30 (0.82, 2.08)	0.2646	
FIGARO-DKD	5/ 290 (1.72)	NE (NE, NE)	6/ 281 (2.14)	NE (56.8, NE)	0.79 (0.24, 2.62)	0.7014	
FIDELIO-DKD	21/ 195 (10.77)	NE (NE, NE)	31/ 241 (12.86)	NE (NE, NE)	0.82 (0.47, 1.44)	0.4941	

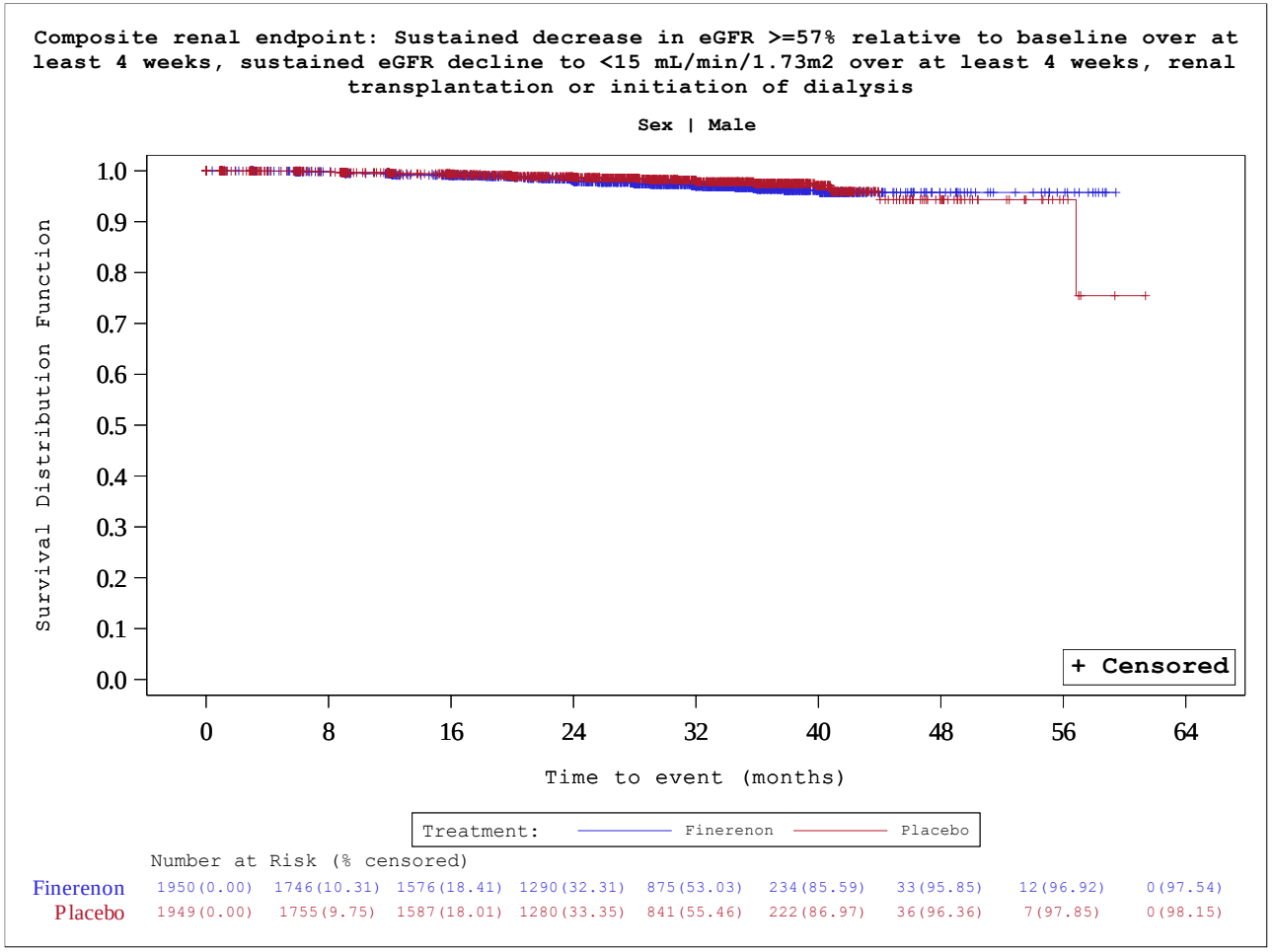
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Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



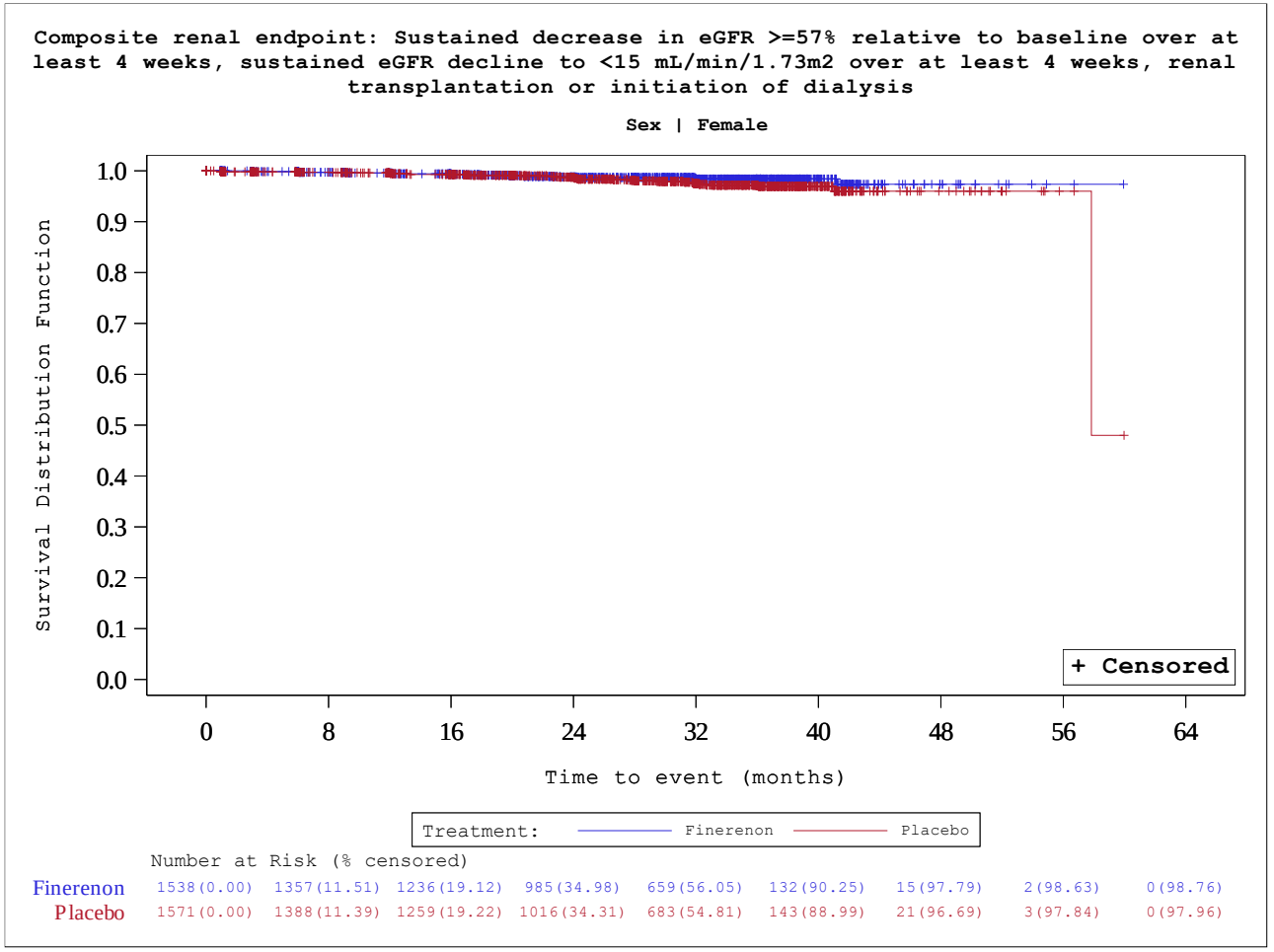
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Composite renal endpoint: Sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks, sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks, renal transplantation or initiation of dialysis
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	50/ 3488 (1.43)	51/ 3520 (1.45)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	57.8 (57.8, NE)
Median (95% CI)	NE (NE, NE)	NE (57.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (57.8, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.06 (0.72, 1.58)	
p-value	0.7598	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.03 (0.69, 1.52)	
p-value	0.8941	

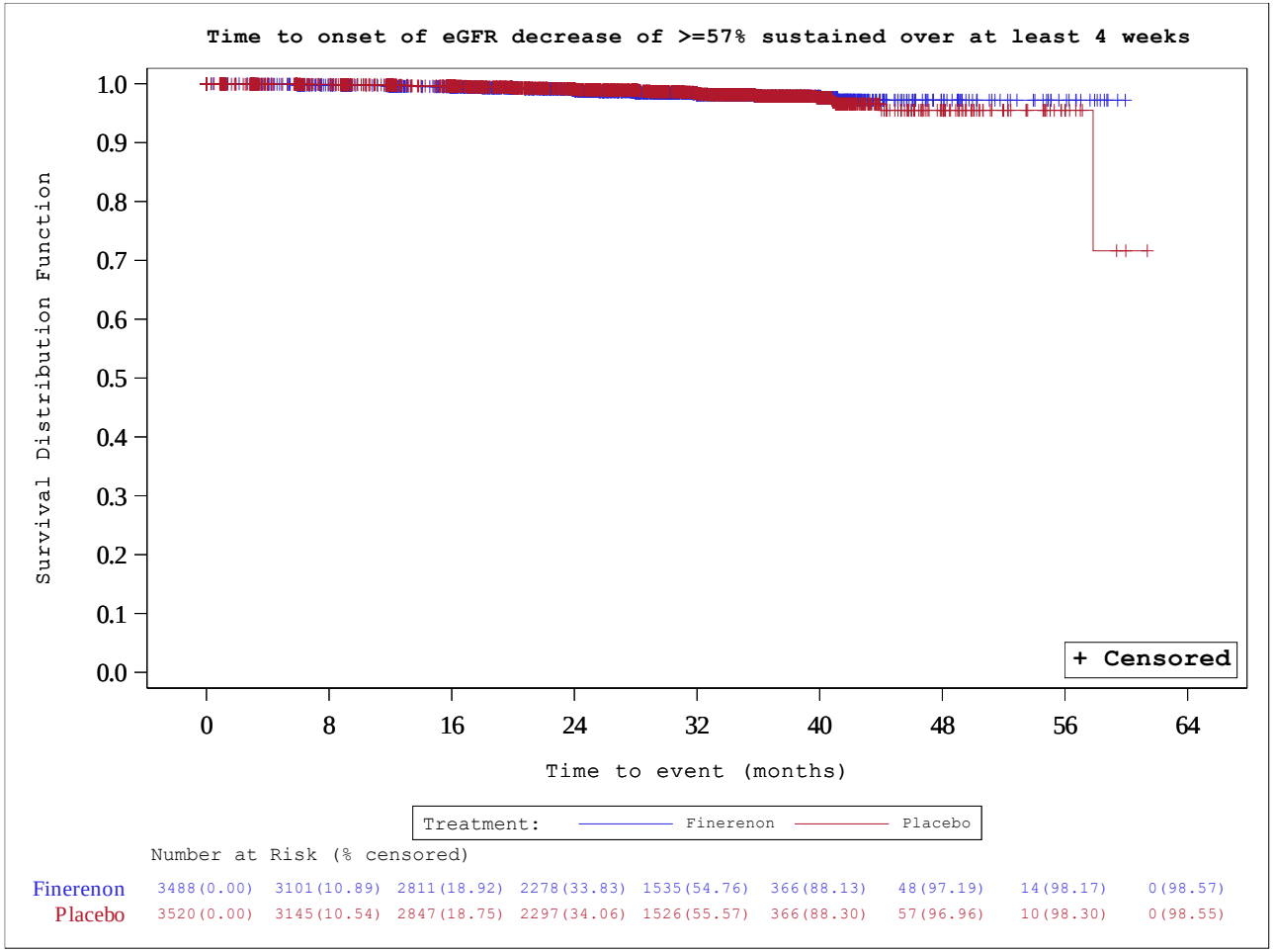
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.1104
Male	33/ 1950 (1.69)	NE (NE, NE)	26/ 1949 (1.33)	NE (NE, NE)	1.35 (0.81, 2.26)	0.2495	
Female	17/ 1538 (1.11)	NE (NE, NE)	25/ 1571 (1.59)	57.8 (57.8, NE)	0.72 (0.39, 1.33)	0.2899	
Region							0.5154
Western Europe, Oceania and Others	8/ 694 (1.15)	NE (NE, NE)	12/ 717 (1.67)	NE (NE, NE)	0.80 (0.33, 1.96)	0.6248	
Eastern Europe	15/ 1580 (0.95)	NE (NE, NE)	18/ 1569 (1.15)	NE (NE, NE)	0.93 (0.46, 1.85)	0.8307	
Asia	12/ 555 (2.16)	NE (NE, NE)	8/ 553 (1.45)	NE (NE, NE)	1.37 (0.56, 3.37)	0.4855	
North America	7/ 318 (2.20)	NE (NE, NE)	9/ 317 (2.84)	NE (57.8, NE)	0.79 (0.29, 2.14)	0.6429	
Latin America	8/ 341 (2.35)	NE (NE, NE)	4/ 364 (1.10)	NE (NE, NE)	2.57 (0.74, 8.92)	0.1254	
Age group (years)							0.7303
<= median in FAS	30/ 1830 (1.64)	NE (NE, NE)	33/ 1835 (1.80)	NE (57.8, NE)	0.97 (0.59, 1.60)	0.9195	
> median in FAS	20/ 1658 (1.21)	NE (NE, NE)	18/ 1685 (1.07)	NE (NE, NE)	1.09 (0.57, 2.06)	0.7963	
Study							0.2682
FINEARTS-HF	35/ 3003 (1.17)	NE (NE, NE)	26/ 2998 (0.87)	NE (NE, NE)	1.32 (0.80, 2.20)	0.2773	
FIGARO-DKD	3/ 290 (1.03)	NE (NE, NE)	5/ 281 (1.78)	NE (57.8, NE)	0.58 (0.14, 2.46)	0.4555	
FIDELIO-DKD	12/ 195 (6.15)	NE (NE, NE)	20/ 241 (8.30)	NE (NE, NE)	0.72 (0.35, 1.48)	0.3684	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained decrease in eGFR >=57% relative to baseline over at least 4 weeks
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	35/ 3488 (1.00)	29/ 3520 (0.82)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.34 (0.81, 2.20)	
p-value	0.2510	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	1.31 (0.80, 2.15)	
p-value	0.2772	

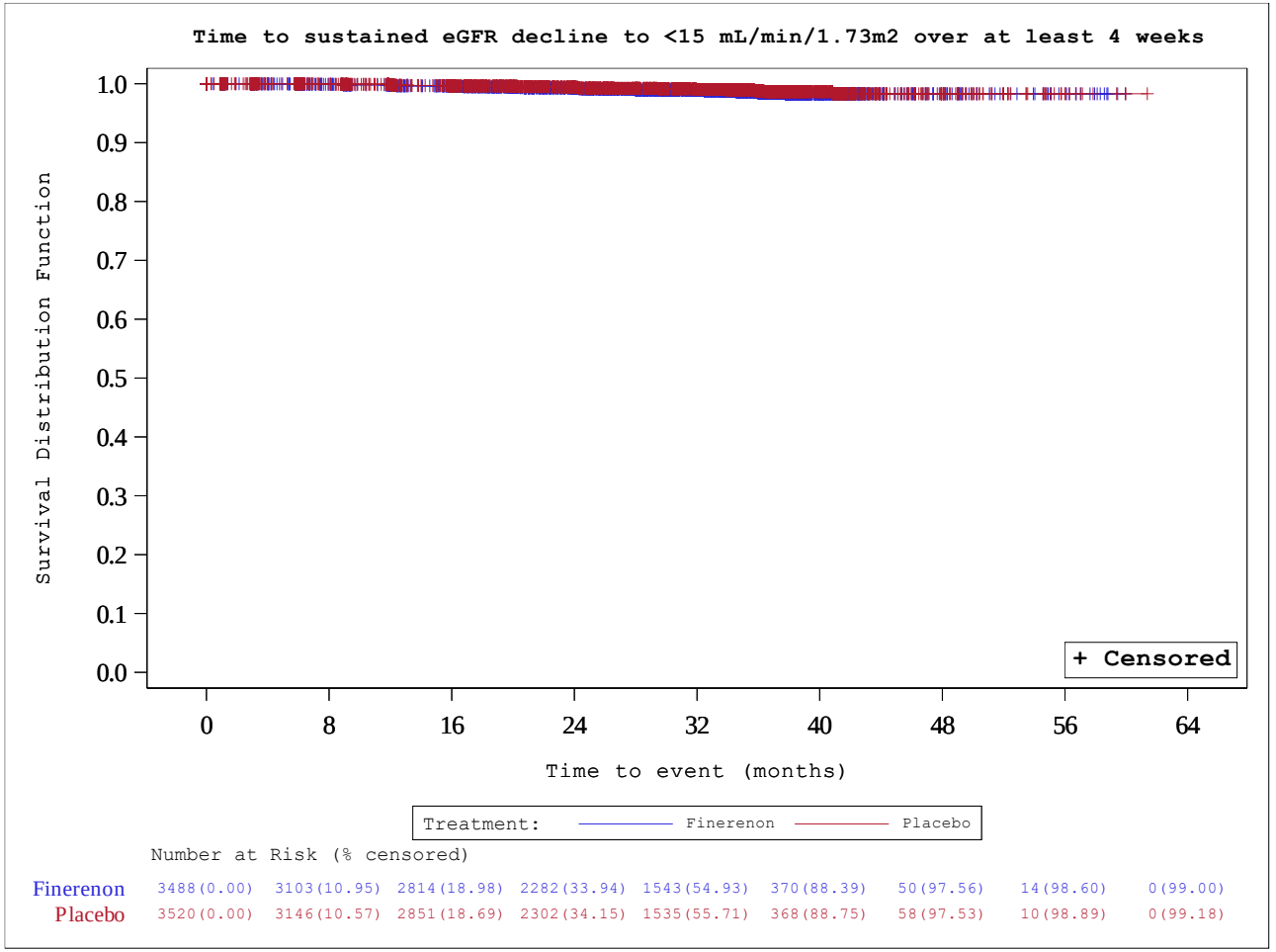
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks - Subgroup analysis
Full Analysis Set

Subgroup	Finerenone (N=3488)		Placebo (N=3520)				Interaction
Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
Sex							0.2233
Male	24/ 1950 (1.23)	NE (NE, NE)	16/ 1949 (0.82)	NE (NE, NE)	1.62 (0.86, 3.05)	0.1327	
Female	11/ 1538 (0.72)	NE (NE, NE)	13/ 1571 (0.83)	NE (NE, NE)	0.90 (0.40, 2.01)	0.7931	
Region							0.5687
Western Europe, Oceania and Others	6/ 694 (0.86)	NE (NE, NE)	10/ 717 (1.39)	NE (NE, NE)	0.72 (0.26, 1.98)	0.5215	
Eastern Europe	9/ 1580 (0.57)	NE (NE, NE)	7/ 1569 (0.45)	NE (NE, NE)	1.49 (0.55, 4.00)	0.4295	
Asia	10/ 555 (1.80)	NE (NE, NE)	5/ 553 (0.90)	NE (NE, NE)	1.73 (0.59, 5.06)	0.3148	
North America	4/ 318 (1.26)	NE (NE, NE)	4/ 317 (1.26)	NE (NE, NE)	1.04 (0.26, 4.19)	0.9524	
Latin America	6/ 341 (1.76)	NE (NE, NE)	3/ 364 (0.82)	NE (NE, NE)	3.05 (0.71, 13.21)	0.1202	
Age group (years)							0.9976
<= median in FAS	22/ 1830 (1.20)	NE (NE, NE)	19/ 1835 (1.04)	NE (NE, NE)	1.33 (0.72, 2.47)	0.3581	
> median in FAS	13/ 1658 (0.78)	NE (NE, NE)	10/ 1685 (0.59)	NE (NE, NE)	1.30 (0.57, 2.96)	0.5349	
Study							0.1733
FINEARTS-HF	25/ 3003 (0.83)	NE (NE, NE)	12/ 2998 (0.40)	NE (NE, NE)	2.07 (1.04, 4.12)	0.0341	
FIGARO-DKD	0/ 290 (0.00)	NE (NE, NE)	1/ 281 (0.36)	NE (NE, NE)	NE (NE, NE)	NE	
FIDELIO-DKD	10/ 195 (5.13)	NE (NE, NE)	16/ 241 (6.64)	NE (NE, NE)	0.77 (0.35, 1.70)	0.5134	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
eGFR=estimated glomerular filtration rate
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to sustained eGFR decline to <15 mL/min/1.73m2 over at least 4 weeks
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	20/ 3488 (0.57)	22/ 3520 (0.63)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	NE (NE, NE)	NE (56.8, NE)
Median (95% CI)	NE (NE, NE)	NE (56.8, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.91 (0.49, 1.67)	
p-value	0.7560	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.98 (0.53, 1.79)	
p-value	0.9359	

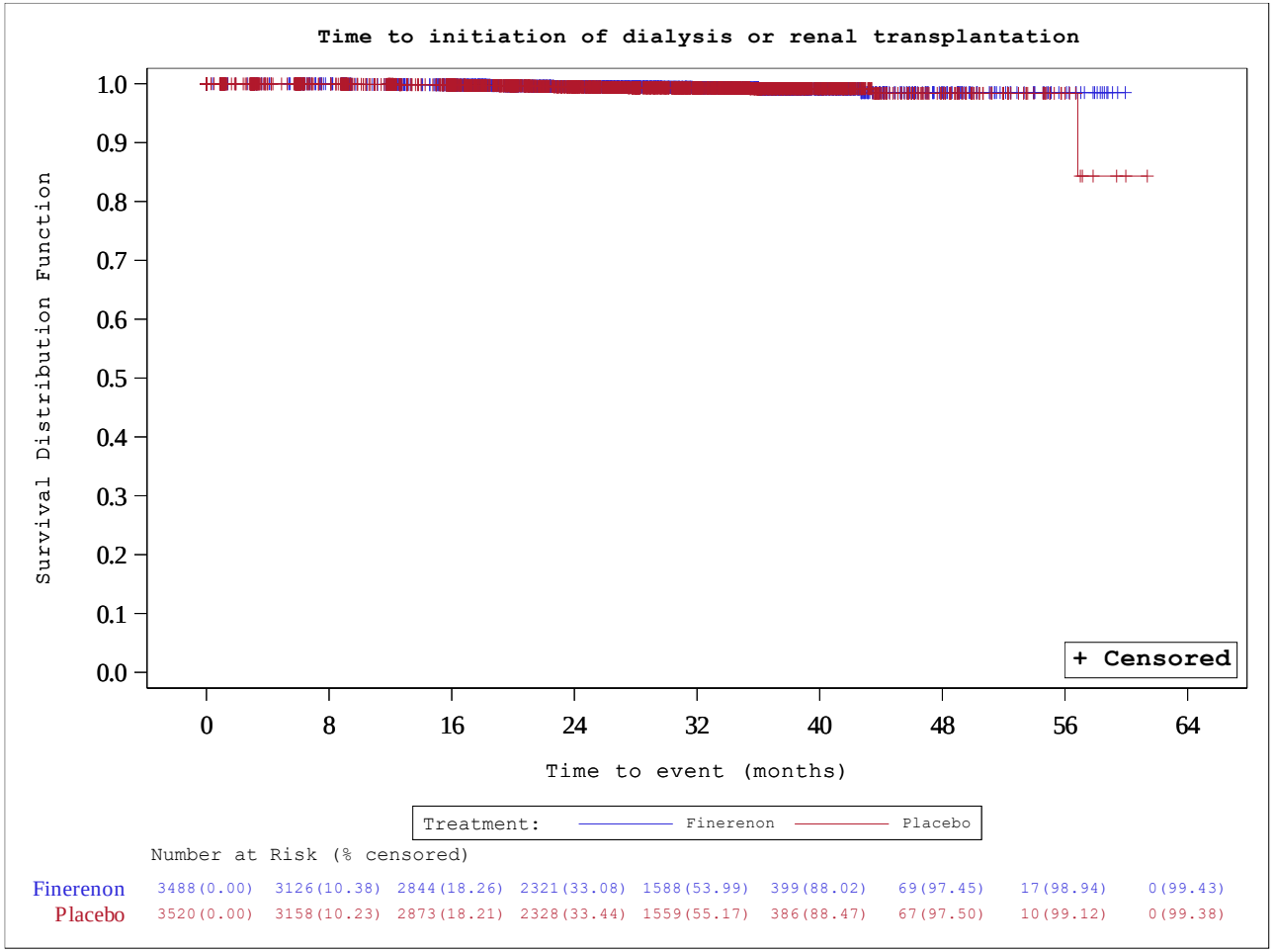
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Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to initiation of dialysis or renal transplantation - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.0326
Male	18/ 1950 (0.92)	NE (NE, NE)	13/ 1949 (0.67)	NE (56.8, NE)	1.48 (0.72, 3.02)	0.2837	
Female	2/ 1538 (0.13)	NE (NE, NE)	9/ 1571 (0.57)	NE (NE, NE)	0.25 (0.05, 1.15)	0.0546	
Region							0.7368
Western Europe, Oceania and Others	4/ 694 (0.58)	NE (NE, NE)	5/ 717 (0.70)	NE (NE, NE)	0.98 (0.26, 3.64)	0.9727	
Eastern Europe	2/ 1580 (0.13)	NE (NE, NE)	6/ 1569 (0.38)	NE (NE, NE)	0.39 (0.08, 1.94)	0.2322	
Asia	5/ 555 (0.90)	NE (NE, NE)	4/ 553 (0.72)	56.8 (56.8, NE)	0.87 (0.23, 3.30)	0.8432	
North America	7/ 318 (2.20)	NE (NE, NE)	5/ 317 (1.58)	NE (NE, NE)	1.37 (0.43, 4.32)	0.5921	
Latin America	2/ 341 (0.59)	NE (NE, NE)	2/ 364 (0.55)	NE (NE, NE)	1.10 (0.15, 7.88)	0.9231	
Age group (years)							0.7245
<= median in FAS	14/ 1830 (0.77)	NE (NE, NE)	15/ 1835 (0.82)	NE (NE, NE)	1.09 (0.53, 2.27)	0.8130	
> median in FAS	6/ 1658 (0.36)	NE (NE, NE)	7/ 1685 (0.42)	56.8 (56.8, NE)	0.86 (0.28, 2.57)	0.7812	
Study							0.8302
FINEARTS-HF	7/ 3003 (0.23)	NE (NE, NE)	6/ 2998 (0.20)	NE (NE, NE)	1.16 (0.39, 3.45)	0.7891	
FIGARO-DKD	2/ 290 (0.69)	NE (NE, NE)	1/ 281 (0.36)	NE (56.8, NE)	1.63 (0.14, 18.29)	0.6910	
FIDELIO-DKD	11/ 195 (5.64)	NE (NE, NE)	15/ 241 (6.22)	NE (NE, NE)	0.84 (0.39, 1.84)	0.6704	

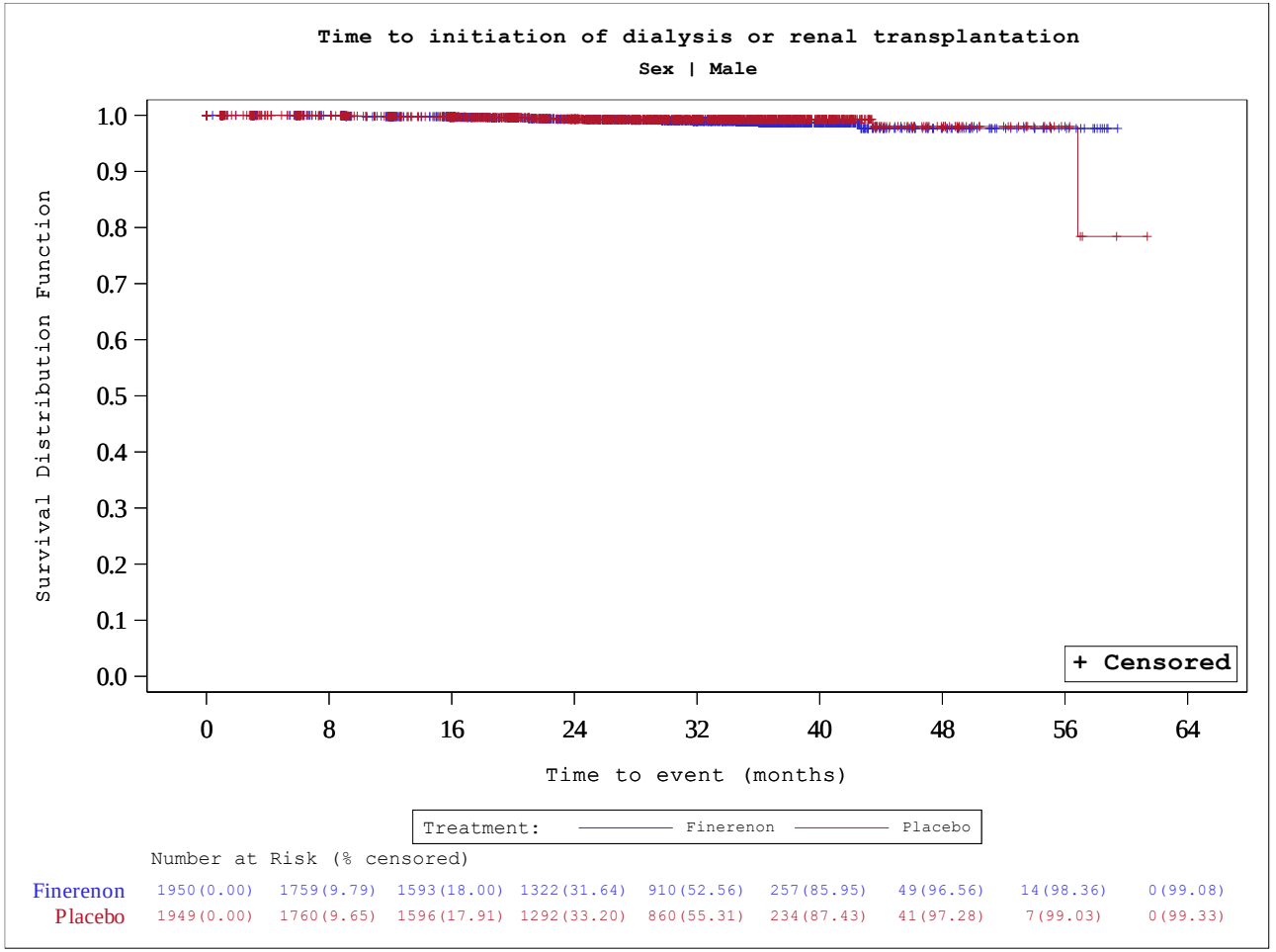
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



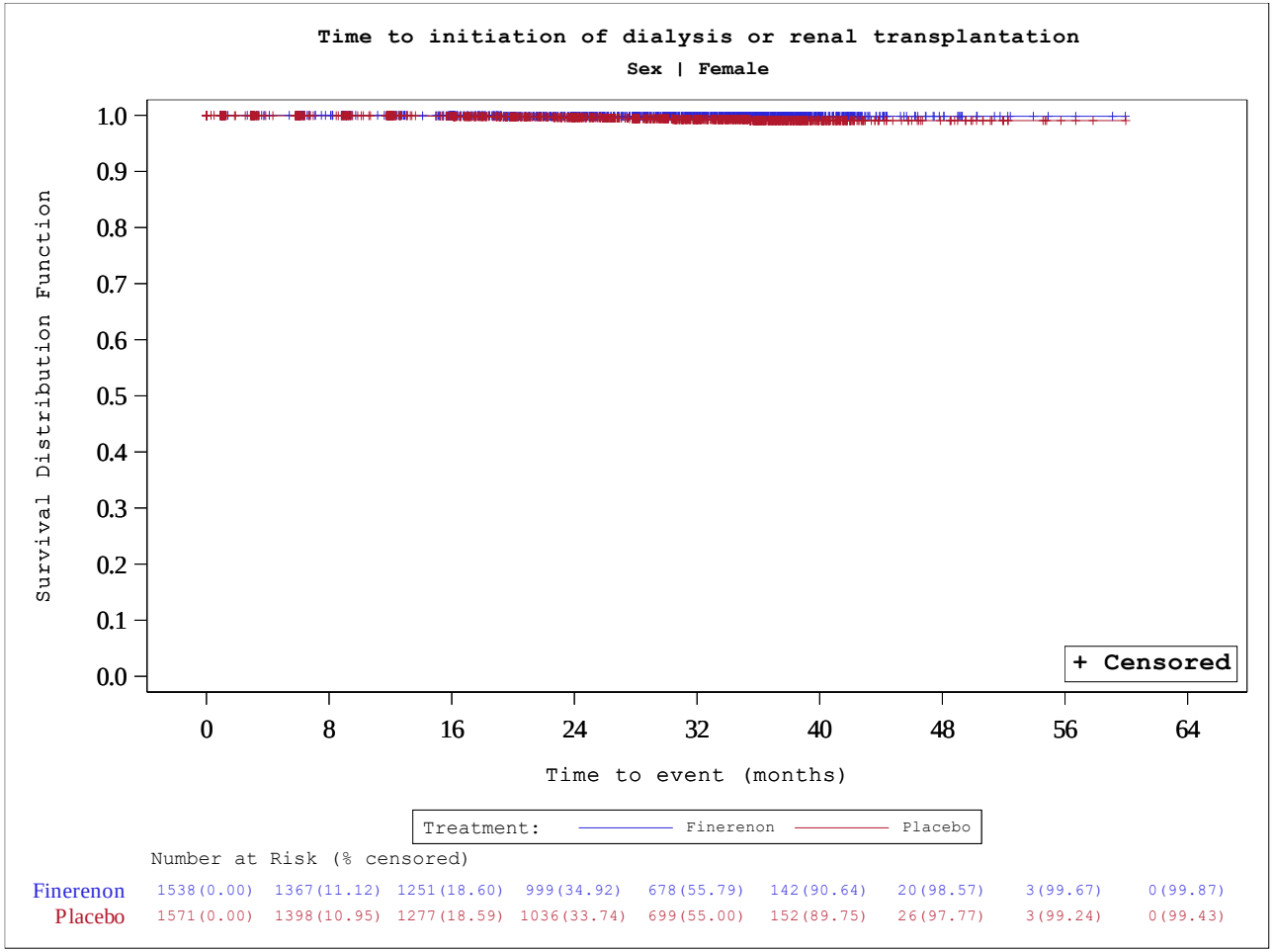
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to initiation of dialysis or renal transplantation
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first all-cause hospitalization
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	1684/ 3488 (48.28)	1764/ 3520 (50.11)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.8 (9.0, 11.0)	9.0 (8.3, 9.7)
Median (95% CI)	33.4 (31.1, 35.3)	30.6 (27.7, 33.6)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.95 (0.88, 1.01)	
p-value	0.0989	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.94 (0.88, 1.01)	
p-value	0.0818	

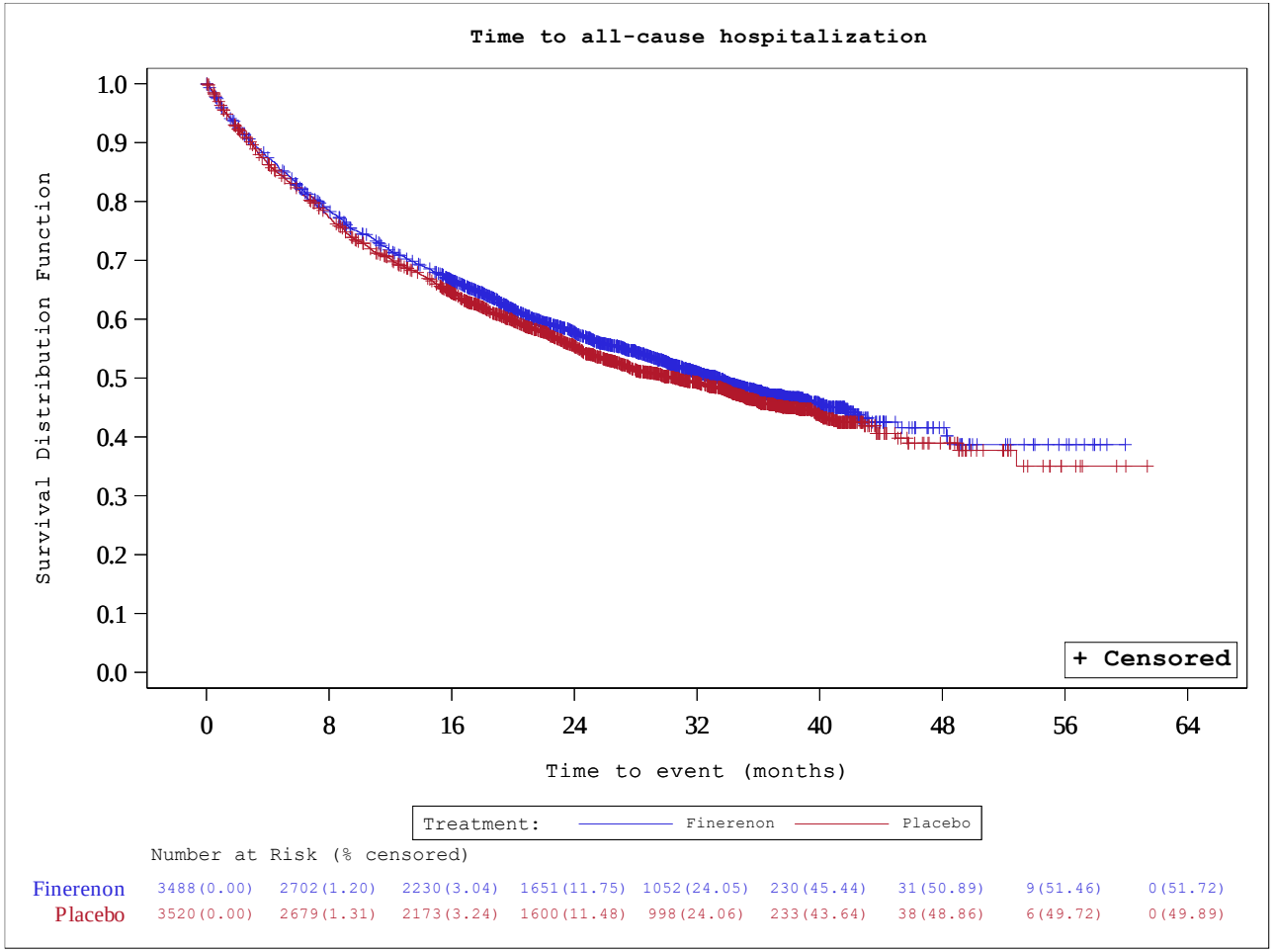
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first all-cause hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5512
Male	977/ 1950 (50.10)	31.1 (29.1, 34.2)	982/ 1949 (50.38)	29.7 (26.1, 34.1)	0.96 (0.88, 1.05)	0.3596	
Female	707/ 1538 (45.97)	35.6 (32.3, NE)	782/ 1571 (49.78)	31.7 (27.3, 34.6)	0.92 (0.83, 1.02)	0.0998	
Region							0.4061
Western Europe, Oceania and Others	405/ 694 (58.36)	22.0 (19.5, 25.7)	457/ 717 (63.74)	19.9 (17.5, 22.0)	0.89 (0.78, 1.01)	0.0791	
Eastern Europe	652/ 1580 (41.27)	NE (41.7, NE)	657/ 1569 (41.87)	49.1 (42.9, NE)	0.97 (0.87, 1.09)	0.6285	
Asia	303/ 555 (54.59)	27.5 (23.2, 31.5)	312/ 553 (56.42)	23.4 (19.3, 27.0)	0.94 (0.80, 1.10)	0.4589	
North America	187/ 318 (58.81)	19.9 (17.5, 25.9)	173/ 317 (54.57)	22.8 (18.3, 30.5)	1.10 (0.90, 1.35)	0.3626	
Latin America	137/ 341 (40.18)	37.6 (34.1, NE)	165/ 364 (45.33)	31.1 (24.3, NE)	0.84 (0.66, 1.05)	0.1215	
Age group (years)							0.0942
<= median in FAS	779/ 1830 (42.57)	43.2 (40.3, NE)	854/ 1835 (46.54)	35.9 (32.2, 43.6)	0.89 (0.81, 0.98)	0.0209	
> median in FAS	905/ 1658 (54.58)	26.4 (24.3, 29.3)	910/ 1685 (54.01)	24.8 (23.1, 28.0)	1.00 (0.91, 1.09)	0.9730	
Study							0.7053
FINEARTS-HF	1433/ 3003 (47.72)	33.5 (31.1, 35.6)	1481/ 2998 (49.40)	31.4 (28.0, 34.1)	0.94 (0.88, 1.02)	0.1229	
FIGARO-DKD	150/ 290 (51.72)	33.8 (25.8, 48.3)	144/ 281 (51.25)	34.9 (25.7, 49.1)	1.00 (0.79, 1.25)	0.9665	
FIDELIO-DKD	101/ 195 (51.79)	28.7 (20.0, 42.6)	139/ 241 (57.68)	24.4 (18.8, 27.7)	0.86 (0.66, 1.11)	0.2397	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with event, n/N (%)	1795/ 3488 (51.46)	1898/ 3520 (53.92)
Kaplan-Meier estimates of Time to Event in months		
25%-ile (95% CI)	9.2 (8.7, 10.2)	8.6 (8.0, 9.1)
Median (95% CI)	30.8 (29.0, 32.7)	27.2 (25.3, 29.2)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.88, 1.00)	
p-value	0.0408	
Unstratified Analysis Finerenone vs. Placebo		
Hazard Ratio (95% CI)	0.93 (0.87, 0.99)	
p-value	0.0319	

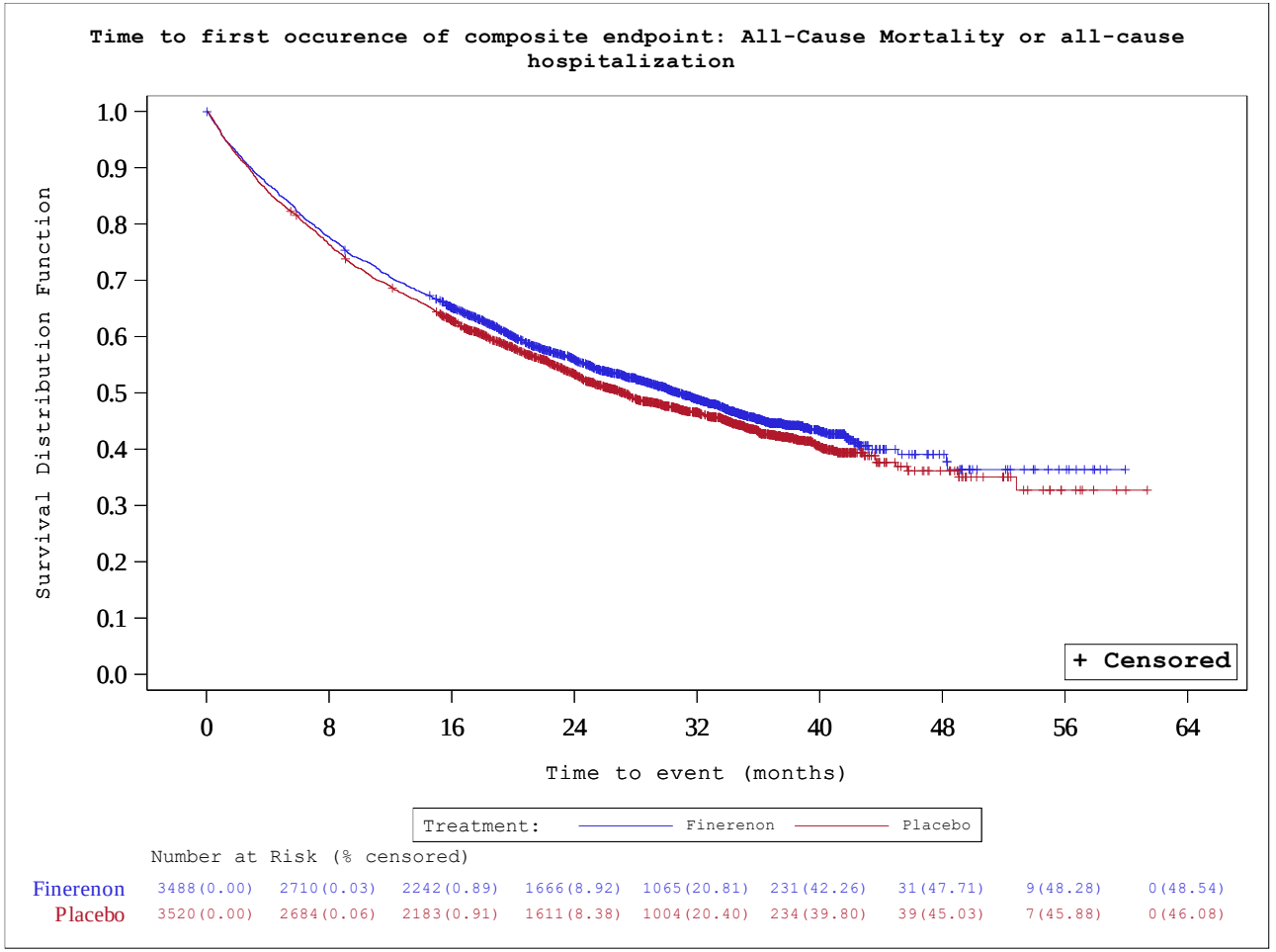
Kaplan-Meier estimates based on the Brookmeyer and Crowley method.
Unstratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
Stratified Hazard Ratio, confidence intervall using Cox Proportional Hazard Model including stratification factors according to dossier. p-value estimated using the stratified Log-Rank-Test
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Finerenone (N=3488) Median (95% CI)	Placebo (N=3520) n/ N (%)	Placebo (N=3520) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Sex							0.5835
Male	1043/ 1950 (53.49)	29.4 (26.4, 31.6)	1061/ 1949 (54.44)	26.0 (24.2, 28.5)	0.95 (0.87, 1.03)	0.2089	
Female	752/ 1538 (48.89)	33.5 (29.9, 36.5)	837/ 1571 (53.28)	27.7 (25.7, 32.0)	0.91 (0.82, 1.00)	0.0610	
Region							0.2996
Western Europe, Oceania and Others	419/ 694 (60.37)	21.4 (19.3, 24.5)	468/ 717 (65.27)	19.3 (16.7, 21.3)	0.89 (0.78, 1.01)	0.0813	
Eastern Europe	719/ 1580 (45.51)	41.7 (35.5, NE)	733/ 1569 (46.72)	39.6 (35.1, NE)	0.96 (0.87, 1.06)	0.4434	
Asia	317/ 555 (57.12)	25.2 (21.0, 29.7)	332/ 553 (60.04)	21.8 (18.4, 25.4)	0.93 (0.80, 1.09)	0.3796	
North America	196/ 318 (61.64)	19.5 (16.8, 24.7)	183/ 317 (57.73)	22.0 (17.3, 27.3)	1.09 (0.89, 1.33)	0.4247	
Latin America	144/ 341 (42.23)	37.6 (32.7, NE)	182/ 364 (50.00)	27.7 (23.3, 35.4)	0.80 (0.64, 0.99)	0.0428	
Age group (years)							0.0566
<= median in FAS	832/ 1830 (45.46)	41.7 (35.6, 45.1)	924/ 1835 (50.35)	31.4 (28.1, 35.1)	0.88 (0.80, 0.96)	0.0059	
> median in FAS	963/ 1658 (58.08)	25.0 (22.7, 27.1)	974/ 1685 (57.80)	23.3 (21.6, 25.3)	0.99 (0.91, 1.09)	0.8731	
Study							0.7343
FINEARTS-HF	1536/ 3003 (51.15)	30.7 (28.8, 32.9)	1596/ 2998 (53.24)	27.6 (25.3, 30.1)	0.94 (0.87, 1.01)	0.0707	
FIGARO-DKD	154/ 290 (53.10)	32.3 (24.7, 43.2)	155/ 281 (55.16)	27.7 (24.3, 42.9)	0.95 (0.76, 1.19)	0.6605	
FIDELIO-DKD	105/ 195 (53.85)	27.8 (20.0, 38.9)	147/ 241 (61.00)	22.7 (18.3, 26.6)	0.84 (0.65, 1.08)	0.1740	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Kaplan-Meier estimates for Median based on the Brookmeyer and Crowley method.
Hazard Ratio, confidence intervall and p-value estimated using Cox Proportional Hazard Model with Study-Id as additional covariate. p-value estimated using the Log-Rank-Test
p-Value for interaction is calculated from Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Kaplan-Meier Plot of Time to first occurence of composite endpoint: All-Cause Mortality or all-cause hospitalization
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with reponse, n/N (%)	877/ 3289 (26.66)	886/ 3310 (26.77)
Number of imputed values	372	351
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.01 (0.91, 1.13)	
p-value	0.8151	
Risk Ratio (95% CI)	1.01 (0.95, 1.07)	
p-value	0.7687	
Risk Difference (95% CI)	0.01 (-0.01, 0.03)	
p-value	0.5079	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.99 (0.89, 1.11)	
p-value	0.8829	
Risk Ratio (95% CI)	0.99 (0.92, 1.08)	
p-value	0.8828	
Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
p-value	0.8829	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Number and Proportion of Patients with Improvement >=15 points of EQ5D-VAS - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Placebo (N=3520) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.2409
Male	503/ 1855 (27.12)	484/ 1857 (26.06)	1.04 (0.93, 1.15)	0.5178	1.05 (0.91, 1.21)	0.5183	0.01 (-0.02, 0.04)	0.5183	
Female	374/ 1434 (26.08)	402/ 1453 (27.67)	0.94 (0.83, 1.06)	0.3202	0.92 (0.78, 1.08)	0.3201	-0.02 (-0.05, 0.02)	0.3198	
Region									0.7635
Western Europe, Oceania and Others	156/ 636 (24.53)	153/ 670 (22.84)	1.08 (0.88, 1.31)	0.4672	1.10 (0.85, 1.42)	0.4673	0.02 (-0.03, 0.06)	0.4674	
Eastern Europe	387/ 1520 (25.46)	386/ 1507 (25.61)	0.99 (0.88, 1.12)	0.9202	0.99 (0.84, 1.17)	0.9202	-0.00 (-0.03, 0.03)	0.9202	
Asia	146/ 516 (28.29)	152/ 506 (30.04)	0.94 (0.78, 1.14)	0.5516	0.92 (0.70, 1.21)	0.5512	-0.02 (-0.07, 0.04)	0.5512	
North America	75/ 292 (25.68)	84/ 289 (29.07)	0.89 (0.68, 1.16)	0.3754	0.85 (0.59, 1.22)	0.3762	-0.03 (-0.11, 0.04)	0.3756	
Latin America	113/ 325 (34.77)	111/ 338 (32.84)	1.05 (0.85, 1.30)	0.6668	1.07 (0.78, 1.48)	0.6668	0.02 (-0.06, 0.09)	0.6668	
Age group (years)									0.2671
<= median in FAS	471/ 1733 (27.18)	490/ 1721 (28.47)	0.95 (0.86, 1.06)	0.3732	0.93 (0.80, 1.09)	0.3731	-0.01 (-0.04, 0.02)	0.3730	
> median in FAS	406/ 1556 (26.09)	396/ 1589 (24.92)	1.04 (0.93, 1.18)	0.4886	1.06 (0.90, 1.24)	0.4885	0.01 (-0.02, 0.04)	0.4885	
Study									0.0402
FINEARTS-HF	800/ 2841 (28.16)	790/ 2826 (27.95)	1.01 (0.93, 1.09)	0.8640	1.01 (0.90, 1.13)	0.8640	0.00 (-0.02, 0.03)	0.8640	
FIGARO-DKD	34/ 267 (12.73)	53/ 262 (20.23)	0.63 (0.42, 0.93)	0.0218	0.58 (0.36, 0.92)	0.0210	-0.07 (-0.14, -0.01)	0.0197	
FIDELIO-DKD	43/ 181 (23.76)	43/ 222 (19.37)	1.23 (0.84, 1.78)	0.2851	1.30 (0.80, 2.09)	0.2856	0.04 (-0.04, 0.12)	0.2879	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
Number of subjects with reponse, n/N (%)	629/ 3289 (19.12)	657/ 3310 (19.85)
Number of imputed values	372	351
Stratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.94 (0.83, 1.07)	
p-value	0.3692	
Risk Ratio (95% CI)	0.95 (0.86, 1.05)	
p-value	0.3008	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.1639	
Unstratified Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.96 (0.85, 1.08)	
p-value	0.4592	
Risk Ratio (95% CI)	0.96 (0.87, 1.06)	
p-value	0.4594	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.4592	

Stratified analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with baseline values, treatment and stratification factors
Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder. For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Number and Proportion of Patients with Worsening >=15 points of EQ5D-VAS - Subgroup analysis
Full Analysis Set

Subgroup Level	Finerenone (N=3488) n/ N (%)	Placebo (N=3520) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.0803
Male	330/ 1855 (17.79)	371/ 1857 (19.98)	0.89 (0.78, 1.01)	0.0811	0.86 (0.73, 1.02)	0.0808	-0.02 (-0.05, 0.00)	0.0805	
Female	299/ 1434 (20.85)	286/ 1453 (19.68)	1.06 (0.92, 1.22)	0.4420	1.07 (0.90, 1.29)	0.4420	0.01 (-0.02, 0.04)	0.4420	
Region									0.9968
Western Europe, Oceania and Others	153/ 636 (24.06)	169/ 670 (25.22)	0.95 (0.79, 1.15)	0.5927	0.93 (0.73, 1.20)	0.5932	-0.01 (-0.06, 0.03)	0.5930	
Eastern Europe	271/ 1520 (17.83)	275/ 1507 (18.25)	0.98 (0.84, 1.14)	0.7752	0.97 (0.81, 1.17)	0.7750	-0.00 (-0.03, 0.02)	0.7750	
Asia	82/ 516 (15.89)	82/ 506 (16.21)	0.97 (0.74, 1.29)	0.8520	0.97 (0.69, 1.35)	0.8522	-0.00 (-0.05, 0.04)	0.8522	
North America	62/ 292 (21.23)	61/ 289 (21.11)	1.00 (0.73, 1.36)	0.9763	0.99 (0.67, 1.48)	0.9763	-0.00 (-0.07, 0.07)	0.9763	
Latin America	61/ 325 (18.77)	70/ 338 (20.71)	0.93 (0.68, 1.27)	0.6308	0.91 (0.62, 1.34)	0.6282	-0.01 (-0.08, 0.05)	0.6280	
Age group (years)									0.5619
<= median in FAS	279/ 1733 (16.10)	278/ 1721 (16.15)	1.00 (0.86, 1.16)	0.9980	1.00 (0.83, 1.20)	0.9980	-0.00 (-0.02, 0.02)	0.9980	
> median in FAS	350/ 1556 (22.49)	379/ 1589 (23.85)	0.94 (0.83, 1.07)	0.3646	0.93 (0.78, 1.09)	0.3646	-0.01 (-0.04, 0.02)	0.3644	
Study									0.7627
FINEARTS-HF	549/ 2841 (19.32)	563/ 2826 (19.92)	0.97 (0.87, 1.08)	0.5709	0.96 (0.84, 1.10)	0.5709	-0.01 (-0.03, 0.01)	0.5709	
FIGARO-DKD	48/ 267 (17.98)	47/ 262 (17.94)	1.00 (0.70, 1.44)	0.9908	1.00 (0.64, 1.56)	0.9908	0.00 (-0.07, 0.07)	0.9908	
FIDELIO-DKD	32/ 181 (17.68)	47/ 222 (21.17)	0.84 (0.56, 1.25)	0.3820	0.80 (0.49, 1.32)	0.3804	-0.03 (-0.11, 0.04)	0.3760	

Unstratified RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. 95% confidence intervals and p-values constructed using normal approximation (Wald test)
Missing data was replaced using last observation carried forward(LOCF) Imputation; Patients with missing baseline value will be excluded from the analysis.
For improvement, if death occurs before/at Month 12, a patient counts as non-responder.For worsening, death occuring before/at Month 12 means that patient will count as having an event.
Patients who cannot achieve improvement or worsening due to their very high/low baseline values respectively remain included and will count as having an event if they hold that value at Month 12/last post-baseline score before Month 12
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Mean values and absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

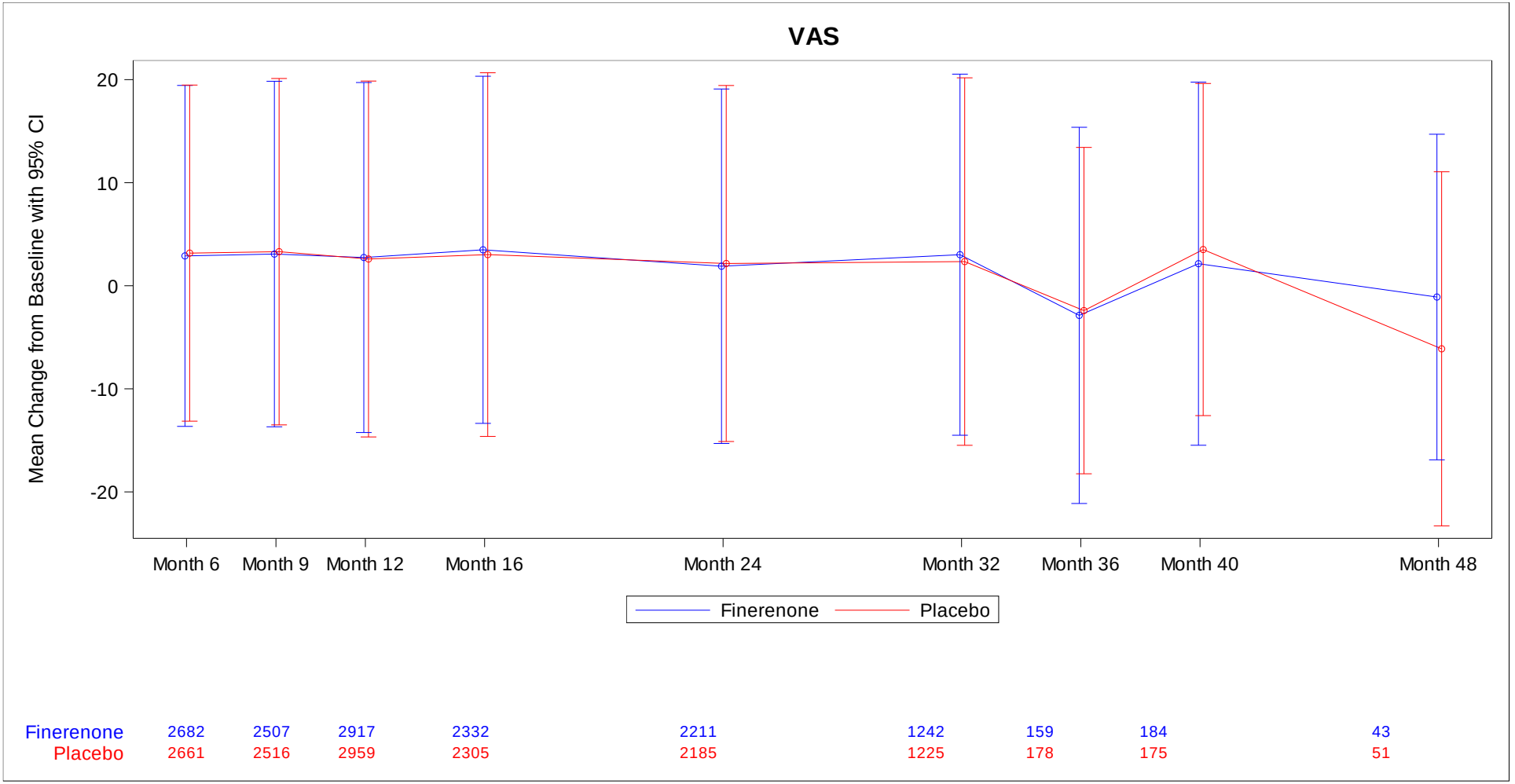
	Finerenone (N=3488)				Placebo (N=3520)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	3471	67.67 (17.29)	-	-	3490	67.11 (17.60)	-	-
Month 6	2691	71.20 (17.11)	2682	2.90 (16.54)	2671	70.60 (17.24)	2661	3.17 (16.30)
Month 9	2516	71.42 (17.01)	2507	3.08 (16.76)	2524	70.93 (17.09)	2516	3.31 (16.80)
Month 12	2924	71.07 (17.34)	2917	2.74 (16.98)	2975	70.16 (17.47)	2959	2.60 (17.26)
Month 16	2339	72.20 (16.77)	2332	3.49 (16.84)	2314	70.78 (17.62)	2305	3.02 (17.64)
Month 24	2218	70.49 (17.24)	2211	1.90 (17.20)	2202	70.10 (17.34)	2185	2.16 (17.27)
Month 32	1245	71.52 (16.93)	1242	3.01 (17.52)	1231	69.99 (16.80)	1225	2.35 (17.83)
Month 36	160	66.11 (18.68)	159	-2.87 (18.25)	180	65.39 (17.82)	178	-2.41 (15.83)
Month 40	184	69.36 (18.28)	184	2.14 (17.61)	176	69.30 (16.38)	175	3.51 (16.11)
Month 48	43	68.84 (16.07)	43	-1.09 (15.79)	51	67.22 (17.21)	51	-6.12 (17.18)
Premature discontinuation	129	63.69 (21.21)	129	-2.34 (19.30)	149	63.81 (19.85)	148	-4.32 (21.37)
End of Study Visit	2477	71.33 (17.36)	2469	2.51 (17.70)	2452	70.46 (17.47)	2438	2.51 (17.82)

n describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Mixed Model Repeated Measures analysis of absolute change from Baseline in EQ5D-VAS over time
Full Analysis Set

	Finerenone (N=3488)		Placebo (N=3520)		Difference of			
Timepoint	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
OVERALL	3151	1.59 (0.39)	3163	1.36 (0.39)	0.24 (-0.36, 0.84)	0.4417	0.01 (-0.04, 0.06)	0.6713

Mixed model for repeated measures (MMRM) for change from baseline including treatment, baseline,study visit, baseline-by-visit interaction, and stratification factors. An unstructured covariance structure is used.
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to visit cutpoint.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval



n=Number of patients with event; N=Number of patients included in the analysis;
CV=cardiovascular; HF=heart failure; HHF=hospitalization for heart failure; eGFR=estimated glomerular filtration rate

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	2983/ 3477 (85.79)	2972/ 3515 (84.55)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.11 (0.97, 1.26)	
p-value	0.1371	
Risk Ratio (95% CI)	1.02 (1.00, 1.04)	
p-value	0.1314	
Risk Difference (95% CI)	0.01 (-0.00, 0.03)	
p-value	0.1324	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.6847
Male	1670/ 1945 (85.86)	1652/ 1947 (84.85)	1.01 (0.99, 1.04)	0.3374	1.09 (0.91, 1.31)	0.3279	0.01 (-0.01, 0.03)	0.3353	
Female	1313/ 1532 (85.70)	1320/ 1568 (84.18)	1.02 (0.99, 1.05)	0.1663	1.12 (0.92, 1.37)	0.2440	0.02 (-0.01, 0.04)	0.1787	
Region									0.7327
Western Europe, Oceania and Others	642/ 688 (93.31)	660/ 716 (92.18)	1.01 (0.98, 1.04)	0.6616	1.20 (0.80, 1.79)	0.3875	0.01 (-0.02, 0.03)	0.6387	
Eastern Europe	1261/ 1577 (79.96)	1240/ 1567 (79.13)	1.01 (0.98, 1.05)	0.5109	1.05 (0.88, 1.25)	0.5697	0.01 (-0.02, 0.04)	0.5260	
Asia	518/ 554 (93.50)	512/ 551 (92.92)	1.01 (0.98, 1.05)	0.4263	1.10 (0.69, 1.76)	0.6848	0.01 (-0.02, 0.04)	0.4434	
North America	284/ 317 (89.59)	272/ 317 (85.80)	1.04 (0.98, 1.11)	0.1577	1.46 (0.90, 2.36)	0.1230	0.04 (-0.01, 0.09)	0.1516	
Latin America	278/ 341 (81.52)	288/ 364 (79.12)	1.05 (0.97, 1.14)	0.1885	1.24 (0.85, 1.81)	0.2573	0.04 (-0.02, 0.10)	0.1960	
Age group (years)									0.4833
<= median in FAS	1499/ 1825 (82.14)	1492/ 1831 (81.49)	1.01 (0.98, 1.04)	0.6393	1.05 (0.89, 1.25)	0.5465	0.01 (-0.02, 0.03)	0.6191	
> median in FAS	1484/ 1652 (89.83)	1480/ 1684 (87.89)	1.02 (1.00, 1.05)	0.0832	1.22 (0.98, 1.52)	0.0716	0.02 (-0.00, 0.04)	0.0813	
Study									0.0791
FINEARTS-HF	2580/ 2993 (86.20)	2519/ 2993 (84.16)	1.02 (1.00, 1.05)	0.0265	1.18 (1.02, 1.36)	0.0266	0.02 (0.00, 0.04)	0.0264	
FIGARO-DKD	236/ 289 (81.66)	242/ 281 (86.12)	0.95 (0.88, 1.02)	0.1479	0.72 (0.46, 1.13)	0.1490	-0.04 (-0.10, 0.02)	0.1465	
FIDELIO-DKD	167/ 195 (85.64)	211/ 241 (87.55)	0.98 (0.91, 1.05)	0.5622	0.85 (0.49, 1.48)	0.5594	-0.02 (-0.08, 0.05)	0.5615	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	2972/ 3477 (85.48)	2963/ 3515 (84.30)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.10 (0.96, 1.25)	
p-value	0.1588	
Risk Ratio (95% CI)	1.01 (0.99, 1.03)	
p-value	0.1520	
Risk Difference (95% CI)	0.01 (-0.00, 0.03)	
p-value	0.1533	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	1563/ 3477 (44.95)	1611/ 3515 (45.83)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.97 (0.88, 1.06)	
p-value	0.4711	
Risk Ratio (95% CI)	0.98 (0.93, 1.03)	
p-value	0.4572	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.4751	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.3471
Male	898/ 1945 (46.17)	898/ 1947 (46.12)	1.00 (0.94, 1.07)	0.9724	1.00 (0.89, 1.14)	0.9502	0.00 (-0.03, 0.03)	0.9475	
Female	665/ 1532 (43.41)	713/ 1568 (45.47)	0.95 (0.88, 1.03)	0.2254	0.92 (0.80, 1.06)	0.2405	-0.02 (-0.06, 0.01)	0.2485	
Region									0.5326
Western Europe, Oceania and Others	372/ 688 (54.07)	410/ 716 (57.26)	0.94 (0.86, 1.04)	0.2295	0.88 (0.71, 1.09)	0.2375	-0.03 (-0.08, 0.02)	0.2351	
Eastern Europe	605/ 1577 (38.36)	604/ 1567 (38.54)	1.00 (0.91, 1.09)	0.9417	0.99 (0.86, 1.15)	0.9321	-0.00 (-0.04, 0.03)	0.9272	
Asia	267/ 554 (48.19)	284/ 551 (51.54)	0.94 (0.83, 1.05)	0.2809	0.88 (0.69, 1.11)	0.2882	-0.03 (-0.09, 0.03)	0.2872	
North America	181/ 317 (57.10)	169/ 317 (53.31)	1.07 (0.93, 1.23)	0.3367	1.18 (0.86, 1.62)	0.2980	0.04 (-0.04, 0.12)	0.3016	
Latin America	138/ 341 (40.47)	144/ 364 (39.56)	1.03 (0.86, 1.24)	0.7303	1.05 (0.77, 1.42)	0.7523	0.01 (-0.06, 0.08)	0.7568	
Age group (years)									0.0170
<= median in FAS	697/ 1825 (38.19)	763/ 1831 (41.67)	0.92 (0.85, 0.99)	0.0342	0.87 (0.76, 0.99)	0.0368	-0.03 (-0.07, -0.00)	0.0378	
> median in FAS	866/ 1652 (52.42)	848/ 1684 (50.36)	1.04 (0.97, 1.11)	0.2362	1.09 (0.95, 1.24)	0.2341	0.02 (-0.01, 0.05)	0.2342	
Study									0.1908
FINEARTS-HF	1359/ 2993 (45.41)	1378/ 2993 (46.04)	0.99 (0.93, 1.04)	0.6221	0.97 (0.88, 1.08)	0.6220	-0.01 (-0.03, 0.02)	0.6220	
FIGARO-DKD	123/ 289 (42.56)	112/ 281 (39.86)	1.07 (0.88, 1.30)	0.5126	1.12 (0.80, 1.56)	0.5123	0.03 (-0.05, 0.11)	0.5120	
FIDELIO-DKD	81/ 195 (41.54)	121/ 241 (50.21)	0.83 (0.67, 1.02)	0.0750	0.70 (0.48, 1.03)	0.0715	-0.09 (-0.18, 0.01)	0.0696	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	1544/ 3477 (44.41)	1591/ 3515 (45.26)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.97 (0.88, 1.06)	
p-value	0.4828	
Risk Ratio (95% CI)	0.98 (0.93, 1.03)	
p-value	0.4709	
Risk Difference (95% CI)	-0.01 (-0.03, 0.02)	
p-value	0.4864	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	913/ 3477 (26.26)	971/ 3515 (27.62)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.93 (0.84, 1.04)	
p-value	0.2091	
Risk Ratio (95% CI)	0.95 (0.88, 1.03)	
p-value	0.2094	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.2085	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.7523
Male	539/ 1945 (27.71)	575/ 1947 (29.53)	0.94 (0.85, 1.04)	0.2288	0.92 (0.80, 1.06)	0.2280	-0.02 (-0.05, 0.01)	0.2265	
Female	374/ 1532 (24.41)	396/ 1568 (25.26)	0.97 (0.85, 1.09)	0.5687	0.96 (0.81, 1.12)	0.5814	-0.01 (-0.04, 0.02)	0.6149	
Region									0.8063
Western Europe, Oceania and Others	227/ 688 (32.99)	239/ 716 (33.38)	0.99 (0.85, 1.15)	0.8988	0.98 (0.79, 1.23)	0.8924	-0.00 (-0.05, 0.05)	0.8863	
Eastern Europe	323/ 1577 (20.48)	334/ 1567 (21.31)	0.96 (0.84, 1.10)	0.5668	0.95 (0.80, 1.13)	0.5566	-0.01 (-0.04, 0.02)	0.5196	
Asia	149/ 554 (26.90)	172/ 551 (31.22)	0.86 (0.72, 1.03)	0.1101	0.81 (0.63, 1.05)	0.1180	-0.04 (-0.09, 0.01)	0.1270	
North America	122/ 317 (38.49)	125/ 317 (39.43)	0.99 (0.81, 1.20)	0.8881	0.97 (0.71, 1.34)	0.8602	-0.01 (-0.08, 0.07)	0.8524	
Latin America	92/ 341 (26.98)	101/ 364 (27.75)	0.98 (0.77, 1.25)	0.8672	0.97 (0.69, 1.35)	0.8383	-0.01 (-0.08, 0.06)	0.7927	
Age group (years)									0.9714
<= median in FAS	411/ 1825 (22.52)	435/ 1831 (23.76)	0.95 (0.84, 1.07)	0.4047	0.94 (0.80, 1.09)	0.4022	-0.01 (-0.04, 0.02)	0.3978	
> median in FAS	502/ 1652 (30.39)	536/ 1684 (31.83)	0.95 (0.86, 1.05)	0.3571	0.93 (0.81, 1.08)	0.3634	-0.01 (-0.05, 0.02)	0.3683	
Study									0.9865
FINEARTS-HF	789/ 2993 (26.36)	827/ 2993 (27.63)	0.95 (0.88, 1.04)	0.2687	0.94 (0.84, 1.05)	0.2686	-0.01 (-0.04, 0.01)	0.2685	
FIGARO-DKD	69/ 289 (23.88)	72/ 281 (25.62)	0.93 (0.70, 1.24)	0.6289	0.91 (0.62, 1.33)	0.6289	-0.02 (-0.09, 0.05)	0.6289	
FIDELIO-DKD	55/ 195 (28.21)	72/ 241 (29.88)	0.94 (0.70, 1.27)	0.7031	0.92 (0.61, 1.40)	0.7027	-0.02 (-0.10, 0.07)	0.7021	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	897/ 3477 (25.80)	948/ 3515 (26.97)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	0.94 (0.85, 1.05)	
p-value	0.2793	
Risk Ratio (95% CI)	0.96 (0.89, 1.04)	
p-value	0.2789	
Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
p-value	0.2799	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	177/ 3477 (5.09)	157/ 3515 (4.47)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.16 (0.93, 1.44)	
p-value	0.1924	
Risk Ratio (95% CI)	1.15 (0.93, 1.42)	
p-value	0.1887	
Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
p-value	0.2450	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
Sex									0.7608
Male	104/ 1945 (5.35)	94/ 1947 (4.83)	1.12 (0.85, 1.46)	0.4325	1.12 (0.84, 1.49)	0.4359	0.00 (-0.01, 0.02)	0.5026	
Female	73/ 1532 (4.77)	63/ 1568 (4.02)	1.19 (0.86, 1.65)	0.2960	1.20 (0.85, 1.70)	0.2949	0.01 (-0.01, 0.02)	0.2807	
Region									0.6990
Western Europe, Oceania and Others	60/ 688 (8.72)	48/ 716 (6.70)	1.32 (0.91, 1.90)	0.1397	1.34 (0.90, 1.99)	0.1444	0.02 (-0.01, 0.05)	0.1882	
Eastern Europe	47/ 1577 (2.98)	49/ 1567 (3.13)	0.96 (0.64, 1.42)	0.8232	0.96 (0.64, 1.43)	0.8252	-0.00 (-0.01, 0.01)	0.8743	
Asia	28/ 554 (5.05)	26/ 551 (4.72)	1.06 (0.63, 1.77)	0.8397	1.06 (0.61, 1.84)	0.8289	0.00 (-0.02, 0.03)	0.7321	
North America	28/ 317 (8.83)	20/ 317 (6.31)	1.46 (0.84, 2.53)	0.1789	1.51 (0.83, 2.75)	0.1781	0.03 (-0.01, 0.08)	0.1677	
Latin America	14/ 341 (4.11)	14/ 364 (3.85)	1.10 (0.53, 2.29)	0.8017	1.11 (0.52, 2.38)	0.7891	0.01 (-0.02, 0.04)	0.6448	
Age group (years)									0.8330
<= median in FAS	70/ 1825 (3.84)	61/ 1831 (3.33)	1.19 (0.85, 1.67)	0.3039	1.20 (0.84, 1.70)	0.3117	0.00 (-0.01, 0.02)	0.4418	
> median in FAS	107/ 1652 (6.48)	96/ 1684 (5.70)	1.14 (0.87, 1.49)	0.3383	1.15 (0.87, 1.53)	0.3360	0.01 (-0.01, 0.02)	0.3213	
Study									0.3788
FINEARTS-HF	147/ 2993 (4.91)	128/ 2993 (4.28)	1.15 (0.91, 1.45)	0.2412	1.16 (0.91, 1.47)	0.2412	0.01 (-0.00, 0.02)	0.2407	
FIGARO-DKD	11/ 289 (3.81)	14/ 281 (4.98)	0.76 (0.35, 1.65)	0.4945	0.75 (0.34, 1.69)	0.4943	-0.01 (-0.05, 0.02)	0.4937	
FIDELIO-DKD	19/ 195 (9.74)	15/ 241 (6.22)	1.57 (0.82, 3.00)	0.1766	1.63 (0.80, 3.29)	0.1763	0.04 (-0.02, 0.09)	0.1813	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	172/ 3477 (4.95)	150/ 3515 (4.27)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.18 (0.94, 1.48)	
p-value	0.1515	
Risk Ratio (95% CI)	1.17 (0.95, 1.45)	
p-value	0.1493	
Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
p-value	0.1834	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	115/ 3477 (3.31)	112/ 3515 (3.19)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.05 (0.80, 1.36)	
p-value	0.7437	
Risk Ratio (95% CI)	1.04 (0.81, 1.35)	
p-value	0.7439	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.7406	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Serious)
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	103/ 3477 (2.96)	99/ 3515 (2.82)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.06 (0.80, 1.40)	
p-value	0.6997	
Risk Ratio (95% CI)	1.06 (0.80, 1.39)	
p-value	0.6979	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.7676	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with SMQ:Sepsis (Severe)
Safety Analysis Set

	Finerenone (N=3477)	Placebo (N=3515)
Number of subjects with event, n/N (%)	79/ 3477 (2.27)	77/ 3515 (2.19)
Analysis Finerenone vs. Placebo		
Odds Ratio (95% CI)	1.04 (0.76, 1.44)	
p-value	0.7878	
Risk Ratio (95% CI)	1.04 (0.77, 1.42)	
p-value	0.7868	
Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
p-value	0.8237	

Analysis based on all AE starting at beginning of treatment until end of study.
All PTs related to SMQ of Sepsis according to MedDRA 27.0 were used for the analysis
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	428/ 3477 (12.31)	428/ 3515 (12.18)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.89, 1.18)	
	p-value	0.7663	
	Risk Ratio (95% CI)	1.02 (0.90, 1.15)	
	p-value	0.7712	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.7566	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	288/ 3477 (8.28)	272/ 3515 (7.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.91, 1.29)	
	p-value	0.3522	
	Risk Ratio (95% CI)	1.08 (0.92, 1.26)	
	p-value	0.3556	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.3359	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Iron deficiency anaemia	Number of subjects with event, n/N (%)	50/ 3477 (1.44)	76/ 3515 (2.16)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.66 (0.46, 0.94)	
	p-value	0.0231	
	Risk Ratio (95% CI)	0.66 (0.47, 0.95)	
	p-value	0.0231	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0231	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	878/ 3477 (25.25)	894/ 3515 (25.43)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.99 (0.89, 1.11)	
	p-value	0.8930	
	Risk Ratio (95% CI)	0.99 (0.92, 1.08)	
	p-value	0.8684	
	Risk Difference (95% CI)	-0.00 (-0.02, 0.02)	
	p-value	0.9331	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Angina pectoris	Number of subjects with event, n/N (%)	63/ 3477 (1.81)	75/ 3515 (2.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.60, 1.19)	
	p-value	0.3306	
	Risk Ratio (95% CI)	0.85 (0.61, 1.18)	
	p-value	0.3308	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3194	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	50/ 3477 (1.44)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.78, 1.76)	
	p-value	0.4525	
	Risk Ratio (95% CI)	1.17 (0.78, 1.75)	
	p-value	0.4504	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.6412	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Atrial fibrillation	Number of subjects with event, n/N (%)	170/ 3477 (4.89)	178/ 3515 (5.06)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.77, 1.19)	
	p-value	0.6936	
	Risk Ratio (95% CI)	0.96 (0.78, 1.18)	
	p-value	0.6985	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5240	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Bradycardia	Number of subjects with event, n/N (%)	67/ 3477 (1.93)	63/ 3515 (1.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.77, 1.53)	
	p-value	0.6498	
	Risk Ratio (95% CI)	1.08 (0.77, 1.52)	
	p-value	0.6544	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4935	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	217/ 3477 (6.24)	255/ 3515 (7.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.71, 1.03)	
	p-value	0.0978	
	Risk Ratio (95% CI)	0.86 (0.72, 1.03)	
	p-value	0.0978	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.0952	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Coronary artery disease	Number of subjects with event, n/N (%)	49/ 3477 (1.41)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.77, 1.75)	
	p-value	0.4870	
	Risk Ratio (95% CI)	1.16 (0.77, 1.74)	
	p-value	0.4872	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4731	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Mitral valve incompetence	Number of subjects with event, n/N (%)	38/ 3477 (1.09)	42/ 3515 (1.19)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.92 (0.59, 1.44)	
	p-value	0.7235	
	Risk Ratio (95% CI)	0.93 (0.60, 1.43)	
	p-value	0.7262	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.6249	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Palpitations	Number of subjects with event, n/N (%)	34/ 3477 (0.98)	51/ 3515 (1.45)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.43, 1.04)	
	p-value	0.0714	
	Risk Ratio (95% CI)	0.67 (0.44, 1.04)	
	p-value	0.0716	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.0636	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Ventricular extrasystoles	Number of subjects with event, n/N (%)	40/ 3477 (1.15)	33/ 3515 (0.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.24 (0.78, 1.97)	
	p-value	0.3651	
	Risk Ratio (95% CI)	1.24 (0.78, 1.96)	
	p-value	0.3650	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3934	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	113/ 3477 (3.25)	107/ 3515 (3.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.83, 1.41)	
	p-value	0.5728	
	Risk Ratio (95% CI)	1.08 (0.83, 1.40)	
	p-value	0.5721	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5782	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Ear and labyrinth disorders; PT: Vertigo	Number of subjects with event, n/N (%)	53/ 3477 (1.52)	57/ 3515 (1.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.94 (0.64, 1.37)	
	p-value	0.7482	
	Risk Ratio (95% CI)	0.94 (0.65, 1.36)	
	p-value	0.7492	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.7031	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Endocrine disorders	Number of subjects with event, n/N (%)	91/ 3477 (2.62)	99/ 3515 (2.82)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.70, 1.25)	
	p-value	0.6478	
	Risk Ratio (95% CI)	0.94 (0.71, 1.24)	
	p-value	0.6418	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.7875	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Endocrine disorders; PT: Hypothyroidism	Number of subjects with event, n/N (%)	40/ 3477 (1.15)	47/ 3515 (1.34)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.56, 1.31)	
	p-value	0.4674	
	Risk Ratio (95% CI)	0.86 (0.56, 1.30)	
	p-value	0.4667	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5828	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Eye disorders	Number of subjects with event, n/N (%)	219/ 3477 (6.30)	233/ 3515 (6.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.79, 1.16)	
	p-value	0.6848	
	Risk Ratio (95% CI)	0.96 (0.81, 1.15)	
	p-value	0.6752	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.7040	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Eye disorders; PT: Cataract	Number of subjects with event, n/N (%)	79/ 3477 (2.27)	83/ 3515 (2.36)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.71, 1.33)	
	p-value	0.8508	
	Risk Ratio (95% CI)	0.97 (0.72, 1.32)	
	p-value	0.8636	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5787	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	891/ 3477 (25.63)	820/ 3515 (23.33)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (1.02, 1.27)	
	p-value	0.0232	
	Risk Ratio (95% CI)	1.10 (1.01, 1.19)	
	p-value	0.0230	
	Risk Difference (95% CI)	0.02 (0.00, 0.04)	
	p-value	0.0235	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Abdominal pain	Number of subjects with event, n/N (%)	60/ 3477 (1.73)	53/ 3515 (1.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.14 (0.79, 1.66)	
	p-value	0.4807	
	Risk Ratio (95% CI)	1.14 (0.79, 1.65)	
	p-value	0.4783	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5764	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Abdominal pain upper	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	44/ 3515 (1.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.12 (0.74, 1.69)	
	p-value	0.5930	
	Risk Ratio (95% CI)	1.12 (0.74, 1.68)	
	p-value	0.5936	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5629	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Constipation	Number of subjects with event, n/N (%)	160/ 3477 (4.60)	127/ 3515 (3.61)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.29 (1.02, 1.64)	
	p-value	0.0362	
	Risk Ratio (95% CI)	1.28 (1.02, 1.60)	
	p-value	0.0368	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0259	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	213/ 3477 (6.13)	177/ 3515 (5.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.23 (1.00, 1.51)	
	p-value	0.0451	
	Risk Ratio (95% CI)	1.22 (1.00, 1.48)	
	p-value	0.0448	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.0533	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Dyspepsia	Number of subjects with event, n/N (%)	39/ 3477 (1.12)	39/ 3515 (1.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.65, 1.58)	
	p-value	0.9706	
	Risk Ratio (95% CI)	1.01 (0.65, 1.57)	
	p-value	0.9706	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.9696	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Gastritis	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	33/ 3515 (0.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (0.81, 2.03)	
	p-value	0.2842	
	Risk Ratio (95% CI)	1.28 (0.81, 2.01)	
	p-value	0.2863	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1928	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Gastrointestinal haemorrhage	Number of subjects with event, n/N (%)	38/ 3477 (1.09)	22/ 3515 (0.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.77 (1.04, 3.00)	
	p-value	0.0338	
	Risk Ratio (95% CI)	1.76 (1.04, 2.97)	
	p-value	0.0337	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0510	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Gastrooesophageal reflux disease	Number of subjects with event, n/N (%)	53/ 3477 (1.52)	37/ 3515 (1.05)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.45 (0.95, 2.21)	
	p-value	0.0869	
	Risk Ratio (95% CI)	1.44 (0.95, 2.19)	
	p-value	0.0853	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1704	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Haemorrhoids	Number of subjects with event, n/N (%)	40/ 3477 (1.15)	35/ 3515 (1.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.15 (0.73, 1.82)	
	p-value	0.5409	
	Risk Ratio (95% CI)	1.15 (0.73, 1.81)	
	p-value	0.5425	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4577	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Large intestine polyp	Number of subjects with event, n/N (%)	35/ 3477 (1.01)	32/ 3515 (0.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.11 (0.68, 1.79)	
	p-value	0.6762	
	Risk Ratio (95% CI)	1.11 (0.69, 1.78)	
	p-value	0.6774	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5994	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	104/ 3477 (2.99)	92/ 3515 (2.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.15 (0.87, 1.53)	
	p-value	0.3274	
	Risk Ratio (95% CI)	1.15 (0.87, 1.51)	
	p-value	0.3286	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3123	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Vomiting	Number of subjects with event, n/N (%)	66/ 3477 (1.90)	53/ 3515 (1.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.27 (0.88, 1.83)	
	p-value	0.2025	
	Risk Ratio (95% CI)	1.26 (0.88, 1.81)	
	p-value	0.2027	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1927	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	683/ 3477 (19.64)	755/ 3515 (21.48)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.80, 1.01)	
	p-value	0.0663	
	Risk Ratio (95% CI)	0.92 (0.84, 1.01)	
	p-value	0.0648	
	Risk Difference (95% CI)	-0.02 (-0.04, 0.00)	
	p-value	0.0700	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	81/ 3477 (2.33)	66/ 3515 (1.88)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.24 (0.90, 1.73)	
	p-value	0.1935	
	Risk Ratio (95% CI)	1.24 (0.90, 1.71)	
	p-value	0.1937	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1884	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Chest pain	Number of subjects with event, n/N (%)	120/ 3477 (3.45)	135/ 3515 (3.84)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.70, 1.15)	
	p-value	0.3829	
	Risk Ratio (95% CI)	0.90 (0.71, 1.14)	
	p-value	0.3827	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3859	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	74/ 3477 (2.13)	104/ 3515 (2.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.52, 0.96)	
	p-value	0.0248	
	Risk Ratio (95% CI)	0.71 (0.53, 0.96)	
	p-value	0.0249	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0247	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Fatigue	Number of subjects with event, n/N (%)	85/ 3477 (2.44)	71/ 3515 (2.02)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.21 (0.88, 1.67)	
	p-value	0.2328	
	Risk Ratio (95% CI)	1.21 (0.89, 1.65)	
	p-value	0.2330	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2249	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	149/ 3477 (4.29)	161/ 3515 (4.58)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.75, 1.19)	
	p-value	0.6422	
	Risk Ratio (95% CI)	0.95 (0.76, 1.18)	
	p-value	0.6166	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9585	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Peripheral swelling	Number of subjects with event, n/N (%)	40/ 3477 (1.15)	40/ 3515 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.66, 1.59)	
	p-value	0.9306	
	Risk Ratio (95% CI)	1.02 (0.66, 1.58)	
	p-value	0.9316	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.8665	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Pyrexia	Number of subjects with event, n/N (%)	63/ 3477 (1.81)	76/ 3515 (2.16)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.83 (0.60, 1.17)	
	p-value	0.2942	
	Risk Ratio (95% CI)	0.84 (0.60, 1.17)	
	p-value	0.2938	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3349	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	163/ 3477 (4.69)	188/ 3515 (5.35)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.88 (0.71, 1.09)	
	p-value	0.2365	
	Risk Ratio (95% CI)	0.89 (0.72, 1.09)	
	p-value	0.2422	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1784	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders; PT: Cholelithiasis	Number of subjects with event, n/N (%)	30/ 3477 (0.86)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.72 (0.45, 1.15)	
	p-value	0.1728	
	Risk Ratio (95% CI)	0.72 (0.46, 1.15)	
	p-value	0.1724	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2242	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	1580/ 3477 (45.44)	1582/ 3515 (45.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.93, 1.12)	
	p-value	0.7035	
	Risk Ratio (95% CI)	1.01 (0.96, 1.06)	
	p-value	0.7160	
	Risk Difference (95% CI)	0.00 (-0.02, 0.03)	
	p-value	0.7013	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Bronchitis	Number of subjects with event, n/N (%)	134/ 3477 (3.85)	131/ 3515 (3.73)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.82, 1.33)	
	p-value	0.7410	
	Risk Ratio (95% CI)	1.04 (0.82, 1.32)	
	p-value	0.7414	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.7392	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	402/ 3477 (11.56)	392/ 3515 (11.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.03 (0.89, 1.19)	
	p-value	0.7035	
	Risk Ratio (95% CI)	1.03 (0.90, 1.17)	
	p-value	0.6898	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.4190	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19 pneumonia	Number of subjects with event, n/N (%)	34/ 3477 (0.98)	40/ 3515 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.54, 1.34)	
	p-value	0.4813	
	Risk Ratio (95% CI)	0.85 (0.54, 1.34)	
	p-value	0.4813	
	Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
	p-value	0.8122	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	85/ 3477 (2.44)	87/ 3515 (2.48)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.99 (0.73, 1.35)	
	p-value	0.9682	
	Risk Ratio (95% CI)	0.99 (0.74, 1.34)	
	p-value	0.9709	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8974	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Cystitis	Number of subjects with event, n/N (%)	32/ 3477 (0.92)	40/ 3515 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.50, 1.28)	
	p-value	0.3630	
	Risk Ratio (95% CI)	0.81 (0.51, 1.28)	
	p-value	0.3623	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4134	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Gastroenteritis	Number of subjects with event, n/N (%)	44/ 3477 (1.27)	23/ 3515 (0.65)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.97 (1.19, 3.27)	
	p-value	0.0088	
	Risk Ratio (95% CI)	1.95 (1.18, 3.23)	
	p-value	0.0089	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0066	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Herpes zoster	Number of subjects with event, n/N (%)	40/ 3477 (1.15)	46/ 3515 (1.31)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.57, 1.34)	
	p-value	0.5306	
	Risk Ratio (95% CI)	0.87 (0.57, 1.33)	
	p-value	0.5300	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.6207	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Influenza	Number of subjects with event, n/N (%)	92/ 3477 (2.65)	98/ 3515 (2.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.71, 1.26)	
	p-value	0.7118	
	Risk Ratio (95% CI)	0.95 (0.72, 1.26)	
	p-value	0.7131	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.6598	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	153/ 3477 (4.40)	140/ 3515 (3.98)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.89, 1.42)	
	p-value	0.3245	
	Risk Ratio (95% CI)	1.12 (0.89, 1.40)	
	p-value	0.3350	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.2228	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	274/ 3477 (7.88)	285/ 3515 (8.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.82, 1.16)	
	p-value	0.7847	
	Risk Ratio (95% CI)	0.98 (0.83, 1.14)	
	p-value	0.7599	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9728	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Respiratory tract infection	Number of subjects with event, n/N (%)	91/ 3477 (2.62)	78/ 3515 (2.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.19 (0.87, 1.61)	
	p-value	0.2731	
	Risk Ratio (95% CI)	1.18 (0.88, 1.59)	
	p-value	0.2723	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2986	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Respiratory tract infection viral	Number of subjects with event, n/N (%)	39/ 3477 (1.12)	34/ 3515 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.73, 1.85)	
	p-value	0.5232	
	Risk Ratio (95% CI)	1.16 (0.73, 1.83)	
	p-value	0.5252	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4041	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	55/ 3477 (1.58)	38/ 3515 (1.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.49 (0.98, 2.26)	
	p-value	0.0613	
	Risk Ratio (95% CI)	1.48 (0.98, 2.23)	
	p-value	0.0622	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0366	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Upper respiratory tract infection	Number of subjects with event, n/N (%)	120/ 3477 (3.45)	120/ 3515 (3.41)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.79, 1.32)	
	p-value	0.8640	
	Risk Ratio (95% CI)	1.02 (0.80, 1.31)	
	p-value	0.8576	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.9775	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	255/ 3477 (7.33)	247/ 3515 (7.03)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.87, 1.26)	
	p-value	0.6125	
	Risk Ratio (95% CI)	1.04 (0.88, 1.24)	
	p-value	0.6152	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.5853	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	546/ 3477 (15.70)	600/ 3515 (17.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.80, 1.03)	
	p-value	0.1504	
	Risk Ratio (95% CI)	0.92 (0.83, 1.03)	
	p-value	0.1427	
	Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
	p-value	0.1741	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Contusion	Number of subjects with event, n/N (%)	52/ 3477 (1.50)	68/ 3515 (1.93)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.77 (0.54, 1.12)	
	p-value	0.1702	
	Risk Ratio (95% CI)	0.78 (0.54, 1.11)	
	p-value	0.1692	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2502	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Fall	Number of subjects with event, n/N (%)	120/ 3477 (3.45)	105/ 3515 (2.99)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.89, 1.52)	
	p-value	0.2697	
	Risk Ratio (95% CI)	1.16 (0.89, 1.50)	
	p-value	0.2691	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2985	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Limb injury	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	39/ 3515 (1.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (0.83, 1.96)	
	p-value	0.2587	
	Risk Ratio (95% CI)	1.27 (0.84, 1.94)	
	p-value	0.2577	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3213	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations	Number of subjects with event, n/N (%)	633/ 3477 (18.21)	600/ 3515 (17.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.96, 1.23)	
	p-value	0.1704	
	Risk Ratio (95% CI)	1.07 (0.97, 1.18)	
	p-value	0.1817	
	Risk Difference (95% CI)	0.01 (-0.00, 0.03)	
	p-value	0.1527	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood creatinine increased	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	38/ 3515 (1.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.29 (0.84, 1.98)	
	p-value	0.2433	
	Risk Ratio (95% CI)	1.28 (0.84, 1.96)	
	p-value	0.2456	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1627	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood potassium increased	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	19/ 3515 (0.54)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.31 (1.34, 3.98)	
	p-value	0.0026	
	Risk Ratio (95% CI)	2.29 (1.33, 3.93)	
	p-value	0.0026	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0042	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood pressure increased	Number of subjects with event, n/N (%)	33/ 3477 (0.95)	60/ 3515 (1.71)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.56 (0.37, 0.86)	
	p-value	0.0087	
	Risk Ratio (95% CI)	0.57 (0.37, 0.87)	
	p-value	0.0086	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0167	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	192/ 3477 (5.52)	141/ 3515 (4.01)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.41 (1.13, 1.76)	
	p-value	0.0025	
	Risk Ratio (95% CI)	1.38 (1.12, 1.71)	
	p-value	0.0026	
	Risk Difference (95% CI)	0.02 (0.01, 0.03)	
	p-value	0.0015	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	1038/ 3477 (29.85)	966/ 3515 (27.48)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (1.02, 1.26)	
	p-value	0.0196	
	Risk Ratio (95% CI)	1.09 (1.01, 1.17)	
	p-value	0.0219	
	Risk Difference (95% CI)	0.03 (0.00, 0.05)	
	p-value	0.0183	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Dehydration	Number of subjects with event, n/N (%)	81/ 3477 (2.33)	50/ 3515 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.64 (1.15, 2.34)	
	p-value	0.0066	
	Risk Ratio (95% CI)	1.62 (1.14, 2.30)	
	p-value	0.0067	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0119	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Diabetes mellitus	Number of subjects with event, n/N (%)	57/ 3477 (1.64)	74/ 3515 (2.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.79 (0.55, 1.12)	
	p-value	0.1777	
	Risk Ratio (95% CI)	0.79 (0.56, 1.11)	
	p-value	0.1760	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2639	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Gout	Number of subjects with event, n/N (%)	85/ 3477 (2.44)	93/ 3515 (2.65)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.93 (0.69, 1.25)	
	p-value	0.6188	
	Risk Ratio (95% CI)	0.93 (0.70, 1.24)	
	p-value	0.6214	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5454	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia	Number of subjects with event, n/N (%)	47/ 3477 (1.35)	38/ 3515 (1.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.29 (0.84, 1.99)	
	p-value	0.2463	
	Risk Ratio (95% CI)	1.28 (0.84, 1.96)	
	p-value	0.2474	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3064	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	351/ 3477 (10.09)	161/ 3515 (4.58)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	2.38 (1.96, 2.89)	
	p-value	<.0001	
	Risk Ratio (95% CI)	2.23 (1.86, 2.67)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.05 (0.04, 0.07)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyperuricaemia	Number of subjects with event, n/N (%)	110/ 3477 (3.16)	105/ 3515 (2.99)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.82, 1.41)	
	p-value	0.6015	
	Risk Ratio (95% CI)	1.07 (0.82, 1.39)	
	p-value	0.6130	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4335	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hypoglycaemia	Number of subjects with event, n/N (%)	58/ 3477 (1.67)	52/ 3515 (1.48)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.80, 1.72)	
	p-value	0.4153	
	Risk Ratio (95% CI)	1.16 (0.80, 1.67)	
	p-value	0.4339	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.1694	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hypokalaemia	Number of subjects with event, n/N (%)	127/ 3477 (3.65)	244/ 3515 (6.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.50 (0.41, 0.63)	
	p-value	<.0001	
	Risk Ratio (95% CI)	0.52 (0.42, 0.65)	
	p-value	<.0001	
	Risk Difference (95% CI)	-0.03 (-0.04, -0.02)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyponatraemia	Number of subjects with event, n/N (%)	78/ 3477 (2.24)	42/ 3515 (1.19)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.91 (1.31, 2.78)	
	p-value	0.0008	
	Risk Ratio (95% CI)	1.89 (1.30, 2.74)	
	p-value	0.0008	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0004	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Iron deficiency	Number of subjects with event, n/N (%)	53/ 3477 (1.52)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.25 (0.83, 1.87)	
	p-value	0.2812	
	Risk Ratio (95% CI)	1.25 (0.84, 1.86)	
	p-value	0.2813	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3463	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Type 2 diabetes mellitus	Number of subjects with event, n/N (%)	85/ 3477 (2.44)	95/ 3515 (2.70)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.67, 1.21)	
	p-value	0.4751	
	Risk Ratio (95% CI)	0.90 (0.67, 1.20)	
	p-value	0.4752	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4757	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Vitamin D deficiency	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	34/ 3515 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.44 (0.93, 2.25)	
	p-value	0.1040	
	Risk Ratio (95% CI)	1.44 (0.93, 2.22)	
	p-value	0.1043	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0957	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	704/ 3477 (20.25)	739/ 3515 (21.02)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.85, 1.07)	
	p-value	0.4576	
	Risk Ratio (95% CI)	0.96 (0.88, 1.06)	
	p-value	0.4456	
	Risk Difference (95% CI)	-0.01 (-0.03, 0.01)	
	p-value	0.4870	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	150/ 3477 (4.31)	160/ 3515 (4.55)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.75, 1.19)	
	p-value	0.6334	
	Risk Ratio (95% CI)	0.95 (0.76, 1.18)	
	p-value	0.6376	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5589	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	152/ 3477 (4.37)	169/ 3515 (4.81)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.91 (0.73, 1.14)	
	p-value	0.4063	
	Risk Ratio (95% CI)	0.91 (0.74, 1.13)	
	p-value	0.4068	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.4011	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	39/ 3515 (1.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.26 (0.82, 1.93)	
	p-value	0.2859	
	Risk Ratio (95% CI)	1.26 (0.83, 1.91)	
	p-value	0.2854	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3036	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia	Number of subjects with event, n/N (%)	39/ 3477 (1.12)	26/ 3515 (0.74)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.56 (0.94, 2.56)	
	p-value	0.0830	
	Risk Ratio (95% CI)	1.55 (0.94, 2.54)	
	p-value	0.0833	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0804	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Osteoarthritis	Number of subjects with event, n/N (%)	78/ 3477 (2.24)	88/ 3515 (2.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.65, 1.21)	
	p-value	0.4599	
	Risk Ratio (95% CI)	0.89 (0.66, 1.21)	
	p-value	0.4578	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.5467	

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity	Number of subjects with event, n/N (%)	97/ 3477 (2.79)	89/ 3515 (2.53)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.11 (0.83, 1.49)	
	p-value	0.4843	
	Risk Ratio (95% CI)	1.11 (0.83, 1.47)	
	p-value	0.4869	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4205	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Spinal osteoarthritis	Number of subjects with event, n/N (%)	22/ 3477 (0.63)	39/ 3515 (1.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.58 (0.34, 0.98)	
	p-value	0.0417	
	Risk Ratio (95% CI)	0.58 (0.35, 0.98)	
	p-value	0.0417	
	Risk Difference (95% CI)	-0.00 (-0.01, -0.00)	
	p-value	0.0481	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	244/ 3477 (7.02)	251/ 3515 (7.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.82, 1.18)	
	p-value	0.8668	
	Risk Ratio (95% CI)	0.99 (0.83, 1.17)	
	p-value	0.8681	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8545	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	730/ 3477 (21.00)	733/ 3515 (20.85)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.90, 1.13)	
	p-value	0.8606	
	Risk Ratio (95% CI)	1.01 (0.92, 1.10)	
	p-value	0.8724	
	Risk Difference (95% CI)	0.00 (-0.02, 0.02)	
	p-value	0.8314	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	203/ 3477 (5.84)	183/ 3515 (5.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.92, 1.38)	
	p-value	0.2608	
	Risk Ratio (95% CI)	1.12 (0.92, 1.36)	
	p-value	0.2558	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.3800	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Headache	Number of subjects with event, n/N (%)	125/ 3477 (3.60)	117/ 3515 (3.33)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.83, 1.39)	
	p-value	0.5624	
	Risk Ratio (95% CI)	1.08 (0.84, 1.38)	
	p-value	0.5603	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.6270	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Syncope	Number of subjects with event, n/N (%)	93/ 3477 (2.67)	75/ 3515 (2.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.27 (0.93, 1.73)	
	p-value	0.1282	
	Risk Ratio (95% CI)	1.26 (0.93, 1.70)	
	p-value	0.1306	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.0772	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	263/ 3477 (7.56)	268/ 3515 (7.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.83, 1.19)	
	p-value	0.9674	
	Risk Ratio (95% CI)	1.00 (0.85, 1.17)	
	p-value	0.9658	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9722	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Anxiety	Number of subjects with event, n/N (%)	43/ 3477 (1.24)	32/ 3515 (0.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.37 (0.86, 2.17)	
	p-value	0.1815	
	Risk Ratio (95% CI)	1.36 (0.87, 2.15)	
	p-value	0.1811	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2127	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Depression	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	53/ 3515 (1.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.53, 1.21)	
	p-value	0.2944	
	Risk Ratio (95% CI)	0.81 (0.54, 1.21)	
	p-value	0.2931	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3654	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Insomnia	Number of subjects with event, n/N (%)	95/ 3477 (2.73)	90/ 3515 (2.56)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.80, 1.44)	
	p-value	0.6206	
	Risk Ratio (95% CI)	1.07 (0.81, 1.43)	
	p-value	0.6235	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5523	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	763/ 3477 (21.94)	672/ 3515 (19.12)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.19 (1.06, 1.34)	
	p-value	0.0027	
	Risk Ratio (95% CI)	1.15 (1.05, 1.26)	
	p-value	0.0031	
	Risk Difference (95% CI)	0.03 (0.01, 0.05)	
	p-value	0.0020	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	188/ 3477 (5.41)	135/ 3515 (3.84)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.46 (1.16, 1.83)	
	p-value	0.0012	
	Risk Ratio (95% CI)	1.42 (1.15, 1.77)	
	p-value	0.0013	
	Risk Difference (95% CI)	0.02 (0.01, 0.03)	
	p-value	0.0004	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Chronic kidney disease	Number of subjects with event, n/N (%)	75/ 3477 (2.16)	80/ 3515 (2.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.95 (0.69, 1.31)	
	p-value	0.7676	
	Risk Ratio (95% CI)	0.95 (0.70, 1.30)	
	p-value	0.7650	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8510	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Haematuria	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	44/ 3515 (1.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.63, 1.47)	
	p-value	0.8496	
	Risk Ratio (95% CI)	0.96 (0.63, 1.46)	
	p-value	0.8488	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.8360	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Microalbuminuria	Number of subjects with event, n/N (%)	39/ 3477 (1.12)	58/ 3515 (1.65)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.44, 1.01)	
	p-value	0.0533	
	Risk Ratio (95% CI)	0.67 (0.45, 1.01)	
	p-value	0.0534	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.4738	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Renal cyst	Number of subjects with event, n/N (%)	36/ 3477 (1.04)	53/ 3515 (1.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.45, 1.06)	
	p-value	0.0873	
	Risk Ratio (95% CI)	0.69 (0.46, 1.06)	
	p-value	0.0897	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0259	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Renal failure	Number of subjects with event, n/N (%)	98/ 3477 (2.82)	64/ 3515 (1.82)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.57 (1.14, 2.15)	
	p-value	0.0058	
	Risk Ratio (95% CI)	1.55 (1.14, 2.12)	
	p-value	0.0058	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0079	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	236/ 3477 (6.79)	147/ 3515 (4.18)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.67 (1.35, 2.07)	
	p-value	<.0001	
	Risk Ratio (95% CI)	1.63 (1.33, 1.99)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.02 (0.01, 0.04)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	124/ 3477 (3.57)	123/ 3515 (3.50)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.02 (0.79, 1.32)	
	p-value	0.8623	
	Risk Ratio (95% CI)	1.02 (0.80, 1.31)	
	p-value	0.8630	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8555	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Reproductive system and breast disorders; PT: Benign prostatic hyperplasia	Number of subjects with event, n/N (%)	58/ 3477 (1.67)	39/ 3515 (1.11)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.51 (1.00, 2.27)	
	p-value	0.0483	
	Risk Ratio (95% CI)	1.50 (1.00, 2.25)	
	p-value	0.0485	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0497	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	700/ 3477 (20.13)	712/ 3515 (20.26)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.89, 1.12)	
	p-value	0.9541	
	Risk Ratio (95% CI)	1.00 (0.91, 1.09)	
	p-value	0.9296	
	Risk Difference (95% CI)	0.00 (-0.02, 0.02)	
	p-value	0.9898	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	100/ 3477 (2.88)	95/ 3515 (2.70)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.08 (0.81, 1.44)	
	p-value	0.5932	
	Risk Ratio (95% CI)	1.08 (0.82, 1.42)	
	p-value	0.5885	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.6855	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough	Number of subjects with event, n/N (%)	108/ 3477 (3.11)	109/ 3515 (3.10)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.76, 1.31)	
	p-value	0.9911	
	Risk Ratio (95% CI)	1.00 (0.77, 1.30)	
	p-value	0.9926	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9379	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	189/ 3477 (5.44)	183/ 3515 (5.21)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.86, 1.30)	
	p-value	0.6204	
	Risk Ratio (95% CI)	1.05 (0.86, 1.28)	
	p-value	0.6205	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.6217	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Epistaxis	Number of subjects with event, n/N (%)	50/ 3477 (1.44)	75/ 3515 (2.13)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.67 (0.46, 0.96)	
	p-value	0.0279	
	Risk Ratio (95% CI)	0.67 (0.47, 0.96)	
	p-value	0.0281	
	Risk Difference (95% CI)	-0.01 (-0.01, -0.00)	
	p-value	0.0215	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleural effusion	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.65, 1.54)	
	p-value	0.9946	
	Risk Ratio (95% CI)	1.00 (0.66, 1.53)	
	p-value	0.9991	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.8219	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Respiratory failure	Number of subjects with event, n/N (%)	42/ 3477 (1.21)	25/ 3515 (0.71)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.74 (1.06, 2.86)	
	p-value	0.0299	
	Risk Ratio (95% CI)	1.73 (1.06, 2.83)	
	p-value	0.0296	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0583	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	378/ 3477 (10.87)	363/ 3515 (10.33)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.92, 1.25)	
	p-value	0.3787	
	Risk Ratio (95% CI)	1.06 (0.93, 1.22)	
	p-value	0.3858	
	Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
	p-value	0.3644	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Pruritus	Number of subjects with event, n/N (%)	50/ 3477 (1.44)	56/ 3515 (1.59)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.62, 1.33)	
	p-value	0.6104	
	Risk Ratio (95% CI)	0.91 (0.62, 1.32)	
	p-value	0.6102	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.6215	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Rash	Number of subjects with event, n/N (%)	45/ 3477 (1.29)	34/ 3515 (0.97)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.34 (0.86, 2.10)	
	p-value	0.1951	
	Risk Ratio (95% CI)	1.34 (0.86, 2.09)	
	p-value	0.1958	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0848	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Skin ulcer	Number of subjects with event, n/N (%)	61/ 3477 (1.75)	63/ 3515 (1.79)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.00 (0.70, 1.43)	
	p-value	0.9999	
	Risk Ratio (95% CI)	1.00 (0.71, 1.42)	
	p-value	0.9969	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8460	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	184/ 3477 (5.29)	161/ 3515 (4.58)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.17 (0.94, 1.46)	
	p-value	0.1485	
	Risk Ratio (95% CI)	1.16 (0.95, 1.43)	
	p-value	0.1548	
	Risk Difference (95% CI)	0.01 (-0.00, 0.02)	
	p-value	0.0923	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	674/ 3477 (19.38)	660/ 3515 (18.78)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.05 (0.93, 1.18)	
	p-value	0.4568	
	Risk Ratio (95% CI)	1.04 (0.94, 1.14)	
	p-value	0.4827	
	Risk Difference (95% CI)	0.01 (-0.01, 0.03)	
	p-value	0.4002	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Hypertension	Number of subjects with event, n/N (%)	169/ 3477 (4.86)	246/ 3515 (7.00)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.68 (0.56, 0.84)	
	p-value	0.0002	
	Risk Ratio (95% CI)	0.70 (0.58, 0.85)	
	p-value	0.0002	
	Risk Difference (95% CI)	-0.02 (-0.03, -0.01)	
	p-value	0.0002	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	270/ 3477 (7.77)	181/ 3515 (5.15)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.55 (1.28, 1.88)	
	p-value	<.0001	
	Risk Ratio (95% CI)	1.51 (1.26, 1.81)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.03 (0.01, 0.04)	
	p-value	<.0001	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Orthostatic hypotension	Number of subjects with event, n/N (%)	36/ 3477 (1.04)	23/ 3515 (0.65)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.61 (0.95, 2.73)	
	p-value	0.0754	
	Risk Ratio (95% CI)	1.60 (0.95, 2.70)	
	p-value	0.0753	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.0796	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Peripheral arterial occlusive disease	Number of subjects with event, n/N (%)	47/ 3477 (1.35)	50/ 3515 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.64, 1.44)	
	p-value	0.8471	
	Risk Ratio (95% CI)	0.96 (0.65, 1.42)	
	p-value	0.8356	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.7099	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Study									0.7666
	FINEARTS-HF	349/ 2993 (11.66)	345/ 2993 (11.53)	1.01 (0.88, 1.16)	0.8717	1.01 (0.86, 1.19)	0.8717	0.00 (-0.01, 0.02)	0.8717	
	FIGARO-DKD	41/ 289 (14.19)	34/ 281 (12.10)	1.17 (0.77, 1.79)	0.4619	1.20 (0.74, 1.96)	0.4615	0.02 (-0.03, 0.08)	0.4605	
	FIDELIO-DKD	38/ 195 (19.49)	49/ 241 (20.33)	0.96 (0.66, 1.40)	0.8264	0.95 (0.59, 1.52)	0.8263	-0.01 (-0.08, 0.07)	0.8260	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Anaemia	Study									0.8423
	FINEARTS-HF	236/ 2993 (7.89)	218/ 2993 (7.28)	1.08 (0.91, 1.29)	0.3797	1.09 (0.90, 1.32)	0.3796	0.01 (-0.01, 0.02)	0.3795	
	FIGARO-DKD	28/ 289 (9.69)	23/ 281 (8.19)	1.18 (0.70, 2.00)	0.5302	1.20 (0.68, 2.14)	0.5300	0.02 (-0.03, 0.06)	0.5289	
	FIDELIO-DKD	24/ 195 (12.31)	31/ 241 (12.86)	0.96 (0.58, 1.57)	0.8622	0.95 (0.54, 1.68)	0.8621	-0.01 (-0.07, 0.06)	0.8619	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Iron deficiency anaemia	Sex									0.8718
	Male	26/ 1945 (1.34)	38/ 1947 (1.95)	0.68 (0.42, 1.12)	0.1341	0.68 (0.41, 1.13)	0.1340	-0.01 (-0.01, 0.00)	0.1206	
	Female	24/ 1532 (1.57)	38/ 1568 (2.42)	0.65 (0.39, 1.07)	0.0906	0.64 (0.38, 1.07)	0.0903	-0.01 (-0.02, 0.00)	0.0871	
	Region									0.7086
	Western Europe, Oceania and Others	19/ 688 (2.76)	23/ 716 (3.21)	0.87 (0.48, 1.59)	0.6522	0.86 (0.47, 1.60)	0.6436	-0.01 (-0.02, 0.01)	0.4659	
	Eastern Europe	19/ 1577 (1.20)	34/ 1567 (2.17)	0.55 (0.32, 0.96)	0.0361	0.55 (0.31, 0.96)	0.0359	-0.01 (-0.02, -0.00)	0.0453	
	Asia	8/ 554 (1.44)	14/ 551 (2.54)	0.58 (0.24, 1.36)	0.2070	0.57 (0.24, 1.37)	0.2099	-0.01 (-0.03, 0.01)	0.2412	
	North America	4/ 317 (1.26)	5/ 317 (1.58)	0.78 (0.21, 2.89)	0.7127	0.78 (0.21, 2.93)	0.7115	-0.00 (-0.06, 0.05)	0.8849	
	Latin America	0/ 341 (0.00)	0/ 364 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Age group (years)									0.1347
	<= median in FAS	15/ 1825 (0.82)	32/ 1831 (1.75)	0.46 (0.25, 0.85)	0.0126	0.46 (0.25, 0.84)	0.0125	-0.01 (-0.03, 0.00)	0.1196	
	> median in FAS	35/ 1652 (2.12)	44/ 1684 (2.61)	0.82 (0.53, 1.27)	0.3653	0.81 (0.52, 1.27)	0.3569	-0.01 (-0.02, 0.00)	0.2329	
	Study									0.1562
	FINEARTS-HF	40/ 2993 (1.34)	67/ 2993 (2.24)	0.60 (0.40, 0.88)	0.0092	0.59 (0.40, 0.88)	0.0092	-0.01 (-0.02, -0.00)	0.0084	
	FIGARO-DKD	5/ 289 (1.73)	7/ 281 (2.49)	0.69 (0.22, 2.16)	0.5293	0.69 (0.22, 2.20)	0.5292	-0.01 (-0.03, 0.02)	0.5278	
	FIDELIO-DKD	5/ 195 (2.56)	2/ 241 (0.83)	3.09 (0.61, 15.75)	0.1747	3.14 (0.60, 16.39)	0.1738	0.02 (-0.01, 0.04)	0.1734	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders	Study									0.0391
	FINEARTS-HF	757/ 2993 (25.29)	742/ 2993 (24.79)	1.02 (0.93, 1.11)	0.6545	1.03 (0.91, 1.15)	0.6545	0.01 (-0.02, 0.03)	0.6545	
	FIGARO-DKD	77/ 289 (26.64)	71/ 281 (25.27)	1.05 (0.80, 1.39)	0.7079	1.07 (0.74, 1.56)	0.7078	0.01 (-0.06, 0.09)	0.7077	
	FIDELIO-DKD	44/ 195 (22.56)	81/ 241 (33.61)	0.67 (0.49, 0.92)	0.0131	0.58 (0.37, 0.88)	0.0117	-0.11 (-0.19, -0.03)	0.0097	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Angina pectoris	Study									0.6883
	FINEARTS-HF	53/ 2993 (1.77)	65/ 2993 (2.17)	0.82 (0.57, 1.17)	0.2654	0.81 (0.56, 1.17)	0.2654	-0.00 (-0.01, 0.00)	0.2645	
	FIGARO-DKD	7/ 289 (2.42)	5/ 281 (1.78)	1.36 (0.44, 4.24)	0.5946	1.37 (0.43, 4.37)	0.5945	0.01 (-0.02, 0.03)	0.5922	
	FIDELIO-DKD	3/ 195 (1.54)	5/ 241 (2.07)	0.74 (0.18, 3.06)	0.6796	0.74 (0.17, 3.13)	0.6795	-0.01 (-0.03, 0.02)	0.6735	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Angina unstable	Study									NE
	FINEARTS-HF	50/ 2993 (1.67)	40/ 2993 (1.34)	1.25 (0.83, 1.89)	0.2892	1.25 (0.83, 1.91)	0.2892	0.00 (-0.00, 0.01)	0.2881	
	FIGARO-DKD	0/ 289 (0.00)	1/ 281 (0.36)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	0/ 195 (0.00)	2/ 241 (0.83)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Atrial fibrillation	Study									0.3316
	FINEARTS-HF	160/ 2993 (5.35)	163/ 2993 (5.45)	0.98 (0.79, 1.21)	0.8637	0.98 (0.78, 1.23)	0.8637	-0.00 (-0.01, 0.01)	0.8637	
	FIGARO-DKD	8/ 289 (2.77)	7/ 281 (2.49)	1.11 (0.41, 3.02)	0.8364	1.11 (0.40, 3.12)	0.8364	0.00 (-0.02, 0.03)	0.8362	
	FIDELIO-DKD	2/ 195 (1.03)	8/ 241 (3.32)	0.31 (0.07, 1.44)	0.1344	0.30 (0.06, 1.44)	0.1327	-0.02 (-0.05, 0.00)	0.0919	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Bradycardia	Study									0.1238
	FINEARTS-HF	59/ 2993 (1.97)	49/ 2993 (1.64)	1.20 (0.83, 1.75)	0.3323	1.21 (0.82, 1.77)	0.3322	0.00 (-0.00, 0.01)	0.3315	
	FIGARO-DKD	6/ 289 (2.08)	4/ 281 (1.42)	1.46 (0.42, 5.11)	0.5554	1.47 (0.41, 5.26)	0.5553	0.01 (-0.01, 0.03)	0.5518	
	FIDELIO-DKD	2/ 195 (1.03)	10/ 241 (4.15)	0.25 (0.05, 1.11)	0.0690	0.24 (0.05, 1.11)	0.0671	-0.03 (-0.06, -0.00)	0.0340	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level		Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Cardiac failure	Study									0.2582
	FINEARTS-HF	194/ 2993 (6.48)	212/ 2993 (7.08)	0.92 (0.76, 1.10)	0.3550	0.91 (0.74, 1.11)	0.3550	-0.01 (-0.02, 0.01)	0.3548	
	FIGARO-DKD	12/ 289 (4.15)	19/ 281 (6.76)	0.61 (0.30, 1.24)	0.1745	0.60 (0.28, 1.25)	0.1737	-0.03 (-0.06, 0.01)	0.1703	
	FIDELIO-DKD	11/ 195 (5.64)	24/ 241 (9.96)	0.57 (0.28, 1.13)	0.1055	0.54 (0.26, 1.13)	0.1033	-0.04 (-0.09, 0.01)	0.0891	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Coronary artery disease	Study									0.9173
	FINEARTS-HF	42/ 2993 (1.40)	35/ 2993 (1.17)	1.20 (0.77, 1.87)	0.4227	1.20 (0.77, 1.89)	0.4227	0.00 (-0.00, 0.01)	0.4220	
	FIGARO-DKD	4/ 289 (1.38)	4/ 281 (1.42)	0.97 (0.25, 3.85)	0.9681	0.97 (0.24, 3.92)	0.9681	-0.00 (-0.02, 0.02)	0.9681	
	FIDELIO-DKD	3/ 195 (1.54)	4/ 241 (1.66)	0.93 (0.21, 4.09)	0.9202	0.93 (0.20, 4.19)	0.9202	-0.00 (-0.02, 0.02)	0.9199	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Mitral valve incompetence	Study									0.3565
	FINEARTS-HF	26/ 2993 (0.87)	30/ 2993 (1.00)	0.87 (0.51, 1.46)	0.5916	0.87 (0.51, 1.47)	0.5916	-0.00 (-0.01, 0.00)	0.5912	
	FIGARO-DKD	9/ 289 (3.11)	5/ 281 (1.78)	1.75 (0.59, 5.16)	0.3101	1.77 (0.59, 5.36)	0.3095	0.01 (-0.01, 0.04)	0.3011	
	FIDELIO-DKD	3/ 195 (1.54)	7/ 241 (2.90)	0.53 (0.14, 2.02)	0.3524	0.52 (0.13, 2.05)	0.3514	-0.01 (-0.04, 0.01)	0.3276	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Palpitations	Study									0.8721
	FINEARTS-HF	32/ 2993 (1.07)	46/ 2993 (1.54)	0.70 (0.44, 1.09)	0.1126	0.69 (0.44, 1.09)	0.1125	-0.00 (-0.01, 0.00)	0.1105	
	FIGARO-DKD	1/ 289 (0.35)	2/ 281 (0.71)	0.49 (0.04, 5.33)	0.5550	0.48 (0.04, 5.37)	0.5549	-0.00 (-0.02, 0.01)	0.5481	
	FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Ventricular extrasystoles	Study									0.1373
	FINEARTS-HF	30/ 2993 (1.00)	25/ 2993 (0.84)	1.20 (0.71, 2.04)	0.4988	1.20 (0.71, 2.05)	0.4988	0.00 (-0.00, 0.01)	0.4982	
	FIGARO-DKD	8/ 289 (2.77)	2/ 281 (0.71)	3.89 (0.83, 18.16)	0.0840	3.97 (0.84, 18.87)	0.0828	0.02 (-0.00, 0.04)	0.0586	
	FIDELIO-DKD	2/ 195 (1.03)	6/ 241 (2.49)	0.41 (0.08, 2.02)	0.2741	0.41 (0.08, 2.03)	0.2728	-0.01 (-0.04, 0.01)	0.2363	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Ear and labyrinth disorders	Study									0.7431
	FINEARTS-HF	91/ 2993 (3.04)	83/ 2993 (2.77)	1.10 (0.82, 1.47)	0.5384	1.10 (0.81, 1.49)	0.5384	0.00 (-0.01, 0.01)	0.5382	
	FIGARO-DKD	10/ 289 (3.46)	12/ 281 (4.27)	0.81 (0.36, 1.85)	0.6163	0.80 (0.34, 1.89)	0.6162	-0.01 (-0.04, 0.02)	0.6160	
	FIDELIO-DKD	12/ 195 (6.15)	12/ 241 (4.98)	1.24 (0.57, 2.69)	0.5934	1.25 (0.55, 2.85)	0.5935	0.01 (-0.03, 0.06)	0.5966	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Ear and labyrinth disorders, PT: Vertigo	Study									0.8492
	FINEARTS-HF	42/ 2993 (1.40)	47/ 2993 (1.57)	0.89 (0.59, 1.35)	0.5936	0.89 (0.59, 1.36)	0.5935	-0.00 (-0.01, 0.00)	0.5933	
	FIGARO-DKD	7/ 289 (2.42)	6/ 281 (2.14)	1.13 (0.39, 3.33)	0.8187	1.14 (0.38, 3.43)	0.8187	0.00 (-0.02, 0.03)	0.8184	
	FIDELIO-DKD	4/ 195 (2.05)	4/ 241 (1.66)	1.24 (0.31, 4.88)	0.7624	1.24 (0.31, 5.03)	0.7624	0.00 (-0.02, 0.03)	0.7645	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Endocrine disorders	Study									0.1361
	FINEARTS-HF	76/ 2993 (2.54)	80/ 2993 (2.67)	0.95 (0.70, 1.30)	0.7456	0.95 (0.69, 1.30)	0.7456	-0.00 (-0.01, 0.01)	0.7455	
	FIGARO-DKD	10/ 289 (3.46)	5/ 281 (1.78)	1.94 (0.67, 5.62)	0.2192	1.98 (0.67, 5.86)	0.2183	0.02 (-0.01, 0.04)	0.2074	
	FIDELIO-DKD	5/ 195 (2.56)	14/ 241 (5.81)	0.44 (0.16, 1.20)	0.1102	0.43 (0.15, 1.21)	0.1082	-0.03 (-0.07, 0.00)	0.0851	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Endocrine disorders, PT: Hypothyroidism	Study									0.6665
	FINEARTS-HF	36/ 2993 (1.20)	44/ 2993 (1.47)	0.82 (0.53, 1.27)	0.3687	0.82 (0.52, 1.27)	0.3687	-0.00 (-0.01, 0.00)	0.3678	
	FIGARO-DKD	2/ 289 (0.69)	2/ 281 (0.71)	0.97 (0.14, 6.86)	0.9775	0.97 (0.14, 6.95)	0.9775	-0.00 (-0.01, 0.01)	0.9775	
	FIDELIO-DKD	2/ 195 (1.03)	1/ 241 (0.41)	2.47 (0.23, 27.06)	0.4586	2.49 (0.22, 27.63)	0.4583	0.01 (-0.01, 0.02)	0.4629	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders	Study									0.1966
	FINEARTS-HF	161/ 2993 (5.38)	169/ 2993 (5.65)	0.95 (0.77, 1.18)	0.6506	0.95 (0.76, 1.19)	0.6505	-0.00 (-0.01, 0.01)	0.6505	
	FIGARO-DKD	35/ 289 (12.11)	25/ 281 (8.90)	1.36 (0.84, 2.21)	0.2138	1.41 (0.82, 2.43)	0.2130	0.03 (-0.02, 0.08)	0.2098	
	FIDELIO-DKD	23/ 195 (11.79)	39/ 241 (16.18)	0.73 (0.45, 1.18)	0.1961	0.69 (0.40, 1.21)	0.1938	-0.04 (-0.11, 0.02)	0.1851	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders, PT: Cataract	Study									0.0969
	FINEARTS-HF	54/ 2993 (1.80)	63/ 2993 (2.10)	0.86 (0.60, 1.23)	0.4012	0.85 (0.59, 1.23)	0.4012	-0.00 (-0.01, 0.00)	0.4007	
	FIGARO-DKD	18/ 289 (6.23)	8/ 281 (2.85)	2.19 (0.97, 4.95)	0.0602	2.27 (0.97, 5.30)	0.0591	0.03 (-0.00, 0.07)	0.0511	
	FIDELIO-DKD	7/ 195 (3.59)	12/ 241 (4.98)	0.72 (0.29, 1.80)	0.4823	0.71 (0.27, 1.84)	0.4818	-0.01 (-0.05, 0.02)	0.4723	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders	Sex								0.3981
Male	500/ 1945 (25.71)	442/ 1947 (22.70)	1.14 (1.02, 1.27)	0.0241	1.18 (1.02, 1.37)	0.0248	0.03 (0.00, 0.06)	0.0256	
Female	391/ 1532 (25.52)	378/ 1568 (24.11)	1.06 (0.94, 1.20)	0.3625	1.08 (0.92, 1.27)	0.3601	0.01 (-0.02, 0.04)	0.3553	
Region									0.1535
Western Europe, Oceania and Others	230/ 688 (33.43)	233/ 716 (32.54)	1.02 (0.88, 1.19)	0.7680	1.04 (0.83, 1.30)	0.7145	0.01 (-0.04, 0.06)	0.6844	
Eastern Europe	262/ 1577 (16.61)	240/ 1567 (15.32)	1.08 (0.92, 1.27)	0.3319	1.10 (0.91, 1.33)	0.3312	0.01 (-0.01, 0.04)	0.3281	
Asia	221/ 554 (39.89)	203/ 551 (36.84)	1.09 (0.94, 1.27)	0.2571	1.15 (0.90, 1.46)	0.2690	0.03 (-0.03, 0.09)	0.2711	
North America	111/ 317 (35.02)	75/ 317 (23.66)	1.48 (1.16, 1.90)	0.0016	1.79 (1.26, 2.54)	0.0012	0.12 (0.05, 0.19)	0.0009	
Latin America	67/ 341 (19.65)	69/ 364 (18.96)	1.10 (0.81, 1.48)	0.5547	1.14 (0.78, 1.67)	0.5013	0.02 (-0.04, 0.08)	0.4638	
Age group (years)									0.3314
<= median in FAS	400/ 1825 (21.92)	382/ 1831 (20.86)	1.05 (0.93, 1.19)	0.4100	1.07 (0.91, 1.25)	0.4084	0.01 (-0.02, 0.04)	0.4057	
> median in FAS	491/ 1652 (29.72)	438/ 1684 (26.01)	1.14 (1.03, 1.28)	0.0161	1.20 (1.03, 1.40)	0.0164	0.04 (0.01, 0.07)	0.0167	
Study									0.7312
FINEARTS-HF	757/ 2993 (25.29)	687/ 2993 (22.95)	1.10 (1.01, 1.21)	0.0346	1.14 (1.01, 1.28)	0.0345	0.02 (0.00, 0.05)	0.0344	
FIGARO-DKD	75/ 289 (25.95)	72/ 281 (25.62)	1.01 (0.77, 1.34)	0.9285	1.02 (0.70, 1.48)	0.9285	0.00 (-0.07, 0.08)	0.9285	
FIDELIO-DKD	59/ 195 (30.26)	61/ 241 (25.31)	1.20 (0.88, 1.62)	0.2500	1.28 (0.84, 1.95)	0.2508	0.05 (-0.04, 0.13)	0.2524	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Abdominal pain	Study									0.2203
	FINEARTS-HF	46/ 2993 (1.54)	47/ 2993 (1.57)	0.98 (0.65, 1.46)	0.9168	0.98 (0.65, 1.47)	0.9168	-0.00 (-0.01, 0.01)	0.9168	
	FIGARO-DKD	10/ 289 (3.46)	4/ 281 (1.42)	2.43 (0.77, 7.66)	0.1294	2.48 (0.77, 8.01)	0.1282	0.02 (-0.00, 0.05)	0.1134	
	FIDELIO-DKD	4/ 195 (2.05)	2/ 241 (0.83)	2.47 (0.46, 13.35)	0.2930	2.50 (0.45, 13.81)	0.2925	0.01 (-0.01, 0.04)	0.2970	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Abdominal pain upper	Study									0.9488
	FINEARTS-HF	40/ 2993 (1.34)	36/ 2993 (1.20)	1.11 (0.71, 1.74)	0.6444	1.11 (0.71, 1.75)	0.6444	0.00 (-0.00, 0.01)	0.6442	
	FIGARO-DKD	3/ 289 (1.04)	2/ 281 (0.71)	1.46 (0.25, 8.66)	0.6780	1.46 (0.24, 8.82)	0.6780	0.00 (-0.01, 0.02)	0.6753	
	FIDELIO-DKD	5/ 195 (2.56)	6/ 241 (2.49)	1.03 (0.32, 3.32)	0.9607	1.03 (0.31, 3.43)	0.9606	0.00 (-0.03, 0.03)	0.9607	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Constipation									
Sex									0.2126
Male	98/ 1945 (5.04)	68/ 1947 (3.49)	1.44 (1.07, 1.95)	0.0177	1.47 (1.07, 2.02)	0.0170	0.02 (0.00, 0.03)	0.0096	
Female	62/ 1532 (4.05)	59/ 1568 (3.76)	1.08 (0.76, 1.53)	0.6837	1.08 (0.75, 1.55)	0.6831	0.00 (-0.01, 0.02)	0.6740	
Region									0.0697
Western Europe, Oceania and Others	39/ 688 (5.67)	39/ 716 (5.45)	1.05 (0.68, 1.61)	0.8322	1.06 (0.67, 1.67)	0.8100	0.01 (-0.02, 0.03)	0.6420	
Eastern Europe	26/ 1577 (1.65)	32/ 1567 (2.04)	0.80 (0.48, 1.34)	0.4054	0.80 (0.47, 1.35)	0.4035	-0.01 (-0.02, 0.00)	0.2297	
Asia	65/ 554 (11.73)	38/ 551 (6.90)	1.73 (1.18, 2.53)	0.0049	1.84 (1.21, 2.80)	0.0046	0.05 (0.02, 0.08)	0.0039	
North America	17/ 317 (5.36)	10/ 317 (3.15)	1.78 (0.83, 3.82)	0.1387	1.83 (0.82, 4.08)	0.1383	0.02 (-0.02, 0.05)	0.2878	
Latin America	13/ 341 (3.81)	8/ 364 (2.20)	NE (NE, NE)	NE	2.47 (0.95, 6.42)	0.0638	0.02 (-0.00, 0.04)	0.0699	
Age group (years)									0.7963
<= median in FAS	65/ 1825 (3.56)	53/ 1831 (2.89)	1.23 (0.86, 1.76)	0.2487	1.25 (0.86, 1.80)	0.2412	0.01 (-0.00, 0.02)	0.1065	
> median in FAS	95/ 1652 (5.75)	74/ 1684 (4.39)	1.31 (0.98, 1.76)	0.0727	1.33 (0.97, 1.82)	0.0729	0.01 (-0.00, 0.03)	0.0783	
Study									0.2019
FINEARTS-HF	139/ 2993 (4.64)	99/ 2993 (3.31)	1.40 (1.09, 1.81)	0.0085	1.42 (1.09, 1.85)	0.0084	0.01 (0.00, 0.02)	0.0081	
FIGARO-DKD	13/ 289 (4.50)	15/ 281 (5.34)	0.84 (0.41, 1.74)	0.6432	0.84 (0.39, 1.79)	0.6432	-0.01 (-0.04, 0.03)	0.6431	
FIDELIO-DKD	8/ 195 (4.10)	13/ 241 (5.39)	0.76 (0.32, 1.80)	0.5329	0.75 (0.30, 1.85)	0.5324	-0.01 (-0.05, 0.03)	0.5253	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Diarrhoea	Sex									0.6181
	Male	111/ 1945 (5.71)	96/ 1947 (4.93)	1.17 (0.89, 1.52)	0.2541	1.18 (0.89, 1.56)	0.2577	0.01 (-0.01, 0.02)	0.3212	
	Female	102/ 1532 (6.66)	81/ 1568 (5.17)	1.29 (0.97, 1.71)	0.0790	1.31 (0.97, 1.77)	0.0797	0.01 (-0.00, 0.03)	0.0919	
	Region									0.7189
	Western Europe, Oceania and Others	67/ 688 (9.74)	64/ 716 (8.94)	1.09 (0.78, 1.50)	0.6178	1.10 (0.77, 1.58)	0.6032	0.01 (-0.02, 0.04)	0.5119	
	Eastern Europe	62/ 1577 (3.93)	47/ 1567 (3.00)	1.32 (0.91, 1.91)	0.1477	1.33 (0.90, 1.96)	0.1473	0.01 (-0.00, 0.02)	0.2555	
	Asia	45/ 554 (8.12)	41/ 551 (7.44)	1.09 (0.73, 1.64)	0.6702	1.10 (0.71, 1.72)	0.6578	0.01 (-0.02, 0.04)	0.5645	
	North America	27/ 317 (8.52)	17/ 317 (5.36)	1.60 (0.89, 2.86)	0.1146	1.70 (0.90, 3.21)	0.1017	0.04 (-0.00, 0.07)	0.0522	
	Latin America	12/ 341 (3.52)	8/ 364 (2.20)	1.59 (0.65, 3.86)	0.3089	1.61 (0.64, 4.04)	0.3074	0.01 (-0.03, 0.06)	0.5829	
	Age group (years)									0.8626
	<= median in FAS	84/ 1825 (4.60)	71/ 1831 (3.88)	1.20 (0.88, 1.63)	0.2536	1.21 (0.87, 1.67)	0.2542	0.01 (-0.01, 0.02)	0.2657	
	> median in FAS	129/ 1652 (7.81)	106/ 1684 (6.29)	1.24 (0.97, 1.59)	0.0886	1.26 (0.97, 1.65)	0.0882	0.02 (-0.00, 0.03)	0.0855	
	Study									0.3454
	FINEARTS-HF	189/ 2993 (6.31)	148/ 2993 (4.94)	1.28 (1.04, 1.57)	0.0219	1.30 (1.04, 1.62)	0.0218	0.01 (0.00, 0.03)	0.0214	
	FIGARO-DKD	11/ 289 (3.81)	15/ 281 (5.34)	0.71 (0.33, 1.53)	0.3834	0.70 (0.32, 1.56)	0.3830	-0.02 (-0.05, 0.02)	0.3816	
	FIDELIO-DKD	13/ 195 (6.67)	14/ 241 (5.81)	1.15 (0.55, 2.38)	0.7120	1.16 (0.53, 2.53)	0.7120	0.01 (-0.04, 0.05)	0.7137	

Analysis based on all AE starting at beginning of treatment until end of study.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Dyspepsia	Study									0.9157
	FINEARTS-HF	33/ 2993 (1.10)	34/ 2993 (1.14)	0.97 (0.60, 1.56)	0.9022	0.97 (0.60, 1.57)	0.9022	-0.00 (-0.01, 0.00)	0.9022	
	FIGARO-DKD	4/ 289 (1.38)	3/ 281 (1.07)	1.30 (0.29, 5.74)	0.7324	1.30 (0.29, 5.86)	0.7323	0.00 (-0.01, 0.02)	0.7311	
	FIDELIO-DKD	2/ 195 (1.03)	2/ 241 (0.83)	1.24 (0.18, 8.69)	0.8315	1.24 (0.17, 8.87)	0.8315	0.00 (-0.02, 0.02)	0.8330	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Gastritis	Study									0.5224
	FINEARTS-HF	32/ 2993 (1.07)	26/ 2993 (0.87)	1.23 (0.74, 2.06)	0.4294	1.23 (0.73, 2.07)	0.4294	0.00 (-0.00, 0.01)	0.4285	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	4/ 195 (2.05)	0/ 241 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Gastrointestinal haemorrhage	Sex									0.6975
	Male	21/ 1945 (1.08)	11/ 1947 (0.56)	1.95 (0.94, 4.03)	0.0725	1.96 (0.94, 4.07)	0.0730	0.00 (-0.00, 0.01)	0.1287	
	Female	17/ 1532 (1.11)	11/ 1568 (0.70)	1.58 (0.74, 3.37)	0.2337	1.59 (0.74, 3.40)	0.2338	0.00 (-0.00, 0.01)	0.2867	
	Region									0.0997
	Western Europe, Oceania and Others	8/ 688 (1.16)	2/ 716 (0.28)	4.08 (0.87, 19.16)	0.0744	4.12 (0.87, 19.50)	0.0738	0.01 (-0.03, 0.05)	0.5949	
	Eastern Europe	5/ 1577 (0.32)	7/ 1567 (0.45)	0.70 (0.22, 2.19)	0.5343	0.69 (0.22, 2.19)	0.5341	-0.00 (-0.03, 0.02)	0.8687	
	Asia	11/ 554 (1.99)	2/ 551 (0.36)	5.32 (1.19, 23.83)	0.0290	5.42 (1.19, 24.63)	0.0286	0.02 (-0.03, 0.06)	0.4529	
	North America	12/ 317 (3.79)	7/ 317 (2.21)	1.74 (0.69, 4.37)	0.2382	1.77 (0.69, 4.56)	0.2384	0.02 (-0.01, 0.04)	0.2571	
	Latin America	2/ 341 (0.59)	4/ 364 (1.10)	0.50 (0.09, 2.69)	0.4153	0.49 (0.09, 2.71)	0.4150	-0.01 (-0.06, 0.04)	0.8014	
	Age group (years)									0.5738
	<= median in FAS	20/ 1825 (1.10)	10/ 1831 (0.55)	2.06 (0.96, 4.38)	0.0620	2.07 (0.96, 4.43)	0.0622	0.01 (-0.00, 0.01)	0.0873	
	> median in FAS	18/ 1652 (1.09)	12/ 1684 (0.71)	1.52 (0.74, 3.15)	0.2580	1.53 (0.73, 3.18)	0.2578	0.00 (-0.02, 0.03)	0.7144	
	Study									0.4204
	FINEARTS-HF	31/ 2993 (1.04)	19/ 2993 (0.63)	1.63 (0.92, 2.88)	0.0916	1.64 (0.92, 2.91)	0.0915	0.00 (-0.00, 0.01)	0.0883	
	FIGARO-DKD	2/ 289 (0.69)	2/ 281 (0.71)	0.97 (0.14, 6.86)	0.9775	0.97 (0.14, 6.95)	0.9775	-0.00 (-0.01, 0.01)	0.9775	
	FIDELIO-DKD	5/ 195 (2.56)	1/ 241 (0.41)	6.18 (0.73, 52.45)	0.0951	6.32 (0.73, 54.52)	0.0938	0.02 (-0.00, 0.05)	0.0746	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Study								0.1392
FINEARTS-HF	38/ 2993 (1.27)	33/ 2993 (1.10)	1.15 (0.72, 1.83)	0.5509	1.15 (0.72, 1.84)	0.5509	0.00 (-0.00, 0.01)	0.5505	
FIGARO-DKD	12/ 289 (4.15)	3/ 281 (1.07)	3.89 (1.11, 13.64)	0.0338	4.01 (1.12, 14.38)	0.0328	0.03 (0.00, 0.06)	0.0198	
FIDELIO-DKD	3/ 195 (1.54)	1/ 241 (0.41)	3.71 (0.39, 35.36)	0.2548	3.75 (0.39, 36.31)	0.2540	0.01 (-0.01, 0.03)	0.2486	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Haemorrhoids	Study									0.5029
	FINEARTS-HF	32/ 2993 (1.07)	28/ 2993 (0.94)	1.14 (0.69, 1.89)	0.6040	1.14 (0.69, 1.91)	0.6040	0.00 (-0.00, 0.01)	0.6037	
	FIGARO-DKD	5/ 289 (1.73)	6/ 281 (2.14)	0.81 (0.25, 2.62)	0.7257	0.81 (0.24, 2.67)	0.7257	-0.00 (-0.03, 0.02)	0.7256	
	FIDELIO-DKD	3/ 195 (1.54)	1/ 241 (0.41)	3.71 (0.39, 35.36)	0.2548	3.75 (0.39, 36.31)	0.2540	0.01 (-0.01, 0.03)	0.2486	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Large intestine polyp	Study									0.7833
	FINEARTS-HF	29/ 2993 (0.97)	24/ 2993 (0.80)	1.21 (0.71, 2.07)	0.4909	1.21 (0.70, 2.08)	0.4909	0.00 (-0.00, 0.01)	0.4903	
	FIGARO-DKD	4/ 289 (1.38)	5/ 281 (1.78)	0.78 (0.21, 2.87)	0.7058	0.77 (0.21, 2.92)	0.7058	-0.00 (-0.02, 0.02)	0.7055	
	FIDELIO-DKD	2/ 195 (1.03)	3/ 241 (1.24)	0.82 (0.14, 4.88)	0.8311	0.82 (0.14, 4.97)	0.8310	-0.00 (-0.02, 0.02)	0.8291	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Nausea	Study									0.9388
	FINEARTS-HF	81/ 2993 (2.71)	69/ 2993 (2.31)	1.17 (0.85, 1.61)	0.3216	1.18 (0.85, 1.63)	0.3216	0.00 (-0.00, 0.01)	0.3210	
	FIGARO-DKD	15/ 289 (5.19)	13/ 281 (4.63)	1.12 (0.54, 2.31)	0.7556	1.13 (0.53, 2.42)	0.7556	0.01 (-0.03, 0.04)	0.7552	
	FIDELIO-DKD	8/ 195 (4.10)	10/ 241 (4.15)	0.99 (0.40, 2.46)	0.9805	0.99 (0.38, 2.55)	0.9805	-0.00 (-0.04, 0.04)	0.9805	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Vomiting	Study									0.8318
	FINEARTS-HF	57/ 2993 (1.90)	43/ 2993 (1.44)	1.33 (0.90, 1.96)	0.1594	1.33 (0.89, 1.99)	0.1594	0.00 (-0.00, 0.01)	0.1579	
	FIGARO-DKD	5/ 289 (1.73)	5/ 281 (1.78)	0.97 (0.28, 3.32)	0.9643	0.97 (0.28, 3.39)	0.9643	-0.00 (-0.02, 0.02)	0.9643	
	FIDELIO-DKD	4/ 195 (2.05)	5/ 241 (2.07)	0.99 (0.27, 3.63)	0.9864	0.99 (0.26, 3.73)	0.9864	-0.00 (-0.03, 0.03)	0.9864	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions	Study									0.7882
	FINEARTS-HF	581/ 2993 (19.41)	630/ 2993 (21.05)	0.92 (0.83, 1.02)	0.1151	0.90 (0.80, 1.03)	0.1150	-0.02 (-0.04, 0.00)	0.1148	
	FIGARO-DKD	58/ 289 (20.07)	59/ 281 (21.00)	0.96 (0.69, 1.32)	0.7841	0.94 (0.63, 1.42)	0.7841	-0.01 (-0.08, 0.06)	0.7841	
	FIDELIO-DKD	44/ 195 (22.56)	66/ 241 (27.39)	0.82 (0.59, 1.15)	0.2521	0.77 (0.50, 1.20)	0.2497	-0.05 (-0.13, 0.03)	0.2451	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Asthenia	Study									0.7667
	FINEARTS-HF	67/ 2993 (2.24)	56/ 2993 (1.87)	1.20 (0.84, 1.70)	0.3169	1.20 (0.84, 1.72)	0.3169	0.00 (-0.00, 0.01)	0.3162	
	FIGARO-DKD	9/ 289 (3.11)	7/ 281 (2.49)	1.25 (0.47, 3.31)	0.6533	1.26 (0.46, 3.43)	0.6532	0.01 (-0.02, 0.03)	0.6520	
	FIDELIO-DKD	5/ 195 (2.56)	3/ 241 (1.24)	2.06 (0.50, 8.51)	0.3182	2.09 (0.49, 8.85)	0.3178	0.01 (-0.01, 0.04)	0.3243	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Chest pain	Study									0.4891
	FINEARTS-HF	99/ 2993 (3.31)	114/ 2993 (3.81)	0.87 (0.67, 1.13)	0.2957	0.86 (0.66, 1.14)	0.2957	-0.01 (-0.01, 0.00)	0.2953	
	FIGARO-DKD	12/ 289 (4.15)	14/ 281 (4.98)	0.83 (0.39, 1.77)	0.6354	0.83 (0.38, 1.82)	0.6354	-0.01 (-0.04, 0.03)	0.6353	
	FIDELIO-DKD	9/ 195 (4.62)	7/ 241 (2.90)	1.59 (0.60, 4.19)	0.3492	1.62 (0.59, 4.42)	0.3490	0.02 (-0.02, 0.05)	0.3555	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death									
Sex									0.9727
Male	42/ 1945 (2.16)	58/ 1947 (2.98)	0.72 (0.48, 1.06)	0.0962	0.71 (0.48, 1.06)	0.0962	-0.01 (-0.02, 0.00)	0.1147	
Female	32/ 1532 (2.09)	46/ 1568 (2.93)	0.71 (0.45, 1.11)	0.1309	0.70 (0.44, 1.11)	0.1296	-0.01 (-0.02, 0.00)	0.1589	
Region									0.6842
Western Europe, Oceania and Others	16/ 688 (2.33)	17/ 716 (2.37)	0.97 (0.49, 1.91)	0.9317	0.97 (0.49, 1.94)	0.9318	-0.00 (-0.02, 0.02)	0.9168	
Eastern Europe	36/ 1577 (2.28)	52/ 1567 (3.32)	0.69 (0.45, 1.05)	0.0800	0.68 (0.44, 1.05)	0.0795	-0.01 (-0.02, 0.01)	0.2698	
Asia	11/ 554 (1.99)	19/ 551 (3.45)	0.59 (0.28, 1.22)	0.1518	0.58 (0.27, 1.22)	0.1506	-0.02 (-0.04, 0.00)	0.1245	
North America	9/ 317 (2.84)	10/ 317 (3.15)	0.90 (0.37, 2.19)	0.8233	0.90 (0.36, 2.25)	0.8236	-0.00 (-0.04, 0.03)	0.7941	
Latin America	2/ 341 (0.59)	6/ 364 (1.65)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.06, 0.04)	0.6371	
Age group (years)									0.4832
<= median in FAS	25/ 1825 (1.37)	40/ 1831 (2.18)	0.63 (0.38, 1.03)	0.0631	0.62 (0.37, 1.03)	0.0628	-0.01 (-0.02, 0.00)	0.0638	
> median in FAS	49/ 1652 (2.97)	64/ 1684 (3.80)	0.78 (0.54, 1.12)	0.1812	0.77 (0.53, 1.13)	0.1811	-0.01 (-0.03, 0.01)	0.4386	
Study									0.8897
FINEARTS-HF	70/ 2993 (2.34)	97/ 2993 (3.24)	0.72 (0.53, 0.98)	0.0350	0.72 (0.52, 0.98)	0.0349	-0.01 (-0.02, -0.00)	0.0340	
FIGARO-DKD	3/ 289 (1.04)	4/ 281 (1.42)	0.73 (0.16, 3.23)	0.6775	0.73 (0.16, 3.28)	0.6774	-0.00 (-0.02, 0.01)	0.6768	
FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Fatigue	Study									0.3440
	FINEARTS-HF	76/ 2993 (2.54)	57/ 2993 (1.90)	1.33 (0.95, 1.87)	0.0969	1.34 (0.95, 1.90)	0.0968	0.01 (-0.00, 0.01)	0.0956	
	FIGARO-DKD	6/ 289 (2.08)	8/ 281 (2.85)	0.73 (0.26, 2.07)	0.5540	0.72 (0.25, 2.11)	0.5538	-0.01 (-0.03, 0.02)	0.5529	
	FIDELIO-DKD	3/ 195 (1.54)	6/ 241 (2.49)	0.62 (0.16, 2.44)	0.4920	0.61 (0.15, 2.48)	0.4915	-0.01 (-0.04, 0.02)	0.4764	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Study									0.3623
	FINEARTS-HF	114/ 2993 (3.81)	109/ 2993 (3.64)	1.05 (0.81, 1.35)	0.7329	1.05 (0.80, 1.37)	0.7329	0.00 (-0.01, 0.01)	0.7329	
	FIGARO-DKD	19/ 289 (6.57)	24/ 281 (8.54)	0.77 (0.43, 1.37)	0.3757	0.75 (0.40, 1.41)	0.3754	-0.02 (-0.06, 0.02)	0.3746	
	FIDELIO-DKD	16/ 195 (8.21)	28/ 241 (11.62)	0.71 (0.39, 1.27)	0.2435	0.68 (0.36, 1.30)	0.2417	-0.03 (-0.09, 0.02)	0.2311	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Peripheral swelling	Study									0.8393
	FINEARTS-HF	34/ 2993 (1.14)	33/ 2993 (1.10)	1.03 (0.64, 1.66)	0.9022	1.03 (0.64, 1.67)	0.9022	0.00 (-0.00, 0.01)	0.9022	
	FIGARO-DKD	3/ 289 (1.04)	2/ 281 (0.71)	1.46 (0.25, 8.66)	0.6780	1.46 (0.24, 8.82)	0.6780	0.00 (-0.01, 0.02)	0.6753	
	FIDELIO-DKD	3/ 195 (1.54)	5/ 241 (2.07)	0.74 (0.18, 3.06)	0.6796	0.74 (0.17, 3.13)	0.6795	-0.01 (-0.03, 0.02)	0.6735	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Pyrexia	Study									0.8318
	FINEARTS-HF	56/ 2993 (1.87)	68/ 2993 (2.27)	0.82 (0.58, 1.17)	0.2770	0.82 (0.57, 1.17)	0.2769	-0.00 (-0.01, 0.00)	0.2761	
	FIGARO-DKD	4/ 289 (1.38)	3/ 281 (1.07)	1.30 (0.29, 5.74)	0.7324	1.30 (0.29, 5.86)	0.7323	0.00 (-0.01, 0.02)	0.7311	
	FIDELIO-DKD	3/ 195 (1.54)	5/ 241 (2.07)	0.74 (0.18, 3.06)	0.6796	0.74 (0.17, 3.13)	0.6795	-0.01 (-0.03, 0.02)	0.6735	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Hepatobiliary disorders	Study									0.3875
	FINEARTS-HF	123/ 2993 (4.11)	148/ 2993 (4.94)	0.83 (0.66, 1.05)	0.1207	0.82 (0.65, 1.05)	0.1206	-0.01 (-0.02, 0.00)	0.1201	
	FIGARO-DKD	24/ 289 (8.30)	18/ 281 (6.41)	1.30 (0.72, 2.34)	0.3874	1.32 (0.70, 2.50)	0.3869	0.02 (-0.02, 0.06)	0.3846	
	FIDELIO-DKD	16/ 195 (8.21)	22/ 241 (9.13)	0.90 (0.49, 1.66)	0.7342	0.89 (0.45, 1.75)	0.7340	-0.01 (-0.06, 0.04)	0.7326	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Hepatobiliary disorders, PT: Cholelithiasis	Study									0.4316
	FINEARTS-HF	24/ 2993 (0.80)	29/ 2993 (0.97)	0.83 (0.48, 1.42)	0.4909	0.83 (0.48, 1.42)	0.4909	-0.00 (-0.01, 0.00)	0.4903	
	FIGARO-DKD	1/ 289 (0.35)	5/ 281 (1.78)	0.19 (0.02, 1.65)	0.1338	0.19 (0.02, 1.65)	0.1327	-0.01 (-0.03, 0.00)	0.0960	
	FIDELIO-DKD	5/ 195 (2.56)	9/ 241 (3.73)	0.69 (0.23, 2.02)	0.4937	0.68 (0.22, 2.06)	0.4933	-0.01 (-0.04, 0.02)	0.4822	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Study									0.4892
	FINEARTS-HF	1358/ 2993 (45.37)	1329/ 2993 (44.40)	1.02 (0.97, 1.08)	0.4511	1.04 (0.94, 1.15)	0.4511	0.01 (-0.02, 0.03)	0.4511	
	FIGARO-DKD	131/ 289 (45.33)	139/ 281 (49.47)	0.92 (0.77, 1.09)	0.3229	0.85 (0.61, 1.18)	0.3228	-0.04 (-0.12, 0.04)	0.3222	
	FIDELIO-DKD	91/ 195 (46.67)	114/ 241 (47.30)	0.99 (0.81, 1.21)	0.8948	0.97 (0.67, 1.42)	0.8947	-0.01 (-0.10, 0.09)	0.8947	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	Study									0.9598
	FINEARTS-HF	109/ 2993 (3.64)	105/ 2993 (3.51)	1.04 (0.80, 1.35)	0.7807	1.04 (0.79, 1.37)	0.7807	0.00 (-0.01, 0.01)	0.7807	
	FIGARO-DKD	14/ 289 (4.84)	12/ 281 (4.27)	1.13 (0.53, 2.41)	0.7429	1.14 (0.52, 2.51)	0.7429	0.01 (-0.03, 0.04)	0.7425	
	FIDELIO-DKD	11/ 195 (5.64)	14/ 241 (5.81)	0.97 (0.45, 2.09)	0.9402	0.97 (0.43, 2.19)	0.9403	-0.00 (-0.05, 0.04)	0.9401	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: COVID-19	Study									0.5130
	FINEARTS-HF	396/ 2993 (13.23)	382/ 2993 (12.76)	1.04 (0.91, 1.18)	0.5905	1.04 (0.90, 1.21)	0.5905	0.00 (-0.01, 0.02)	0.5905	
	FIGARO-DKD	6/ 289 (2.08)	8/ 281 (2.85)	0.73 (0.26, 2.07)	0.5540	0.72 (0.25, 2.11)	0.5538	-0.01 (-0.03, 0.02)	0.5529	
	FIDELIO-DKD	0/ 195 (0.00)	2/ 241 (0.83)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: COVID-19 pneumonia	Study									0.9226
	FINEARTS-HF	33/ 2993 (1.10)	39/ 2993 (1.30)	0.85 (0.53, 1.34)	0.4774	0.84 (0.53, 1.35)	0.4773	-0.00 (-0.01, 0.00)	0.4768	
	FIGARO-DKD	1/ 289 (0.35)	1/ 281 (0.36)	0.97 (0.06, 15.47)	0.9841	0.97 (0.06, 15.62)	0.9841	-0.00 (-0.01, 0.01)	0.9841	
	FIDELIO-DKD	0/ 195 (0.00)	0/ 241 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Cellulitis	Study									0.6721
	FINEARTS-HF	65/ 2993 (2.17)	68/ 2993 (2.27)	0.96 (0.68, 1.34)	0.7925	0.95 (0.68, 1.35)	0.7925	-0.00 (-0.01, 0.01)	0.7925	
	FIGARO-DKD	13/ 289 (4.50)	9/ 281 (3.20)	1.40 (0.61, 3.23)	0.4247	1.42 (0.60, 3.38)	0.4243	0.01 (-0.02, 0.04)	0.4208	
	FIDELIO-DKD	7/ 195 (3.59)	10/ 241 (4.15)	0.87 (0.34, 2.23)	0.7644	0.86 (0.32, 2.30)	0.7643	-0.01 (-0.04, 0.03)	0.7624	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Cystitis	Study									0.3816
	FINEARTS-HF	29/ 2993 (0.97)	31/ 2993 (1.04)	0.94 (0.57, 1.55)	0.7953	0.93 (0.56, 1.56)	0.7953	-0.00 (-0.01, 0.00)	0.7952	
	FIGARO-DKD	2/ 289 (0.69)	6/ 281 (2.14)	0.32 (0.07, 1.59)	0.1654	0.32 (0.06, 1.60)	0.1644	-0.01 (-0.03, 0.00)	0.1452	
	FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Gastroenteritis	Sex								0.2529
Male	24/ 1945 (1.23)	9/ 1947 (0.46)	2.68 (1.25, 5.75)	0.0116	2.70 (1.25, 5.83)	0.0114	0.01 (0.00, 0.01)	0.0035	
Female	20/ 1532 (1.31)	14/ 1568 (0.89)	1.47 (0.75, 2.91)	0.2618	1.48 (0.74, 2.95)	0.2630	0.00 (-0.00, 0.01)	0.3656	
Region									0.4679
Western Europe, Oceania and Others	16/ 688 (2.33)	4/ 716 (0.56)	4.24 (1.42, 12.60)	0.0094	4.34 (1.44, 13.06)	0.0091	0.02 (0.00, 0.03)	0.0070	
Eastern Europe	6/ 1577 (0.38)	3/ 1567 (0.19)	1.99 (0.50, 7.95)	0.3306	1.99 (0.50, 7.99)	0.3317	0.00 (-0.00, 0.00)	0.6554	
Asia	9/ 554 (1.62)	6/ 551 (1.09)	1.52 (0.54, 4.24)	0.4235	1.53 (0.54, 4.34)	0.4223	0.01 (-0.01, 0.02)	0.3624	
North America	7/ 317 (2.21)	3/ 317 (0.95)	2.32 (0.60, 8.92)	0.2199	2.36 (0.60, 9.26)	0.2170	0.01 (-0.00, 0.03)	0.1113	
Latin America	6/ 341 (1.76)	7/ 364 (1.92)	1.02 (0.34, 3.06)	0.9667	1.02 (0.33, 3.14)	0.9688	-0.00 (-0.02, 0.02)	0.9967	
Age group (years)									0.1615
<= median in FAS	17/ 1825 (0.93)	13/ 1831 (0.71)	1.34 (0.65, 2.75)	0.4293	1.34 (0.65, 2.77)	0.4303	0.00 (-0.00, 0.01)	0.5691	
> median in FAS	27/ 1652 (1.63)	10/ 1684 (0.59)	2.77 (1.35, 5.70)	0.0057	2.81 (1.35, 5.83)	0.0055	0.01 (0.00, 0.02)	0.0020	
Study									0.7770
FINEARTS-HF	34/ 2993 (1.14)	16/ 2993 (0.53)	2.12 (1.18, 3.84)	0.0126	2.14 (1.18, 3.88)	0.0125	0.01 (0.00, 0.01)	0.0105	
FIGARO-DKD	6/ 289 (2.08)	3/ 281 (1.07)	1.94 (0.49, 7.70)	0.3435	1.96 (0.49, 7.93)	0.3430	0.01 (-0.01, 0.03)	0.3317	
FIDELIO-DKD	4/ 195 (2.05)	4/ 241 (1.66)	1.24 (0.31, 4.88)	0.7624	1.24 (0.31, 5.03)	0.7624	0.00 (-0.02, 0.03)	0.7645	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	Study									0.6729
	FINEARTS-HF	35/ 2993 (1.17)	41/ 2993 (1.37)	0.85 (0.55, 1.34)	0.4890	0.85 (0.54, 1.34)	0.4890	-0.00 (-0.01, 0.00)	0.4885	
	FIGARO-DKD	3/ 289 (1.04)	4/ 281 (1.42)	0.73 (0.16, 3.23)	0.6775	0.73 (0.16, 3.28)	0.6774	-0.00 (-0.02, 0.01)	0.6768	
	FIDELIO-DKD	2/ 195 (1.03)	1/ 241 (0.41)	2.47 (0.23, 27.06)	0.4586	2.49 (0.22, 27.63)	0.4583	0.01 (-0.01, 0.02)	0.4629	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Influenza	Study									0.3648
	FINEARTS-HF	84/ 2993 (2.81)	82/ 2993 (2.74)	1.02 (0.76, 1.38)	0.8749	1.03 (0.75, 1.40)	0.8749	0.00 (-0.01, 0.01)	0.8749	
	FIGARO-DKD	5/ 289 (1.73)	8/ 281 (2.85)	0.61 (0.20, 1.84)	0.3771	0.60 (0.19, 1.86)	0.3767	-0.01 (-0.04, 0.01)	0.3731	
	FIDELIO-DKD	3/ 195 (1.54)	8/ 241 (3.32)	0.46 (0.12, 1.72)	0.2511	0.46 (0.12, 1.74)	0.2497	-0.02 (-0.05, 0.01)	0.2200	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	Study									0.5574
	FINEARTS-HF	118/ 2993 (3.94)	98/ 2993 (3.27)	1.20 (0.93, 1.57)	0.1664	1.21 (0.92, 1.59)	0.1663	0.01 (-0.00, 0.02)	0.1657	
	FIGARO-DKD	19/ 289 (6.57)	20/ 281 (7.12)	0.92 (0.50, 1.69)	0.7974	0.92 (0.48, 1.76)	0.7974	-0.01 (-0.05, 0.04)	0.7975	
	FIDELIO-DKD	16/ 195 (8.21)	22/ 241 (9.13)	0.90 (0.49, 1.66)	0.7342	0.89 (0.45, 1.75)	0.7340	-0.01 (-0.06, 0.04)	0.7326	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Pneumonia	Study									0.0343
	FINEARTS-HF	238/ 2993 (7.95)	221/ 2993 (7.38)	1.08 (0.90, 1.28)	0.4091	1.08 (0.90, 1.31)	0.4090	0.01 (-0.01, 0.02)	0.4089	
	FIGARO-DKD	20/ 289 (6.92)	28/ 281 (9.96)	0.69 (0.40, 1.20)	0.1938	0.67 (0.37, 1.22)	0.1930	-0.03 (-0.08, 0.02)	0.1911	
	FIDELIO-DKD	16/ 195 (8.21)	36/ 241 (14.94)	0.55 (0.31, 0.96)	0.0353	0.51 (0.27, 0.95)	0.0334	-0.07 (-0.13, -0.01)	0.0259	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	Study									0.1960
	FINEARTS-HF	75/ 2993 (2.51)	69/ 2993 (2.31)	1.09 (0.79, 1.50)	0.6129	1.09 (0.78, 1.52)	0.6129	0.00 (-0.01, 0.01)	0.6128	
	FIGARO-DKD	7/ 289 (2.42)	6/ 281 (2.14)	1.13 (0.39, 3.33)	0.8187	1.14 (0.38, 3.43)	0.8187	0.00 (-0.02, 0.03)	0.8184	
	FIDELIO-DKD	9/ 195 (4.62)	3/ 241 (1.24)	3.71 (1.02, 13.51)	0.0470	3.84 (1.02, 14.37)	0.0459	0.03 (0.00, 0.07)	0.0428	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection viral	Study									0.3122
	FINEARTS-HF	30/ 2993 (1.00)	22/ 2993 (0.74)	1.36 (0.79, 2.36)	0.2671	1.37 (0.79, 2.38)	0.2671	0.00 (-0.00, 0.01)	0.2651	
	FIGARO-DKD	8/ 289 (2.77)	7/ 281 (2.49)	1.11 (0.41, 3.02)	0.8364	1.11 (0.40, 3.12)	0.8364	0.00 (-0.02, 0.03)	0.8362	
	FIDELIO-DKD	1/ 195 (0.51)	5/ 241 (2.07)	0.25 (0.03, 2.10)	0.2003	0.24 (0.03, 2.10)	0.1987	-0.02 (-0.04, 0.00)	0.1373	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Study									0.4343
	FINEARTS-HF	45/ 2993 (1.50)	27/ 2993 (0.90)	1.67 (1.04, 2.68)	0.0348	1.68 (1.04, 2.71)	0.0347	0.01 (0.00, 0.01)	0.0328	
	FIGARO-DKD	6/ 289 (2.08)	4/ 281 (1.42)	1.46 (0.42, 5.11)	0.5554	1.47 (0.41, 5.26)	0.5553	0.01 (-0.01, 0.03)	0.5518	
	FIDELIO-DKD	4/ 195 (2.05)	7/ 241 (2.90)	0.71 (0.21, 2.38)	0.5744	0.70 (0.20, 2.43)	0.5742	-0.01 (-0.04, 0.02)	0.5652	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	Study									0.7240
	FINEARTS-HF	92/ 2993 (3.07)	95/ 2993 (3.17)	0.97 (0.73, 1.28)	0.8236	0.97 (0.72, 1.29)	0.8236	-0.00 (-0.01, 0.01)	0.8236	
	FIGARO-DKD	14/ 289 (4.84)	11/ 281 (3.91)	1.24 (0.57, 2.68)	0.5887	1.25 (0.56, 2.80)	0.5886	0.01 (-0.02, 0.04)	0.5873	
	FIDELIO-DKD	14/ 195 (7.18)	14/ 241 (5.81)	1.24 (0.60, 2.53)	0.5623	1.25 (0.58, 2.70)	0.5623	0.01 (-0.03, 0.06)	0.5656	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Urinary tract infection	Study									0.1274
	FINEARTS-HF	217/ 2993 (7.25)	204/ 2993 (6.82)	1.06 (0.88, 1.28)	0.5112	1.07 (0.88, 1.30)	0.5112	0.00 (-0.01, 0.02)	0.5111	
	FIGARO-DKD	19/ 289 (6.57)	28/ 281 (9.96)	0.66 (0.38, 1.15)	0.1448	0.64 (0.35, 1.17)	0.1440	-0.03 (-0.08, 0.01)	0.1416	
	FIDELIO-DKD	19/ 195 (9.74)	15/ 241 (6.22)	1.57 (0.82, 3.00)	0.1766	1.63 (0.80, 3.29)	0.1763	0.04 (-0.02, 0.09)	0.1813	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications	Study									0.5158
	FINEARTS-HF	466/ 2993 (15.57)	492/ 2993 (16.44)	0.95 (0.84, 1.06)	0.3595	0.94 (0.82, 1.08)	0.3594	-0.01 (-0.03, 0.01)	0.3593	
	FIGARO-DKD	41/ 289 (14.19)	45/ 281 (16.01)	0.89 (0.60, 1.31)	0.5426	0.87 (0.55, 1.37)	0.5425	-0.02 (-0.08, 0.04)	0.5424	
	FIDELIO-DKD	39/ 195 (20.00)	63/ 241 (26.14)	0.77 (0.54, 1.09)	0.1359	0.71 (0.45, 1.11)	0.1330	-0.06 (-0.14, 0.02)	0.1273	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications, PT: Contusion	Study									0.4216
	FINEARTS-HF	45/ 2993 (1.50)	58/ 2993 (1.94)	0.78 (0.53, 1.14)	0.1976	0.77 (0.52, 1.14)	0.1975	-0.00 (-0.01, 0.00)	0.1963	
	FIGARO-DKD	4/ 289 (1.38)	2/ 281 (0.71)	1.94 (0.36, 10.53)	0.4404	1.96 (0.36, 10.78)	0.4400	0.01 (-0.01, 0.02)	0.4294	
	FIDELIO-DKD	3/ 195 (1.54)	8/ 241 (3.32)	0.46 (0.12, 1.72)	0.2511	0.46 (0.12, 1.74)	0.2497	-0.02 (-0.05, 0.01)	0.2200	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications, PT: Fall	Study									0.8250
	FINEARTS-HF	107/ 2993 (3.58)	91/ 2993 (3.04)	1.18 (0.89, 1.55)	0.2481	1.18 (0.89, 1.57)	0.2480	0.01 (-0.00, 0.01)	0.2475	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	7/ 195 (3.59)	7/ 241 (2.90)	1.24 (0.44, 3.46)	0.6871	1.24 (0.43, 3.61)	0.6871	0.01 (-0.03, 0.04)	0.6897	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications, PT: Limb injury	Study									0.9057
	FINEARTS-HF	35/ 2993 (1.17)	29/ 2993 (0.97)	1.21 (0.74, 1.97)	0.4515	1.21 (0.74, 1.98)	0.4515	0.00 (-0.00, 0.01)	0.4508	
	FIGARO-DKD	5/ 289 (1.73)	3/ 281 (1.07)	1.62 (0.39, 6.72)	0.5058	1.63 (0.39, 6.89)	0.5055	0.01 (-0.01, 0.03)	0.4999	
	FIDELIO-DKD	8/ 195 (4.10)	7/ 241 (2.90)	1.41 (0.52, 3.83)	0.4971	1.43 (0.51, 4.02)	0.4970	0.01 (-0.02, 0.05)	0.5022	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations	Study									0.3891
	FINEARTS-HF	509/ 2993 (17.01)	468/ 2993 (15.64)	1.09 (0.97, 1.22)	0.1518	1.11 (0.96, 1.27)	0.1517	0.01 (-0.01, 0.03)	0.1515	
	FIGARO-DKD	75/ 289 (25.95)	63/ 281 (22.42)	1.16 (0.86, 1.55)	0.3261	1.21 (0.83, 1.78)	0.3254	0.04 (-0.03, 0.11)	0.3243	
	FIDELIO-DKD	49/ 195 (25.13)	69/ 241 (28.63)	0.88 (0.64, 1.20)	0.4150	0.84 (0.55, 1.28)	0.4134	-0.04 (-0.12, 0.05)	0.4107	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood creatinine increased	Study								0.3502
FINEARTS-HF	38/ 2993 (1.27)	26/ 2993 (0.87)	1.46 (0.89, 2.40)	0.1339	1.47 (0.89, 2.42)	0.1339	0.00 (-0.00, 0.01)	0.1315	
FIGARO-DKD	5/ 289 (1.73)	8/ 281 (2.85)	0.61 (0.20, 1.84)	0.3771	0.60 (0.19, 1.86)	0.3767	-0.01 (-0.04, 0.01)	0.3731	
FIDELIO-DKD	5/ 195 (2.56)	4/ 241 (1.66)	1.54 (0.42, 5.68)	0.5124	1.56 (0.41, 5.89)	0.5123	0.01 (-0.02, 0.04)	0.5181	

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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood potassium increased	Sex									0.9534
	Male	29/ 1945 (1.49)	13/ 1947 (0.67)	2.31 (1.20, 4.43)	0.0118	2.33 (1.21, 4.50)	0.0119	0.01 (0.00, 0.01)	0.0183	
	Female	13/ 1532 (0.85)	6/ 1568 (0.38)	2.23 (0.85, 5.85)	0.1030	2.24 (0.85, 5.92)	0.1027	0.00 (-0.00, 0.01)	0.1048	
	Region									0.2414
	Western Europe, Oceania and Others	16/ 688 (2.33)	4/ 716 (0.56)	4.26 (1.43, 12.68)	0.0092	4.34 (1.44, 13.06)	0.0091	0.02 (0.00, 0.03)	0.0193	
	Eastern Europe	9/ 1577 (0.57)	9/ 1567 (0.57)	1.01 (0.40, 2.54)	0.9801	1.01 (0.40, 2.56)	0.9798	0.00 (-0.01, 0.01)	0.8443	
	Asia	10/ 554 (1.81)	4/ 551 (0.73)	2.48 (0.79, 7.85)	0.1213	2.54 (0.79, 8.20)	0.1184	0.01 (-0.00, 0.02)	0.0867	
	North America	5/ 317 (1.58)	2/ 317 (0.63)	2.67 (0.52, 13.66)	0.2374	2.72 (0.52, 14.19)	0.2352	0.01 (-0.04, 0.07)	0.6902	
	Latin America	2/ 341 (0.59)	0/ 364 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Age group (years)									0.1712
	<= median in FAS	14/ 1825 (0.77)	10/ 1831 (0.55)	1.48 (0.66, 3.32)	0.3439	1.48 (0.65, 3.35)	0.3462	0.00 (-0.00, 0.01)	0.5506	
	> median in FAS	28/ 1652 (1.69)	9/ 1684 (0.53)	3.19 (1.51, 6.74)	0.0023	3.23 (1.52, 6.88)	0.0023	0.01 (0.00, 0.02)	0.0028	
	Study									0.9006
	FINEARTS-HF	32/ 2993 (1.07)	15/ 2993 (0.50)	2.13 (1.16, 3.93)	0.0151	2.15 (1.16, 3.97)	0.0150	0.01 (0.00, 0.01)	0.0127	
	FIGARO-DKD	3/ 289 (1.04)	1/ 281 (0.36)	2.92 (0.31, 27.88)	0.3526	2.94 (0.30, 28.40)	0.3521	0.01 (-0.01, 0.02)	0.3256	
	FIDELIO-DKD	7/ 195 (3.59)	3/ 241 (1.24)	2.88 (0.76, 11.01)	0.1212	2.95 (0.75, 11.58)	0.1202	0.02 (-0.01, 0.05)	0.1208	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood pressure increased	Sex									0.5165
	Male	14/ 1945 (0.72)	30/ 1947 (1.54)	0.49 (0.26, 0.93)	0.0288	0.49 (0.26, 0.93)	0.0295	-0.00 (-0.01, 0.00)	0.1730	
	Female	19/ 1532 (1.24)	30/ 1568 (1.91)	0.66 (0.37, 1.16)	0.1449	0.65 (0.36, 1.16)	0.1431	-0.01 (-0.01, 0.00)	0.1429	
	Region									0.8429
	Western Europe, Oceania and Others	4/ 688 (0.58)	7/ 716 (0.98)	0.61 (0.18, 2.08)	0.4331	0.61 (0.18, 2.10)	0.4317	-0.00 (-0.01, 0.01)	0.4257	
	Eastern Europe	21/ 1577 (1.33)	32/ 1567 (2.04)	0.67 (0.39, 1.15)	0.1478	0.66 (0.38, 1.16)	0.1502	-0.01 (-0.01, 0.00)	0.1697	
	Asia	5/ 554 (0.90)	12/ 551 (2.18)	0.42 (0.15, 1.18)	0.1007	0.42 (0.15, 1.19)	0.1010	-0.01 (-0.03, 0.00)	0.1317	
	North America	2/ 317 (0.63)	7/ 317 (2.21)	0.29 (0.06, 1.39)	0.1219	0.29 (0.06, 1.39)	0.1213	-0.02 (-0.04, 0.01)	0.2072	
	Latin America	1/ 341 (0.29)	2/ 364 (0.55)	0.50 (0.05, 5.44)	0.5654	0.49 (0.04, 5.47)	0.5653	-0.00 (-0.06, 0.05)	0.8827	
	Age group (years)									0.0939
	<= median in FAS	26/ 1825 (1.42)	37/ 1831 (2.02)	0.73 (0.44, 1.20)	0.2104	0.73 (0.44, 1.21)	0.2150	-0.00 (-0.01, 0.00)	0.3836	
	> median in FAS	7/ 1652 (0.42)	23/ 1684 (1.37)	0.32 (0.14, 0.73)	0.0073	0.31 (0.13, 0.73)	0.0071	-0.01 (-0.01, -0.00)	0.0053	
	Study									0.6086
	FINEARTS-HF	23/ 2993 (0.77)	40/ 2993 (1.34)	0.58 (0.35, 0.96)	0.0336	0.57 (0.34, 0.96)	0.0335	-0.01 (-0.01, -0.00)	0.0312	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	4/ 195 (2.05)	13/ 241 (5.39)	0.38 (0.13, 1.15)	0.0863	0.37 (0.12, 1.15)	0.0843	-0.03 (-0.07, 0.00)	0.0595	

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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Glomerular filtration rate decreased	Sex									0.5958
	Male	108/ 1945 (5.55)	75/ 1947 (3.85)	1.46 (1.10, 1.95)	0.0097	1.49 (1.10, 2.02)	0.0094	0.02 (0.00, 0.03)	0.0072	
	Female	84/ 1532 (5.48)	66/ 1568 (4.21)	1.30 (0.95, 1.78)	0.0992	1.32 (0.95, 1.84)	0.0976	0.01 (-0.00, 0.03)	0.0778	
	Region									0.1734
	Western Europe, Oceania and Others	50/ 688 (7.27)	34/ 716 (4.75)	1.54 (1.01, 2.35)	0.0461	1.58 (1.01, 2.48)	0.0453	0.03 (0.00, 0.05)	0.0356	
	Eastern Europe	79/ 1577 (5.01)	58/ 1567 (3.70)	1.37 (0.98, 1.91)	0.0628	1.39 (0.98, 1.97)	0.0621	0.01 (-0.00, 0.03)	0.0534	
	Asia	21/ 554 (3.79)	6/ 551 (1.09)	3.51 (1.43, 8.62)	0.0062	3.63 (1.45, 9.09)	0.0058	0.03 (0.01, 0.04)	0.0029	
	North America	14/ 317 (4.42)	16/ 317 (5.05)	0.89 (0.44, 1.80)	0.7495	0.89 (0.43, 1.86)	0.7545	-0.00 (-0.04, 0.03)	0.8346	
	Latin America	28/ 341 (8.21)	27/ 364 (7.42)	1.15 (0.69, 1.92)	0.5956	1.16 (0.67, 2.03)	0.5964	0.01 (-0.03, 0.05)	0.5955	
	Age group (years)									0.9577
	<= median in FAS	98/ 1825 (5.37)	72/ 1831 (3.93)	1.38 (1.02, 1.86)	0.0346	1.40 (1.03, 1.92)	0.0333	0.02 (0.00, 0.03)	0.0189	
	> median in FAS	94/ 1652 (5.69)	69/ 1684 (4.10)	1.39 (1.03, 1.89)	0.0316	1.42 (1.03, 1.95)	0.0313	0.02 (0.00, 0.03)	0.0318	
	Study									0.2882
	FINEARTS-HF	161/ 2993 (5.38)	112/ 2993 (3.74)	1.44 (1.14, 1.82)	0.0026	1.46 (1.14, 1.87)	0.0025	0.02 (0.01, 0.03)	0.0024	
	FIGARO-DKD	18/ 289 (6.23)	10/ 281 (3.56)	1.75 (0.82, 3.73)	0.1464	1.80 (0.82, 3.97)	0.1453	0.03 (-0.01, 0.06)	0.1382	
	FIDELIO-DKD	13/ 195 (6.67)	19/ 241 (7.88)	0.85 (0.43, 1.67)	0.6287	0.83 (0.40, 1.74)	0.6284	-0.01 (-0.06, 0.04)	0.6251	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Sex									0.9819
	Male	601/ 1945 (30.90)	556/ 1947 (28.56)	1.09 (0.99, 1.20)	0.0687	1.14 (0.99, 1.30)	0.0709	0.03 (-0.00, 0.05)	0.0719	
	Female	437/ 1532 (28.52)	410/ 1568 (26.15)	1.09 (0.97, 1.22)	0.1347	1.13 (0.96, 1.32)	0.1310	0.02 (-0.01, 0.06)	0.1270	
	Region									0.2316
	Western Europe, Oceania and Others	247/ 688 (35.90)	249/ 716 (34.78)	1.03 (0.90, 1.19)	0.6676	1.06 (0.85, 1.32)	0.5877	0.01 (-0.03, 0.06)	0.5597	
	Eastern Europe	347/ 1577 (22.00)	313/ 1567 (19.97)	1.09 (0.96, 1.25)	0.1901	1.13 (0.95, 1.34)	0.1659	0.02 (-0.01, 0.05)	0.1225	
	Asia	245/ 554 (44.22)	229/ 551 (41.56)	1.08 (0.95, 1.24)	0.2497	1.11 (0.87, 1.41)	0.3992	0.03 (-0.03, 0.08)	0.3957	
	North America	117/ 317 (36.91)	85/ 317 (26.81)	1.40 (1.11, 1.75)	0.0040	1.61 (1.14, 2.26)	0.0064	0.09 (0.02, 0.17)	0.0095	
	Latin America	82/ 341 (24.05)	90/ 364 (24.73)	1.00 (0.77, 1.29)	0.9984	1.06 (0.74, 1.50)	0.7596	0.01 (-0.05, 0.08)	0.6699	
	Age group (years)									0.9091
	<= median in FAS	518/ 1825 (28.38)	481/ 1831 (26.27)	1.09 (0.98, 1.21)	0.1182	1.13 (0.98, 1.31)	0.1033	0.02 (-0.00, 0.05)	0.0903	
	> median in FAS	520/ 1652 (31.48)	485/ 1684 (28.80)	1.10 (0.99, 1.22)	0.0794	1.14 (0.98, 1.32)	0.0839	0.03 (-0.00, 0.06)	0.0886	
	Study									0.7171
	FINEARTS-HF	856/ 2993 (28.60)	777/ 2993 (25.96)	1.10 (1.01, 1.20)	0.0220	1.14 (1.02, 1.28)	0.0219	0.03 (0.00, 0.05)	0.0218	
	FIGARO-DKD	103/ 289 (35.64)	91/ 281 (32.38)	1.10 (0.88, 1.38)	0.4127	1.16 (0.82, 1.64)	0.4123	0.03 (-0.05, 0.11)	0.4117	
	FIDELIO-DKD	79/ 195 (40.51)	98/ 241 (40.66)	1.00 (0.79, 1.25)	0.9745	0.99 (0.68, 1.46)	0.9745	-0.00 (-0.09, 0.09)	0.9745	

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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Dehydration	Sex									0.6458
	Male	51/ 1945 (2.62)	33/ 1947 (1.69)	1.52 (0.99, 2.35)	0.0567	1.54 (0.99, 2.39)	0.0569	0.01 (-0.00, 0.02)	0.1609	
	Female	30/ 1532 (1.96)	17/ 1568 (1.08)	1.81 (1.00, 3.27)	0.0492	1.82 (1.00, 3.32)	0.0494	0.01 (-0.00, 0.02)	0.0722	
	Region									0.8414
	Western Europe, Oceania and Others	18/ 688 (2.62)	15/ 716 (2.09)	1.25 (0.63, 2.45)	0.5257	1.25 (0.62, 2.50)	0.5280	0.00 (-0.01, 0.02)	0.6537	
	Eastern Europe	22/ 1577 (1.40)	13/ 1567 (0.83)	1.69 (0.86, 3.35)	0.1303	1.70 (0.86, 3.40)	0.1298	0.01 (-0.02, 0.03)	0.5986	
	Asia	25/ 554 (4.51)	14/ 551 (2.54)	1.80 (0.95, 3.42)	0.0729	1.85 (0.95, 3.59)	0.0715	0.02 (-0.02, 0.06)	0.2996	
	North America	16/ 317 (5.05)	8/ 317 (2.52)	1.89 (0.82, 4.35)	0.1329	1.94 (0.81, 4.62)	0.1341	0.02 (-0.03, 0.07)	0.4367	
	Latin America	0/ 341 (0.00)	0/ 364 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Age group (years)									0.5667
	<= median in FAS	22/ 1825 (1.21)	11/ 1831 (0.60)	1.97 (0.96, 4.05)	0.0651	1.98 (0.96, 4.10)	0.0648	0.01 (-0.00, 0.01)	0.0708	
	> median in FAS	59/ 1652 (3.57)	39/ 1684 (2.32)	1.55 (1.04, 2.31)	0.0314	1.57 (1.04, 2.36)	0.0320	0.01 (-0.00, 0.02)	0.0706	
	Study									0.7556
	FINEARTS-HF	72/ 2993 (2.41)	46/ 2993 (1.54)	1.57 (1.08, 2.26)	0.0166	1.58 (1.09, 2.29)	0.0165	0.01 (0.00, 0.02)	0.0156	
	FIGARO-DKD	8/ 289 (2.77)	3/ 281 (1.07)	2.59 (0.69, 9.67)	0.1561	2.64 (0.69, 10.05)	0.1551	0.02 (-0.01, 0.04)	0.1369	
	FIDELIO-DKD	1/ 195 (0.51)	1/ 241 (0.41)	1.24 (0.08, 19.63)	0.8807	1.24 (0.08, 19.91)	0.8807	0.00 (-0.01, 0.01)	0.8818	

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Pooled Population - Finerenone vs. Placebo
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Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Diabetes mellitus	Study									0.8520
	FINEARTS-HF	42/ 2993 (1.40)	50/ 2993 (1.67)	0.84 (0.56, 1.26)	0.4012	0.84 (0.55, 1.27)	0.4012	-0.00 (-0.01, 0.00)	0.4006	
	FIGARO-DKD	8/ 289 (2.77)	12/ 281 (4.27)	0.65 (0.27, 1.56)	0.3339	0.64 (0.26, 1.59)	0.3334	-0.02 (-0.05, 0.02)	0.3308	
	FIDELIO-DKD	7/ 195 (3.59)	12/ 241 (4.98)	0.72 (0.29, 1.80)	0.4823	0.71 (0.27, 1.84)	0.4818	-0.01 (-0.05, 0.02)	0.4723	

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Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Gout	Study									0.5349
	FINEARTS-HF	67/ 2993 (2.24)	78/ 2993 (2.61)	0.86 (0.62, 1.19)	0.3556	0.86 (0.61, 1.19)	0.3555	-0.00 (-0.01, 0.00)	0.3551	
	FIGARO-DKD	10/ 289 (3.46)	7/ 281 (2.49)	1.39 (0.54, 3.60)	0.4986	1.40 (0.53, 3.74)	0.4984	0.01 (-0.02, 0.04)	0.4954	
	FIDELIO-DKD	8/ 195 (4.10)	8/ 241 (3.32)	1.24 (0.47, 3.23)	0.6660	1.25 (0.46, 3.38)	0.6660	0.01 (-0.03, 0.04)	0.6687	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyperglycaemia	Study									0.4185
	FINEARTS-HF	25/ 2993 (0.84)	19/ 2993 (0.63)	1.32 (0.73, 2.38)	0.3655	1.32 (0.72, 2.40)	0.3655	0.00 (-0.00, 0.01)	0.3639	
	FIGARO-DKD	15/ 289 (5.19)	8/ 281 (2.85)	1.82 (0.79, 4.23)	0.1622	1.87 (0.78, 4.48)	0.1612	0.02 (-0.01, 0.06)	0.1528	
	FIDELIO-DKD	7/ 195 (3.59)	11/ 241 (4.56)	0.79 (0.31, 1.99)	0.6122	0.78 (0.30, 2.05)	0.6119	-0.01 (-0.05, 0.03)	0.6066	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyperkalaemia	Sex									0.4081
	Male	215/ 1945 (11.05)	93/ 1947 (4.78)	2.39 (1.89, 3.02)	<.0001	2.58 (2.00, 3.33)	<.0001	0.06 (0.04, 0.08)	<.0001	
	Female	136/ 1532 (8.88)	68/ 1568 (4.34)	2.04 (1.54, 2.71)	<.0001	2.16 (1.60, 2.91)	<.0001	0.05 (0.03, 0.06)	<.0001	
	Region									0.5189
	Western Europe, Oceania and Others	76/ 688 (11.05)	36/ 716 (5.03)	2.21 (1.51, 3.24)	<.0001	2.38 (1.57, 3.59)	<.0001	0.06 (0.03, 0.09)	<.0001	
	Eastern Europe	120/ 1577 (7.61)	53/ 1567 (3.38)	2.27 (1.65, 3.11)	<.0001	2.38 (1.70, 3.31)	<.0001	0.04 (0.03, 0.06)	<.0001	
	Asia	81/ 554 (14.62)	37/ 551 (6.72)	2.21 (1.53, 3.18)	<.0001	2.40 (1.59, 3.62)	<.0001	0.07 (0.03, 0.10)	0.0001	
	North America	49/ 317 (15.46)	16/ 317 (5.05)	3.11 (1.82, 5.33)	<.0001	3.59 (1.98, 6.52)	<.0001	0.10 (0.05, 0.14)	<.0001	
	Latin America	25/ 341 (7.33)	19/ 364 (5.22)	1.50 (0.84, 2.69)	0.1690	1.58 (0.84, 2.98)	0.1527	0.03 (-0.00, 0.07)	0.0911	
	Age group (years)									0.0341
	<= median in FAS	188/ 1825 (10.30)	71/ 1831 (3.88)	2.73 (2.10, 3.56)	<.0001	3.01 (2.26, 3.99)	<.0001	0.06 (0.05, 0.08)	<.0001	
	> median in FAS	163/ 1652 (9.87)	90/ 1684 (5.34)	1.85 (1.44, 2.37)	<.0001	1.94 (1.49, 2.53)	<.0001	0.05 (0.03, 0.06)	<.0001	
	Study									0.7365
	FINEARTS-HF	285/ 2993 (9.52)	123/ 2993 (4.11)	2.32 (1.89, 2.85)	<.0001	2.46 (1.97, 3.05)	<.0001	0.05 (0.04, 0.07)	<.0001	
	FIGARO-DKD	28/ 289 (9.69)	14/ 281 (4.98)	1.94 (1.05, 3.62)	0.0356	2.05 (1.05, 3.97)	0.0346	0.05 (0.00, 0.09)	0.0302	
	FIDELIO-DKD	38/ 195 (19.49)	24/ 241 (9.96)	1.96 (1.22, 3.15)	0.0056	2.19 (1.26, 3.80)	0.0053	0.10 (0.03, 0.16)	0.0055	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyperuricaemia	Study									0.5736
	FINEARTS-HF	84/ 2993 (2.81)	72/ 2993 (2.41)	1.17 (0.86, 1.59)	0.3308	1.17 (0.85, 1.61)	0.3308	0.00 (-0.00, 0.01)	0.3302	
	FIGARO-DKD	15/ 289 (5.19)	16/ 281 (5.69)	0.91 (0.46, 1.81)	0.7910	0.91 (0.44, 1.87)	0.7910	-0.01 (-0.04, 0.03)	0.7911	
	FIDELIO-DKD	11/ 195 (5.64)	17/ 241 (7.05)	0.80 (0.38, 1.67)	0.5509	0.79 (0.36, 1.72)	0.5504	-0.01 (-0.06, 0.03)	0.5450	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hypoglycaemia	Study									0.4518
	FINEARTS-HF	30/ 2993 (1.00)	20/ 2993 (0.67)	1.50 (0.85, 2.64)	0.1585	1.50 (0.85, 2.66)	0.1584	0.00 (-0.00, 0.01)	0.1555	
	FIGARO-DKD	17/ 289 (5.88)	16/ 281 (5.69)	1.03 (0.53, 2.00)	0.9233	1.04 (0.51, 2.09)	0.9233	0.00 (-0.04, 0.04)	0.9233	
	FIDELIO-DKD	11/ 195 (5.64)	16/ 241 (6.64)	0.85 (0.40, 1.79)	0.6679	0.84 (0.38, 1.86)	0.6676	-0.01 (-0.06, 0.04)	0.6647	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Sex									0.0571
	Male	76/ 1945 (3.91)	120/ 1947 (6.16)	0.63 (0.48, 0.84)	0.0014	0.62 (0.46, 0.83)	0.0013	-0.02 (-0.04, -0.01)	0.0011	
	Female	51/ 1532 (3.33)	124/ 1568 (7.91)	0.42 (0.31, 0.58)	<.0001	0.40 (0.28, 0.56)	<.0001	-0.04 (-0.07, -0.02)	0.0002	
	Region									0.4052
	Western Europe, Oceania and Others	36/ 688 (5.23)	66/ 716 (9.22)	0.57 (0.38, 0.84)	0.0048	0.54 (0.36, 0.83)	0.0045	-0.04 (-0.07, -0.02)	0.0024	
	Eastern Europe	15/ 1577 (0.95)	45/ 1567 (2.87)	0.33 (0.19, 0.59)	0.0002	0.32 (0.18, 0.59)	0.0002	-0.02 (-0.04, -0.00)	0.0394	
	Asia	51/ 554 (9.21)	89/ 551 (16.15)	0.57 (0.41, 0.79)	0.0007	0.52 (0.36, 0.76)	0.0006	-0.07 (-0.11, -0.03)	0.0006	
	North America	17/ 317 (5.36)	24/ 317 (7.57)	0.70 (0.38, 1.27)	0.2382	0.68 (0.36, 1.29)	0.2361	-0.02 (-0.06, 0.01)	0.2208	
	Latin America	8/ 341 (2.35)	20/ 364 (5.49)	0.41 (0.18, 0.92)	0.0306	0.40 (0.17, 0.91)	0.0298	-0.03 (-0.08, 0.02)	0.1960	
	Age group (years)									0.9014
	<= median in FAS	50/ 1825 (2.74)	93/ 1831 (5.08)	0.53 (0.38, 0.75)	0.0003	0.52 (0.37, 0.74)	0.0002	-0.02 (-0.04, -0.01)	0.0005	
	> median in FAS	77/ 1652 (4.66)	151/ 1684 (8.97)	0.52 (0.40, 0.68)	<.0001	0.50 (0.37, 0.66)	<.0001	-0.04 (-0.06, -0.03)	<.0001	
	Study									0.4658
	FINEARTS-HF	118/ 2993 (3.94)	223/ 2993 (7.45)	0.53 (0.43, 0.66)	<.0001	0.51 (0.41, 0.64)	<.0001	-0.04 (-0.05, -0.02)	<.0001	
	FIGARO-DKD	7/ 289 (2.42)	10/ 281 (3.56)	0.68 (0.26, 1.76)	0.4282	0.67 (0.25, 1.79)	0.4279	-0.01 (-0.04, 0.02)	0.4261	
	FIDELIO-DKD	2/ 195 (1.03)	11/ 241 (4.56)	0.22 (0.05, 1.00)	0.0503	0.22 (0.05, 0.99)	0.0484	-0.04 (-0.07, -0.01)	0.0204	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hyponatraemia	Sex									0.4825
	Male	34/ 1945 (1.75)	21/ 1947 (1.08)	1.64 (0.96, 2.82)	0.0719	1.66 (0.96, 2.87)	0.0713	0.01 (-0.00, 0.01)	0.0527	
	Female	44/ 1532 (2.87)	21/ 1568 (1.34)	2.15 (1.28, 3.59)	0.0036	2.18 (1.29, 3.69)	0.0036	0.02 (0.01, 0.03)	0.0026	
	Region									0.0069
	Western Europe, Oceania and Others	21/ 688 (3.05)	5/ 716 (0.70)	4.40 (1.67, 11.61)	0.0027	4.52 (1.69, 12.06)	0.0026	0.03 (0.01, 0.04)	0.0005	
	Eastern Europe	10/ 1577 (0.63)	12/ 1567 (0.77)	0.83 (0.36, 1.92)	0.6653	0.83 (0.36, 1.93)	0.6664	-0.00 (-0.01, 0.01)	0.9409	
	Asia	14/ 554 (2.53)	13/ 551 (2.36)	1.07 (0.51, 2.26)	0.8529	1.08 (0.50, 2.32)	0.8473	0.00 (-0.01, 0.02)	0.6724	
	North America	26/ 317 (8.20)	5/ 317 (1.58)	5.22 (2.03, 13.45)	0.0006	5.60 (2.12, 14.80)	0.0005	0.07 (0.03, 0.10)	<.0001	
	Latin America	7/ 341 (2.05)	7/ 364 (1.92)	1.08 (0.38, 3.07)	0.8886	1.08 (0.37, 3.16)	0.8864	0.00 (-0.04, 0.05)	0.9404	
	Age group (years)									0.6916
	<= median in FAS	25/ 1825 (1.37)	15/ 1831 (0.82)	1.71 (0.90, 3.24)	0.0985	1.73 (0.91, 3.29)	0.0967	0.01 (0.00, 0.01)	0.0380	
	> median in FAS	53/ 1652 (3.21)	27/ 1684 (1.60)	2.01 (1.27, 3.17)	0.0029	2.04 (1.28, 3.26)	0.0029	0.02 (0.01, 0.03)	0.0028	
	Study									0.3941
	FINEARTS-HF	68/ 2993 (2.27)	33/ 2993 (1.10)	2.06 (1.36, 3.11)	0.0006	2.09 (1.37, 3.17)	0.0006	0.01 (0.01, 0.02)	0.0004	
	FIGARO-DKD	6/ 289 (2.08)	3/ 281 (1.07)	1.94 (0.49, 7.70)	0.3435	1.96 (0.49, 7.93)	0.3430	0.01 (-0.01, 0.03)	0.3317	
	FIDELIO-DKD	4/ 195 (2.05)	6/ 241 (2.49)	0.82 (0.24, 2.88)	0.7616	0.82 (0.23, 2.95)	0.7615	-0.00 (-0.03, 0.02)	0.7588	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Iron deficiency	Study									0.8919
	FINEARTS-HF	49/ 2993 (1.64)	40/ 2993 (1.34)	1.22 (0.81, 1.85)	0.3373	1.23 (0.81, 1.87)	0.3373	0.00 (-0.00, 0.01)	0.3364	
	FIGARO-DKD	1/ 289 (0.35)	1/ 281 (0.36)	0.97 (0.06, 15.47)	0.9841	0.97 (0.06, 15.62)	0.9841	-0.00 (-0.01, 0.01)	0.9841	
	FIDELIO-DKD	3/ 195 (1.54)	2/ 241 (0.83)	1.85 (0.31, 10.98)	0.4965	1.87 (0.31, 11.29)	0.4964	0.01 (-0.01, 0.03)	0.5028	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Type 2 diabetes mellitus	Study									0.9189
	FINEARTS-HF	76/ 2993 (2.54)	83/ 2993 (2.77)	0.92 (0.67, 1.24)	0.5738	0.91 (0.67, 1.25)	0.5738	-0.00 (-0.01, 0.01)	0.5737	
	FIGARO-DKD	6/ 289 (2.08)	8/ 281 (2.85)	0.73 (0.26, 2.07)	0.5540	0.72 (0.25, 2.11)	0.5538	-0.01 (-0.03, 0.02)	0.5529	
	FIDELIO-DKD	3/ 195 (1.54)	4/ 241 (1.66)	0.93 (0.21, 4.09)	0.9202	0.93 (0.20, 4.19)	0.9202	-0.00 (-0.02, 0.02)	0.9199	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Vitamin D deficiency	Study									0.1365
	FINEARTS-HF	38/ 2993 (1.27)	26/ 2993 (0.87)	1.46 (0.89, 2.40)	0.1339	1.47 (0.89, 2.42)	0.1339	0.00 (-0.00, 0.01)	0.1315	
	FIGARO-DKD	8/ 289 (2.77)	2/ 281 (0.71)	3.89 (0.83, 18.16)	0.0840	3.97 (0.84, 18.87)	0.0828	0.02 (-0.00, 0.04)	0.0586	
	FIDELIO-DKD	2/ 195 (1.03)	6/ 241 (2.49)	0.41 (0.08, 2.02)	0.2741	0.41 (0.08, 2.03)	0.2728	-0.01 (-0.04, 0.01)	0.2363	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders	Study									0.6868
	FINEARTS-HF	592/ 2993 (19.78)	602/ 2993 (20.11)	0.98 (0.89, 1.09)	0.7464	0.98 (0.86, 1.11)	0.7464	-0.00 (-0.02, 0.02)	0.7464	
	FIGARO-DKD	65/ 289 (22.49)	72/ 281 (25.62)	0.88 (0.66, 1.18)	0.3822	0.84 (0.57, 1.24)	0.3820	-0.03 (-0.10, 0.04)	0.3817	
	FIDELIO-DKD	47/ 195 (24.10)	65/ 241 (26.97)	0.89 (0.65, 1.24)	0.4968	0.86 (0.56, 1.33)	0.4957	-0.03 (-0.11, 0.05)	0.4936	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Study									0.1572
	FINEARTS-HF	120/ 2993 (4.01)	139/ 2993 (4.64)	0.86 (0.68, 1.10)	0.2279	0.86 (0.67, 1.10)	0.2278	-0.01 (-0.02, 0.00)	0.2274	
	FIGARO-DKD	19/ 289 (6.57)	11/ 281 (3.91)	1.68 (0.81, 3.46)	0.1606	1.73 (0.81, 3.70)	0.1595	0.03 (-0.01, 0.06)	0.1530	
	FIDELIO-DKD	11/ 195 (5.64)	10/ 241 (4.15)	1.36 (0.59, 3.13)	0.4712	1.38 (0.57, 3.32)	0.4711	0.01 (-0.03, 0.06)	0.4760	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Study									0.8085
	FINEARTS-HF	123/ 2993 (4.11)	136/ 2993 (4.54)	0.90 (0.71, 1.15)	0.4091	0.90 (0.70, 1.16)	0.4091	-0.00 (-0.01, 0.01)	0.4089	
	FIGARO-DKD	18/ 289 (6.23)	16/ 281 (5.69)	1.09 (0.57, 2.10)	0.7878	1.10 (0.55, 2.20)	0.7877	0.01 (-0.03, 0.04)	0.7875	
	FIDELIO-DKD	11/ 195 (5.64)	17/ 241 (7.05)	0.80 (0.38, 1.67)	0.5509	0.79 (0.36, 1.72)	0.5504	-0.01 (-0.06, 0.03)	0.5450	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms	Study									0.2011
	FINEARTS-HF	37/ 2993 (1.24)	29/ 2993 (0.97)	1.28 (0.79, 2.07)	0.3233	1.28 (0.78, 2.09)	0.3233	0.00 (-0.00, 0.01)	0.3220	
	FIGARO-DKD	4/ 289 (1.38)	7/ 281 (2.49)	0.56 (0.16, 1.88)	0.3441	0.55 (0.16, 1.90)	0.3436	-0.01 (-0.03, 0.01)	0.3383	
	FIDELIO-DKD	7/ 195 (3.59)	3/ 241 (1.24)	2.88 (0.76, 11.01)	0.1212	2.95 (0.75, 11.58)	0.1202	0.02 (-0.01, 0.05)	0.1208	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Study									0.3157
	FINEARTS-HF	33/ 2993 (1.10)	18/ 2993 (0.60)	1.83 (1.03, 3.25)	0.0378	1.84 (1.04, 3.28)	0.0377	0.01 (0.00, 0.01)	0.0348	
	FIGARO-DKD	1/ 289 (0.35)	3/ 281 (1.07)	0.32 (0.03, 3.10)	0.3279	0.32 (0.03, 3.11)	0.3274	-0.01 (-0.02, 0.01)	0.3052	
	FIDELIO-DKD	5/ 195 (2.56)	5/ 241 (2.07)	1.24 (0.36, 4.21)	0.7347	1.24 (0.35, 4.35)	0.7347	0.00 (-0.02, 0.03)	0.7370	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Osteoarthritis	Study									0.3816
	FINEARTS-HF	66/ 2993 (2.21)	74/ 2993 (2.47)	0.89 (0.64, 1.24)	0.4941	0.89 (0.64, 1.24)	0.4941	-0.00 (-0.01, 0.00)	0.4939	
	FIGARO-DKD	7/ 289 (2.42)	11/ 281 (3.91)	0.62 (0.24, 1.57)	0.3134	0.61 (0.23, 1.59)	0.3129	-0.01 (-0.04, 0.01)	0.3095	
	FIDELIO-DKD	5/ 195 (2.56)	3/ 241 (1.24)	2.06 (0.50, 8.51)	0.3182	2.09 (0.49, 8.85)	0.3178	0.01 (-0.01, 0.04)	0.3243	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity	Study									0.4085
	FINEARTS-HF	81/ 2993 (2.71)	69/ 2993 (2.31)	1.17 (0.85, 1.61)	0.3216	1.18 (0.85, 1.63)	0.3216	0.00 (-0.00, 0.01)	0.3210	
	FIGARO-DKD	11/ 289 (3.81)	9/ 281 (3.20)	1.19 (0.50, 2.82)	0.6959	1.20 (0.49, 2.93)	0.6958	0.01 (-0.02, 0.04)	0.6951	
	FIDELIO-DKD	5/ 195 (2.56)	11/ 241 (4.56)	0.56 (0.20, 1.59)	0.2772	0.55 (0.19, 1.61)	0.2758	-0.02 (-0.05, 0.01)	0.2551	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Spinal osteoarthritis	Sex									0.4527
	Male	14/ 1945 (0.72)	21/ 1947 (1.08)	0.69 (0.35, 1.35)	0.2791	0.69 (0.35, 1.36)	0.2795	-0.00 (-0.01, 0.00)	0.4715	
	Female	8/ 1532 (0.52)	18/ 1568 (1.15)	0.46 (0.20, 1.05)	0.0647	0.45 (0.20, 1.05)	0.0649	-0.00 (-0.01, 0.00)	0.1272	
	Region									0.1737
	Western Europe, Oceania and Others	6/ 688 (0.87)	4/ 716 (0.56)	1.60 (0.46, 5.66)	0.4620	1.60 (0.45, 5.72)	0.4682	0.00 (-0.03, 0.04)	0.8829	
	Eastern Europe	7/ 1577 (0.44)	22/ 1567 (1.40)	0.32 (0.14, 0.76)	0.0092	0.32 (0.14, 0.75)	0.0091	-0.01 (-0.01, -0.00)	0.0163	
	Asia	8/ 554 (1.44)	9/ 551 (1.63)	0.87 (0.34, 2.25)	0.7818	0.87 (0.33, 2.28)	0.7814	-0.00 (-0.04, 0.03)	0.9079	
	North America	0/ 317 (0.00)	2/ 317 (0.63)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Latin America	1/ 341 (0.29)	2/ 364 (0.55)	0.50 (0.05, 5.44)	0.5654	0.49 (0.04, 5.47)	0.5653	-0.00 (-0.06, 0.05)	0.8827	
	Age group (years)									0.4436
	<= median in FAS	9/ 1825 (0.49)	20/ 1831 (1.09)	0.46 (0.21, 1.01)	0.0539	0.46 (0.21, 1.01)	0.0535	-0.01 (-0.01, -0.00)	0.0369	
	> median in FAS	13/ 1652 (0.79)	19/ 1684 (1.13)	0.70 (0.35, 1.40)	0.3129	0.70 (0.34, 1.42)	0.3191	-0.00 (-0.01, 0.00)	0.5146	
	Study									0.8507
	FINEARTS-HF	18/ 2993 (0.60)	29/ 2993 (0.97)	0.62 (0.35, 1.12)	0.1106	0.62 (0.34, 1.12)	0.1105	-0.00 (-0.01, 0.00)	0.1071	
	FIGARO-DKD	1/ 289 (0.35)	3/ 281 (1.07)	0.32 (0.03, 3.10)	0.3279	0.32 (0.03, 3.11)	0.3274	-0.01 (-0.02, 0.01)	0.3052	
	FIDELIO-DKD	3/ 195 (1.54)	7/ 241 (2.90)	0.53 (0.14, 2.02)	0.3524	0.52 (0.13, 2.05)	0.3514	-0.01 (-0.04, 0.01)	0.3276	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Study									0.9064
	FINEARTS-HF	205/ 2993 (6.85)	209/ 2993 (6.98)	0.98 (0.81, 1.18)	0.8385	0.98 (0.80, 1.20)	0.8385	-0.00 (-0.01, 0.01)	0.8385	
	FIGARO-DKD	21/ 289 (7.27)	22/ 281 (7.83)	0.93 (0.52, 1.65)	0.7993	0.92 (0.50, 1.72)	0.7993	-0.01 (-0.05, 0.04)	0.7993	
	FIDELIO-DKD	18/ 195 (9.23)	20/ 241 (8.30)	1.11 (0.61, 2.04)	0.7316	1.12 (0.58, 2.19)	0.7317	0.01 (-0.04, 0.06)	0.7328	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders	Study									0.0795
	FINEARTS-HF	637/ 2993 (21.28)	605/ 2993 (20.21)	1.05 (0.95, 1.16)	0.3078	1.07 (0.94, 1.21)	0.3078	0.01 (-0.01, 0.03)	0.3077	
	FIGARO-DKD	55/ 289 (19.03)	65/ 281 (23.13)	0.82 (0.60, 1.13)	0.2311	0.78 (0.52, 1.17)	0.2305	-0.04 (-0.11, 0.03)	0.2298	
	FIDELIO-DKD	38/ 195 (19.49)	63/ 241 (26.14)	0.75 (0.52, 1.06)	0.1054	0.68 (0.43, 1.08)	0.1026	-0.07 (-0.15, 0.01)	0.0968	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Dizziness	Study									0.0124
	FINEARTS-HF	189/ 2993 (6.31)	157/ 2993 (5.25)	1.20 (0.98, 1.48)	0.0768	1.22 (0.98, 1.51)	0.0767	0.01 (-0.00, 0.02)	0.0763	
	FIGARO-DKD	5/ 289 (1.73)	18/ 281 (6.41)	0.27 (0.10, 0.72)	0.0086	0.26 (0.09, 0.70)	0.0081	-0.05 (-0.08, -0.01)	0.0046	
	FIDELIO-DKD	9/ 195 (4.62)	8/ 241 (3.32)	1.39 (0.55, 3.54)	0.4889	1.41 (0.53, 3.72)	0.4889	0.01 (-0.02, 0.05)	0.4940	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Headache	Study									0.2560
	FINEARTS-HF	106/ 2993 (3.54)	103/ 2993 (3.44)	1.03 (0.79, 1.34)	0.8327	1.03 (0.78, 1.36)	0.8327	0.00 (-0.01, 0.01)	0.8327	
	FIGARO-DKD	15/ 289 (5.19)	7/ 281 (2.49)	2.08 (0.86, 5.03)	0.1028	2.14 (0.86, 5.34)	0.1017	0.03 (-0.00, 0.06)	0.0921	
	FIDELIO-DKD	4/ 195 (2.05)	7/ 241 (2.90)	0.71 (0.21, 2.38)	0.5744	0.70 (0.20, 2.43)	0.5742	-0.01 (-0.04, 0.02)	0.5652	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Syncope	Study									0.0703
	FINEARTS-HF	83/ 2993 (2.77)	56/ 2993 (1.87)	1.48 (1.06, 2.07)	0.0214	1.50 (1.06, 2.11)	0.0213	0.01 (0.00, 0.02)	0.0204	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	4/ 195 (2.05)	12/ 241 (4.98)	0.41 (0.13, 1.26)	0.1193	0.40 (0.13, 1.26)	0.1173	-0.03 (-0.06, 0.00)	0.0906	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders	Study									0.3549
	FINEARTS-HF	229/ 2993 (7.65)	219/ 2993 (7.32)	1.05 (0.87, 1.25)	0.6233	1.05 (0.87, 1.27)	0.6233	0.00 (-0.01, 0.02)	0.6233	
	FIGARO-DKD	16/ 289 (5.54)	23/ 281 (8.19)	0.68 (0.37, 1.25)	0.2139	0.66 (0.34, 1.27)	0.2132	-0.03 (-0.07, 0.02)	0.2110	
	FIDELIO-DKD	18/ 195 (9.23)	26/ 241 (10.79)	0.86 (0.48, 1.51)	0.5922	0.84 (0.45, 1.58)	0.5917	-0.02 (-0.07, 0.04)	0.5885	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders, PT: Anxiety	Study									0.2974
	FINEARTS-HF	34/ 2993 (1.14)	29/ 2993 (0.97)	1.17 (0.72, 1.92)	0.5270	1.17 (0.71, 1.93)	0.5270	0.00 (-0.00, 0.01)	0.5265	
	FIGARO-DKD	4/ 289 (1.38)	2/ 281 (0.71)	1.94 (0.36, 10.53)	0.4404	1.96 (0.36, 10.78)	0.4400	0.01 (-0.01, 0.02)	0.4294	
	FIDELIO-DKD	5/ 195 (2.56)	1/ 241 (0.41)	6.18 (0.73, 52.45)	0.0951	6.32 (0.73, 54.52)	0.0938	0.02 (-0.00, 0.05)	0.0746	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders, PT: Depression	Study									0.0989
	FINEARTS-HF	39/ 2993 (1.30)	39/ 2993 (1.30)	1.00 (0.64, 1.55)	1.0000	1.00 (0.64, 1.56)	1.0000	-0.00 (-0.01, 0.01)	1.0000	
	FIGARO-DKD	1/ 289 (0.35)	7/ 281 (2.49)	0.14 (0.02, 1.12)	0.0640	0.14 (0.02, 1.11)	0.0627	-0.02 (-0.04, -0.00)	0.0306	
	FIDELIO-DKD	2/ 195 (1.03)	7/ 241 (2.90)	0.35 (0.07, 1.68)	0.1909	0.35 (0.07, 1.69)	0.1894	-0.02 (-0.04, 0.01)	0.1485	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders, PT: Insomnia	Study									0.6163
	FINEARTS-HF	83/ 2993 (2.77)	74/ 2993 (2.47)	1.12 (0.82, 1.53)	0.4669	1.13 (0.82, 1.55)	0.4669	0.00 (-0.01, 0.01)	0.4667	
	FIGARO-DKD	6/ 289 (2.08)	5/ 281 (1.78)	1.17 (0.36, 3.78)	0.7970	1.17 (0.35, 3.88)	0.7970	0.00 (-0.02, 0.03)	0.7966	
	FIDELIO-DKD	6/ 195 (3.08)	11/ 241 (4.56)	0.67 (0.25, 1.79)	0.4287	0.66 (0.24, 1.83)	0.4281	-0.01 (-0.05, 0.02)	0.4155	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Sex									0.3183
	Male	477/ 1945 (24.52)	402/ 1947 (20.65)	1.19 (1.06, 1.34)	0.0032	1.26 (1.08, 1.46)	0.0031	0.04 (0.01, 0.07)	0.0029	
	Female	286/ 1532 (18.67)	270/ 1568 (17.22)	1.08 (0.93, 1.26)	0.3051	1.11 (0.92, 1.33)	0.2851	0.02 (-0.01, 0.04)	0.2367	
	Region									0.1312
	Western Europe, Oceania and Others	222/ 688 (32.27)	168/ 716 (23.46)	1.38 (1.16, 1.63)	0.0003	1.56 (1.23, 1.98)	0.0002	0.09 (0.04, 0.14)	0.0002	
	Eastern Europe	222/ 1577 (14.08)	213/ 1567 (13.59)	1.04 (0.87, 1.24)	0.6773	1.04 (0.85, 1.28)	0.6917	0.00 (-0.02, 0.03)	0.7800	
	Asia	151/ 554 (27.26)	123/ 551 (22.32)	1.21 (0.98, 1.48)	0.0735	1.31 (1.00, 1.73)	0.0520	0.05 (0.00, 0.10)	0.0361	
	North America	97/ 317 (30.60)	89/ 317 (28.08)	1.10 (0.87, 1.40)	0.4159	1.15 (0.82, 1.63)	0.4166	0.03 (-0.04, 0.10)	0.4177	
	Latin America	71/ 341 (20.82)	79/ 364 (21.70)	0.98 (0.73, 1.30)	0.8637	0.97 (0.68, 1.40)	0.8877	-0.00 (-0.06, 0.06)	0.9302	
	Age group (years)									0.0506
	<= median in FAS	342/ 1825 (18.74)	330/ 1831 (18.02)	1.04 (0.91, 1.20)	0.5443	1.06 (0.89, 1.25)	0.5099	0.01 (-0.01, 0.04)	0.4198	
	> median in FAS	421/ 1652 (25.48)	342/ 1684 (20.31)	1.26 (1.11, 1.42)	0.0004	1.34 (1.14, 1.58)	0.0004	0.05 (0.02, 0.08)	0.0003	
	Study									0.0157
	FINEARTS-HF	662/ 2993 (22.12)	542/ 2993 (18.11)	1.22 (1.10, 1.35)	0.0001	1.28 (1.13, 1.46)	0.0001	0.04 (0.02, 0.06)	0.0001	
	FIGARO-DKD	54/ 289 (18.69)	65/ 281 (23.13)	0.81 (0.59, 1.11)	0.1929	0.76 (0.51, 1.15)	0.1923	-0.04 (-0.11, 0.02)	0.1914	
	FIDELIO-DKD	47/ 195 (24.10)	65/ 241 (26.97)	0.89 (0.65, 1.24)	0.4968	0.86 (0.56, 1.33)	0.4957	-0.03 (-0.11, 0.05)	0.4936	

Analysis based on all AE starting at beginning of treatment until end of study.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Sex									0.8517
	Male	115/ 1945 (5.91)	81/ 1947 (4.16)	1.45 (1.10, 1.91)	0.0084	1.50 (1.12, 2.01)	0.0069	0.02 (0.01, 0.03)	0.0013	
	Female	73/ 1532 (4.77)	54/ 1568 (3.44)	1.39 (0.98, 1.96)	0.0610	1.41 (0.98, 2.02)	0.0619	0.01 (-0.00, 0.03)	0.0826	
	Region									0.4798
	Western Europe, Oceania and Others	59/ 688 (8.58)	36/ 716 (5.03)	1.71 (1.15, 2.56)	0.0084	1.79 (1.16, 2.75)	0.0079	0.04 (0.01, 0.06)	0.0057	
	Eastern Europe	34/ 1577 (2.16)	21/ 1567 (1.34)	1.60 (0.93, 2.74)	0.0889	1.61 (0.93, 2.79)	0.0886	0.01 (-0.00, 0.02)	0.0851	
	Asia	25/ 554 (4.51)	26/ 551 (4.72)	0.95 (0.57, 1.61)	0.8561	0.97 (0.55, 1.73)	0.9213	0.00 (-0.02, 0.03)	0.6844	
	North America	58/ 317 (18.30)	41/ 317 (12.93)	1.42 (0.98, 2.04)	0.0610	1.53 (0.99, 2.38)	0.0561	0.05 (-0.00, 0.11)	0.0509	
	Latin America	12/ 341 (3.52)	11/ 364 (3.02)	1.17 (0.52, 2.64)	0.7027	1.18 (0.51, 2.73)	0.7027	0.01 (-0.02, 0.03)	0.7111	
	Age group (years)									0.5273
	<= median in FAS	77/ 1825 (4.22)	60/ 1831 (3.28)	1.31 (0.94, 1.82)	0.1078	1.34 (0.94, 1.89)	0.1015	0.01 (-0.00, 0.02)	0.0510	
	> median in FAS	111/ 1652 (6.72)	75/ 1684 (4.45)	1.51 (1.14, 2.00)	0.0045	1.56 (1.15, 2.11)	0.0041	0.02 (0.01, 0.04)	0.0029	
	Study									0.3356
	FINEARTS-HF	146/ 2993 (4.88)	93/ 2993 (3.11)	1.57 (1.22, 2.03)	0.0005	1.60 (1.23, 2.08)	0.0005	0.02 (0.01, 0.03)	0.0005	
	FIGARO-DKD	22/ 289 (7.61)	18/ 281 (6.41)	1.19 (0.65, 2.17)	0.5734	1.20 (0.63, 2.30)	0.5733	0.01 (-0.03, 0.05)	0.5723	
	FIDELIO-DKD	20/ 195 (10.26)	24/ 241 (9.96)	1.03 (0.59, 1.81)	0.9182	1.03 (0.55, 1.93)	0.9181	0.00 (-0.05, 0.06)	0.9183	

Analysis based on all AE starting at beginning of treatment until end of study.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Chronic kidney disease	Study									0.4968
	FINEARTS-HF	67/ 2993 (2.24)	66/ 2993 (2.21)	1.02 (0.73, 1.42)	0.9301	1.02 (0.72, 1.43)	0.9301	0.00 (-0.01, 0.01)	0.9301	
	FIGARO-DKD	4/ 289 (1.38)	4/ 281 (1.42)	0.97 (0.25, 3.85)	0.9681	0.97 (0.24, 3.92)	0.9681	-0.00 (-0.02, 0.02)	0.9681	
	FIDELIO-DKD	4/ 195 (2.05)	10/ 241 (4.15)	0.49 (0.16, 1.55)	0.2275	0.48 (0.15, 1.57)	0.2259	-0.02 (-0.05, 0.01)	0.2000	

Analysis based on all AE starting at beginning of treatment until end of study.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Haematuria	Study									0.4446
	FINEARTS-HF	37/ 2993 (1.24)	33/ 2993 (1.10)	1.12 (0.70, 1.79)	0.6308	1.12 (0.70, 1.80)	0.6308	0.00 (-0.00, 0.01)	0.6306	
	FIGARO-DKD	5/ 289 (1.73)	7/ 281 (2.49)	0.69 (0.22, 2.16)	0.5293	0.69 (0.22, 2.20)	0.5292	-0.01 (-0.03, 0.02)	0.5278	
	FIDELIO-DKD	0/ 195 (0.00)	4/ 241 (1.66)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Microalbuminuria	Study									NE
	FINEARTS-HF	39/ 2993 (1.30)	58/ 2993 (1.94)	0.67 (0.45, 1.01)	0.0534	0.67 (0.44, 1.01)	0.0533	-0.01 (-0.01, 0.00)	0.0517	
	FIGARO-DKD	0/ 289 (0.00)	0/ 281 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	0/ 195 (0.00)	0/ 241 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal cyst	Study									0.0392
	FINEARTS-HF	21/ 2993 (0.70)	40/ 2993 (1.34)	0.53 (0.31, 0.89)	0.0163	0.52 (0.31, 0.89)	0.0162	-0.01 (-0.01, -0.00)	0.0144	
	FIGARO-DKD	7/ 289 (2.42)	10/ 281 (3.56)	0.68 (0.26, 1.76)	0.4282	0.67 (0.25, 1.79)	0.4279	-0.01 (-0.04, 0.02)	0.4261	
	FIDELIO-DKD	8/ 195 (4.10)	3/ 241 (1.24)	3.30 (0.89, 12.26)	0.0751	3.39 (0.89, 12.97)	0.0740	0.03 (-0.00, 0.06)	0.0723	

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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal failure									
Sex									0.6466
Male	62/ 1945 (3.19)	38/ 1947 (1.95)	1.64 (1.10, 2.45)	0.0149	1.66 (1.10, 2.50)	0.0148	0.01 (0.00, 0.02)	0.0162	
Female	36/ 1532 (2.35)	26/ 1568 (1.66)	1.41 (0.86, 2.33)	0.1740	1.42 (0.86, 2.37)	0.1741	0.01 (-0.00, 0.02)	0.2083	
Region									0.2077
Western Europe, Oceania and Others	44/ 688 (6.40)	28/ 716 (3.91)	1.63 (1.03, 2.58)	0.0388	1.67 (1.03, 2.72)	0.0384	0.03 (0.00, 0.05)	0.0322	
Eastern Europe	19/ 1577 (1.20)	11/ 1567 (0.70)	1.74 (0.83, 3.65)	0.1406	1.75 (0.83, 3.70)	0.1403	0.01 (-0.02, 0.03)	0.6351	
Asia	29/ 554 (5.23)	13/ 551 (2.36)	2.22 (1.16, 4.22)	0.0154	2.28 (1.17, 4.44)	0.0149	0.03 (0.01, 0.05)	0.0092	
North America	3/ 317 (0.95)	6/ 317 (1.89)	0.51 (0.13, 2.03)	0.3408	0.51 (0.12, 2.05)	0.3388	-0.01 (-0.03, 0.01)	0.2554	
Latin America	3/ 341 (0.88)	6/ 364 (1.65)	0.56 (0.14, 2.23)	0.4089	0.56 (0.14, 2.27)	0.4144	-0.01 (-0.05, 0.04)	0.8022	
Age group (years)									0.2483
<= median in FAS	37/ 1825 (2.03)	30/ 1831 (1.64)	1.26 (0.78, 2.03)	0.3480	1.26 (0.78, 2.05)	0.3483	0.00 (-0.00, 0.01)	0.3931	
> median in FAS	61/ 1652 (3.69)	34/ 1684 (2.02)	1.82 (1.21, 2.76)	0.0044	1.86 (1.21, 2.84)	0.0044	0.02 (0.01, 0.03)	0.0050	
Study									0.4486
FINEARTS-HF	90/ 2993 (3.01)	54/ 2993 (1.80)	1.67 (1.19, 2.33)	0.0027	1.69 (1.20, 2.37)	0.0027	0.01 (0.00, 0.02)	0.0024	
FIGARO-DKD	4/ 289 (1.38)	4/ 281 (1.42)	0.97 (0.25, 3.85)	0.9681	0.97 (0.24, 3.92)	0.9681	-0.00 (-0.02, 0.02)	0.9681	
FIDELIO-DKD	4/ 195 (2.05)	6/ 241 (2.49)	0.82 (0.24, 2.88)	0.7616	0.82 (0.23, 2.95)	0.7615	-0.00 (-0.03, 0.02)	0.7588	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Renal impairment									
Sex									0.7760
Male	131/ 1945 (6.74)	79/ 1947 (4.06)	1.67 (1.28, 2.20)	0.0002	1.72 (1.29, 2.30)	0.0002	0.03 (0.01, 0.04)	0.0003	
Female	105/ 1532 (6.85)	68/ 1568 (4.34)	1.58 (1.17, 2.12)	0.0026	1.62 (1.18, 2.22)	0.0026	0.02 (0.01, 0.04)	0.0047	
Region									0.5301
Western Europe, Oceania and Others	85/ 688 (12.35)	63/ 716 (8.80)	1.40 (1.03, 1.90)	0.0326	1.45 (1.03, 2.05)	0.0334	0.03 (-0.00, 0.06)	0.0529	
Eastern Europe	57/ 1577 (3.61)	34/ 1567 (2.17)	1.66 (1.09, 2.52)	0.0175	1.69 (1.10, 2.59)	0.0176	0.01 (-0.00, 0.02)	0.0560	
Asia	49/ 554 (8.84)	23/ 551 (4.17)	2.10 (1.30, 3.40)	0.0025	2.21 (1.33, 3.69)	0.0023	0.05 (0.02, 0.08)	0.0015	
North America	21/ 317 (6.62)	9/ 317 (2.84)	2.43 (1.13, 5.22)	0.0227	2.53 (1.14, 5.63)	0.0228	0.03 (-0.00, 0.07)	0.0784	
Latin America	24/ 341 (7.04)	18/ 364 (4.95)	1.48 (0.81, 2.70)	0.2029	1.51 (0.80, 2.86)	0.2064	0.02 (-0.01, 0.06)	0.2447	
Age group (years)									0.5911
<= median in FAS	87/ 1825 (4.77)	58/ 1831 (3.17)	1.52 (1.10, 2.11)	0.0117	1.55 (1.10, 2.17)	0.0116	0.02 (0.00, 0.03)	0.0175	
> median in FAS	149/ 1652 (9.02)	89/ 1684 (5.29)	1.70 (1.32, 2.19)	<.0001	1.77 (1.35, 2.33)	<.0001	0.04 (0.02, 0.05)	<.0001	
Study									0.5625
FINEARTS-HF	216/ 2993 (7.22)	128/ 2993 (4.28)	1.69 (1.36, 2.09)	<.0001	1.74 (1.39, 2.18)	<.0001	0.03 (0.02, 0.04)	<.0001	
FIGARO-DKD	8/ 289 (2.77)	7/ 281 (2.49)	1.11 (0.41, 3.02)	0.8364	1.11 (0.40, 3.12)	0.8364	0.00 (-0.02, 0.03)	0.8362	
FIDELIO-DKD	12/ 195 (6.15)	12/ 241 (4.98)	1.24 (0.57, 2.69)	0.5934	1.25 (0.55, 2.85)	0.5935	0.01 (-0.03, 0.06)	0.5966	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Reproductive system and breast disorders	Study									0.8622
	FINEARTS-HF	99/ 2993 (3.31)	97/ 2993 (3.24)	1.02 (0.77, 1.34)	0.8845	1.02 (0.77, 1.36)	0.8845	0.00 (-0.01, 0.01)	0.8845	
	FIGARO-DKD	15/ 289 (5.19)	16/ 281 (5.69)	0.91 (0.46, 1.81)	0.7910	0.91 (0.44, 1.87)	0.7910	-0.01 (-0.04, 0.03)	0.7911	
	FIDELIO-DKD	10/ 195 (5.13)	10/ 241 (4.15)	1.24 (0.53, 2.91)	0.6277	1.25 (0.51, 3.06)	0.6277	0.01 (-0.03, 0.05)	0.6307	

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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Reproductive system and breast disorders, PT: Benign prostatic hyperplasia	Sex									NE
	Male	58/ 1945 (2.98)	39/ 1947 (2.00)	1.48 (0.99, 2.21)	0.0560	1.49 (0.99, 2.25)	0.0557	0.01 (-0.00, 0.02)	0.0554	
	Female	0/ 1532 (0.00)	0/ 1568 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	Region									0.4695
	Western Europe, Oceania and Others	6/ 688 (0.87)	5/ 716 (0.70)	1.29 (0.40, 4.17)	0.6702	1.30 (0.39, 4.33)	0.6683	0.00 (-0.03, 0.04)	0.9008	
	Eastern Europe	23/ 1577 (1.46)	15/ 1567 (0.96)	1.54 (0.80, 2.93)	0.1937	1.54 (0.80, 2.97)	0.1966	0.00 (-0.00, 0.01)	0.4270	
	Asia	21/ 554 (3.79)	10/ 551 (1.81)	2.11 (1.00, 4.43)	0.0497	2.15 (1.00, 4.61)	0.0491	0.02 (0.00, 0.04)	0.0356	
	North America	2/ 317 (0.63)	5/ 317 (1.58)	0.38 (0.07, 1.96)	0.2492	0.38 (0.07, 1.97)	0.2471	-0.01 (-0.03, 0.01)	0.2171	
	Latin America	6/ 341 (1.76)	4/ 364 (1.10)	1.58 (0.45, 5.58)	0.4761	1.60 (0.44, 5.75)	0.4736	0.01 (-0.04, 0.05)	0.7664	
	Age group (years)									0.8696
	<= median in FAS	37/ 1825 (2.03)	24/ 1831 (1.31)	1.54 (0.93, 2.57)	0.0967	1.55 (0.92, 2.60)	0.0970	0.01 (-0.00, 0.01)	0.1205	
	> median in FAS	21/ 1652 (1.27)	15/ 1684 (0.89)	1.44 (0.74, 2.78)	0.2808	1.45 (0.74, 2.82)	0.2763	0.01 (-0.00, 0.01)	0.1618	
	Study									0.9662
	FINEARTS-HF	46/ 2993 (1.54)	30/ 2993 (1.00)	1.53 (0.97, 2.42)	0.0669	1.54 (0.97, 2.45)	0.0668	0.01 (-0.00, 0.01)	0.0647	
	FIGARO-DKD	9/ 289 (3.11)	6/ 281 (2.14)	1.46 (0.53, 4.04)	0.4683	1.47 (0.52, 4.19)	0.4681	0.01 (-0.02, 0.04)	0.4641	
	FIDELIO-DKD	3/ 195 (1.54)	3/ 241 (1.24)	1.24 (0.25, 6.06)	0.7939	1.24 (0.25, 6.21)	0.7939	0.00 (-0.02, 0.03)	0.7957	

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Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders	Study									0.4734
	FINEARTS-HF	590/ 2993 (19.71)	577/ 2993 (19.28)	1.02 (0.92, 1.13)	0.6715	1.03 (0.90, 1.17)	0.6715	0.00 (-0.02, 0.02)	0.6715	
	FIGARO-DKD	64/ 289 (22.15)	68/ 281 (24.20)	0.92 (0.68, 1.23)	0.5613	0.89 (0.60, 1.32)	0.5612	-0.02 (-0.09, 0.05)	0.5612	
	FIDELIO-DKD	46/ 195 (23.59)	67/ 241 (27.80)	0.85 (0.61, 1.17)	0.3209	0.80 (0.52, 1.24)	0.3188	-0.04 (-0.12, 0.04)	0.3151	

Analysis based on all AE starting at beginning of treatment until end of study.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Chronic obstructive pulmonary disease	Study									0.8362
	FINEARTS-HF	76/ 2993 (2.54)	73/ 2993 (2.44)	1.04 (0.76, 1.43)	0.8035	1.04 (0.75, 1.44)	0.8035	0.00 (-0.01, 0.01)	0.8034	
	FIGARO-DKD	11/ 289 (3.81)	10/ 281 (3.56)	1.07 (0.46, 2.48)	0.8754	1.07 (0.45, 2.57)	0.8754	0.00 (-0.03, 0.03)	0.8753	
	FIDELIO-DKD	13/ 195 (6.67)	12/ 241 (4.98)	1.34 (0.63, 2.87)	0.4526	1.36 (0.61, 3.06)	0.4526	0.02 (-0.03, 0.06)	0.4573	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Study									0.4996
	FINEARTS-HF	93/ 2993 (3.11)	90/ 2993 (3.01)	1.03 (0.78, 1.37)	0.8218	1.03 (0.77, 1.39)	0.8218	0.00 (-0.01, 0.01)	0.8218	
	FIGARO-DKD	12/ 289 (4.15)	11/ 281 (3.91)	1.06 (0.48, 2.36)	0.8854	1.06 (0.46, 2.45)	0.8854	0.00 (-0.03, 0.03)	0.8853	
	FIDELIO-DKD	3/ 195 (1.54)	8/ 241 (3.32)	0.46 (0.12, 1.72)	0.2511	0.46 (0.12, 1.74)	0.2497	-0.02 (-0.05, 0.01)	0.2200	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Study									0.7115
	FINEARTS-HF	160/ 2993 (5.35)	148/ 2993 (4.94)	1.08 (0.87, 1.34)	0.4828	1.09 (0.86, 1.37)	0.4827	0.00 (-0.01, 0.02)	0.4826	
	FIGARO-DKD	13/ 289 (4.50)	16/ 281 (5.69)	0.79 (0.39, 1.61)	0.5171	0.78 (0.37, 1.65)	0.5170	-0.01 (-0.05, 0.02)	0.5165	
	FIDELIO-DKD	16/ 195 (8.21)	19/ 241 (7.88)	1.04 (0.55, 1.97)	0.9023	1.04 (0.52, 2.09)	0.9023	0.00 (-0.05, 0.05)	0.9025	

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis	Sex									0.5794
	Male	34/ 1945 (1.75)	47/ 1947 (2.41)	0.72 (0.47, 1.12)	0.1429	0.72 (0.46, 1.12)	0.1426	-0.01 (-0.02, 0.00)	0.1275	
	Female	16/ 1532 (1.04)	28/ 1568 (1.79)	0.58 (0.32, 1.07)	0.0834	0.58 (0.31, 1.07)	0.0831	-0.01 (-0.02, 0.00)	0.0832	
	Region									0.4377
	Western Europe, Oceania and Others	13/ 688 (1.89)	28/ 716 (3.91)	0.49 (0.26, 0.94)	0.0316	0.48 (0.25, 0.93)	0.0307	-0.02 (-0.04, -0.00)	0.0210	
	Eastern Europe	15/ 1577 (0.95)	26/ 1567 (1.66)	0.57 (0.30, 1.07)	0.0791	0.56 (0.30, 1.07)	0.0791	-0.01 (-0.03, 0.01)	0.5200	
	Asia	11/ 554 (1.99)	11/ 551 (2.00)	0.99 (0.43, 2.26)	0.9745	0.99 (0.42, 2.29)	0.9732	-0.00 (-0.04, 0.04)	0.9787	
	North America	7/ 317 (2.21)	8/ 317 (2.52)	0.84 (0.31, 2.30)	0.7415	0.84 (0.30, 2.36)	0.7430	-0.01 (-0.03, 0.02)	0.6505	
	Latin America	4/ 341 (1.17)	2/ 364 (0.55)	1.98 (0.37, 10.74)	0.4279	1.99 (0.36, 10.96)	0.4275	0.01 (-0.04, 0.06)	0.8020	
	Age group (years)									0.7250
	<= median in FAS	18/ 1825 (0.99)	29/ 1831 (1.58)	0.62 (0.35, 1.11)	0.1097	0.62 (0.34, 1.11)	0.1088	-0.01 (-0.02, 0.00)	0.0659	
	> median in FAS	32/ 1652 (1.94)	46/ 1684 (2.73)	0.71 (0.45, 1.11)	0.1292	0.70 (0.44, 1.11)	0.1287	-0.01 (-0.02, 0.00)	0.1067	
	Study									0.5527
	FINEARTS-HF	44/ 2993 (1.47)	65/ 2993 (2.17)	0.68 (0.46, 0.99)	0.0437	0.67 (0.46, 0.99)	0.0437	-0.01 (-0.01, -0.00)	0.0423	
	FIGARO-DKD	5/ 289 (1.73)	5/ 281 (1.78)	0.97 (0.28, 3.32)	0.9643	0.97 (0.28, 3.39)	0.9643	-0.00 (-0.02, 0.02)	0.9643	
	FIDELIO-DKD	1/ 195 (0.51)	5/ 241 (2.07)	0.25 (0.03, 2.10)	0.2003	0.24 (0.03, 2.10)	0.1987	-0.02 (-0.04, 0.00)	0.1373	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pleural effusion	Study									0.2908
	FINEARTS-HF	34/ 2993 (1.14)	33/ 2993 (1.10)	1.03 (0.64, 1.66)	0.9022	1.03 (0.64, 1.67)	0.9022	0.00 (-0.00, 0.01)	0.9022	
	FIGARO-DKD	5/ 289 (1.73)	2/ 281 (0.71)	2.43 (0.48, 12.43)	0.2860	2.46 (0.47, 12.76)	0.2853	0.01 (-0.01, 0.03)	0.2665	
	FIDELIO-DKD	3/ 195 (1.54)	8/ 241 (3.32)	0.46 (0.12, 1.72)	0.2511	0.46 (0.12, 1.74)	0.2497	-0.02 (-0.05, 0.01)	0.2200	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Respiratory failure	Sex									0.1599
	Male	21/ 1945 (1.08)	17/ 1947 (0.87)	1.28 (0.68, 2.42)	0.4445	1.28 (0.67, 2.44)	0.4491	0.00 (-0.00, 0.01)	0.6312	
	Female	21/ 1532 (1.37)	8/ 1568 (0.51)	2.69 (1.19, 6.05)	0.0170	2.71 (1.20, 6.14)	0.0168	0.01 (0.00, 0.02)	0.0269	
	Region									0.2740
	Western Europe, Oceania and Others	24/ 688 (3.49)	9/ 716 (1.26)	2.85 (1.33, 6.07)	0.0068	2.92 (1.35, 6.35)	0.0067	0.02 (0.00, 0.04)	0.0102	
	Eastern Europe	3/ 1577 (0.19)	6/ 1567 (0.38)	0.51 (0.13, 2.06)	0.3476	0.51 (0.13, 2.06)	0.3464	-0.00 (-0.01, 0.00)	0.2844	
	Asia	7/ 554 (1.26)	5/ 551 (0.91)	1.37 (0.44, 4.30)	0.5865	1.38 (0.43, 4.37)	0.5857	0.00 (-0.03, 0.04)	0.8467	
	North America	5/ 317 (1.58)	4/ 317 (1.26)	1.33 (0.36, 4.90)	0.6711	1.33 (0.35, 5.01)	0.6757	0.00 (-0.05, 0.06)	0.9049	
	Latin America	3/ 341 (0.88)	1/ 364 (0.27)	2.97 (0.31, 28.42)	0.3444	2.99 (0.31, 28.90)	0.3439	0.01 (-0.05, 0.06)	0.7882	
	Age group (years)									0.1098
	<= median in FAS	9/ 1825 (0.49)	10/ 1831 (0.55)	0.93 (0.38, 2.29)	0.8797	0.93 (0.38, 2.30)	0.8783	-0.00 (-0.01, 0.00)	0.7106	
	> median in FAS	33/ 1652 (2.00)	15/ 1684 (0.89)	2.26 (1.23, 4.14)	0.0084	2.28 (1.23, 4.22)	0.0086	0.01 (0.00, 0.02)	0.0160	
	Study									0.2847
	FINEARTS-HF	33/ 2993 (1.10)	20/ 2993 (0.67)	1.65 (0.95, 2.87)	0.0760	1.66 (0.95, 2.89)	0.0759	0.00 (-0.00, 0.01)	0.0728	
	FIGARO-DKD	2/ 289 (0.69)	3/ 281 (1.07)	0.65 (0.11, 3.85)	0.6334	0.65 (0.11, 3.89)	0.6333	-0.00 (-0.02, 0.01)	0.6316	
	FIDELIO-DKD	7/ 195 (3.59)	2/ 241 (0.83)	4.33 (0.91, 20.59)	0.0658	4.45 (0.91, 21.67)	0.0646	0.03 (-0.00, 0.06)	0.0578	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders	Study									0.7847
	FINEARTS-HF	296/ 2993 (9.89)	277/ 2993 (9.25)	1.07 (0.91, 1.25)	0.4040	1.08 (0.91, 1.28)	0.4040	0.01 (-0.01, 0.02)	0.4039	
	FIGARO-DKD	46/ 289 (15.92)	39/ 281 (13.88)	1.15 (0.77, 1.70)	0.4953	1.17 (0.74, 1.86)	0.4950	0.02 (-0.04, 0.08)	0.4942	
	FIDELIO-DKD	36/ 195 (18.46)	47/ 241 (19.50)	0.95 (0.64, 1.40)	0.7834	0.93 (0.58, 1.51)	0.7832	-0.01 (-0.08, 0.06)	0.7827	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Study									0.7879
	FINEARTS-HF	41/ 2993 (1.37)	45/ 2993 (1.50)	0.91 (0.60, 1.39)	0.6641	0.91 (0.59, 1.39)	0.6641	-0.00 (-0.01, 0.00)	0.6639	
	FIGARO-DKD	6/ 289 (2.08)	5/ 281 (1.78)	1.17 (0.36, 3.78)	0.7970	1.17 (0.35, 3.88)	0.7970	0.00 (-0.02, 0.03)	0.7966	
	FIDELIO-DKD	3/ 195 (1.54)	6/ 241 (2.49)	0.62 (0.16, 2.44)	0.4920	0.61 (0.15, 2.48)	0.4915	-0.01 (-0.04, 0.02)	0.4764	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders, PT: Rash	Study									0.6327
	FINEARTS-HF	40/ 2993 (1.34)	31/ 2993 (1.04)	1.29 (0.81, 2.06)	0.2839	1.29 (0.81, 2.07)	0.2839	0.00 (-0.00, 0.01)	0.2826	
	FIGARO-DKD	3/ 289 (1.04)	0/ 281 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	2/ 195 (1.03)	3/ 241 (1.24)	0.82 (0.14, 4.88)	0.8311	0.82 (0.14, 4.97)	0.8310	-0.00 (-0.02, 0.02)	0.8291	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders, PT: Skin ulcer	Study									0.2574
	FINEARTS-HF	38/ 2993 (1.27)	41/ 2993 (1.37)	0.93 (0.60, 1.44)	0.7341	0.93 (0.59, 1.44)	0.7341	-0.00 (-0.01, 0.00)	0.7340	
	FIGARO-DKD	15/ 289 (5.19)	8/ 281 (2.85)	1.82 (0.79, 4.23)	0.1622	1.87 (0.78, 4.48)	0.1612	0.02 (-0.01, 0.06)	0.1528	
	FIDELIO-DKD	8/ 195 (4.10)	14/ 241 (5.81)	0.71 (0.30, 1.65)	0.4214	0.69 (0.28, 1.69)	0.4206	-0.02 (-0.06, 0.02)	0.4099	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Surgical and medical procedures	Study									0.1827
	FINEARTS-HF	151/ 2993 (5.05)	120/ 2993 (4.01)	1.26 (1.00, 1.59)	0.0546	1.27 (1.00, 1.63)	0.0545	0.01 (-0.00, 0.02)	0.0539	
	FIGARO-DKD	21/ 289 (7.27)	18/ 281 (6.41)	1.13 (0.62, 2.08)	0.6843	1.14 (0.60, 2.20)	0.6842	0.01 (-0.03, 0.05)	0.6838	
	FIDELIO-DKD	12/ 195 (6.15)	23/ 241 (9.54)	0.64 (0.33, 1.26)	0.2006	0.62 (0.30, 1.28)	0.1986	-0.03 (-0.08, 0.02)	0.1851	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	Study									0.3994
	FINEARTS-HF	556/ 2993 (18.58)	521/ 2993 (17.41)	1.07 (0.96, 1.19)	0.2391	1.08 (0.95, 1.24)	0.2390	0.01 (-0.01, 0.03)	0.2389	
	FIGARO-DKD	66/ 289 (22.84)	74/ 281 (26.33)	0.87 (0.65, 1.16)	0.3328	0.83 (0.57, 1.21)	0.3325	-0.03 (-0.11, 0.04)	0.3321	
	FIDELIO-DKD	52/ 195 (26.67)	65/ 241 (26.97)	0.99 (0.72, 1.35)	0.9432	0.98 (0.64, 1.51)	0.9432	-0.00 (-0.09, 0.08)	0.9431	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypertension	Sex									0.0358
	Male	95/ 1945 (4.88)	113/ 1947 (5.80)	0.86 (0.66, 1.12)	0.2606	0.85 (0.64, 1.12)	0.2468	-0.01 (-0.02, 0.00)	0.1463	
	Female	74/ 1532 (4.83)	133/ 1568 (8.48)	0.57 (0.43, 0.75)	<.0001	0.55 (0.41, 0.74)	<.0001	-0.03 (-0.05, -0.02)	0.0001	
	Region									0.4801
	Western Europe, Oceania and Others	36/ 688 (5.23)	46/ 716 (6.42)	0.83 (0.54, 1.27)	0.3873	0.82 (0.52, 1.29)	0.3848	-0.01 (-0.03, 0.01)	0.3847	
	Eastern Europe	75/ 1577 (4.76)	114/ 1567 (7.28)	0.65 (0.49, 0.86)	0.0028	0.63 (0.47, 0.85)	0.0027	-0.03 (-0.04, -0.01)	0.0027	
	Asia	21/ 554 (3.79)	27/ 551 (4.90)	0.78 (0.45, 1.35)	0.3759	0.76 (0.42, 1.36)	0.3560	-0.01 (-0.04, 0.01)	0.2726	
	North America	19/ 317 (5.99)	20/ 317 (6.31)	0.95 (0.52, 1.75)	0.8784	0.95 (0.49, 1.82)	0.8705	-0.00 (-0.04, 0.03)	0.7909	
	Latin America	18/ 341 (5.28)	39/ 364 (10.71)	0.50 (0.29, 0.86)	0.0126	0.47 (0.26, 0.85)	0.0120	-0.05 (-0.09, -0.01)	0.0107	
	Age group (years)									0.4150
	<= median in FAS	97/ 1825 (5.32)	131/ 1831 (7.15)	0.75 (0.58, 0.97)	0.0273	0.73 (0.56, 0.96)	0.0259	-0.02 (-0.03, -0.00)	0.0165	
	> median in FAS	72/ 1652 (4.36)	115/ 1684 (6.83)	0.64 (0.48, 0.85)	0.0023	0.62 (0.46, 0.85)	0.0023	-0.02 (-0.04, -0.01)	0.0044	
	Study									0.7574
	FINEARTS-HF	129/ 2993 (4.31)	190/ 2993 (6.35)	0.68 (0.55, 0.84)	0.0005	0.66 (0.53, 0.84)	0.0005	-0.02 (-0.03, -0.01)	0.0004	
	FIGARO-DKD	22/ 289 (7.61)	30/ 281 (10.68)	0.71 (0.42, 1.21)	0.2068	0.69 (0.39, 1.23)	0.2061	-0.03 (-0.08, 0.02)	0.2044	
	FIDELIO-DKD	18/ 195 (9.23)	26/ 241 (10.79)	0.86 (0.48, 1.51)	0.5922	0.84 (0.45, 1.58)	0.5917	-0.02 (-0.07, 0.04)	0.5885	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypotension	Sex									0.8178
	Male	149/ 1945 (7.66)	101/ 1947 (5.19)	1.48 (1.16, 1.89)	0.0017	1.52 (1.17, 1.97)	0.0016	0.02 (0.01, 0.04)	0.0016	
	Female	121/ 1532 (7.90)	80/ 1568 (5.10)	1.55 (1.18, 2.03)	0.0018	1.59 (1.19, 2.13)	0.0018	0.03 (0.01, 0.04)	0.0020	
	Region									0.5060
	Western Europe, Oceania and Others	76/ 688 (11.05)	66/ 716 (9.22)	1.19 (0.87, 1.63)	0.2689	1.22 (0.86, 1.73)	0.2658	0.02 (-0.01, 0.05)	0.2355	
	Eastern Europe	77/ 1577 (4.88)	46/ 1567 (2.94)	1.67 (1.17, 2.39)	0.0049	1.70 (1.17, 2.47)	0.0050	0.02 (0.00, 0.03)	0.0250	
	Asia	55/ 554 (9.93)	31/ 551 (5.63)	1.78 (1.17, 2.72)	0.0075	1.87 (1.18, 2.96)	0.0072	0.04 (0.01, 0.07)	0.0061	
	North America	42/ 317 (13.25)	26/ 317 (8.20)	1.63 (1.03, 2.60)	0.0382	1.72 (1.03, 2.90)	0.0393	0.05 (-0.00, 0.10)	0.0506	
	Latin America	20/ 341 (5.87)	12/ 364 (3.30)	1.72 (0.85, 3.47)	0.1296	1.77 (0.85, 3.68)	0.1289	0.02 (-0.02, 0.07)	0.3178	
	Age group (years)									0.2745
	<= median in FAS	108/ 1825 (5.92)	63/ 1831 (3.44)	1.72 (1.27, 2.34)	0.0004	1.77 (1.29, 2.43)	0.0004	0.03 (0.01, 0.04)	0.0003	
	> median in FAS	162/ 1652 (9.81)	118/ 1684 (7.01)	1.40 (1.11, 1.75)	0.0041	1.44 (1.12, 1.84)	0.0039	0.03 (0.01, 0.05)	0.0023	
	Study									0.7441
	FINEARTS-HF	236/ 2993 (7.89)	158/ 2993 (5.28)	1.49 (1.23, 1.82)	<.0001	1.54 (1.25, 1.89)	<.0001	0.03 (0.01, 0.04)	<.0001	
	FIGARO-DKD	18/ 289 (6.23)	13/ 281 (4.63)	1.35 (0.67, 2.70)	0.4012	1.37 (0.66, 2.85)	0.4008	0.02 (-0.02, 0.05)	0.3979	
	FIDELIO-DKD	16/ 195 (8.21)	10/ 241 (4.15)	1.98 (0.92, 4.26)	0.0815	2.06 (0.92, 4.66)	0.0808	0.04 (-0.01, 0.09)	0.0841	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Orthostatic hypotension	Study									0.3594
	FINEARTS-HF	29/ 2993 (0.97)	21/ 2993 (0.70)	1.38 (0.79, 2.42)	0.2580	1.38 (0.79, 2.43)	0.2580	0.00 (-0.00, 0.01)	0.2559	
	FIGARO-DKD	2/ 289 (0.69)	0/ 281 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	5/ 195 (2.56)	2/ 241 (0.83)	3.09 (0.61, 15.75)	0.1747	3.14 (0.60, 16.39)	0.1738	0.02 (-0.01, 0.04)	0.1734	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Peripheral arterial occlusive disease	Study									0.2069
	FINEARTS-HF	36/ 2993 (1.20)	30/ 2993 (1.00)	1.20 (0.74, 1.94)	0.4583	1.20 (0.74, 1.96)	0.4583	0.00 (-0.00, 0.01)	0.4577	
	FIGARO-DKD	8/ 289 (2.77)	10/ 281 (3.56)	0.78 (0.31, 1.94)	0.5905	0.77 (0.30, 1.98)	0.5904	-0.01 (-0.04, 0.02)	0.5900	
	FIDELIO-DKD	3/ 195 (1.54)	10/ 241 (4.15)	0.37 (0.10, 1.33)	0.1276	0.36 (0.10, 1.33)	0.1257	-0.03 (-0.06, 0.00)	0.0938	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	76/ 3477 (2.19)	79/ 3515 (2.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.71, 1.34)	
	p-value	0.8695	
	Risk Ratio (95% CI)	0.97 (0.71, 1.33)	
	p-value	0.8692	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.8811	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	50/ 3477 (1.44)	50/ 3515 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.68, 1.49)	
	p-value	0.9762	
	Risk Ratio (95% CI)	1.01 (0.68, 1.48)	
	p-value	0.9763	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.9630	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	378/ 3477 (10.87)	361/ 3515 (10.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.06 (0.91, 1.23)	
	p-value	0.4757	
	Risk Ratio (95% CI)	1.05 (0.92, 1.20)	
	p-value	0.4678	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.7044	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	44/ 3477 (1.27)	40/ 3515 (1.14)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.10 (0.72, 1.70)	
	p-value	0.6521	
	Risk Ratio (95% CI)	1.10 (0.72, 1.69)	
	p-value	0.6512	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.8959	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Atrial fibrillation	Number of subjects with event, n/N (%)	97/ 3477 (2.79)	81/ 3515 (2.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.20 (0.89, 1.62)	
	p-value	0.2245	
	Risk Ratio (95% CI)	1.20 (0.90, 1.60)	
	p-value	0.2253	
	Risk Difference (95% CI)	0.00 (-0.01, 0.02)	
	p-value	0.5326	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	48/ 3477 (1.38)	41/ 3515 (1.17)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.18 (0.78, 1.80)	
	p-value	0.4332	
	Risk Ratio (95% CI)	1.18 (0.78, 1.79)	
	p-value	0.4323	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5329	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	214/ 3477 (6.15)	171/ 3515 (4.86)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.28 (1.04, 1.58)	
	p-value	0.0185	
	Risk Ratio (95% CI)	1.26 (1.04, 1.54)	
	p-value	0.0186	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0188	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	202/ 3477 (5.81)	231/ 3515 (6.57)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.88 (0.72, 1.06)	
	p-value	0.1843	
	Risk Ratio (95% CI)	0.88 (0.74, 1.06)	
	p-value	0.1845	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1827	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	74/ 3477 (2.13)	104/ 3515 (2.96)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.71 (0.52, 0.96)	
	p-value	0.0248	
	Risk Ratio (95% CI)	0.71 (0.53, 0.96)	
	p-value	0.0249	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0247	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	47/ 3477 (1.35)	56/ 3515 (1.59)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.84 (0.57, 1.25)	
	p-value	0.3906	
	Risk Ratio (95% CI)	0.85 (0.58, 1.24)	
	p-value	0.3925	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3149	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	571/ 3477 (16.42)	572/ 3515 (16.27)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.89, 1.15)	
	p-value	0.8380	
	Risk Ratio (95% CI)	1.01 (0.91, 1.12)	
	p-value	0.8393	
	Risk Difference (95% CI)	0.00 (-0.02, 0.02)	
	p-value	0.8336	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	87/ 3477 (2.50)	86/ 3515 (2.45)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.75, 1.37)	
	p-value	0.9437	
	Risk Ratio (95% CI)	1.01 (0.75, 1.36)	
	p-value	0.9414	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.9896	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	39/ 3477 (1.12)	38/ 3515 (1.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.06 (0.67, 1.66)	
	p-value	0.8047	
	Risk Ratio (95% CI)	1.06 (0.68, 1.65)	
	p-value	0.8025	
	Risk Difference (95% CI)	0.00 (-0.00, 0.00)	
	p-value	0.9255	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	163/ 3477 (4.69)	185/ 3515 (5.26)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.72, 1.11)	
	p-value	0.3119	
	Risk Ratio (95% CI)	0.90 (0.73, 1.10)	
	p-value	0.3007	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.4509	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	52/ 3477 (1.50)	33/ 3515 (0.94)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.61 (1.04, 2.50)	
	p-value	0.0328	
	Risk Ratio (95% CI)	1.60 (1.04, 2.47)	
	p-value	0.0329	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0258	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	47/ 3477 (1.35)	49/ 3515 (1.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.97 (0.65, 1.45)	
	p-value	0.8803	
	Risk Ratio (95% CI)	0.97 (0.65, 1.44)	
	p-value	0.8807	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.8474	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	176/ 3477 (5.06)	193/ 3515 (5.49)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.92 (0.75, 1.13)	
	p-value	0.4329	
	Risk Ratio (95% CI)	0.92 (0.76, 1.13)	
	p-value	0.4354	
	Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
	p-value	0.3843	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	132/ 3477 (3.80)	119/ 3515 (3.39)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.16 (0.90, 1.49)	
	p-value	0.2633	
	Risk Ratio (95% CI)	1.14 (0.90, 1.45)	
	p-value	0.2879	
	Risk Difference (95% CI)	0.01 (-0.00, 0.01)	
	p-value	0.1425	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	78/ 3477 (2.24)	92/ 3515 (2.62)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.85 (0.63, 1.16)	
	p-value	0.3008	
	Risk Ratio (95% CI)	0.85 (0.63, 1.15)	
	p-value	0.3007	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3040	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	133/ 3477 (3.83)	152/ 3515 (4.32)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.88 (0.70, 1.12)	
	p-value	0.3006	
	Risk Ratio (95% CI)	0.89 (0.71, 1.11)	
	p-value	0.2992	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3563	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	135/ 3477 (3.88)	142/ 3515 (4.04)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.96 (0.76, 1.23)	
	p-value	0.7646	
	Risk Ratio (95% CI)	0.97 (0.77, 1.22)	
	p-value	0.7644	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.7677	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Syncope	Number of subjects with event, n/N (%)	37/ 3477 (1.06)	36/ 3515 (1.02)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.04 (0.66, 1.66)	
	p-value	0.8540	
	Risk Ratio (95% CI)	1.04 (0.66, 1.65)	
	p-value	0.8531	
	Risk Difference (95% CI)	0.00 (-0.00, 0.00)	
	p-value	0.9312	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	169/ 3477 (4.86)	138/ 3515 (3.93)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.27 (1.01, 1.60)	
	p-value	0.0443	
	Risk Ratio (95% CI)	1.25 (1.00, 1.55)	
	p-value	0.0501	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0085	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	94/ 3477 (2.70)	67/ 3515 (1.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.44 (1.05, 1.98)	
	p-value	0.0231	
	Risk Ratio (95% CI)	1.43 (1.05, 1.95)	
	p-value	0.0243	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0057	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	206/ 3477 (5.92)	196/ 3515 (5.58)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.07 (0.87, 1.31)	
	p-value	0.5202	
	Risk Ratio (95% CI)	1.06 (0.88, 1.29)	
	p-value	0.5200	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.5241	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	37/ 3477 (1.06)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.87 (0.56, 1.35)	
	p-value	0.5347	
	Risk Ratio (95% CI)	0.87 (0.56, 1.35)	
	p-value	0.5352	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.4970	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	87/ 3477 (2.50)	79/ 3515 (2.25)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.13 (0.83, 1.53)	
	p-value	0.4470	
	Risk Ratio (95% CI)	1.12 (0.83, 1.52)	
	p-value	0.4486	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4303	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	118/ 3477 (3.39)	122/ 3515 (3.47)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.98 (0.75, 1.26)	
	p-value	0.8509	
	Risk Ratio (95% CI)	0.98 (0.76, 1.25)	
	p-value	0.8454	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9773	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Study									0.8393
	FINEARTS-HF	65/ 2993 (2.17)	66/ 2993 (2.21)	0.98 (0.70, 1.38)	0.9296	0.98 (0.70, 1.39)	0.9296	-0.00 (-0.01, 0.01)	0.9296	
	FIGARO-DKD	7/ 289 (2.42)	6/ 281 (2.14)	1.13 (0.39, 3.33)	0.8187	1.14 (0.38, 3.43)	0.8187	0.00 (-0.02, 0.03)	0.8184	
	FIDELIO-DKD	4/ 195 (2.05)	7/ 241 (2.90)	0.71 (0.21, 2.38)	0.5744	0.70 (0.20, 2.43)	0.5742	-0.01 (-0.04, 0.02)	0.5652	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Anaemia	Study									0.9315
	FINEARTS-HF	43/ 2993 (1.44)	44/ 2993 (1.47)	0.98 (0.64, 1.48)	0.9140	0.98 (0.64, 1.49)	0.9140	-0.00 (-0.01, 0.01)	0.9140	
	FIGARO-DKD	5/ 289 (1.73)	4/ 281 (1.42)	1.22 (0.33, 4.48)	0.7695	1.22 (0.32, 4.59)	0.7694	0.00 (-0.02, 0.02)	0.7688	
	FIDELIO-DKD	2/ 195 (1.03)	2/ 241 (0.83)	1.24 (0.18, 8.69)	0.8315	1.24 (0.17, 8.87)	0.8315	0.00 (-0.02, 0.02)	0.8330	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders	Study									0.3018
	FINEARTS-HF	361/ 2993 (12.06)	340/ 2993 (11.36)	1.06 (0.92, 1.22)	0.3987	1.07 (0.91, 1.25)	0.3987	0.01 (-0.01, 0.02)	0.3986	
	FIGARO-DKD	13/ 289 (4.50)	10/ 281 (3.56)	1.26 (0.56, 2.84)	0.5698	1.28 (0.55, 2.96)	0.5696	0.01 (-0.02, 0.04)	0.5680	
	FIDELIO-DKD	4/ 195 (2.05)	11/ 241 (4.56)	0.45 (0.15, 1.39)	0.1649	0.44 (0.14, 1.40)	0.1631	-0.03 (-0.06, 0.01)	0.1358	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Angina unstable	Study									NE
	FINEARTS-HF	44/ 2993 (1.47)	39/ 2993 (1.30)	1.13 (0.74, 1.73)	0.5807	1.13 (0.73, 1.74)	0.5807	0.00 (-0.00, 0.01)	0.5805	
	FIGARO-DKD	0/ 289 (0.00)	0/ 281 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	0/ 195 (0.00)	1/ 241 (0.41)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Atrial fibrillation	Study									NE
	FINEARTS-HF	96/ 2993 (3.21)	81/ 2993 (2.71)	1.19 (0.89, 1.59)	0.2530	1.19 (0.88, 1.61)	0.2530	0.01 (-0.00, 0.01)	0.2524	
	FIGARO-DKD	1/ 289 (0.35)	0/ 281 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	
	FIDELIO-DKD	0/ 195 (0.00)	0/ 241 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders, PT: Cardiac failure	Study									0.4927
	FINEARTS-HF	45/ 2993 (1.50)	35/ 2993 (1.17)	1.29 (0.83, 1.99)	0.2616	1.29 (0.83, 2.01)	0.2616	0.00 (-0.00, 0.01)	0.2603	
	FIGARO-DKD	2/ 289 (0.69)	3/ 281 (1.07)	0.65 (0.11, 3.85)	0.6334	0.65 (0.11, 3.89)	0.6333	-0.00 (-0.02, 0.01)	0.6316	
	FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders									
Sex									0.9061
Male	125/ 1945 (6.43)	100/ 1947 (5.14)	1.25 (0.97, 1.62)	0.0859	1.27 (0.97, 1.66)	0.0858	0.01 (-0.00, 0.03)	0.0856	
Female	89/ 1532 (5.81)	71/ 1568 (4.53)	1.28 (0.95, 1.74)	0.1098	1.30 (0.94, 1.79)	0.1096	0.01 (-0.00, 0.03)	0.1126	
Region									0.9399
Western Europe, Oceania and Others	65/ 688 (9.45)	56/ 716 (7.82)	1.20 (0.85, 1.69)	0.2935	1.22 (0.84, 1.77)	0.2968	0.01 (-0.02, 0.04)	0.3689	
Eastern Europe	59/ 1577 (3.74)	45/ 1567 (2.87)	1.29 (0.88, 1.89)	0.1859	1.31 (0.88, 1.94)	0.1839	0.01 (-0.00, 0.02)	0.0786	
Asia	41/ 554 (7.40)	33/ 551 (5.99)	1.24 (0.80, 1.93)	0.3382	1.26 (0.79, 2.03)	0.3324	0.02 (-0.01, 0.05)	0.2939	
North America	34/ 317 (10.73)	23/ 317 (7.26)	1.52 (0.92, 2.52)	0.1054	1.58 (0.90, 2.75)	0.1089	0.03 (-0.01, 0.08)	0.1464	
Latin America	15/ 341 (4.40)	14/ 364 (3.85)	1.09 (0.53, 2.22)	0.8221	1.09 (0.52, 2.29)	0.8242	0.00 (-0.04, 0.05)	0.9021	
Age group (years)									0.3503
<= median in FAS	86/ 1825 (4.71)	76/ 1831 (4.15)	1.13 (0.84, 1.53)	0.4131	1.14 (0.83, 1.57)	0.4128	0.01 (-0.01, 0.02)	0.4056	
> median in FAS	128/ 1652 (7.75)	95/ 1684 (5.64)	1.37 (1.06, 1.77)	0.0161	1.40 (1.06, 1.84)	0.0162	0.02 (0.00, 0.04)	0.0245	
Study									0.1992
FINEARTS-HF	187/ 2993 (6.25)	152/ 2993 (5.08)	1.23 (1.00, 1.51)	0.0508	1.25 (1.00, 1.55)	0.0507	0.01 (-0.00, 0.02)	0.0503	
FIGARO-DKD	12/ 289 (4.15)	12/ 281 (4.27)	0.97 (0.44, 2.13)	0.9440	0.97 (0.43, 2.20)	0.9440	-0.00 (-0.03, 0.03)	0.9440	
FIDELIO-DKD	15/ 195 (7.69)	7/ 241 (2.90)	2.65 (1.10, 6.37)	0.0295	2.79 (1.11, 6.98)	0.0287	0.05 (0.00, 0.09)	0.0291	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions	Study									0.8877
	FINEARTS-HF	182/ 2993 (6.08)	207/ 2993 (6.92)	0.88 (0.73, 1.07)	0.1903	0.87 (0.71, 1.07)	0.1902	-0.01 (-0.02, 0.00)	0.1898	
	FIGARO-DKD	9/ 289 (3.11)	11/ 281 (3.91)	0.80 (0.33, 1.89)	0.6045	0.79 (0.32, 1.93)	0.6044	-0.01 (-0.04, 0.02)	0.6041	
	FIDELIO-DKD	11/ 195 (5.64)	13/ 241 (5.39)	1.05 (0.48, 2.28)	0.9105	1.05 (0.46, 2.40)	0.9105	0.00 (-0.04, 0.05)	0.9107	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death	Sex									0.9727
	Male	42/ 1945 (2.16)	58/ 1947 (2.98)	0.72 (0.48, 1.06)	0.0962	0.71 (0.48, 1.06)	0.0962	-0.01 (-0.02, 0.00)	0.1147	
	Female	32/ 1532 (2.09)	46/ 1568 (2.93)	0.71 (0.45, 1.11)	0.1309	0.70 (0.44, 1.11)	0.1296	-0.01 (-0.02, 0.00)	0.1589	
	Region									0.6842
	Western Europe, Oceania and Others	16/ 688 (2.33)	17/ 716 (2.37)	0.97 (0.49, 1.91)	0.9317	0.97 (0.49, 1.94)	0.9318	-0.00 (-0.02, 0.02)	0.9168	
	Eastern Europe	36/ 1577 (2.28)	52/ 1567 (3.32)	0.69 (0.45, 1.05)	0.0800	0.68 (0.44, 1.05)	0.0795	-0.01 (-0.02, 0.01)	0.2698	
	Asia	11/ 554 (1.99)	19/ 551 (3.45)	0.59 (0.28, 1.22)	0.1518	0.58 (0.27, 1.22)	0.1506	-0.02 (-0.04, 0.00)	0.1245	
	North America	9/ 317 (2.84)	10/ 317 (3.15)	0.90 (0.37, 2.19)	0.8233	0.90 (0.36, 2.25)	0.8236	-0.00 (-0.04, 0.03)	0.7941	
	Latin America	2/ 341 (0.59)	6/ 364 (1.65)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.06, 0.04)	0.6371	
	Age group (years)									0.4832
	<= median in FAS	25/ 1825 (1.37)	40/ 1831 (2.18)	0.63 (0.38, 1.03)	0.0631	0.62 (0.37, 1.03)	0.0628	-0.01 (-0.02, 0.00)	0.0638	
	> median in FAS	49/ 1652 (2.97)	64/ 1684 (3.80)	0.78 (0.54, 1.12)	0.1812	0.77 (0.53, 1.13)	0.1811	-0.01 (-0.03, 0.01)	0.4386	
	Study									0.8897
	FINEARTS-HF	70/ 2993 (2.34)	97/ 2993 (3.24)	0.72 (0.53, 0.98)	0.0350	0.72 (0.52, 0.98)	0.0349	-0.01 (-0.02, -0.00)	0.0340	
	FIGARO-DKD	3/ 289 (1.04)	4/ 281 (1.42)	0.73 (0.16, 3.23)	0.6775	0.73 (0.16, 3.28)	0.6774	-0.00 (-0.02, 0.01)	0.6768	
	FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Hepatobiliary disorders	Study									0.5089
	FINEARTS-HF	37/ 2993 (1.24)	48/ 2993 (1.60)	0.77 (0.50, 1.18)	0.2309	0.77 (0.50, 1.18)	0.2308	-0.00 (-0.01, 0.00)	0.2294	
	FIGARO-DKD	8/ 289 (2.77)	5/ 281 (1.78)	1.56 (0.52, 4.70)	0.4332	1.57 (0.51, 4.86)	0.4328	0.01 (-0.01, 0.03)	0.4276	
	FIDELIO-DKD	2/ 195 (1.03)	3/ 241 (1.24)	0.82 (0.14, 4.88)	0.8311	0.82 (0.14, 4.97)	0.8310	-0.00 (-0.02, 0.02)	0.8291	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Study									0.9676
	FINEARTS-HF	486/ 2993 (16.24)	480/ 2993 (16.04)	1.01 (0.90, 1.14)	0.8330	1.01 (0.88, 1.16)	0.8330	0.00 (-0.02, 0.02)	0.8330	
	FIGARO-DKD	49/ 289 (16.96)	46/ 281 (16.37)	1.04 (0.72, 1.50)	0.8514	1.04 (0.67, 1.62)	0.8514	0.01 (-0.06, 0.07)	0.8514	
	FIDELIO-DKD	36/ 195 (18.46)	46/ 241 (19.09)	0.97 (0.65, 1.43)	0.8681	0.96 (0.59, 1.56)	0.8682	-0.01 (-0.08, 0.07)	0.8678	

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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: COVID-19	Study									0.3871
	FINEARTS-HF	85/ 2993 (2.84)	82/ 2993 (2.74)	1.04 (0.77, 1.40)	0.8139	1.04 (0.76, 1.41)	0.8139	0.00 (-0.01, 0.01)	0.8139	
	FIGARO-DKD	2/ 289 (0.69)	4/ 281 (1.42)	0.49 (0.09, 2.63)	0.4028	0.48 (0.09, 2.66)	0.4024	-0.01 (-0.02, 0.01)	0.3943	
	FIDELIO-DKD	0/ 195 (0.00)	0/ 241 (0.00)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Cellulitis	Study									0.7633
	FINEARTS-HF	28/ 2993 (0.94)	29/ 2993 (0.97)	0.97 (0.58, 1.62)	0.8941	0.97 (0.57, 1.63)	0.8941	-0.00 (-0.01, 0.00)	0.8941	
	FIGARO-DKD	5/ 289 (1.73)	3/ 281 (1.07)	1.62 (0.39, 6.72)	0.5058	1.63 (0.39, 6.89)	0.5055	0.01 (-0.01, 0.03)	0.4999	
	FIDELIO-DKD	6/ 195 (3.08)	6/ 241 (2.49)	1.24 (0.40, 3.77)	0.7098	1.24 (0.39, 3.92)	0.7099	0.01 (-0.03, 0.04)	0.7123	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Pneumonia	Study									0.1724
	FINEARTS-HF	140/ 2993 (4.68)	143/ 2993 (4.78)	0.98 (0.78, 1.23)	0.8550	0.98 (0.77, 1.24)	0.8550	-0.00 (-0.01, 0.01)	0.8550	
	FIGARO-DKD	12/ 289 (4.15)	15/ 281 (5.34)	0.78 (0.37, 1.63)	0.5065	0.77 (0.35, 1.67)	0.5063	-0.01 (-0.05, 0.02)	0.5058	
	FIDELIO-DKD	11/ 195 (5.64)	27/ 241 (11.20)	0.50 (0.26, 0.99)	0.0464	0.47 (0.23, 0.98)	0.0444	-0.06 (-0.11, -0.00)	0.0337	

Analysis based on all AE starting at beginning of treatment until end of study.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Sex								0.3597
Male	33/ 1945 (1.70)	24/ 1947 (1.23)	1.39 (0.82, 2.34)	0.2208	1.39 (0.82, 2.37)	0.2198	0.00 (-0.00, 0.01)	0.1880	
Female	19/ 1532 (1.24)	9/ 1568 (0.57)	2.16 (0.98, 4.75)	0.0563	2.17 (0.98, 4.82)	0.0561	0.01 (-0.02, 0.03)	0.5403	
Region									0.2953
Western Europe, Oceania and Others	12/ 688 (1.74)	7/ 716 (0.98)	1.85 (0.74, 4.67)	0.1900	1.87 (0.73, 4.80)	0.1935	0.01 (-0.01, 0.02)	0.3176	
Eastern Europe	13/ 1577 (0.82)	4/ 1567 (0.26)	3.30 (1.08, 10.09)	0.0367	3.32 (1.08, 10.21)	0.0364	0.01 (0.00, 0.01)	0.0344	
Asia	6/ 554 (1.08)	7/ 551 (1.27)	0.86 (0.29, 2.53)	0.7775	0.85 (0.29, 2.56)	0.7794	-0.00 (-0.01, 0.01)	0.8929	
North America	14/ 317 (4.42)	13/ 317 (4.10)	1.09 (0.52, 2.29)	0.8149	1.09 (0.50, 2.37)	0.8211	-0.00 (-0.04, 0.03)	0.9340	
Latin America	7/ 341 (2.05)	2/ 364 (0.55)	3.47 (0.73, 16.56)	0.1191	3.52 (0.73, 17.09)	0.1181	0.01 (-0.03, 0.06)	0.5526	
Age group (years)									0.4932
<= median in FAS	26/ 1825 (1.42)	14/ 1831 (0.76)	1.89 (0.99, 3.61)	0.0536	1.91 (0.99, 3.67)	0.0531	0.01 (0.00, 0.01)	0.0338	
> median in FAS	26/ 1652 (1.57)	19/ 1684 (1.13)	1.39 (0.77, 2.51)	0.2687	1.40 (0.77, 2.54)	0.2689	0.00 (-0.00, 0.01)	0.2948	
Study									0.6752
FINEARTS-HF	44/ 2993 (1.47)	25/ 2993 (0.84)	1.76 (1.08, 2.87)	0.0233	1.77 (1.08, 2.90)	0.0232	0.01 (0.00, 0.01)	0.0214	
FIGARO-DKD	4/ 289 (1.38)	4/ 281 (1.42)	0.97 (0.25, 3.85)	0.9681	0.97 (0.24, 3.92)	0.9681	-0.00 (-0.02, 0.02)	0.9681	
FIDELIO-DKD	4/ 195 (2.05)	4/ 241 (1.66)	1.24 (0.31, 4.88)	0.7624	1.24 (0.31, 5.03)	0.7624	0.00 (-0.02, 0.03)	0.7645	

Analysis based on all AE starting at beginning of treatment until end of study.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Urinary tract infection	Study									0.4275
	FINEARTS-HF	43/ 2993 (1.44)	40/ 2993 (1.34)	1.07 (0.70, 1.65)	0.7402	1.08 (0.70, 1.66)	0.7402	0.00 (-0.00, 0.01)	0.7402	
	FIGARO-DKD	2/ 289 (0.69)	5/ 281 (1.78)	0.39 (0.08, 1.99)	0.2566	0.38 (0.07, 2.00)	0.2559	-0.01 (-0.03, 0.01)	0.2409	
	FIDELIO-DKD	2/ 195 (1.03)	4/ 241 (1.66)	0.62 (0.11, 3.34)	0.5760	0.61 (0.11, 3.39)	0.5757	-0.01 (-0.03, 0.02)	0.5623	

Analysis based on all AE starting at beginning of treatment until end of study.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications	Study									0.0786
	FINEARTS-HF	151/ 2993 (5.05)	172/ 2993 (5.75)	0.88 (0.71, 1.09)	0.2300	0.87 (0.70, 1.09)	0.2299	-0.01 (-0.02, 0.00)	0.2296	
	FIGARO-DKD	9/ 289 (3.11)	12/ 281 (4.27)	0.73 (0.31, 1.70)	0.4658	0.72 (0.30, 1.74)	0.4656	-0.01 (-0.04, 0.02)	0.4645	
	FIDELIO-DKD	16/ 195 (8.21)	9/ 241 (3.73)	2.20 (0.99, 4.86)	0.0522	2.30 (1.00, 5.34)	0.0513	0.04 (-0.00, 0.09)	0.0533	

Analysis based on all AE starting at beginning of treatment until end of study.
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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

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Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Study									0.0382
	FINEARTS-HF	91/ 2993 (3.04)	73/ 2993 (2.44)	1.25 (0.92, 1.69)	0.1550	1.25 (0.92, 1.71)	0.1549	0.01 (-0.00, 0.01)	0.1540	
	FIGARO-DKD	26/ 289 (9.00)	15/ 281 (5.34)	1.69 (0.91, 3.11)	0.0956	1.75 (0.91, 3.38)	0.0945	0.04 (-0.01, 0.08)	0.0891	
	FIDELIO-DKD	15/ 195 (7.69)	31/ 241 (12.86)	0.60 (0.33, 1.08)	0.0859	0.56 (0.30, 1.08)	0.0836	-0.05 (-0.11, 0.00)	0.0726	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders	Study									0.8731
	FINEARTS-HF	66/ 2993 (2.21)	75/ 2993 (2.51)	0.88 (0.63, 1.22)	0.4434	0.88 (0.63, 1.23)	0.4434	-0.00 (-0.01, 0.00)	0.4430	
	FIGARO-DKD	9/ 289 (3.11)	11/ 281 (3.91)	0.80 (0.33, 1.89)	0.6045	0.79 (0.32, 1.93)	0.6044	-0.01 (-0.04, 0.02)	0.6041	
	FIDELIO-DKD	3/ 195 (1.54)	6/ 241 (2.49)	0.62 (0.16, 2.44)	0.4920	0.61 (0.15, 2.48)	0.4915	-0.01 (-0.04, 0.02)	0.4764	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Study									0.3246
	FINEARTS-HF	113/ 2993 (3.78)	136/ 2993 (4.54)	0.83 (0.65, 1.06)	0.1372	0.82 (0.64, 1.06)	0.1371	-0.01 (-0.02, 0.00)	0.1365	
	FIGARO-DKD	10/ 289 (3.46)	6/ 281 (2.14)	1.62 (0.60, 4.40)	0.3434	1.64 (0.59, 4.58)	0.3429	0.01 (-0.01, 0.04)	0.3364	
	FIDELIO-DKD	10/ 195 (5.13)	10/ 241 (4.15)	1.24 (0.53, 2.91)	0.6277	1.25 (0.51, 3.06)	0.6277	0.01 (-0.03, 0.05)	0.6307	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders	Study									0.6549
	FINEARTS-HF	112/ 2993 (3.74)	120/ 2993 (4.01)	0.93 (0.73, 1.20)	0.5922	0.93 (0.72, 1.21)	0.5922	-0.00 (-0.01, 0.01)	0.5922	
	FIGARO-DKD	13/ 289 (4.50)	9/ 281 (3.20)	1.40 (0.61, 3.23)	0.4247	1.42 (0.60, 3.38)	0.4243	0.01 (-0.02, 0.04)	0.4208	
	FIDELIO-DKD	10/ 195 (5.13)	13/ 241 (5.39)	0.95 (0.43, 2.12)	0.9017	0.95 (0.41, 2.21)	0.9017	-0.00 (-0.04, 0.04)	0.9014	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Syncope	Study									0.5204
	FINEARTS-HF	31/ 2993 (1.04)	31/ 2993 (1.04)	1.00 (0.61, 1.64)	1.0000	1.00 (0.61, 1.65)	1.0000	-0.00 (-0.01, 0.01)	1.0000	
	FIGARO-DKD	2/ 289 (0.69)	3/ 281 (1.07)	0.65 (0.11, 3.85)	0.6334	0.65 (0.11, 3.89)	0.6333	-0.00 (-0.02, 0.01)	0.6316	
	FIDELIO-DKD	4/ 195 (2.05)	2/ 241 (0.83)	2.47 (0.46, 13.35)	0.2930	2.50 (0.45, 13.81)	0.2925	0.01 (-0.01, 0.04)	0.2970	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Study									0.0044
	FINEARTS-HF	144/ 2993 (4.81)	94/ 2993 (3.14)	1.53 (1.19, 1.98)	0.0010	1.56 (1.20, 2.03)	0.0010	0.02 (0.01, 0.03)	0.0009	
	FIGARO-DKD	14/ 289 (4.84)	18/ 281 (6.41)	0.76 (0.38, 1.49)	0.4199	0.74 (0.36, 1.53)	0.4196	-0.02 (-0.05, 0.02)	0.4187	
	FIDELIO-DKD	11/ 195 (5.64)	26/ 241 (10.79)	0.52 (0.27, 1.03)	0.0613	0.49 (0.24, 1.03)	0.0592	-0.05 (-0.10, -0.00)	0.0471	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Sex									0.8736
	Male	56/ 1945 (2.88)	39/ 1947 (2.00)	1.46 (0.98, 2.19)	0.0638	1.49 (0.98, 2.26)	0.0603	0.01 (0.00, 0.02)	0.0150	
	Female	38/ 1532 (2.48)	28/ 1568 (1.79)	1.39 (0.86, 2.26)	0.1794	1.40 (0.86, 2.30)	0.1800	0.01 (-0.00, 0.02)	0.1933	
	Region									0.3690
	Western Europe, Oceania and Others	30/ 688 (4.36)	19/ 716 (2.65)	1.65 (0.94, 2.91)	0.0820	1.68 (0.94, 3.02)	0.0807	0.02 (-0.00, 0.04)	0.0611	
	Eastern Europe	18/ 1577 (1.14)	10/ 1567 (0.64)	1.77 (0.82, 3.81)	0.1476	1.78 (0.82, 3.86)	0.1475	0.01 (-0.02, 0.03)	0.6462	
	Asia	9/ 554 (1.62)	14/ 551 (2.54)	0.64 (0.28, 1.46)	0.2922	0.64 (0.27, 1.50)	0.3020	-0.00 (-0.02, 0.01)	0.6006	
	North America	32/ 317 (10.09)	21/ 317 (6.62)	1.51 (0.89, 2.55)	0.1286	1.58 (0.89, 2.82)	0.1191	0.04 (-0.00, 0.08)	0.0674	
	Latin America	5/ 341 (1.47)	3/ 364 (0.82)	1.78 (0.43, 7.45)	0.4269	1.81 (0.42, 7.69)	0.4235	0.01 (-0.04, 0.06)	0.7600	
	Age group (years)									0.0810
	<= median in FAS	35/ 1825 (1.92)	34/ 1831 (1.86)	1.04 (0.65, 1.66)	0.8634	1.05 (0.65, 1.69)	0.8513	0.00 (-0.01, 0.01)	0.4884	
	> median in FAS	59/ 1652 (3.57)	33/ 1684 (1.96)	1.82 (1.20, 2.78)	0.0051	1.86 (1.21, 2.87)	0.0049	0.02 (0.01, 0.03)	0.0025	
	Study									0.0637
	FINEARTS-HF	78/ 2993 (2.61)	44/ 2993 (1.47)	1.77 (1.23, 2.56)	0.0022	1.79 (1.23, 2.60)	0.0021	0.01 (0.00, 0.02)	0.0019	
	FIGARO-DKD	10/ 289 (3.46)	11/ 281 (3.91)	0.88 (0.38, 2.05)	0.7736	0.88 (0.37, 2.11)	0.7735	-0.00 (-0.04, 0.03)	0.7736	
	FIDELIO-DKD	6/ 195 (3.08)	12/ 241 (4.98)	0.62 (0.24, 1.62)	0.3266	0.61 (0.22, 1.64)	0.3253	-0.02 (-0.06, 0.02)	0.3087	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders	Study									0.9662
	FINEARTS-HF	172/ 2993 (5.75)	162/ 2993 (5.41)	1.06 (0.86, 1.31)	0.5734	1.07 (0.85, 1.33)	0.5734	0.00 (-0.01, 0.01)	0.5733	
	FIGARO-DKD	21/ 289 (7.27)	18/ 281 (6.41)	1.13 (0.62, 2.08)	0.6843	1.14 (0.60, 2.20)	0.6842	0.01 (-0.03, 0.05)	0.6838	
	FIDELIO-DKD	13/ 195 (6.67)	16/ 241 (6.64)	1.00 (0.50, 2.04)	0.9908	1.00 (0.47, 2.14)	0.9908	0.00 (-0.05, 0.05)	0.9908	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Chronic obstructive pulmonary disease	Study									0.4502
	FINEARTS-HF	28/ 2993 (0.94)	35/ 2993 (1.17)	0.80 (0.49, 1.31)	0.3763	0.80 (0.48, 1.32)	0.3763	-0.00 (-0.01, 0.00)	0.3753	
	FIGARO-DKD	5/ 289 (1.73)	6/ 281 (2.14)	0.81 (0.25, 2.62)	0.7257	0.81 (0.24, 2.67)	0.7257	-0.00 (-0.03, 0.02)	0.7256	
	FIDELIO-DKD	4/ 195 (2.05)	2/ 241 (0.83)	2.47 (0.46, 13.35)	0.2930	2.50 (0.45, 13.81)	0.2925	0.01 (-0.01, 0.04)	0.2970	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Surgical and medical procedures	Study									0.3591
	FINEARTS-HF	69/ 2993 (2.31)	63/ 2993 (2.10)	1.10 (0.78, 1.54)	0.5976	1.10 (0.78, 1.55)	0.5976	0.00 (-0.01, 0.01)	0.5974	
	FIGARO-DKD	11/ 289 (3.81)	5/ 281 (1.78)	2.14 (0.75, 6.08)	0.1535	2.18 (0.75, 6.37)	0.1525	0.02 (-0.01, 0.05)	0.1403	
	FIDELIO-DKD	7/ 195 (3.59)	11/ 241 (4.56)	0.79 (0.31, 1.99)	0.6122	0.78 (0.30, 2.05)	0.6119	-0.01 (-0.05, 0.03)	0.6066	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	Study									0.0410
	FINEARTS-HF	105/ 2993 (3.51)	97/ 2993 (3.24)	1.08 (0.83, 1.42)	0.5670	1.09 (0.82, 1.44)	0.5670	0.00 (-0.01, 0.01)	0.5669	
	FIGARO-DKD	6/ 289 (2.08)	18/ 281 (6.41)	0.32 (0.13, 0.80)	0.0152	0.31 (0.12, 0.79)	0.0145	-0.04 (-0.08, -0.01)	0.0102	
	FIDELIO-DKD	7/ 195 (3.59)	7/ 241 (2.90)	1.24 (0.44, 3.46)	0.6871	1.24 (0.43, 3.61)	0.6871	0.01 (-0.03, 0.04)	0.6897	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	36/ 3477 (1.04)	53/ 3515 (1.51)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.45, 1.06)	
	p-value	0.0872	
	Risk Ratio (95% CI)	0.69 (0.45, 1.05)	
	p-value	0.0866	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.1451	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	26/ 3477 (0.75)	36/ 3515 (1.02)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.73 (0.44, 1.21)	
	p-value	0.2264	
	Risk Ratio (95% CI)	0.73 (0.44, 1.21)	
	p-value	0.2258	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3145	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	171/ 3477 (4.92)	171/ 3515 (4.86)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.81, 1.25)	
	p-value	0.9319	
	Risk Ratio (95% CI)	1.01 (0.82, 1.24)	
	p-value	0.9257	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.9179	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	94/ 3477 (2.70)	78/ 3515 (2.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.22 (0.90, 1.66)	
	p-value	0.1923	
	Risk Ratio (95% CI)	1.22 (0.91, 1.64)	
	p-value	0.1918	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.2102	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	154/ 3477 (4.43)	191/ 3515 (5.43)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.80 (0.65, 1.00)	
	p-value	0.0501	
	Risk Ratio (95% CI)	0.81 (0.66, 1.00)	
	p-value	0.0503	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.0561	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Death	Number of subjects with event, n/N (%)	72/ 3477 (2.07)	103/ 3515 (2.93)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.69 (0.51, 0.94)	
	p-value	0.0194	
	Risk Ratio (95% CI)	0.70 (0.52, 0.94)	
	p-value	0.0195	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0199	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	272/ 3477 (7.82)	308/ 3515 (8.76)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.75, 1.05)	
	p-value	0.1658	
	Risk Ratio (95% CI)	0.90 (0.77, 1.05)	
	p-value	0.1651	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.1729	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	28/ 3477 (0.81)	38/ 3515 (1.08)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.74 (0.45, 1.20)	
	p-value	0.2188	
	Risk Ratio (95% CI)	0.74 (0.45, 1.20)	
	p-value	0.2190	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.2070	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	75/ 3477 (2.16)	86/ 3515 (2.45)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.65, 1.22)	
	p-value	0.4653	
	Risk Ratio (95% CI)	0.89 (0.66, 1.21)	
	p-value	0.4592	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.6089	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	38/ 3477 (1.09)	22/ 3515 (0.63)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.78 (1.05, 3.02)	
	p-value	0.0317	
	Risk Ratio (95% CI)	1.77 (1.05, 2.99)	
	p-value	0.0322	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0154	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	96/ 3477 (2.76)	108/ 3515 (3.07)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.90 (0.68, 1.19)	
	p-value	0.4727	
	Risk Ratio (95% CI)	0.91 (0.69, 1.19)	
	p-value	0.4770	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3867	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	74/ 3477 (2.13)	66/ 3515 (1.88)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.15 (0.82, 1.62)	
	p-value	0.4046	
	Risk Ratio (95% CI)	1.15 (0.83, 1.60)	
	p-value	0.4022	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.5022	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	46/ 3477 (1.32)	43/ 3515 (1.22)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.09 (0.72, 1.65)	
	p-value	0.6959	
	Risk Ratio (95% CI)	1.09 (0.72, 1.64)	
	p-value	0.6942	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.7986	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	80/ 3477 (2.30)	91/ 3515 (2.59)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.89 (0.66, 1.21)	
	p-value	0.4501	
	Risk Ratio (95% CI)	0.89 (0.66, 1.20)	
	p-value	0.4480	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.01)	
	p-value	0.5852	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	62/ 3477 (1.78)	80/ 3515 (2.28)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	0.78 (0.56, 1.09)	
	p-value	0.1497	
	Risk Ratio (95% CI)	0.79 (0.57, 1.09)	
	p-value	0.1498	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.1510	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	124/ 3477 (3.57)	95/ 3515 (2.70)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.36 (1.04, 1.79)	
	p-value	0.0262	
	Risk Ratio (95% CI)	1.34 (1.03, 1.74)	
	p-value	0.0309	
	Risk Difference (95% CI)	0.01 (0.00, 0.02)	
	p-value	0.0022	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	66/ 3477 (1.90)	50/ 3515 (1.42)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.37 (0.94, 1.98)	
	p-value	0.1003	
	Risk Ratio (95% CI)	1.35 (0.94, 1.94)	
	p-value	0.1057	
	Risk Difference (95% CI)	0.01 (0.00, 0.01)	
	p-value	0.0160	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	116/ 3477 (3.34)	116/ 3515 (3.30)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.01 (0.78, 1.32)	
	p-value	0.9176	
	Risk Ratio (95% CI)	1.01 (0.79, 1.30)	
	p-value	0.9204	
	Risk Difference (95% CI)	0.00 (-0.01, 0.01)	
	p-value	0.8580	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	74/ 3477 (2.13)	67/ 3515 (1.91)
	Analysis Finerenone vs. Placebo		
	Odds Ratio (95% CI)	1.12 (0.80, 1.57)	
	p-value	0.4923	
	Risk Ratio (95% CI)	1.12 (0.81, 1.56)	
	p-value	0.4930	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.4682	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Study									0.3182
	FINEARTS-HF	33/ 2993 (1.10)	43/ 2993 (1.44)	0.77 (0.49, 1.20)	0.2498	0.76 (0.48, 1.21)	0.2497	-0.00 (-0.01, 0.00)	0.2483	
	FIGARO-DKD	2/ 289 (0.69)	2/ 281 (0.71)	0.97 (0.14, 6.86)	0.9775	0.97 (0.14, 6.95)	0.9775	-0.00 (-0.01, 0.01)	0.9775	
	FIDELIO-DKD	1/ 195 (0.51)	8/ 241 (3.32)	0.15 (0.02, 1.22)	0.0770	0.15 (0.02, 1.21)	0.0750	-0.03 (-0.05, -0.00)	0.0262	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Anaemia	Study									0.4780
	FINEARTS-HF	24/ 2993 (0.80)	30/ 2993 (1.00)	0.80 (0.47, 1.37)	0.4131	0.80 (0.47, 1.37)	0.4131	-0.00 (-0.01, 0.00)	0.4121	
	FIGARO-DKD	2/ 289 (0.69)	1/ 281 (0.36)	1.94 (0.18, 21.33)	0.5862	1.95 (0.18, 21.64)	0.5861	0.00 (-0.01, 0.02)	0.5774	
	FIDELIO-DKD	0/ 195 (0.00)	5/ 241 (2.07)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders	Study									0.1637
	FINEARTS-HF	159/ 2993 (5.31)	148/ 2993 (4.94)	1.07 (0.86, 1.34)	0.5193	1.08 (0.86, 1.36)	0.5193	0.00 (-0.01, 0.01)	0.5192	
	FIGARO-DKD	8/ 289 (2.77)	10/ 281 (3.56)	0.78 (0.31, 1.94)	0.5905	0.77 (0.30, 1.98)	0.5904	-0.01 (-0.04, 0.02)	0.5900	
	FIDELIO-DKD	4/ 195 (2.05)	13/ 241 (5.39)	0.38 (0.13, 1.15)	0.0863	0.37 (0.12, 1.15)	0.0843	-0.03 (-0.07, 0.00)	0.0595	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders	Study									0.5297
	FINEARTS-HF	76/ 2993 (2.54)	67/ 2993 (2.24)	1.13 (0.82, 1.57)	0.4465	1.14 (0.82, 1.59)	0.4465	0.00 (-0.00, 0.01)	0.4462	
	FIGARO-DKD	11/ 289 (3.81)	7/ 281 (2.49)	1.53 (0.60, 3.89)	0.3733	1.55 (0.59, 4.05)	0.3728	0.01 (-0.02, 0.04)	0.3677	
	FIDELIO-DKD	7/ 195 (3.59)	4/ 241 (1.66)	2.16 (0.64, 7.28)	0.2129	2.21 (0.64, 7.65)	0.2123	0.02 (-0.01, 0.05)	0.2178	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions	Study									0.9821
	FINEARTS-HF	142/ 2993 (4.74)	174/ 2993 (5.81)	0.82 (0.66, 1.01)	0.0649	0.81 (0.64, 1.01)	0.0648	-0.01 (-0.02, 0.00)	0.0643	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	6/ 195 (3.08)	10/ 241 (4.15)	0.74 (0.27, 2.00)	0.5556	0.73 (0.26, 2.05)	0.5552	-0.01 (-0.05, 0.02)	0.5475	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Death									
Sex									0.8432
Male	40/ 1945 (2.06)	58/ 1947 (2.98)	0.68 (0.46, 1.02)	0.0602	0.68 (0.45, 1.02)	0.0601	-0.01 (-0.02, 0.00)	0.0760	
Female	32/ 1532 (2.09)	45/ 1568 (2.87)	0.73 (0.46, 1.13)	0.1593	0.72 (0.45, 1.14)	0.1579	-0.01 (-0.02, 0.00)	0.1668	
Region									0.6922
Western Europe, Oceania and Others	15/ 688 (2.18)	17/ 716 (2.37)	0.91 (0.46, 1.81)	0.7888	0.91 (0.45, 1.83)	0.7890	-0.00 (-0.02, 0.01)	0.7694	
Eastern Europe	36/ 1577 (2.28)	51/ 1567 (3.25)	0.70 (0.46, 1.07)	0.0983	0.69 (0.45, 1.07)	0.0979	-0.01 (-0.02, 0.01)	0.2789	
Asia	10/ 554 (1.81)	19/ 551 (3.45)	0.53 (0.25, 1.13)	0.1023	0.52 (0.24, 1.14)	0.1011	-0.02 (-0.04, 0.00)	0.0894	
North America	9/ 317 (2.84)	10/ 317 (3.15)	0.90 (0.37, 2.19)	0.8233	0.90 (0.36, 2.25)	0.8236	-0.00 (-0.04, 0.03)	0.7941	
Latin America	2/ 341 (0.59)	6/ 364 (1.65)	0.33 (0.07, 1.62)	0.1728	0.33 (0.07, 1.63)	0.1719	-0.01 (-0.06, 0.04)	0.6371	
Age group (years)									0.4203
<= median in FAS	24/ 1825 (1.32)	40/ 1831 (2.18)	0.60 (0.36, 0.99)	0.0462	0.59 (0.36, 0.99)	0.0459	-0.01 (-0.02, -0.00)	0.0494	
> median in FAS	48/ 1652 (2.91)	63/ 1684 (3.74)	0.78 (0.54, 1.12)	0.1771	0.77 (0.52, 1.13)	0.1770	-0.01 (-0.03, 0.01)	0.4372	
Study									0.8957
FINEARTS-HF	68/ 2993 (2.27)	96/ 2993 (3.21)	0.71 (0.52, 0.96)	0.0274	0.70 (0.51, 0.96)	0.0274	-0.01 (-0.02, -0.00)	0.0266	
FIGARO-DKD	3/ 289 (1.04)	4/ 281 (1.42)	0.73 (0.16, 3.23)	0.6775	0.73 (0.16, 3.28)	0.6774	-0.00 (-0.02, 0.01)	0.6768	
FIDELIO-DKD	1/ 195 (0.51)	3/ 241 (1.24)	0.41 (0.04, 3.93)	0.4409	0.41 (0.04, 3.96)	0.4403	-0.01 (-0.02, 0.01)	0.4047	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Study									0.9059
	FINEARTS-HF	231/ 2993 (7.72)	254/ 2993 (8.49)	0.91 (0.77, 1.08)	0.2762	0.90 (0.75, 1.09)	0.2761	-0.01 (-0.02, 0.01)	0.2759	
	FIGARO-DKD	23/ 289 (7.96)	27/ 281 (9.61)	0.83 (0.49, 1.41)	0.4871	0.81 (0.45, 1.46)	0.4869	-0.02 (-0.06, 0.03)	0.4866	
	FIDELIO-DKD	18/ 195 (9.23)	27/ 241 (11.20)	0.82 (0.47, 1.45)	0.5022	0.81 (0.43, 1.51)	0.5015	-0.02 (-0.08, 0.04)	0.4968	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level		Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: COVID-19	Study									0.1912
	FINEARTS-HF	27/ 2993 (0.90)	32/ 2993 (1.07)	0.84 (0.51, 1.40)	0.5135	0.84 (0.50, 1.41)	0.5135	-0.00 (-0.01, 0.00)	0.5130	
	FIGARO-DKD	1/ 289 (0.35)	5/ 281 (1.78)	0.19 (0.02, 1.65)	0.1338	0.19 (0.02, 1.65)	0.1327	-0.01 (-0.03, 0.00)	0.0960	
	FIDELIO-DKD	0/ 195 (0.00)	1/ 241 (0.41)	NE (NE, NE)	NE	NE (NE, NE)	NE	NE (NE, NE)	NE	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

Subgroup Level		Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Pneumonia	Study									0.2202
	FINEARTS-HF	66/ 2993 (2.21)	65/ 2993 (2.17)	1.02 (0.72, 1.42)	0.9296	1.02 (0.72, 1.44)	0.9296	0.00 (-0.01, 0.01)	0.9296	
	FIGARO-DKD	4/ 289 (1.38)	7/ 281 (2.49)	0.56 (0.16, 1.88)	0.3441	0.55 (0.16, 1.90)	0.3436	-0.01 (-0.03, 0.01)	0.3383	
	FIDELIO-DKD	5/ 195 (2.56)	14/ 241 (5.81)	0.44 (0.16, 1.20)	0.1102	0.43 (0.15, 1.21)	0.1082	-0.03 (-0.07, 0.00)	0.0851	

Analysis based on all AE starting at beginning of treatment until end of study.
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p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

Subgroup Level	_Finerenone (N=3477)_ n/ N (%)	_Placebo (N=3515)_ n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Sepsis	Sex								0.3338
Male	23/ 1945 (1.18)	16/ 1947 (0.82)	1.46 (0.77, 2.76)	0.2428	1.47 (0.77, 2.79)	0.2419	0.00 (-0.00, 0.01)	0.2036	
Female	15/ 1532 (0.98)	6/ 1568 (0.38)	2.56 (1.00, 6.57)	0.0509	2.59 (1.00, 6.69)	0.0500	0.01 (-0.02, 0.03)	0.5513	
	Region								0.0714
Western Europe, Oceania and Others	9/ 688 (1.31)	4/ 716 (0.56)	2.41 (0.75, 7.77)	0.1403	2.45 (0.75, 8.02)	0.1393	0.01 (-0.00, 0.02)	0.1055	
Eastern Europe	11/ 1577 (0.70)	1/ 1567 (0.06)	11.24 (1.45, 87.01)	0.0204	11.37 (1.46, 88.32)	0.0201	0.03 (-0.02, 0.07)	0.2662	
Asia	5/ 554 (0.90)	6/ 551 (1.09)	0.82 (0.25, 2.66)	0.7357	0.81 (0.25, 2.69)	0.7366	-0.00 (-0.04, 0.04)	0.9180	
North America	6/ 317 (1.89)	9/ 317 (2.84)	0.70 (0.25, 1.95)	0.4942	0.69 (0.24, 1.97)	0.4875	-0.01 (-0.04, 0.01)	0.3110	
Latin America	7/ 341 (2.05)	2/ 364 (0.55)	3.47 (0.73, 16.56)	0.1191	3.52 (0.73, 17.09)	0.1181	0.01 (-0.03, 0.06)	0.5526	
	Age group (years)								0.8073
<= median in FAS	20/ 1825 (1.10)	11/ 1831 (0.60)	1.89 (0.91, 3.94)	0.0886	1.91 (0.91, 4.01)	0.0872	0.01 (0.00, 0.01)	0.0401	
> median in FAS	18/ 1652 (1.09)	11/ 1684 (0.65)	1.66 (0.79, 3.50)	0.1836	1.67 (0.79, 3.54)	0.1834	0.00 (-0.02, 0.03)	0.6739	
	Study								0.3969
FINEARTS-HF	32/ 2993 (1.07)	15/ 2993 (0.50)	2.13 (1.16, 3.93)	0.0151	2.15 (1.16, 3.97)	0.0150	0.01 (0.00, 0.01)	0.0127	
FIGARO-DKD	3/ 289 (1.04)	2/ 281 (0.71)	1.46 (0.25, 8.66)	0.6780	1.46 (0.24, 8.82)	0.6780	0.00 (-0.01, 0.02)	0.6753	
FIDELIO-DKD	3/ 195 (1.54)	5/ 241 (2.07)	0.74 (0.18, 3.06)	0.6796	0.74 (0.17, 3.13)	0.6795	-0.01 (-0.03, 0.02)	0.6735	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Injury, poisoning and procedural complications	Study									0.4039
	FINEARTS-HF	79/ 2993 (2.64)	90/ 2993 (3.01)	0.88 (0.65, 1.18)	0.3911	0.87 (0.64, 1.19)	0.3910	-0.00 (-0.01, 0.00)	0.3907	
	FIGARO-DKD	6/ 289 (2.08)	9/ 281 (3.20)	0.65 (0.23, 1.80)	0.4047	0.64 (0.23, 1.82)	0.4044	-0.01 (-0.04, 0.02)	0.4019	
	FIDELIO-DKD	11/ 195 (5.64)	9/ 241 (3.73)	1.51 (0.64, 3.57)	0.3475	1.54 (0.63, 3.80)	0.3473	0.02 (-0.02, 0.06)	0.3534	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Study									0.8177
	FINEARTS-HF	49/ 2993 (1.64)	44/ 2993 (1.47)	1.11 (0.74, 1.67)	0.6015	1.12 (0.74, 1.68)	0.6015	0.00 (-0.00, 0.01)	0.6013	
	FIGARO-DKD	16/ 289 (5.54)	11/ 281 (3.91)	1.41 (0.67, 2.99)	0.3650	1.44 (0.66, 3.16)	0.3645	0.02 (-0.02, 0.05)	0.3607	
	FIDELIO-DKD	9/ 195 (4.62)	11/ 241 (4.56)	1.01 (0.43, 2.39)	0.9798	1.01 (0.41, 2.49)	0.9798	0.00 (-0.04, 0.04)	0.9798	

Analysis based on all AE starting at beginning of treatment until end of study.
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders	Study									0.6360
	FINEARTS-HF	34/ 2993 (1.14)	34/ 2993 (1.14)	1.00 (0.62, 1.60)	1.0000	1.00 (0.62, 1.61)	1.0000	0.00 (-0.01, 0.01)	1.0000	
	FIGARO-DKD	7/ 289 (2.42)	6/ 281 (2.14)	1.13 (0.39, 3.33)	0.8187	1.14 (0.38, 3.43)	0.8187	0.00 (-0.02, 0.03)	0.8184	
	FIDELIO-DKD	5/ 195 (2.56)	3/ 241 (1.24)	2.06 (0.50, 8.51)	0.3182	2.09 (0.49, 8.85)	0.3178	0.01 (-0.01, 0.04)	0.3243	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
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Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Study									0.2019
	FINEARTS-HF	67/ 2993 (2.24)	82/ 2993 (2.74)	0.82 (0.59, 1.12)	0.2142	0.81 (0.59, 1.13)	0.2141	-0.01 (-0.01, 0.00)	0.2133	
	FIGARO-DKD	7/ 289 (2.42)	2/ 281 (0.71)	3.40 (0.71, 16.24)	0.1246	3.46 (0.71, 16.80)	0.1235	0.02 (-0.00, 0.04)	0.0981	
	FIDELIO-DKD	6/ 195 (3.08)	7/ 241 (2.90)	1.06 (0.36, 3.10)	0.9162	1.06 (0.35, 3.21)	0.9162	0.00 (-0.03, 0.03)	0.9165	

Analysis based on all AE starting at beginning of treatment until end of study.
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Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders	Study									0.9795
	FINEARTS-HF	52/ 2993 (1.74)	66/ 2993 (2.21)	0.79 (0.55, 1.13)	0.1941	0.78 (0.54, 1.13)	0.1941	-0.00 (-0.01, 0.00)	0.1930	
	FIGARO-DKD	6/ 289 (2.08)	7/ 281 (2.49)	0.83 (0.28, 2.45)	0.7404	0.83 (0.28, 2.50)	0.7404	-0.00 (-0.03, 0.02)	0.7403	
	FIDELIO-DKD	4/ 195 (2.05)	7/ 241 (2.90)	0.71 (0.21, 2.38)	0.5744	0.70 (0.20, 2.43)	0.5742	-0.01 (-0.04, 0.02)	0.5652	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders	Sex									0.2645
	Male	80/ 1945 (4.11)	68/ 1947 (3.49)	1.21 (0.88, 1.66)	0.2435	1.23 (0.88, 1.72)	0.2191	0.01 (-0.00, 0.02)	0.0549	
	Female	44/ 1532 (2.87)	27/ 1568 (1.72)	1.67 (1.04, 2.68)	0.0341	1.70 (1.04, 2.75)	0.0327	0.01 (0.00, 0.02)	0.0136	
	Region									0.2194
	Western Europe, Oceania and Others	39/ 688 (5.67)	22/ 716 (3.07)	1.86 (1.12, 3.09)	0.0168	1.97 (1.15, 3.37)	0.0136	0.03 (0.01, 0.05)	0.0043	
	Eastern Europe	35/ 1577 (2.22)	22/ 1567 (1.40)	1.60 (0.95, 2.72)	0.0795	1.63 (0.95, 2.79)	0.0763	0.01 (0.00, 0.02)	0.0287	
	Asia	19/ 554 (3.43)	23/ 551 (4.17)	0.80 (0.44, 1.44)	0.4536	0.81 (0.43, 1.51)	0.5021	0.00 (-0.02, 0.02)	0.9823	
	North America	20/ 317 (6.31)	15/ 317 (4.73)	1.32 (0.69, 2.52)	0.4091	1.35 (0.67, 2.71)	0.3949	0.02 (-0.01, 0.05)	0.2695	
	Latin America	11/ 341 (3.23)	13/ 364 (3.57)	0.94 (0.43, 2.08)	0.8814	0.95 (0.41, 2.17)	0.8977	0.00 (-0.02, 0.03)	0.8777	
	Age group (years)									0.1112
	<= median in FAS	58/ 1825 (3.18)	55/ 1831 (3.00)	1.09 (0.76, 1.56)	0.6565	1.10 (0.75, 1.60)	0.6317	0.01 (-0.01, 0.02)	0.3090	
	> median in FAS	66/ 1652 (4.00)	40/ 1684 (2.38)	1.67 (1.13, 2.46)	0.0093	1.72 (1.15, 2.57)	0.0078	0.02 (0.01, 0.03)	0.0012	
	Study									0.0040
	FINEARTS-HF	103/ 2993 (3.44)	58/ 2993 (1.94)	1.78 (1.29, 2.44)	0.0004	1.80 (1.30, 2.50)	0.0004	0.02 (0.01, 0.02)	0.0003	
	FIGARO-DKD	10/ 289 (3.46)	13/ 281 (4.63)	0.75 (0.33, 1.68)	0.4811	0.74 (0.32, 1.71)	0.4808	-0.01 (-0.04, 0.02)	0.4800	
	FIDELIO-DKD	11/ 195 (5.64)	24/ 241 (9.96)	0.57 (0.28, 1.13)	0.1055	0.54 (0.26, 1.13)	0.1033	-0.04 (-0.09, 0.01)	0.0891	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Renal and urinary disorders, PT: Acute kidney injury	Study									0.0224
	FINEARTS-HF	55/ 2993 (1.84)	29/ 2993 (0.97)	1.90 (1.21, 2.97)	0.0050	1.91 (1.22, 3.01)	0.0050	0.01 (0.00, 0.01)	0.0043	
	FIGARO-DKD	6/ 289 (2.08)	9/ 281 (3.20)	0.65 (0.23, 1.80)	0.4047	0.64 (0.23, 1.82)	0.4044	-0.01 (-0.04, 0.02)	0.4019	
	FIDELIO-DKD	5/ 195 (2.56)	12/ 241 (4.98)	0.51 (0.18, 1.44)	0.2049	0.50 (0.17, 1.45)	0.2032	-0.02 (-0.06, 0.01)	0.1800	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders	Study									0.4695
	FINEARTS-HF	97/ 2993 (3.24)	92/ 2993 (3.07)	1.05 (0.80, 1.40)	0.7117	1.06 (0.79, 1.41)	0.7117	0.00 (-0.01, 0.01)	0.7117	
	FIGARO-DKD	10/ 289 (3.46)	15/ 281 (5.34)	0.65 (0.30, 1.42)	0.2779	0.64 (0.28, 1.44)	0.2773	-0.02 (-0.05, 0.01)	0.2746	
	FIDELIO-DKD	9/ 195 (4.62)	9/ 241 (3.73)	1.24 (0.50, 3.05)	0.6463	1.25 (0.49, 3.21)	0.6463	0.01 (-0.03, 0.05)	0.6491	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup Level	Finerenone (N=3477) n/ N (%)	Placebo (N=3515) n/ N (%)	Risk Ratio (95% CI)	p-Value	Odds Ratio (95% CI)	p-Value	Risk Difference (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	Study									0.6936
	FINEARTS-HF	62/ 2993 (2.07)	53/ 2993 (1.77)	1.17 (0.81, 1.68)	0.3973	1.17 (0.81, 1.70)	0.3972	0.00 (-0.00, 0.01)	0.3967	
	FIGARO-DKD	6/ 289 (2.08)	8/ 281 (2.85)	0.73 (0.26, 2.07)	0.5540	0.72 (0.25, 2.11)	0.5538	-0.01 (-0.03, 0.02)	0.5529	
	FIDELIO-DKD	6/ 195 (3.08)	6/ 241 (2.49)	1.24 (0.40, 3.77)	0.7098	1.24 (0.39, 3.92)	0.7099	0.01 (-0.03, 0.04)	0.7123	

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Risk Ratio (alpha=0.05).
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Anaemia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Nephrogenic anaemia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Blood and lymphatic system disorders; PT: Pancytopenia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders	Number of subjects with event, n/N (%)	15/ 3477 (0.43)	14/ 3515 (0.40)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Angina unstable	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac amyloidosis	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac arrest	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac failure	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiac failure congestive	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Cardiogenic shock	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Coronary artery disease	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Coronary artery occlusion	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Heart failure with preserved ejection fraction	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Heart failure with reduced ejection fraction	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Left ventricular dysfunction	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Mitral valve incompetence	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Palpitations	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Supraventricular tachycardia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Cardiac disorders; PT: Ventricular tachycardia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Ear and labyrinth disorders	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Ear and labyrinth disorders; PT: Vertigo	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders	Number of subjects with event, n/N (%)	18/ 3477 (0.52)	17/ 3515 (0.48)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Abdominal distension	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Abdominal pain	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Abdominal pain upper	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Acid peptic disease	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Ascites	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Constipation Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Diabetic gastroenteropathy	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Diarrhoea	Number of subjects with event, n/N (%)	6/ 3477 (0.17)	5/ 3515 (0.14)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Dyspepsia	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Gastrointestinal pain	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Intestinal ischaemia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Nausea	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	5/ 3515 (0.14)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Pancreatitis Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Rectal haemorrhage	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Swollen tongue	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Upper gastrointestinal haemorrhage	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Gastrointestinal disorders; PT: Vomiting	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	9/ 3477 (0.26)	6/ 3515 (0.17)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Asthenia	Number of subjects with event, n/N (%)	7/ 3477 (0.20)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Chest discomfort	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Chest pain	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Discomfort	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Fatigue	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Malaise	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Oedema peripheral	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: General disorders and administration site conditions; PT: Swelling	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	3/ 3515 (0.09)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders; PT: Cardiac cirrhosis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders; PT: Cirrhosis alcoholic	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Hepatobiliary disorders; PT: Hepatic failure Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Immune system disorders	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Immune system disorders; PT: Amyloidosis	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Immune system disorders; PT: Hypersensitivity Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Immune system disorders; PT: Primary amyloidosis	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	13/ 3477 (0.37)	18/ 3515 (0.51)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: COVID-19 pneumonia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Cellulitis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Eczema infected	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Endocarditis staphylococcal	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Erysipelas	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Gastroenteritis	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Localised infection	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Nasopharyngitis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Onychomycosis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Pneumonia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Pneumonia aspiration	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Post procedural infection	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Postoperative wound infection	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Sepsis	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Septic shock Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Urinary tract infection	Number of subjects with event, n/N (%)	4/ 3477 (0.12)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Infections and infestations; PT: Urosepsis	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	3/ 3515 (0.09)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Extradural haematoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Fall	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Femoral neck fracture	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Hip fracture	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Multiple injuries	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Road traffic accident	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Spinal cord injury cervical	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Spinal fracture	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Injury, poisoning and procedural complications; PT: Subdural haematoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations	Number of subjects with event, n/N (%)	11/ 3477 (0.32)	10/ 3515 (0.28)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood creatinine increased	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood potassium increased Number of subjects with event, n/N (%)	5/ 3477 (0.14)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Blood pressure increased Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Ejection fraction decreased	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Gamma-glutamyltransferase increased	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Glomerular filtration rate decreased	Number of subjects with event, n/N (%)	4/ 3477 (0.12)	7/ 3515 (0.20)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Investigations; PT: Weight decreased	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders	Number of subjects with event, n/N (%)	28/ 3477 (0.81)	15/ 3515 (0.43)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Cachexia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Decreased appetite	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Electrolyte imbalance	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Failure to thrive	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Gout Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia	Number of subjects with event, n/N (%)	23/ 3477 (0.66)	11/ 3515 (0.31)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hyponatraemia	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Hypovolaemia	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Metabolism and nutrition disorders; PT: Malnutrition	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	5/ 3515 (0.14)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Back pain	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Immobilisation syndrome	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Mobility decreased	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with event, n/N (%)	25/ 3477 (0.72)	19/ 3515 (0.54)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Adenocarcinoma gastric	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Adenocarcinoma of colon	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Bile duct cancer	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Bladder cancer	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Brain neoplasm	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Breast cancer	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Cholangiocarcinoma	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Colon cancer	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Colon neoplasm	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Hepatic cancer	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Hodgkin's disease	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Laryngeal neoplasm	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lung infiltration malignant	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lung neoplasm malignant	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Lymphoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Malignant neoplasm of renal pelvis	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Metastases to liver	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Neuroendocrine carcinoma of the skin	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Neuroendocrine tumour of the lung	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Non-small cell lung cancer	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Oesophageal adenocarcinoma	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Oesophageal squamous cell carcinoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Pancreatic carcinoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Papillary serous endometrial carcinoma	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Papillary thyroid cancer	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Prostate cancer	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Prostate cancer metastatic	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Small cell lung cancer	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Squamous cell carcinoma of skin	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Tongue neoplasm malignant stage unspecified	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders	Number of subjects with event, n/N (%)	11/ 3477 (0.32)	20/ 3515 (0.57)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Aphasia	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Cerebral haemorrhage	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Cerebral infarction	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Cognitive disorder	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Dementia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Dizziness	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	5/ 3515 (0.14)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Dysstasia	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Encephalopathy Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Essential tremor	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Guillain-Barre syndrome	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Headache	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Metabolic encephalopathy	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Orthostatic intolerance	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Parkinson's disease	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Sciatica	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Somnolence	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Nervous system disorders; PT: Vascular dementia	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	7/ 3515 (0.20)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Anxiety	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Anxiety disorder	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Confusional state Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Delusion	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Depression	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Insomnia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Schizophrenia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Psychiatric disorders; PT: Stress	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders	Number of subjects with event, n/N (%)	29/ 3477 (0.83)	18/ 3515 (0.51)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Acute kidney injury	Number of subjects with event, n/N (%)	4/ 3477 (0.12)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Chronic kidney disease	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: End stage renal disease	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT	Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Incontinence Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Renal failure	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	5/ 3515 (0.14)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Renal impairment	Number of subjects with event, n/N (%)	14/ 3477 (0.40)	6/ 3515 (0.17)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Renal and urinary disorders; PT: Urinary retention	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Reproductive system and breast disorders	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Reproductive system and breast disorders; PT: Gynaecomastia	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	8/ 3477 (0.23)	9/ 3515 (0.26)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Acute respiratory failure	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Chronic obstructive pulmonary disease	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea	Number of subjects with event, n/N (%)	4/ 3477 (0.12)	3/ 3515 (0.09)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea exertional	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Interstitial lung disease	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleural effusion	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Pleurisy	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Rales	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Respiratory, thoracic and mediastinal disorders; PT: Respiratory failure	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	3/ 3477 (0.09)	8/ 3515 (0.23)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Dermatitis allergic	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Eczema	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Henoch-Schonlein purpura	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Hyperhidrosis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Pruritus	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Rash	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Skin and subcutaneous tissue disorders; PT: Rash pruritic	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Surgical and medical procedures	Number of subjects with event, n/N (%)	2/ 3477 (0.06)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Surgical and medical procedures; PT: Internal fixation of fracture	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Surgical and medical procedures; PT: Pancreaticosplenectomy	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders	Number of subjects with event, n/N (%)	5/ 3477 (0.14)	4/ 3515 (0.11)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Arterial thrombosis	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Flushing	Number of subjects with event, n/N (%)	0/ 3477 (0.00)	2/ 3515 (0.06)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Hypotension	Number of subjects with event, n/N (%)	4/ 3477 (0.12)	1/ 3515 (0.03)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Finerenone (N=3477)	Placebo (N=3515)
SOC: Vascular disorders; PT: Vasculitis	Number of subjects with event, n/N (%)	1/ 3477 (0.03)	0/ 3515 (0.00)

Analysis based on all AE starting at beginning of treatment until end of study.
Analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with Study-Id as additional covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

BayerVital
Meta-Analysis - Datacut: 25JUL2024+19APR2021+29JUL2020
Pooled Population - Finerenone vs. Placebo
Summary of medical history of interest
Full Analysis Set

	Finerenone (N=3488)	Placebo (N=3520)
	n (%)	n (%)
Atrial Fibrillation And Atrial Flutter (PBMQ)	1777 (50.95)	1754 (49.83)
Hyperlipidemia (MLG)	937 (26.86)	968 (27.50)
Type 2 Diabetes Mellitus (PT)	1702 (48.80)	1745 (49.57)
Chronic Kidney Disease (PT)	1049 (30.07)	1071 (30.43)
Hypertension (MLG)	3113 (89.25)	3193 (90.71)
Ischaemic Stroke/Transitory Ischaemic Attack (PBMQ)	520 (14.91)	510 (14.49)
Cardiac Failure (MLG)	3488 (100.00)	3520 (100.00)
Carotid Endarterectomy (PT)	26 (0.75)	19 (0.54)
Coronary Artery Bypass Graft (PBMQ)	530 (15.19)	535 (15.20)
Myocardial Infarction (MLG)	934 (26.78)	922 (26.19)
Percutaneous Coronary Intervention (PBMQ)	803 (23.02)	776 (22.05)
Coronary Artery Disease (PBMQ)	1487 (42.63)	1541 (43.78)
Peripheral Arterial Disease (PBMQ)	415 (11.90)	410 (11.65)

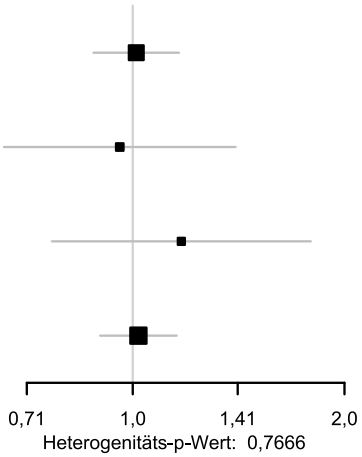
Forest-Plots für Unerwünschte Ereignisse nach SOC und PT
Aus Gründen der Übersicht erfolgt die Darstellung der Ergebnisse der Analysen nach SOC und PT anhand Forest-Plots in diesem Anhang.

Forest-Plots wurden für eine SOC bzw. ein PT generiert, sofern die Häufigkeitskriterien für die Darstellung (Ereignisse, die bei mindestens 1% der Patienten in einem Studienarm auftraten) für die gepoolte Population und mindestens eine Einzelstudie erfüllt waren. Sind die Häufigkeitskriterien für eine Einzelstudie nicht erfüllt, wird die Studie im Forest-Plot nicht dargestellt; Patienten mit Ereignis fließen weiterhin in die Analyse der gepoolten Population mit ein.

Jegliche UE nach SOC und PT

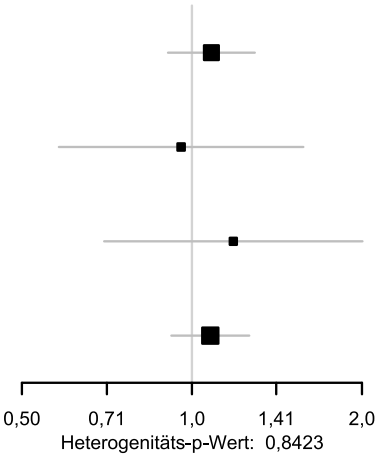
Jegliche UE:
SOC Erkrankungen des Blutes und des Lymphsystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	349/2.993 (11,7)	345/2.993 (11,5)	1,01 [0,88; 1,16]
FIDELIO-DKD	38/195 (19,5)	49/241 (20,3)	0,96 [0,66; 1,40]
FIGARO-DKD	41/289 (14,2)	34/281 (12,1)	1,17 [0,77; 1,79]
Gepoolte Population	428/3.477 (12,3)	428/3.515 (12,2)	1,02 [0,90; 1,15]



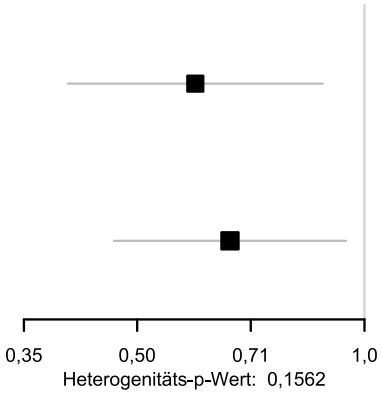
Jegliche UE:
PT Anämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	236/2.993 (7,9)	218/2.993 (7,3)	1,08 [0,91; 1,29]
FIDELIO-DKD	24/195 (12,3)	31/241 (12,9)	0,96 [0,58; 1,57]
FIGARO-DKD	28/289 (9,7)	23/281 (8,2)	1,18 [0,70; 2,00]
Gepoolte Population	288/3.477 (8,3)	272/3.515 (7,7)	1,08 [0,92; 1,26]



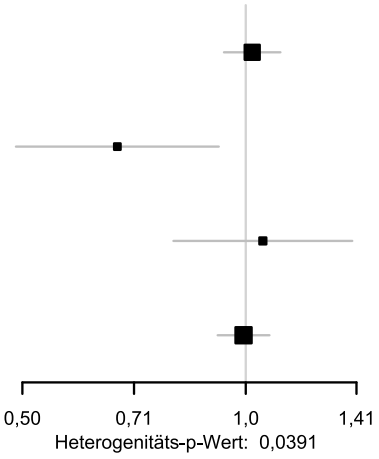
Jegliche UE:
PT Eisenmangelanämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	40/2.993 (1,3)	67/2.993 (2,2)	0,60 [0,40; 0,88]
Gepoolte Population	50/3.477 (1,4)	76/3.515 (2,2)	0,66 [0,47; 0,95]



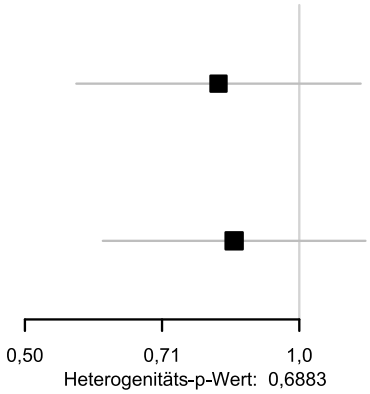
Jegliche UE:
SOC Herzerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	757/2.993 (25,3)	742/2.993 (24,8)	1,02 [0,93; 1,11]
FIDELIO-DKD	44/195 (22,6)	81/241 (33,6)	0,67 [0,49; 0,92]
FIGARO-DKD	77/289 (26,6)	71/281 (25,3)	1,05 [0,80; 1,39]
Gepoolte Population	878/3.477 (25,3)	894/3.515 (25,4)	0,99 [0,92; 1,08]



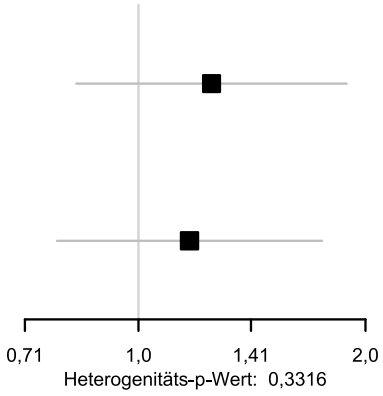
Jegliche UE:
PT Angina pectoris

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	53/2.993 (1,8)	65/2.993 (2,2)	0,82 [0,57; 1,17]
Gepoolte Population	63/3.477 (1,8)	75/3.515 (2,1)	0,85 [0,61; 1,18]



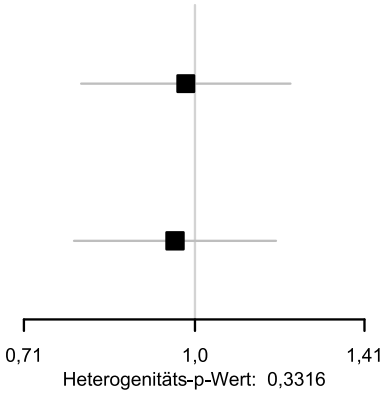
Jegliche UE:
PT Angina pectoris instabil

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	50/2.993 (1,7)	40/2.993 (1,3)	1,25 [0,83; 1,89]
Gepoolte Population	50/3.477 (1,4)	43/3.515 (1,2)	1,17 [0,78; 1,75]



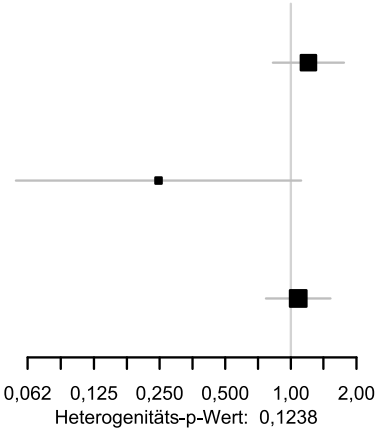
Jegliche UE:
PT Vorhofflimmern

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	160/2.993 (5,3)	163/2.993 (5,4)	0,98 [0,79; 1,21]
Gepoolte Population	170/3.477 (4,9)	178/3.515 (5,1)	0,96 [0,78; 1,18]



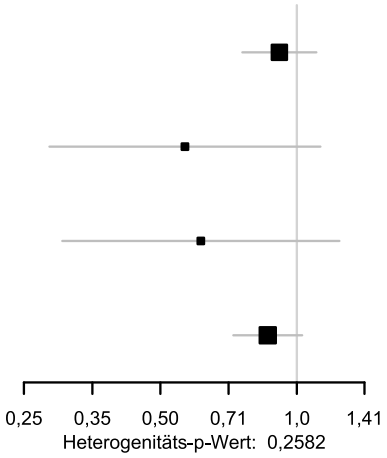
Jegliche UE:
PT Bradykardie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	59/2.993 (2,0)	49/2.993 (1,6)	1,20 [0,83; 1,75]
FIDELIO-DKD	2/195 (1,0)	10/241 (4,1)	0,25 [0,05; 1,11]
Gepoolte Population	67/3.477 (1,9)	63/3.515 (1,8)	1,08 [0,77; 1,52]



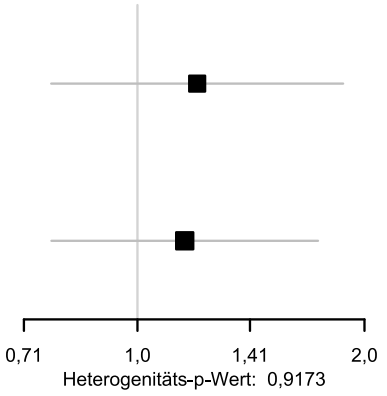
Jegliche UE:
PT Herzinsuffizienz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	194/2.993 (6,5)	212/2.993 (7,1)	0,92 [0,76; 1,10]
FIDELIO-DKD	11/195 (5,6)	24/241 (10,0)	0,57 [0,28; 1,13]
FIGARO-DKD	12/289 (4,2)	19/281 (6,8)	0,61 [0,30; 1,24]
Gepoolte Population	217/3.477 (6,2)	255/3.515 (7,3)	0,86 [0,72; 1,03]



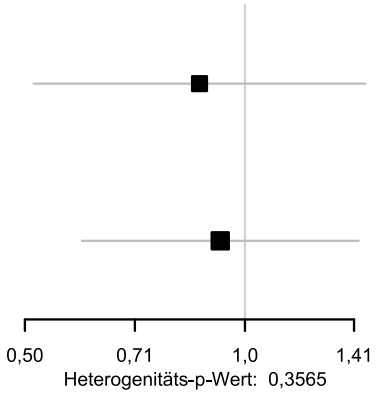
Jegliche UE:
PT Koronare Herzerkrankung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	42/2.993 (1,4)	35/2.993 (1,2)	1,20 [0,77; 1,87]
Gepoolte Population	49/3.477 (1,4)	43/3.515 (1,2)	1,16 [0,77; 1,74]



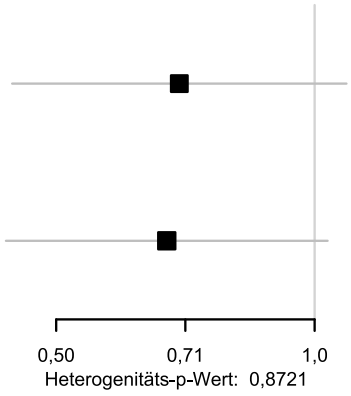
Jegliche UE:
PT Mitralklappeninsuffizienz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	26/2.993 (0,9)	30/2.993 (1,0)	0,87 [0,51; 1,46]
Gepoolte Population	38/3.477 (1,1)	42/3.515 (1,2)	0,93 [0,60; 1,43]



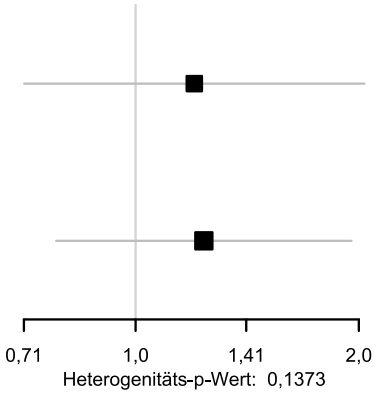
Jegliche UE:
PT Palpitationen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	32/2.993 (1,1)	46/2.993 (1,5)	0,70 [0,44; 1,09]
Gepoolte Population	34/3.477 (1,0)	51/3.515 (1,5)	0,67 [0,44; 1,04]



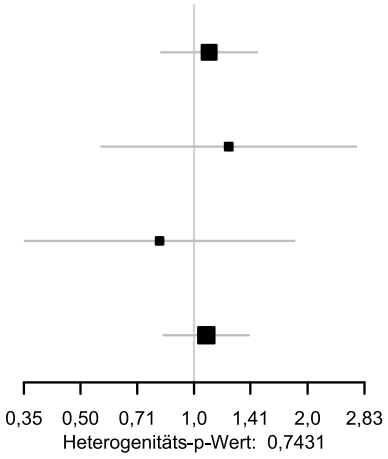
Jegliche UE:
PT Ventrikuläre Extrasystolen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	30/2.993 (1,0)	25/2.993 (0,8)	1,20 [0,71; 2,04]
Gepoolte Population	40/3.477 (1,2)	33/3.515 (0,9)	1,24 [0,78; 1,96]



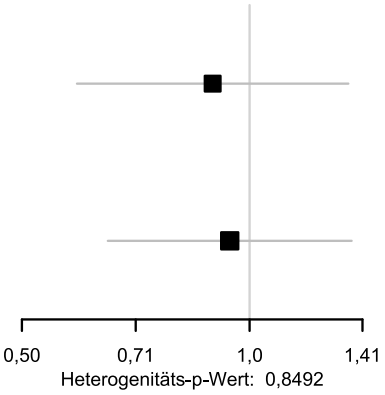
Jegliche UE:
SOC Erkrankungen des Ohrs und des Labyrinths

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	91/2.993 (3,0)	83/2.993 (2,8)	1,10 [0,82; 1,47]
FIDELIO-DKD	12/195 (6,2)	12/241 (5,0)	1,24 [0,57; 2,69]
FIGARO-DKD	10/289 (3,5)	12/281 (4,3)	0,81 [0,36; 1,85]
Gepoolte Population	113/3.477 (3,2)	107/3.515 (3,0)	1,08 [0,83; 1,40]



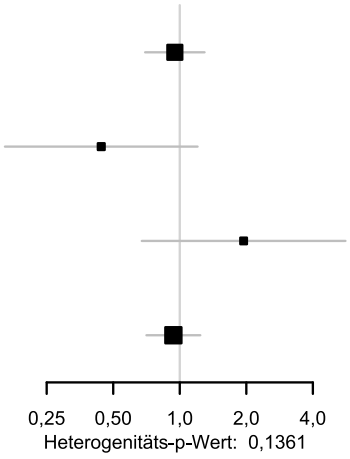
Jegliche UE:
PT Vertigo

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	42/2.993 (1,4)	47/2.993 (1,6)	0,89 [0,59; 1,35]
Gepoolte Population	53/3.477 (1,5)	57/3.515 (1,6)	0,94 [0,65; 1,36]



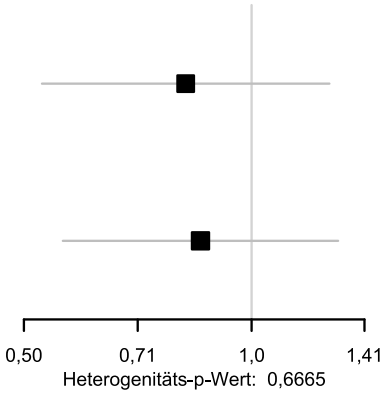
Jegliche UE:
SOC Endokrine Erkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	76/2.993 (2,5)	80/2.993 (2,7)	0,95 [0,70; 1,30]
FIDELIO-DKD	5/195 (2,6)	14/241 (5,8)	0,44 [0,16; 1,20]
FIGARO-DKD	10/289 (3,5)	5/281 (1,8)	1,94 [0,67; 5,62]
Gepoolte Population	91/3.477 (2,6)	99/3.515 (2,8)	0,94 [0,71; 1,24]



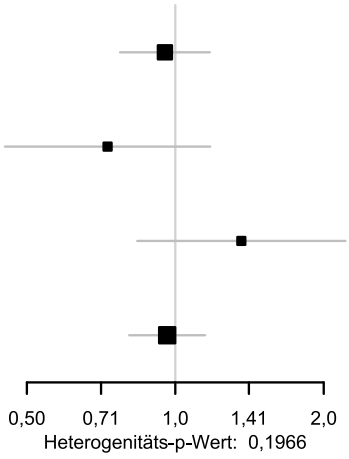
Jegliche UE:
PT Hypothyreose

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	36/2.993 (1,2)	44/2.993 (1,5)	0,82 [0,53; 1,27]
Gepoolte Population	40/3.477 (1,2)	47/3.515 (1,3)	0,86 [0,56; 1,30]



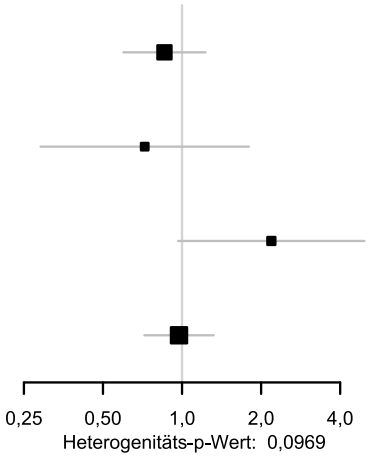
Jegliche UE:
SOC Augenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	161/2.993 (5,4)	169/2.993 (5,6)	0,95 [0,77; 1,18]
FIDELIO-DKD	23/195 (11,8)	39/241 (16,2)	0,73 [0,45; 1,18]
FIGARO-DKD	35/289 (12,1)	25/281 (8,9)	1,36 [0,84; 2,21]
Gepoolte Population	219/3.477 (6,3)	233/3.515 (6,6)	0,96 [0,81; 1,15]



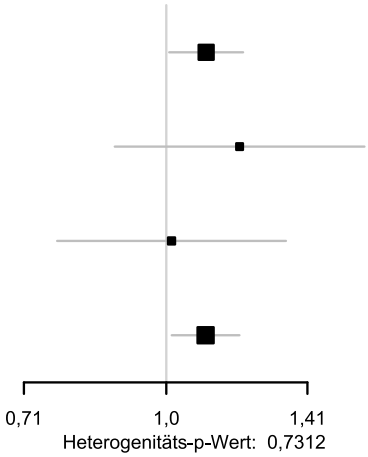
Jegliche UE:
PT Katarakt

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	54/2.993 (1,8)	63/2.993 (2,1)	0,86 [0,60; 1,23]
FIDELIO-DKD	7/195 (3,6)	12/241 (5,0)	0,72 [0,29; 1,80]
FIGARO-DKD	18/289 (6,2)	8/281 (2,8)	2,19 [0,97; 4,95]
Gepoolte Population	79/3.477 (2,3)	83/3.515 (2,4)	0,97 [0,72; 1,32]



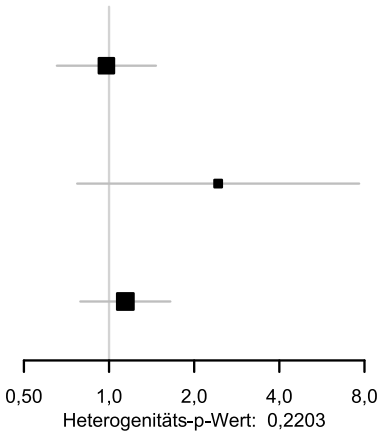
Jegliche UE:
SOC Erkrankungen des Gastrointestinaltrakts

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	757/2.993 (25,3)	687/2.993 (23,0)	1,10 [1,01; 1,21]
FIDELIO-DKD	59/195 (30,3)	61/241 (25,3)	1,20 [0,88; 1,62]
FIGARO-DKD	75/289 (26,0)	72/281 (25,6)	1,01 [0,77; 1,34]
Gepoolte Population	891/3.477 (25,6)	820/3.515 (23,3)	1,10 [1,01; 1,19]



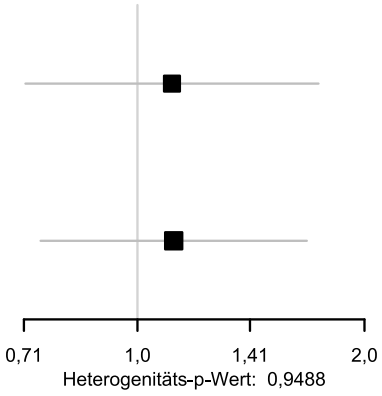
Jegliche UE:
PT Abdominalschmerz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	46/2.993 (1,5)	47/2.993 (1,6)	0,98 [0,65; 1,46]
FIGARO-DKD	10/289 (3,5)	4/281 (1,4)	2,43 [0,77; 7,66]
Gepoolte Population	60/3.477 (1,7)	53/3.515 (1,5)	1,14 [0,79; 1,65]



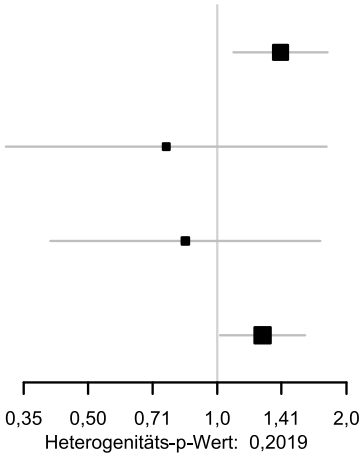
Jegliche UE:
PT Schmerzen Oberbauch

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	40/2.993 (1,3)	36/2.993 (1,2)	1,11 [0,71; 1,74]
Gepoolte Population	48/3.477 (1,4)	44/3.515 (1,3)	1,12 [0,74; 1,68]



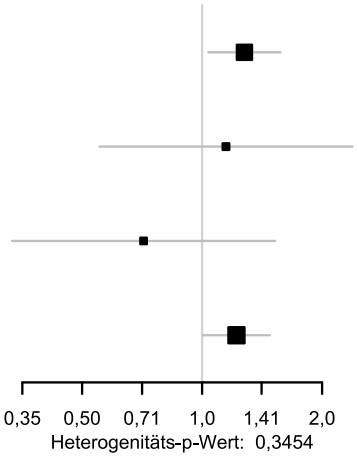
Jegliche UE:
PT Obstipation

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	139/2.993 (4,6)	99/2.993 (3,3)	1,40 [1,09; 1,81]
FIDELIO-DKD	8/195 (4,1)	13/241 (5,4)	0,76 [0,32; 1,80]
FIGARO-DKD	13/289 (4,5)	15/281 (5,3)	0,84 [0,41; 1,74]
Gepoolte Population	160/3.477 (4,6)	127/3.515 (3,6)	1,28 [1,02; 1,60]



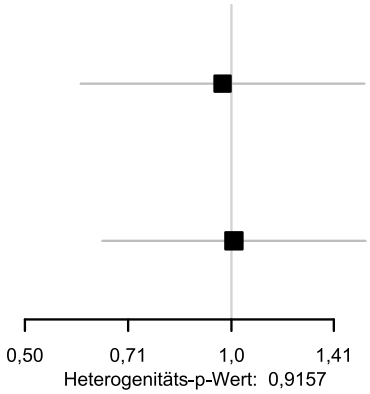
Jegliche UE:
PT Diarrhö

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	189/2.993 (6,3)	148/2.993 (4,9)	1,28 [1,04; 1,57]
FIDELIO-DKD	13/195 (6,7)	14/241 (5,8)	1,15 [0,55; 2,38]
FIGARO-DKD	11/289 (3,8)	15/281 (5,3)	0,71 [0,33; 1,53]
Gepoolte Population	213/3.477 (6,1)	177/3.515 (5,0)	1,22 [1,00; 1,48]



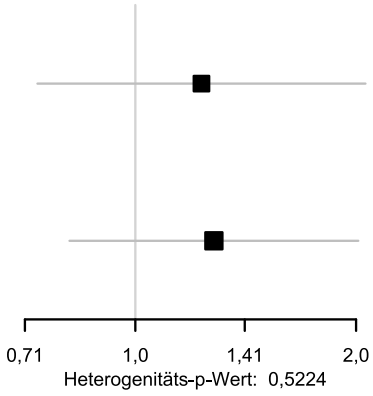
Jegliche UE:
PT Dyspepsie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	33/2.993 (1,1)	34/2.993 (1,1)	0,97 [0,60; 1,56]
Gepoolte Population	39/3.477 (1,1)	39/3.515 (1,1)	1,01 [0,65; 1,57]



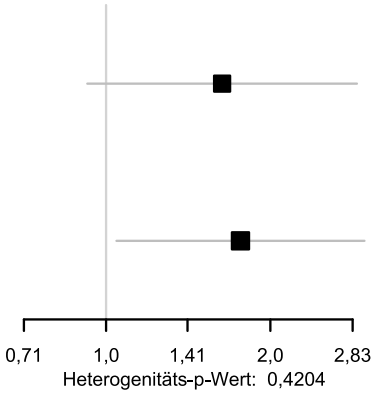
Jegliche UE:
PT Gastritis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	32/2.993 (1,1)	26/2.993 (0,9)	1,23 [0,74; 2,06]
Gepoolte Population	42/3.477 (1,2)	33/3.515 (0,9)	1,28 [0,81; 2,01]



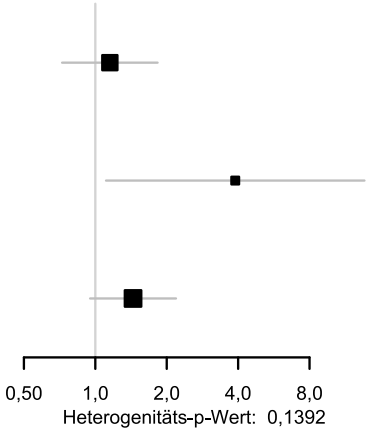
Jegliche UE:
PT Gastrointestinalblutung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	31/2.993 (1,0)	19/2.993 (0,6)	1,63 [0,92; 2,88]
Gepoolte Population	38/3.477 (1,1)	22/3.515 (0,6)	1,76 [1,04; 2,97]



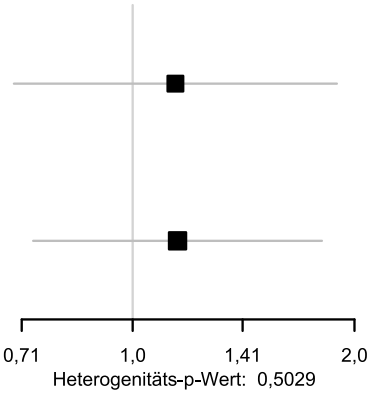
Jegliche UE:
PT Gastroösophageale Refluxerkrankung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	38/2.993 (1,3)	33/2.993 (1,1)	1,15 [0,72; 1,83]
FIGARO-DKD	12/289 (4,2)	3/281 (1,1)	3,89 [1,11; 13,64]
Gepoolte Population	53/3.477 (1,5)	37/3.515 (1,1)	1,44 [0,95; 2,19]



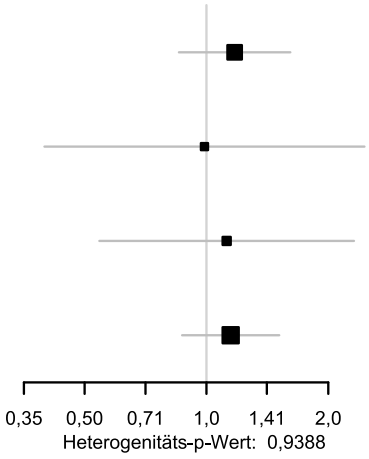
Jegliche UE:
PT Hämorrhoiden

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	32/2.993 (1,1)	28/2.993 (0,9)	1,14 [0,69; 1,89]
Gepoolte Population	40/3.477 (1,2)	35/3.515 (1,0)	1,15 [0,73; 1,81]



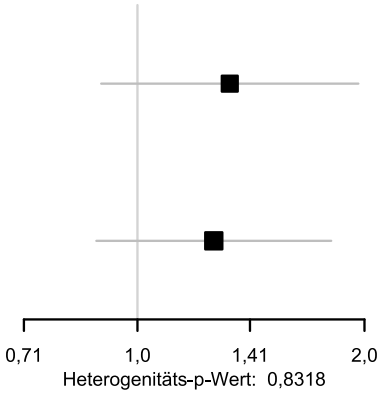
Jegliche UE:
PT Übelkeit

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	81/2.993 (2,7)	69/2.993 (2,3)	1,17 [0,85; 1,61]
FIDELIO-DKD	8/195 (4,1)	10/241 (4,1)	0,99 [0,40; 2,46]
FIGARO-DKD	15/289 (5,2)	13/281 (4,6)	1,12 [0,54; 2,31]
Gepoolte Population	104/3.477 (3,0)	92/3.515 (2,6)	1,15 [0,87; 1,51]



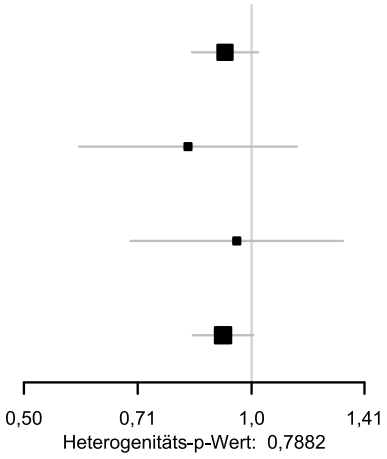
Jegliche UE:
PT Erbrechen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	57/2.993 (1,9)	43/2.993 (1,4)	1,33 [0,90; 1,96]
Gepoolte Population	66/3.477 (1,9)	53/3.515 (1,5)	1,26 [0,88; 1,81]



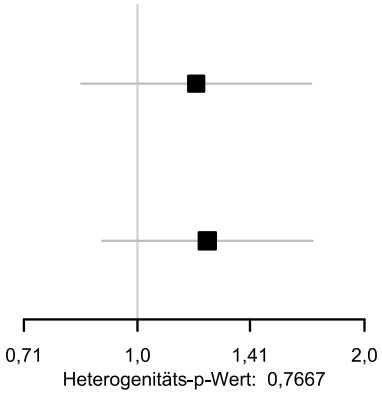
Jegliche UE:
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	581/2.993 (19,4)	630/2.993 (21,0)	0,92 [0,83; 1,02]
FIDELIO-DKD	44/195 (22,6)	66/241 (27,4)	0,82 [0,59; 1,15]
FIGARO-DKD	58/289 (20,1)	59/281 (21,0)	0,96 [0,69; 1,32]
Gepoolte Population	683/3.477 (19,6)	755/3.515 (21,5)	0,92 [0,84; 1,01]



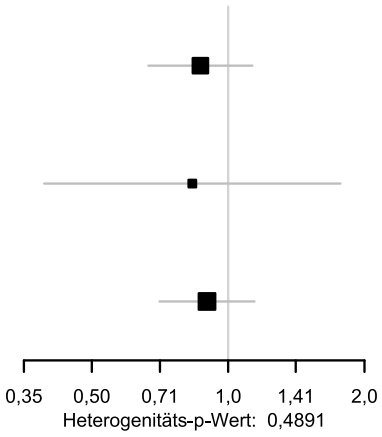
Jegliche UE:
PT Asthenie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	67/2.993 (2,2)	56/2.993 (1,9)	1,20 [0,84; 1,70]
Gepoolte Population	81/3.477 (2,3)	66/3.515 (1,9)	1,24 [0,90; 1,71]



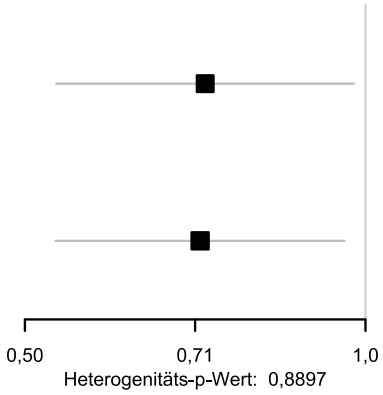
Jegliche UE:
PT Brustkorbschmerz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	99/2.993 (3,3)	114/2.993 (3,8)	0,87 [0,67; 1,13]
FIGARO-DKD	12/289 (4,2)	14/281 (5,0)	0,83 [0,39; 1,77]
Gepoolte Population	120/3.477 (3,5)	135/3.515 (3,8)	0,90 [0,71; 1,14]



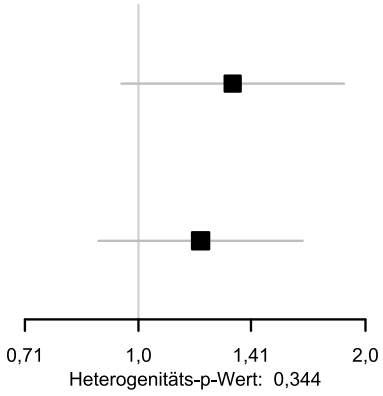
Jegliche UE:
PT Tod

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	70/2.993 (2,3)	97/2.993 (3,2)	0,72 [0,53; 0,98]
Gepoolte Population	74/3.477 (2,1)	104/3.515 (3,0)	0,71 [0,53; 0,96]



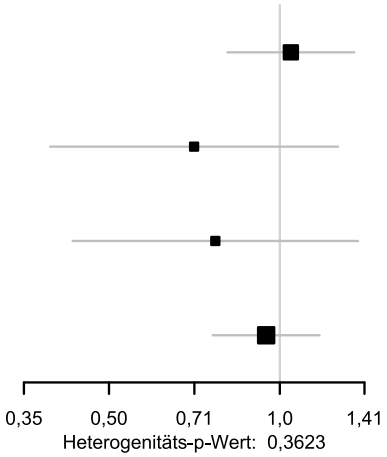
Jegliche UE:
PT Ermüdung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	76/2.993 (2,5)	57/2.993 (1,9)	1,33 [0,95; 1,87]
Gepoolte Population	85/3.477 (2,4)	71/3.515 (2,0)	1,21 [0,89; 1,65]



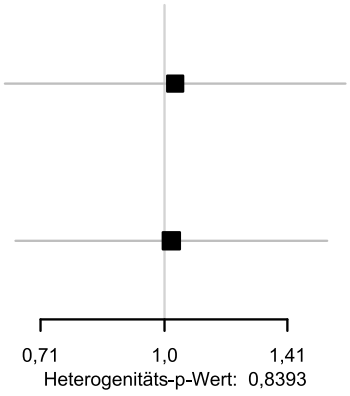
Jegliche UE:
PT Ödem peripher

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	114/2.993 (3,8)	109/2.993 (3,6)	1,05 [0,81; 1,35]
FIDELIO-DKD	16/195 (8,2)	28/241 (11,6)	0,71 [0,39; 1,27]
FIGARO-DKD	19/289 (6,6)	24/281 (8,5)	0,77 [0,43; 1,37]
Gepoolte Population	149/3.477 (4,3)	161/3.515 (4,6)	0,95 [0,76; 1,18]



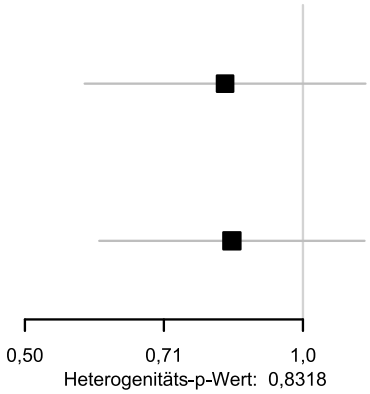
Jegliche UE:
PT Periphere Schwellung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	34/2.993 (1,1)	33/2.993 (1,1)	1,03 [0,64; 1,66]
Gepoolte Population	40/3.477 (1,2)	40/3.515 (1,1)	1,02 [0,66; 1,58]



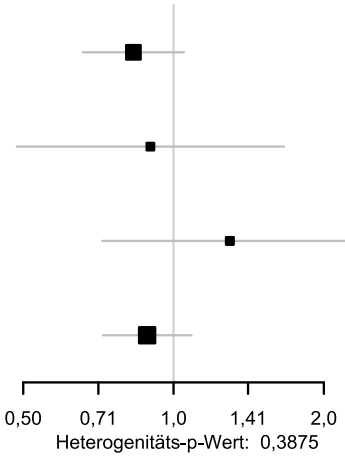
Jegliche UE:
PT Fieber

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	56/2.993 (1,9)	68/2.993 (2,3)	0,82 [0,58; 1,17]
Gepoolte Population	63/3.477 (1,8)	76/3.515 (2,2)	0,84 [0,60; 1,17]



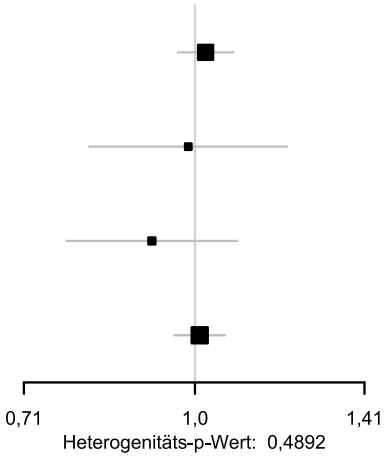
Jegliche UE:
SOC Leber- und Gallenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	123/2.993 (4,1)	148/2.993 (4,9)	0,83 [0,66; 1,05]
FIDELIO-DKD	16/195 (8,2)	22/241 (9,1)	0,90 [0,49; 1,66]
FIGARO-DKD	24/289 (8,3)	18/281 (6,4)	1,30 [0,72; 2,34]
Gepoolte Population	163/3.477 (4,7)	188/3.515 (5,3)	0,89 [0,72; 1,09]



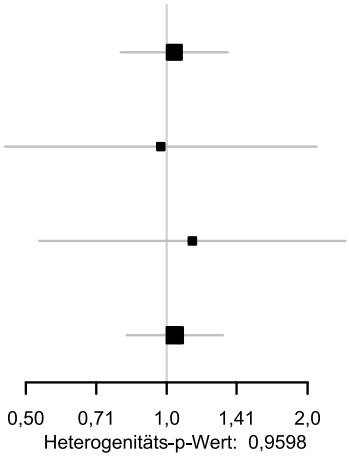
Jegliche UE:
SOC Infektionen und parasitäre Erkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	1.358/2.993 (45,4)	1.329/2.993 (44,4)	1,02 [0,97; 1,08]
FIDELIO-DKD	91/195 (46,7)	114/241 (47,3)	0,99 [0,81; 1,21]
FIGARO-DKD	131/289 (45,3)	139/281 (49,5)	0,92 [0,77; 1,09]
Gepoolte Population	1.580/3.477 (45,4)	1.582/3.515 (45,0)	1,01 [0,96; 1,06]



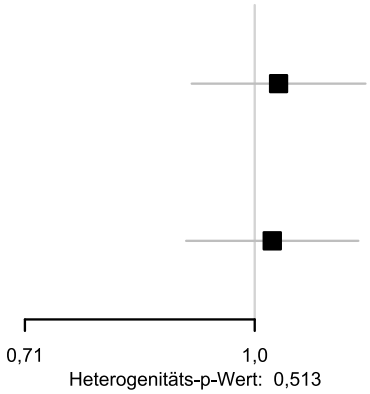
Jegliche UE:
PT Bronchitis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	109/2.993 (3,6)	105/2.993 (3,5)	1,04 [0,80; 1,35]
FIDELIO-DKD	11/195 (5,6)	14/241 (5,8)	0,97 [0,45; 2,09]
FIGARO-DKD	14/289 (4,8)	12/281 (4,3)	1,13 [0,53; 2,41]
Gepoolte Population	134/3.477 (3,9)	131/3.515 (3,7)	1,04 [0,82; 1,32]



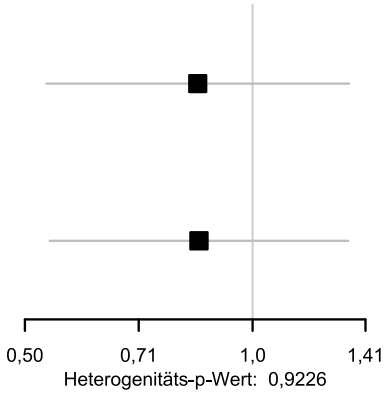
Jegliche UE:
PT COVID-19

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	396/2.993 (13,2)	382/2.993 (12,8)	1,04 [0,91; 1,18]
Gepoolte Population	402/3.477 (11,6)	392/3.515 (11,2)	1,03 [0,90; 1,17]



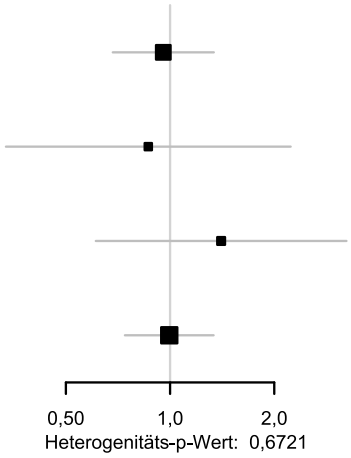
Jegliche UE:
PT COVID-19-Lungenentzündung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	33/2.993 (1,1)	39/2.993 (1,3)	0,85 [0,53; 1,34]
Gepoolte Population	34/3.477 (1,0)	40/3.515 (1,1)	0,85 [0,54; 1,34]



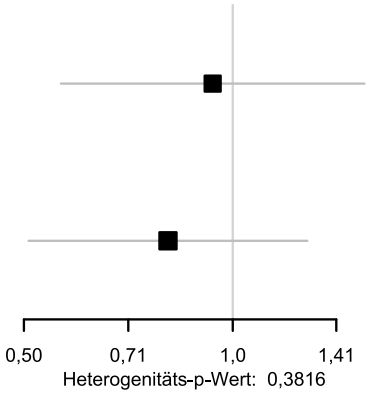
Jegliche UE:
PT Zellulitis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	65/2.993 (2,2)	68/2.993 (2,3)	0,96 [0,68; 1,34]
FIDELIO-DKD	7/195 (3,6)	10/241 (4,1)	0,87 [0,34; 2,23]
FIGARO-DKD	13/289 (4,5)	9/281 (3,2)	1,40 [0,61; 3,23]
Gepoolte Population	85/3.477 (2,4)	87/3.515 (2,5)	0,99 [0,74; 1,34]



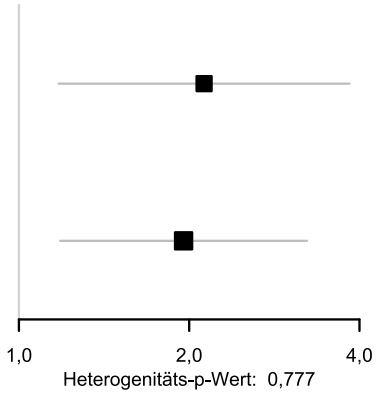
Jegliche UE:
PT Zystitis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	29/2.993 (1,0)	31/2.993 (1,0)	0,94 [0,57; 1,55]
Gepoolte Population	32/3.477 (0,9)	40/3.515 (1,1)	0,81 [0,51; 1,28]



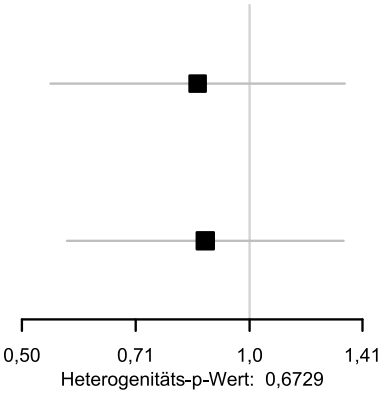
Jegliche UE:
PT Gastroenteritis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	34/2.993 (1,1)	16/2.993 (0,5)	2,13 [1,18; 3,84]
Gepoolte Population	44/3.477 (1,3)	23/3.515 (0,7)	1,95 [1,18; 3,23]



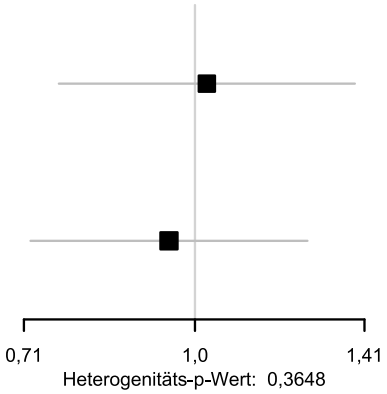
Jegliche UE:
PT Herpes zoster

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	35/2.993 (1,2)	41/2.993 (1,4)	0,85 [0,55; 1,34]
Gepoolte Population	40/3.477 (1,2)	46/3.515 (1,3)	0,87 [0,57; 1,33]



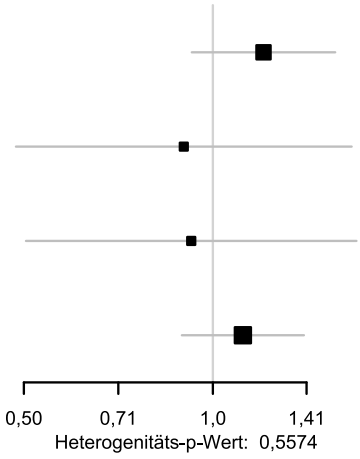
Jegliche UE:
PT Grippe

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	84/2.993 (2,8)	82/2.993 (2,7)	1,02 [0,76; 1,38]
Gepoolte Population	92/3.477 (2,6)	98/3.515 (2,8)	0,95 [0,72; 1,26]



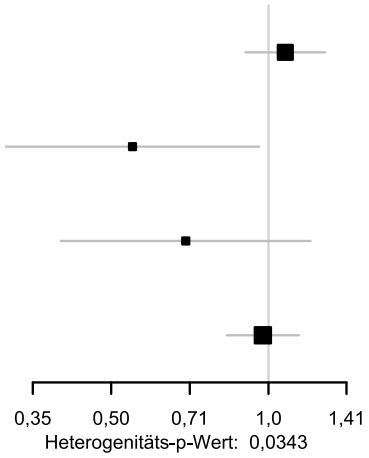
Jegliche UE:
PT Nasopharyngitis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	118/2.993 (3,9)	98/2.993 (3,3)	1,20 [0,93; 1,57]
FIDELIO-DKD	16/195 (8,2)	22/241 (9,1)	0,90 [0,49; 1,66]
FIGARO-DKD	19/289 (6,6)	20/281 (7,1)	0,92 [0,50; 1,69]
Gepoolte Population	153/3.477 (4,4)	140/3.515 (4,0)	1,12 [0,89; 1,40]



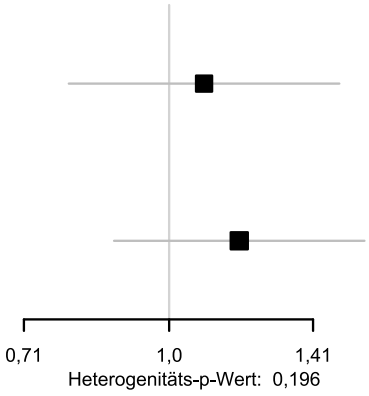
Jegliche UE:
PT Pneumonie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	238/2.993 (8,0)	221/2.993 (7,4)	1,08 [0,90; 1,28]
FIDELIO-DKD	16/195 (8,2)	36/241 (14,9)	0,55 [0,31; 0,96]
FIGARO-DKD	20/289 (6,9)	28/281 (10,0)	0,69 [0,40; 1,20]
Gepoolte Population	274/3.477 (7,9)	285/3.515 (8,1)	0,98 [0,83; 1,14]



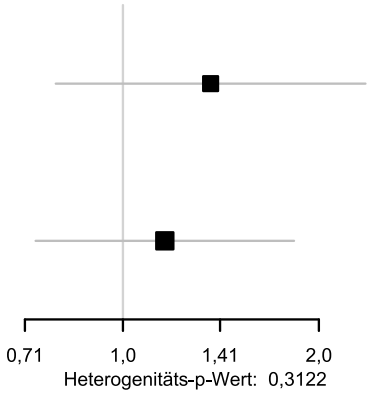
Jegliche UE:
PT Atemwegsinfektion

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	75/2.993 (2,5)	69/2.993 (2,3)	1,09 [0,79; 1,50]
Gepoolte Population	91/3.477 (2,6)	78/3.515 (2,2)	1,18 [0,88; 1,59]



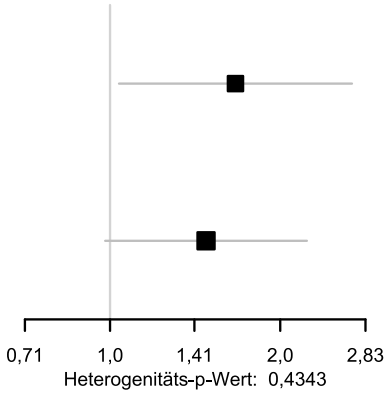
Jegliche UE:
PT Virusinfektion der Atemwege

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	30/2.993 (1,0)	22/2.993 (0,7)	1,36 [0,79; 2,36]
Gepoolte Population	39/3.477 (1,1)	34/3.515 (1,0)	1,16 [0,73; 1,83]



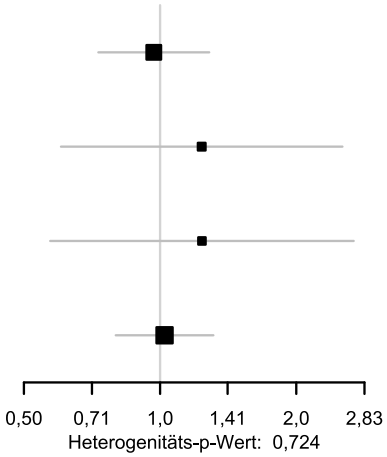
Jegliche UE:
PT Sepsis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	45/2.993 (1,5)	27/2.993 (0,9)	1,67 [1,04; 2,68]
Gepoolte Population	55/3.477 (1,6)	38/3.515 (1,1)	1,48 [0,98; 2,23]



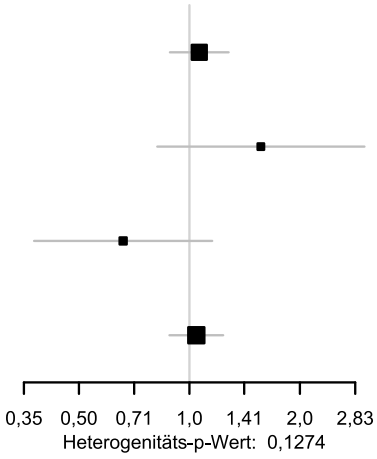
Jegliche UE:
PT Infektion der oberen Atemwege

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	92/2.993 (3,1)	95/2.993 (3,2)	0,97 [0,73; 1,28]
FIDELIO-DKD	14/195 (7,2)	14/241 (5,8)	1,24 [0,60; 2,53]
FIGARO-DKD	14/289 (4,8)	11/281 (3,9)	1,24 [0,57; 2,68]
Gepoolte Population	120/3.477 (3,5)	120/3.515 (3,4)	1,02 [0,80; 1,31]



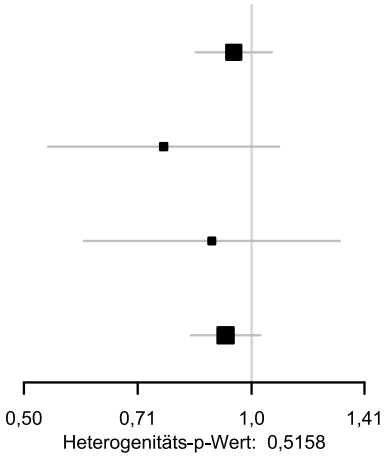
Jegliche UE:
PT Harnwegsinfektion

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	217/2.993 (7,3)	204/2.993 (6,8)	1,06 [0,88; 1,28]
FIDELIO-DKD	19/195 (9,7)	15/241 (6,2)	1,57 [0,82; 3,00]
FIGARO-DKD	19/289 (6,6)	28/281 (10,0)	0,66 [0,38; 1,15]
Gepoolte Population	255/3.477 (7,3)	247/3.515 (7,0)	1,04 [0,88; 1,24]



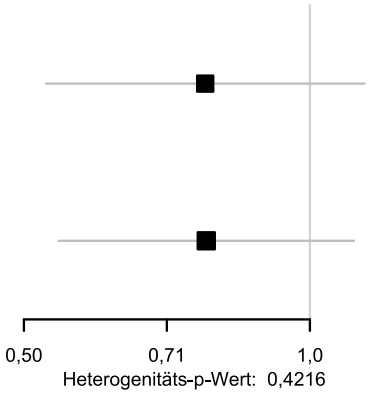
Jegliche UE:
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	466/2.993 (15,6)	492/2.993 (16,4)	0,95 [0,84; 1,06]
FIDELIO-DKD	39/195 (20,0)	63/241 (26,1)	0,77 [0,54; 1,09]
FIGARO-DKD	41/289 (14,2)	45/281 (16,0)	0,89 [0,60; 1,31]
Gepoolte Population	546/3.477 (15,7)	600/3.515 (17,1)	0,92 [0,83; 1,03]



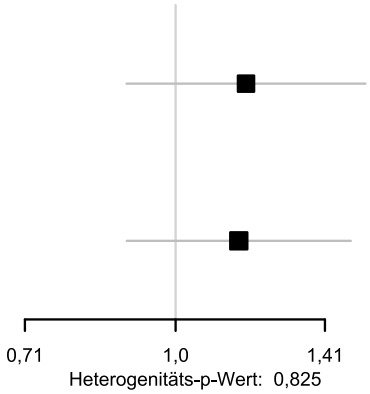
Jegliche UE:
PT Kontusion

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	45/2.993 (1,5)	58/2.993 (1,9)	0,78 [0,53; 1,14]
Gepoolte Population	52/3.477 (1,5)	68/3.515 (1,9)	0,78 [0,54; 1,11]



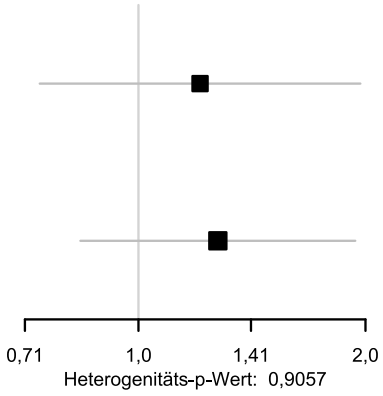
Jegliche UE:
PT Sturz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	107/2.993 (3,6)	91/2.993 (3,0)	1,18 [0,89; 1,55]
Gepoolte Population	120/3.477 (3,5)	105/3.515 (3,0)	1,16 [0,89; 1,50]



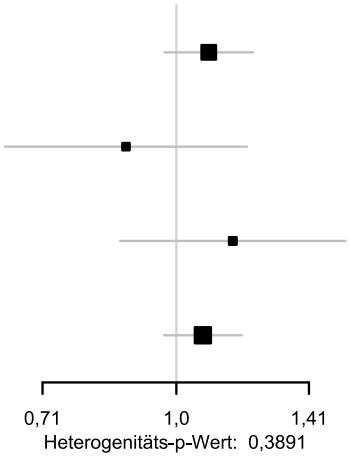
Jegliche UE:
PT Verletzung der Gliedmaßen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	35/2.993 (1,2)	29/2.993 (1,0)	1,21 [0,74; 1,97]
Gepoolte Population	48/3.477 (1,4)	39/3.515 (1,1)	1,27 [0,84; 1,94]



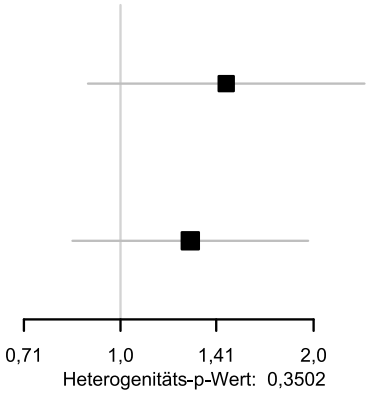
Jegliche UE:
SOC Untersuchungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	509/2.993 (17,0)	468/2.993 (15,6)	1,09 [0,97; 1,22]
FIDELIO-DKD	49/195 (25,1)	69/241 (28,6)	0,88 [0,64; 1,20]
FIGARO-DKD	75/289 (26,0)	63/281 (22,4)	1,16 [0,86; 1,55]
Gepoolte Population	633/3.477 (18,2)	600/3.515 (17,1)	1,07 [0,97; 1,18]



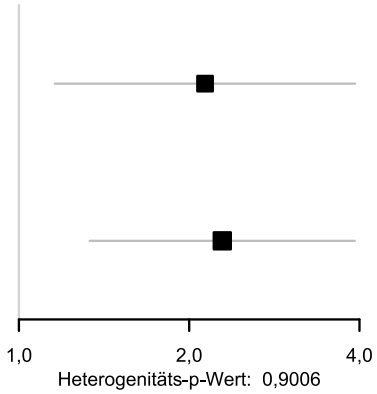
Jegliche UE:
PT Kreatinin im Blut erhöht

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	38/2.993 (1,3)	26/2.993 (0,9)	1,46 [0,89; 2,40]
Gepoolte Population	48/3.477 (1,4)	38/3.515 (1,1)	1,28 [0,84; 1,96]



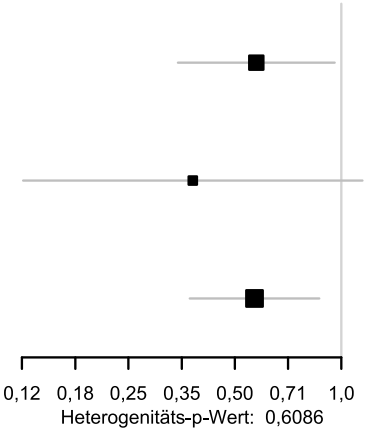
Jegliche UE:
PT Kalium im Blut erhöht

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	32/2.993 (1,1)	15/2.993 (0,5)	2,13 [1,16; 3,93]
Gepoolte Population	42/3.477 (1,2)	19/3.515 (0,5)	2,29 [1,33; 3,93]



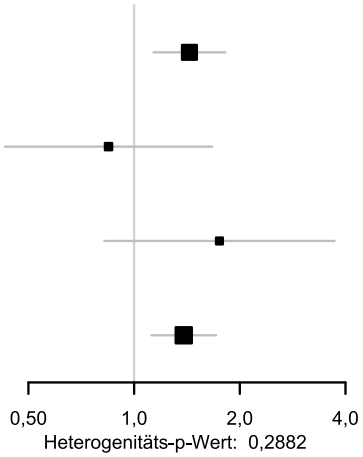
Jegliche UE:
PT Blutdruck erhöht

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	23/2.993 (0,8)	40/2.993 (1,3)	0,57 [0,35; 0,96]
FIDELIO-DKD	4/195 (2,1)	13/241 (5,4)	0,38 [0,13; 1,15]
Gepoolte Population	33/3.477 (0,9)	60/3.515 (1,7)	0,57 [0,37; 0,87]



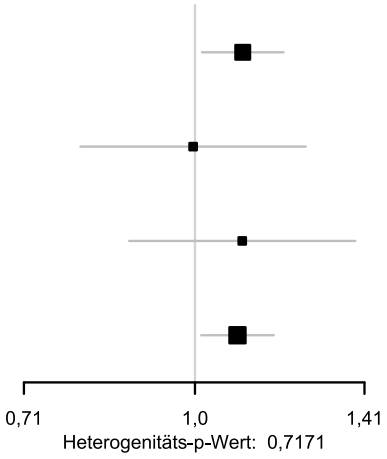
Jegliche UE:
PT Glomeruläre Filtrationsrate vermindert

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	161/2.993 (5,4)	112/2.993 (3,7)	1,44 [1,14; 1,82]
FIDELIO-DKD	13/195 (6,7)	19/241 (7,9)	0,85 [0,43; 1,67]
FIGARO-DKD	18/289 (6,2)	10/281 (3,6)	1,75 [0,82; 3,73]
Gepoolte Population	192/3.477 (5,5)	141/3.515 (4,0)	1,38 [1,12; 1,71]



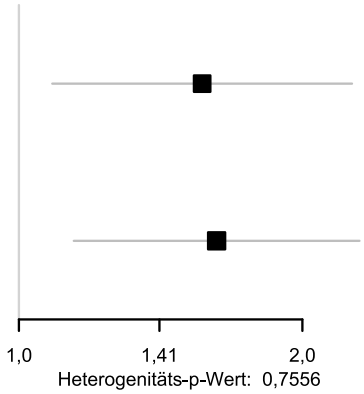
Jegliche UE:
SOC Stoffwechsel- und Ernährungsstörungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	856/2.993 (28,6)	777/2.993 (26,0)	1,10 [1,01; 1,20]
FIDELIO-DKD	79/195 (40,5)	98/241 (40,7)	1,00 [0,79; 1,25]
FIGARO-DKD	103/289 (35,6)	91/281 (32,4)	1,10 [0,88; 1,38]
Gepoolte Population	1.038/3.477 (29,9)	966/3.515 (27,5)	1,09 [1,01; 1,17]



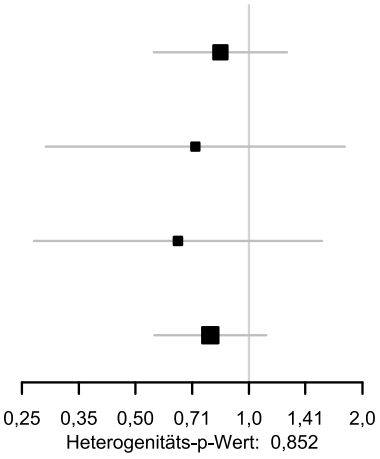
Jegliche UE:
PT Dehydratation

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	72/2.993 (2,4)	46/2.993 (1,5)	1,57 [1,08; 2,26]
Gepoolte Population	81/3.477 (2,3)	50/3.515 (1,4)	1,62 [1,14; 2,30]



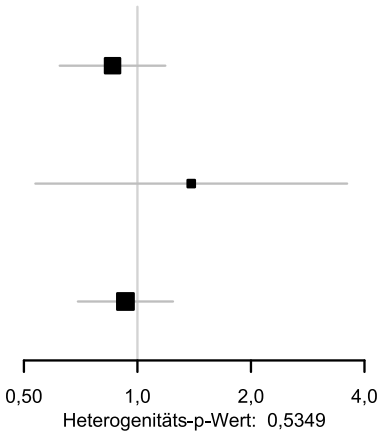
Jegliche UE:
PT Diabetes mellitus

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	42/2.993 (1,4)	50/2.993 (1,7)	0,84 [0,56; 1,26]
FIDELIO-DKD	7/195 (3,6)	12/241 (5,0)	0,72 [0,29; 1,80]
FIGARO-DKD	8/289 (2,8)	12/281 (4,3)	0,65 [0,27; 1,56]
Gepoolte Population	57/3.477 (1,6)	74/3.515 (2,1)	0,79 [0,56; 1,11]



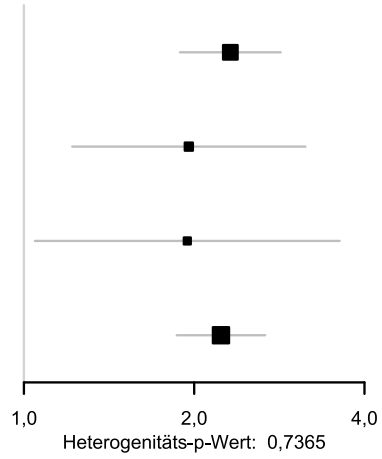
Jegliche UE:
PT Gicht

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	67/2.993 (2,2)	78/2.993 (2,6)	0,86 [0,62; 1,19]
FIGARO-DKD	10/289 (3,5)	7/281 (2,5)	1,39 [0,54; 3,60]
Gepoolte Population	85/3.477 (2,4)	93/3.515 (2,6)	0,93 [0,70; 1,24]



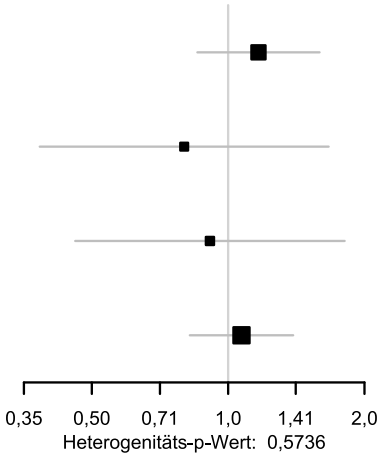
Jegliche UE:
PT Hyperkaliämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	285/2.993 (9,5)	123/2.993 (4,1)	2,32 [1,89; 2,85]
FIDELIO-DKD	38/195 (19,5)	24/241 (10,0)	1,96 [1,22; 3,15]
FIGARO-DKD	28/289 (9,7)	14/281 (5,0)	1,94 [1,05; 3,62]
Gepoolte Population	351/3.477 (10,1)	161/3.515 (4,6)	2,23 [1,86; 2,67]



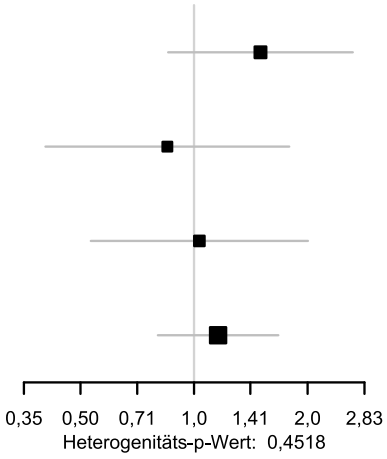
Jegliche UE:
PT Hyperurikämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	84/2.993 (2,8)	72/2.993 (2,4)	1,17 [0,86; 1,59]
FIDELIO-DKD	11/195 (5,6)	17/241 (7,1)	0,80 [0,38; 1,67]
FIGARO-DKD	15/289 (5,2)	16/281 (5,7)	0,91 [0,46; 1,81]
Gepoolte Population	110/3.477 (3,2)	105/3.515 (3,0)	1,07 [0,82; 1,39]



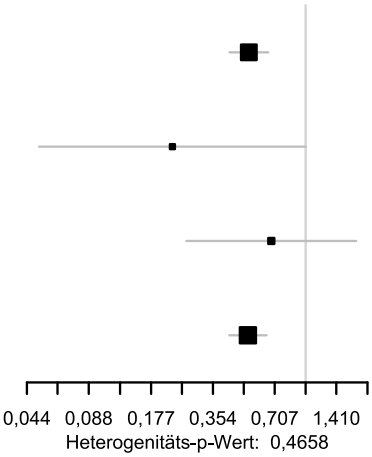
Jegliche UE:
PT Hypoglykämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	30/2.993 (1,0)	20/2.993 (0,7)	1,50 [0,85; 2,64]
FIDELIO-DKD	11/195 (5,6)	16/241 (6,6)	0,85 [0,40; 1,79]
FIGARO-DKD	17/289 (5,9)	16/281 (5,7)	1,03 [0,53; 2,00]
Gepoolte Population	58/3.477 (1,7)	52/3.515 (1,5)	1,16 [0,80; 1,67]



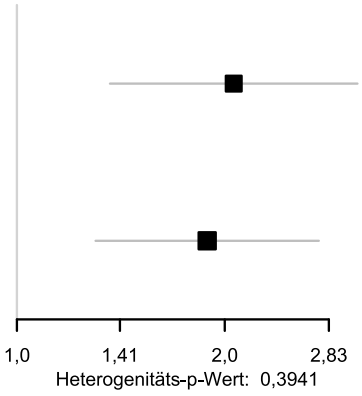
Jegliche UE:
PT Hypokaliämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	118/2.993 (3,9)	223/2.993 (7,5)	0,53 [0,43; 0,66]
FIDELIO-DKD	2/195 (1,0)	11/241 (4,6)	0,22 [0,05; 1,00]
FIGARO-DKD	7/289 (2,4)	10/281 (3,6)	0,68 [0,26; 1,76]
Gepoolte Population	127/3.477 (3,7)	244/3.515 (6,9)	0,52 [0,42; 0,65]



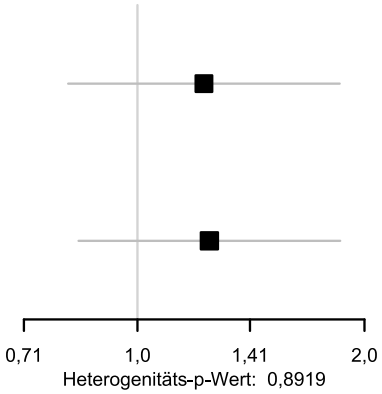
Jegliche UE:
PT Hyponatriämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	68/2.993 (2,3)	33/2.993 (1,1)	2,06 [1,36; 3,11]
Gepoolte Population	78/3.477 (2,2)	42/3.515 (1,2)	1,89 [1,30; 2,74]



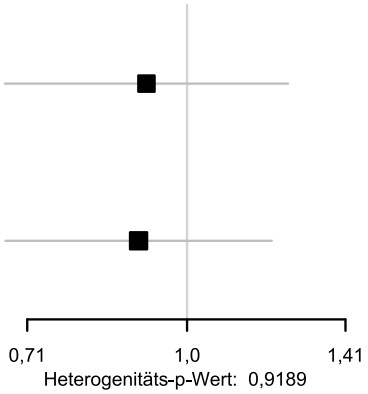
Jegliche UE:
PT Eisenmangel

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	49/2.993 (1,6)	40/2.993 (1,3)	1,23 [0,81; 1,85]
Gepoolte Population	53/3.477 (1,5)	43/3.515 (1,2)	1,25 [0,84; 1,86]



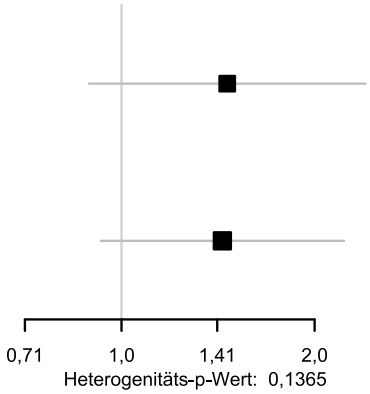
Jegliche UE:
PT Diabetes mellitus Typ 2

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	76/2.993 (2,5)	83/2.993 (2,8)	0,92 [0,67; 1,24]
Gepoolte Population	85/3.477 (2,4)	95/3.515 (2,7)	0,90 [0,67; 1,20]



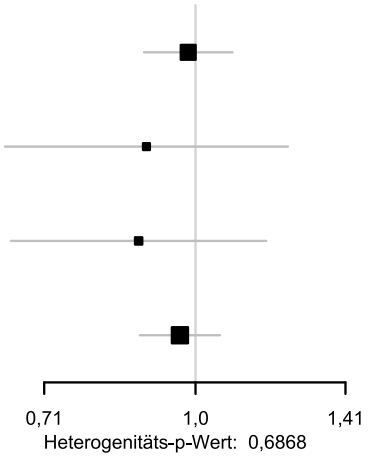
Jegliche UE:
PT Vitamin D-Mangel

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	38/2.993 (1,3)	26/2.993 (0,9)	1,46 [0,89; 2,40]
Gepoolte Population	48/3.477 (1,4)	34/3.515 (1,0)	1,44 [0,93; 2,22]



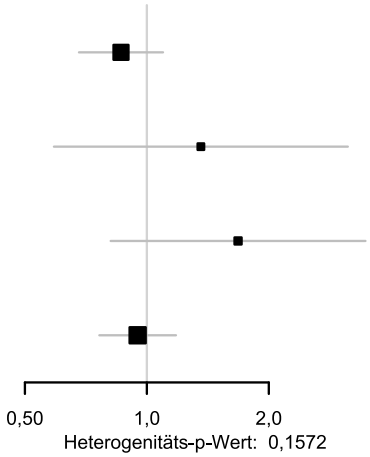
Jegliche UE:
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	592/2.993 (19,8)	602/2.993 (20,1)	0,98 [0,89; 1,09]
FIDELIO-DKD	47/195 (24,1)	65/241 (27,0)	0,89 [0,65; 1,24]
FIGARO-DKD	65/289 (22,5)	72/281 (25,6)	0,88 [0,66; 1,18]
Gepoolte Population	704/3.477 (20,2)	739/3.515 (21,0)	0,96 [0,88; 1,06]



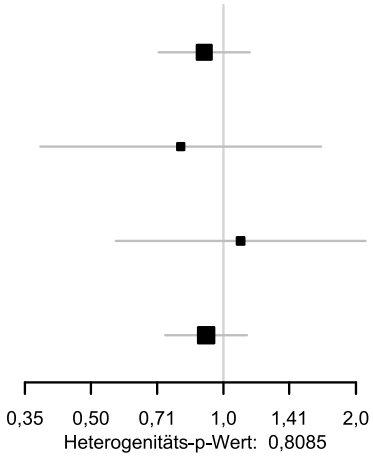
Jegliche UE:
PT Arthralgie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	120/2.993 (4,0)	139/2.993 (4,6)	0,86 [0,68; 1,10]
FIDELIO-DKD	11/195 (5,6)	10/241 (4,1)	1,36 [0,59; 3,13]
FIGARO-DKD	19/289 (6,6)	11/281 (3,9)	1,68 [0,81; 3,46]
Gepoolte Population	150/3.477 (4,3)	160/3.515 (4,6)	0,95 [0,76; 1,18]



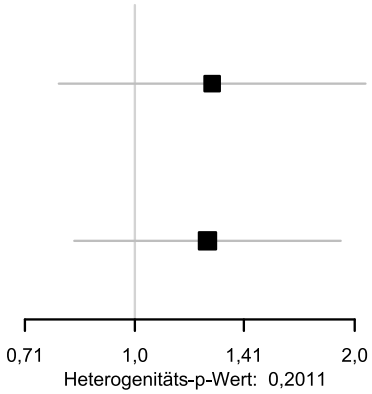
Jegliche UE:
PT Rückenschmerzen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	123/2.993 (4,1)	136/2.993 (4,5)	0,90 [0,71; 1,15]
FIDELIO-DKD	11/195 (5,6)	17/241 (7,1)	0,80 [0,38; 1,67]
FIGARO-DKD	18/289 (6,2)	16/281 (5,7)	1,09 [0,57; 2,10]
Gepoolte Population	152/3.477 (4,4)	169/3.515 (4,8)	0,91 [0,74; 1,13]



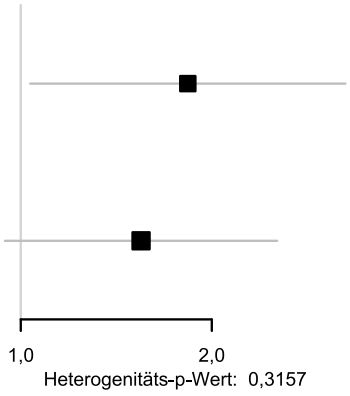
Jegliche UE:
PT Muskelspasmen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	37/2.993 (1,2)	29/2.993 (1,0)	1,28 [0,79; 2,07]
Gepoolte Population	48/3.477 (1,4)	39/3.515 (1,1)	1,26 [0,83; 1,91]



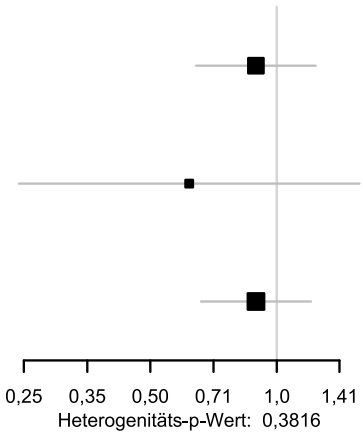
Jegliche UE:
PT Myalgie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	33/2.993 (1,1)	18/2.993 (0,6)	1,83 [1,03; 3,25]
Gepoolte Population	39/3.477 (1,1)	26/3.515 (0,7)	1,55 [0,94; 2,54]



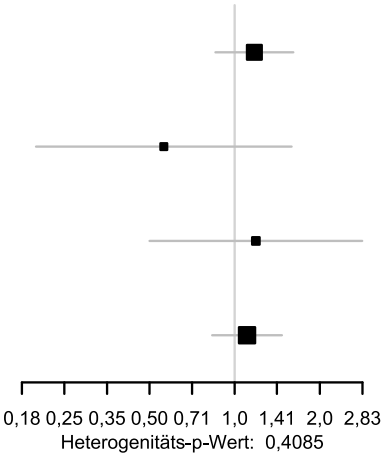
Jegliche UE:
PT Osteoarthrose

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	66/2.993 (2,2)	74/2.993 (2,5)	0,89 [0,64; 1,24]
FIGARO-DKD	7/289 (2,4)	11/281 (3,9)	0,62 [0,24; 1,57]
Gepoolte Population	78/3.477 (2,2)	88/3.515 (2,5)	0,89 [0,66; 1,21]



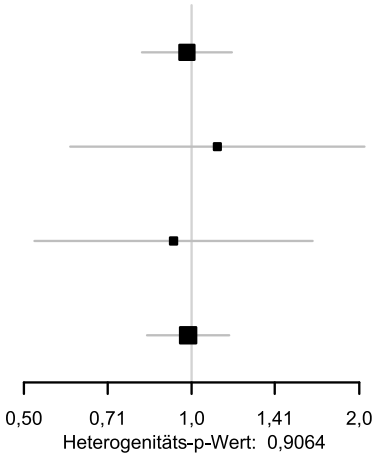
Jegliche UE:
PT Schmerz in einer Extremität

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	81/2.993 (2,7)	69/2.993 (2,3)	1,17 [0,85; 1,61]
FIDELIO-DKD	5/195 (2,6)	11/241 (4,6)	0,56 [0,20; 1,59]
FIGARO-DKD	11/289 (3,8)	9/281 (3,2)	1,19 [0,50; 2,82]
Gepoolte Population	97/3.477 (2,8)	89/3.515 (2,5)	1,11 [0,83; 1,47]



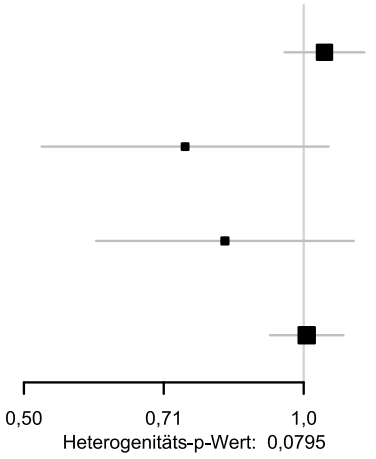
Jegliche UE:
SOC Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	205/2.993 (6,8)	209/2.993 (7,0)	0,98 [0,81; 1,18]
FIDELIO-DKD	18/195 (9,2)	20/241 (8,3)	1,11 [0,61; 2,04]
FIGARO-DKD	21/289 (7,3)	22/281 (7,8)	0,93 [0,52; 1,65]
Gepoolte Population	244/3.477 (7,0)	251/3.515 (7,1)	0,99 [0,83; 1,17]



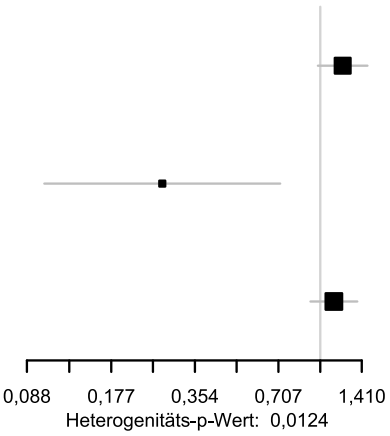
Jegliche UE:
SOC Erkrankungen des Nervensystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	637/2.993 (21,3)	605/2.993 (20,2)	1,05 [0,95; 1,16]
FIDELIO-DKD	38/195 (19,5)	63/241 (26,1)	0,75 [0,52; 1,06]
FIGARO-DKD	55/289 (19,0)	65/281 (23,1)	0,82 [0,60; 1,13]
Gepoolte Population	730/3.477 (21,0)	733/3.515 (20,9)	1,01 [0,92; 1,10]



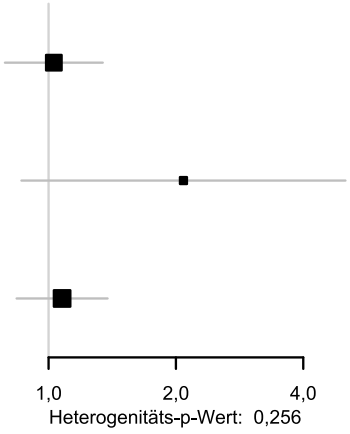
Jegliche UE:
PT Schwindelgefühl

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	189/2.993 (6,3)	157/2.993 (5,2)	1,20 [0,98; 1,48]
FIGARO-DKD	5/289 (1,7)	18/281 (6,4)	0,27 [0,10; 0,72]
Gepoolte Population	203/3.477 (5,8)	183/3.515 (5,2)	1,12 [0,92; 1,36]



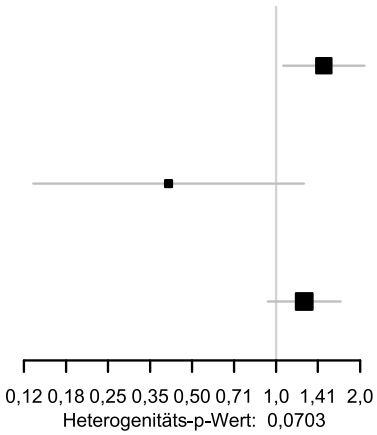
Jegliche UE:
PT Kopfschmerzen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	106/2.993 (3,5)	103/2.993 (3,4)	1,03 [0,79; 1,34]
FIGARO-DKD	15/289 (5,2)	7/281 (2,5)	2,08 [0,86; 5,03]
Gepoolte Population	125/3.477 (3,6)	117/3.515 (3,3)	1,08 [0,84; 1,38]



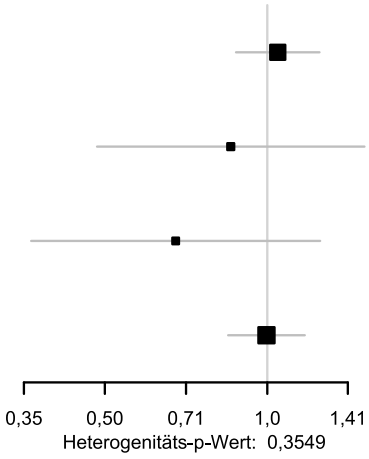
Jegliche UE:
PT Synkope

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	83/2.993 (2,8)	56/2.993 (1,9)	1,48 [1,06; 2,07]
FIDELIO-DKD	4/195 (2,1)	12/241 (5,0)	0,41 [0,13; 1,26]
Gepoolte Population	93/3.477 (2,7)	75/3.515 (2,1)	1,26 [0,93; 1,70]



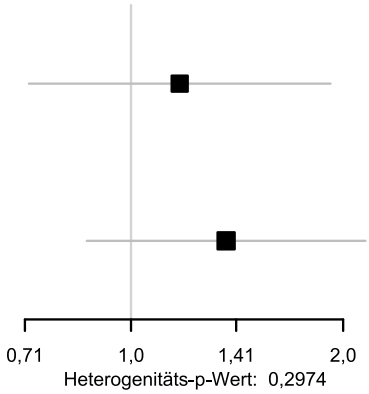
Jegliche UE:
SOC Psychiatrische Erkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	229/2.993 (7,7)	219/2.993 (7,3)	1,05 [0,87; 1,25]
FIDELIO-DKD	18/195 (9,2)	26/241 (10,8)	0,86 [0,48; 1,51]
FIGARO-DKD	16/289 (5,5)	23/281 (8,2)	0,68 [0,37; 1,25]
Gepoolte Population	263/3.477 (7,6)	268/3.515 (7,6)	1,00 [0,85; 1,17]



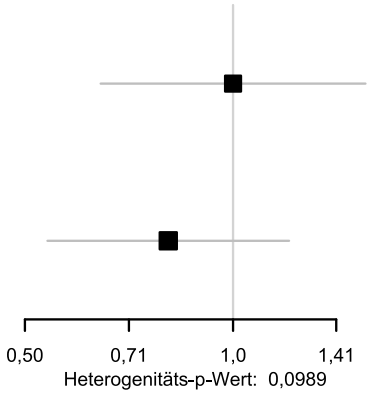
Jegliche UE:
PT Angst

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	34/2.993 (1,1)	29/2.993 (1,0)	1,17 [0,72; 1,92]
Gepoolte Population	43/3.477 (1,2)	32/3.515 (0,9)	1,36 [0,87; 2,15]



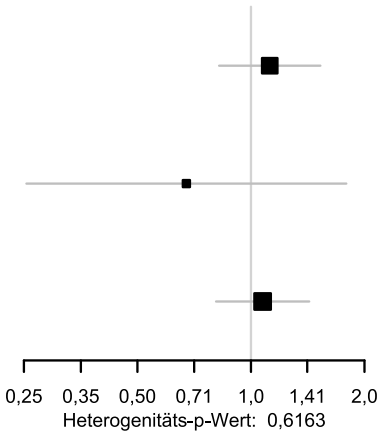
Jegliche UE:
PT Depression

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	39/2.993 (1,3)	39/2.993 (1,3)	1,00 [0,64; 1,55]
Gepoolte Population	42/3.477 (1,2)	53/3.515 (1,5)	0,81 [0,54; 1,21]



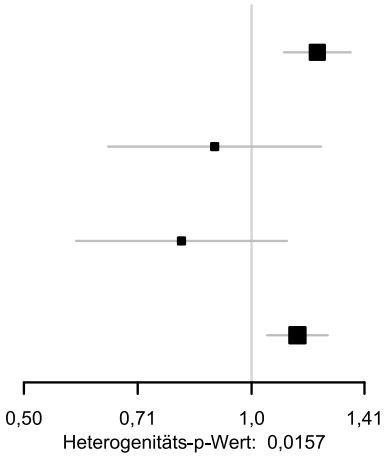
Jegliche UE:
PT Schlaflosigkeit

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	83/2.993 (2,8)	74/2.993 (2,5)	1,12 [0,82; 1,53]
FIDELIO-DKD	6/195 (3,1)	11/241 (4,6)	0,67 [0,25; 1,79]
Gepoolte Population	95/3.477 (2,7)	90/3.515 (2,6)	1,07 [0,81; 1,43]



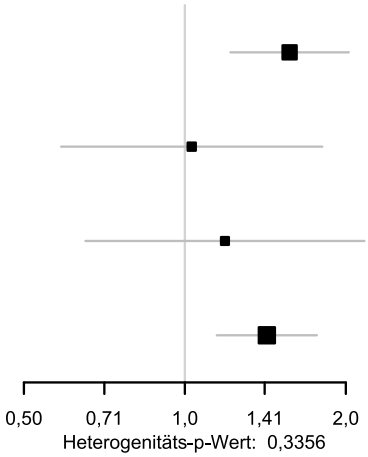
Jegliche UE:
SOC Erkrankungen der Nieren und Harnwege

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	662/2.993 (22,1)	542/2.993 (18,1)	1,22 [1,10; 1,35]
FIDELIO-DKD	47/195 (24,1)	65/241 (27,0)	0,89 [0,65; 1,24]
FIGARO-DKD	54/289 (18,7)	65/281 (23,1)	0,81 [0,59; 1,11]
Gepoolte Population	763/3.477 (21,9)	672/3.515 (19,1)	1,15 [1,05; 1,26]



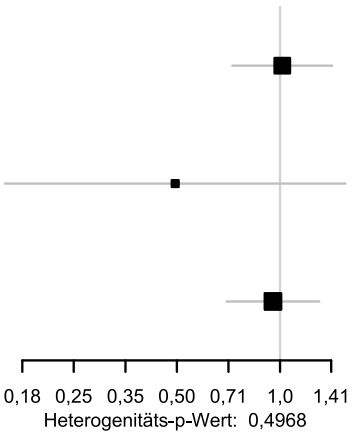
Jegliche UE:
PT Akute Nierenschädigung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	146/2.993 (4,9)	93/2.993 (3,1)	1,57 [1,22; 2,03]
FIDELIO-DKD	20/195 (10,3)	24/241 (10,0)	1,03 [0,59; 1,81]
FIGARO-DKD	22/289 (7,6)	18/281 (6,4)	1,19 [0,65; 2,17]
Gepoolte Population	188/3.477 (5,4)	135/3.515 (3,8)	1,42 [1,15; 1,77]



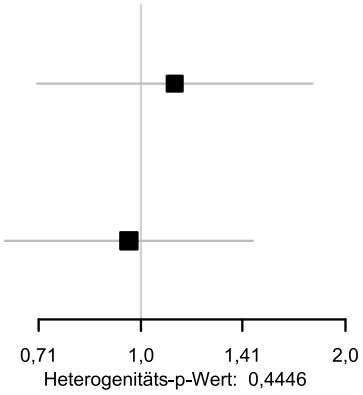
Jegliche UE:
PT Chronische Nierenerkrankung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	67/2.993 (2,2)	66/2.993 (2,2)	1,02 [0,73; 1,42]
FIDELIO-DKD	4/195 (2,1)	10/241 (4,1)	0,49 [0,16; 1,55]
Gepoolte Population	75/3.477 (2,2)	80/3.515 (2,3)	0,95 [0,70; 1,30]



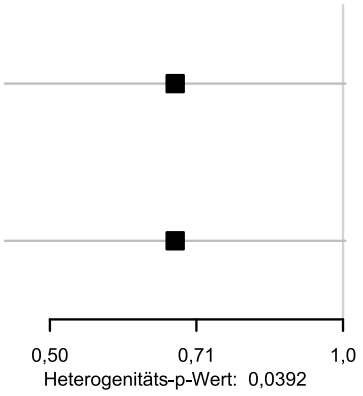
Jegliche UE:
PT Hämaturie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	37/2.993 (1,2)	33/2.993 (1,1)	1,12 [0,70; 1,79]
Gepoolte Population	42/3.477 (1,2)	44/3.515 (1,3)	0,96 [0,63; 1,46]



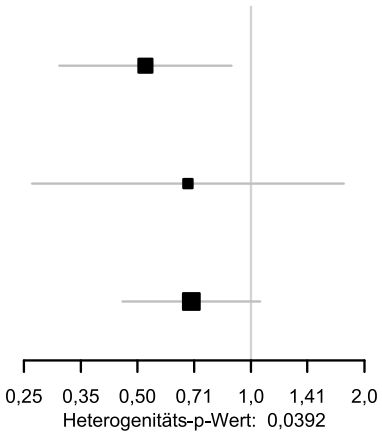
Jegliche UE:
PT Mikroalbuminurie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	39/2.993 (1,3)	58/2.993 (1,9)	0,67 [0,45; 1,01]
Gepoolte Population	39/3.477 (1,1)	58/3.515 (1,7)	0,67 [0,45; 1,01]



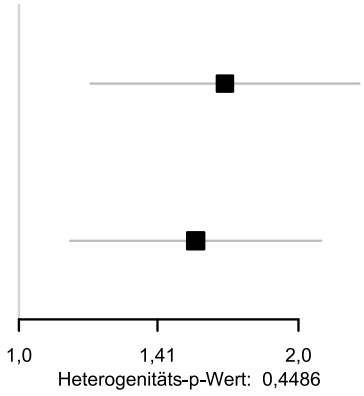
Jegliche UE:
PT Nierenzyste

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	21/2.993 (0,7)	40/2.993 (1,3)	0,53 [0,31; 0,89]
FIGARO-DKD	7/289 (2,4)	10/281 (3,6)	0,68 [0,26; 1,76]
Gepoolte Population	36/3.477 (1,0)	53/3.515 (1,5)	0,69 [0,46; 1,06]



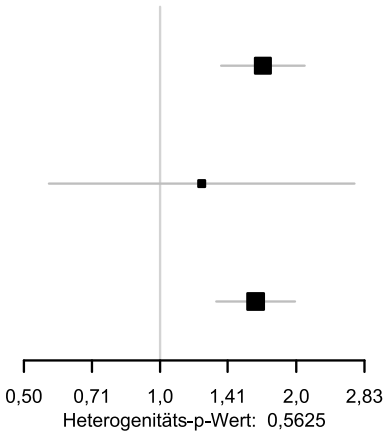
Jegliche UE:
PT Nierenversagen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	90/2.993 (3,0)	54/2.993 (1,8)	1,67 [1,19; 2,33]
Gepoolte Population	98/3.477 (2,8)	64/3.515 (1,8)	1,55 [1,14; 2,12]



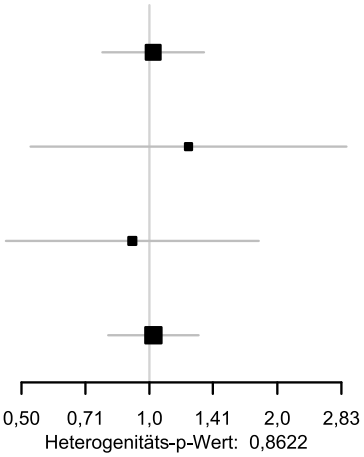
Jegliche UE:
PT Nierenfunktionsbeeinträchtigung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	216/2.993 (7,2)	128/2.993 (4,3)	1,69 [1,36; 2,09]
FIDELIO-DKD	12/195 (6,2)	12/241 (5,0)	1,24 [0,57; 2,69]
Gepoolte Population	236/3.477 (6,8)	147/3.515 (4,2)	1,63 [1,33; 1,99]



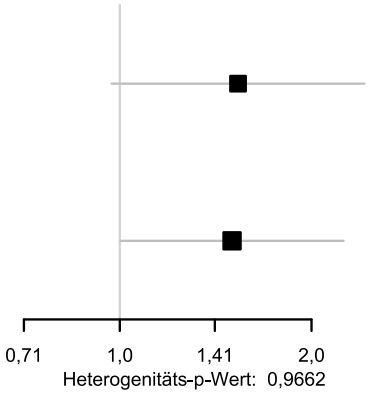
Jegliche UE:
SOC Erkrankungen der Geschlechtsorgane und der Brustdrüse

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	99/2.993 (3,3)	97/2.993 (3,2)	1,02 [0,77; 1,34]
FIDELIO-DKD	10/195 (5,1)	10/241 (4,1)	1,24 [0,53; 2,91]
FIGARO-DKD	15/289 (5,2)	16/281 (5,7)	0,91 [0,46; 1,81]
Gepoolte Population	124/3.477 (3,6)	123/3.515 (3,5)	1,02 [0,80; 1,31]



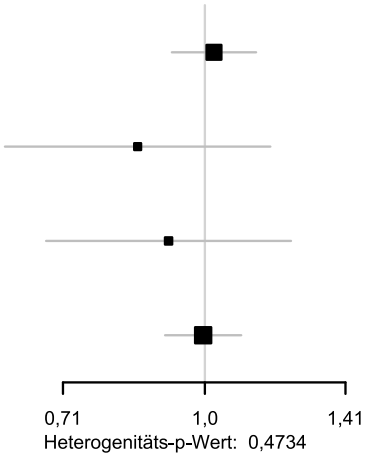
Jegliche UE:
PT Gutartige Prostatahyperplasie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	46/2.993 (1,5)	30/2.993 (1,0)	1,53 [0,97; 2,42]
Gepoolte Population	58/3.477 (1,7)	39/3.515 (1,1)	1,50 [1,00; 2,25]



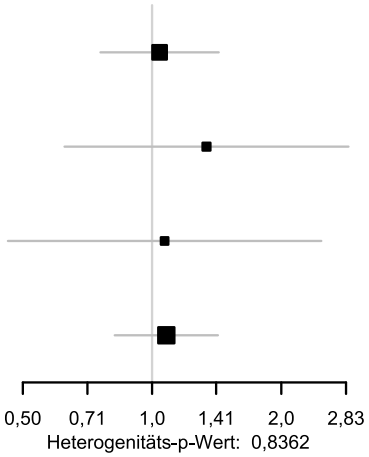
Jegliche UE:
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	590/2.993 (19,7)	577/2.993 (19,3)	1,02 [0,92; 1,13]
FIDELIO-DKD	46/195 (23,6)	67/241 (27,8)	0,85 [0,61; 1,17]
FIGARO-DKD	64/289 (22,1)	68/281 (24,2)	0,92 [0,68; 1,23]
Gepoolte Population	700/3.477 (20,1)	712/3.515 (20,3)	1,00 [0,91; 1,09]



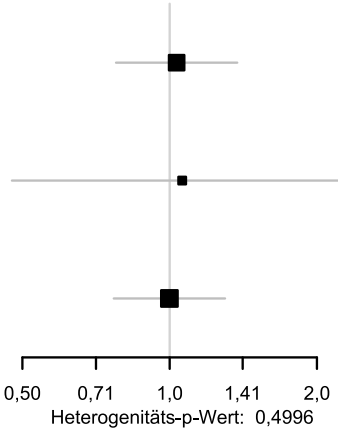
Jegliche UE:
PT Chronisch-obstruktive Lungenerkrankung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	76/2.993 (2,5)	73/2.993 (2,4)	1,04 [0,76; 1,43]
FIDELIO-DKD	13/195 (6,7)	12/241 (5,0)	1,34 [0,63; 2,87]
FIGARO-DKD	11/289 (3,8)	10/281 (3,6)	1,07 [0,46; 2,48]
Gepoolte Population	100/3.477 (2,9)	95/3.515 (2,7)	1,08 [0,82; 1,42]



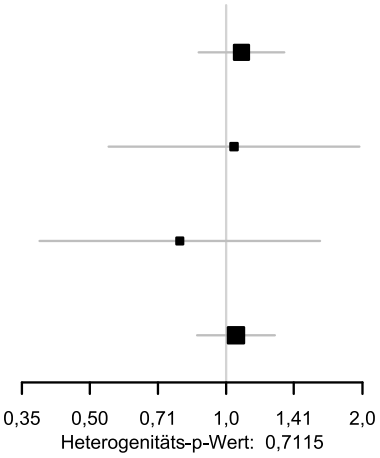
Jegliche UE:
PT Husten

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	93/2.993 (3,1)	90/2.993 (3,0)	1,03 [0,78; 1,37]
FIGARO-DKD	12/289 (4,2)	11/281 (3,9)	1,06 [0,48; 2,36]
Gepoolte Population	108/3.477 (3,1)	109/3.515 (3,1)	1,00 [0,77; 1,30]



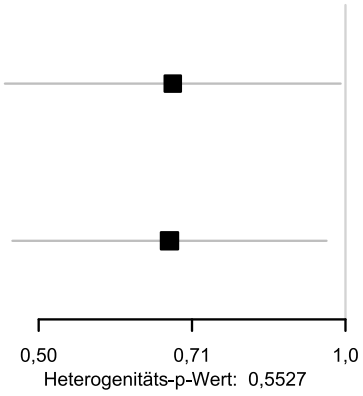
Jegliche UE:
PT Dyspnoe

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	160/2.993 (5,3)	148/2.993 (4,9)	1,08 [0,87; 1,34]
FIDELIO-DKD	16/195 (8,2)	19/241 (7,9)	1,04 [0,55; 1,97]
FIGARO-DKD	13/289 (4,5)	16/281 (5,7)	0,79 [0,39; 1,61]
Gepoolte Population	189/3.477 (5,4)	183/3.515 (5,2)	1,05 [0,86; 1,28]



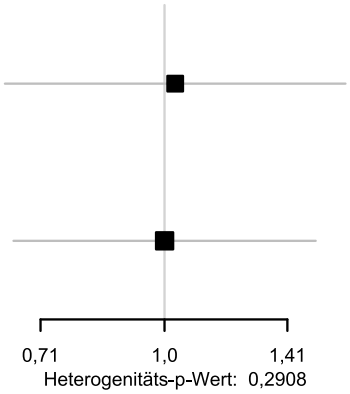
Jegliche UE:
PT Epistaxis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	44/2.993 (1,5)	65/2.993 (2,2)	0,68 [0,46; 0,99]
Gepoolte Population	50/3.477 (1,4)	75/3.515 (2,1)	0,67 [0,47; 0,96]



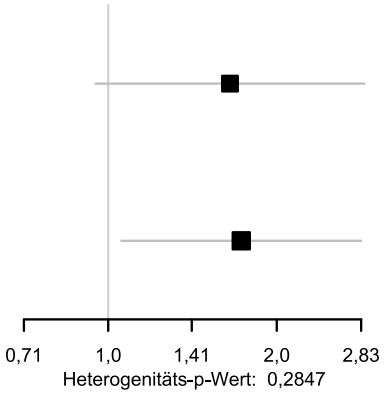
Jegliche UE:
PT Pleuraerguss

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	34/2.993 (1,1)	33/2.993 (1,1)	1,03 [0,64; 1,66]
Gepoolte Population	42/3.477 (1,2)	43/3.515 (1,2)	1,00 [0,66; 1,53]



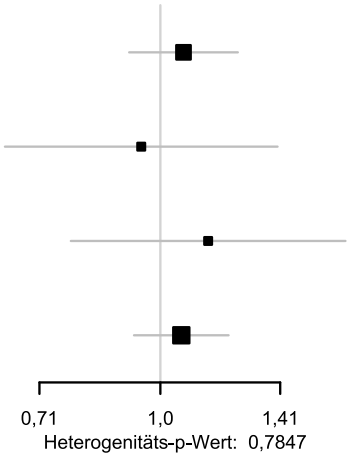
Jegliche UE:
PT Respiratorische Insuffizienz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	33/2.993 (1,1)	20/2.993 (0,7)	1,65 [0,95; 2,87]
Gepoolte Population	42/3.477 (1,2)	25/3.515 (0,7)	1,73 [1,06; 2,83]



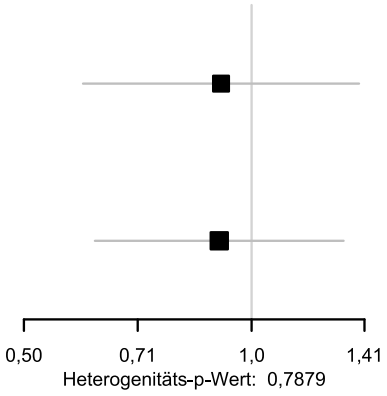
Jegliche UE:
SOC Erkrankungen der Haut und des Unterhautgewebes

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	296/2.993 (9,9)	277/2.993 (9,3)	1,07 [0,91; 1,25]
FIDELIO-DKD	36/195 (18,5)	47/241 (19,5)	0,95 [0,64; 1,40]
FIGARO-DKD	46/289 (15,9)	39/281 (13,9)	1,15 [0,77; 1,70]
Gepoolte Population	378/3.477 (10,9)	363/3.515 (10,3)	1,06 [0,93; 1,22]



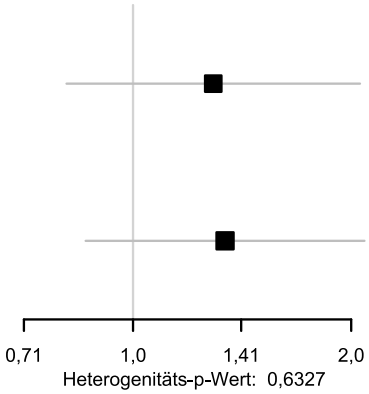
Jegliche UE:
PT Pruritus

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	41/2.993 (1,4)	45/2.993 (1,5)	0,91 [0,60; 1,39]
Gepoolte Population	50/3.477 (1,4)	56/3.515 (1,6)	0,91 [0,62; 1,32]



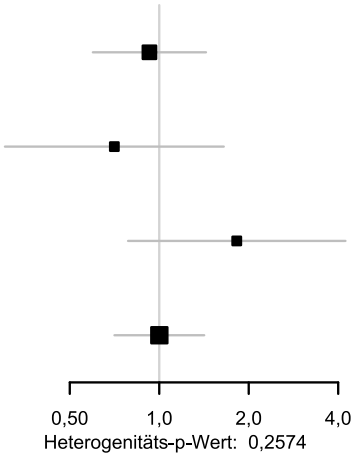
Jegliche UE:
PT Ausschlag

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	40/2.993 (1,3)	31/2.993 (1,0)	1,29 [0,81; 2,06]
Gepoolte Population	45/3.477 (1,3)	34/3.515 (1,0)	1,34 [0,86; 2,09]



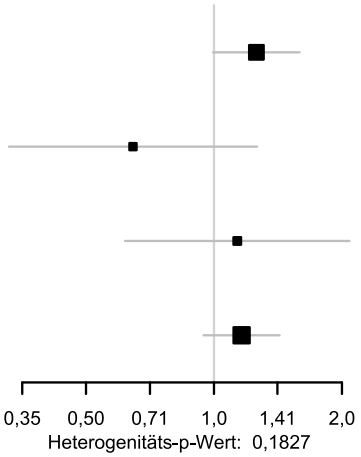
Jegliche UE:
PT Hautulkus

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	38/2.993 (1,3)	41/2.993 (1,4)	0,93 [0,60; 1,44]
FIDELIO-DKD	8/195 (4,1)	14/241 (5,8)	0,71 [0,30; 1,65]
FIGARO-DKD	15/289 (5,2)	8/281 (2,8)	1,82 [0,79; 4,23]
Gepoolte Population	61/3.477 (1,8)	63/3.515 (1,8)	1,00 [0,71; 1,42]



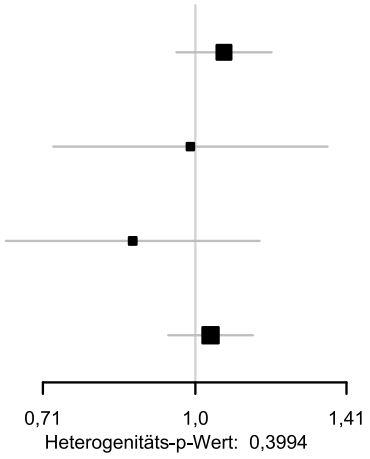
Jegliche UE:
SOC Chirurgische und medizinische Eingriffe

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	151/2.993 (5,0)	120/2.993 (4,0)	1,26 [1,00; 1,59]
FIDELIO-DKD	12/195 (6,2)	23/241 (9,5)	0,64 [0,33; 1,26]
FIGARO-DKD	21/289 (7,3)	18/281 (6,4)	1,13 [0,62; 2,08]
Gepoolte Population	184/3.477 (5,3)	161/3.515 (4,6)	1,16 [0,95; 1,43]



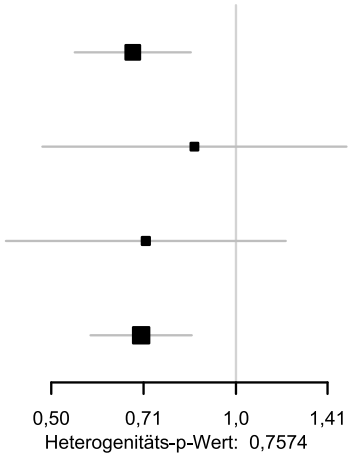
Jegliche UE:
SOC Gefäßerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	556/2.993 (18,6)	521/2.993 (17,4)	1,07 [0,96; 1,19]
FIDELIO-DKD	52/195 (26,7)	65/241 (27,0)	0,99 [0,72; 1,35]
FIGARO-DKD	66/289 (22,8)	74/281 (26,3)	0,87 [0,65; 1,16]
Gepoolte Population	674/3.477 (19,4)	660/3.515 (18,8)	1,04 [0,94; 1,14]



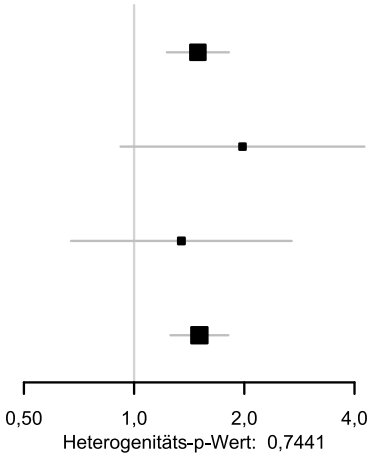
Jegliche UE:
PT Hypertonie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	129/2.993 (4,3)	190/2.993 (6,3)	0,68 [0,55; 0,84]
FIDELIO-DKD	18/195 (9,2)	26/241 (10,8)	0,86 [0,48; 1,51]
FIGARO-DKD	22/289 (7,6)	30/281 (10,7)	0,71 [0,42; 1,21]
Gepoolte Population	169/3.477 (4,9)	246/3.515 (7,0)	0,70 [0,58; 0,85]



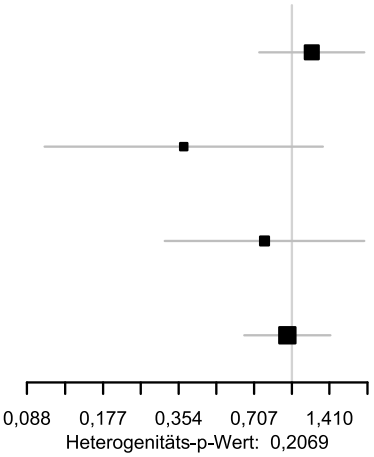
Jegliche UE:
PT Hypotonie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	236/2.993 (7,9)	158/2.993 (5,3)	1,49 [1,23; 1,82]
FIDELIO-DKD	16/195 (8,2)	10/241 (4,1)	1,98 [0,92; 4,26]
FIGARO-DKD	18/289 (6,2)	13/281 (4,6)	1,35 [0,67; 2,70]
Gepoolte Population	270/3.477 (7,8)	181/3.515 (5,1)	1,51 [1,26; 1,81]



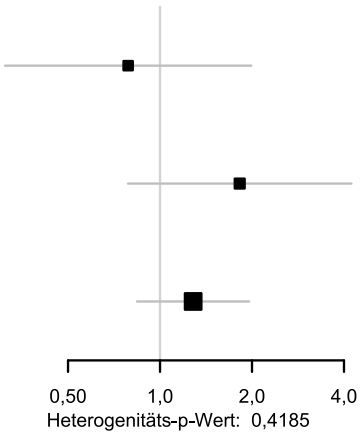
Jegliche UE:
PT Periphere arterielle Verschlusskrankheit

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	36/2.993 (1,2)	30/2.993 (1,0)	1,20 [0,74; 1,94]
FIDELIO-DKD	3/195 (1,5)	10/241 (4,1)	0,37 [0,10; 1,33]
FIGARO-DKD	8/289 (2,8)	10/281 (3,6)	0,78 [0,31; 1,94]
Gepoolte Population	47/3.477 (1,4)	50/3.515 (1,4)	0,96 [0,65; 1,42]



Jegliche UE:
PT Hyperglykämie

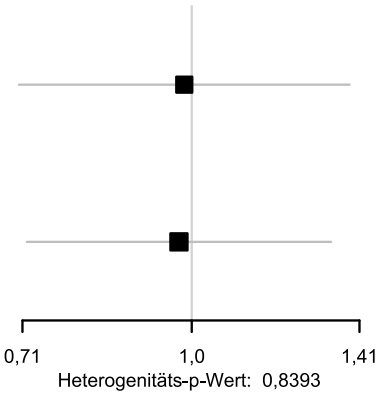
	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FIDELIO-DKD	7/195 (3,6)	11/241 (4,6)	0,79 [0,31; 1,99]
FIGARO-DKD	15/289 (5,2)	8/281 (2,8)	1,82 [0,79; 4,23]
Gepoolte Population	47/3.477 (1,4)	38/3.515 (1,1)	1,28 [0,84; 1,96]



SUE nach SOC und PT

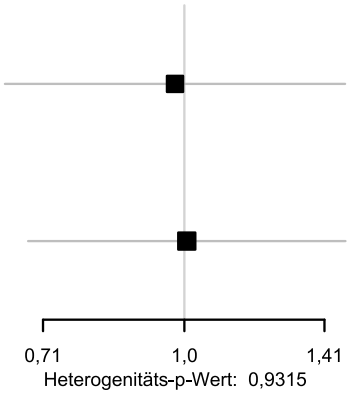
SUE:
SOC Erkrankungen des Blutes und des Lymphsystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	65/2.993 (2,2)	66/2.993 (2,2)	0,98 [0,70; 1,38]
Gepoolte Population	76/3.477 (2,2)	79/3.515 (2,2)	0,97 [0,71; 1,33]



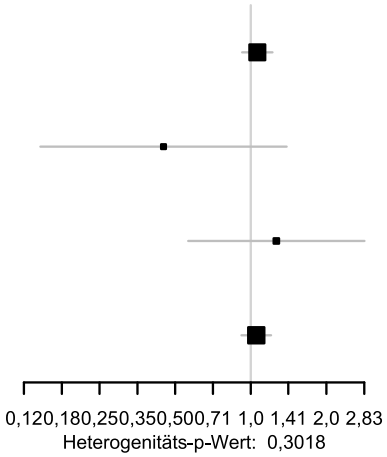
SUE:
PT Anämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	43/2.993 (1,4)	44/2.993 (1,5)	0,98 [0,64; 1,48]
Gepoolte Population	50/3.477 (1,4)	50/3.515 (1,4)	1,01 [0,68; 1,48]



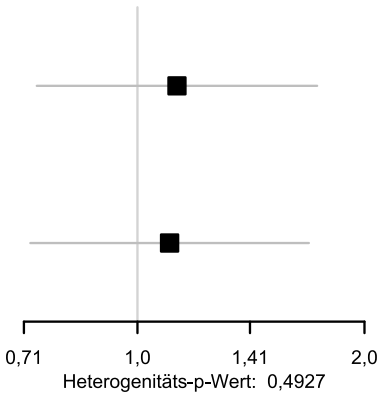
SUE:
SOC Herzerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	361/2.993 (12,1)	340/2.993 (11,4)	1,06 [0,92; 1,22]
FIDELIO-DKD	4/195 (2,1)	11/241 (4,6)	0,45 [0,15; 1,39]
FIGARO-DKD	13/289 (4,5)	10/281 (3,6)	1,26 [0,56; 2,84]
Gepoolte Population	378/3.477 (10,9)	361/3.515 (10,3)	1,05 [0,92; 1,20]



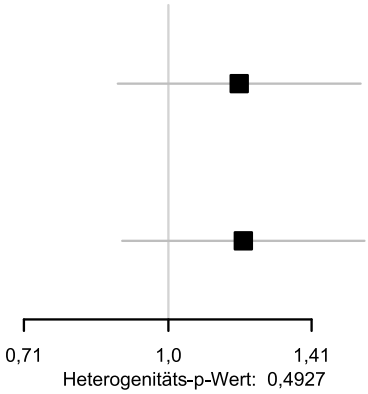
SUE:
PT Angina pectoris instabil

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	44/2.993 (1,5)	39/2.993 (1,3)	1,13 [0,74; 1,73]
Gepoolte Population	44/3.477 (1,3)	40/3.515 (1,1)	1,10 [0,72; 1,69]



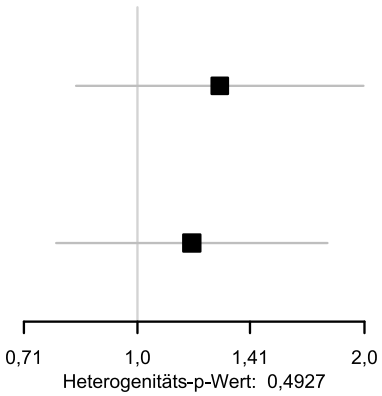
SUE:
PT Vorhofflimmern

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	96/2.993 (3,2)	81/2.993 (2,7)	1,19 [0,89; 1,59]
Gepoolte Population	97/3.477 (2,8)	81/3.515 (2,3)	1,20 [0,90; 1,60]



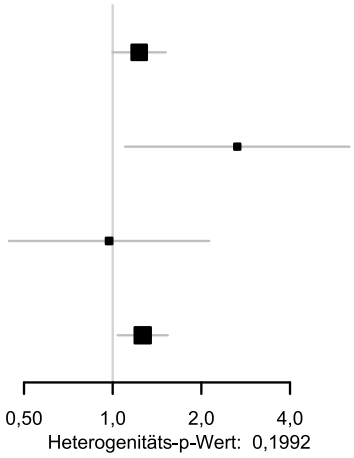
SUE:
PT Herzinsuffizienz

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	45/2.993 (1,5)	35/2.993 (1,2)	1,29 [0,83; 1,99]
Gepoolte Population	48/3.477 (1,4)	41/3.515 (1,2)	1,18 [0,78; 1,79]



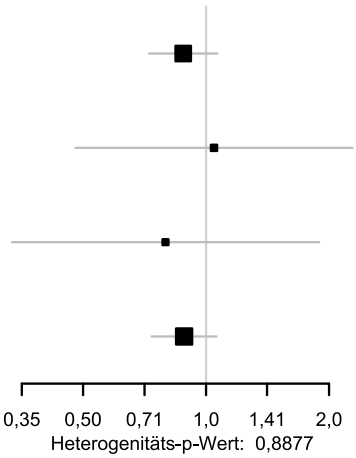
SUE:
SOC Erkrankungen des Gastrointestinaltrakts

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	187/2.993 (6,2)	152/2.993 (5,1)	1,23 [1,00; 1,51]
FIDELIO-DKD	15/195 (7,7)	7/241 (2,9)	2,65 [1,10; 6,37]
FIGARO-DKD	12/289 (4,2)	12/281 (4,3)	0,97 [0,44; 2,13]
Gepoolte Population	214/3.477 (6,2)	171/3.515 (4,9)	1,26 [1,04; 1,54]



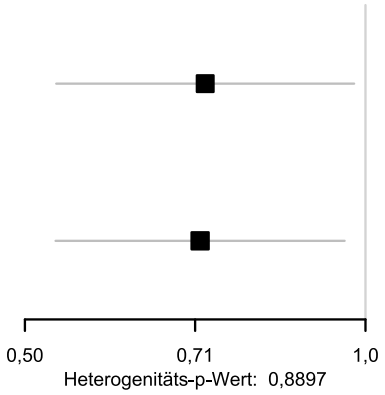
SUE:
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	182/2.993 (6,1)	207/2.993 (6,9)	0,88 [0,73; 1,07]
FIDELIO-DKD	11/195 (5,6)	13/241 (5,4)	1,05 [0,48; 2,28]
FIGARO-DKD	9/289 (3,1)	11/281 (3,9)	0,80 [0,33; 1,89]
Gepoolte Population	202/3.477 (5,8)	231/3.515 (6,6)	0,88 [0,74; 1,06]



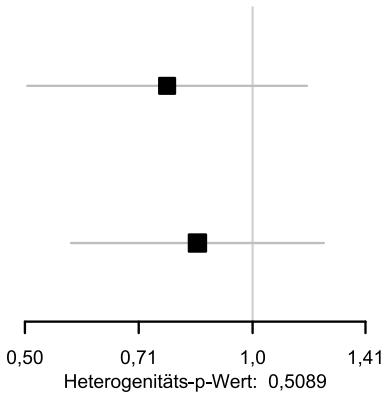
SUE:
PT Tod

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	70/2.993 (2,3)	97/2.993 (3,2)	0,72 [0,53; 0,98]
Gepoolte Population	74/3.477 (2,1)	104/3.515 (3,0)	0,71 [0,53; 0,96]



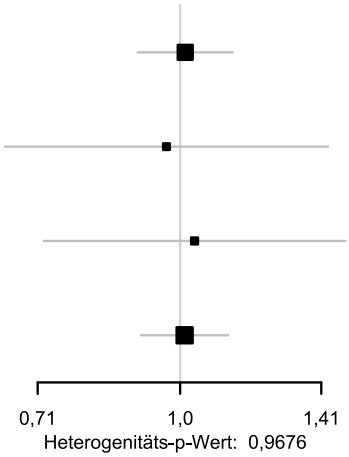
SUE:
SOC Leber- und Gallenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	37/2.993 (1,2)	48/2.993 (1,6)	0,77 [0,50; 1,18]
Gepoolte Population	47/3.477 (1,4)	56/3.515 (1,6)	0,85 [0,58; 1,24]



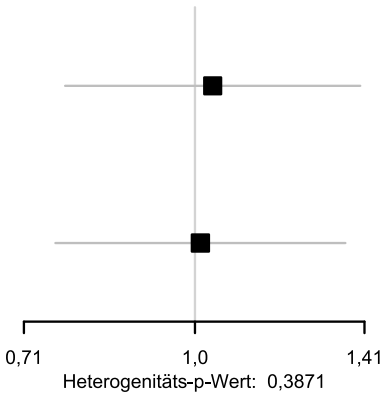
SUE:
SOC Infektionen und parasitäre Erkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	486/2.993 (16,2)	480/2.993 (16,0)	1,01 [0,90; 1,14]
FIDELIO-DKD	36/195 (18,5)	46/241 (19,1)	0,97 [0,65; 1,43]
FIGARO-DKD	49/289 (17,0)	46/281 (16,4)	1,04 [0,72; 1,50]
Gepoolte Population	571/3.477 (16,4)	572/3.515 (16,3)	1,01 [0,91; 1,12]



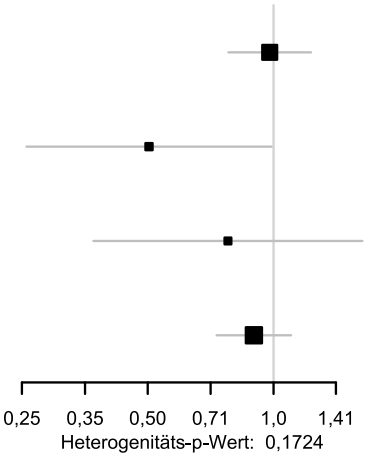
SUE:
PT COVID-19

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	85/2.993 (2,8)	82/2.993 (2,7)	1,04 [0,77; 1,40]
Gepoolte Population	87/3.477 (2,5)	86/3.515 (2,4)	1,01 [0,75; 1,36]



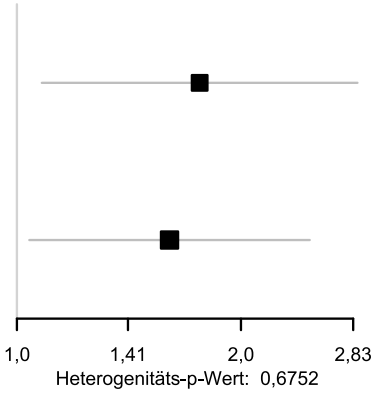
SUE:
PT Pneumonie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	140/2.993 (4,7)	143/2.993 (4,8)	0,98 [0,78; 1,23]
FIDELIO-DKD	11/195 (5,6)	27/241 (11,2)	0,50 [0,26; 0,99]
FIGARO-DKD	12/289 (4,2)	15/281 (5,3)	0,78 [0,37; 1,63]
Gepoolte Population	163/3.477 (4,7)	185/3.515 (5,3)	0,90 [0,73; 1,10]



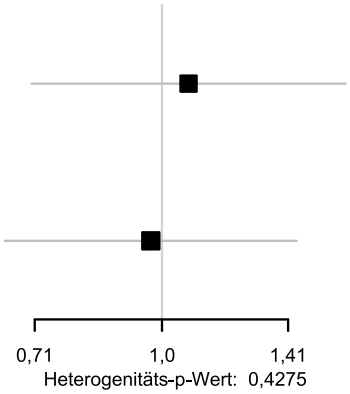
SUE:
PT Sepsis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	44/2.993 (1,5)	25/2.993 (0,8)	1,76 [1,08; 2,87]
Gepoolte Population	52/3.477 (1,5)	33/3.515 (0,9)	1,60 [1,04; 2,47]



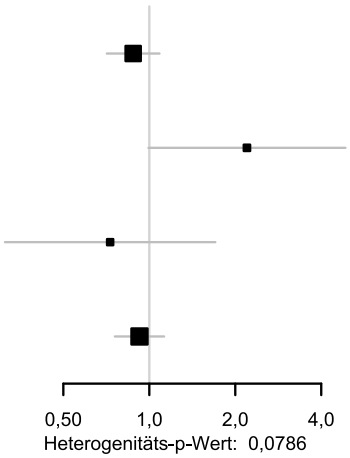
SUE:
PT Harnwegsinfektion

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	43/2.993 (1,4)	40/2.993 (1,3)	1,08 [0,70; 1,65]
Gepoolte Population	47/3.477 (1,4)	49/3.515 (1,4)	0,97 [0,65; 1,44]



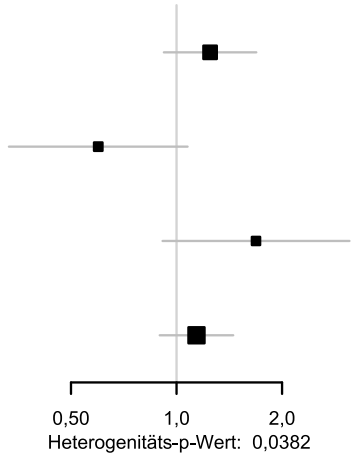
SUE:
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	151/2.993 (5,0)	172/2.993 (5,7)	0,88 [0,71; 1,09]
FIDELIO-DKD	16/195 (8,2)	9/241 (3,7)	2,20 [0,99; 4,86]
FIGARO-DKD	9/289 (3,1)	12/281 (4,3)	0,73 [0,31; 1,70]
Gepoolte Population	176/3.477 (5,1)	193/3.515 (5,5)	0,92 [0,76; 1,13]



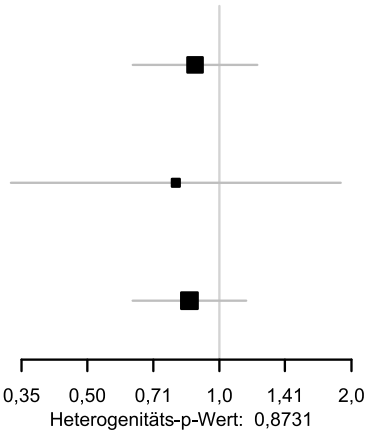
SUE:
SOC Stoffwechsel- und Ernährungsstörungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	91/2.993 (3,0)	73/2.993 (2,4)	1,25 [0,92; 1,69]
FIDELIO-DKD	15/195 (7,7)	31/241 (12,9)	0,60 [0,33; 1,08]
FIGARO-DKD	26/289 (9,0)	15/281 (5,3)	1,69 [0,91; 3,11]
Gepoolte Population	132/3.477 (3,8)	119/3.515 (3,4)	1,14 [0,90; 1,45]



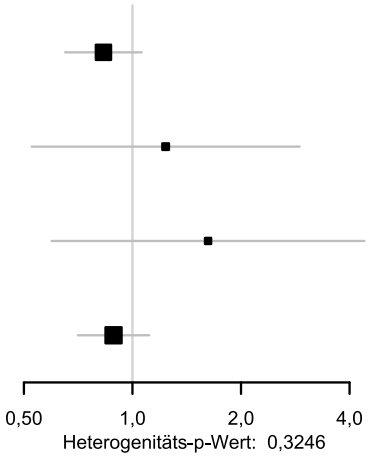
SUE:
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	66/2.993 (2,2)	75/2.993 (2,5)	0,88 [0,63; 1,22]
FIGARO-DKD	9/289 (3,1)	11/281 (3,9)	0,80 [0,33; 1,89]
Gepoolte Population	78/3.477 (2,2)	92/3.515 (2,6)	0,85 [0,63; 1,15]



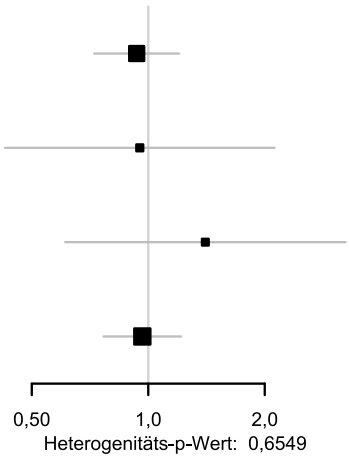
SUE:
SOC Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	113/2.993 (3,8)	136/2.993 (4,5)	0,83 [0,65; 1,06]
FIDELIO-DKD	10/195 (5,1)	10/241 (4,1)	1,24 [0,53; 2,91]
FIGARO-DKD	10/289 (3,5)	6/281 (2,1)	1,62 [0,60; 4,40]
Gepoolte Population	133/3.477 (3,8)	152/3.515 (4,3)	0,89 [0,71; 1,11]



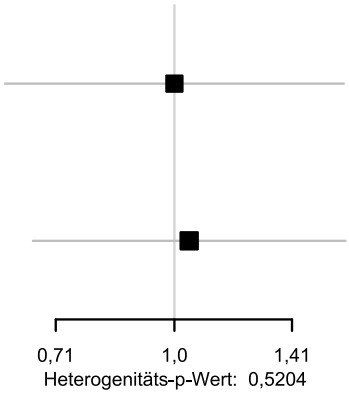
SUE:
SOC Erkrankungen des Nervensystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	112/2.993 (3,7)	120/2.993 (4,0)	0,93 [0,73; 1,20]
FIDELIO-DKD	10/195 (5,1)	13/241 (5,4)	0,95 [0,43; 2,12]
FIGARO-DKD	13/289 (4,5)	9/281 (3,2)	1,40 [0,61; 3,23]
Gepoolte Population	135/3.477 (3,9)	142/3.515 (4,0)	0,97 [0,77; 1,22]



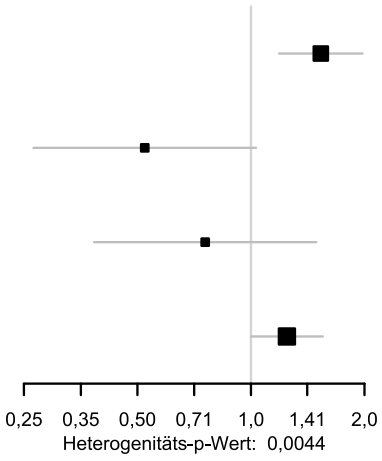
SUE:
PT Synkope

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	31/2.993 (1,0)	31/2.993 (1,0)	1,00 [0,61; 1,64]
Gepoolte Population	37/3.477 (1,1)	36/3.515 (1,0)	1,04 [0,66; 1,65]



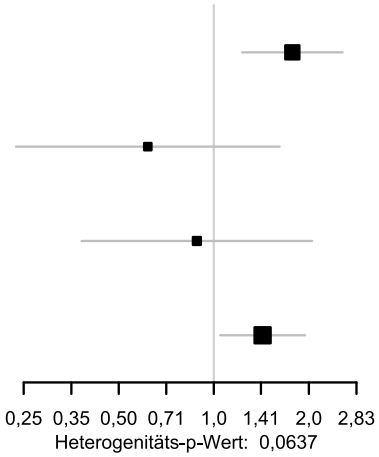
SUE:
SOC Erkrankungen der Nieren und Harnwege

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	144/2.993 (4,8)	94/2.993 (3,1)	1,53 [1,19; 1,98]
FIDELIO-DKD	11/195 (5,6)	26/241 (10,8)	0,52 [0,27; 1,03]
FIGARO-DKD	14/289 (4,8)	18/281 (6,4)	0,76 [0,38; 1,49]
Gepoolte Population	169/3.477 (4,9)	138/3.515 (3,9)	1,25 [1,00; 1,55]



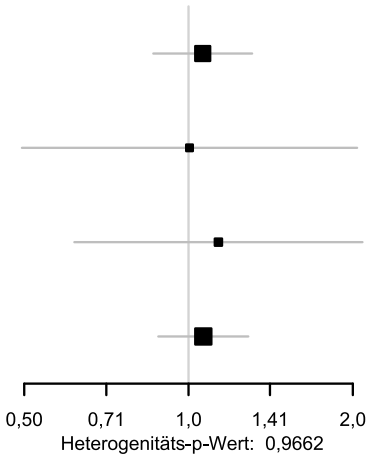
SUE:
PT Akute Nierenschädigung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	78/2.993 (2,6)	44/2.993 (1,5)	1,77 [1,23; 2,56]
FIDELIO-DKD	6/195 (3,1)	12/241 (5,0)	0,62 [0,24; 1,62]
FIGARO-DKD	10/289 (3,5)	11/281 (3,9)	0,88 [0,38; 2,05]
Gepoolte Population	94/3.477 (2,7)	67/3.515 (1,9)	1,43 [1,05; 1,95]



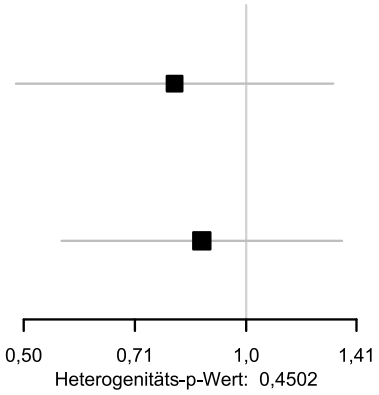
SUE:
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	172/2.993 (5,7)	162/2.993 (5,4)	1,06 [0,86; 1,31]
FIDELIO-DKD	13/195 (6,7)	16/241 (6,6)	1,00 [0,50; 2,04]
FIGARO-DKD	21/289 (7,3)	18/281 (6,4)	1,13 [0,62; 2,08]
Gepoolte Population	206/3.477 (5,9)	196/3.515 (5,6)	1,06 [0,88; 1,29]



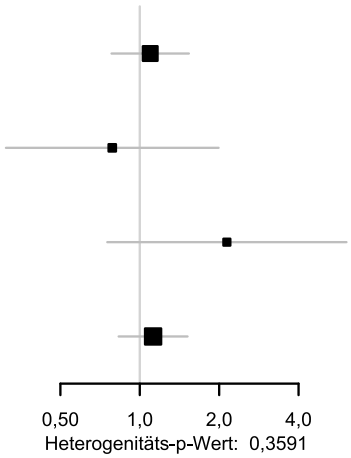
SUE:
PT Chronisch-obstruktive Lungenerkrankung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	28/2.993 (0,9)	35/2.993 (1,2)	0,80 [0,49; 1,31]
Gepoolte Population	37/3.477 (1,1)	43/3.515 (1,2)	0,87 [0,56; 1,35]



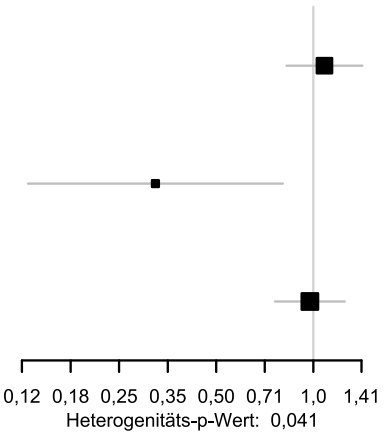
SUE:
SOC Chirurgische und medizinische Eingriffe

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	69/2.993 (2,3)	63/2.993 (2,1)	1,10 [0,78; 1,54]
FIDELIO-DKD	7/195 (3,6)	11/241 (4,6)	0,79 [0,31; 1,99]
FIGARO-DKD	11/289 (3,8)	5/281 (1,8)	2,14 [0,75; 6,08]
Gepoolte Population	87/3.477 (2,5)	79/3.515 (2,2)	1,12 [0,83; 1,52]



SUE:
SOC Gefäßerkrankungen

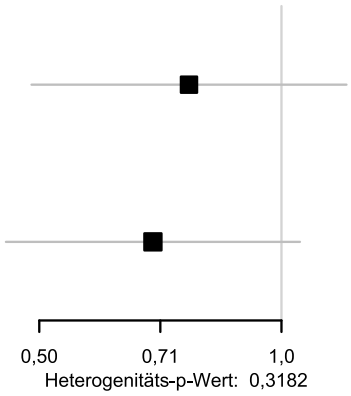
	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	105/2.993 (3,5)	97/2.993 (3,2)	1,08 [0,83; 1,42]
FIGARO-DKD	6/289 (2,1)	18/281 (6,4)	0,32 [0,13; 0,80]
Gepoolte Population	118/3.477 (3,4)	122/3.515 (3,5)	0,98 [0,76; 1,25]



Schwere UE nach SOC und PT

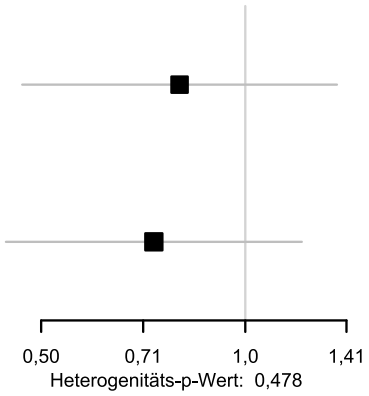
Schwere UE:
SOC Erkrankungen des Blutes und des Lymphsystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	33/2.993 (1,1)	43/2.993 (1,4)	0,77 [0,49; 1,20]
Gepoolte Population	36/3.477 (1,0)	53/3.515 (1,5)	0,69 [0,45; 1,05]



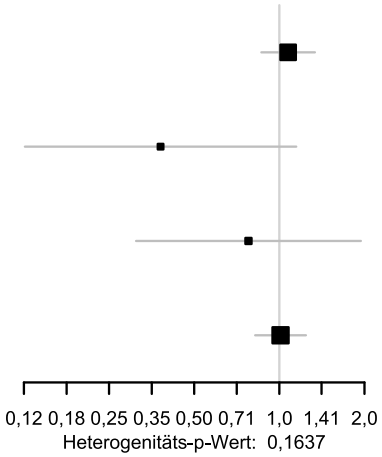
Schwere UE:
PT Anämie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	24/2.993 (0,8)	30/2.993 (1,0)	0,80 [0,47; 1,37]
Gepoolte Population	26/3.477 (0,7)	36/3.515 (1,0)	0,73 [0,44; 1,21]



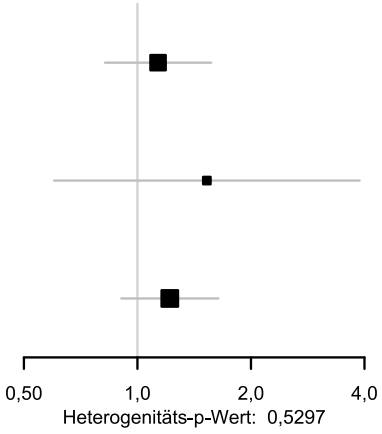
Schwere UE:
SOC Herzerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	159/2.993 (5,3)	148/2.993 (4,9)	1,07 [0,86; 1,34]
FIDELIO-DKD	4/195 (2,1)	13/241 (5,4)	0,38 [0,13; 1,15]
FIGARO-DKD	8/289 (2,8)	10/281 (3,6)	0,78 [0,31; 1,94]
Gepoolte Population	171/3.477 (4,9)	171/3.515 (4,9)	1,01 [0,82; 1,24]



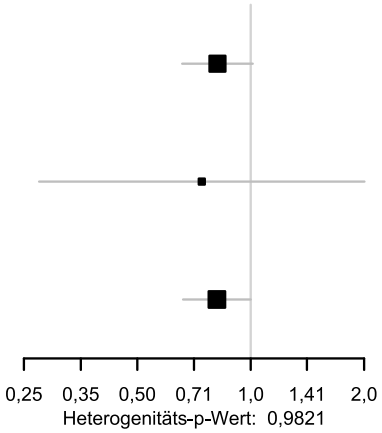
Schwere UE:
SOC Erkrankungen des Gastrointestinaltrakts

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	76/2.993 (2,5)	67/2.993 (2,2)	1,13 [0,82; 1,57]
FIGARO-DKD	11/289 (3,8)	7/281 (2,5)	1,53 [0,60; 3,89]
Gepoolte Population	94/3.477 (2,7)	78/3.515 (2,2)	1,22 [0,91; 1,64]



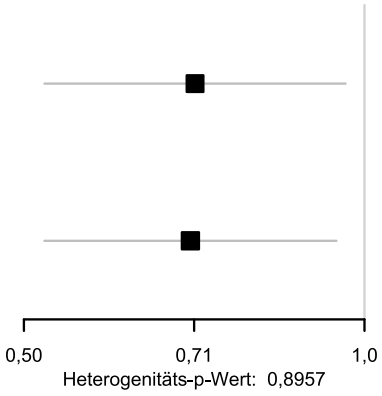
Schwere UE:
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	142/2.993 (4,7)	174/2.993 (5,8)	0,82 [0,66; 1,01]
FIDELIO-DKD	6/195 (3,1)	10/241 (4,1)	0,74 [0,27; 2,00]
Gepoolte Population	154/3.477 (4,4)	191/3.515 (5,4)	0,81 [0,66; 1,00]



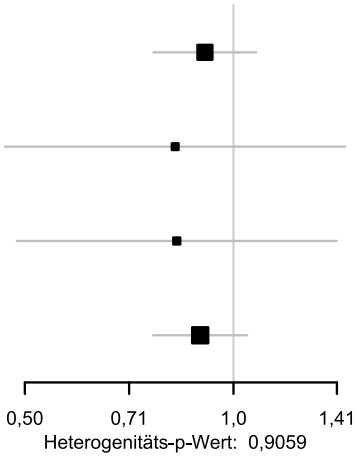
Schwere UE:
PT Tod

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	68/2.993 (2,3)	96/2.993 (3,2)	0,71 [0,52; 0,96]
Gepoolte Population	72/3.477 (2,1)	103/3.515 (2,9)	0,70 [0,52; 0,94]



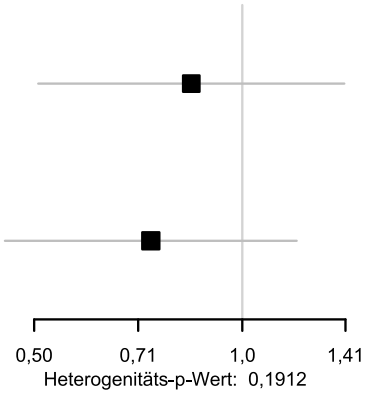
Schwere UE:
SOC Infektionen und parasitäre Erkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	231/2.993 (7,7)	254/2.993 (8,5)	0,91 [0,77; 1,08]
FIDELIO-DKD	18/195 (9,2)	27/241 (11,2)	0,82 [0,47; 1,45]
FIGARO-DKD	23/289 (8,0)	27/281 (9,6)	0,83 [0,49; 1,41]
Gepoolte Population	272/3.477 (7,8)	308/3.515 (8,8)	0,90 [0,77; 1,05]



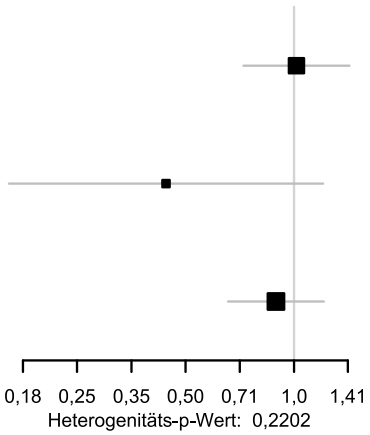
Schwere UE:
PT COVID-19

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	27/2.993 (0,9)	32/2.993 (1,1)	0,84 [0,51; 1,40]
Gepoolte Population	28/3.477 (0,8)	38/3.515 (1,1)	0,74 [0,45; 1,20]



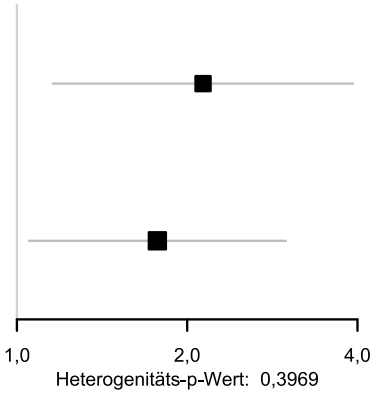
Schwere UE:
PT Pneumonie

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	66/2.993 (2,2)	65/2.993 (2,2)	1,02 [0,72; 1,42]
FIDELIO-DKD	5/195 (2,6)	14/241 (5,8)	0,44 [0,16; 1,20]
Gepoolte Population	75/3.477 (2,2)	86/3.515 (2,4)	0,89 [0,66; 1,21]



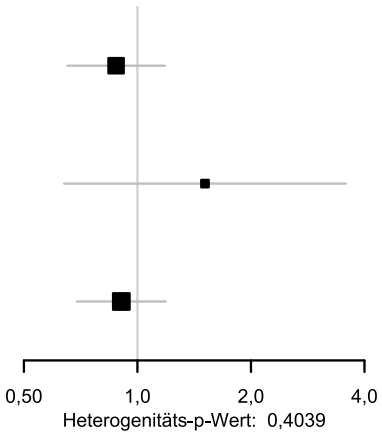
Schwere UE:
PT Sepsis

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	32/2.993 (1,1)	15/2.993 (0,5)	2,13 [1,16; 3,93]
Gepoolte Population	38/3.477 (1,1)	22/3.515 (0,6)	1,77 [1,05; 2,99]



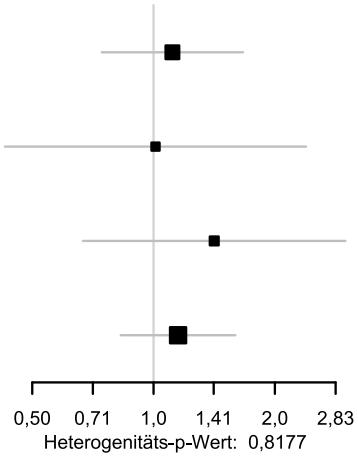
Schwere UE:
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	79/2.993 (2,6)	90/2.993 (3,0)	0,88 [0,65; 1,18]
FIDELIO-DKD	11/195 (5,6)	9/241 (3,7)	1,51 [0,64; 3,57]
Gepoolte Population	96/3.477 (2,8)	108/3.515 (3,1)	0,91 [0,69; 1,19]



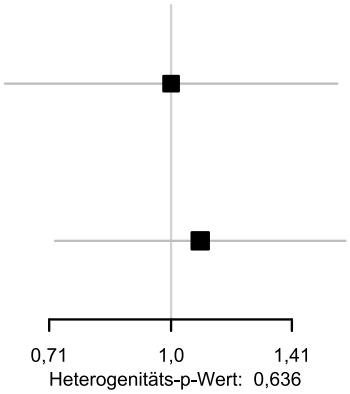
Schwere UE:
SOC Stoffwechsel- und Ernährungsstörungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	49/2.993 (1,6)	44/2.993 (1,5)	1,11 [0,74; 1,67]
FIDELIO-DKD	9/195 (4,6)	11/241 (4,6)	1,01 [0,43; 2,39]
FIGARO-DKD	16/289 (5,5)	11/281 (3,9)	1,41 [0,67; 2,99]
Gepoolte Population	74/3.477 (2,1)	66/3.515 (1,9)	1,15 [0,83; 1,60]



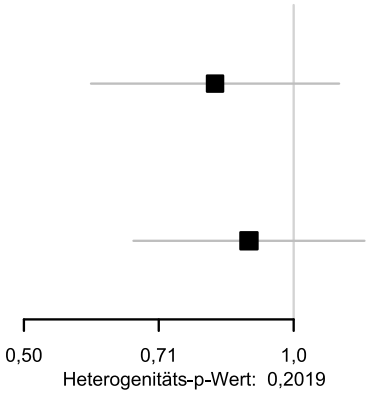
Schwere UE:
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	34/2.993 (1,1)	34/2.993 (1,1)	1,00 [0,62; 1,60]
Gepoolte Population	46/3.477 (1,3)	43/3.515 (1,2)	1,09 [0,72; 1,64]



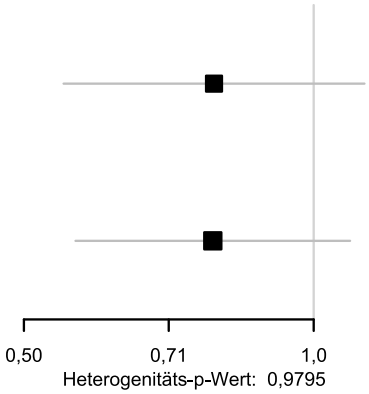
Schwere UE:
SOC Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	67/2.993 (2,2)	82/2.993 (2,7)	0,82 [0,59; 1,12]
Gepoolte Population	80/3.477 (2,3)	91/3.515 (2,6)	0,89 [0,66; 1,20]



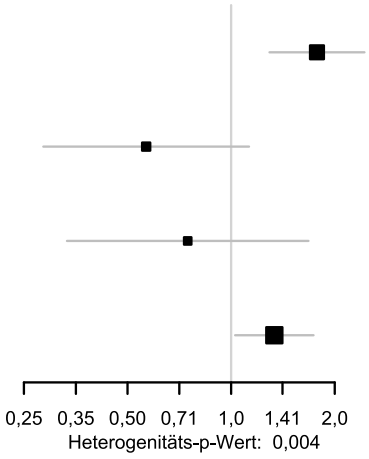
Schwere UE:
SOC Erkrankungen des Nervensystems

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	52/2.993 (1,7)	66/2.993 (2,2)	0,79 [0,55; 1,13]
Gepoolte Population	62/3.477 (1,8)	80/3.515 (2,3)	0,79 [0,57; 1,09]



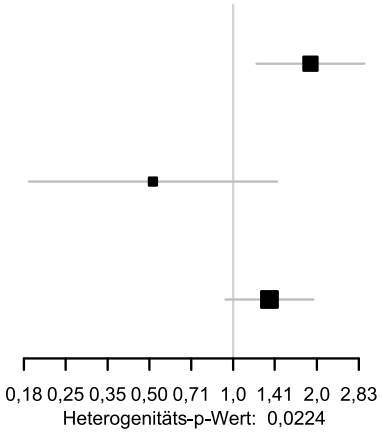
Schwere UE:
SOC Erkrankungen der Nieren und Harnwege

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	103/2.993 (3,4)	58/2.993 (1,9)	1,78 [1,29; 2,44]
FIDELIO-DKD	11/195 (5,6)	24/241 (10,0)	0,57 [0,28; 1,13]
FIGARO-DKD	10/289 (3,5)	13/281 (4,6)	0,75 [0,33; 1,68]
Gepoolte Population	124/3.477 (3,6)	95/3.515 (2,7)	1,34 [1,03; 1,74]



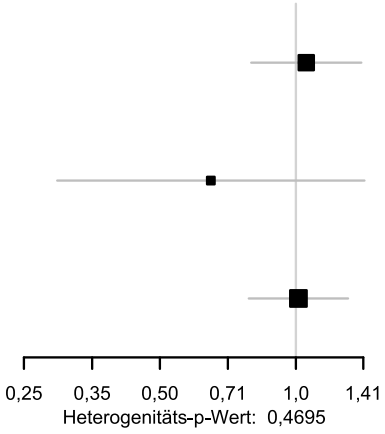
Schwere UE:
PT Akute Nierenschädigung

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	55/2.993 (1,8)	29/2.993 (1,0)	1,90 [1,21; 2,97]
FIDELIO-DKD	5/195 (2,6)	12/241 (5,0)	0,51 [0,18; 1,44]
Gepoolte Population	66/3.477 (1,9)	50/3.515 (1,4)	1,35 [0,94; 1,94]



Schwere UE:
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	97/2.993 (3,2)	92/2.993 (3,1)	1,05 [0,80; 1,40]
FIGARO-DKD	10/289 (3,5)	15/281 (5,3)	0,65 [0,30; 1,42]
Gepoolte Population	116/3.477 (3,3)	116/3.515 (3,3)	1,01 [0,79; 1,30]



Schwere UE:
SOC Gefäßerkrankungen

	Finerenon + SoC n/N (%)	Placebo + SoC n/N (%)	RR [95%-KI]
FINEARTS-HF	62/2.993 (2,1)	53/2.993 (1,8)	1,17 [0,81; 1,68]
Gepoolte Population	74/3.477 (2,1)	67/3.515 (1,9)	1,12 [0,81; 1,56]

